

Human Research Protection Program
Standard Operating Procedures
June 2026

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HRP-001 Definitions

1 PURPOSE

1.1 This policy establishes the definitions followed by the human research protection program.

2 POLICY

2.1 Pre-2018 Requirements: For purposes of this section, the pre-2018 Requirements means this subpart as published in the 2016 edition of the Code of Federal Regulations.

2.2 2018 Requirements: For purposes of this section, the 2018 Requirements means the Federal Policy for the Protection of Human Subjects requirements contained in this subpart. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date of 45 CFR 46.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

2.3 Research subject to pre-2018 requirements will not be transitioned to 2018 Requirements.

2.3.1 The pre-2018 Requirements shall apply to the following research,

2.3.1.1 Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019

2.3.1.2 Research for which IRB review was waived pursuant to 46.101(i) of the pre-2018 Requirements before January 21, 2019, and

2.3.1.3 Research for which a determination was made that the research was exempt under 46.101(b) of the pre-2018 Requirements before January 21, 2019.

2.4 Access: means the ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any system resource for the purpose of using, transmitting, or receiving private identifiable information.

2.5 Administer or administration: the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means, **Pharmacy.la.gov**

2.6 Administrative Hold: A voluntary action initiated by the principal investigator to temporarily stop some or all approved research activities. Administrative holds are not considered suspensions or terminations. During administrative hold, the research remains subject to continuing review and requirements for reporting non-compliance and unanticipated problems involving risks to subjects or others.

2.7 Advocate: An individual who has the background and experience to act in, and agrees to act in, the best interest of the vulnerable subject for the duration of the subject's participation in the clinical investigation. Vulnerable subjects may include, but are not limited to children, fetuses, neonates, and adults with intellectual disabilities, prisoners, financially or educationally disadvantaged.

2.8 Adverse Event (AE): For Veterans Administration (VA) research any untoward occurrence (physical, psychological, social, or economic) in a human subject participating in research. An AE in research can be any unfavorable or unintended event, including abnormal laboratory findings, symptom or disease, or death associated with the research or the use of a medical investigational test article. An AE in research may occur even in the absence of any error or protocol deviation and does not necessarily have to be caused by any identifiable aspect of the research.

2.9 Affiliated Member: is an employee or agent of LSU Health Sciences Center (or a member of that person's immediate family). Affiliated members include but are not limited to individuals who are: Full- or part-time employees; current students; members of any governing panel or board of the institution; paid or unpaid consultants; health care providers holding credentials to practice at the institution; and volunteers working at the institution on business unrelated to the IRB.

2.10 Agent: An individual who is an employee is considered to be an agent of LSUHSC-S if the individual is performing institutionally designated activities or exercising institutionally delegated authority or responsibility. This would include, among others, students or volunteers when interacting with human subjects for classroom activities that qualify as human research; employees when conducting research with subjects or when using or controlling human subject records; and any individual conducting research with subjects at LSUHSC-S facilities or for whom LSUHSC-S has responsibility.

2.10.1 An individual who is not an employee is considered an agent of the organization for purposes of engagement in Human Research when that individual has been specifically authorized to conduct research on behalf of the organization. Examples of individuals who would not be considered agents would be employees when conducting human research while on sabbatical through a separate institution; or employees when conducting research for another entity while acting in a consulting role that is not assigned by LSUHSC-S. However, if data derived from consulting work could reasonably be expected to be used later for university related purposes, the employee would be considered an agent. When an LSUHSC-S investigator conducts a consenting process, he/she is then engaged which makes LSUHSC-S engaged.

2.10.2 Legal counsel has the ultimate authority to determine whether someone is acting as an agent of the organization.

2.11 Allegation of Non-Compliance: An unproved assertion of Non-Compliance.

2.12 Alternate Member: Alternate members are part of the IRB and may attend convened meetings and perform all the assigned or delegated duties of the primary members. The appointment of alternate members should be based on experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB voting member whom the alternate would replace. An alternate member may vote only when the regular voting member is absent.

2.13 Approval Period (Interval): The time period between the first day of IRB approval (Start Date) of a protocol and the last day (End Date) of IRB approval of a protocol.

2.14 Assent: A child's affirmative agreement to participate in research. Mere failure to object is not the same as assent.

2.15 Assurance of Compliance (Human Subjects) or Federalwide Assurance: A legally binding written document that commits an institution to complying with the Federal Policy (Common Rule) and other applicable Federal and VA standards for the protection of human subjects.

2.16 Authorization Agreement: Also called a Reliance Agreement, is the agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical review and a participating institution relying on the ethical review.

2.17 Biologic: Any therapeutic serum, toxin, anti-toxin, or analogous microbial drug applicable to the prevention, treatment or cure of disease or injuring.

2.18 Case History: A case history is a record of all observations and other data pertinent in the investigation on each research subject. An investigator is required to prepare and maintain adequate and accurate case histories. Case histories include the case report forms and supporting data including signed and dated consent forms, any medical records including, but are not limited to, progress notes of the physician, the individual's hospital chart(s), and nurses' notes. The case history for each individual must document that informed consent was obtained prior to participation in the study.

2.19 Case Report (also called Limited Case Series): A description of the clinical characteristics or treatment(s) provided to a single patient or a small group of patients that share a common condition, which did not involve activities defined as research. (A series of 3 or more case reports requires IRB review).

2.20 Case Report Form (CRF): A printed, optical or electronic document designed to record all the protocol-required information to be reported to the clinical trials sponsor or entered into the research database for each clinical trial subject.

2.21 Certification: The official notification by the institution to the supporting Federal department or agency component that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

2.22 Children: Children means under the following:

2.22.1 DHHS and FDA: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

2.22.2 Louisiana Law: Child means a person under eighteen (18) years of age who, prior to juvenile proceedings, has not been judicially emancipated under Civil Code Article 385 or emancipated by marriage under Civil Code Articles 379 through 384.

2.23 Classified Research: In the interest of national security, federally funded research can be classified in terms of limited access to data, information, and facilities that may be required to carry out the research or in terms of the limited distribution of the results of the research.

2.24 Clinical Investigation: Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act (FD&C Act), or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part. (See 21 CFR 56.102)

2.25 Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

2.26 Collaborative Study: A study in which two or more institutions coordinate, with each institution completing a portion of the research activities outlined in a specific protocol.

2.27 Coded Information/Data: Identifying information that would enable the Investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

2.28 Coded Samples: Biological samples that are identified by a code or link to the subjects' identities rather than by a direct identifier such as a name or medical record number. These samples may also be called "linked."

2.29 Coercion: Coercion means that a person is forced to some degree, or strongly urged to do something that may not be good for them or against their judgment. In research involving human subjects "under influence" is often used to describe the concept of coercion. It is the practice of using threats, rewards, intimidation, or any other incentive to affect another. Such actions are used as leverage to force or influence the victim to act in the desired way.

2.30 Cognitively Impaired: Individuals that have a psychiatric disorder (e.g., psychosis, neurosis, personality, or behavior disorder), a developmental disorder (e.g., mental retardation/intellectual disabilities) or a neurological disorder that affects cognitive or emotional functions to the extent that capacity for judgment is significantly diminished. These individuals may be considered to have a "Diminished Autonomous Decision-Making Capacity". Individuals with cognitive impairment should not automatically be considered unable to provide valid consent or assent. Additionally, individuals may be considered cognitively impaired or have a diminished autonomous decision-making capacity or have limited decision-making ability because they are under the influence of drugs or alcohol; suffering from degenerative diseases affecting the brain; are terminally ill; or have disabling physical handicaps; or other circumstances temporary or permanent that affect their cognitive abilities.

2.31 Combination Product: A product containing a combination of a drug, a device, or a biological product. Studies of combination products are regulated according to the IND or IDE regulations, depending on the components of the product. The FDA determines which of its organizational components has primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of a drug, device, and/or biological. (See 21 CFR 3.2(e))

2.32 Common Rule: The Common Rule refers to the "Federal Policy for the Protection of Human Subjects" that provides for the primary source of regulation of research. It has been adopted by several federal agencies. Although the Common Rule is codified by each agency separately, the text is identical to Department of Health and Human Services (DHHS) regulations in 45 CFR 46 Subpart A. For the purposes of this document, references to the Common Rule will cite the DHHS regulations and VA regulations at 38 CFR 16.

2.33 Compensation:

2.33.1 Compensation is payment for participation in research or a way to reimburse a subject for time, travel, parking, and other experiences incurred due to participation. However, payment for participation is not considered a research benefit. Investigators should also make sure that compensation is not used to impart undue influence towards participation in research.

2.33.2 Payment of medical care provided to subjects injured in research; does not refer to pay (re-numeration) for participation in research.

2.34 Competence: Competence is a legal term, technically used to denote capacity to act in one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

2.35 Confidentiality: Confidentiality is the right of an individual to have personal, identifiable health information kept private; such information should not be disclosed to others unless the individual has given informed consent.

2.36 Conflicting Interest: An individual involved in research review is automatically considered to have a conflicting interest when the individual or the individual's spouse, domestic partner, children, and dependents have any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual's immediate family:

2.36.1 Involvement in the design, conduct, or reporting of the research.

2.36.2 Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly traded, diversified mutual funds.

2.36.3 Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research.

2.36.4 Proprietary interest including, but not limited to, a patent, trademark, copyright, or licensing agreement.

2.36.5 Board or executive relationship, regardless of compensation.

2.36.6 Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.

2.36.7 Any other reason for which the individual believes that he or she cannot be independent.

2.37 Continuing Non-Compliance: A pattern of Non-Compliance that shows multiple or repeated instances of noncompliance, particularly after written notice from the IRB that the investigator must take action to correct noncompliance. The multiple or repeated instances of noncompliance may occur on one protocol or on more than one protocol and may occur simultaneously or over a period.

2.37.1 For Veterans Administration (VA) research Continuing Non-Compliance includes a persistent failure to adhere to the legal and policy requirements governing Human Research.

2.38 Continuing Review: Under federal regulations this is periodic review of ongoing research activities by the IRB at intervals appropriate to the degree of risk, but not less than once per year. 45 CFR 46.109(e).

2.39 Corrective Action: An action usually required of the Principal Investigator, which is necessary to reduce the risk to the subjects and/or prevent a recurrence of the reported protocol deviation/violation or other non-compliance. Examples of corrective actions include revision of the protocol and/or consent form, re-consent of subjects, further training of study staff, or formal notification to the appropriate government oversight agencies.

2.40 Covered Entity: Individuals, organizations and agencies that must comply with HIPAA rules. A Covered Entity is one of the following (See 45 CFR 160.103 for further information):

2.40.1 A Health Care Provider that includes doctors, clinics, psychologists, dentists, chiropractors, nursing homes, pharmacies; but only if they transmit any information in an electronic form in connection with a transaction for which HHS has adopted a standard.

2.40.2 A Health Plan that includes Health Insurance Companies, HMOs, Company Health Plans, Government programs that pay for health care, such as Medicare, Medicaid, and the Military and Veterans healthcare programs.

2.40.3 A Health Care Clearinghouse that includes entities that process non-standard health information they receive from another entity into a standard (i.e., standard electronic format or data content), or vice-versa.

2.41 Data Safety Monitoring Board: A clinical trial DSMB is a group of individuals with pertinent expertise that reviews on a regular basis accumulating data from one or more ongoing clinical trials. The DSMB advises the sponsor regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial.

2.42 Data Safety Monitoring Plan (DSMP): A DSMP plan is a general description of a system for appropriate oversight and monitoring of the data and subject safety in a clinical research study. The plan is developed by the investigator, included in the protocol, and submitted to the IRB for review and approval before the study begins. An appropriate plan is commensurate with the risks, size and complexity of the study. An investigator's DSMP may or may not include a Data and Safety Monitoring Board (DSMB).

2.43 Data Use Agreement: An agreement between LSUHSC-S and the recipient of the protected health information (PHI). This agreement establishes who is permitted to use or receive the limited data set; and provides that the limited data set recipient will:

2.43.1 Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;

2.43.2 Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;

2.43.3 Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;

2.43.4 Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and

2.43.5 Not identify the information or contact the individuals.

2.43.6 Investigators who will be receiving limited data sets must submit a signed copy of the covered entity's data use agreement to the LSUHSC-S IRB for approval, prior to initiating the research.

2.44 De-identified Data: Data that has been stripped of all 18 elements considered by the HIPAA Privacy Rule to be Protected Health Information (PHI) or direct identifiers that could be used to identify the individual or the individual's relatives, employers, or household members. This includes unique identifying numbers, characteristics or codes. List of 18 Identifiers:

2.44.1 Names

2.44.2 All geographical subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geographical codes, except for the initial three digits of a ZIP code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000

2.44.3 All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

2.44.4 Phone numbers

2.44.5 Fax numbers

2.44.6 Electronic mail addresses

2.44.7 Social Security numbers

2.44.8 Medical record numbers; prescription numbers

2.44.9 Health plan beneficiary numbers

2.44.10 Account numbers

2.44.11 Certificate/license numbers;

2.44.12 Vehicle identifiers and serial numbers, including license plate numbers

2.44.13 Device identifiers and serial numbers

2.44.14 Web Universal Resource Locators (URLs)

2.44.15 Internet Protocol (IP) address numbers

2.44.16 Biometric identifiers, including finger and voice prints

2.44.17 Full face photographic images and any comparable images

2.44.18 Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data) *These 16 items must be removed for a limited data set.

2.45 Declaration of Helsinki: Statement of ethical principles for human participation in biomedical research. The Declaration was first adopted in 1964 by the World Medical Association. The Declaration has been revised several times, most recently in 2008. Like the Nuremberg Code that preceded it, the Declaration of Helsinki makes consent a central requirement of ethical research.

2.46 Deferred: The IRB cannot make one or more of the determinations required for approval by the HHS regulations at 45 CFR 46.111 and, if applicable, subparts B, C, or D of 45 CFR 46.

2.46.1 This action is taken if substantial modification or clarification is required, or insufficient information is provided to judge the protocol application adequately the IRB;

2.46.1.1 is unable to make the required determinations about research risks and benefits, the adequacy of privacy and confidentiality protections, or the adequacy of the informed consent process because the research protocol provides insufficient information related to these aspects of the research, and

2.46.1.2 is unable to specify changes to the research protocol or consent document that if made would allow the IRB to make these required determinations. The research may not proceed until the IRB reviews the revised research protocol and approves it at a subsequent convened meeting.

2.46.2 When a research protocol is Deferred, the IRB under its authority to require modifications in order for an investigator to secure approval, may require that the investigator;

2.46.2.1 make changes to the protocol or informed consent documents, or

2.46.2.2 submit clarifications or additional documents prior to the next review.

2.46.3 In order to receive approval for a research protocol Deferred: The investigator's response, revised research protocol and all requested documents must be submitted for review at a subsequent, convened meeting of the same IRB committee. The HRPP Staff will process the investigator's response, the revised proposal along with the previously submitted proposal. The item will be placed on the agenda for re-review at the next convened meeting.

2.47 Department or agency head: means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.

2.48 Department of Health and Human Services (DHHS): The United States government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. DHHS has more than 300 programs including FDA, NIH, CMS, OHRP, CDC, and SAMHSA.

2.49 Designated Reviewer: The IRB chair or an Experienced IRB Member designated by the IRB chair to conduct Non-Committee Reviews.

2.50 Deviations: Departure from, or changes to, the IRB-approved protocol initiated without prior IRB approval.

2.51 Device (Medical Device): A device per the FDA is: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

2.51.1 recognized in the United States Pharmacopeia- National Formulary, or any supplement to them,

2.51.2 intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

2.51.3 intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. FD&C Act 210(h).

2.52 Dispense or dispensing: means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. "Dispense" necessarily includes a transfer of possession of a drug or device to the patient or the patient's agent (Pharmacy.la.gov). Louisiana law requires that dispensing may only be performed by a licensed pharmacist or a physician who is registered with the board as a dispensing physician in accordance with Title 46:Chapter 65:Subchapter C.

2.53 Distribute or distribution: means the delivery of a drug or device other than by administering or dispensing.

2.54 Drug as defined by FDA:

2.54.1 articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

2.54.2 articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

2.54.3 articles 26 (other than food) intended to affect the structure or any function of the body of man or other animals; and

2.54.4 articles intended for use as a component of any articles specified in clause (3.50.1), (3.50.2), or (3.50.3).

2.55 Drug Dispensing: Louisiana law requires that dispensing may only be done by a licensed pharmacist or a physician who is registered with the Louisiana State Board of Medical Examiners as a dispensing physician in accordance with 46 CFR 65: Subchapter C or 46 CFR 65 (c).

2.56 Drug Labeling: The Code of Federal Regulations specifies the following labeling requirements for an investigational new drug:

2.56.1 The immediate package of an investigational new drug intended for human use shall bear a label with the statement "Caution: New Drug - Limited by Federal (or United States) law to investigational use."

2.56.2 The label or labeling of an investigational new drug shall not bear any statement that is false or misleading and shall not represent that the investigational new drug is safe or effective for the purposes for which it is being investigated.

2.56.3 State of Louisiana Regulations and LSUHSC-S policy states that all drugs dispensed shall contain a medication label with the following: a) Patient name, identifier b) Protocol number or name c) Name of prescriber / INVESTIGATOR d) Strength and volume of drug e) Directions for use or administration f) Dose g) Number of units dispensed h) Expiration date i) Initials of preparer j) Initials of pharmacist performing final check k) "Investigational Drug" l) Any auxiliary stickers or warning labels

2.57 Emancipated Minor: A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation.

2.58 Emergency Research: Research conducted in subjects who are in a life-threatening or emergent situation, where available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigation, is necessary to determine the safety and effectiveness of particular interventions.

2.59 Emergency Treatment IDE: A mechanism through the FDA for providing eligible subjects with investigational devices for the treatment of an immediate serious or life-threatening illness for which there are no satisfactory alternatives. See FDA Guidance for Emergency IDE.

2.60 Emergency Treatment IND: A mechanism through the FDA for providing eligible subjects with investigational drugs, agents, or biologics for the treatment of an immediate serious or life-threatening illness for which there are no satisfactory alternatives. See: FDA Guidance for Emergency IND.

2.61 Emergency Use: The use of an investigational drug or device on a human subject in accordance with a treatment/procedure in a life-threatening situation in which no comparable or standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval. This is not to be confused with Planned Emergency Research.

2.62 Engaged in Human Subjects Research: In general, an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain:

2.62.1 data about the subjects of the research through intervention or interaction with them;

2.62.2 identifiable private information about the subjects of the research; or

2.62.3 the informed consent of human subjects for the research. The institution considers private information or specimens to be individually identifiable as defined in 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

2.63 Experienced IRB Member: An IRB member is considered experienced if the IRB chair considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.

2.64 Exempt Research: Certain minimal risk research protocols may meet criteria for exemption if the only involvement of human subjects will be in one or more of the eight (8) categories described in the federal regulations. Any research involving prisoners (except for research aimed at involving a broader subject population that only incidentally includes prisoners) or certain activities with children are not exempt. Only the IRB can make the determination of exemption. 45 CFR 46.101, 38 CFR 16.101(b).

2.65 Ex-Officio IRB Member: Ex-officio members on the IRB Committees may include persons who are automatically members by virtue of the position held. These individuals do not have voting privileges and do not count toward quorum.

2.66 Expedited Review Procedures for Research: Expedited research is research determined by the IRB to present no more than minimal risk to human subjects and involve only procedures in certain specific categories. Minor changes to previously approved research during the period for which approval is authorized may also be approved through the expedited process. 38 CFR 16.110(b), 45 CFR 46.110.

2.67 Experienced IRB member: An IRB member is considered experienced in terms of professional competence if they have been an IRB member for at least one (1) year and the IRB chair considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.

2.68 Expiration Date: The first date that the protocol is no longer approved. The date after the end date of the approval period.

2.69 Federalwide Assurance (FWA): The Federalwide Assurance (FWA) is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by HHS. Under an FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the Terms of Assurance. An institution must have an FWA to receive HHS support for research involving human subjects. Each FWA must designate at least one IRB registered with OHRP.

2.70 Federal department or agency: refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative

action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

2.71 Financial Conflict of Interest: Refers to any financial interest that competes with an individual's obligation to protect the integrity of the academic pursuit and especially the rights and welfare of research subjects. While financial interests may not compromise intellectual honesty or institutional integrity, they must not have the appearance of compromising LSUHSC-S values and missions of teaching, research, and public service.

2.72 Finding of Non-Compliance: Non-Compliance in fact.

2.73 Full Committee Review: Review of proposed research at a convened meeting at which most of the membership of the IRB is present, including at least one member whose primary concerns are in scientific areas, at least one member whose primary concerns are in nonscientific areas, at least one member who is unaffiliated, and at least one member who represents the general perspective of subjects. For the research to be approved, it must receive the approval of a majority of those members present at the meeting. 45 CFR 46.108.

2.74 Generalizable Knowledge: An investigation designed to draw general conclusions, inform policy or generalize findings beyond a single individual or an internal program (e.g., publications or presentations). However, research results do not have to be published or presented to qualify the experiment or data gathering as research. The intent to contribute to "generalizable (scholarly) knowledge" makes an experiment or data collection research, regardless of publication. Examples of activities that typically are not generalizable include:

2.74.1 quality assurance/improvement activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the institution

2.74.2 classroom exercises solely to fulfill course requirements or to train students in the use of methods or devices at the institution

2.75 Good Clinical Practice (GCP): is an international ethical and scientific quality standard for the planning, initiating, performing, recording, oversight, evaluation, analysis, and reporting of clinical trials that provides assurance that the data and reported results are reliable and that the rights, safety, and well-being of trial participants are protected.

2.76 Guardian: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. 45 CFR 46.402 (3). LA ChC 116(12.1)(a)(I)(b)

2.77 HIPAA Authorization: A document/form, that gives permission to use specified protected health information (PHI) for a specific purpose, or to disclose PHI to a third-party specified by the Investigator other than for treatment, payment or healthcare operations.

2.78 Human Research: Any activity that either:[1]

2.78.1 Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or

2.78.2 Is Research as Defined by FDA and involves Human Subjects as Defined by FDA.

2.79 Human Research Protections Program (HRPP): An HRPP is a comprehensive system to ensure the protection of human subjects participating in research. The HRPP consist of a variety of individuals and committees. The objective of this program is to assist the Institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research

2.80 Human Subject as Defined by DHHS: A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through Intervention or Interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For this definition:

2.80.1 Intervention: Physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

2.80.2 Interaction: Communication or interpersonal contact between investigator and subject.

2.80.3 Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

2.80.4 Identifiable Private Information: Private Information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

[1] The terms "Human Subject Research," "Research Involving Human Subjects," "Clinical Research," "Clinical Investigation," "Clinical Study" and similar phrases are considered to be synonyms for the term Human Research.

2.80.5 Identifiable Biospecimen: A biospecimen for which the identity or the subject is or may be readily ascertained by the investigator or associated with the biospecimen.

2.81 Human Subject

2.81.1 Defined by FDA: Human subject means an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject might be either a healthy individual or a patient. For research involving medical devices a human subject is also an individual on whose specimen an investigational device is used. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

2.81.2 Defined by Department of Defense (DoD):

2.81.2.1 Non-exempt classified research must be conducted following the requirements of Instruction 3216.02 13.

2.81.2.2 Written materials define “experimental subject” as an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving experimental subjects as defined in DoD 3216.02 is a subset of research involving human subjects.

2.81.3 When following DOE requirements:

2.81.3.1 Requirements for human subject protections for classified research apply to all research conducted or supported by the DOE, including contracts, and including Human Terrain Mapping research.

2.81.3.2 Requirements for human subject protections and their accompanying Contractor Requirements Documents (CRDs) apply to all research conducted at DOE institutions regardless of funding source, or by DOE employees/contractor personnel regardless of funding source or location conducted, and whether done domestically or in an international environment, and including Human Terrain Mapping research. DOE workers are considered vulnerable subjects and shall be afforded additional protections as determined by the IRB. **https://www.directives.doe.gov/directives-documents/400-series/0443.1-BOrder-c/@@images/file.**

2.81.3.3 When conducting classified research, the use of exemptions is prohibited. The fact that research meets a particular exemption category may be noted, but review by a convened IRB is required.

2.81.3.4 When conducting classified research, the IRB may not grant a waiver of the consent process or waiver of documentation of consent.

2.81.4 When following DOJ requirements: For research conducted within the Bureau of Prisons: Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

2.82 HUD: A Humanitarian Use Device (HUD) is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in no more than 8,000 individuals in the United States per year. HUDs cannot be sold for profit except in narrow circumstances and they can only be used in a facility after an IRB has approved their use in that facility, except in emergencies where the physician determines that approval cannot be obtained in time to prevent serious harm or death to the patient. Although the use of a HUD within treatment does not constitute research, the FDA requires IRB approval to be obtained before a HUD can be used in a facility.

2.83 Humanitarian Device Exemption (HDE) Application: To obtain approval for a HUD, a humanitarian device exemption (HDE) application is submitted to FDA.

2.84 Immediate Family: Spouse, domestic partner; and dependent children.

2.85 Institution: means any public or private entity, or department or agency (including federal, state, and other agencies).

2.86 Institutional Official/ Organizational Official (IO/OO):

2.86.1 Institutional Official (IO): Term utilized by DHHS - The Institutional Official (IO) is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the terms of the assurance. The IO is responsible for ensuring that the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federalwide Assurance (FWA)[2]. The IO is often the Vice President for Research.

2.86.2 Organizational Official (OO): Term utilized by AAHRPP - An identified, knowledgeable leader of the HRPP who is responsible for the program and has the authority to implement the program. This individual may rely on others for the interpretation of laws, regulations, codes, and guidance and the day-to-day operations of the HRPP, and should have a basic understanding of the relevant laws, codes, regulations and guidance that govern research involving human subjects, the responsibilities of an organizational official, and the

[2] **https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-september-18-letter/index.html**

responsibilities of the IRB and investigators and research staff in protecting research subjects. This individual should be directly involved in the allocation of resources to the HRPP. In some circumstances, more than one individual serves in this capacity[3].

2.87 Institutional Profile: A record of information an institution keeps about another collaborating institution/organization for one or more Collaborative Studies or Multi-Site Studies.

2.88 Intervention: Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

2.89 Interaction: Includes communication or interpersonal contact between investigator and subject.

2.90 Investigation: A searching inquiry for facts; detailed or careful examination.

2.91 Investigational Device: means a new medical device that has not been cleared for marketing by the FDA or an existing FDA-approved medical device which is being used for a new purpose in a clinical investigation.

2.92 Investigational Device Exemption (IDE): An investigational device exemption (IDE) gives the device manufacturer permission to use the device in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to FDA. Significant risk investigational devices must have an IDE issued by FDA before they can be shipped. Non-significant risk devices are considered to have an approved IDE when the IRB agrees with the sponsor that the device meets the criteria for a non-significant risk device.

2.93 Investigational Drug: any new drug or biological product that has not been cleared for marketing by the FDA or an existing FDA-approved drug which is being used in a new way not indicated on the approved label or a new purpose in a clinical investigation.

2.94 Investigational New Drug (IND) Application: is a request for Food and Drug Administration (FDA) authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved new drug application.

2.95 Investigational Product (IP) (also known as Test Article): Defined by the FDA as any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act

[3] AAHRPP Evaluation Instrument (2018-10-15); **http://www.aahrpp.org/apply/web-document-library/domain-i-organization**

or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n).

2.96 Investigator: An individual who conducts a clinical investigation, or other type of research under whose immediate direction a test article or experiment is administered or dispensed to, or used involving, a human subject. In the event of an investigation conducted by a team of individuals, the principal investigator is responsible leader of that team.

2.97 Investigator-Initiated: refers to a situation in which the individual investigator is a LSUHSC-S investigator who both initiates and conducts an investigation, is the holder of the IND or IDE and under whose immediate direction the investigational drug or experiment is administered, dispensed or used.

2.98 IRB: means an institutional review board established in accord with and for the purposes expressed in this policy.

2.99 IRB approval: the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

2.100 Legally Authorized Representative (LAR): An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures(s) involved in the research.

2.100.1 If there is no applicable law addressing this issue, then this individual is recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

2.100.2 See SOP: HRP-013 LARs, Children, and Guardians for who may serve as a Legally Authorized Representative at this institution.

2.101 Legal Guardianship: The duty and authority to make important decisions in matters having a permanent effect on the life and development of the child and the responsibility for the child's general welfare until he reaches the age of majority, subject to any residual rights possessed by the child's parents. It shall include but not necessarily be limited to: The authority to consent to marriage, to enlist in the armed forces of the United States, or to major medical, psychiatric, and surgical treatment, to represent the minor in legal actions, to make other decisions of substantial legal significance concerning the minor. The term "legal guardian" means the caretaker in such a relationship. LA ChC 116(12.1)(a)(i)(b).

2.102 Limited Data Set: Protected health information that is not fully de-identified and retains certain direct patient identifiers. The recipient of a limited data set must get IRB approval and sign a Data Use Agreement.

2.103 Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.[4]

2.103.1 For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

2.103.2 When following DoD regulations, the definition of minimal risk based on the phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests" shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

2.104 Minor Modification: A proposed change in research related activities that does not materially affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study.

2.105 Multi-Site Study: A study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol.

2.106 Non-Affiliated/Unaffiliated Member: is an individual that has no affiliation with LSU Health Sciences Center (nor is a member of any employee's or any affiliated agent's immediate family) other than as an IRB member.

2.107 Non-Committee Review: Any of the following:

2.107.1 Determination of whether an activity is Human Research.

[4] The phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests" should not be interpreted to include the inherent risks certain categories of subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

2.107.2 Determination of whether Human Research is exempt from regulation.

2.107.3 Reviews of non-exempt research using the expedited procedure.

2.107.4 Determinations of which subjects can continue in expired research.

2.107.5 Concurrence of IRB Chair or designee for non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use) or non-emergency individual patient expanded access IND with request for authorization to use alternative IRB review procedures.

2.108 Non-Compliance: Failure to follow the regulations, or the requirements or determinations of the IRB.

2.108.1 In the case of research funded or conducted by the DoD, Non-Compliance includes failure of a person, group, or institution to act in accordance with DoD instruction 3216.02, its references, or applicable requirements.

2.108.2 In the case of Veterans Administration (VA) research, Non-Compliance is any failure to adhere to the requirements for conducting VA research covered by the VHA Handbook.

2.109 Non-Financial Conflict of Interest: Non-financial conflicts of interest may exist when an individual serves dual role, such as healthcare provider and Investigator. Other interests such as publication, promotion, or tenure, can also become conflicts of interest that may affect an individual's judgment. Membership in oversight committees such as the IRB as well as positions of authority may pose actual, perceived or potential conflicts of interest. Any position that includes responsibilities for the review and approval of research projects or 36 contracts may potentially affect the design of, decisions made and/or action taken surrounding a specific study.

2.110 Nonscientist: Members will be considered "nonscientists" when the preponderance and recency of their training, professional experience (type, duration) and personal experience would incline them to view scientific activities from the viewpoint of a lay person.

2.111 Non-Significant Risk (NSR) Device: An investigational device that does not meet the definition of a significant risk device.

2.112 Off-Label Use: Use of an approved drug, an approved or cleared device, or a licensed biologic for an indication not in the approved labeling. Most research involving off-label uses requires IND or IDE applications.

2.113 Participating Site (pSite): An institution that participates in a Single IRB (sIRB) Study.

2.114 Planned Emergency Research: Research involving human subjects who are in need of emergency medical intervention (e.g., comparison of methods for providing cardiopulmonary resuscitation), but who cannot give informed consent because of their life-threatening medical conditions and who do not have an available legally authorized representative.

2.115 Preparatory to Research: Any action taken in assessing the research question or hypothesis, such as accessing medical records, querying of databases for any type of individually identifiable health information, or any activity where PHI is accessed to prepare a research protocol.

2.116 Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

2.116.1 For DoD research the term includes military personnel in either civilian or military custody.

2.117 Privacy Rule: The Health Insurance Portability and Accountability Act of 1996 (HIPAA), mandated the establishment of standards for the privacy of individually identifiable health information. The Privacy Rule created national standards to protect individuals' medical records and other personal health information. Covered entities are required to take reasonable steps to limit the use or disclosure of, and requests for protected health information (PHI) to the minimum necessary to accomplish the intended purpose. Covered entities include most health plans, health care clearinghouses, health care providers and agents of such entities.

2.118 Private Information: Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

2.119 Prompt Reporting: LSUHSC-S policy states that prompt reporting of unanticipated problems/events will occur immediately after the PI learns of the event, but in all cases within five (5) working days with the exception of death of a LSUHSC-S study subject. Prompt reporting requirements for a death of a study subject is as soon as the PI becomes aware of the event but no more than five (5) days following the event. Please see HRPP Policy for other events and emergency situations that require prompt reporting.

2.120 Protected Health Information (PHI)/HIPAA Authorization: (PHI) is any information about health status, provision of health care, or payment for health care that can be linked to a specific individual. The HIPAA Privacy Rule permits the use and disclosure of PHI if certain standards are met and the individual signs a PHI Authorization Form

2.121 Protocol: A document (including subsequent amendments) that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol reference documents. Throughout the ICH GCP Guidance, the term protocol refers to protocol and protocol amendments. Good Clinical Practice: Consolidated Guidance (ICH-E6). The protocol should include:

2.121.1 background information

2.121.2 rational for performing the study

2.121.3 objectives or hypothesis

2.121.4 description of research design

2.121.5 methodology (schedule of testing, procedures, medications and dosages and any other interventions or interactions with research subjects)

2.121.6 statistical considerations that will be employed

2.121.7 number of subjects to be enrolled

2.121.8 inclusion and exclusion criteria

2.121.9 safety oversight and monitoring

2.121.10 description of risks and benefits

2.121.11 informed consent process

2.122 Protocol Deviation(s): A protocol deviation is non-adherence to protocol specific study procedures or schedules that does not involve inclusion/exclusion criteria, primary objective variable criteria, and/or Good Clinical Practice (GCP) Guidelines. Deviations are considered minor and do not impact the study. This non-adherence is without prior sponsor and IRB approval and

2.122.1 increases the risk or decreases the benefit, and

2.122.2 significantly affects the subject's rights, safety or welfare and/or the integrity of the Research data. The term "protocol deviation" is not defined by either the HHS human subjects regulations (45 CFR 46) Common Rule or the FDA human subjects regulations (21 CFR 50).

2.123 Protocol Exception: A protocol exception is an impermanent (temporary) protocol deviation that is pre-approved by the Sponsor or funding agency, (and the FDA if applicable, for investigational device studies) and the IRB prior to implementation. Protocol exceptions are generally for a single subject or, occasionally, a small group of subjects.

2.124 Protocol Violation(s): A protocol violation is any significant divergence from the protocol, i.e., non-adherence on the part of the patient, investigator, or the sponsor to protocol-specific inclusion/exclusion criteria, primary objective variable criteria, and/or GCP guidelines without prior sponsor and IRB approval. Protocol Violations generally increase the risk and/or decrease the benefit; affect the subject's rights, safety or welfare and/or the integrity of the Research data. The term "protocol violation" is not defined by either the HHS human subjects regulations (45 CFR 46) Common Rule or the FDA human subjects regulations (21 CFR 50).

2.125 Public health authority: means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a 5 person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

2.126 Quality Assurance: Systems and procedures designed to ensure that a study is being performed in compliance with applicable federal regulations and guidelines; institutional policies; and that the data being generated is accurate.

2.127 Quality Improvement: Routine Quality Improvement (QI) means systematic, data guided activities designed to bring about immediate, positive changes in the delivery of services in particular settings such as healthcare. QI involves deliberate actions to improve care, guided by data reflecting the effects (e.g., types of practical problem solving; an evidence-based management style; the application of science of how to bring about system change; review of aggregate data at the patient/provider/unit/ organizational level to identify a clinical or management change that can be expected to improve care). QI is generally not considered research - however, QI activities can be research if they are also intended to contribute to generalizable knowledge.

2.128 Quorum: A quorum is defined as a majority of the voting members as listed on the IRB membership. In the case of the IRB, a quorum must include at least one member whose primary concerns are in non-scientific areas, at least one member whose primary concerns are in scientific areas, at least one unaffiliated member, and at least one member who represents the

general perspective of subjects. At meetings of the IRB, a quorum must be established and maintained for the deliberation and vote on all matters requiring a vote.

2.129 Related to the Research: A financial interest is Related to the Research when the interest is in:

2.129.1 A sponsor of the research

2.129.2 A competitor of the sponsor of the research

2.129.3 A product or service being tested or

2.129.4 A competitor of the product or service being tested

2.130 Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether they are conducted or supported under a program that is considered research for other purposes or not. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

2.130.1 Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

2.130.2 Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during an event or crisis that threatens public health (including natural or man-made disasters).

2.130.3 Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

2.130.4 Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

2.131 Research as Defined by FDA: Research is any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505 (i) or 520 (g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug, and Cosmetic Act, Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. .

2.132 Reportable Event / Reportable New Information (RNI): Information items that are likely to adversely affect the rights and welfare of the research subjects, the safety of the research subjects, or the integrity of the research data. Such events or information are to be reported to the IRB within 5 business days.

2.133 Repository: The terms data and/or specimen bank, tissue bank, repository, registry and database are often used interchangeably. These all involve the collection, storage and distribution of human data and or biological specimens. Repositories established for research purposes require IRB oversight

2.134 Restricted: Applies to investigators who are delinquent in meeting IRB requirements.

2.135 Scientist: Members will be considered “scientists” when the preponderance and recency of their training, professional experience (type, duration) and personal experience would incline them to view scientific activities from the viewpoint of a researcher.

2.136 Serious Adverse Event (SAE): An undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported to the FDA and the IRB when the patient outcome is; death, life-threatening, requires initial or prolonged hospitalization, disability or permanent damage, congenital anomaly/birth defect, required intervention to prevent permanent impairment or damage (devices) or other serious medical events (e.g., drug dependence).

2.137 Serious Non-Compliance: Non-Compliance such that the failure to comply could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject’s willingness to participate in research; significantly decreases potential benefits; or compromises the integrity of the Human Research protection Program (HRPP).

2.137.1 For DoD research Serious Non-Compliance includes failure of a person, group, or institution to act in accordance with DoD Instruction 3216.02 and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject’s

willingness to participate in research; or damage or compromise the scientific integrity of research data.

2.137.2 For Veterans Administration (VA) research Serious Non-Compliance is any failure to adhere to requirements for conducting Human Research that may reasonably be regarded as:

2.137.2.1 Presenting a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or

2.137.2.2 Substantively compromising a Veterans Administration (VA) facility's human research protection program (HRPP).

2.138 Significant-Risk (SR) Device: An investigational device that:

2.138.1 Is intended as an implant and presents a potential for serious risk to the health, safety or welfare of a subject

2.138.2 Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety or welfare of a subject

2.138.3 Is for a use of substantial importance in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety or welfare of a subject

2.138.4 Otherwise presents a potential for serious risk to the health, safety or welfare of a subject

2.139 Single Case Report: The external reporting (e.g., publication or poster/verbal presentation) of an interesting clinical situation or medical condition of a single patient. Case reports normally contain detailed information about an individual patient and may include demographic information and information on diagnosis, treatment, response to treatment, follow-up after treatment, as well as a discussion of existing relevant literature. The patient information used in the report must have been originally collected solely for non-research purposes as the result of a clinical experience. A single case report does not meet the definition of a systematic investigation and may not be human subject research.

2.140 Single IRB (sIRB) Study: A study in which two or more institutions (participating sites, or pSites) coordinate to complete the research activities, but all institutions rely on a single institution's/organization's IRB for ethical review. The reviewing IRB may or may not be affiliated with any of the pSites.

2.140.1 The requirement for single IRB review applies to awardees in the United States and participating research sites in the United States. The requirement for single IRB review does not apply to organizations outside the United States. The awardee organizations are responsible for ensuring authorization agreements are in place, and that documentation is maintained. Participating sites are expected to rely on the single IRB, though they may conduct their own review in accordance with NIH policy on exceptions from single IRB review.

2.141 Surrogate Consent: The use of a legally authorized representative with reasonable knowledge of the research subject, who shall include any of the persons and/or in descending order of 45 priority, described under Louisiana law.

2.142 Suspension of IRB Approval: An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review.

2.142.1 For Veterans Administration (VA) research, Suspension of IRB Approval:

2.142.1.1 Refers to a temporary interruption in selected research activities (e.g., new enrollments or specific interventions) due to concerns about the safety, rights, or welfare of human subjects, research personnel, or others, regardless of whether the action was taken by an investigator, facility official, research review committee, or external entity.

2.142.1.2 Does not refer to interruptions in research for other reasons, including the expiration of project approval periods.

2.143 Systematic: Having or involving a system, method, or plan

2.144 Termination of IRB Approval: An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.

2.144.1 For Veterans Administration (VA) research, Termination of IRB Approval:

2.144.1.1 Refers to a permanent halt in all research activities due to concerns about the safety, rights, or welfare of human subjects, research personnel, or others, regardless of whether the action was taken by an investigator, facility official, research review committee, or external entity.

2.144.1.2 Does not refer to interruptions in research for other reasons, including the expiration of project approval periods.

2.145 Test Article: Any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354-360F of the Public Health Service Act. (See 21 CFR 56.102) Note: This includes but is not limited to food products, medical foods, dietary supplements, and any other substance that is generally recognized as safe (GRAS) for human use; over-the-counter drugs, currently marketed prescription drugs, infant formulas, vaccines, and blood products.

2.146 Treatment IDE: A mechanism through the FDA for providing eligible subjects with investigational devices for the treatment of a serious or life-threatening illness for which there are no satisfactory alternatives. 21 CFR 812.36.

2.147 Treatment IND: A mechanism through the FDA for providing eligible subjects with investigational drugs for the treatment of a serious or life-threatening illness for which there are no satisfactory alternatives. 21 CFR 312.34.

2.148 Unanticipated: (unexpected) problems/events are those that are not already described as potential risks in the consent form, not listed in the Investigator's Brochure, or not part of an underlying disease. A problem/event is unanticipated when it was unforeseeable at the time of its occurrence. A problem/event is unanticipated when it occurs at an increased frequency or at an increased severity than expected.

2.149 Unanticipated Adverse Device Effect (UADE): Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

2.150 Unanticipated Problem Involving Risks to Subjects or Others: Any information that is (1) unanticipated, (2) related to the research, and (3) indicates that subjects or others are at increased risk of harm.

2.150.1 For DoD research the term Unanticipated Problem Involving Risks to Subjects or Others includes any incident, experience, or outcome that meets ALL three of the following conditions:

2.150.1.1 Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied.

2.150.1.2 Is related or possibly related to participation in the research (in this Instruction, possibly related means there is a reasonable possibility that the incident,

experience, or outcome may have been caused by the procedures involved in the research).

2.150.1.3 Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has occurred.

2.150.2 For Veterans Administration (VA) research:

2.150.2.1 Unanticipated Problem Involving Risks to Subjects or Others would include any serious problem or local serious adverse event (SAE) that is both unanticipated and related to the research.

2.150.2.2 The term “serious problem” includes a problem in human research or research information security that may reasonably be regarded as:

2.150.2.2.1 Presenting a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or

2.150.2.2.2 Substantively compromising a Veterans Administration (VA) facility’s human research protection program (HRPP) or research information security program.

2.150.2.3 The term “serious adverse event” refers to an untoward occurrence in human research that results in death, a life-threatening experience, inpatient hospitalization, persistent or significant disability or incapacity, congenital abnormality, or birth defect, or that requires medical, surgical, behavioral, social, or other intervention to prevent such outcome.

2.150.2.4 The terms “unanticipated” and “unexpected” refer to an event or problem in human research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol documents and the characteristics of the study population.

2.150.2.5 The term “related” means the problem may reasonably be regarded as caused by, or probably caused by, the research.

2.151 Written, or in writing, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

2.152 Viable: As it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

2.153 Ward: As defined by FDA, a child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law.

2.154 Withdrawal: A subject who signed a consent form but does not complete the entire study, regardless of the reason for withdrawal. Subject-initiated withdrawals and investigator or sponsor- initiated withdrawals should be included in the reported number of withdrawals.

2.155 1572: The 1572 is the Statement of the Investigator form submitted by the PI to the Sponsor 48 acknowledging their obligations in the conduction of the research. Principal Investigators on treatment protocols that involve an IND must complete Form FDA 1572. The 1572 is the contract between the clinical investigator and the federal government assuring that he or she will comply with FDA regulations 21 CFR 312.53. In signing the form the investigator assumes full responsibility for the study.

3 RESPONSIBILITIES

3.1 Individuals writing policies and procedures are to indicate terms defined in this policy with a single underline.

3.2 Individuals using policies and procedures are to consult this policy for the definitions of single underlined terms.

4 MATERIALS

4.1 SOP: HRP-013 LARs, Children, and Guardians

5REFERENCES

5.1 45 CFR 46

5.2 21 CFR 50.3; 21 CFR 56.102; 21 CFR 312.3; 21 CFR 812.2(a); 21 CFR 812.3(p)

5.3 VHA Handbook 1058.01; VHA Directive 1058

5.4 AAHRPP I.1.A.;I.1.B..;I.1.C.; I.1.F.; I.1.G.; I.2.; I.4.A.; I.5.D.; I.6.B.; I.7.A.; I.7.C.; I.9.; II.1.D.; II.2.B.; II.2.E.; II.2.F.; II.2.G.; II.2.H.; II.2.I.; II.3.A.; II.3.C.; II.3.D.; II.3.F.; II.4.; III.1.B.; III.1.C.; III.2.C.;

HRP-002 Education

1 PURPOSE

1.1 This policy establishes the procedure for educating Louisiana State University Health Sciences Center at Shreveport (LSUHSC-S) Institutional Review Board (IRB) members, IRB staff, investigators, and site research staff to ensure adequate training in human research protection and qualifications and credentialing of all staff.

1.2 The policy begins when the individual becomes an IRB member or is engaged in LSUHSC-S human subject research.

1.3 The guidance ends when the individual's involvement with LSUHSC-S human subjects research ceases.

2 POLICY

2.1 The LSUHSC-S HRPP offers comprehensive human research protection education to the LSUHSC-S research community and affiliate organizations.

2.2 Education is offered in many areas of research, including ethical standards, LSUHSC-S policies and procedures, and applicable federal, state, and local law. The foundation of ethical training at LSUHSC-S is the Belmont Report, which is made available through the IRB website and the Collaborative Institutional Training Initiative (CITI) website.

2.3 IRB members, IRB staff, investigators, and all site research staff involved in the design, conduct, or reporting of research are required to complete initial education and training on human subject protection and refresher courses, as applicable.

2.3.1 Investigators should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirements, and should provide evidence of such qualifications through up-to-date curriculum vitae, CITI training certificates and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authorities.

2.3.2 Principal Investigator: This Institution will allow a faculty or senior staff to serve as the Principal Investigator on a research project involving human subjects in their field of expertise. Adjunct and Gratis faculty members are approved by the IRB chair IO or designee on a case-by-case basis in consultation with HRPP Counsel and Human Resources.

2.3.3 Student Investigators: This Institution allows students and/or medical residents and fellows to act as Principal Investigators in specific human subject research as follows: investigator initiated retrospective review of data, documents or specimens and minimal risk survey research. They are required to obtain a Faculty Advisor for guidance. The Faculty Advisor is required to be listed as part of the research personnel (staff) of the study and to complete human subject research online training courses. Students, medical residents, or fellows may not serve as the principal investigator for any research that is determined to be greater than minimal risk.

2.3.4 IRB approval will not be granted for proposed research in which members of the research team have not completed the required human research protections training.

2.3.5 Initial training and education requirements and refresher updates including timeframes is specified for IRB members, IRB staff, and site research staff.

2.4 All educational requirements by all site research staff must be met for IRB study approval (initial and continuation).

2.4.1 If site research staff education requirements are not fulfilled, the study is not approved until all site research staff meets requirements.

2.5 Monitoring of education requirements of IRB members, IRB staff, and all site research staff is performed regularly as applicable to the role.

3 RESPONSIBILITIES

3.1 IRB staff performs these procedures.

3.2 IRB members, IRB staff, and all site research staff must fulfill the required training and information requirements set forth in this guidance.

3.3 Investigators ensure that site research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials and, when relevant, privileges) to perform procedures assigned to them during the study.

3.4 IRB staff monitors investigator and site research staff education requirements during the initial IRB review process and during the continuation request process.

4 PROCEDURE

4.1 Education Planning

4.1.1 Before the beginning of a new IRB Year (July 1), the IRB reviews and updates this IRB education guidance as needed.

4.1.2 The IRB incorporates input received from IRB members, IRB staff, and investigators and from monitoring and evaluation activities. Trends in research at LSUHSC-S are considered and new federal, state, or local regulations (or published guidance) are integrated. Compliance activities (e.g., internal, and external audits) also provide input into the education plan.

4.2 Required Initial and Continuing Training:

4.2.1 Institutional Official Required Training:

Initial or Refresher Course	Course	Timeline
Initial Course	CITI IRB Members Basic	Within 30 days of appointment
Initial Course	CITI Conflict of Interest	Within 30 days of appointment
Initial Course	CITI Good Clinical Practice	Within 30 days of appointment
Initial Course	CITI Health Information Privacy & Security	Within 30 days of appointment
Initial Course	CITI Institutional/Signatory Official: Human Subject Research	Within 30 days of appointment
Initial Course	Research Security: A Basic Course	Within 30 days of appointment
Refresher Course	CITI IRB Members Refresher	Every 3 years
Refresher Course	CITI Conflict of Interest	Every 4 years or upon change
Refresher Course	Research Security: A Basic Course	Every year

4.2.2 IRB Members Required Training:

Initial or Refresher Course	Course	Timeline

Initial Course	CITI IRB Members Basic	Within 45 days of appointment
Initial Course	CITI Conflict of Interest	Within 45 days of appointment
Initial Course	CITI Good Clinical Practice	Within 45 days of appointment
Initial Course	CITI Health Information Privacy & Security	Within 45 days of appointment
Initial Course	IRB Member Orientation	Prior to Voting and Review Assignments
Initial Course	Research Security: A Basic Course	Within 45 days of appointment
Refresher Courses	CITI IRB Members Refresher	Every 3 years
Refresher Course	CITI Conflict of Interest	Every 4 years or upon change
Refresher Course	Research Security: A Basic Course	Every year

4.2.3 IRB Staff (including Office of Research staff – CTMT, CTO and HRPP) Required Training:

Initial or Refresher Course	Course	Timeline
Initial Course	CITI Biomedical Research Basic	Within 14 days of appointment
Initial Course	CITI Conflict of Interest	Within 14 days of appointment
Initial Course	CITI Good Clinical Practice	Within 14 days of appointment
Initial Course	CITI Health Information Privacy & Security	Within 14 days of appointment
Initial Course	Clinical Trial Billing Compliance (Required for CTMT Team only)	Within 14 days of appointment
Initial Course	Research Security: A Basic Course	Within 14 days of appointment
Refresher Course	CITI Biomedical Refresher	Every 3 years
Refresher Course	CITI Conflict of Interest	Every 4 years or upon change

Refresher Course	Research Security: A Basic Course	Every year

4.2.4 Investigator and Site Research Staff Required Training: Courses for Clinical Studies:

Initial or Refresher Course	Course	Timeline
Initial Course	CITI Biomedical Research Basic	Prior to IRB Submission
Initial Course	CITI Conflict of Interest	Prior to IRB Submission
Initial Course	CITI Good Clinical Practice	Prior to IRB Submission
Initial Course	CITI Health Information Privacy & Security	Prior to IRB Submission
Initial Course	Research Security: A Basic Course	Prior to IRB Submission
Refresher Course	CITI Biomedical Refresher	Every 3 years
Refresher Course	CITI Conflict of Interest	Every 4 years or upon change
Refresher Course	Research Security: A Basic Course	Every year

4.2.5 Investigator and Research Staff involved in Non-Clinical Studies (Surveys, Qualitative, Educational, Record Reviews) Required Training:

Initial or Refresher Course	Course	Timeline
Initial Course	CITI Biomedical Research Basic or CITI Social and Behavioral Research Basic	Prior to IRB Submission
Initial Course	CITI Conflict of Interest	Prior to IRB Submission
Initial Course	CITI Health Information Privacy & Security	Prior to IRB Submission
Initial Course	Research Security: A Basic Course	Prior to IRB Submission
Refresher Course	CITI Biomedical or Social & Behavioral Refresher	Every 3 years

Refresher Course	CITI Conflict of Interest	Every 4 years or upon change
Refresher Course	Research Security: A Basic Course	Every year

4.3 IRB Member Orientation

4.3.1.1 New IRB members, including alternate members will meet with the IRB Chairs, IRB Director or HRPP Education Coordinator for an informal orientation session. At the session, the new member will be provided education about

4.3.1.1.1 LSUHSC-S Federal Wide Assurance (FWA)

4.3.1.1.2 LSUHSC-S Policies and Procedures for the Protection of Human Subjects

4.3.1.1.3 Reviewer Checklist

4.3.1.1.4 DHHS OHRP IRB Guidebook

4.3.1.1.5 Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research

4.3.1.1.6 Applicable Federal & State regulations including:

- Title 45, part 46 — The Common Rule
- 21 CFR part 50 — Protection of Human Subjects
- 21 CFR part 56 — Institutional Review Boards
- 21 CFR part 312 — Investigational New Drugs
- 21 CFR part 812 — Investigational Device Exemptions

4.3.1.1.7 FDA Information Sheets Guidance or website address

4.3.1.1.8 OHRP Guidance Sheets or website address

4.3.1.1.9 SHIeLDS Training

4.3.2 The IRB/HRPP Office Professional Staff

4.3.2.1 Initial Education: The HRPP Office Staff will be given an orientation binder or electronic links that includes:

4.3.2.1.1 LSUHSC-S Shreveport's Federal-wide Assurance (FWA)

4.3.2.1.2 LSUHSC-S Policies and Procedures for the Protection of Human Subjects

4.3.2.1.3 Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research

4.3.2.1.4 Applicable Federal and State regulations including: - Title 45, part 46 — The Common Rule - 21 CFR part 50 — Protection of Human Subjects - 21 CFR part 56 — Institutional Review Boards - 21 CFR part 312- Investigational New Drugs - 21 CFR part 812 — Investigational Device Exemptions

4.3.2.1.5 FDA Information Sheets Guidance or website address

4.3.2.1.6 OHRP Guidance Sheets or website address

4.3.2.2 Each new staff member is expected to complete and submit the following:

4.3.2.2.1 LSUHSC-S HIPAA Training (if not done upon hire to the institution)

4.3.2.2.2 The CITI Human Subjects Research Basic Courses for Biomedical, GCP, HIPS, COI and Research Security training.

4.3.2.3 Continuing Education Continuing training and education is provided on a daily basis through discussions of regulatory and ethical issues that arise during the processing of IRB proposals. Other educational activities include, but are not limited to:

4.3.2.3.1 CITI (Collaborative Institutional Training Initiative) Refresher courses required every three (3) years;

4.3.2.3.2 At least quarterly attendance of a full IRB meeting;

4.3.2.3.3 Annual conferences on human research protections on a rotating basis. Additionally, the IRB/HRPP Office Professional Staff will be encouraged to become CIP certified.

4.3.3 New LSUHSC-S employees may use previously completed CITI human subject protections training from their prior institution if within the applicable timeframe.

4.3.3.1 When Human Research is conducted or funded by the DoD, this organization commits to apply the DoD Directive 3216.02, which includes the

requirement to apply 45 CFR §46 Subparts B,C, and D. Initial and continuing research ethics education is required for all personnel who conduct, review, approve, oversee, support, or manage human subject research. There may be additional protocol-specific educational requirements or certification required for investigators and site research staff based on additional regulations (e.g., DoD or sponsor requirements, due to the complexity and risk of the research). When research is funded or conducted by the DoD, investigators will be asked to contact the program office funding the research to ask about specific education requirements, and then demonstrate they have been completed.

4.3.4 Orientation**:** All Principal Investigators and members of their research team must review core training documentation including:

4.3.4.1 LSUHSC-S Standard Operating Policies and Procedures for Human Research Protection: **http://www.lsuhscshreveport.edu/Research/HRPP-Home/index**

4.3.4.2 LSUHSC-S Federal Wide Assurance (FWA): **https://www.hhs.gov/ohrp/irbs-and-283assurances.html**

4.3.4.3 The "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research: **https://www.hhs.gov/ohrp/regulations-andpolicy/belmont-report/index.html**

4.3.4.4 Applicable Federal and State Regulations

4.3.4.5 Title 45, part 46-The Common Rule: **https://www.hhs.gov/ohrp/regulations-andpolicy/regulations/45-cfr-46/index.html**

4.3.4.6 21 CFR part 50-Protection of Human Subjects and 21 CFR part 56-Institutional Review

4.3.4.7 Boards: Electronic Code of Federal Regulations

4.3.4.8 VHA 1200.05(1): **VHA Directive 1200.05 - Requirements for the Protection of Human Subjects in Research**

4.3.4.9 FDA website and Information Sheets Guidance: **http://www.fda.gov/default.htm Information Sheet Guidance for Institutional Review Boards (IRBs), Clinical Investigators, and Sponsors**

4.3.4.10 OHRP Guidance: **https://www.hhs.gov/ohrp/regulations-and-policy/guidance/**

4.3.5 All personnel involved in the collection, transfer, shipping or processing of human biological samples are required to complete biosafety training and educational courses, both for their own protection and to maintain compliance with numerous local, state and federal

regulations including the Office of Risk Management, the Occupational Safety and Health Administration (OSHA) and/or the National Institutes of Health (NIH).

4.3.6 The following courses as well as other related courses are available through the CITI online research training program: **http://www.citiprogram.org**

- Basic Biosafety Training
- OSHA Bloodborne Pathogens
- OHSA Personal Protective Equipment Training
- (IATA) Shipping and Transport of Regulated Biological Materials
- Biohazard Spills and Releases
- Human Gene Transfer Trials
- NIH Recombinant DNA (rDNA) Guidelines

4.3.7 For the Department of the Navy (DoN). See Department of Navy Human Research Protection Program (DON HRPP) Required Training and References. **https://www.onr.navy.mil/en/AboutONR/compliance-protections/Research-Protections/Research-Protection-Training-References** Research under the purview of the Under Secretary of State (personnel and Readiness): Requires annual training on human subject protections for investigators and research directly involved in human subject research. For other military branches (e.g. Army, Air Force), the investigator must contact the program offices for specific instruction about their respective education requirements

4.3.8 All individuals who are subject to VA regulations are required to complete training in the ethical principles on which human research is to be conducted before they may participate in human subjects research in accordance with requirements specified by ORD; the local site can require additional training.

4.4 Training and Education Records:

4.4.1 All IRB-required education records and appropriate certificates of completion are maintained by the investigator. Individual investigators maintain their own training records and provide to the IRB as required.

4.4.2 IRB staff will be given access to the CITI online education certificates of completion for all individuals covered by this policy.

4.5 Each investigator and/or study team member, will complete the minimum required, mandatory, CITI education module - "Conflict of Interest mini-course" and then register in SHIeLDS to complete their COI disclosure and submit study application in IRB SHIeLDS.

4.5.1.1 The IRB staff will verify completion of other mandatory CITI education required as per the type of the protocol submitted by the investigator to the IRB. If they submit a "Not Human Subject Research" protocol (such as QI/case series), they would not be required to complete the other CITI modules (such as Biomedical, GCP, HIPS, Social and Behavioral or Research Security: A Basic Course), unless the IRB determines that their project is "Human Subject Research". The IRB staff will notify the investigator if his CITI education is incomplete.

4.5.1.2 For research involving human subjects, everyone involved in research (e.g., research staff listed on the delegation log or 1572, those involved in research oversight, and those responsible for resource allocation) are required to report potential Conflicts of Interest through the Conflict of Interest in Research reporting mechanisms. Each person must report annually, and within thirty (30) days of a change subject to reporting requirements. It should be noted that reporting is required for each individual's immediate household.

4.6 Ongoing education will be provided to IRB members at convened meetings. Additionally, the educational information will be distributed to all members through email.

4.7 LSUHSC-S faculty or employees that are also IRB members will complete a COI disclosure through the electronic system in addition to the other requirements specified in SOP: HRP-050 Conflicting Interests of IRB Members and HRP-325 - WORKSHEET - IRB Member and Consultant COI.

5 MATERIALS

5.1 SOP: HRP-050 Conflicting Interests of IRB Members

5.2 HRP-325 - WORKSHEET - IRB Member and Consultant COI

6 REFERENCES

6.1AAHRPP I.1.A.; I.1.E. ; I.6.B.; III.2.A.

HRP-003 HRPP Organization

1 PURPOSE

1.1 LSUHSC-S ensures that the Human Research Protection Program (HRPP) has resources sufficient to protect the rights and welfare of research subjects for the research activities that the Organization conducts or oversees.

1.2 This procedure establishes the process that allow the Institutional Review Board (IRB) to function independently of other organizational entities in protecting research subjects.

1.3 This procedure establishes the process to ensure that the handling of investigational or unlicensed test articles conforms to legal and regulatory requirements.

2 POLICY

2.1 The HRPP is a comprehensive system to ensure the protection of human subjects participating in research. The HRPP consists of a mission statement; ethical principles; policies and supporting SOPs; and various individuals and committees such as: the IO, the Vice Chancellor for Research, the Assistant Vice Chancellor for Research Management, the IRB, other committees or subcommittees addressing human subjects protection (e.g., Bio-safety Committee, Radiation Safety Committee, Pharmacy and Therapeutics Committee, Radioactive Drug Research Committee, Conflict of Interest Committee), investigators, IRB staff, HRPP staff, Clinical Trials Office (CTO) including research staff, health and safety staff (e.g., Hospital Safety Officer Research Compliance Specialist, Privacy Officer) and research pharmacy staff. The objective of this system is to assist the Institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research.

2.1.1 The mission of the HRPP is to:

2.1.1.1 Safeguard and promote the health and welfare of human research subjects by ensuring that their rights, safety and well-being are protected.

2.1.1.2 Provide ongoing training and education, timely review and monitoring of human research projects.

2.1.1.3 Facilitate excellence in human subjects research.

2.1.1.4 Cultivate a culture of consciousness in the research community to ensure the highest level of protections and advocacy for research subjects by actively

engaging and working cooperatively with the Institutional Official, Institutional Leaders, and all components of the HRPP; by facilitating ethical and scientifically sound research institutional oversight and Institutional Review Board (IRB) review processes; contributing to the knowledge of investigators and research personnel through education and training programs; communicating with sponsors, and serving as a consistent resource for past, present, and prospective subjects.

2.1.1.5 Have open communications with Investigators and Research Staff and be responsive to their questions, concerns, and suggestions regarding the HRPP. Investigators are free to contact staff members of HRPP. See **https://www.lsuhs.edu/research/irb** .

2.1.1.6 The HRPP includes mechanisms to:

2.1.1.6.1 Establish a formal process to monitor, evaluate and continually improve the protection of human research subjects.

2.1.1.6.2 Dedicate resources sufficient to do so.

2.1.1.6.3 Exercise oversight of research protection.

2.1.1.6.4 Educate IRB Committee members, IRB support staff, investigators and research staff about their ethical responsibility to protect research subjects.

2.1.1.6.5 When appropriate, intervene in research and respond directly to concerns of research subjects.

2.1.1.6.6 Educate research subjects and the community.

2.1.2 Ethical Principles: The Institution is committed to ensuring that all human research in which it is engaged is conducted in accordance with ethical and legal principles. The primary ethical principles applied to research covered by the HRPP, including protocols exempt under federal regulations pertaining to human subject research are set forth in the Belmont Report **(http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm).**

2.1.2.1 The Institution holds the conduct of research with the highest regard for the welfare of human subjects. It upholds and adheres to the principles of The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (1979).

2.1.2.2 The three (3) main principles are:

1. Respect for Persons, which is ensured by obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations. Individuals should be treated as autonomous agents afforded the right to make decisions themselves. Those with decreased or diminished autonomy such as minors, prisoners, people who are mentally disabled or challenged are entitled to additional protections.

2. Beneficence, which is assured by ensuring that possible benefits are maximized, and possible risks are minimized to all human subjects. Application of this principle involves a risk/benefit analysis in which the risks to subjects must be reasonable compared to the potential for benefit either to subjects directly or to society. Risk evaluation must include the consideration of both the probability and magnitude of harm, including psychological, physical, legal, social, and economic harm.

3. Justice, the equitable selection of subjects. The possibility for benefits and the potential burdens of the research should be equitably distributed among the potential research subjects. Application of this principle requires the scrutiny of the enrollment process to ensure that particular classes are not selected for their compromised position or convenience to the research investigator. Such classes are welfare patients, racial and ethnic minorities or persons confined to institutions.

2.1.2.3 All parties involved in the conduct of research are expected to also adhere to the principles of expertise (competent to work) and integrity (faithfully adhere to professional principles). Ethical principles from other sources (e.g., International Conference on Harmonization) may also be applied to research covered by the HRPP, for example:

2.1.2.3.1.1 To an individual protocol because its particular circumstances raise a type of ethical issue that most other protocols do not

2.1.2.3.1.2 When they are recognized by the federal or other funding source or the state or country where the research will occur

2.1.2.3.1.3 When they have been developed for specific areas or types of subjects (e.g., embryos and fetal tissue, illiterate subjects).

2.1.2.3.2 Clinical Trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with Good Clinical Practice (GCP) and the applicable regulatory requirements(s).

2.1.2.3.3 Investigator training on the ethical principles governing human subject research and investigator responsibilities is provided in the CITI tutorial for investigators, IRB Members, and IRB Staff, and in the orientation given to new IRB members.

2.1.2.3.4 With respect to sponsored research, LSUHSC-S address the protection of research subjects by including in their standard contract language a provision that the sponsor acknowledges and understands that the LSUHSC-S HRPP is applicable to all human subject research.

2.1.2.4 The basic legal principles governing human subject research, covered by the HRPP and applicable to individual protocols are:

2.1.2.4.1 Federal Policy for Protection of Human Subjects (Common Rule) in 45 CFR Part 46

2.1.2.4.2 Food and Drug Administration Regulations for the Protection of Human Subjects in 21 CFR Parts 50 and 56

2.1.2.4.3 Standards for Privacy of Individually Identifiable Health Information (HIPAA Privacy Rule) in 45 CFR Parts 160 and 164

2.1.2.4.4 Department of Veterans Affairs regulations in 38 CFR Part 16 and VHA Directive 1200.5

2.1.2.4.5 Applicable Louisiana law. These and other legal principles are addressed when applicable in individual HRPP chapters. The LSUHSC-S Human Research Protections Program (HRPP), in partnership with its research community, is responsible for ensuring the ethical and equitable treatment of all human subjects in research conducted under its auspices.

2.2 The Institution's Human Research Protections Program operates under the authority of the Institutional policy "Human Research Protections Program (HRPP)" adopted on August 5, 2008. As stated in that policy, the operating procedures in this document "...serve as the governing procedures for the conduct and review of all human subjects research conducted under the auspices of the Institution."

2.2.1 The HRPP Policy and these operating procedures are made available to investigators, research staff, IRB committee members, IRB support staff, Research Affiliates, sponsors and all components identified under the Institutional Federal Wide Assurance (FWA), and all Assurances relying upon the LSUHSC-S IRB. The HRPP and IRB Standard Operating Procedures are located on the LSUHSC-S IRB website, **https://www.lsuhs.edu/research/irb**.

2.3 The following officials, administrative units and individuals have primary responsibilities for implementing the HRPP:

2.3.1 Chancellor: The Chancellor is responsible for the overall operations at LSUHSC-S. The Chancellor may retain the responsibilities of IO or may delegate the ultimate responsibility and authority of the HRPP.

2.3.2 Institutional Official (IO): The ultimate responsibility of the HRPP resides with the Vice Chancellor for Research who serves as the Institutional Official (IO). The IO is responsible for ensuring that the Institution's HRPP has the resources and support necessary to comply with all Institutional policies and with applicable Federal regulations and guidelines that govern human subject research. The IO is legally authorized to represent the Institution and is the signatory of the FWA and assumes the obligations of the FWA.

2.3.3 Assistant Vice Chancellor for Research Management: The Assistant Vice Chancellor for Research Management (AVCRM) reports to the Vice Chancellor for Research and is responsible for the duties below. These duties, or portions thereof, may be delegated to a responsible party as deemed appropriate by the AVCRM, the Vice Chancellor for Research or the IO.

2.3.3.1 Developing, managing, and evaluating policies and procedures that ensure compliance with all state, federal, and local regulations governing research. This includes monitoring changes in regulations and policies that relate to human research protections and overseeing all aspects of the HRPP program.

2.3.3.2 Advising the Institutional Official (IO) on key matters regarding research at the Institution.

2.3.3.3 Implementing the institution's HRPP policy.

2.3.3.4 Submitting, implementing and maintaining an approved FWA through the Institutional Official (IO) and the Department of Health and Human Services Office of Human Research Protections (OHRP)

2.3.3.5 Providing information to the IO regarding the needs and resources required for the HRPP operation.

2.3.3.6 Serving as the primary contact at LSUHSC-S for the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services and other federal regulatory agencies.

2.3.3.7 Assisting the investigators in their efforts to carry out the Institution's research mission.

2.3.3.8 Developing and implementing needed improvements and ensuring follow-up of actions, as appropriate for the purpose of managing risk in the HRPP.

2.3.4 HRPP Staff

2.3.4.1 Institutional Official (IO) designee is responsible for:

2.3.4.1.1 Advising the Institutional Official (IO) on key matters regarding research at the Institution.

2.3.4.1.2 Implementing the institution's HRPP policy.

2.3.4.1.3 Assisting the investigators in their efforts to carry out the Institution's research mission.

2.3.4.1.4 Developing and implementing needed improvements and ensuring follow-up of actions, as appropriate for the purpose of managing risk in the HRPP.

2.3.4.2 IRB Director: reports directly to the AVCRM and indirectly to the IO.

2.3.4.2.1 Advises the AVCRM on day-to-day operations of the IRB.

2.3.4.2.2 Ensuring constructive communication concerning HRPP, IRB and Clinical Trial Office(CTO) matters among the officials of the Institution, investigators, clinical care staff, and human subjects as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

2.3.4.2.3 Assist the AVCRM in developing, managing and evaluating policies and procedures that ensure compliance with all state, federal, and local regulations governing research. This includes monitoring changes in regulations and policies that relate to human research protections and overseeing all aspects of the HRPP program.

2.3.4.2.4 Assisting investigators in their efforts to carry out the Institution's research mission.

2.3.4.2.5 Developing and implementing needed improvements and ensuring follow-up of actions, as appropriate, for the purpose of managing risk in the research program.

2.3.4.2.6 Developing training requirements as required and as appropriate for investigators, subcommittee members and research staff, and ensuring that training is completed on a timely basis.

2.3.4.3 HRPP Educator & Subject Outreach Coordinator: The HRPP Educator & Subject Outreach Coordinator is responsible for:

2.3.4.3.1 Developing, coordinating, and implementing the LSUHSC-S comprehensive education program for the protection of human subjects in research, GCP, investigator responsibilities, IRB and regulatory reporting.

2.3.4.3.2 Assuring that all components of the education program are in strict compliance with federal and state regulations and Institutional policies governing human research.

2.3.4.3.3 Assists the IRB Director and/or AVCRM in determining that all initial and biannual certification requirements have been met by all members of the IRB and IRB staff; Investigators and research staff; and students engaged in research involving human subjects.

2.3.4.3.4 The development and implementation of educational materials (manuals for faculty, staff, and investigators; newsletters; web updates; announcements).

2.3.4.3.5 The development and implementation of outreach resources and educational materials for research subjects, prospective research subjects and community members. 6. Participating in the periodic evaluation of community outreach activities. This Coordinator is supervised by the IRB Director and evaluated annually as per Institutional policy.

2.3.4.4 HRPP Quality Assurance/Quality Improvement Coordinators (QA/QI Coordinators): The HRPP Quality Assurance/Quality Improvement Coordinators oversee and ensure that research conducted at the Institution is in compliance with research regulations applicable to human subjects. In this capacity, the QA/QI Coordinators are responsible for

2.3.4.4.1 developing and implementing policies and procedures to ensure compliance with research regulations and requirements.

2.3.4.4.2 conducting training and education regarding research compliance topics; and (3) conducting audits and monitoring research activity.

2.3.4.4.3 The QA/QI Coordinators serve as ex-officio guests of the IRB to provide information regarding routine or for cause audits, monitoring activities, compliance deviations and violations and assist with corrective measure(s). The HRPP Quality Assurance/Quality Improvement Coordinators evaluate and implement measures

to improve Human Research Protections in compliance with organizational policies and procedures.

2.3.4.4.4 When Protocol Exceptions and Deviations are deemed to be serious or continuing), the IRB Director (or designee) shall report the Exception or Deviation to the QA Coordinator for review. The coordinator will review/monitor the information and investigate, as needed, and report to the IRB recommendations for a corrective action plan.

2.3.4.4.5 The QA Coordinators review and investigate all credible complaints and Allegations of Non-Compliance that are submitted to the IRB or that have been brought to their attention, and will make a report, as appropriate, to the IRB with recommendation for a corrective action plan.

2.4 Institutional Review Board

2.4.1 LSUHSC-S has established one (1) Institutional Review Board (IRB) to ensure the protection of human subjects' research under the auspices of the Institution, appointed by the Institutional Official. It is Louisiana State University Health Sciences Center-Shreveport IRB 1 (IRB 00000178) (IORG0000109). The IO retains the authority to create or dissolve IRBs. Members of the IRBs are also appointed by the IO. The IRB is one of five (5) LSUHSC-S Research Assurance Committees. This IRB is comprised of members with varying backgrounds to promote complete and adequate review of research activities commonly conducted. IRB approval must be obtained prior to beginning any research activity involving human subjects. The IRB prospectively and retrospectively reviews and makes decisions concerning all human research conducted at its facilities or by its employees or agents, or under its auspices. The IRB is responsible protecting the rights and welfare of human research subjects involved in research conducted under the auspices of the Institution. It discharges this duty by complying with the requirements of the Common Rule and other applicable federal regulations, state regulations, the FWA, and institutional policies.

2.4.2 The LSUHSC-S IRB serves as the IRB of record for LSUHSC-S; Overton Brooks VA Medical Center; Overton Brooks Research Corporation; Biomedical Research Foundation-Northwest LA; Ochsner Health System and any other IRB affiliated sites through MOUs/Agreements.

2.4.3 IRB Authority

2.4.3.1 Under Human Research Protections Program (HRPP), institutional policy, the IRB is authorized:

2.4.3.1.1 To approve, require modifications to secure approval, or disapprove all human subjects research activities overseen and conducted under the auspices of the LSUHSC-S

2.4.3.1.2 To suspend or terminate approval of research not being conducted in accordance with the IRB(s) requirements or that has been associated with unexpected serious harm to subjects

2.4.3.1.3 To observe, or have a third-party observe, the consent process

2.4.3.1.4 To observe, or have a third-party observe, the conduct of the research

2.4.4 Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. However, those officials may NOT approve research if it has been disapproved by the IRB. Institutional Officials may strengthen requirements and/or conditions or add other modifications to secure Institutional approval or approval by another Institutional committee. Previously approved research proposals and/or consent forms must be re-approved by the IRB before initiating the changes or modifications. The IRB Chairs make the determination whether the changes require full IRB re-review or expedited review.

2.4.5 VA Research: Through a Memorandum of Understanding (MOU), VA has designated the LSUHSC-S IRB as its IRB of record. The LSUHSC-S IRB is responsible for performing all the functions required under 38 CFR 16 (Common Rule) for reviewing and approving human subjects research conducted under the auspices of Overton Brooks VAMC(s) FWA #00002051. This includes, but is not limited to, VA supported research or research conducted at a VA facility and research involving VA patients as research subject (hereafter "VA research"). Regulations & Guidance: DHHS 45 CFR § 46.112; FDA 21 CFR § 56.103; 21 CFR§ 56.109; 21 CFR §56.112; and 21 CFR §56.113.

2.4.6 When projects are approved at a convened meeting of the Board, or at continuing review, the committee members will engage in a discussion to determine whether the project should be required to be reviewed again more often than annually. In projects where the risks of study intervention(s) are not well known, and when there is a concern that risks may be substantial in terms of magnitude or probability of harm, the Board will consider shorter periods of approval to re-evaluate the criteria for approval more often than annually. In cases where the IRB members are aware of relevant events or issues with a study team or site, or there are other confounding events (e.g., pandemic), the panel will also consider shorter periods of approval and may require specific monitoring of the conduct of the study by the local RCO or another independent monitoring group.

2.5 Counsel for the HRPP

2.5.1 The Institution's Office of Legal Affairs and Organizational Integrity provides advice to the HRPP, the IO and the Institutional Agents, PIs, Investigators, and research staff with respect to laws, regulations, and requirements applicable to Human Subjects Research. This includes interpretation and application of Federal, State and local laws where research is conducted. Counsel is responsible for addressing all of the legal issues arising out of the activities of LSUHSC-S. A representative of the Office of Legal Affairs and Organizational Integrity is available for consultation on issues regarding human subject research and subject protection.

2.5.2 The IRB follows and must adhere to all applicable state and local laws in the jurisdictions where the research is taking place. The HRPP and the LSUHSC-S IRB rely on the Counsel for the HRPP for the interpretation and application of Louisiana State law and the laws of any other jurisdiction where research is conducted as they apply to human subject research. All consent forms must be consistent with applicable state and local laws.

2.6 Department Chair

2.6.1 The Department Chair is responsible for ensuring that the Principal Investigator (PI) is qualified by training and experience to conduct the proposed research. In addition, Department Chairs are responsible for ensuring that the PI has sufficient resources and facilities to conduct the proposed research. Such resources include but are not necessarily limited to personnel, space, equipment, and time. For each proposal submitted to the LSUHSC-S IRB for approval, the Department Chair must certify that they accept responsibility for assuring adherence to the federal and state regulations and institutional policies governing the protection of human subject's research, including applicable institutional credentialing requirements. The Department Chair is required to review all proposals before they are submitted to the IRB for review. The signature of the Department Chair indicates that the study is found to be scientifically sound and can reasonably be expected to answer the proposed question.

2.7 The Principal Investigator (PI)

2.7.1 The Principal Investigator bears the ultimate responsibility for the protection of human subjects who participate in research. The PI is expected to abide by the highest ethical standards for developing a protocol that incorporates the principles of the Belmont Report. He/she is expected to conduct research in accordance with the IRB approved research protocol and to oversee all aspects of the research by providing supervision of support staff, including oversight of the informed consent process. All subjects must provide their informed consent and the investigator must establish and maintain an open line of communication with all research subjects within his/her responsibility. In addition to complying with all the policies and standards of the governing regulatory bodies, the

investigator must comply with institutional and administrative requirements for conducting research. The PI is responsible for ensuring that all research staff are appropriately qualified and complete all required training prior to initiating research. When investigational drugs or devices are used, the investigator is responsible for providing written procedures for their storage, security, dispensing and disposal. The PI is ultimately responsible for ensuring that no subject is enrolled before IRB approval is issued and any related sponsor agreement is fully executed. This Institution will allow a faculty or senior staff to serve as the Principal Investigator on a research project involving human subjects in their field of expertise. Adjunct and Gratis faculty members are approved by the IRB chair IO or designee on a case-by-case basis in consultation with HRPP Counsel and Human Resources.

2.7.2 According to Health and Human Services Regulations an investigator refers to an individual performing tasks involving the conduct of human subjects research activities such as obtaining information about living individuals by intervening or interacting with them for research purposes; obtaining identifiable private information about living individuals for research purposes; obtaining the voluntary informed consent of individuals to be subjects in research; and studying, interpreting, or analyzing identifiable private information of data for research purposes. Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. Some research studies are conducted by one or more investigators, and at LSUHSC-S there will be only one Principal Investigator on a research study. In every human subject's research study, investigators have certain responsibilities regarding the ethical treatment of human subjects. Principal Investigators are ultimately responsible for the conduct of research. Research must be conducted according to the signed investigator statement, the investigational plan and applicable regulations; for protecting the rights, safety, and welfare of subjects under the PI(s) care. Principal Investigators may delegate research responsibility. However, investigators must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility. Research procedures that are delegated to other members of the research team by the PI are documented on a Delegation of Authority Log. Delegation of Authority Logs is to be submitted with Initial Proposals and at the time of continuing review. In the event of changes to the research staff or changes in the delegated responsibilities, the PI is to submit these changes to the IRB for review and approval.

2.7.3 Investigators are expected to:

2.7.3.1 Protect the rights and welfare of prospective subjects.

2.7.3.2 Assume overall administrative responsibilities for all aspects of each IRB-approved research study, conducting the research according to the IRB-approved protocol, maintaining appropriate oversight of the research study and supervision of the research staff, appropriately delegating research responsibilities.

2.7.3.3 Investigators are expected to have sufficient resources necessary to protect human subjects, including:

2.7.3.3.1 Sufficient time to conduct and complete the research.

2.7.3.3.2 Adequate numbers of qualified staff.

2.7.3.3.3 Adequate facilities.

2.7.3.3.4 A process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.

2.7.3.3.5 Availability of medical and psychological resources that subjects might require as a consequence of the research. Assure that all procedures in a study are performed with the appropriate level of supervision and only by individuals who are licensed or other qualified to perform such under the laws of Louisiana and policies of LSUHSCS.

2.7.3.4 Having a procedure to receive complaints or requests for additional information from subjects and respond appropriately. Investigators should explain to research subjects how the Research Staff can be contacted to ask questions, express concerns, or express complaints about the research and seeking guidance from the HRPP or IRB when necessary.

2.7.3.5 Investigators are expected to ensure that risks to subjects are minimized and protect subjects' rights and welfare by recruiting subjects in a fair and equitable manner, avoiding practices that place subjects at risk for coercion or undue influence.

2.7.3.6 Assure all key personnel under his/her supervision are adequately trained and supervised in the regulatory requirements regarding the conduct of research and the ethical principles upon which they are based including mandatory institutional CITI training.

2.7.3.7 Assure that research duties are delegated to individuals who are qualified to perform the assigned tasks and informing research staff of any pertinent changes during the course of the study.

2.7.3.8 Develop and conduct a research plan that is in accordance with the ethical principles in the Belmont Report.

2.7.3.9 Develop a research plan that is scientifically sound and in accordance with the standards of their discipline.

2.7.3.10 Studies should be in a design that minimizes risks to subjects

2.7.3.11 Follow Good Clinical Practice (GCP) guidelines when conducting any study that meets the definition of human subjects' research and involves,

2.7.3.11.1 FDA regulated approved or unapproved drugs, devices or biologics or any other FDA regulated product; or

2.7.3.11.2 where the sponsor or funding agency requires the use of GCP guidelines

2.7.3.12 Ensure that pertinent laws, regulations, and institutional procedures and guidelines are observed by participating investigators and research staff. Investigators must be knowledgeable about and comply with requirements of Common Rule and other federal research laws and regulations, applicable state law, LSUHSC-S FWA, and institutional policies and procedures for protection of human subjects

2.7.3.13 Maintain contact with the sponsor, the monitoring entity if applicable, and receive reports from the sponsor

2.7.3.14 Ensure that every investigator discloses any potential conflict of interest

2.7.3.15 Cooperate with evaluations, inspections, and audits performed by authorized internal oversight authorities, such as the IRB, as well as external reviews (e.g., sponsor or government agency such as FDA)

2.7.3.16 Maintain adequate and accurate records in accordance with 21 CFR 312.62, making those records available for inspection in accordance with 21 CFR 312.68

2.7.3.17 Make a reasonable effort to ascertain the reason for a subject withdrawal from a clinical trial while fully respecting the subject's rights, although the subject is not obliged to give his or her reasons for withdrawing from a clinical trial.

2.7.3.18 The investigator informs the subject's primary physician about the subject's participation in the clinical trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.

2.7.3.19 The investigator will provide evidence of his or her qualifications through up- to-date curriculum vitae or other relevant documentation requested by the sponsor, the IRB, the regulatory authority.

2.7.3.20 The investigator is familiar with the appropriate use of the investigational, as described in the protocol, in the current investigator brochure, in the product information, and in other information sources provided by the sponsor.

2.7.3.21 A qualified physician (or dentist when appropriate), who is an investigator or a coinvestigator for the clinical trial, is responsible for all clinical trial related medical (or dental) decisions.

2.7.3.22 During and following a subject's participation in a clinical trial, the investigator ensures that adequate medical care is provided to a subject for any adverse events, including significant laboratory values, related to the clinical trial.

2.7.3.23 The investigator ensures the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor.

2.7.3.24 The investigator permits monitoring and auditing by the sponsor and inspection by the appropriate regulatory authority.

2.7.3.25 Investigators are expected to comply with IRB

2.8 The Office of Sponsored Programs and Technology Transfer (OSPTT)

2.8.1 The OSPTT reviews grants and contracts involving human subjects. OSPTT works with departments to secure and document departmental commitments. OSPTT acts as the authorized official and single point of contact for grant applications and awards. When a grant involves human subject research, the grant information will be shared with the IRB.

2.8.2 OSPTT processes determine compliance with state, federal, and institutional policies prior to accepting awards. Federal regulations and institutional commitments can change between time of application and the time of the award. The institution reserves the right to accept or reject awards based on reported levels of financial commitment. This institutional review ensures that all terms of award are in compliance with institutional policies.

2.9 When the grant includes human research activities that will be conducted by investigators who are not employees or agents of LSUHSC-S, an agreement or subcontract is executed between LSUHSC-S and the collaborating institution. All agreements and subcontracts are

reviewed by the Office of Legal Affairs and Organizational Integrity or LSU Compliance or Assistant Vice Chancellor of Research Management. The agreement or subcontract includes the requirement for the collaborating institution to assure compliance with federal regulations for the protection of human subjects in research and to provide documentation of current and ongoing IRB approval. The collaborating institution must also ensure that key personnel involved in human subjects' research are in compliance with other appropriate federal agencies policy on education in the protection of human subjects and provide documentation of education of key personnel to LSUHSC-S.

2.10 Research Pharmacy

2.10.1 FDA regulates clinical investigations (research) “that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.” (See 21 CFR 56.101). All such investigations must be conducted in accordance with FDA requirements for informed consent and IRB review, regardless of funding source or sponsor. Research with FDA-regulated test articles will be approved only after the IRB:

2.10.1.1 Receives documentation that the research will be conducted under an applicable Investigational New Drug Application (IND) or Investigational Device Exemption (IDE); or

2.10.1.2 Formally determines and documents that the proposed use of any investigational device satisfies the FDA criteria for non-significant risk devices; or

2.10.1.3 Receives satisfactory documentation or justification from the investigator that the FDA has determined that an IND or IDE is not required

2.10.2 All test articles including investigational drugs, devices, biologics and combination products used in human subjects research are stored, handled, and dispensed in compliance with regulations or requirements of the FDA, The Joint Commission, Federal and State Boards of Pharmacy, other applicable organizations and in accordance with applicable Hospital, Medical Center and Institutional policies and guidelines.

2.10.3 LSUHSC-S policy requires that the IRB review and approve all research using investigational products/test articles involving human subjects prior to initiation of the study, regardless of whether these studies are conducted with inpatient or outpatient subjects.

2.10.4 Investigators conducting investigational drug research at Overton Brooks VA Medical Center are responsible for following the VA Research and Investigational Drug Policies and Procedures.

2.10.5 Investigators conducting research involving the use of an approved drug or legally marketed device for an indication not in the approved labeling must comply with all Federal Regulations and Louisiana Laws for record-keeping, labeling, packaging, storage and all other requirements for the dispensing and administration of such drugs or devices.

2.10.6 The Research Pharmacy provides services to achieve safe and responsible handling of medications. The main purpose is to maintain control and accountability of medication use in research subjects in order to provide maximum benefit and safety for those participating in research protocols. Pharmacy staff also serve as collaborators in the planning of research protocols to ensure feasibility of implementation.

2.10.7 The FDA regulates radiology devices and radioactive materials used in research. Oversight at LSUHSC-S is handled by the Radiation Safety Committee. Most research involving radiation is covered by an IND or an IDE and must be approved by the IRB. However, the IRB will not approve any research involving radiology devices or radioactive materials without the approval of the Radiation Safety Committee. Therefore, any protocol involving radioactive materials and devices will be reviewed and approved by the Radiation Safety Committee prior to submission to the IRB for approval.

2.10.8 Responsibilities for Control of Investigation Products

2.10.8.1 Dispensing and Record Keeping

2.10.8.1.1 Inpatient Studies: Investigational products or test articles including drugs, devices, biologics or combination products for inpatient research studies are housed and dispensed by the Research Pharmacy. Investigational products or test articles including drugs, devices, biologics or combination products for inpatient research studies may be dispensed by the Principal Investigator if the Principal Investigator provides adequate justification, submits a detailed accountability plan, and has received prior approval from the LSUHSC-S IRB. To ensure that adequate procedures are in place to be able to maintain and document drug accountability, a consult between the PI and Research Pharmacy Services regarding maintenance and documentation of IP accountability may be sought. The PI is responsible for Drug Accountability.

2.10.8.1.2 Out-Patient Studies: Investigational products or test articles including drugs, devices, biologics or combination products for outpatient research studies, may be housed and dispensed by the Research Pharmacy or by the Principal Investigator if the principal investigator provides adequate justification, submits a

detailed accountability plan, and has received prior approval from the LSUHSC-S IRB. To ensure that adequate procedures are in place to be able to maintain and document drug accountability, a consult between the PI and Research Pharmacy Services regarding maintenance and documentation of IP accountability may be sought. The PI is responsible for Drug Accountability.

2.10.8.1.3 Proper Handling of Investigational Test Articles: The Investigator, pharmacist, or any other designated individual will maintain records of the delivery of the investigational product to the site, the inventory, use by each subject, and return to Sponsor or alternative disposition of unused investigational products. The records will include dates, quantities, batch or serial numbers and expiration dates, and the unique code assigned to the investigational products and study subjects. ICH-GCP (E6).

2.10.8.1.4 Good Clinical Practice Guidelines: (ICH-GCP (E6) – Investigators are to follow Good Clinical Practice (GCP) guidelines when the research involves (1) FDA regulated approved or unapproved drugs, devices or biologics or any other FDA regulated product; or (2) where the sponsor or funding agency requires the use of GCP guidelines.

2.10.8.2 Investigator and Research Pharmacy Services – Handling of Investigational Product

2.10.8.2.1 Dispensing by investigator – In the event the investigator requests to have control of the investigational product (drug, device or biologic) approval of the accountability plan must first be obtained from the IRB. To be eligible to retain control of the investigational drug product the investigator must be currently registered with the Louisiana State Board of Medical Examiners as a dispensing physician in accordance with Title 46 Chapter 65 Subchapter C.

2.10.8.2.2 RPS Coordination – The investigator is required to use Research Pharmacy Services as the coordinating and control center for the investigational product (drug, device or biologic) unless prior approval from the IRB has been granted. As the coordinating and control center, RPS assumes the responsibility for maintaining records of the investigational products delivered to the RPS, inventory of the investigational product, dispensing of investigational product to research subjects, and the return to the sponsor or disposition of unused investigational product. RPS will store and dispense the investigational product as specified by the sponsor and in accordance with applicable regulatory requirements.

2.10.8.2.2.1 For research drugs RPS may initiate or adjust drug therapy and/or order laboratory tests associated with a research protocol when requested to do so by the PI. Any pharmacist participating in such a protocol must be

trained and deemed competent to participate by the Investigator or his/her designee. Specific details on the adjustment of drug therapy or ordering of laboratory tests should be reviewed during the protocol initiation visit.

2.10.8.2.2.2 When RPS is the coordinating and control center for the research drug, RPS will store the returned dispensed investigational drug in a designated return area when a study protocol requires the subject to return the empty investigational drug container or any amount of the unused investigational drug. However, it is the responsibility of the investigator to deliver the returned dispensed investigational drug to RPS when subjects leave the dispensed investigational drug in the PI's department.

2.10.8.2.2.3 When RPS is coordinating the control of the investigational product, the investigator will forward a copy of the complete research protocol, a copy of the Investigator's brochure, ordering procedures, any special storage, handling or preparation requirements, and any pertinent dispensing or use information to the research pharmacist.

2.10.8.2.2.4 During the Cost Analysis process, RPS will be asked to provide the cost of locally provided drugs required by the protocol. The mandatory institutional pharmacy fee will be applied to all research involving investigational products.

2.10.8.2.3 Controlled Substances - The investigator should be aware that controlled substances may not be stored outside the Research Pharmacy.

2.10.8.2.4 Investigational Devices – If a device is considered Non-Significant Risk by the investigator or sponsor, but after reviewing the IRB determines the device to have Significant Risk, upon receipt of written notice the investigator is responsible for notifying the sponsor of the IRB(s) determination. The investigator must provide the IRB with confirmation of this action.

2.10.8.2.5 Investigator Control of Investigational Product Supply – If the Research Pharmacy is not coordinating the control of the investigational product, as outlined above, then the principal investigator is responsible for the control of the investigational product and must provide a plan at the time of application submission for the adequate storage and control over the distribution and dispensing or use of an investigational product. (If the investigator is requesting to maintain control of a research drug product, the plan must include a copy of the investigator's registration as a dispensing physician with the Louisiana State Board of Medical Examiners.)

2.10.8.2.6 When the investigator retains control of investigational product supplies, the investigator is responsible for ensuring that the research is conducted according to all regulatory guidelines and LSUHSC-S policies and procedures. Other specific responsibilities include:

2.10.8.2.6.1 Investigational Product Accountability Record – The investigator must maintain records of the product's delivery to the study site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product. These records should include dates, quantities, batch/serial numbers, expiration dates, and the unique code numbers assigned to the investigational product(s) and trial subjects. Investigators should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile all investigational product(s) received from the sponsor. Regarding the use by each subject, investigators should maintain investigational product accountability records that document adequately which subject(s) received the investigational product; when the subject(s) received the investigational product; the specific dosage or amount the subject(s) received; and any returned amount of the dispensed investigational product.

2.10.8.2.6.2 Storage of Investigational Product – Investigational product(s) should be stored as specified by the sponsor and in accordance with applicable regulatory requirement(s). Storage guidelines include:

i. Storage area is large enough for the supply of investigational product.

ii. Storage area can be locked.

iii. Investigational drug is stored separately from other compounds.

iv. Non-dispensed investigational product is stored separately from returned dispensed investigational product.

v. If the study protocol requires the subject to return the empty investigational product container or any amount of the unused investigational product, it is the investigator's responsibility to store the returned dispensed investigational product separately from the non-dispensed investigational product.

vi. It is the responsibility of the investigator to deliver the returned dispensed investigational product to the Research Pharmacy if it is the coordinating and control center for the research product.

vii. Inventory control procedures are used.

viii. Any environmental controls are maintained.

ix. Access is limited to study staff.

2.10.8.2.6.3 Drug Dispensing – Louisiana law requires that dispensing may only be done by a licensed pharmacist or a physician who is registered with the Louisiana State Board of Medical Examiners as a dispensing physician in accordance with Title 46: Chapter 65: Subchapter C.

2.10.8.2.6.4 Drug Labeling – The Code of Federal Regulations specify the following labeling requirements for an investigational new drug:

1. The immediate package of an investigational new drug intended for human use shall bear a label with the statement “Caution: New Drug – Limited by Federal (or United States) law to investigational use.”

2. The label or labeling of an investigational new drug shall not bear any statement that is false or misleading and shall not represent that the investigational new drug is safe or effective for the purposes for which it is being investigated.

3. State of Louisiana Regulations and LSUHSC-S policy states that all drugs dispensed shall contain a medication label with the following:

    I. Patient name, identifier
    II. Protocol number or name
    III. Name of prescriber / INVESTIGATOR
    IV. Strength and volume of drug
    V. Directions for use or administration
    VI. Dose
    VII. Number of units dispensed
    VIII. Expiration date
    IX. Initials of preparer
    X. Initials of pharmacist performing final check
    XI. “Investigational Drug”
    XII. Any auxiliary stickers or warning labels)

2.10.8.2.6.5 Investigational Product Administration — Investigational products shall be administered in accordance with any applicable State or Federal Regulations and in accordance with any policies or procedures set forth by

LSUHSC-S. An informed consent, signed and dated by the subject and the investigator must be in place before administering the investigational product.

i. Only a person licensed within the state of Louisiana and so authorized by their professional scope of practice shall administer an investigational product to a subject. A principal investigator may designate the responsibility of administering the investigational product only after the designee has been given and has demonstrated an understanding of basic pharmacologic information about the drug. This education and delegation of responsibility must be documented.

ii. Investigational products are to be administered in accordance with the research protocol and in accordance with any other hospital or clinic policy pertaining to the administration of investigational products. The investigator will document that the amount provided to the research subject is the amount specified in the approved protocol.

iii. An investigator shall administer a drug only to subjects under the investigator's personal supervision or under the supervision of a sub-investigator responsible to the investigator. The investigator shall not supply the investigational drug to any person not authorized to receive it. FDA 21CFR 312.61. AAHRPP 3.2.B.

iv. An investigator can permit use of the investigational device only with subjects under his/her supervision and cannot not supply an investigational device to any person not authorized under the IDE regulation to receive it. FDA 21CFR 812.110; AAHRPP 3.2.B.

2.10.8.2.7 For research involving investigational products:

2.10.8.2.7.1 The investigator is required to inform the Research Pharmacy that the IRB has approved the protocol through submission of the IRB approval letters.

2.10.8.2.7.2 The investigator must inform the IRB and the Research Pharmacy when a study involving investigational products has been terminated by the sponsor.

2.10.8.2.7.3 The investigator will report to the sponsor any adverse effect or adverse device effects that may reasonably be regarded as caused by, or probably caused by, the investigational product (21 CFR 312 (b); 21 CFR 812.140) according to the procedures in the protocol.

2.10.8.2.7.4 The investigator will maintain the following:

i. Current curriculum vitae (CV)

ii. For devices statement of the investigator's relevant experience, including the dates, location, extent, and type of experience, where applicable

iii. Protocol

iv. Records of receipt and disposition of investigational product

v. List of any sub-investigators with their curriculum vitae

vi. Certification that all physicians, dentists, and/or nurses responsible in the study have appropriate valid licenses for the duration of the investigation, and

vii. Case histories with particular documentation on evidence of drug effects. Emphasis is on toxicity and possible untoward happenings. All unexpected adverse effects are reportable; even if the investigator considers that the event is not related to the drug. All unexpected adverse effects shall be reported immediately to RPS and the IRB in the manner defined by the protocol and HRPP/IRB polices.

viii. IRB letters of approval.

ix. Other documents as outlined in the Human Subject Protection Program Standard Operating Procedures.

x. The investigator must inform the Chief, VA Pharmacy Service, and the R&D Committee when a study involving investigational drugs has been closed.

2.10.8.2.8 Record Retention – An investigator shall retain records in accordance with whichever is the greater of the following:

2.10.8.2.8.1 as required by the FDA for a period of two (2) years following the date a marketing application is approved for the drug or device for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two (2) years after the investigation is discontinued and FDA is notified; or

2.10.8.2.8.2 In accordance with the Common Rule and FDA regulations (45 CFR 46.115(b) and 21 CFR 56.115(b)), IRB records are retained for at least three (3) years after the completion of the research, either electronically or as hard copy. Protocol files are to be retained as long as required

by law or as stated in clinical trial agreement but no less than three (3) years after completion of the research and then destroyed. Protocols in which there was no subject enrollment, or no research was conducted are to be retained the same as protocols where research was conducted. In accordance with federal HIPAA privacy regulations, IRB records pertaining to records containing protected health information (PHI) are retained for at least six (6) years after the completion of the research. It is LSUHSC-S policy to retain records for the greatest amount of mandated time. Thus, the IRB retains all research records for at least six (6) years.

2.10.8.2.8.3 Sponsored grants and contracts may require additional periods for record retention.

2.10.8.2.8.4 For VA Research - All research records, including the investigator's research records, are the property of VA and must be maintained within the VA according to disposition instructions approved by the National Archives and Records Administration and published in VHA's Records Control Schedule (RCS 10-1).

2.10.8.2.9 Quality Assurance Audits – The HRPP or IRB will periodically conduct audits of studies of all IND or IDE studies. However, when the LSUHSC-S INVESTIGATOR is acting as a sponsor and holds an IND or IDE for the test article (Investigator-Initiated Studies) there is an increased chance or increased frequency of being audited by the HRPP Quality Improvement/Assurance Program.

2.10.9 Ancillary Units Involved in Research All units involved in research may include but are not limited to Lab, Cardiopulmonary, Radiology, Pharmacy, Nursing, Social Services and Others.

2.11 Protocol Specific Coordination

2.11.1 For research conducted under the auspices of the LSUHSC-S IRB, protocol-specific coordination must take place. The Principal Investigator must identify services to be provided by ancillary units within the Ochsner Health System that are above standard of care. These services will require reimbursement to the hospital. Each department/unit that is to provide the service must be identified in the IRB Initial Application Form and appropriate signatures must be obtained on the Cost Analysis (CA) before IRB approval can be made and services obtained. A copy of the Cost Analysis is located in the document library of the electronic IRB data system (SHIeLDS) along with the necessary IRB forms.

2.11.2 The Cost Analysis (CA) document must be submitted with every proposal/protocol that involves a funding source or any prospective study procedure or a third-party vendor/institution/source. The CA requires PIs to indicate the Institutional support required for the research. The cost analysis process serves to: 1. identify Medicare Qualifying Trials; 2. identify costs to the institution for conducting the research; 3. provide documentation of specific details for services and procedures from the provider of services in collaboration with LSU Health Shreveport in performing clinical research; and 4. identify and document the funding source for all research procedures.

2.11.3 The CA document details the services, procedures, use of the research pharmacy, use of equipment, procedures to be billed to insurance and professional services needed, if any, and the associated costs. The Investigator Financial Attestation page, completed by the PI, will designate the cost of research covered by either the study sponsor budget or departmental funds. A finalized Cost Analysis will be provided to the institution and/or the applicable Professional Billing Service for billing purposes related to the study by the Clinical Trials Management Team. -

2.11.4 The CA document will not be required for any proposal/protocol that listed in the table below,

Type of studies	Funding
Retrospective Chart Review (not involving any third-party)	No
Prospective Chart Review (not involving any third-party)	No
Existing Specimen Review(not involving any third-party)	No
Educational/Survey/Interview/Focus groups(not involving any third-party)	No

2.12 The CA document will not be required for any proposal/protocol determined to be “Not Human Subject Research”, by the IRB.

2.13 Clinical Trials Office (CTO)

2.13.1 The Clinical Trials Office (CTO) serves as a central location for principal investigators, study staff, and departments involved in clinical research. The CTO’s primary functions are to:

2.13.1.1 Review and negotiate the Clinical Trial Agreement

2.13.1.2 Complete all study startup required documents in a timely manner (Informed consent, Cost Analysis) and maintain the regulatory needs of the clinical trial

2.13.1.3 Provide clinical research coordinators to support and coordinate the daily clinical trial activities

2.13.1.4 Monitor and ensure accurate clinical trial account finances

2.13.1.5 Coordinate, educate and train on clinical trial research

2.14 Relationship between Components

2.14.1 The IRB functions independently of, but in coordination with, other institutional regulatory committees. The IRB, however, makes its independent determination whether to approve or disapprove a protocol based upon whether or not human subjects are adequately protected. The IRB has review jurisdiction over all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that has adopted the human subjects' regulations.

2.14.2 The Institutional Official's Advisory Committee (Translational Research Committee, TRC) will meet to ensure a dialogue is maintained between the various entities at the Institution. Membership is determined by the Institutional Official, but will include the AVCRM, Office of Legal Affairs and Organizational Integrity, representation from the IRB, among others. The committee will act in an advisory capacity to the IO, monitoring the effectiveness of existing compliance programs, developing new or revised policies as changes in requirements occur, and disseminating updated compliance information to the research community.

2.14.3 Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the Institution. However, those officials may NOT approve research involving Human Subjects if it has been disapproved by the IRB.

3 REFERENCES

3.1 AAHRPP I.1.A.; I.1.B.; I.1.C.; I.1.D.; I.1.F.; I.1.G.; I.2.; I.5.A.; I.5.B.; I.7.A.; I.7.B.; I.8.B.; I.8.C.; I.8.D.; I.8.E.; II.1.; II.2.; II.3.; II.4.; III.1.; III.2.

HRP-004 Outreach and Community Involvement

1 PURPOSE

1.1 This guidance establishes the procedure for enhancing understanding of human research with subjects, potential subjects, and their communities and conducting outreach activities for increased involvement to human research subjects and their communities.

1.2 This guidance begins when a human subjects' research study is initiated at LSU Health Shreveport.

1.3 This guidance ends when the outcome of the human subjects' research is disseminated.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The HRPP ensures the availability of information and resources to improve community awareness and involvement with research at LSUHSC-S to comply with the ethical principal of respect for persons participating in research and maximize their involvement in the research process, including proactive outreach activities.

4 RESPONSIBILITIES

4.1 The IO is responsible for ensuring the respect for human subjects and their awareness of and involvement in LSUHSC-S research protocols.

4.2 Site investigators are responsible for day–to-day assurance of compliance with all aspects of the HRPP, including subject awareness and outreach activities.

4.3 Investigators involved in human research protocols are responsible for maintaining respectful interactions with subjects, involving research subjects at every stage, enhancing appropriate safeguards, answering questions in a complete and sensitive manner, and participating in outreach and educational activities for subjects and their communities.

5 PROCEDURES:

5.1 Informed consent form/s (ICF) associated with research activities are to be reviewed and approved by the LSUHSC-S Institutional Review Board (IRB) to ensure that procedures are in place to facilitate the ability of research subjects to ask questions, express concerns, or voice complaints to the IRB, or investigator.

5.2 LSUHSC-S enhances the understanding of human research with subjects, potential subjects, and communities, as appropriate, using a variety of methods. These include, among others:

5.2.1 Regular communications.

5.2.2 General and specialized research communications available on the institutional website.

5.2.3 Internal resources for investigators to share with the research community on the HRPP website.

5.2.4 Individual and group meetings and presentations.

5.2.5 Hosted events, such as workshops, seminars, and training courses.

5.3 To involve and inform current and future research subjects, in accordance with the Belmont principle of Respect for Persons, IRB maintains a “Research Subjects” page on the LSUHSC-S/HRPP website. This page provides resources for current and future research subjects, including:

5.3.1 The opportunity to submit concerns, questions, or comments, and receive feedback.

5.3.2 Subject Brochure. See HRP-104 - BROCHURE - Should I Take Part in Research.

5.3.3 Links to government websites where research information may be obtained (e.g., OHRP, FDA, NIH).

5.4 For LSUHSC-S investigator-initiated research, investigators incorporate community input as appropriate in the design (including reducing invasiveness), implementation, and dissemination of research. Based on the type of research, investigators may employ one or more of the following methods, among others:

5.4.1 Planned community sessions

5.4.2 Community advisory groups

5.4.3 Subject advocates

5.4.4 Partnerships with community-based organizations

5.4.5 Community-based subject research design methodologies

5.5 Investigators make available information regarding a safe, confidential, and reliable channel for current, prospective, or past research subjects or their designated representatives or their community to discuss concerns, raise questions, obtain information, complaint about the research, or ask questions about rights as a research subject, or provided input on the design of future studies.

5.5.1 This information is available to all persons who are going to participate in the human research protocol.

5.5.2 Contact information for reporting complaints or concerns is provided in the informed consent, subject brochure, and the LSUHSC-S/IRB website.

5.5.3 Research subjects are invited via the LSUHSC-S/IRB website to contact the HRPP or IRB staff to provide feedback and/or obtain information about human subjects' research and LSUHSC-S HRPP activities.

5.6 Any form of subject communication received by the HRPP, or investigator will be acknowledged and forwarded to the appropriate individual within the organization for handling and follow-up. While a prompt resolution is expected, the timeframe is dependent on the complexity of the complaint or concern. The HRPP is not affiliated with a specific research study and is available to current, former, and prospective research subjects to discuss problems, concerns, and questions and to obtain information and to offer input. Informed consent forms (ICF) associated with research activities are reviewed and approved by the LSUHSC-S Institutional Review Board (IRB) to ensure that procedures are in place for research subjects to ask questions, express concerns, or voice complaints to the HRPP, IRB, or investigator. All questions, concerns or complaints received by the HRPP office from any individual through any form of communication (written, verbal, electronic) will be acknowledged and forwarded to the appropriate official within the institution for handling and follow-up. Complaints will also be forwarded to the HRPP QA/QI Coordinators. While a prompt resolution is expected, the time frame for resolution of complaints is dependent upon the nature and complexity of the issue. HRPP contact information for reporting concerns or complaints is provided in the Informed Consent Form, Subject Brochure and the HRPP website. Research subjects are invited via the LSUHSC-S/HRPP website to contact the HRPP or the IRB staff to provide feedback and/or obtain information about human subjects' research and LSUHSC-S HRPP activities.

5.7 The LSUHSC-S IRB will review all complaints, protocol deviations, allegations of noncompliance, findings of serious or continuing noncompliance, and take any necessary action to ensure that the rights and welfare of human subjects are protected. The Chair of the IRB will promptly handle (or delegate staff to handle), and, if necessary, investigate all complaints, concerns, and appeals received by the IRB. This includes complaints, concerns,

and appeals from investigators, research subjects and others. A Reportable New Information (RNI) Report must be submitted to the IRB when an investigator including LSUHSC-S personnel, the research team, faculty, staff, administration, residents, fellows, or students become aware of any noncompliance with respect to a specific study. Reports of noncompliance may also result from an audit or a monitoring report. Research subjects, subject's family members, and others external to the Institution, including regulatory agencies may report suspected noncompliance to the HRPP, IRB or to the Institutional Official. These reports may be in the form of complaints and may be made anonymously. Reports of research misconduct or Whistleblower reports are subject to different rules and will be referred to the Office of Research or LSUHSC-S Compliance Office if received by the IRB or HRPP. All complaints, written or verbal (including telephone complaints), and regardless of point of origin, are forwarded to the IRB Chair, the IO or designee. Upon receipt of the complaint, the Chair, IO or designee will make a preliminary assessment whether the complaint warrants immediate suspension of the research project. If the complaint meets the definition of noncompliance, it will be considered an allegation of non-compliance according to section HRP-018. If the complaint meets the definition of an unanticipated problem involving risk to subjects or others, it will be handled according to SOP: HRP-024 New Information. Within three (3) business days of receipt of the complaint, the IRB Chair, IO or designee shall generate a letter to acknowledge that the complaint has been received and is being investigated, providing a follow-up contact name.

5.8 Feedback from investigators and other research community members, the consent process, formal and informal evaluations, and audits are used as input for improvements to the LSUHSCS's HRPP program plan, including community awareness and outreach activities.

5.9 The HRPP periodically evaluates its community involvement activities and makes changes, when appropriate, to improve outreach methods; adjust content and materials; and collaborate and educate others on updating such activities.

5.9.1 These evaluations take place in an informal, ongoing manner. HRPP staff will report both positive and negative feedback regarding community awareness and outreach activities to the Assistant Vice Chancellor for Research Management or designee, who tracks the input and recommends changes to improve community involvement.

5.9.2 The Assistant Vice Chancellor for Research Management or designee summarizes the feedback annually to formally evaluate its outreach activities and determine:

5.9.2.1 The specific community outreach activities being used; and

5.9.2.2 Whether or not these community outreach activities have an evaluative component, and if so what, if any, changes in the outreach activities have resulted from these.

6 MATERIALS

6.1 HRP-104 - BROCHURE - Should I Take Part in Research

6.2 SOP: HRP-024 New Information

7 REFERENCES

7.1 AAHRPP I.1.D.; I.1.E.; I.4.; I.5.C.; III.1.G.

HRP-005 HRPP Quality Assurance/Quality Improvement Program

1 PURPOSE

1.1 This Standard Operating Procedure defines the Human Research Protection Program (HRPP) Quality Assurance/Quality Improvement function at LSU Health Shreveport.

1.2 The goal of the Institution's HRPP Quality Assurance (QA)/Quality Improvement (QI) Plan is to design, implement and maintain a program to evaluate and monitor the effectiveness and compliance of the Institution's Human Research Protection Program while improving human research protections. A primary objective of the HRPP QA/QI Plan is to maintain compliance with organizational policies and procedures and applicable federal, state, and local laws, including adherence to the IRB approved protocol.

2 AUTHORITY AND SCOPE

2.1 The LSUHSC-S Human Research Protection Program (HRPP) QA/QI Program is under the general direction of the Assistant Vice Chancellor for Research Management and the IRB. The HRPP QA/QI Program includes the following:

2.1.1 Post Approval Monitoring: Conducted based upon selection of the, QA/QI Auditor or at the request of the IRB, Institutional Official or designee. Circumstances where Post Approval Monitoring may occur include, but are not limited to:

2.1.1.1 Monthly selection of active human research studies with enrolled subjects;

2.1.1.2 Investigator Initiated Studies (minimal risk and greater than minimal risk);

2.1.1.3 Investigator/Sponsor Investigational New Drug (IND)/Investigational Device Exemption (IDE) studies;

2.1.1.4 Re-assessment of studies previously reviewed to evaluate adherence to corrective action plans and ongoing compliance;

2.1.1.5 Studies assessed by the IRB to include a high degree of risk (adverse events, protocol deviations, type of study, or vulnerable populations); or

2.1.1.6 New, or inexperienced investigator or research staff.

2.1.2 Directed or For-Cause Review: Conducted at the request of IRB, IRB Chair, IRB Director, Institutional Official or designee. Circumstances where a For-Cause Review may occur include, but are not limited to:

2.1.2.1 As part of an ongoing corrective action;

2.1.2.2 To support a review associated with an RNI or IRB's assessment of potential noncompliance including failure to follow the approved protocol, and/or;

2.1.2.3 When there are concerns regarding whether the rights and welfare of subjects enrolled in research are adequately protected.

2.1.2.4 When there are concerns about the validity or integrity of the data collected.

2.1.3 Voluntary Reviews: Conducted upon request of Principal Investigator to support self - assessment and improvement efforts by Investigator and Study Team.

2.1.3.1 The investigator may also use HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment to conduct a voluntary self-assessment.

2.1.4 IRB Minutes Review: Conducted quarterly to assure compliance and support the operations of the IRB.

2.1.5 Human Research Protection Program Quality Improvement: Conducted quarterly to track and improve overall satisfaction and institutional compliance with human research protection program requirements.

2.1.5.1 These reviews may include the following along with other areas of concern as they arise.

2.1.5.1.1 Review of the IRB minutes to determine that adequate documentation of the meeting discussion has occurred. This review will include assessing the documentation surrounding the discussion for protections of vulnerable populations as well as other risk/benefit ratio and consent issues that are included in the criteria for approval. HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment.

2.1.5.1.2 Assess the IRB minutes to assure that quorum was met and maintained. HRP-304 - WORKSHEET - IRB Composition

2.1.5.1.3 Assess the unanticipated problem reporting process.

2.1.5.1.4 Assess that privacy provisions have been adequately reviewed, discussed and documented in the IRB minutes.

2.1.5.1.5 Evaluate the continuing review discussions to assure they are substantive and meaningful.

2.1.5.1.6 Monitor the frequency of lapses in IRB approval.

2.1.5.1.7 Observe the IRB meetings or other related activities.

2.1.5.1.8 Review IRB files to assure retention of appropriate documentation and consistent organization of the IRB file according to current policies and procedures.

2.1.5.1.9 Review of evaluations by the IRB members.

2.1.5.1.10 Verification of IRB approvals for collaborating institutions or external performance sites.

2.1.5.1.11 Monitor other activities deemed appropriate.

2.1.5.2 The QA/QI coordinator will utilize various audit tools during the audit process. Depending on the type of audit, QA/QI staff may select any of the following documents, or add additional tools as needed.

2.1.5.2.1 Agenda Quality Improvement Assessment Checklist

2.1.5.2.2 Audit tool – Consenting Process Checklist

2.1.5.2.3 Contract, Consent, HIPAA Audit

2.1.5.2.4 HRP-312 - WORKSHEET - Exemption Determination

2.1.5.2.5 HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process

2.1.5.2.6 HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent

2.1.5.2.7 HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment

2.1.5.2.8 HRP-441 - CHECKLIST - HIPAA Waiver of Authorization

2.1.5.2.9 IRB Files Evaluation

2.1.5.2.10 IRB HRPP Evaluation Quarterly Report

2.1.5.2.11 IRB Notice Assessment

2.1.5.2.12 IRB Quorum and Expertise Checklist

2.1.5.2.13 Subject Specific Consent – Audit Findings

2.1.5.3 The Assistant Vice-Chancellor for Research Management will discuss the results of the review with the IRB chair, the Institutional Official (IO) and the HRPP staff as appropriate. The Assistant Vice Chancellor for Research Management develops a corrective action plan if necessary or provides clarification to the findings, communicates the findings and any corrective actions as appropriate. The results may impact current practices and may require additional educational activities for HRPP staff, IRB members, or study personnel.

2.1.6 Non-Institution Institutional Audits and Compliance Reviews

2.1.6.1 External directed (for-cause audits), post-approval monitoring, and voluntary reviews will be conducted at non-LSUHSC-S Institutional sites, where the Institution's IRB serves as the IRB of Record, to assess compliance with federal, state, and local law, research subject safety, and IRB requirements. Directed audits are implemented in response to identified concerns that require an IRB determination. These reviews may include items listed above.

2.1.6.2 VA Research: Beginning in FY 2009 Veteran Health Administration (VHA) research facilities must conduct audits of informed consent documents for all research studies annually and audits of regulatory documents are performed every three (3) years.

3 RESPONSIBILITIES

3.1 The Quality Assessment/Improvement Team (QA/QI Auditor) is responsible for ensuring these procedures are carried out.

4 PROCEDURE

4.1 Post Approval Monitoring:

4.1.1 Selection and Scheduling:

4.1.1.1 The QA/QI Auditor selects studies as follows:

4.1.1.1.1 From a list of active studies selects from 1-4 each month.

4.1.1.1.2 Through request by the IRB, IRB Chair, IRB Director, Institutional Official or designee, to assess general programmatic compliance with regulatory and institutional requirements based upon specified study characteristics.

4.1.1.2 The QA/QI Auditor contacts the Principal Investigator and Study Coordinator in writing (email) to:

4.1.1.3 Schedule the review in a timely manner;

4.1.1.4 Provide an overview of the scope, process and required workspace needed for the review; and

4.1.1.5 Provide a copy of the HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment to be used as a general guide for review to the Investigator and Study Coordinator.

4.1.2 Review Procedures:

4.1.2.1 In advance of the review visit, the QA/QI auditor reviews the protocol information on file with the IRB;

4.1.2.2 On the day of the review, the QA/QI auditor will meet with the Investigator and designated study staff at the open and close of the review if possible. The investigator will arrange for a private work area for the conduct of the review. At a minimum, designated study staff should make themselves available for documentation retrieval, answer any questions or provide clarification as may be needed;

4.1.2.3 The investigator will provide the following study files (as applicable) for the QA/QI auditor's review:

4.1.2.3.1 All study related regulatory documents;

4.1.2.3.2 Subject screening/enrollment log;

4.1.2.3.3 Case report forms;

4.1.2.3.4 Source documents;

4.1.2.3.5 Informed consents, assents and HIPAA for all enrolled and screened subjects

4.1.2.3.6 Study drug accountability logs (to be reviewed in the Research Pharmacy, as applicable);

4.1.2.3.7 Device accountability logs (as applicable);

4.1.2.3.8 Lab logs (as applicable);

4.1.2.3.9 Other documents/files as requested that support the study administration

4.1.2.4 Research records are expected to be maintained by study team in a review-ready state at all times. Study team will have an opportunity to locate and provide materials or documentation not present in the files at time of review, but the initial absence of material or documentation will be noted in the findings.

4.1.3 Findings

4.1.3.1 Finding types may include, but are not limited to:

4.1.3.1.1 No further action necessary;

4.1.3.1.2 Minor administrative issue(s) with best practice or additional education recommendation for corrective action;

4.1.3.1.3 Finding that meets the definition of 'Reportable New Information' with best practice or additional education recommendation for corrective action.

4.1.3.1.4 Major finding indicating potential harm or imminent risk of harm to subjects' safety and well-being. These findings will be reported immediately by QA/QI auditor to the Clinical Trials Office (CTO) Director and IRB Chair and when necessary to Institutional Official or designee.

4.1.3.1.5 Potential misconduct will also be reported to the Research Integrity Officer in accordance with the LSUHSC-S Policy and Procedures for Dealing with Allegations of Research Fraud, **https://resources.finalsite.net/images/v1611182087/lsuhscshreveportedu/ozbosx2i7i4pzjumx1ah/PoliciesandProceduresforDealingwithAllegedResearchMisconduct.pdf**.

4.1.4 Documentation and Distribution of Findings

4.1.4.1 The QA/QI auditor will document observations, findings and any concerns.

4.1.4.2 At the conclusion of the review, the QA/QI auditor verbally debriefs the investigator and/or designated study team members regarding findings, applicable recommendations and next steps.

4.1.4.3 The QA/QI auditor generates a written report of findings and recommendations. The written report of findings is shared with the principal investigator, HRPP and IRB Chair .

4.1.4.4 The QA/QI auditor submits a copy of the written report into the electronic IRB submission system (SHIeLDS) and references all applicable research through the Reportable New Information activity.

4.1.4.5 The investigator is asked to review the written report and provide a response and a corrective action when necessary.

4.1.4.6 In the event the Investigator disagrees with the findings of fact or wishes to provide clarification, the Investigator may provide the rebuttal and/or clarifications, in writing. The provided information and any corrective action plan will be submitted into the electronic IRB submission system (SHIeLDS).

4.1.4.7 The investigator is also asked to submit each incident of Reportable New Information found through the audit that has not already been reported to the IRB.

4.1.4.8 Follow-up reviews may be scheduled to confirm ongoing adherence to corrective action recommendation and continued compliance.

4.2 Directed or For Cause Review

4.2.1 Selection and Scheduling

4.2.1.1 The IRB Chair, IRB Director, Institutional Official or designee ("Requestor") may request a directed or for-cause review.

4.2.1.2 The Requestor will notify the HRPP QA/QI auditor of the investigator that is to have a directed or for-cause review. An official notification will be sent to the investigator with a cc to their department chairperson. This notice will include the scope, timing, scheduling process and next steps.

4.2.1.3 Unless directed to contact investigator sooner, the QA/QI auditor will contact the investigator by the next business day following receipt of the audit request to schedule the review and will work with investigator and study team to schedule review within the timeline established by the requestor.

4.2.1.3.1 If scheduling and/or completion of audit will not be possible within the established timeframe due to circumstances beyond the investigator's control, the QA/QI auditor will notify the Requestor and request additional guidance.

4.2.1.3.2 As research records are expected to be maintained in an audit-ready state at all times, time needed for record preparation is not an acceptable reason to request delay.

4.2.2 Review Procedures

4.2.2.1 Review procedures will follow those outlined in 4.1.2, above.

4.2.3 Documentation and Distribution of Findings

4.2.3.1 The report and associated findings are shared with the Requestor, CTO Director and IRB Chair . The findings are also cc'd to the Investigator and their department chairperson.

4.2.3.2 Remainder of Documentation and Distribution of Findings procedures will follow those as outlined in 4.1.4, above.

4.3 Voluntary Reviews

4.3.1 The HRPP makes the Investigator Self-Assessment (HRP-430) available to investigators and study teams;

4.3.2 The Principal Investigator, or study team member with Principal Investigator's support, may conduct a self-assessment or ask for a voluntary review/assistive review by the QA/QI team.

4.3.2.1 The review procedures will follow those outlined in 4.1.2, above.

4.4 IRB Minutes Reviews

4.4.1 The QA/QI auditor or designee reviews the IRB minutes for compliance with HRP-043 IRB Meeting Minutes.

4.4.2 The QA/QI auditor or designee uses the HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment to guide and document the review;

4.4.3 The QA/QI auditor or designee prepares a report of findings, if any, and forwards to the IRB Director and Staff.

4.4.4 The IRB Director or designee develops a corrective action plan if necessary or provides clarification to findings and communicates the findings and any corrective action plan as appropriate.

4.5 Human Research Protection Program Quality Improvement

4.5.1 Routine Monitoring Trends Assessment

4.5.1.1 On an annual basis or more often if requested by the CTO Director, Institutional Official or designee, the QA/QI team will provide a report of general trends and findings from the audits to the Institutional Official, CTO Director, IRB Director, IRB Chair and others as necessary.

4.5.1.2 The QA/QI team and individuals listed in 4.5.1.1 will review the findings and develop corrective and education action plans as necessary.

4.5.1.3 The QA/QI team will monitor the impact of the corrective and education plans on findings and will report outcomes to the individuals listed in 4.5.1.1.

4.6 Investigator Concerns

4.6.1 Investigators who have concerns or suggestions regarding LSUHSC-S's Human Research Protections Program should convey them to the HRPP, Institutional Official or designee or other responsible parties regarding the issue, when appropriate. The Institutional Official or designee will research the issue, and when deemed necessary, convene the parties involved to form a response for the investigator or make necessary procedural or policy modifications, as warranted. In addition, the Chair of the IRB, IO or designee will be available to address investigators' questions, concerns and suggestions.

5 MATERIALS

5.1 SOP: HRP-043 IRB Meeting Minutes

5.2 HRP-304 - WORKSHEET - IRB Composition

5.3 HRP-312 - WORKSHEET - Exemption Determination

5.4 HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process

5.5 HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent

5.6 HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment

5.7 HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment

5.8 HRP-441 - CHECKLIST - HIPAA Waiver of Authorization

5.9 Policy and Procedures for Dealing with Allegations of Research Fraud, https://resources.finalsite.net/images/v1611182087/lsuhscshreveportedu/ozbosx2i7i4pzjumx1ah/PoliciesandProceduresforDealingwithAllegedResearchMisconduct.pdf

6 REFERENCES

6.1 45 CFR 46.103(b)(5); 45 CFR 46.109(e)

6.2 21 CFR 56.108(b); 21 CFR 56.109(f)

6.3 AAHRPP I.4.A.; I.5.A.; I.5.B.; I.5.C.; I.7.A.; II.3.G.; II.4.A.; II.5.B.

HRP-006 Research Covered by the HRPP

1 PURPOSE

1.1 This Standard Operating Procedure defines research covered by LSUHSC-S.

2 POLICY

2.1 LSUHSC-S conducts or oversees biomedical, social science and behavioral research. Human subject research is covered as stated in the Federalwide Assurance for LSUHSC-S and any affiliated organization. All research engaged in at LSU Health Shreveport is covered by the HRPP. The LSUHSC-S HRPP covers all research involving human subjects that is under the auspices of the Institution regardless of funding. The research may be externally funded, funded from LSUHSC-S sources, or conducted without direct funding. An activity is covered by the HRPP when:

2.1.1 It is considered human subject research as defined in any one of the following:

2.1.1.1 FDA regulations

2.1.1.2 DHHS regulations or other Common Rule regulations

2.1.1.3 VA regulations (VA Handbook 1200.5) or

2.1.1.4 Any other applicable state or local regulations, e.g. Louisiana regulations and

2.1.2 LSUHSC-S (or its employees or agents) is engaged research - as defined by being involved in one or more of the following activities:

2.1.2.1 Receiving an HHS award for research

2.1.2.2 Intervening with subjects for research purposes (invasive or noninvasive)

2.1.2.3 Manipulating the environment

2.1.2.4 Interacting with subjects for research purposes

2.1.2.5 Obtaining identifiable private information or identified biological specimens from any source for research purposes, according to the OHRP guidance Engagement of Institutions in Human Subjects Research. http://www.hhs.gov/ohrp/policy/engage08.html.

2.2 Agents include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility, including students, faculty, staff, employees or visiting scholars.

2.3 LSU Health Shreveport research affiliate organizations are Biomedical Research Foundation of Northwest Louisiana and Ochsner Health System.

2.4 VA Research - Classified research involving human subjects cannot be approved by a VA IRB or R&D Committee or performed at a VA facility, including space leased to, and used by VA.

3 RESPONSIBILITIES

3.1 The investigators are responsible for ensuring these procedures are carried out.

4 PROCEDURE

4.1 Sponsored Research

4.1.1 The HRPP, in collaboration with the LSU Health Shreveport Office of Legal Affairs and Organizational Integrity, is responsible for ensuring that negotiations between LSU Health Shreveport and Sponsors relative to Clinical Investigations that will take place under the purview of LSUHSC-S IRB follow all relevant Federal and State laws, rules and regulations and Institutional policies and procedures. The PI cannot commence research and/or otherwise enroll subjects until the IRB has approved the study and, to the extent that the activity is sponsored, a fully executed sponsor agreement is in place between the Sponsor and the Institution.

4.1.2 The Contract Coordinators of the HRPP and AVCRM in collaboration with the Office of Legal Affairs and Organizational Integrity negotiate all contracts for clinical trial research involving human subjects to be conducted at LSU Health Shreveport. Contracts will not be approved by the Chancellor or designee until all institutional requirements have been satisfied. It is both LSU Health Shreveport and the Sponsor's obligation to protect human research subjects. All Clinical Trial Agreements (CTA) and Confidential Disclosure Agreements (CDA) must be reviewed and approved by the institution prior to execution.

4.1.3 Definitions

4.1.3.1 Self-Sponsored ("Investigator-Initiated," "Investigator-Sponsored," or "Unsponsored") - refers to a situation in which the individual Investigator is a LSUHSC-S Investigator and is conducting research without an extra mural sponsor. This happens in

such cases as when the PI is the holder of the IND or IDE and therefore assumes the duties of the Sponsor of the clinical Investigator under the applicable FDA regulations.

4.1.3.1.1 When an investigator files an IND or IDE, the investigator is considered the sponsor and as such is accountable for all of the FDA regulatory responsibilities and reporting obligations of both the investigator and the sponsor, as described in the FDA regulations. An individual or group of individuals or medical center is considered a sponsor for an investigation if they hold the IND or IDE. At LSUHSC-S these studies are typically called investigator-initiated studies when they involve the use an investigational drug or device or use an approved drug or device for investigational purposes. The sponsors' or the investigator as a Sponsor's responsibilities include the following:

4.1.3.1.1.1 Selecting qualified investigators

4.1.3.1.1.2 Providing all investigators with the information they need to conduct the investigation properly

4.1.3.1.1.3 Ensuring proper monitoring of the investigation. The investigator will include in the Data Safety Monitoring Plan submitted to the IRB the use of a Contract Research Organization (CRO) or other independent body to monitor compliance with the protocol and all applicable regulations

4.1.3.1.1.4 Ensuring that the FDA and (for devices) any reviewing IRB(s) or (for drugs) all participating investigators are promptly informed of significant new information about an investigation

4.1.3.1.1.5 Additionally, if the IND or IDE product will be manufactured or produced at LSUHSC-S, the Principal Investigator must submit documentation that the product preparation and manufacture meet the standards for current Good Manufacturing Practice (GMP), or any modification to those standards approved by the FDA in issuing the IND or IDE f. The GMP plan has been approved by the applicable LSUHSC-S Institutional Official g. The GMP plan has been reviewed and accepted by LSUHSC-S Risk Management and Compliance Office.

4.1.3.1.1.6 When following FDA requirements: The IND goes into effect 30 days after the FDA receives the IND, unless the sponsor receives earlier notice from the FDA.

4.1.3.1.1.7 The IRB will verify if the IND is valid by checking the sponsor protocol imprinted with the IND number or through written communication from the sponsor documenting the IND number or through written communication from the FDA documenting the IND number. (Required if the investigator holds the IND).

4.1.3.1.1.8 If the IRB cannot verify the IND, then the IRB will approve the protocol and inform the sponsor or clinical research organization and site not to begin until there is a valid IND, or The IRB can withhold IRB approval until the IND goes into effect, or The IRB can approve the trial but delay sending the approval letter until the IND goes into effect.

4.1.3.2 Sponsor - Sponsor means the company, institution, individual donor, or organization responsible for the initiation, management, or financing of a research study. Sponsor is responsible for registering the clinical investigation and submitting clinical trial information to the Clinical Trial Registry Data Bank **https://clinicaltrials.gov**.

4.1.3.3 Sponsored research - Sponsored research means research funded by external entities through a grant or contract that involves a specified statement of work (e.g., the research proposal) with a related transfer of value to the sponsor, including clinical trials involving investigational drugs, devices or biologics.

4.1.4 Office of Legal Affairs and Organizational Integrity Review

4.1.4.1 The AVCRM and Office of Legal Affairs and Organizational Integrity are designated as institutional representative and are responsible for securing authorized signatures on agreements with Sponsors. They serve as the intermediary between a Sponsor and the PI for purposes of negotiation, budget changes, modifications to an agreement, agreement date extensions, and other administrative matters. In consultation with the PI and/or OSPTT for grants, AVCRM, the Contract Coordinators of HRPP and the Office of Legal Affairs and Organizational Integrity review the clinical trial agreement terms and conditions and the budget before obtaining authorized signatures. They are responsible for ensuring Institutional compliance with the terms and conditions of the agreement, as well as any applicable Federal, State, and Institutional regulations and guidelines. Under special circumstances, electronic signatures/digital signatures may be allowed in lieu of traditional “wet ink” or “handwritten” signatures. An example of such a special circumstance would be the COVID-19 pandemic, which has unexpectedly required institutional and sponsor staff to operate in a remote work environment. This abrupt change has increased the importance of relying on electronic signatures/digital signatures. As per the ESIGN ACT, the electronic signature (or e-signature) can be any “electronic sound, symbol or process, attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.”

4.1.4.2 Elements of Contracts

4.1.4.2.1 Applicable Law - A statement should be included in the standard template or any proposed contract stating all work performed by the Institution under the agreement shall be conducted in accordance with the terms of the Protocol, and consistent with applicable laws and the Institution’s policies and procedures.

4.1.4.2.2 HIPAA/Protected Health Information (PHI) - Protecting and maintaining the integrity of patient’s protected health information is required of the Institution. LSU Health Shreveport is and will always comply with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). A statement reflecting HIPAA compliance should be included in any proposed contract and is in the standard

LSUHSC-S template. A statement should also be included by the sponsor on how they will treat LSU Health Shreveport patient's protected health information. PHI shall only be disclosed to individuals who agree to the terms of the Agreement and who reasonably require such information for the performance of the agreement. PHI should be kept confidential and not be released for any purpose other than authorized by the patient in the Consent document or HIPAA authorization or enumerated in the Agreement.

4.1.4.2.3 Informed Consent/HIPAA Authorization - A statement should be included in the contract stating that a sponsor and IRB approved informed consent form and HIPAA authorization form will be obtained from each study subject, or their legal representative, prior to participation in the Study.

4.1.4.2.4 Indemnification - Studies with pharmaceutical sponsors must provide indemnification coverage and defense of LSU Health Shreveport for performing the study, including its trustees, officers, agents, faculty, and employees for all claims arising from the Institution's conduct of the study that are not due to negligence or willful misconduct on Institution's part. The indemnification terms must at a minimum, cover claims arising from study subject injury or illness caused by the product or protocol and the Institution's proper conduct of the protocol. Because we are an Institute of the State of Louisiana, the Attorney General of the state shall represent the state and all departments and agencies of state government in all litigation arising out of or involving tort or contract. Language in the contract should state the following:

4.1.4.2.4.1 "Subject to the statutory duties of the Attorney General of the State of Louisiana, Sponsor, as Indemnitor, shall have the right to select counsel and has sole control over the disposition of such claim or suit, provided, however, that the Sponsor shall sign no settlement of Institution's behalf without first receiving written input from the Institution, and the right to settle any such claim at Sponsor's sole expense provided that any settlement will not include admission of liability on the Indemnities without their prior written consent."

4.1.4.2.4.2 Subject Injury - Prior to the start of any clinical research involving human research subjects, arrangements for medical care for research-related injuries are defined within the contract, including who will provide such care and who will be responsible for paying for the care. Also defined is who will determine whether the injury or illness is related to the study drug/procedure. LSU Health Shreveport in conjunction with the Ochsner Health System will provide the medical treatment and care for any illness or injury caused as a result of study drug/study device. Investigator will determine, either by himself, or in consultation with the Sponsor/CRO, if the injury or illness was a direct result of the study drug/study device. LSU Health Shreveport does not expect the Sponsor to pay for subject injury claims if the injury or illness is due to (i) the negligence or malfeasance of the Institution or Investigator (ii) the failure of the Investigator to follow the Protocol, good clinical practices, any applicable laws or regulations, or any IRB approved written

instructions by the Sponsor concerning the study. The Patient Informed Consent form should reflect the contract language.

4.1.4.2.4.3 Insurance: Insurance terms of the Sponsor should be stated in the contract. Sponsor should ensure that it maintains enough insurance to cover any indemnification obligations, product liability or subject injury claims relating to the Agreement. The minimum per occurrence amount and the annual aggregate amount will depend on the risk level of the study. For lower risk studies, the amounts should be $2,000,000 per occurrence and $5,000,000 annual aggregate; the higher the risk level for the study, the higher the insurance amounts should be. For evidence of insurance coverage, a certificate of insurance (COI) is requested for each study and the contract will not be sent for final review until the COI has been obtained. LSU Health Shreveport (employees, while acting on behalf of the State of Louisiana) is covered by the Office of Risk Management, State of Louisiana Self-Insurance Fund for general liability insurance with limits of $5,000,000 per occurrence, professional liability insurance with limits of $5,000,000 per occurrence subject to LA R.S. 40:1237 et seq., and Worker's Compensation Insurance with limits of $5,000,000. A certificate of insurance is available to Sponsors/CRO's upon request.

4.1.4.2.5 Travel Language: For PI and study coordinator staff to travel, LSU Health Shreveport travel language must be included in the clinical trial agreement. The language must reflect that any required travel must (i) either be paid directly to or (ii) on behalf of the travelers. This language must be agreed upon prior to PI and/or coordinator traveling (the entire contract does not have to be agreed upon at this time, just the travel language).Safety Concerns/Data and Safety Monitoring Reports: LSU Health Shreveport has an obligation to protect the human subjects participating in human subjects research. In order to help protect subjects, LSU Health Shreveport will need the assistance of the Sponsor/CRO. It is stipulated in the clinical trial agreement that the Sponsor/CRO shall immediately/promptly send reports of any findings of serious or continuing non-compliance detected during the monitoring process to the Institution's HRPP/Organization or Investigator that could: (i) affect the safety of subjects (ii) affect the subjects willingness to continue study participation (iii) influence the conduct of the study and (iv) alter the IRB's approval to continue the study. Some findings are risks that were not anticipated at the time the study was designed. Subjects, past and present, should be notified of these results. The Sponsor/CRO should agree to notify the Investigator and/or the Institution's Human Research Protection Program, who then, will communicate these findings to the subjects and IRB as warranted. The Sponsor should be given a time frame after the closure of the study during which they will report such findings to the Institution/Human Research Protection Program. Contracts or other funding agreements require the Sponsor/CRO to send data and safety monitoring plans and reports to the Organization or Investigator who then provides them to the IRB for review within five (5) days of receipt. The contract or funding agreement must specify the time frame for providing routine and urgent data and safety monitoring reports to the Organization.

4.1.4.2.5.1 Publications: Sponsor recognizes that the results of the Project must be publishable and agrees that investigator(s) engaged in the Project shall be permitted to present at symposia, international, national, or regional professional meetings and to publish in journals, theses, or dissertations, or otherwise publish through means of their choosing, methods and results of the Project. Sponsor shall be furnished copies of any proposed publication or presentation at least sixty (60) days in advance of the submission of such proposed publication or presentation to a journal, editor, or other third-party and shall have the right to review the documents and make suggestions for appropriate changes. Upon request from the Sponsor, the Institution agrees to delete from publication presentation any “confidential information” owned or provided by the Sponsor. LSU Health Shreveport shall be given the rights to publish data as a result of the study. The Sponsor shall recognize under the Institution’s policy that the results of the study must be publishable and agrees that the Principal Investigator engaged in the study shall be permitted to present and publish these results. The Principal Investigator shall furnish a copy of the proposed publication or presentation to the Sponsor for review and comment; the Sponsor will then approve the presentation or publication or request additional time/information at which the Principal Investigator will comply. Each pharmaceutical company has its own stipulations for publication rights.

4.1.4.2.5.2 IRB Fee Schedule: A fee schedule has been developed for the LSU Health Sciences Center – Shreveport Institutional Review Board for Human Research (IRB) for review and approval of study documents. This fee schedule will be reflected either in the body of the contract or in the study budget worksheet.

4.1.4.2.5.3 Pharmacy Fee Schedule: A fee schedule has been developed for the Research Pharmacy for study drug maintenance. This fee schedule will need to be reflected either in the body of the contract or in the study budget worksheet.

4.1.4.2.5.4 Clinical Trial Billing Compliance Fee Scheduled: A fee schedule has been developed for the Clinical Trial Billing Compliance function. This fee schedule will be reflected in either the body of the contract or in the study budget worksheet.

4.1.4.2.5.5 In studies where sponsors conduct research site monitoring visits or conduct monitoring activities remotely, contracts and funding agreements must obligate the sponsor to promptly, within 30 days, report to LSUHS any findings of study monitors that could affect the safety of participants or influence the conduct of the study, when such provisions were appropriate to the type of research being conducted. Promptly, within thirty (30) days, is now stated in all contracts when the word promptly is used. Each contract will be evaluated for compliance with AAHRPP element 1.8.B during the HRPP QA/QI quarterly audit.

4.1.4.3 Clinical Trial Agreement/Informed Consent Form Review

4.1.4.3.1 Language contained in the Informed Consent Form Document (ICFD) that is completed for Sponsor initiated Clinical Trials shall not contradict the language negotiated in the Clinical Trial Agreement. Certain elements in the ICFD must reflect contract language. These include: (i) Subject Injury language; (ii) Protected Health Information language (PHI); and (iii) Subject Reimbursement for time and travel. It is the responsibility of the Study Coordinator/Regulatory Coordinator to ensure that these elements are reflected in the ICFD. The outlined process is listed below:

4.1.4.3.1.1 Once negotiations for the Clinical Trial Agreement have begun with the Sponsor, if the Regulatory/Study Coordinator does not have a copy of the sponsor ICFD, the Contract Coordinators of the HRPP will provide the sponsor draft ICFD to them.

4.1.4.3.1.2 The Regulatory/Study Coordinator will send the sponsor draft ICFD containing LSUHSC-S required edits to the Contracts Coordinators for review of the following: (i) Subject Injury; (ii) Protected Health Information (PHI); and (iii) Subject Reimbursement. In most cases, the sponsor ICFD will need to be changed to reflect the language proposed for the Clinical Trial Agreement.

4.1.4.3.1.3 An email is sent by the Contract Coordinators of the HRPP to the Regulatory/Study Coordinator outlining the draft ICFD language and the proposed contract language. Sections in the draft ICFD language that are not acceptable to the Institution are highlighted or bolded. The Regulatory/Study Coordinator is instructed to use the proposed contract language for the ICFD (making it read in 5th grade language). It is the department's responsibility to incorporate the changes in the ICF.

4.2 Clinical Trial Agreement Includes Protections for Research Subjects

4.2.1 In LSU Health Shreveport sponsored research, LSUHSC-S addresses the protections of research subjects by:

4.2.1.1 Including in the standard contract templates a provision that the sponsor acknowledges and understands that the LSUHSC-S HRPP is applicable to all human subject research.

4.2.1.2 Asking for the inclusion of such a provision in any proposed contract that does not use the LSUHSC-S standard template.

4.2.1.3 Including in the cover letter accepting and acknowledging the grant an equivalent statement regarding the HRPP in grants to LSUHSC-S.

4.2.1.4 Ensuring that relevant policies and procedures are made available to sponsors, investigators, research staff, research subjects, and the Institutional Review Board(s) as appropriate. Additionally, the IRB will review the proposed consent form and delete any provision that requires a subject to waive or appear to waive any legal rights (i.e., exculpatory provisions).

4.2.2 Communications from Sponsors Affecting IRB Oversight

4.2.2.1 In LSU Health Shreveport sponsored research contracts, LSU Health Shreveport address communication with the sponsors regarding information and findings related to the protocol obtained by the sponsor which could affect the safety of subjects or influence the conduct of the study. LSU Health Shreveport requires Sponsors or its agents to report findings of serious or continuous non-compliance detected during the monitoring process that could affect the safety of subjects or influence the conduct of the study. This is accomplished by:

4.2.2.1.1 Including in standard contract templates a provision that the sponsor will notify the Institution or the IRB of:

4.2.2.1.1.1 Non-compliance with the protocol or applicable laws, particularly those laws related to subjects, that could impact the safety or welfare of the subjects o Serious adverse events that have been reported to the FDA or other governmental agency in relation to the protocol at LSU Health Shreveport or any other site

4.2.2.1.1.2 Unanticipated problems in the protocol at LSUHSC-S or any other site that could relate to risks to participating subjects, and

4.2.2.1.1.3 Circumstances that could affect subject's willingness to continue to participate in the protocol or the IRB's continuing approval of the protocol.

4.2.2.1.2 Ask for the inclusion of such a provision in any proposed contract that does not use their standard template.

4.2.2.1.3 The Institution should receive copies of the monitoring reports that contain findings that could affect the safety of subjects or influence the conduct of the study. These finding will be made available to the IRB.

4.2.2.1.4 As outlined in the Institutional SOPs investigators must promptly (within five (5) days) report to the IRB any information that could affect the safety of subjects or influence the conduct of the study.

4.2.3 Data and Safety Monitoring (DSM) in Sponsored Agreements

4.2.3.1 For sponsored research, LSU Health Shreveport agreements specify that, as appropriate:

4.2.3.1.1 Provisions are made for monitoring study data which could affect the safety of subjects

4.2.3.1.2 The results of this monitoring are reported to the investigator (PI) so that:

4.2.3.1.2.1 Routine monitoring reports will be submitted to the IRB in accordance with Institutional Policy

4.2.3.1.2.2 Urgent reports-Events and Information which require Prompt Reporting to the IRB are submitted according to the Institutional policy outline in Section 8 13.8 Publication of Research Results

4.2.4 LSU Health Shreveport establishes the importance of disseminating research findings. LSU Health Shreveport shall be given the rights to publish data because of the study. The sponsor shall recognize under the Institution's policy that the results of the study may be publishable and agrees that the PI or engaged in the study shall be permitted to present and publish these results at a mutually agreed upon time. The PI shall furnish a copy of the proposed publication or presentation to the Sponsor for review and comment; the Sponsor will then approve the presentation or publication or request additional time/information at which the PI will comply. Each pharmaceutical company has its own stipulations for publication rights but agrees to provide a copy of the manuscript once accepted for publication.

4.2.4.1 For Sponsored research, LSU Health Shreveport implements this policy in agreements concerning sponsored research by:

4.2.4.1.1 Including in its standard template a provision that provides the investigator with a right to publish the research results.

4.2.4.1.2 Revising any provision in any proposed contract that limits an investigator's right to publish research results in a manner that is inconsistent with the policy.

4.2.5 Communicating Study Findings/Results to Subjects

4.2.5.1 For Sponsored research, LSU Health Shreveport address communication with sponsors regarding the impact of research results on subject health and safety by:

4.2.5.1.1 Including in their standard contract templates a provision that the sponsor will develop a plan of communication with the PI that is acceptable with the IRB when new findings or results of the protocol might impact the willingness of subjects to continue to participate in the protocol or directly affect their current or future safety or medical care.

4.2.5.1.2 Ask for the inclusion of such a provision in any proposed contract that does not use the LSU Health Shreveport standard template. Investigators will obtain a copy of the final manuscript from the sponsor and communicate study results to subjects in lay language as applicable

4.3 International Research/Transnational Research

4.3.1 The purpose of this policy is to establish guidelines for LSU Health Shreveport or affiliates when conducting human subject research, for which one or all of the sites or subjects, are located outside the United States (U.S.), regardless of funding.

4.3.2 LSU Health Shreveport transnational research requirements are consistent with the ethical principles set forth in its HRPP and strive to meet equivalent levels of subject protections for research conducted within the United States. For federally funded research, the regulations of the sponsoring agency apply and the required protections must be provided. This policy is to ensure all human subject research, regardless of whether the research is subject to U.S. federal regulations, will be guided by one of the following statements of ethical principles:

4.3.2.1 The Belmont Report

4.3.2.2 Nuremberg Code

4.3.2.3 The World Medical Association's Declaration of Helsinki

4.3.2.4 Other appropriate international ethical standards recognized by the U.S. Federal departments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects, known as the Common Rule.

4.3.3 The LSUHSC-S IRB will review the research in accordance with the applicable Department of Health and Human Services (DHHS) regulations at 45 CFR 46, and the FDA regulations at 21 CFR 50,56,312,600,612, 812 and International Conference on Harmonization (ICH) Guidelines to the extent ICH encompassed in FDA and OHRP regulations. Recognizing the continued growth of international research, the Office of Human Research Protections (OHRP) has developed an International Compilation of Human Subject Research Protections. OHRP provides this compilation of regulations and guidelines that govern human subject research in other countries, as well as standards from a number of international and regional organizations to support investigators in the conduction of human subject research outside the U.S. The Compilation provides direct web links to each country's key Organizations and laws whenever available. LSUHSC-S HRPP directs investigators to these guidelines and requires their compliance while conducting transnational research.

4.3.4 Clinical Trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with Good Clinical Practice (GCP) and the applicable regulatory requirements.

4.3.5 The document noted below provides an overview of what ethical standards different countries follow and what offices you may need local approval from. To use the compilation, go to page 3 of the document and then click the country of interest.

4.3.5.1 See: OHRP website, **hhs.gov/ohrp/international/compilation-human-research-standards/index.html**

4.3.5.2 Conflicts arising between federal or national law and other applicable laws are referred to the LSUHSC-S Department of Legal Affairs and Organizational Integrity In House Counsel for guidance and resolution.

4.4 Principal Investigator Responsibilities for International Research

4.4.1 All LSUHSC-S policies and procedures that are applied to research conducted in the U.S. are also applied to research conducted in other countries as appropriate. In addition, Principal Investigators (PI) should ensure that subjects outside the U.S. have equivalent protections that subjects would be afforded to subjects in the U.S.

4.4.2 The PI must obtain LSUHSC-S IRB approval in addition to approval from the local Ethics Committee, should one exist in the host country, in which the research is conducted.

If an Ethics Committee or other similar review committee does not exist, then a letter of support from a community leader must be obtained and submitted to the LSUHSC-S IRB. The PI will obtain the letter of support from the facility at which the research is conducted, if applicable.

4.4.3 Investigators are required to be knowledgeable about and comply with local laws while conducting their research and take into account the local customs and cultural context. Care must be taken to ensure that the cultural norms of the host country are respected and that the subjects will not suffer adverse consequences from participation, such as being subjected to retaliation from local authorities or local community. The investigator should also consult with investigators familiar with the culture differences of transnational research and become knowledgeable in the different customs, habits, and practices of international study subjects.

4.4.4 Principal Investigators must assist their colleagues from the host country in obtaining a Federalwide Assurance (FWA) if the research is federally funded and requires that the transnational institution receive an approved FWA from the Office of Human Research Protections (OHRP).

4.4.5 Listed below are additional elements the investigator should address prior to IRB review and approval:

4.4.5.1 The qualifications of collaborator(s) at each site.

4.4.5.2 Provide the names and dates of completion of the CITI module on conducting research in an international setting for investigators.

4.4.5.3 Is the investigator providing equivalent protections to US regulations and if federally funded, include the FWA number for each research site?

4.4.5.4 Investigator must be knowledgeable of local laws and cultural context in all locations where research is conducted.

4.4.5.5 Cultural differences that influence study design and the consent process. The rationale for conducting the study with an international population.

4.4.5.6 Investigator must comply with local laws and adhering to local cultural norms (e.g., customs, socio-economic, political, cultural factors, language and literacy).

4.4.5.7 Research methods appropriately minimize the risks to research subjects at the selected sites.

4.4.5.8 Are there any state department warnings that would prohibit travel? Think about potential risks to the research team. Check early and before leaving the US as political or environmental conditions can change at any time.

4.4.5.9 Be sure to allow enough time for additional logistics related to travel (passport, Visas, Immunizations, permits to transport goods into or out of the country).

4.4.5.10 Investigator to consider if biological specimens can be brought back into the US. While designing your protocol you may contact LSUHSC-S Safety Office for guidance.

4.4.5.11 Meaningful Informed Consent- understand and weigh the implications for cultural differences when trying to obtain informed consent, the informed consent process should be based on local cultural norms and laws, quality of translation, local collaborators to assist in explanation

4.4.5.12 Who will translate documents for LSUHSC-S and host country review? Is there funding to cover the costs of translations?

4.4.5.13 Translator certification will be required for the IRB review.

4.4.5.14 English translated documents must be provided to the IRB for IRB review.

4.4.5.15 Will a translator be required on–site?

4.4.5.16 Have risks been minimized based on the methods implemented? Low risk in the U.S. does not mean low risk in host country. Asking certain questions may be offensive or responses could place the subject at risk.

4.4.5.17 Does the host country have provisions for research –related injuries? If clinical studies are conducted, available health care may be minimal or non-existent.

4.4.5.18 What is considered Identifiable Data in the U.S. may differ in the host country. Do not collect any data or specimens without knowing the rules. IP addresses are considered identifiable in European countries.

4.4.5.19 Have you obtained the appropriate approvals in the host country to conduct research?

4.4.5.20 Submit your IRB application to the IRB for IRB review and approval at least 8 to 10 weeks in advance of your planned departure.

4.4.5.21 Determine if written agreements are required. Contact the Department of Legal Affairs & Organizational Integrity Contract Coordinator for guidance as needed.

4.4.5.22 HIPAA is a U.S. regulation that does not apply in other countries.

4.4.5.23 Obtain a description of the host country's ethics review and oversight mechanism for subject protection.

4.4.5.24 All federally funded studies must have Federalwide Assurance (FWA) before the study can begin.

4.4.6 When following VA regulations,

4.4.6.1 Each research project at OBVAMC must be reviewed and approved initially by the designated IRB and the RDC. No initial research may be engaged at OBVAMC facility without the review and approval of the RDC and its appropriate subcommittees. The designated IRB of Record will perform initial review of all research projects involving human subjects and will be a standing subcommittee of the RDC. The RDC reviews the HRPP for compliance and oversight of research in the protection of human subjects in cooperation with the RCO and ACOS/R&D. Overton Brooks VAMC RDC does not serve as the RDC for research for any other VA facility. The RDC reports to the Chief of Staff and the Medical Center Director. The RDC accomplishes its responsibilities through the following activities or procedures:

4.4.6.1.1 planning and developing broad objectives for the Research Program so that it supports VA's mission and determining the extent to which these objectives are met while overseeing all facets of the Research Program for Overton Brooks VAMC for which it serves;

4.4.6.1.2 The RDC will review, ensure, and promote:

4.4.6.1.2.1 maintenance of high scientific standards to include, at a minimum procedure consistent with sound research design; and a research design sound enough to yield the expected knowledge proposed

4.4.6.1.2.2 consideration of the findings of its subcommittees in conducting initial reviews;

4.4.6.1.2.3 protection of human subjects (including privacy and confidentiality) and the implementation of adequate safety measures for research subjects and personnel while ensuring the ability of the investigator to perform and complete the associated research;

4.4.6.1.2.4 security of research laboratories where hazardous agents are stored or utilized;

4.4.6.1.2.5 security of VA data, VA personal information and VA sensitive information including a review of the use, storage and security of such data and information;

4.4.6.1.2.6 ability of the investigator to perform and complete the research including the qualifications of the investigator and other information deemed relevant;

4.4.6.1.2.7 availability of adequate resources (financial and other) to conduct and complete the research including the budget, requirements for space, personnel, equipment, and supplies; and

4.4.6.1.2.8 relevance of research to, and in support of, VHA's mission and this facility's research program.

4.4.6.2 International Research includes VA-approved research conducted at international sites not within the United States, its territories, or Commonwealths; and includes research where human tissues are sent outside the United States. For VA purposes, international research does not include studies in which VA is only one of multiple participating sites where the overall study-wide PI is not a VA investigator (i.e., the PI for the study as a whole is not a VA investigator)." The investigator must provide the IRB documentation that the facility director has approved any international research involving the VA. The investigator must conduct the research in accordance with VA requirements and all other applicable federal requirements for protecting human subjects, tissue banking, use of databases, federal criminal laws, and the standards of ethical conduct for employees of the executive branch.

4.4.6.3 Overton Brooks VA Medical Center does not participate in international research.

4.5 Investigator Responsibilities

4.5.1 Investigator obligations when conducting studies involving human subjects are listed below. This is a general guide and not a comprehensive description of all investigator responsibilities. Investigators are expected to:

4.5.1.1 Protect the rights and welfare of prospective subjects

4.5.1.2 Assume overall administrative responsibilities for all aspects of each IRB-approved research study, conducting the research according to the IRB-approved protocol, maintaining appropriate oversight of the research study and supervision of the research staff, appropriately delegating research responsibilities

4.5.1.3 Assure all key personnel under his/her supervision are adequately trained and supervised in the regulatory requirements regarding the conduct of research and the ethical principles upon which they are based Collaborative Institutional Training Initiative (CITI) course as its training program

4.5.1.4 Assure that research duties are delegated to individuals who are qualified to perform the assigned tasks and informing research staff of any pertinent changes during the course of the study

4.5.1.5 Develop and conduct a research plan that is in accordance with the ethical principles in the Belmont Report

4.5.1.6 Develop a research plan that is scientifically sound and in accordance with the standards of their discipline. Studies should be in a design that minimizes risks to subjects

4.5.1.7 Follow Good Clinical Practice (GCP) guidelines when conducting any study that meets the definition of human subjects' research and involves

(1) FDA regulated approved or unapproved drugs, devices or biologics or any other FDA regulated product/

(2) where the sponsor or funding agency requires the use of GCP guidelines

4.5.1.8 Ensure that pertinent laws, regulations, and institutional procedures and guidelines are observed by participating investigators and research staff. Investigators must be knowledgeable about and comply with requirements of Common Rule and other federal research laws and regulations, applicable state law, LSUHSC-S FWA, and institutional policies and procedures for protection of human subjects

4.5.1.9 Maintain contact with the sponsor, the monitoring entity if applicable, and receive reports from the sponsor

4.5.1.10 Ensure that every investigator discloses any potential conflict of interest

4.5.1.11 Cooperate with evaluations, inspections, and audits performed by authorized internal oversight authorities, such as the IRB, as well as external reviews (e.g., sponsor or government agency such as FDA)

4.5.1.12 Maintain adequate and accurate records in accordance with 21 CFR 312.62, making those records available for inspection in accordance with 21 CFR 312.68. An investigator shall retain records in accordance with whichever is the greater of the following:

(1) as required by the FDA for a period of two (2) years following the date a marketing application is approved for the drug or device for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two (2) years after the investigation is discontinued and FDA is notified; or

(2) In accordance with the Common Rule and FDA regulations (45 CFR 46.115(b) and 21 CFR 56.115(b)), IRB records are retained for at least three (3) years after the completion of the research, either electronically or as hard copy. Protocol files are to be retained as long as required by law or as stated in clinical trial agreement but no less than three (3) years after completion of the research and then destroyed. Protocols in which there was no subject enrollment, or no research was conducted are to be retained the same as protocols where research was conducted. In accordance with federal HIPAA privacy regulations, IRB records pertaining to records containing protected health information (PHI) are retained for at least six (6) years after the completion of the research. It is LSUHSC-S policy to retain records for the greatest amount of mandated time. Thus, the IRB retains all research records for at least six (6) years.

(3) Sponsored grants and contracts may require additional periods for record retention.; or

(4) For VA research, records will be kept in accordance with the VHA's Records Control Schedule (RCS 10-1).

4.5.1.13 Make a reasonable effort to ascertain the reason for a subject withdrawal from a clinical trial while fully respecting the subject's rights, although the subject is not obliged to give his or her reasons for withdrawing from a clinical trial.

4.5.1.14 The investigator informs the subject's primary physician about the subject's participation in the clinical trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.

4.5.1.15 The investigator will provide evidence of his or her qualifications through up- to-date curriculum vitae or other relevant documentation requested by the sponsor, the IRB, or the regulatory authority.

4.5.1.16 The investigator is familiar with the appropriate use of the investigational, as described in the protocol, in the current investigator brochure, in the product information, and in other information sources provided by the sponsor.

4.5.1.17 A qualified physician (or dentist when appropriate), who is a investigator or a coinvestigator for the clinical trial, is responsible for all clinical trial related medical (or dental) decisions.

4.5.1.18 During and following a subject's participation in a clinical trial, the investigator ensures that adequate medical care is provided to a subject for any adverse events, including significant laboratory values, related to the clinical trial.

4.5.1.19 The investigator ensures the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor.

4.5.1.20 The investigator permits monitoring and auditing by the sponsor and inspection by the appropriate regulatory authority.

4.5.2 Investigators are expected to comply with IRB by:

4.5.2.1 Considering whether their project meets the definition of human subject research or Clinical investigation, understanding which activities are overseen by the HRPP. IRB staff is available to assist investigators to determine if a project needs to be submitted for IRB review. The IRB will make that final determination.

4.5.2.2 Ensuring that all research that qualifies as human subjects research receives IRB review and approval in writing before commencement of research

4.5.2.3 Complying with all IRB decisions, conditions, and requirements

4.5.2.4 Ensuring that protocols receive timely progress reports and continuing IRB reviews and approvals

4.5.2.5 Reporting any unanticipated problems or serious adverse events that require prompt reporting to the IRB

4.5.2.6 Reporting deviations or changes in research activity to the IRB

4.5.2.7 Obtain IRB review and approval in writing before changes are made to approved protocols or consent forms

4.5.2.8 Maintaining a master list of subjects for any given study where informed consent is required and documented, having it readily available at any given time. The IRB may waive this requirement

4.5.2.9 Seeking IRB assistance in determining if proposed activities requires IRB review. The IRB makes the final determination.

4.5.2.10 Reporting the notification as well as the outcome of any external investigation, inspection, or other external review to the IRB and to the Department of Legal Affairs and Organizational Integrity upon notification and upon receipt of the outcome.

4.5.2.11 Being aware of LSUHSC-S IRB reporting requirements for research activities and providing to the IRB prompt reports of serious or continuing noncompliance with the protocol, determinations of the IRB, LSUHSC-S HRPP SOPs, federal regulations or ICH guidelines.

4.5.2.12 In the case of VA research: in the event a determination of serious or continuing non-compliance in violation with any IRB requirement is identified, the PI, Research Office, and RCO will be notified in writing within one (1) business day of the determination. The VA Medical Facility will report the serious or continuing non-compliance to the appropriate ORO workgroup per VHA Directive 1058 and will promptly report these events to OHRP and/or FDA.

4.5.2.13 Any suspension or termination of IRB approval will be communicated in writing to the PI, the Research Office, and the RCO within one (1) business day of the determination being made. The VA Medical Facility will report the suspension or termination of IRB approval to the appropriate ORO workgroup per VHA Directive 1058 and be responsible for promptly reporting these events to OHRP and/or FDA.

4.5.2.14 Investigators must report all serious adverse events (SAEs) to the sponsor, except those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The investigator must follow regulatory requirements related to the reporting of unexpected serious drug reactions to the regulatory authority and to the IRB.

4.5.2.15 The investigator must report adverse events or laboratory abnormalities (that occur in subjects in the study) identified in the protocol as critical to safety evaluations to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.

4.5.2.16 For reported deaths, the investigator should supply the sponsor and the IRB with any additional requested information (e.g., autopsy reports and terminal medical reports).

4.5.2.17 The investigator provides written reports to the sponsor, IRB, and where applicable, the organization on any changes significantly affecting the conduct of the clinical trial or increasing the risk to subjects.

4.5.2.18 If the investigator terminates or suspends a clinical trial without prior written agreement of the sponsor, the investigator should inform the Organization, sponsor and the IRB. The Investigator should contact the Organization through the Department of Legal Affairs and Organizational Integrity Clinical Trial Agreement Coordinator.

4.5.2.19 If the IRB terminates or suspends approval of the clinical trial, the investigator promptly notifies the sponsor.

4.5.2.20 Upon completion of the clinical trial, the investigator informs the Department of Legal Affairs & Organizational Integrity Clinical Trial Agreement Coordinator and the IRB with a summary of the trial's outcome, and the regulatory authority with any required reports.

4.5.3 Investigators are expected to ensure that risks to subjects are minimized and protect subjects' rights and welfare by:

4.5.3.1 Recruiting subjects in a fair and equitable manner, avoiding practices that place subjects at risk for coercion or undue influence

4.5.3.2 Obtaining and documenting informed consent of subjects or subjects' legally authorized representatives prior to the subjects' participation in the research (unless these requirements have been waived) as required by the IRB and ensuring that no human subject is involved in the research prior to obtaining their consent

4.5.3.3 Using procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk

4.5.3.4 Using procedures already being performed on the subjects for diagnostic or treatment purposes, whenever appropriate

4.5.3.5 Having plans to monitor the data collected for the safety of research subjects: Investigators are required to have an appropriate Data Safety Monitoring Plan for all interventional studies that are greater than minimal risk and involve any FDA regulated products (drugs, devices, biologics) invasive procedures or any other study intervention as requested by the IRB. PI's are responsible for establishing a Data Safety Monitoring Board when required

4.5.3.6 Protecting the privacy of subjects and protect the confidentiality of personal information

4.5.3.7 Notifying the subjects' primary physician about the subject's participation in the clinical trial if the subject has a primary physician and if the subject consents to the primary physician being informed of their participation

4.5.3.8 Including additional safeguards in the study to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4.5.3.9 Having sufficient resources necessary to protect human subjects, including

a. Sufficient time to conduct and complete the research.

b. Adequate numbers of qualified staff.

c. Adequate facilities.

d. A process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.

e. Availability of medical and psychological resources that subjects might require as a consequence of the research. Assure that all procedures in a study are performed with the appropriate level of supervision and only by individuals who are licensed or other qualified to perform such under the laws of Louisiana and policies of LSU Health Shreveport.

4.5.3.10 Having a procedure to receive complaints or requests for additional information from subjects and respond appropriately. Investigators should explain to research subjects how the Research Staff can be contacted to ask questions, express concerns, or express complaints about the research and seeking guidance from the HRPP or IRB when necessary.

4.5.3.11 Participation of Non-Veterans as Research Subjects. Non-Veterans may be entered into VA approved research studies only when there are insufficient Veterans available to complete the study in accordance with 38 CFR 17.45 and 38 CFR 17.92. All regulations pertaining to the participation of Veterans as research subjects, including requirements for indemnification in the care of research-related injuries, pertain also to non-Veteran subjects enrolled in VA research.

4.6 IRB Responsibilities for International Research

4.6.1 LSUHSC-S's IRB review of transnational research adheres to the same policies applied to domestic (US) research, when appropriate. The IRB must have knowledge of the local research context. This level of knowledge is in part based upon the level of risk presented by the research. Additional legal or cultural expertise may be consulted by the IRB during its review, and the IRB will make those determinations required by the laws of the countries in which the research is conducted. This knowledge may also be gained from involving legal or cultural expertise as a consultant to the IRB during its review of the research. In addition, the IRB requires documentation that the host country is aware of the research and has agreed for the research to be conducted in that country. When necessary, the IRB will communicate with the host country's Ethics Committee or similar review committee should one exist.

4.6.2 The IRB must review the Informed Consent document which must be translated into the language understandable by the subjects for accuracy and approval. The translated document must be certified or back translated and major discrepancies with the English version must be addressed. In some circumstances it may be inappropriate to document consent by using the standard written and signed informed consent document. There also may be different laws regarding determination as to who may serve as a Legally Authorized Representative (LAR) which the IRB must take into account.

4.6.3 If subjects participating in transnational research will be compensated for their participation in the research, the IRB must ensure that the amount to be provided to subjects is appropriate and reflective of the standard of living in the country in which the research is being conducted as to not unduly influence subjects to participate.

4.6.4 The IRB is responsible for monitoring the research as with all other human subject research under its purview. Any problems encountered with the research should be communicated to the study sponsor, relevant regulatory bodies, and all reviewing IRBs and Ethic Committees as appropriate. Research that is federally funded and FDA regulated must comply with both DHHS and FDA regulations.

4.6.5 When investigators conduct studies in other countries, the IRB that reviews such research will confirm the following when reviewing and approving transnational research

4.6.5.1 The IRB must have the appropriate expertise and knowledge of the country(ies) either through the IRB membership or consultants.

4.6.5.2 The IRB must be knowledgeable about the local laws, regulations, codes, and guidance that govern such research in addition to the cultural context in which the research is conducted. The IRB requires the PI to provide information about the laws and cultural context of other countries in which the research is being conducted.

4.6.5.3 The PI must ensure that all the research procedures described in the IRB application will be conducted at the foreign site for review by the IRB committee and the committee in the host country.

4.6.5.4 The PI must provide the qualifications of all the investigators in the IRB application. The IRB will confirm the qualifications of the investigators and research staff for conducting research in that country.

4.6.5.5 When there is a local IRB in the host country where the research is conducted, the investigator and IRBs must agree prior to approval on a process for ensuring that I initial review, continuing review, review of modifications, post-approval monitoring, handling of complaints, non-compliance and unanticipated problems involving risks to subjects or others are conducted. Depending upon the risk level and other factors, the IRB would consider the following options: LSUHSC-S can enter into agreements with the other IRB requiring the other IRB to report problems and complaints or the investigator can describe a process for reporting problems and complaints.

4.6.5.6 The IRB must approve the plan provided by the PI regarding informed consent process and document and other language issues

4.6.5.7 Coordination and communication with local IRBs when appropriate

4.6.5.8 All policies and procedures that are applied to research conducted domestically should be applied to research conducted in other countries, as appropriate.

4.6.5.9 The IRB should ensure that equivalent protections are provided to research in other countries. The IRB should make determinations and decisions based on laws and knowledge of the country in which the research will be conducted.

4.6.5.10 When following VA regulations and guidance in transnational research the IRB ensures the following:

4.6.5.10.1 Permission must be obtained from the chief research and development officer or designee, prior to initiating any VA-approved international research.

4.6.5.10.2 The VA facility director must approve any request for permission to conduct international research prior to forwarding it to the chief research and development officer.

4.6.5.10.3 All international sites must hold an international Federalwide Assurance, and the research, and the research must be approved by the IRB or Ethics Committee of the participating sites listed on the international Federalwide Assurance.

4.7 Approvals Required Before International Human Subject Research Commences

4.7.1 IRB approval is required before research activities may commence. In addition to approval from the IRB, depending on the funding source, either contract finalization or departmental approval is required before research involving human subjects can commence, as follows:

4.7.1.1 Externally funded research (industry-sponsored clinical trials and other clinical research) undergoes a parallel review process but must have an agreed upon agreement in the signature phase prior to IRB submission.

4.7.1.2 Other research requires the approval of a Section Chief, Department Chair and Senior Associate Dean for Clinical Affairs, as appropriate, confirming:

4.7.1.2.1 Scientific and scholarly validity

4.7.1.2.2 Adequacy of resources

4.8 Some protocol-specific situations require additional review and approval by other organizational components or must meet their standards.

4.8.1 Collaborative Research Projects: In the conduct of cooperative research projects, LSUHSC-S acknowledges that each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal and state regulations. When a cooperative agreement exists, LSUHSC-S may enter into a joint review arrangement. A formal relationship must be established between the Institution and the other institution through either a Cooperative Agreement or a Memorandum of Understanding. This relationship must be formalized before the Institution will accept any human research

proposals from the other institution. It is the policy of LSUHSC-S to assure that all facilities participating in a human subjects study receive adequate documentation about the study in order to protect the interests of study subjects. Before a study can begin, it must be approved by the IRB(s) of record for each participating facility and, where appropriate, the IRB of record for the coordinating facility.

4.8.2 For collaborative research, the PI must identify all institutions participating in the research, the responsible IRB(s), and the procedures for dissemination of protocol information (IRB initial and continuing approvals, relevant reports of unanticipated problems, protocol modifications, and interim reports) between all participating institutions. When LSUHSC-S reviews research conducted at another institution, the particular characteristics of each institution's local research context must be considered, either

i. Through knowledge of its local research context by the LSUHSC-S IRB or

ii. Through subsequent review by appropriate designated institutional officials, such as the chairperson and/or other IRB members. When serving as the coordinating institution for the lead principal investigator, the LSUHSC-S IRB is responsible for the review and tracking of information (including but not limited to reportable events, modifications to previously approved research, consent documents and continuing review reports) for approved multi-site research studies involving human subjects.

4.8.3 The LSUHSC-S lead Principal Investigator serves as an agent of LSUHSC-S and is responsible for the receipt and dissemination of all multi-site research study information to all sites considered engaged in the research. If LSUHSC-S is the coordinating facility, the PI must document how the important human subject protection information will be communicated to the other participating facilities engaged in the research study. The lead LSUHSC-Principal Investigator is responsible for submitting a LSUHSC-S IRB electronic application and providing the following information to the IRB:

4.8.3.1 A list of all sites/locations participating in the research study.

4.8.3.2 Confirmation of contact information (names, e-mails, addresses) for all sites/locations participating in the research study.

4.8.3.3 A plan for the review of each external site's IRB approval correspondence and approved consent documents. The external site's IRB approval correspondence will include the type of review and any conditional approval information.

4.8.3.4 When the research study is federally funded or federally regulated, confirmation that each participating site has on file a Federalwide Assurance (FWA) with the Federal Office of Human Research Protections (OHRP).

4.8.3.5 Registration of an applicable study on **https://clinicaltrials.gov/.**

4.8.3.6 A plan to assure that no participating site will begin the research (including recruitment activities) until IRB approval has been granted.

4.8.3.7 A method to assure that all sites participating in the research have the most current version of the protocol.

4.8.3.8 A method to assure that all sites participating in the research receive, when applicable, protocol amendments.

4.8.3.9 A method to assure that all sites participating in the research receive study related communications including reports of adverse outcomes, unanticipated problems, and interim results.

4.8.3.10 A plan for the collection and management of data from all sites/locations participating in the research.

4.8.3.11 A process for centralized reporting and evaluation of events (and protocol deviations/violations from all sites participating in the research).

4.8.3.12 If the external site plans to rely on the LSUHSC-S IRB, the lead PI is responsible for consulting with the LSUHSC-S AVCRM or designee who will oversee the completion of the LSUHSC-S IRB Authorization Agreement. The Agreement will specify the roles and responsibilities of LSUHSC-S IRB and the relying organization. The external site will be responsible for updating its FWA to reflect reliance upon the LSUHSC-S IRB as appropriate per DHHS OHRP guidance. The external site and the LSUHSC-S IRB will each maintain one fully executed original of the agreement for inspection by OHRP, as requested.

4.8.3.13 IRB submissions (e.g., modifications, continuing review report, reportable events, etc.): If the LSUHSC-S PI's internal application is the mechanism for the initial and continuing IRB review for any external Relying Organization(s), the lead LSUHSC-S PI is responsible for receiving reports from all participating sites and submitting information to IRB in accordance with LSUHSC-S IRB policies. If an external site application is the mechanism for the initial and continuing LSUHSC-S IRB review for the external Relying Organization, the PI for the external site application is responsible for submitting information to the IRB in accordance with LSUHSC-S IRB policies.

4.9 It is the policy of LSUHSC-S that investigators are expected to adhere to the protocol, protocol required procedures and consent documents approved by the Institutional Review Board (IRB) as well as the Louisiana State University Health Sciences Center – Shreveport Human Research Protections Program and Institutional Review Board Standard Operating Procedures. The term Protocol Deviation or Protocol Violation is not defined by either the Health and Human Services human subjects regulations, (45CFR 46) Common Rule or the Food and Drug Administration human subjects regulations (21CFR 50). For the sake of research under the auspices of the Louisiana State University Health Sciences Center the following definitions, policies and procedures apply.

4.10 LSUHSC-S IRB Responsibilities: When LSUHSC-S is serving as the coordinating institution for the lead principal investigator, the LSUHSC-S IRB will perform initial review of each research application and all documentation relevant to the protection of human subjects. The

LSUHSC-S IRB will conduct IRB review, including, but not limited to review of reportable events, modifications to previously approved research, and continuing review reports.

4.11 VA Multi-Site Research: For VA multi-site research, not only the principal investigator, but also all local site investigators, must obtain written approvals from the relevant VA facilities' IRBs of record and all other local committee, subcommittees, and other approvals according to the respective applicable local, VA and other federal requirements. Research cannot be initiated at any given site until the local investigator has obtained written notification that the research can be initiated from the local Chief of Staff for Research and Development. For VA requirements use HRP-318 - WORKSHEET - Additional Federal Agency Criteria for VA research.

4.12 DoD Multi-site Research: For multi-site research involving the DoD, the LSUHSC-S IRB and the lead LSUHSC-S Principal Investigator will adhere to additional responsibilities as set forth in the DoD Addendum. The DoD Addendum is a formal agreement between the LSUHSC-S IRB and DoD organizations specifying requirements, roles, and responsibilities. For DoD requirements use HRP-318 - WORKSHEET - Additional Federal Agency Criteria for DoD research.

4.13 When following DoD requirements: LSUHS will conduct research involving research for prophylactic, protective, or other peaceful purposes involving:

- Chemical agents (a chemical substance that is intended for use in military operations to kill, seriously injure, or incapacitate a person through its physiological effects. Excluded from consideration are riot control agents, chemical herbicides, smoke, and flame) (Section 1520a of Title 50, United States Code (U.S.C.)
- Biological agents (the term "biological agent" means any micro-organism (including bacteria, viruses, fungi, rickettsia, or protozoa), pathogen, or infectious substance, and any naturally occurring, bioengineered, or synthesized component of any such micro-organism, pathogen, or infectious substance, whatever its origin or method of production, that is capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; or deterioration of food, water, equipment, supplies, or materials of any kind; or deleterious alteration of the environment.) (DoD Directive 5210.65)
- Human subject research involving the testing of chemical or biological agents is prohibited, pursuant to Section 1520a of Title 50, United States Code (U.S.C.). Some exceptions for research for prophylactic, protective, or other peaceful purposes apply. Before any excepted testing of chemical or biological agents involving human subject research can begin, the DoD component seeking to conduct such research must obtain explicit written approval from the DoD Office for Human Research Protections (DOHRP).
- LSUHS permits research involving chemical or biological agents under an exception.

- Principal Investigator works in conjunction with OSPTT and IRB to obtain approval of protocol. OSPTT submits IRB-approved protocol to Grants Management contact at DoD. DoD reviews protocol. OSPTT notified by email of DoD approval. PI can start enrolling research subjects.

4.14 Research Involving Pregnant Women or Human Fetuses and Neonates (Subpart B)

4.14.1 Research Not Funded by DHHS: For research not funded by DHHS, no additional safeguards are required by the regulations and there are no restrictions on the involvement of pregnant women in research where the risk to the fetus is no more than minimal. However, it is the policy of the LSUHSC-S IRB to provide additional protections. The IRB does not allow pregnant women, fetuses, or nonviable neonates to be involved in research without specific approval of their involvement in the research (e.g., consultation with professionals in the field).

4.14.2 For DHHS-funded research, 45 CFR Subpart B applies to all research involving pregnant women.

4.14.3 Use HRP-412 - CHECKLIST - Pregnant Women, HRP-413 - CHECKLIST - Non-Viable Neonates and HRP-414 - CHECKLIST - Neonates of Uncertain Viability

4.15 Research Involving Prisoners (Subpart C)

4.15.1 Use HRP-415 - CHECKLIST – Prisoners for all research involving prisoners, regardless of funding source. The requirements in this checklist are consistent with Subpart C of 45 CFR 46, which applies to DHHS-funded research.

4.15.2 Even though the IRB may approve a research protocol involving prisoners as subjects according to this policy, investigators are still subject to the Administrative Regulations of the Louisiana Department of Corrections and any other applicable State or local law. [45 CFR 46.301] There are no additional limitations on research in accordance with Louisiana State law.

4.15.3 The definition of minimal risk in the Subpart C is different than in the rest of the federal regulations. According to 45 CFR 46.303, minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

4.15.4 In addition to satisfying the general requirements detailed in these SOPs, when reviewing research involving prisoners, the IRB must also meet the following requirements [45 CFR 46.304]:

4.15.4.1 A majority of the IRB (exclusive of prisoner members) must have no association with the prison(s) involved, apart from their membership on the IRB.

4.15.4.2 At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity.

4.16 Research Involving Children (Subpart D)

4.16.1 According to Louisiana State Law, minors are persons under the age of eighteen. The general rule is that a person may consent for his or her own medical care at the age of eighteen. Therefore, the LSUHSC-S IRB generally defines children as persons less than eighteen (18) years of age.

4.16.2 Use HRP-416 - CHECKLIST – Children for all research involving children, regardless of funding source. The requirements in this checklist are consistent with Subpart D of 45 CFR 46, which applies to DHHS-funded research and Subpart D of 21 CFR 50, which applies to FDA-regulated research involving children.

4.17 Research Involving Persons with Impaired Decision-Making Capacity

4.17.1 Individuals with impaired decision-making capacity are those with diminished capacity for judgment, impaired capacity to consent, and impaired reasoning due to a psychiatric, organic, developmental, or other disorder that affect cognitive or emotional functions. Other individuals may be considered persons with impaired decision-making capacity or have limited decision making ability, because they are under the influence of or dependent on drugs or alcohol, suffering from degenerative diseases affecting the brain, are terminally ill, or have severely disabling physical handicaps. The IRB reviews the risk-benefit analysis including the possibilities of coercion and undue influence and must deter mine whether such subjects should be recruited and whether support mechanisms, such as surrogate consent, or obtaining consent from a legally authorized representative are appropriate.

4.17.2 Use HRP-417 - CHECKLIST - Cognitively Impaired Adults

5 MATERIALS

5.1 HRP-314 - WORKSHEET - Criteria for Approval

5.2 HRP-318 - WORKSHEET - Additional Federal Agency Criteria

5.3 HRP-412 - CHECKLIST - Pregnant Women

5.4 HRP-413 - CHECKLIST - Non-Viable Neonates

5.5 HRP-414 - CHECKLIST - Neonates of Uncertain Viability

5.6 HRP-415 - CHECKLIST – Prisoners

5.7 HRP-416 - CHECKLIST – Children

5.8 HRP-417 - CHECKLIST - Cognitively Impaired Adults

6 REFERENCES

6.1 45 CFR 46

6.2 21 CFR 50,56,312,600,612, 812

6.3 ICH - GCP

6.4 VHA Handbook 1200.5

6.5 AAHRPP I.1.A.; I.1.B.; I.1.C.; I.1.D.; I.1.F.; I.1.G.; I.1.H.; I.3.; I.4.A.; I.5.D.; I.7.A.; I.8.; II.1.E.; II.2.E.; II.2.G.; II.2.I.; II.3.; II.4.; III.1.; III.2.

HRP-012 Observation of Consent Process

1 PURPOSE

1.1 This procedure establishes the process to observe the consent process.

1.2 The process begins when the IRB determines that the consent process should be observed.

1.3 The process ends when the IRB determines that the consent process no longer should be observed.

2 POLICY

2.1 The IRB may consider observation of the consent process when:

2.1.1 The IRB wants verification from sources other than the investigator that no material changes have taken place since prior IRB review.

2.1.2 There are Allegations or Findings of Non-Compliance.

2.1.3 The nature of the research indicates that the consent process can be improved through observation.

2.2 The IRB, IO/OO, or designee designates who conducts the observation. The IRB may have the observation conducted by:

2.2.1 IRB staff.

2.2.2 IRB members.

2.2.3 A person recommended by the investigator.

2.2.4 An independent person hired by the IRB but paid for by the investigator's funds.

3 RESPONSIBILITIES

3.1 The person designated to conduct the observation of the consent process carries out these procedures.

4 PROCEDURE

4.1 Observe the consent process and determine whether the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally authorized representative, and that informed consent was freely given by the subject or the legally authorized representative.

4.1.1 If no, indicate that consent is not legally effective, and the prospective subject may not be entered into the research.

4.1.2 If yes, document in writing that the consent process was observed, and that informed consent was freely given by the subject or legally authorized representative.

5 MATERIALS

5.1 AUDIT TOOL HRP-336 - WORKSHEET - Audit Tool - Consent Process

6 REFERENCES

6.1 45 CFR 46.109(g)

6.2 21 CFR 56.109(f)

6.3 AAHRPP II.3.F.; II.4.B.

HRP-013 LARs, Children, and Guardians

1 PURPOSE

1.1 This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:

1.1.1 Legally Authorized Representative (LAR)

1.1.2 Children

1.1.3 Guardian

2 POLICY

2.1 Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a Legally Authorized Representative.

2.2 When research is conducted in Louisiana the following individuals meet this definition:

A legally authorized representative is an individual or body authorized under Louisiana law to provide permission on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. For the purposes of this policy, a legally authorized representative includes not only a person appointed as a health care agent under a Durable Power of Attorney for Health Care (DPAHC), a court appointed guardian, tutor or curator of the person, but also next-of-kin in the following order of priority: spouse, not judicially separated; adult child (eighteen (18) years of age or older); any parent, whether adult or minor, for his/her child; adult sibling (eighteen (18) years of age or older); grandparent, or adult grandchild (eighteen (18) years of age or older).

2.2.1 LA. C.E. 510(5) “Representative of a patient” is any person who makes or receives a confidential communication for the purpose of effectuating diagnosis or treatment of a patient.

2.2.2 LA. R.S. 44:17(A) (4) “Representative of a patient” means a person who is a parent, tutor, curator, spouse, trustee, attorney, or other legal agent of the patient and who is authorized, by and on behalf of the patient, to exercise any of the patient’s rights or privileges.

2.2.3 For research outside of Louisiana a determination of who is a legally authorized representative is to be made with consultation from HRPP legal counsel.

2.3 The participation of children who are wards of the state is approved under:

2.3.1 45 CFR 46.406, 45 CFR 46.407 only if 45 CFR 46.409(a) is satisfied, or -21 CFR

2.3.2 50.53, 21 CFR 50.54 only if 21 CFR 50.56(a) is satisfied

2.4 Appropriate involvement of pregnant women, fetuses, and neonates pursuant to:

2.4.1 45 CFR 46.204, 45 CFR 46.205, 45 CFR 46.206, and 45 CFR 46.207

2.5 Approval of research involving prisoners as subjects under the following regulations:

2.5.1 45 CFR 46.305 and 45 CFR 46.306

2.6 DHHS and FDA's Subpart D applies to all research involving children.

2.7 When research is conducted in Louisiana all individuals under the age of eighteen (18) years are children, who prior to juvenile proceedings, have not been judicially emancipated under Civil Code Article 385 or emancipated by marriage under Civil Code Articles 379 through 384. Contact legal counsel for more information.

2.8 For research outside Louisiana, a determination of who is a child is to be made with consultation from legal counsel.

2.9 Unless the IRB has waived the requirement to obtain consent when research involves children consent may only be obtained from biologic or adoptive parents or an individual legally authorized to consent on behalf of the child to general medical care[5]. Before obtaining permission from an individual who is not a parent, contact legal counsel.

2.10 When research is conducted in Louisiana the following individuals are Guardians.

2.10.1 LA ChC 116(12.1)(a)(i)(b) "Legal Guardianship" means the duty and authority to make important decisions in matters having a permanent effect on the life and development of the child and the responsibility for the child's general welfare until he reaches the age of majority, subject to any residual rights possessed by the child's parents. It shall include but not

[5] This is the DHHS and FDA definition of "guardian"

necessarily be limited to: The authority to consent to marriage, to enlist in the armed forces of the United States, or to major medical, psychiatric, and surgical treatment, to represent the minor in legal actions, to make other decisions of substantial legal significance concerning the minor. The term “legal guardian” means the caretaker in such a relationship.

2.10.2 For research conducted in jurisdictions other than Louisiana, the research must comply with the laws regarding guardianship in all relevant jurisdictions. The Counsel for the HRPP will provide assistance about the laws in other jurisdictions.

3 RESPONSIBILITIES

3.1 Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.

4 MATERIALS

4.1 HRP-412 - Checklist - Pregnant Women

4.2 HRP-413 - Checklist - Non-Viable Neonates

4.3 HRP-414 - Checklist - Neonates of Uncertain Viability

4.4 HRP-415 - Checklist – Prisoners

4.5 HRP-416 - Checklist – Children

4.6 HRP-417 - Checklist - Cognitively Impaired Adults

5 REFERENCES

5.1 45 CFR 46.102; 45 CFR 46.402

5.2 21 CFR 50.3

5.3 AAHRPP I.1.D.; I.1.G.; II.2.I.; II.3.B.; II.4.

HRP-014 Flexibility Policy

1 PURPOSE

1.1 This procedure establishes the process for the IRB to determine when research projects are not subject to the terms of the LSUHSC-S Federalwide Assurance.

1.2 The process begins when the IRB receives an application or communication regarding a research activity.

1.3 The process ends when the Designated Reviewer confirms HRP-342 - WORKSHEET - Flexibility Policy and submits the determination.

2 POLICY

2.1 This policy is limited to studies involving no greater than minimal risk.

2.2 Under no circumstances will federally funded or FDA regulated research be reviewed under this policy. Projects that receive federal support are subject to the terms of the LSUHSC-S Federalwide Assurance.

2.3 Research projects outside the scope of the FWA and reviewed under the flexibility policy will be afforded protections commensurate with risk as determined by the IRB and institutional policy.

2.4 Should the funding status of a study reviewed under this policy change, it is the responsibility of the Principal Investigator to notify the IRB, immediately.

2.5 All human subjects research projects conducted or supported at LSUHSC-S or by the institution's faculty, students or employees remain subject to LSUHSC-S HRPP policies and IRB review, whether they qualify for this policy or not.

2.6 Inclusion/exclusion of non-federally funded research projects will be at the discretion of the LSUHSC-S Institutional Review Board.

3 RESPONSIBILITIES

3.1 The IRB staff and Designated Reviewer carry out these procedures.

4 PROCEDURE

4.1 Review all materials

4.2 Complete HRP-401 - CHECKLIST - Pre-Review (all federal departments and agencies must be unchecked)

4.3 Complete the HRP-313 - WORKSHEET - Expedited Review or HRP-312 - WORKSHEET - Exemption Determination

4.4 Verify that the research meets all the following criteria: (1) Not federally funded or supported by federal funds; (2) Minimal Risk; (3) Is not FDA regulated and does not include prisoners.

5 REPORTING REQUIREMENTS

5.1 Research projects reviewed outside the scope of the FWA are not subject to the same federal reporting requirements as federally funded projects. For projects conducted under the flexibility policy, the LSUHSC-S HRPP and IRB follow internal reporting requirements for serious or continuing non-compliance, suspensions, or terminations, or reporting of unanticipated problems involving risk to subjects or others.

5.2 Determinations of serious or continuing non-compliance, suspensions or terminations, or unanticipated problems involving risk to subjects or others made by the HRPP, or the IRB related to research that falls under the scope of the Flexibility Policy are reported to the LSUHS-S Institutional Official and the investigator's Department Chair.

6 CORRECTIVE ACTIONS

6.1 Corrective measures, restrictions or other requirements for research that requires reporting under this policy will be determined by the LSUHSC-S HRPP, IRB or Institutional leadership

7 MONITORING:

7.1 Studies reviewed under this policy will be subject to audit by the HRPP to confirm compliance with institutional policies and that funding status has not changed.

8 MATERIALS

8.1 HRP-312 - WORKSHEET - Exemption Determination

8.2 HRP-313 - WORKSHEET - Expedited Review

8.3 HRP-342 - WORKSHEET - Flexibility Policy

8.4 HRP-401 - CHECKLIST - Pre-Review

9 REFERENCES

9.1 45 CFR 46.101

9.2 21 CFR 50.1(a)

9.3 AAHRPP I.1.A.; I.1.D.; II.2.A.; II.2.G.; II.2.H.; II.2.I.; II.4.A.

HRP-015 Undue Influence of the HRPP

1 PURPOSE

1.1 This procedure establishes the process to manage allegations of undue influence of the HRPP.

1.1.1 Undue influence is defined as a real or perceived action that may influence the review of human subject's research outside of the scientific, regulatory, and ethical principles that guide review of such research. Such action may include, but is not limited to, attempts to influence decisions based upon financial concerns of the Institution or a department; personnel actions such as denying promotion or tenure; or verbal harassment.

1.2 This procedure begins when the IO or designee learns of an allegation of undue influence of the HRPP.

1.3 This procedure ends when any undue influence of the HRPP has been mitigated.

2 POLICY

2.1 Individuals responsible for business development may not serve as IRB members and may not be involved in daily operations of the review process and may not discuss business development with IRB members where the discussions might influence or appear to influence review decisions.

2.2 Staff may explain written procedures to individuals involved in the review process.

2.3 Individuals in the [Institution] may not

2.3.1 Provide information beyond an explanation of written procedures that might influence or appear to influence the review process determinations made as part of the criteria for approval.

2.3.2 Communicate the [Institution]'s financial issues regarding specific protocols to individuals responsible for the review process, aside from relevant information regarding conflicts of interest.

2.3.3 Answer questions about the [Institution]'s business issues posed by individuals responsible for the review process where the answers might influence or appear to influence review decisions.

2.3.4 Attempt to influence the review of human subject's research through real or perceived action on any performance review, promotion or tenure decision of any IRB member, IRB staff or any individual involved in the conduct or review of human subject's research.

2.4 When the IRB does not follow written procedures, the [Institution] can require the IRB to re-review the submission and/or disapprove research approved by the IRB.

2.5 All individuals in the [Institution] are required to ensure that allegations of undue influence of the HRPP or review process are reported to the [Institutional Official] within 5 days of becoming aware of the allegation.

3 RESPONSIBILITY

3.1 The IO or designee carries out these procedures or ensures that others carry them out.

4 PROCEDURE

4.1 Gather information to determine the veracity of the report using your discretion regarding the most efficient and effective methods. Methods to gather information can include, but are not limited to:

4.1.1 Interviews of individuals inside and outside the [Institution]

4.1.2 Review of records inside and outside the [Institution]

4.1.3 Consultation with internal or external entities

4.2 If the report has no basis in fact, document the findings and take no further action under this SOP.

4.3 Take appropriate steps to eliminate the undue influence using your discretion regarding the most efficient and effective methods. Steps may include, but are not limited to:

4.3.1 No action

4.3.2 Verbal counseling

4.3.3 Education

4.3.4 Reassignment of duties

4.3.5 Termination of employment

4.3.6 Evaluate policies and procedures

4.4 Document the findings and actions, if any, related to undue influence of the HRPP.

5 REFERENCES

5.1 45 CFR 46.109(a); 45 CFR 46.109(e); 45 CFR 46.112; 45 CFR 46.113

5.2 21 CFR 56.109(a); 21 CFR 56.109(f); 21 CFR 56.112; 21 CFR 56.113

5.3 AAHRPP I.1.C.; I.2.; II.3.C.; III.1.B.; III.1.C.

HRP-016 Separation of Competing Business Interests from IRB Review Functions

1 PURPOSE

1.1 To avoid influence on IRB determinations from individuals who are responsible for development activities (including raising funds), that may represent competing business interests, or be able to influence programmatic and budgetary decisions and exert undue influence on IRBs or individual IRB members.

2 POLICY

2.1 Individuals responsible for business development or responsible for raising funds or financial support for LSUHSC-S research, including the Vice Chancellor of Research Affairs, will not serve as voting IRB members or be involved in the day-to-day operations of the human subjects review process.

2.2 Senior leadership and department chairs that are also IRB members will not be assigned as designated reviewers or participate in the IRB committee discussion or vote for any research that is submitted by faculty, residents, fellows or students in their departments, divisions, or institutes.

2.3 Department Chairs must identify any personal financial conflict of interest that he or she has in the research sponsor or in an entity that owns or controls the investigational product that is the subject of the research in addition to any other conflict of interest.

2.3.1 When the Department Chair is the investigator the Senior Leadership official responsible for that division will identify any personal financial conflict of interest that he or she has in the research sponsor or in an entity that owns or controls the investigational product that is the subject of the research in addition to any other conflict of interest.

2.4 Neither Senior Leadership and Department Chairs, nor any other LSUHSC-S official or committee may approve research that has been deferred or disapproved by the LSUHSC-S IRB, nor apply undue pressure on the LSUHSC-S IRB to reverse a determination.

2.5 SOP: HRP-054 Institutional Conflicts of Interests describes policies and procedures designed to ensure that research involving human subjects at LSUHSC-S is conducted without untoward influence resulting from either the University's financial investments or holdings or the personal financial interests or holdings of key institutional leaders.

3 RESPONSIBILITIES

3.1 Individuals listed in the above policy and IRB members (regular and alternate) follow these procedures.

4 PROCEDURE

4.1 Department chairs are required to review and sign off on all human subjects research proposals being submitted by faculty, residents, fellows, or students in their departments. This review occurs prior to IRB submission. Use HRP-220 - FORM - Administrative-Approval.

4.2 When the Department Chair is the investigator the Senior Leadership official responsible for that division will complete HRP-220 - FORM - Administrative-Approval.

4.3 Senior leadership and department chairs that are also IRB members will follow SOP: HRP-050 Conflicting Interests of IRB Members for any research proposal submitted by faculty, residents, fellows or students in their departments, divisions or institutes.

5 MATERIALS

5.1 HRP-220 - FORM - Administrative-Approval

5.2 SOP: HRP-050 Conflicting Interests of IRB Members

5.3 SOP: HRP-054 Institutional Conflicts of Interests

6 REFERENCES

6.1 45 CFR 46.107(e)

6.2 21 CFR 56.107(e)

6.3 AAHRPP I.1.C.; II.1.C.; III.1.B.; III.1.C.

HRP-018 Managing Non-Compliance in Human Subject Research

1 PURPOSE

1.1 This procedure establishes the process to manage reports of allegations of suspected or actual noncompliance with federal regulations, state laws, Institutional policies, and/or IRB requirements with respect to human subject research.

1.2 HHS regulations for the protection of human subjects (45 CFR Part 46) require that institutions engaged in human subject research have in place written procedures for ensuring that incidents related to regulatory requirements under the institution's Federalwide Assurance are promptly reported to the Office of Human Research Protections (OHRP).

1.3 These include any serious or continuing noncompliance with the requirements or determinations of the IRB, and any suspension or termination of IRB approval and unanticipated problems.

1.4 This process begins when the HRPP or IRB becomes aware of any allegation of noncompliance in human subject research under the auspices of LSUHCS-Shreveport.

1.5 This process ends when the noncompliance is managed, or the allegation is determined to be unsubstantiated.

2 POLICY

2.1 This policy applies to faculty, staff, students, residents, fellows and affiliated investigators or other affiliated individuals who are involved in human subjects research being conducted under the auspices of the institution regardless of the location of the research, regardless of the funding source or whether the research is funded or unfunded.

2.2 The Institution, which includes the IRB, is expected to comply with Institutional policies as well as all federal regulations and state laws related to the protection of the safety, rights, and welfare of human subjects in research.

2.3 Noncompliance occurs when research involving human subjects is conducted in a manner that disregards or violates federal regulations, the policies, or procedures of the Institutional Review Board (IRB), or institutional policies governing human research. Noncompliance with respect to human research subject protection violates the LSUHSC-Shreveport Federalwide Assurance Registration (FWA) with the Office of Human Research Protections (OHRP). Even

in the absence of intent, an unapproved or otherwise noncompliant research activity may place a research subject at unnecessary risk.

2.4 The LSUHSC-S IRB will review all complaints, protocol deviations, allegations of noncompliance, findings of serious or continuing noncompliance, and take any necessary action to ensure that the rights and welfare of human subjects are protected.

2.5 A Reportable New Information (RNI) Report must be submitted to the IRB when an investigator including LSUHSC-S personnel, the research team, faculty, staff, administration, residents, fellows, or students become aware of any noncompliance with respect to a specific study.

2.6 Allegations of noncompliance reported to the Institutional Official or IRB must be investigated, and it must be determined whether the allegation has a basis in fact or not.

2.7 Investigators are required to respond promptly to any inquiries, correspondence, or directives from either the QA/QI coordinators or the IRB with respect to any allegations of or actual noncompliance. Investigators are also expected to cooperate with any requests for information or any audits or investigations.

2.8 Investigators are encouraged to seek the assistance of the LSUHSC-S HRPP QA/QA/QI team to develop a corrective action plan (CAP) to accompany any reports of noncompliance reported to the IRB.

2.9 Reports of noncompliance may come in the form of a complaint or from the result of an audit or a monitoring report.

2.10 Research subjects, subject's family members, and others external to the Institution, including regulatory agencies may also report suspected noncompliance to the IRB or to the Institutional Official. These reports may be in the form of complaints and may be made anonymously.

2.11 Reports of research misconduct or Whistleblower reports are subject to different rules and will be referred to the Office of Research or LSUHSC-S Compliance Office if received by the IRB or HRPP.

3 RESPONSIBILITIES

3.1 The IRB and the Investigators will carry out the responsibilities as indicated.

4 PROCEDURE

4.1 Investigators are required to self-report to the IRB any instances of noncompliance that involves a potential risk to subjects or others, or involves failure to comply with federal regulations, state laws, Institutional policies, and/or requirements or determinations of the IRB or provisions of the approved protocol. See SOP: HRP-029 Reportable New Information Items.

4.2 Noncompliance that is reported to the IRB by the Principal Investigator will be screened by the IRB Chair, or designee through non-committee review:

4.2.1 To make sure that sufficient information is included for IRB review

4.2.2 To make sure an appropriate corrective action plan is included, when necessary.

4.2.3 To see if immediate action needs to be taken to ensure subject safety

4.3 See SOP: HRP-024 New Information for processing the report.

4.4 If upon initial review by the IRB Chair or designee, it is determined:

4.4.1 There is no serious or continuing noncompliance, correspondence will be generated with a determination of noncompliance that is neither serious nor continuing.

4.4.2 The allegation has no basis in fact, correspondence will be generated with a determination of Allegation of non-compliance with no basis in fact.

4.4.3 The noncompliance is serious and/or continuing it will be sent to a meeting of the convened IRB and applicable parts of this policy will apply.

4.4.4 If it is determined that the activity involves research misconduct, the information will be referred to the appropriate LSUHSC-S office.

4.5 The IRB Chair or designee may request:

4.5.1 Additional information from the PI or from the QA/QI team prior to

review by the convened IRB meeting.

4.5.2 The QA/QA/QI team to conduct an inquiry/audit into the allegation.

4.5.3 The QA/QA/QI staff may call upon the expertise within the IRB, HRPP or outside consultant when conducting the audit.

4.5.3.1 The audit is administrative fact-finding and may be informal or may involve an extensive review of the study records, interviews with the research team, interviews with the complainant, and may include correspondence to the PI or the appropriate person within the institution to obtain additional information.

4.5.4 Correspondence to the PI or the appropriate person within the institution will provide the investigator or the institution with the opportunity to respond to the allegations of suspected noncompliance.

4.6 Upon completion of the initial inquiry into the allegation, the QA/QI staff will prepare a written audit report describing the allegation and the outcome of the audit.

4.6.1 The audit report will be sent to the PI and submitted to the IRB as a Reportable New Information.

4.6.2 If the allegation involves the IRB or any other component of the institution the QA/QI team will forward the report to the CTO Director and/or the Institutional Official as appropriate.

4.6.3 If during the audit it appears that activities in question may also involve research misconduct or whistleblowing the allegation will be directed to the appropriate office at LSUHSC-S.

4.7 When required, a corrective action plan will accompany the audit report submitted to the IRB.

4.7.1 The corrective action plan will outline what steps the investigator has taken or will take to resolve the noncompliance and sufficient detail to ensure adequate measures or training is taken to prevent future violations and to prevent such noncompliance from occurring in any current or future clinical research that may be conducted by the research team.

4.7.2 When appropriate, or upon request by an investigator, the QA/QI team will in cooperation with the PI assist in the development of the corrective action plan to accompany audit reports.

4.7.3 The QA/QI team or the investigator may request additional input from the IRB Chair or other representatives of the HRPP.

4.8 If the noncompliance cannot be resolved as described above or an appropriate corrective action plan that is acceptable to the IRB cannot be developed, the IRB has the authority to impose corrective actions and recommend sanctions to the Institutional Official (IO).

5 MATERIALS

5.1 SOP: HRP-024 New Information

5.2 SOP: HRP-029 Reportable New Information Items

6 REFERENCES

6.1 45 CFR 46.103.b(5)

6.2 21 CFR 56.108 (b)(2)

6.3 AAHRPP I.1.A.; I.5.D.; II.2.H.; III.1.G.

HRP-020 Incoming Items

1 PURPOSE

1.1 This procedure establishes the process to triage information submitted to the IRB.

1.2 The process begins when any communication is received by the IRB.

1.3 The process ends when an IRB staff member determines the appropriate action for the received information.

2 RESPONSIBILITIES

2.1 IRB staff members carry out these procedures.

3 PROCEDURE

3.1 If the item is a request for an approval or determination by this institution's IRB, follow SOP: HRP-021 Pre-review.

3.2 If the item includes new or modified contact information, update the contact information.

3.3 If the item includes new or modified training information, update the training information.

3.4 If the item is a notification of an emergency use of a test article in a life-threatening situation have a Designated Reviewer follow SOP: HRP-023 All Emergency Use, Compassionate Use (Device Only) & IRB Waiver for Individual Patient Expanded Access (Drug Only) Review

3.5 If the item is an investigator's request to continue subjects in expired research have a Designated Reviewer follow HRP-063 Expiration of IRB Approval

3.6 If the item does not fit into the above categories:

3.6.1 If the item is a question, concern, or complaint:

3.6.1.1 Document the nature of the question, concern, or complaint and the contact information of the person contacting the IRB.

3.6.1.2 Respond to any questions or concerns. When appropriate, tell the person that you will call/email him/her once you have been able to find additional information. If necessary, consult with your supervisor.

3.6.2 Follow SOP: HRP-024 New Information

4 MATERIALS

4.1 SOP: HRP-021 Pre-review

4.2 SOP: HRP-023 All Emergency Use, Compassionate Use (Device Only) & IRB Waiver for Individual Patient Expanded Access (Drug Only) Review

4.3 SOP: HRP-024 New Information

4.4 SOP: HRP-055 Financial Conflicts of Interest

4.5 SOP: HRP-063 Expiration of IRB Approval

5 REFERENCES

5.1 AAHRPP I.4.; I.7.C.; I.9.; III.1.G.

HRP-021 Pre-review

1 PURPOSE

1.1 This procedure establishes the process to pre-review a request for approval (approval of new research, humanitarian use device (HUD), continuing review of research, or modification to previously approved research) or a determination whether an activity is exempt Human Research or is not Human Research.

1.2 The process begins when the IRB receives a request for local IRB approval, including requests from other institutions when this institution is the IRB of record, e.g., for a Collaborative Study or Multi-Site Study.

1.3 The process ends when the information has been placed on the agenda for an IRB meeting or will be handled by Non-Committee Review.

2 POLICY

2.1 As part of IRB review, all submissions are reviewed by IRB Staff.

2.1.1 Use HRP-308 - WORKSHEET - Pre-Review to screen submission materials

2.1.2 Identify submissions with missing materials or incomplete information

2.1.3 Identify and document the special determinations that the IRB needs to make to approve research. (For example. waiver of consent, children, prisoners)

2.1.4 Identify, make, and document regulatory determinations that the institution needs to make to approve research (For example, IND/IDE requirements)

2.1.5 Identify any relevant local, state, or international requirements

2.1.6 Arrange for consultation to resolve local, state, or international requirements.

2.1.7 Identify other special review issues.

2.1.8 Determine the likely level of review (Committee Review versus Non-committee Review)

2.1.9 The IRB Staff documents Pre-Review determinations in the electronic system or HRP-401 - CHECKLIST - Pre-Review.

2.1.10 The IRB Chair ensures that issues raised by Pre-Review are covered at meetings.

2.1.11 The addition of a site to a previously approved study is considered a modification to previously approved research.

2.2 The addition of a participating site to a previously approved protocol for which the IRB will serve as the IRB of record for that participating site is considered a modification to previously approved research.

2.3 A new HUD protocol submission must be reviewed at a convened IRB meeting. Continuing review of a HUD can be handled by Non-Committee Review.

2.4 For Veterans Administration (VA) research the approval of minor conditions by the IRB chair or designated IRB voting member must be documented in the minutes of the first IRB meeting that takes place after the date of the approval of the minor conditions.

3 RESPONSIBILITIES

3.1 IRB staff members carry out these procedures.

4 PROCEDURE

4.1 If the submission is a request to use an external IRB follow SOP: HRP-028 Use of External IRB and LSUHSC-S being IRB of Record.

4.2 If the submission is a response to modifications required to secure approval received within 30 days of the IRB review date:

4.2.1 Evaluate whether the investigator made the required modifications.

4.2.2 If the investigator made the required modifications, follow SOP: HRP-052 Post Review to issue an approval.

4.2.3 If the investigator did not make the required modifications or made unrequested modifications, execute the “Request Pre-Review Clarification” activity from the investigator. Offer the investigator the opportunity to correct the submission.

4.2.3.1 If the investigator will correct the submission, have the investigator make changes then execute the “Submit Changes” activity and stop processing the current submission until changes are received.

4.2.3.2 If the investigator will not correct the submission, have the investigator execute the “Submit Changes” activity to resubmit and continue processing.

4.3 For all other submissions, complete Pre-Review activity or review the previously completed Pre-Review Activity and revise as needed, considering the items on HRP-308 - WORKSHEET - Pre-Review and note all remaining contingencies in the “Final Contingencies” section.

4.4 If the information is not complete, contact the investigator by selecting the “Request Pre-Review Clarifications” Activity. Offer the investigator the opportunity to provide additional information.

4.4.1 Continue processing once the investigator responds to the request for additional information.

4.5 If the principal investigator is restricted, notify the investigator of IRB policy to not accept new research protocols from restricted investigators. Provide additional information as appropriate to resolve the issues or withdraw the submission and resubmit when complete.

4.6 Use HRP-308 - WORKSHEET - Pre-Review.

4.6.1 Select the ‘Submit Pre-Review’ Activity in the electronic system.

4.6.2 Document any Pre-Review findings and select special determinations in the electronic system or use HRP-401 - CHECKLIST - Pre-Review.

4.6.3 Then execute the Pre-Review activity to complete the action.

4.6.4 For a modification Submission:

4.6.5 Review the Pre-Review findings associated with prior approval(s) and revise as needed, considering the items on HRP-308 - WORKSHEET - Pre-Review and note all

remaining contingencies in the Final Contingencies section of the electronic system or the form.

4.6.6 Execute the Pre-Review activity to complete the action

4.6.7 For a Continuing Review Submission:

4.6.7.1 If the submission meets the Closure Criteria execute the Pre-Review Activity and assigned to a Designated Reviewer.

4.6.7.2 If the Continuing Review Submission does not meet the criteria for closure, then review the finding associated with prior approval(s).

4.6.7.3 Note the pre-review findings as needed and continue processing.

4.6.8 Identify any relevant local, state, or international regulatory requirements related to human research.

4.6.9 Identify any relevant institutional policy related to human research.

4.6.10 Arrange for consultation, if needed to resolve any policy or regulatory issues.

4.6.11 The 'Manage Ancillary Reviews' activity from the study/submission workspace can be used to provide materials to the consultant as needed.

4.6.12 If the submission is incomplete or requires clarification contact the investigator by selecting the "Request Pre-Review Clarifications" Activity. Offer the investigator the opportunity to make revisions or provide additional information.

4.6.13 Continue processing once the investigator responds to the request for additional information.

4.6.14 If the submission is a new information report determine whether the submission includes information that might represent an Unanticipated Problem Involving Risks to Subjects or Others, Serious Noncompliance, Continuing Noncompliance, Suspension of IRB Approval or Termination of IRB Approval and process under SOP: HRP-024 New Information.

4.7 Evaluate the most likely level of review using HRP-310 - WORKSHEET - Human Research Determination, HRP-311 - WORKSHEET - Engagement Determination, HRP-312 - WORKSHEET - Exemption Determination, HRP-313 - WORKSHEET - Expedited Review, HRP-314 – WORKSHEET – Criteria for Approval and/or HRP-323 - WORKSHEET - Criteria for Approval and Additional Considerations HUD as references:

4.7.1 If the request can be handled as a Non-Committee Review and the principal investigator is not Restricted, Follow SOP: HRP-031 Non-Committee Review Preparation.

4.7.2 If the request cannot be handled as a Non-Committee Review, place the protocol on the agenda for a convened IRB meeting in an IRB with appropriate scope.

4.7.3 If the request is a non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested, follow SOP: HRP-031 Non-Committee Review Preparation and SOP: HRP-023 All Emergency Use, Compassionate Use (Device Only) & IRB Waiver for Individual Patient Expanded Access (Drug Only) Review.

5 MATERIALS

5.1 HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN

5.2 SOP: HRP-023 All Emergency Use, Compassionate Use (Device Only) & IRB Waiver for Individual Patient Expanded Access (Drug Only) Review

5.3 SOP: HRP-024 New Information

5.4 SOP: HRP-028 Use of External IRB and LSUHSC-S being IRB of Record

5.5 SOP: HRP-031 Non-Committee Review Preparation

5.6 SOP: HRP-040 IRB Meeting Preparation

5.7 SOP: HRP-052 Post Review

5.8 HRP-308 - WORKSHEET - Pre-Review

5.9 HRP-310 - WORKSHEET - Human Research Determination

5.10 HRP-311 - WORKSHEET - Engagement Determination

5.11 HRP-312 - WORKSHEET - Exemption Determination

5.12 HRP-313 - WORKSHEET - Expedited Review

5.13 HRP-314 - WORKSHEET - Criteria for Approval

5.14 HRP-323 - WORKSHEET - Criteria for Approval and Additional Considerations HUD

5.15 HRP-401 - CHECKLIST - Pre-Review

6 REFERENCES

6.1 45 CFR 46

6.2 AAHRPP I.1.A.; I.1.F.; I.3.; II.1.E.; II.2.; II.3.G.; II.4.A.

HRP-022 Delegation of Authority Log (DOA)

1 PURPOSE

1.1 The purpose of this policy is to outline which study staff are required to be listed on the Delegation of Authority (DOA) Log for all human subject research projects.

2 POLICY

2.1 As per the following FDA guidance document: *Guidance for Industry: Investigator Responsibilities –Protecting the Rights, Safety, and Welfare of Study Subjects,* **https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigator-responsibilities-protecting-rights-safety-and-welfare-study-subjects** the Principal Investigator (PI) is ultimately responsible for the performance and supervision of a clinical investigation. While the PI may delegate some required tasks to sub-investigators and other research staff, the PI remains accountable for their conduct. The Delegation of Authority Log (DOA) lists all the study staff, including the Investigators and Clinical Research Coordinators (CRCs), and other designated site personnel who are delegated significant trial-related duties from the PI. The DOA Log must be completed for all human subject research projects.

2.2 Delegation of Authority log is not addressed in FDA's Federal Regulations (21 CFR 312 and 812); therefore, it is not a federal requirement. However, the investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties. The list should also describe the delegated tasks, identify the training that individuals have received that qualifies them to perform the delegated tasks, and identify the dates of involvement in the study. A separate list should be maintained for each study conducted by the investigator. it may be a Sponsor requirement and Good Clinical Practice suggests documenting the PI's delegation of tasks to other members of the research team.

2.3 Hospital staff, including nurses (for e.g., Chemotherapy certified, those who provide only FDA approved drugs and not research related drugs/IND drugs), residents, or fellows and office staff who provide ancillary or intermittent care but who do not make a direct and significant contribution to the clinical data, do not need to be listed individually. It is not necessary to include in this section a person with only an occasional role in the conduct of the research, e.g., an on-call physician who temporarily dealt with a possible adverse effect or a temporary substitute for any research staff (see ICH E6, Section 2.3). The PI or the research study team must consult the IRB staff/IRB Chair prior to deciding which staff must not be included on the Delegation of Authority Log (DOA).

2.4 All individuals who have, or are trying to obtain, access to electronic research data (RedCap database for example) should be listed on the DOA log or study staff list in the protocol for that

study. All study team member additions should be IRB approved prior to access being granted to electronic research data, regardless of if the data is de-identified or not. This policy does not apply to a researcher wanting access to a biobank/repository of a separate study.

3 RESPONSIBILITIES

3.1 The PI and the study team fill out and maintain a DOA log throughout the study.

4 PROCEDURE

4.1 Use HRP-509 - TEMPLATE - Delegation of Responsibility Log to facilitate the completion of the Staff Signature and Delegation of Responsibility Log. Template provided by Sponsor can be used as well.

4.2 Submit it along with initial application.

4.3 When HRP-503.1 - TEMPLATE PROTOCOL for Data and Specimen is submitted, HRP-509 - TEMPLATE - Delegation of Responsibility Log or a separate DOA log is not required to be submitted since the HRP-503.1 - TEMPLATE PROTOCOL for Data and Specimen" includes a section which lists the DOA log.

4.4 Handwritten/electronic/digital signatures must be obtained on the DOA log. Studies may have a combination of a hard copy and/or electronic DOA log. In order to be considered equivalent to full handwritten signatures, electronic signatures must comply with all applicable requirements under FDA regulation 21 CFR part 11. Research not subject to 21 CFR parts 50 and 56 is also not generally subject to 21 CFR part 11 (FDA regulations regarding electronic records and electronic signatures).

4.5 Start Date must not be filled in when the DOA log is submitted to the IRB. It must be added upon IRB approval with either the date when the DOA log was approved by the IRB or when the Sponsor required training for that study has been completed by the study team member, whichever is later.

4.6 A new entry must be made for the study team member when there is a revision to the tasks delegated to him/her or their role is changed on the study.

4.7 End date must be filled in when the role of the study team member is complete/or they leave the institution. Then the DOA log must be submitted to the IRB for review.

4.8 Under special circumstances and upon consultation with the IRB Director, the procedure for revising a DOA log and obtaining IRB approval can be altered. An example of such a special circumstance would be when the IRB has approved a study with only one CRC and the PI submits a modification to delegate additional tasks to the CRC. The end date is not required to be filled in for the CRC before the IRB approval until the new entry for the CRC with revised delegated task along with the previously IRB approved delegated tasks have been approved by the IRB. In such a case, end date and start date for both entries of the CRC will be the IRB approval date.

5 MATERIALS

5.1 HRP-503.1 - TEMPLATE PROTOCOL for Data and Specimen

5.2 HRP-509 - TEMPLATE - Delegation of Responsibility Log

6 REFERENCES

6.1 21 CFR 312; 21 CFR 812

6.2 ICH GCP E6 (R3), Guideline Section 2.3.3

6.3 ICH GCP E6 (R3), Guideline Section 2.3

6.4 AAHRPP III.2.B.

HRP-023 All Emergency Use, Compassionate Use (Device Only) & IRB Waiver for Individual Patient Expanded Access (Drug Only) Review

1 PURPOSE

1.1 This procedure establishes the process to review notifications of:

1.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation.

1.1.2 Non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use).

1.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested.

1.2 The process begins when the IRB receives a notification of a proposed or actual use.

1.3 The process ends when a Designated Reviewer has:

1.3.1 Determined whether the proposed or actual use will follow or has followed FDA-regulation and guidance; and

1.3.2 Notified the physician and IRB staff of the determination.

2 POLICY

2.1 Whenever possible physicians are to notify the IRB of a proposed emergency use of a drug, biologic, or device in a life-threatening situation in advance of the use.

2.1.1 Prior notification to the IRB of an impending emergency use of a test article by an investigator is permissible. However, such notification should not be construed as, and does not, evidence prior IRB approval of the emergency use. Prior notice of an impending emergency use of a test article will be used by the IRB only to initiate tracking to ensure the investigator submits a report to the IRB within the five-day time frame required by 21 CFR 56.104I. The IRB may choose to request additional information. When investigators provide prior notifications of their intent to use a test article in an emergency or their intent to invoke the exception to the requirement to obtain consent, the IRB Chair or designee will review the notification to determine whether the circumstances follow FDA regulations.

2.1.2 The one-time emergency use of a test article is permitted provided a patient is in a life-threatening situation in which no standard acceptable treatment is available, and when there is not sufficient time to obtain IRB review and approval. Any subsequent use of a test article at the institution shall have prospective IRB review and approval.

2.1.3 The investigator must obtain the informed consent of the subject (or the subject's legally authorized representative), unless the requirements of an exception from the informed consent requirement (21 CFR 50.23(a)) are satisfied. In addition to obtaining informed consent, the protocol director must obtain the HIPAA authorization from the subject (or the subject's legally authorized representative). Exception from the informed consent requirement are listed in HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research.

2.1.3.1 If, in the investigator's opinion, immediate use of the test article is required because the patient is confronted by a life-threatening or severely debilitating situation and if time is not sufficient to obtain the independent physician determination that the four conditions above apply, the protocol director should make the determination and, within five working days after the use of the article, have the determination reviewed and evaluated in writing by an independent physician, and submit that evaluation to the IRB.

2.2 Physicians are to notify the IRB of a proposed compassionate use of an unapproved device, for the purpose of obtaining concurrence from an IRB Chair.

2.3 Emergency uses and device compassionate uses cannot be claimed as research.

2.4 Investigators are to notify the IRB of a non-emergency individual patient expanded access use of an investigational drug "Request for Authorization to Use Alternative IRB Review Procedures" identified on FDA Form 3926 (field 10.b.) or a separate waiver request included with FDA Form 1571 for the purpose of obtaining concurrence from an IRB Chair or designee.

3 RESPONSIBILITIES

3.1 A Designated Reviewer carries out these procedures.

3.2 IRB staff processes written communications.

4 PROCEDURE

4.1 Determine if the notification/request is one of the following:

4.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation. If so, use the HRP-322 - WORKSHEET - Emergency Use to determine whether the circumstances will meet, or if the use described in the 5-day report have met, the regulatory and guidance criteria for emergency use, and indicate the results of this determination to the IRB staff (or directly to the physician if time sensitive).

4.1.1.1 If the notice is in advance of the use, inform the IRB staff (or physician if time sensitive) that the physician can proceed with the use or work with the physician to identify what additional information/procedures the physician needs to follow. Set a 5-day reminder to request the 5-day report.

4.1.1.2 If the actual emergency use described in the 5-day report did not follow FDA requirements, manage use SOP: HRP-024 New Information as Non-Compliance.

4.1.1.3 If all conditions described in 21 CFR 56.102(d) exist, then the emergency exemption from prospective IRB approval found at 21 CFR 56.104I may be utilized. The emergency use provision in the FDA regulations (21 CFR 56.104I) allows for one emergency use of a test article without prior review and approval by the IRB review. FDA regulations require any subsequent use of the investigational product at the institution have prospective IRB review and approval. However, the FDA acknowledges that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue. The FDA regards emergency use of a test article as a category of clinical investigation (21 CFR 56.104). However, DHHS states, “emergency care may not be claimed as research, nor may the outcome of such care be included in any report of a research activity.” Thus, a patient receiving an emergency use of a test article under FDA regulations, is not considered a research subject by DHHS regulation, and such emergency use is not research as covered under 45 CFR 46. See OHRP guidance Emergency Medical Care.

4.1.1.4 Submission and Reporting Requirements – IRB and FDA Written documentation of the emergency use must be submitted to the IRB within five (5) working days after the use of the test article. 21 CFR 56.104I. The investigator must submit the following documents to the IRB. For Drugs and Biologics: 1. Notification of Emergency Use Form which includes: x information about the patient x indication of the life-threatening nature of the situation x explanation as to why this drug or treatment was necessary x and if the emergency use occurred without obtaining prior informed consent, Section E on this form must also be completed: Independent Physician Certification – Emergency Use of a Test Article Without Informed Consent 2. Written permission from the manufacturer for the use of the test article under their IND. Generally, the investigator will contact the manufacturer and determine if the drug or biologic can be made available for the emergency use under the company’s IND. If the company declines permission or cannot

be reached, the investigator should contact the FDA for authorization of the shipment of the drug in advance of the IND submission. In such a case the FDA may authorize shipment of the test article in advance of the IND submission. The IRB may request that the protocol director contact the FDA to obtain an IND. 3. Signed Consent Form, with HIPAA The HRPP office will check for emergency uses where the IRB is expecting and has not received a report, within 5 days. HRPP will notify or email the investigator of Failure to Submit Emergency Use Report. If the investigator is not working with the IRB to submit the report, HRPP will process the failure to submit as a Finding of Non-Compliance. The HRPP Office will also check for emergency uses where the IRB is expecting and has not received a standing protocol within 30 calendar days. HRPP will notify or email the investigator of failure to Submit Emergency Use Protocol. If the investigator is not working with the IRB to submit the protocol, HRPP will process the failure to submit as a Finding of Non-Compliance.

4.1.1.5 IRB Review (Retrospective) of an Emergency Use of a Test Article - The Chair or designated IRB member will review the documentation submitted in support of an emergency use of a test article. IRB review includes an assessment of whether the conditions for the emergency use were satisfied. The reviewer completes the Exemption from IRB Review: Emergency Use of a Test Article Check sheet. A copy of this form is sent to the investigator and a copy is placed in the IRB's Emergency Use Log. If the emergency use did not meet the criteria allowing an exemption from prior IRB review and approval, the action will be handled according to the non-compliance policy

4.1.2 Compassionate use of a device. If so, use HRP-322 - WORKSHEET - Emergency Use (includes Compassionate Use of an Unapproved Device) to determine whether the circumstances will meet the regulatory and guidance criteria and indicate the results of this determination to the physician.

4.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested. If so, use HRP-314 - WORKSHEET - Criteria for Approval to determine whether the proposed use meets the requirements under 21 CFR 50 and 56.111[6] and indicate the results of this determination to the IRB staff.

4.1.3.1 Execute the "Submit Designated Review" activity. In the "Notes" section document that the decision is to concur (or not) is in lieu of review and approval at a

[6] *"The IRB chairperson (or designated IRB member) would consider the same information that the full IRB would consider, to determine whether to approve the treatment when reviewing and concurring for individual patient expanded access use."* Per FDA correspondence dated 10/10/17

convened IRB meeting at which a majority of the members are present per the request for a waiver under 21 CFR 56.105 of the requirements in 56.108(c).

4.1.4 If none of the above, stop processing the request and inform the physician or submitter.

4.2 Inform IRB staff of the results of the evaluation.

5 MATERIALS

5.1 SOP: HRP-001 Definitions

5.2 SOP: HRP-024 New Information

5.3 HRP-314 - WORKSHEET - Criteria for Approval

5.4 HRP-322 - WORKSHEET - Emergency Use (includes Compassionate Use of an Unapproved Device)

5.5 HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research

6 REFERENCES

6.1 21 CFR 50; 21 CFR 50.23; 21 CFR 50.24

6.2 21 CFR 56.102(d); 21 CFR 50; 21 CFR 56.104(c); 21 CFR 56.111

6.3 21 CFR 812.36; 21 CFR 812.47

6.4 (FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors) Frequently Asked Questions About Medical Devices: **http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf.**

6.5 Individual Patient Expanded Access Applications: Form FDA 3926 Guidance for Industry; **https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm432717.pdf**

6.6 AAHRPP I.7.A.; I.7.C.; II.4.B.; III.1.; III.2.

HRP-024 New Information

1 PURPOSE

1.1 This procedure establishes the process to manage information reported to the IRB to ensure that information that represents Non-Compliance, Unanticipated Problems Involving Risks to Subjects or Others, Suspensions of IRB Approval, and Terminations of IRB Approval are managed to protect the rights and welfare of subjects.

1.2 The process begins when the IRB receives an information item. Information items requiring submission to the IRB are listed on SOP: HRP-029 Reportable New Information Items.

1.3 The process ends when the information item is determined not to represent a problem that requires management, is managed administratively, or referred to the convened IRB for review.

2 POLICY

2.1 The Flexibility Policy may be followed when appropriate. See SOP: HRP-014 Flexibility Policy.

2.2 Allegations of Serious or Continuing Non-Compliance on the part of IRB staff or IRB members will be referred to the Organizational Official for further action.

2.3 The organization will promptly notify the federal department or agency funding the research of any for cause investigation of that research by another federal department or agency or national organization.

For DoD research the report is sent to the DoD human research protection officer. The organization will promptly notify the DoD if the IRB of record changes.

2.4 For Veterans Administration (VA) research:

2.4.1 The determination that Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance must be determined and documented by the convened IRB.

2.4.2 An initial report to the VA Medical Center Director and others of an IRB determination that Serious Non-Compliance or Continuing Non-Compliance is required, even where the determination is preliminary, or disposition of the matter has not been resolved at the time of the report.

2.4.3 The convened IRB must review notifications of apparent Serious Non-Compliance, Continuing Non-Compliance, and external Suspension of IRB Approval, or Termination of IRB Approval within 30-45 days after receiving the notification.

2.4.4 The IRB Chair may take interim action on notifications of apparent Serious Non-Compliance or Continuing Non-Compliance as needed to eliminate apparent immediate hazards to subjects.

2.4.5 Remedial actions involving a specific study or research team must be completed within 120 days after the IRB's determination.

2.4.6 Remedial actions involving programmatic Non-Compliance must be completed within 120 days after the IRB's determination, unless remediation requires substantial renovation, fiscal expenditure, hiring, or legal negotiations.

2.4.7 In the context of a multi-center study, internal adverse events are defined as those experienced by subjects, research staff, or others at the reporting individual's own Veterans Administration (VA) facility or Veterans Administration (VA) approved research site. The term "local adverse event" is considered to be synonymous with the term "internal adverse event."

2.4.8 The IRB must review a report of apparent serious or continuing non-compliance at its next convened meeting.

2.4.9 For Unanticipated Problems Involving Risks to Subjects or Others that are local research deaths, they must be reported orally and in writing to the IRB immediately upon becoming aware of the information.

3 RESPONSIBILITIES

3.1 The IRB staff members carry out this procedure.

4 PROCEDURE

4.1 Review each item of information and answer the following questions and complete the Submit RNI Pre-Review Activity: *(See attached flowchart for a diagram of the flow of this procedure.)*

4.1.1 Is this an Allegation of Non-Compliance?

4.1.2 Is this a Finding of Non-Compliance?

4.1.3 Is this an Unanticipated Problem Involving Risks to Subjects or Others?

4.1.4 Is this a Suspension of IRB Approval or Termination of IRB Approval?

4.2 After completing the Pre-Review Activity assign the New Information item to the IRB chair or designated reviewer.

4.3 If the IRB chair or designated reviewer are unable to answer a question, follow SOP: HRP-025 Investigations.

4.4 If the answer is “yes” to one or more questions, then follow the corresponding sections below.

4.4.1 Allegations of Non-Compliance: Determine whether each Allegation of Non-Compliance has any basis in fact.

4.4.1.1 If yes, follow the procedures under Findings of Non-Compliance.

4.4.1.2 If no, follow any other corresponding sections.

4.4.2 Findings of Non-Compliance: Determine whether each Finding of Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance.

4.4.2.1 If no, follow the procedures under Non-Serious/Non-Continuing Non-Compliance.

4.4.2.2 If yes, follow the procedures under Serious or Continuing Non-Compliance.

4.4.3 Non-Serious/Non-Continuing Non-Compliance

4.4.3.1 Work with the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan.

4.4.3.2 If unable to work with the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan, consider the Non-Compliance to be Continuing Non-Compliance and follow the procedures for Serious or Continuing Non-Compliance.

4.4.4 Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others

4.4.4.1 Confirm your decision with the IRB chair or IRB Director.

4.4.4.2 Place on the agenda for the next available convened IRB meeting in an IRB with appropriate scope as an item of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others.

4.5 If in your opinion the rights and welfare of subjects might be adversely affected before the convened IRB can review the information, contact the IRB chair or IRB Director to consider a Suspension of IRB Approval following the SOP: HRP-026 Suspension or Termination Outside Convened Meeting.

4.6 If the notification involves a subject becoming a Prisoner in a study not approved by the IRB to involve Prisoners:

4.6.1 Confirm that the subject is currently a Prisoner.

4.6.1.1 If the subject is currently not a Prisoner no other action is required.

4.6.2 Consider whether stopping all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject until the regulatory requirements for research involving Prisoners are met or until the subject is no longer a Prisoner would present risks to the subject.

4.6.2.1 If the subject's involvement in the research cannot be stopped for health or safety reasons, do one of the following:

4.6.2.1.1 Keep the subject enrolled in the study and review the research for involvement of Prisoners. If the research is subject to DHHS oversight, notify OHRP.

4.6.2.1.2 Remove the subject from the study and provide the study intervention as clinical care or compassionate use.

4.6.2.2 If the subject's involvement in the research can be stopped, inform the investigator that all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject must be stopped immediately until the regulatory requirements for research involving Prisoners are met or until the subject is no longer a Prisoner,

4.6.3 For DoD research promptly report all decisions to the DoD.

4.6.4 The DoD must concur with the IRB before the subject can continue to participate while a Prisoner.

4.7 If the information involves any of the following, send a letter to AAHRPP as soon as possible but generally within two days of the receipt of the information, in addition to other applicable procedures listed in this SOP:

4.7.1 Negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.

4.7.2 Litigation, arbitration, or settlements initiated related to human research protections.

4.7.3 Press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP.

4.8 Take any additional actions required to resolve any concerns or complaints associated with the information.

4.9 For Veterans Administration (VA) research:

4.9.1 If the information represents Unanticipated Problem Involving Risks to Subjects or Others that is a local research death, alert the ORO by email or telephone within 2 business days after receipt of notification with concurrent notification to the VA facility Director and the Associate Chief of Staff/R&D

4.9.2 Within 5 business days of receipt of information that appears to represent an Unanticipated Problem Involving Risks to Subjects or Others, have the IRB Chair or a Designated Reviewer determine and document whether the reported incident was serious and unanticipated and related to the research, and have the IRB Chair or a Designated Reviewer determine and document whether any actions are warranted to eliminate apparent immediate hazards to subjects.

4.9.2.1 All determinations of the IRB Chair or Designated Reviewer must be reported to the IRB at its next convened meeting.

4.9.2.2 Schedule the Unanticipated Problem Involving Risks to Subjects or Others for the next IRB meeting to be reviewed by the convened IRB.

4.9.2.2.1 If the IRB determines that the problem or event is serious and unanticipated and related to the research, the IRB Chair or designee must report in writing the unanticipated problem or event within 5 business days to:

4.9.2.2.1.1 Facility Director.

4.9.2.2.1.2 Associate chief of staff for research.

4.9.2.2.1.3 The Research and Development Committee.

4.9.2.3 If the IRB determines that the problem or event was serious and unanticipated and related to the research, a simultaneous determination is required regarding the need for any action (e.g., suspension of activities; notification of subjects) necessary to prevent an immediate hazard to subjects.

4.9.3 If the information appears to represent Serious Non-Compliance or Continuing Non-Compliance, schedule the information for the next IRB meeting to be reviewed by the convened IRB (not to exceed 30 days after receipt of the information).

4.9.3.1 If the IRB determines that the information constitutes Serious Non-Compliance or Continuing Non-Compliance, within 5 business days after the determination, the IRB Chair or designee must provide a written report of the determination directly to:

4.9.3.1.1 Facility Director.

4.9.3.1.2 Associate chief of staff for research.

4.9.3.1.3 The Research and Development Committee.

4.9.3.1.4 The Research Compliance Officer (RCO), if the apparent Serious Non-Compliance or Continuing Non-Compliance was identified by an RCO audit, regardless of the outcome.

4.10 If the information does not involve a Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others and a response is expected, complete review and prepare and send letter per SOP: HRP-052 Post Review.

5 MATERIALS

5.1 SOP: HRP-014 Flexibility Policy

5.2 SOP: HRP-025 Investigations

5.3 SOP: HRP-026 Suspension or Termination Outside Convened Meeting

5.4 SOP: HRP-029 Reportable New Information Items

5.5 SOP: HRP-052 Post Review

6 REFERENCES

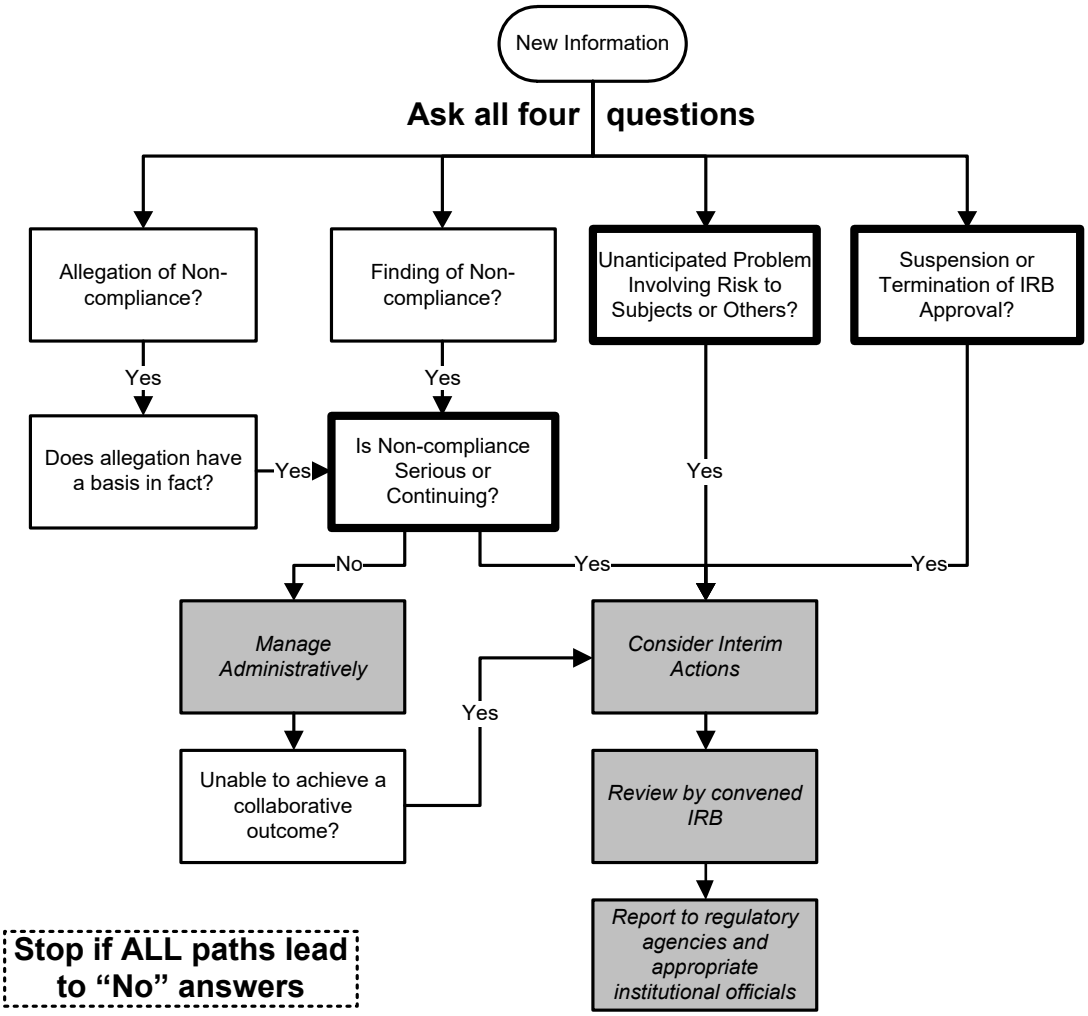
6.1 45 CFR 46.103(b)(5); 45 CFR 46.108(a)

6.2 21 CFR 56.108(b)

6.3 VHA Handbook 1058.01

6.4 AAHRPP I.1.F.; I.4.; I.5.D.; II.2.E.; II.2.F.; II.2.G.; II.2.H.; II.4.A.; II.4.B.; III.1.G.; III.2.D.

7 Flowchart


New Information
Ask all four questions
Allegation of Non-compliance?
Finding of Non-compliance?
Unanticipated Problem Involving Risk to Subjects or Others?
Suspension or Termination of IRB Approval?
Yes
Yes
Does allegation have a basis in fact?
Yes
Is Non-compliance Serious or Continuing?
Yes
No
Yes
Yes
Manage Administratively
Consider Interim Actions
Yes
Unable to achieve a collaborative outcome?
Review by convened IRB
Report to regulatory agencies and appropriate institutional officials
Stop if ALL paths lead to "No" answers

HRP-025 Investigations

1 PURPOSE

1.1 This procedure establishes the process to conduct investigations.

1.2 The process begins when the IRB staff members and chair cannot answer a question required by SOP: HRP-024 New Information.

1.3 The process ends when the investigation is complete, and the answer has been provided to the Institutional Official/Organizational Official (IO/OO) or IO designee.

2 RESPONSIBILITIES

2.1 The IO/OO or IO designee:

2.1.1 Appoints the members of the investigative committee based on the expertise and background needed to answer the question.

2.1.2 Appoints a chair of the investigative committee.

2.1.3 Charges the investigative committee with the question to be answered.

2.2 The investigative committee carries out these procedures within 60 days.

2.3 Investigative committee members make their decisions based on a preponderance of the evidence.

2.4 Investigative committee decisions are made by majority vote.

2.5 Individuals being interviewed may have counsel present. However, counsel cannot address the investigative committee. The investigative committee by a vote of the majority may exclude counsel when in the opinion of the investigative committee that person's presence is disruptive.

3 PROCEDURE

3.1 Notify the investigator that an investigation is being conducted, the question to be answered, and the time frame for completion.

3.2 Determine what information to gather and what individuals to interview.

3.3 Gather information and interview individuals.

3.4 If the investigative committee believes that a transcription of the interviews will be required to make a proper decision, the investigative committee may request a court stenographer to record all interviews.

3.5 Repeat information gathering and interviews until a decision can be made.

3.6 The investigative committee provides a written report of the investigative committee's decision to the IO/OO or IO designee.

4 MATERIALS

4.1 HRP-024 New Information

5 REFERENCES

5.1 AAHRPP I.1.B.; I.5.D.

HRP-026 Suspension or Termination Outside Convened Meeting

1 PURPOSE

1.1 This procedure establishes the process for someone other than the convened IRB to institute a Suspension of IRB Approval or a Termination of IRB Approval.

1.2 The process begins when the Organizational Official / Institutional Official (IO/OO) or IO designee institutes a Suspension of IRB Approval or a Termination of IRB Approval.

1.3 The process ends when the Suspension of IRB Approval or a Termination of IRB Approval has been placed on the agenda for review by the convened IRB.

2 POLICY

2.1 The IRB chair or IRB Director may institute a Suspension of IRB Approval when in the opinion of the IRB chair or IRB Director subjects may be at risk of adverse effects on their rights and welfare before action may be considered by the convened IRB. The risk of adverse effects may be due to Non-Compliance with institutional or other regulatory requirements or an Unanticipated Problem Involving Risks to Subjects or Others.

2.2 The IO/OO or IO designee may institute a Suspension of IRB Approval or Termination of IRB Approval for any reason.

2.3 Whenever possible the individual following these procedures communicates with investigators orally and in writing.

2.4 Administrative Hold:

2.4.1 An “administrative hold” is a voluntary interruption of research enrollments and ongoing research activities by the research investigator or sponsor.

2.4.2 An administrative hold cannot be used to extend IRB approval beyond the expiration date of a protocol without approval of continuing review.

2.4.3 The term “administrative hold” does not apply to interruptions of research related to concerns regarding the safety, rights, or welfare of human research subjects, research investigators, research staff, or others.

2.4.4 An “administrative hold” must not be used to avoid reporting deficiencies or circumstances otherwise covered by institutional policies or other regulatory requirements governing research.

2.4.5 An Administrative Hold directed by the IRB is a suspension and must be classified and reported as such.

2.5 For Veterans Administration (VA) research:

2.5.1 An “administrative hold” is a voluntary interruption of research enrollments and ongoing research activities by an appropriate VA facility official, research investigator, or

sponsor (including the Office of Research and Development (ORD) when ORD is the sponsor).

2.5.2 The term "administrative hold" does not apply to interruptions of VA research related to concerns regarding the safety, rights, or welfare of human research subjects, research investigators, research staff, or others.

2.5.3 An "administrative hold" must not be used to avoid reporting deficiencies or circumstances otherwise covered by VHA Handbooks or other federal requirements governing research.

3 RESPONSIBILITIES

3.1 The individual instituting a Suspension of IRB Approval or Termination of IRB Approval follows these procedures.

4 PROCEDURE

4.1 Notify the investigator of the Suspension of IRB Approval or Termination of IRB Approval along with the reasons for the decision.

4.2 Ask the investigator for a list of Human Subjects currently involved in the research.

4.3 Ask the investigator whether any actions are required to protect those subjects' rights and welfare or to eliminate an apparent immediate hazard.

4.4 Consider whether any of the following additional actions are required to protect those or other subjects' rights and welfare or to eliminate an apparent immediate hazard:

4.4.1 Transferring subjects to another investigator.

4.4.2 Planning for clinical care outside the research.

4.4.3 Allowing continuation of some research activities under the supervision of an independent monitor.

4.4.4 Requiring or permitting follow-up of subjects for safety reasons.

4.4.5 Requiring adverse events or outcomes to be reported to the IRB and the sponsor.

4.4.6 Notification to current Human Subjects.

4.4.7 Notification to former Human Subjects.

4.5 For Veterans Administration (VA) research report the Suspension of IRB Approval or Termination of IRB Approval to the VA facility Director, the Associate Chief of Staff/R&D, and RCO within 5 business days of the determination(s).

4.6 Refer to the IRB staff to place on the agenda for a convened IRB meeting in an IRB with appropriate scope as an item of Suspension of IRB Approval or Termination of IRB Approval. Follow SOP: HRP-041 IRB Meeting Conduct for convened IRB review of the item.

4.7 Complete and send to the investigator HRP-515 - TEMPLATE LETTER - Suspension or Termination.

5 MATERIALS

5.1 SOP: HRP-041 IRB Meeting Conduct

5.2 HRP-515 - TEMPLATE LETTER - Suspension or Termination

6 REFERENCES

6.1 45 CFR 46.103(b)(5)(ii); 45 CFR 46.108(a); 45 CFR 46.113

6.2 21 CFR 56.108(b)(3); 21 CFR 56.113

6.3 VHA Handbook 1058.01

6.4 AAHRPP I.5.D.; II.2.E.; II.2.F.; II.2.G.; II.2.H.

HRP-027 Planned Emergency Research

1 PURPOSE

1.1 This guidance establishes the process for an investigator conducting planned emergency research with a waiver of consent when more than minimal risk is involved.

1.2 The guidance begins when preparing for any planned emergency research or clinical investigation activity that involves human subjects.

1.3 The guidance ends when IRB involvement in the LSUHSC-S planned emergency research or clinical investigation activity is determined.

2 POLICY

2.1 The Health and Human Services (HHS) waiver, just as the Food and Drug Administration (FDA) regulatory change (21 CFR 50.24), provides a narrow exception to the requirement for obtaining and documenting informed consent from each human subject or his or her legally authorized representative prior to initiation of research if the waiver of informed consent is approved by an IRB. The waiver authorization applies to a limited class of research activities involving human subjects who are in need of emergency medical intervention but who cannot give informed consent because of their life-threatening medical condition, and who do not have available a legally authorized representative.

2.2 The intent of these regulations is to allow research on life-threatening conditions for which available treatments are unproven or unsatisfactory and where it is not possible to obtain informed consent, while establishing additional protections to provide for safe and ethical studies.

2.3 Important Notes:

2.3.1 Planned Emergency Research is not the same as Emergency Use of a Test Article. Use SOP: HRP-023 All Emergency Use, Compassionate Use (Device Only) & IRB Waiver for Individual Patient Expanded Access (Drug Only) Review.

2.3.2 In addition, Federal law provides for the conduct of planned research with surrogate informed consent when potential research subjects are unable to consent due to decisional impairment. See SOP: HRP-013 LARs, Children, and Guardians.

3 RESPONSIBILITIES

3.1 Investigators, IRB members, and IRB staff perform these procedures.

4 PROCEDURE

4.1 The LSUHSC-S IRB reviews and may approve planned emergency research without requiring that informed consent of all subjects be obtained if the LSUHSC-S IRB (with the concurrence of a licensed physician who is a member of the IRB and who is not otherwise participating in the clinical investigation) finds and documents each of the following seven points:

4.1.1 The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of interventions.

4.1.2 Obtaining informed consent is not feasible because:

4.1.2.1 The subjects will not be able to give their informed consent as a result of their medical condition.

4.1.2.2 The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible.

4.1.2.3 There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.

4.1.3 Participation in the research holds out the prospect of direct benefit to the subjects because:

4.1.3.1 Subjects are facing life-threatening situation that necessitates intervention.

4.1.3.2 Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects.

4.1.3.3 Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

4.1.4 The clinical investigation could not practicably be carried out without the waiver.

4.1.5 The proposed investigational plan:

4.1.5.1 Defines the length of the potential therapeutic window based on scientific evidence

4.1.5.2 The investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time, and if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent.

4.1.5.3 The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the same time of continuing review.

4.1.5.4 The research plan must be approved in advance by the FDA and the IRB.

4.1.6 The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with 21 CFR 50.25. These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations

where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical investigation consistent with information below.

4.1.7 Additional protections of the rights and welfare of the subjects will be provided, including, at least:

4.1.7.1 Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn.

4.1.7.2 Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits.

4.1.7.3 Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and investigators of the study, including the demographic characteristics of the research population, and its results

4.1.7.4 Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation

4.1.8 If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative and asking whether he or she objects to the subject's participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review. When following the ICH-GCP (E6) guideline: The subject or the subject's legally authorized representative must be informed about the clinical trial as soon as possible and they must provide consent if the subject wishes to continue.

4.1.9 Consenting is an ongoing process. All applicable criteria that would trigger re-consenting a subject in any study also apply to subjects whose consent has been provided by a surrogate. Use SOP: HRP-013 LARs, Children, and Guardians for additional information.

4.1.10 When following DOD requirements: when conducting emergency medicine research, the Secretary of Defense must approve a waiver of the advance informed consent provision of 10 USC 980.

4.1.11 In addition to the situations described under section 5.3 of the SOP: HRP-013 LARs, Children, and Guardians, if the subject is entered into research with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the research should be provided to the subject's legally authorized representative or family member, when feasible.

5 MATERIALS

5.1 SOP: HRP-013 LARs, Children, and Guardians

5.2 SOP: HRP-023 All Emergency Use, Compassionate Use (Device Only) & IRB Waiver for Individual Patient Expanded Access (Drug Only) Review

6 REFERENCES

6.1 21 CFR 50.24

6.2 FDA Guidance: Exception from Informed Consent for Studies Conducted in Emergency Settings: Regulatory Language and Excerpts from Preamble – Information Sheet **https://www.fda.gov/regulatory-information/search-fda-guidance-documents/exception-informed-consent-requirements-emergency-research**

6.3 OPRR Reports: Informed Consent Requirements in Emergency Research, October 31, 1996 **http://www.hhs.gov/ohrp/policy/hsdc97-01.html**

6.4 AAHRPP II.3.G.; II.4.B.; II.4.C.

HRP-028 Use of External IRB and LSUHSC-S being IRB of Record

1 PURPOSE

1.1 This procedure describes how the LSUHSC-S IRB may use an external IRB for human research or become the IRB of Record or the Reviewing IRB for human research.

2 POLICY

2.1 LSUHSC-S may rely on an external IRB to serve as the IRB of Record for certain LSUHSC-S research protocols.

2.1.1 LSUHSC-S may rely upon the IRB of another organization when investigators at LSUHSC-S receive a NIH grant or sub-award (or other federal funds) that mandate the use of an external IRB or when the Institution agrees to rely on an external IRB after evaluating the external IRB and the circumstances of the request.

2.1.2 When relying on an external IRB, whether it is for a single research project or a portion the institution's research portfolio, the external IRB will meet Federal Agency regulations for the conduct of human subject research and IRB review. Non-commercial IRBs will have a Federal wide Assurance and will be part of an AAHRPP organization. Commercial IRBs will be registered with OHRP and will be AAHRPP accredited.

2.1.3 When LSUHSC-S relies on an external IRB to serve as the IRB of record, the external IRB is evaluated by the LSUHSC-S IRB to determine if it meets specific criteria for the protection of human research subjects and, if so, written agreements are executed.

2.1.4 There will be a formal written agreement between LSUHSC-S and the external IRB delineating the roles and specific responsibilities of each party.

2.2 LSUHSC-S IRB may become the IRB of Record (lead or reviewing IRB) or cede oversight of the research activity to another equally qualified IRB.

2.2.1 There will be a formal written agreement between LSUHSC-S IRB and the external sites delineating the roles and specific responsibilities of each party.

3 RESPONSIBILITIES

3.1 The Institution in conjunction with HRPP is responsible for carrying out the policy.

4 PROCEDURE

4.1 IRB Authorization Agreement (Reliance Agreement):

4.1.1 An authorization agreement, initiated by either the external IRB or LSUHSC-S, is used to document the agreement of both parties.

4.1.1.1 When there is a reliance relationship for and IRB review, a written agreement or policies and procedures must describe whether the organization conducting the IRB review, or the relying organization, is responsible for the following:

4.1.1.1.1 Provide education to investigators and research staff.

4.1.1.1.2 Conduct scientific review.

4.1.1.1.3 Review potential non-compliance, including complaints, protocol deviations, and results of audits

4.1.1.1.4 Identify which organization is responsible for deciding whether each allegation of non-compliance has a basis in fact.

4.1.1.1.5 Identify which organization's process is used to decide whether each incident of non-compliance is serious or continuing.

4.1.1.1.6 Obtain management plans for investigator and research staff conflicts of interest. If the relying organization maintains responsibility for this issue, the management plan must be provided to the IRB in a timely manner prior to the decision by the IRB.

4.1.1.1.7 Manage organizational conflict of interest related to the research.

4.1.1.1.8 Ensure that, should termination of a reliance agreement occur, one of the parties clearly is responsible for continued oversight of active studies until closure or a mutually agreed upon transfer of the studies."

4.2 Master Reliance Agreement (MRA): A MRA can be utilized when multiple studies are ceding review to a specific external IRB. Master Agreements may be reciprocal in that signatory institutions can act as the site providing IRB review and oversight or the site relying. Master

Reliance Agreements may be for a single protocol or a number of protocols and are negotiated on a case-by-case basis. MRA eliminates the need for separate IAAs and individual negotiation and documentation. The LSUHSC-S IRB currently has master agreements in place with the following external reliance platforms:

- IRB Reliance Exchange (IREx)
- Smart IRB

4.3 When following DHHS and FDA regulations, a written agreement must define the responsibilities of the relying organization and reviewing IRB, including but not limited to:

4.3.1 Determining whether the relying organization applies its FWA to some or all research and ensuring the IRB review is consistent with requirements in the relying organization's FWA.

4.3.2 Determining which organization is responsible for obtaining any additional approvals from DHHS when the research involves pregnant women, fetuses, and neonates; or children; or prisoners.

4.3.3 Determining which organization is responsible for reporting serious or continuing non-compliance; unanticipated problems involving risks to subjects or others; and suspensions or terminations of IRB approval. Reporting may be done by the reviewing IRB, the relying organization, or jointly, but must be clearly defined in policies or a written agreement.

4.4 The written authorization agreement must outline the responsibilities of the external IRB and LSUHSC-S and the investigator/s.

4.5 The authorization agreement is kept in the IRB administrative files and will be made available upon official request.

4.6 When following NIH policy, the responsibilities for single IRB review, include:

4.6.1 the requirement for single IRB review applies to awardees in the United States and participating research sites in the United States.

4.6.2 the requirement for single IRB review does not apply to organizations outside the United States.

4.6.3 awardee organizations are responsible for ensuring authorization agreements are in place, and that documentation is maintained.

4.6.4 Who is responsible for meeting the additional requirements of the NIH Genomic Data Sharing Policy.

4.6.5 participating sites are expected to rely on the single IRB, though they may conduct their own review in accordance with NIH policy on exceptions from single IRB review.

4.7 LSUHSC-S IRB Responsibilities when ceding review to an External IRB:

4.7.1 The investigator seeks approval from the Assistant Vice Chancellor for Research Management and/or IO designee to use an external IRB to serve as the IRB of Record and provides justification for reliance on the external IRB. Use Request for External IRB. This form is not required when using an external IRB that LSUHSC-S already has an Master Reliance Agreement (MRA) with.

4.7.2 The Assistant Vice Chancellor for Research Management in conjunction with the IO designee and IRB Director/designee assess whether an external IRB is qualified to serve as the IRB of Record for LSUHSC-S human subject research project by verifying the following:

4.7.2.1 Use of an external, single or central IRB is justified when:

(1) a federal agency requires or has designated a single or central IRB,

(2) an industry sponsor has designated a single or central IRB, or

(3) a single or central IRB provides access to knowledge, skills, expertise, or disciplines that LSUHSC-S does not possess.

4.7.2.2 The organization's Human Research Protection Program is accredited by AAHRPP (Under special circumstances, if the organization is not accredited by AAHRPP, then consideration will be made by the IO/IO designee on a case-by-case basis)

4.7.2.3 The non-commercial IRB has an active Federalwide Assurance (FWA) on file with the Federal Office for Human Research Protection.

4.7.2.4 The commercial IRB is registered with OHRP.

4.7.2.5 The organization or external IRB has not received any recent FDA warning letters or OHRP determination letters within the last year.

4.7.2.6 The Board Membership satisfy the requirements of 45 CFR 46.107 and 21 CFR 56.107.

4.7.2.7 The external IRB has an adequate process in place to notify the LSUHSC-S IRB and investigator(s) of its approvals, determinations, reportable events, suspensions, and terminations.

4.7.3 In the opinion of LSUHSC-S IRB leadership, the external IRB can fulfill its responsibilities as outlined in the written authorization agreement.

4.8 If it is determined that the external IRB is qualified to serve as the IRB of Record, a written authorization agreement is initiated, by either the external IRB or LSUHSC-S, which documents the agreement of both parties.

4.9 The following information from the external organization is provided to the LSUHSC-S Assistant Vice Chancellor for Research Management or designee.

4.9.1 A copy of the non-commercial IRB's Federalwide Assurance (FWA)

4.9.2 The commercial IRB's Institution/organization (IORG) number

4.9.3 The contact information for the external IRB's Institutional Official (name, address, telephone number, e-mail address)

4.9.4 The contact information for the external IRB's Administrator and/or designated point of contact (name, address, telephone number, e-mail address)

4.10 LSUHSC-S Investigator Responsibilities:

4.10.1 Comply with the external IRB's requirements, directives per the Authorization Agreement and local institutional requirements.

4.10.2 Must not enroll individuals in any research protocol prior to the following:

4.10.2.1 Review and approval by the external IRB, and

4.10.2.2 Verification of local review requirements and confirmation of the external IRB approval from the LSUHSC-S IRB Administrative Office.

4.10.3 Ensure the safe and appropriate performance of the research. This includes, but is not

limited to ensuring the qualifications of research staff, monitoring protocol compliance,

maintaining compliance with state, local or organizational requirements related to the

protection of human subjects; providing a mechanism to receive and address concerns

from local study subjects and others about the conduct of the research; and investigating,

managing, and providing notification to the external IRB and the LSUHSC-S IRB

Administrative Office of any study-specific incidence, experience, or outcome that rises to

the level of an unanticipated problem and/or serious or continuing non-compliance.

4.10.4 Provide the external IRB with any local context issues relevant to the research protocol.

4.10.5 Disclose financial conflicts of interest according to the agreed upon process and comply with any conflict management plans that may result.

4.10.6 Promptly report to the external IRB any proposed changes in the research. The

4.10.7 investigator must not initiate changes in the research (including changes in the consent document) without prior IRB review and approval or LSUHSC-S IRB Administrative Office confirmation, except where necessary to eliminate apparent immediate hazards to the

subjects.

4.10.8 When responsible for enrolling subjects, will obtain, document, and maintain records of consent for each subject or subject's legally authorized representative as stipulated by

the IRB. The investigator will utilize the LSUHSC-S consent, assent, and/or HIPAA

templates, as appropriate.

4.10.9 Will provide to the external IRB any data and safety monitoring reports they receive,

either at continuing review, upon request by the reviewing IRB, or on an emergent basis, if appropriate.

4.10.10 Provide updates to the external IRB and LSUHSC-S IRB Administrative Office whenever a principal investigator is no longer the responsible party for a research project under the purview of the external IRB.

4.10.11 Provide the contact person and contact information for the LSUHSC-S Assistant Vice Chancellor for Research Management, IRB Director or Designee to the external IRB.

4.10.12 Documenting reliance on the External IRB through the IRB electronic system

(SHIeLDS).

4.10.12.1 Document the initial request for reliance. Use Request for External IRB

4.10.12.2 Document any updates, continuing reviews and modifications to the research approved by the external IRB including the following reportable new information:

4.10.12.2.1 new risks and unanticipated problems

4.10.12.2.2 harm experienced by a subject

4.10.12.2.3 non-compliance, audits by external agencies

4.10.12.2.4 monitoring reports, protocol deviations

4.10.12.2.5 breach of confidentiality

4.10.12.2.6 un-reviewed changes taken to eliminate apparent immediate harm to a subject

4.10.12.2.7 incarceration of a subject

4.10.12.2.8 unresolved subject complaint

4.10.12.2.9 All institutionally required ancillary reviews must be obtained locally (e.g., Conflict of Interest, Institutional Biosafety, Radiation Safety, etc.) Oversight of these ancillary reviews still require local review and approval regardless of ceding IRB review. (Under special circumstances, if these additional reviews relevant to the HRPP are conducted by an external organization, including but not limited to biosafety review, radiation safety review, recombinant DNA, research review, human stem cell research review, and conflict of interest review, then documentation/correspondence related to the reviews must be uploaded in the study application prior to local review).

4.11 External IRB Responsibilities include, but are not limited to:

4.11.1 Conduct review of research according to all applicable regulations and laws, including

initial review, continuing review, and review of modifications to previously approved

research.

4.11.2 Conduct review of potential unanticipated problems, adverse events, and/or serious or

continuing non-compliance.

5.5.3 Provide notification to investigator staff and relying institution in writing of its

determinations and decisions.

4.11.3 Make available relevant IRB minutes, IRB membership rosters, and standard operating procedures to the relying institution upon request.

4.11.4 When appropriate, conduct on-site or remote post-approval monitoring or audits, unless delegated to the relying institution.

4.11.5 Maintain an IRB membership that satisfies the requirements of 45 CFR 46.107 and 21

CFR 56.107 and which provides special expertise as needed to adequately assess all

aspects of each study.

4.11.6 Promptly notify the LSUHSC-S Institutional Official or designee if there is a suspension or termination of the external IRB's authorization to review a study.

4.11.7 Provide the LSUHSC-S Assistant Vice Chancellor for Research Management, IRB Director or Designee, the contact person and contact information for the reviewing IRB.

4.11.8 Maintain appropriate documentation per record retention policies, including an OHRP-

approved Federalwide Assurance (non-commercial IRBs) for human subject research.

Notify the LSUHSC-S IRB Director or designee of any changes to external IRB's FWA.

4.12 Documenting the Reliance on an External IRB of Record

4.12.1 The Investigator is responsible for documenting the reliance when an External IRB

is allowed to serve as the IRB of Record for any LSUHSC-S research by completing the

following:

4.12.2 Create a new study in the IRB electronic system (SHIeLDS) and complete all

forms, as applicable.

4.12.3 Choose 'Yes' when asked: Will an external IRB act as the IRB of record for this study?

4.12.4 Attach copies of protocol specific materials, supporting documents and correspondence in the IRB electronic system. Use HRP-335 - WORKSHEET - External IRB Review of Onsite Research as guide.

4.12.5 Submit External IRB study to the IRB Administrative Staff for Institutional Confirmation of External IRB Research.

4.13 Institutional Confirmation of Research and verification of local review requirements when LSUHSC-S relies on an external IRB to serve as the IRB of record.

4.13.1 The IRB administrative staff carry out these activities:

4.13.1.1 Use HRP-335 - WORKSHEET - External IRB Review of Onsite Research to verify that the External IRB Research submitted by the investigator is complete.

4.13.1.2 If submission is not complete or requires clarifications, contact the investigator by selecting the “Request Pre-Review Clarifications” Activity. Offer the investigator the opportunity to make to provide additional information.

4.13.1.3 Continue processing once the investigator responds to the request for additional information.

4.13.1.4 Select the ‘Submit Pre-Review’ Activity in the electronic system and document any special determination made by the external IRB.

4.13.1.5 Then execute the Pre-Review activity to complete the action.

4.13.1.6 Obtain institutional approvals, when necessary, through the ‘Manage Ancillary Reviews’ Activity in the electronic system.

4.13.1.7 If a required ancillary review is not received or requires clarification, obtain clarification as needed or arrange a meeting with the ancillary review team. The ancillary review team will make one of the following determinations.

4.13.1.8 The research is appropriate for the institution and may be conducted in accordance with the protocol approved by the external IRB.

4.13.1.9 The research is not appropriate for the institution. (Provide the reason for the determination).

4.13.2 Assign the submission to a staff designated reviewer for processing after ancillary review team makes determination.

4.13.3 The staff designated reviewer will choose the following option in SHIeLDS if the ancillary review team determines the new research is appropriate for the institution: 'Modifications Required to Secure Approval'.

4.13.3.1 The IRB staff will generate correspondence notifying the investigator that they may submit a request to the External IRB to add this site to the research.

4.13.3.2 Upon receipt of external IRB correspondence approving the local site as part of the research, the investigator is to submit the correspondence as a response to the 'Modifications Required'.

4.13.3.3 The IRB staff will verify the External IRB approval and generate correspondence to the investigator 'Confirming External IRB Review of On-Site Research' allowing the investigator to proceed with study procedures.

4.13.3.4 The IRB staff and reviewers will ensure research is being reviewed appropriately and complies with applicable law and regulations. The local review will confirm compliance with the organization's ethical standards and with applicable law and regulations. The extent of the review of the non-accredited IRB can vary, depending upon the level of risk to subjects in the research.

4.13.4 If the ancillary review team determines the research is not appropriate for the institution, the staff designated reviewer will choose the following option in SHIeLDS: Reject External IRB Review of On-Site Research.

4.13.5 The IRB staff will generate correspondence notifying the investigator that the research may not be carried out at this site

4.14 When LSUHSC-S IRB is the Lead site or Reviewing IRB (when LSUHSC-S IRB is the IRB of Record):

4.14.1 LSUHSC-S IRB Responsibilities:

4.14.1.1 Ensuring that the composition of the IRB is appropriate for the research to be reviewed and complies with applicable laws, i.e., the IRB is properly constituted; members are appropriately qualified; those members do not participate in the review of studies in which they have a conflict of interest; and the IRB follows policy to separate business functions from ethics review services.

4.14.1.2 Conducting IRB review of research according to all applicable regulations and laws, including initial review, continuing review, and review of modifications to determine that the research is ethically justifiable.

4.14.1.3 Conducting review of the addition of investigative sites to previously approved protocols. The IRB may decide to review these additions as separate protocols or as modifications to previously approved research, and they may decide to handle such modifications using the expedited procedure rather than the convened IRB for review. When the expedited procedure is used, the IRB must specify the criteria for when the addition of an investigative site is a minor modification.

4.14.1.4 Ensuring that the organization has final authority to determine whether investigator/staff conflict of interest and any proposed management allows the research to be approved.

4.14.1.5 Reviewing unanticipated problems involving risks to subjects or other.

4.14.1.6 Ensuring procedure for suspending or terminating approval.

4.14.1.7 Having procedures for notifying the investigator of IRB decisions and the relying organization.

4.14.1.8 Making available relevant IRB records, including but not limited to minutes, approved protocols, consent documents, and other records that document the IRB's determinations to the relying organization upon request.

4.14.1.9 Having the authority to perform or request an audit of research under its review.

4.14.1.10 Making relevant IRB policies readily available to the relying organization and communicating updates to the relying organization as needed.

4.14.1.11 Specifying the contact person and the contact information for the reviewing IRB so investigators/staff can ask questions, express concerns, and convey suggestions.

4.14.1.12 Records must include documentation specifying the responsibilities that a relying organization and an organization operating an IRB each will undertake compliance with the requirements of the Common Rule. (45CFR46.103(e)

4.14.1.13 When serving as the reviewing IRB for a DoD-covered research study:

4.14.1.13.1 Provide a written agreement that defines the responsibilities of the DoD organization and non-DoD reviewing IRB, including all requirements for this Standard for IRBs serving as reviewing IRBs, and the following additional requirements, including but not limited to:

- The process for serving as a reviewing IRB for DoD institutions collaborating with non-DoD institutions, including who is responsible and the process they go through to obtain DoD approval for a non-DoD institution to be designated to review for DoD research, including ensuring the following conditions are met (DoDI 3216.02 section 3.5):

- Each institution engaged in non-exempt human subject research must have a current federal assurance of compliance.

- The non-DoD institution's IRB is registered in accordance with Subpart E of 45 CFR 46.

- The DoD institution reviews the protocol to ensure all applicable local and DoD requirements are addressed in the protocol.

- The DoD institution, non-DoD institution, and the non-DoD institution's IRB have a written agreement defining the responsibilities and authorities of each institution in complying with all legal requirements. This agreement must specify that the non-DoD IRB will apply the DoD requirements specified in DoDI 3216.02, including but not limited to non-DoD institutional responsibilities defined under DoDI 3216.02 section 3.6(b).

- If the research constitutes classified human subject research, the COHRP must approve the agreement to rely on the non-DoD institution's IRB.

4.15 LSUHSC-S Investigator Responsibilities:

4.15.1 Submit a request to the IRB to make the LSUHSC-S IRB, the reviewing IRB for the research protocol.

4.15.2 Ensure compliance with the IRB's requirements and directives per the Authorization Agreement and local institutional requirements.

4.15.3 Assist the LSUHSC-S IRB in obtaining information about the external site's local requirements or context relevant to the research.

4.15.4 Must not enroll individuals in the research protocol at any sites including those which confirm reliance on LSUHSC-S IRB, prior to the review and approval by the LSUHSC-S IRB.

4.15.5 Ensure the safe and appropriate performance of the research. This includes, but is not limited to ensuring the qualifications of research staff, monitoring protocol compliance, maintaining compliance with state, local or organizational requirements related to the protection of human subjects; providing a mechanism to receive and address concerns from local study subjects and others about the conduct of the research; and investigating, managing, and providing notification to the LSUHSC-S IRB Administrative Office of any study-specific incidence, experience, or outcome that rises to the level of an unanticipated problem and/or serious or continuing non-compliance.

4.15.6 Disclose financial conflicts of interest according to the agreed upon process and comply with any conflict management plans that may result.

4.15.7 Consult the IRB staff and document reliance on appropriate reliance platform to be used for the research (for e.g., SMART IRB, IRB Reliance Exchange (IREx)). Document the initial request for reliance. Use Request for External IRB.

4.15.8 Submit the research protocol in SHIeLDS as a new study application as per the regular process. Obtain LSUHSC-S IRB approval for the research protocol.

4.15.9 Follow instructions on the reliance platform to build the study application on their website.

4.15.10 Submit modification in SHIeLDS to add external sites to the research once they confirm their reliance on the LSUHSC-S IRB on the reliance platform.

4.15.11 Document any updates, continuing reviews, and modifications to the research in SHIeLDS and the reliance platform to notify the external sites, including the following reportable new information:

4.15.11.1 new risks and unanticipated problems

4.15.11.2 harm experienced by a subject

4.15.11.3 non-compliance, audits by external agencies

4.15.11.4 monitoring reports, protocol deviations

4.15.11.5 breach of confidentiality

4.15.11.6 un-reviewed changes taken to eliminate apparent immediate harm to a subject

4.15.11.7 incarceration of a subject

4.15.11.8 unresolved subject complaint

4.15.12 All institutionally required ancillary reviews must be obtained locally (e.g., Conflict of Interest, Institutional Biosafety, Radiation Safety, etc.) Oversight of these ancillary reviews still require local review and approval regardless of ceding IRB review. (Under special circumstances, if these additional reviews relevant to the HRPP are conducted by an external organization, including but not limited to biosafety review, radiation safety review, recombinant DNA, research review, human stem cell research review, and conflict of interest review, then documentation/correspondence related to the reviews must be uploaded in the study application prior to local review).

5 MATERIALS

5.1 HRP-335 - WORKSHEET - External IRB Review of Onsite Research

5.2 Request for External IRB

6 REFERENCES

6.1 45 CFR 46.114

6.2 AAHRPP I.1.F.; I.4.; I.6.; I.9.; II.4.A.; II.4.B.; II.5.B.; III.1.B.; III.1.C.; III.1.G.;

HRP-029 Reportable New Information Items

1 PURPOSE

1.1 This procedure establishes the process to identify new information that requires reporting to the IRB.

1.2 The process begins when an individual receives an information item.

1.3 The process ends when the item is submitted to the IRB for review.

2 POLICY

2.1 New Information Items are to be reported to the IRB within 5 business days.

2.2 The IRB will manage the new information item in accordance with SOP: HRP-024 New Information.

3 RESPONSIBILITY

3.1 Investigators or other individuals receiving reportable new information items carry out these procedures.

4 PROCEDURE

4.1 Report information items that fall into one or more of the following categories to the IRB within five (5) business days.

4.1.1 Information that indicates a new or increased risk, or a new safety issue. For example:

4.1.1.1 New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor correspondence or report, CRO report, or investigator finding) that may indicate an increase in the frequency or magnitude of a previously known risk or uncovers a new risk.

4.1.1.2 An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk or describe a new risk.

4.1.1.3 Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.

4.1.1.4 Protocol deviation/violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.

4.1.1.5 Protocol exception is a temporary protocol deviation or eligibility waiver that is granted by the Sponsor or funding agency, (and the FDA if applicable, for investigational device studies) and the IRB prior to implementation. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.

4.1.1.6 Any changes significantly affecting the conduct of the research

4.1.2 Harm experienced by a subject or other individual, which in the opinion of the investigator are

unexpected and probably related to the research procedures.

4.1.2.1 A harm is “unexpected” when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.

4.1.2.2 A harm is “probably related” to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.

4.1.3 Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB or the institution or an allegation of such non-compliance.

4.1.4 Audit, inspection, or inquiry by a federal agency or any other outside entity and any resulting reports (e.g., FDA Form 483.)

4.1.5 Written reports of study monitors.

4.1.6 Failure to follow the protocol due to the action or inaction of the investigator or research staff whether planned or unplanned.

4.1.7 Change to the protocol taken without prior IRB review to eliminate an apparent immediate

4.1.8 Breach of confidentiality (inappropriate disclosure of or access to confidential information).

4.1.9 Incarceration of a subject in a study not approved by the IRB to involve prisoners.

4.1.10 Complaint of a subject that cannot be resolved by the research team.

4.1.11 Premature suspension or termination of the protocol by the sponsor, investigator, or institution.

4.1.12 Unanticipated adverse device effect (any serious adverse effect on health or safety or any life- threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.)

4.1.13 For Veterans Administration (VA) research all local or internal serious adverse events.

4.2 Use the IRB electronic submission system (SHIeLDS) or equivalent to submit the reportable new items.

4.2.1 Select the Action “Report New Information”.

4.2.2 Name the report so that it can be easily identified.

4.2.3 Provide the date you became aware of the problem.

4.2.4 Provide a description of the problem and determine the following:

4.2.5 Does this information indicate a new or increased risk, or a safety issue?

4.2.6 Does the study need revision?

4.2.7 Does the consent document need revision?

4.3 Provide a list of all studies related to the reportable new information.

4.4 Attach supporting documentation and a description of any corrective actions when required.

4.5 Submit the item to the IRB when your description of the reportable new information is complete.

4.6 Protocol Violations:

4.6.1 A Protocol Violation is a subset of Protocol Deviations. It includes:

4.6.1.1 Any planned or unplanned change or deviation from the IRB approved study protocol, consent document, recruitment process, or study materials that were not approved by the IRB prior to implementation that may affect the subject's rights, safety, or wellbeing and/or the completeness, accuracy, and reliability of the study data.

4.6.1.2 Any significant divergence from the protocol, i.e., non-adherence on the part of the patient, investigator, or the sponsor to protocol-specific inclusion/exclusion criteria, primary objective variable criteria, and/or GCP guidelines without prior sponsor and IRB approval.

4.6.1.3 A divergence from the protocol that generally increases the risk and/or decreases the benefits; affect the subject's rights, safety, or welfare and/or the completeness, accuracy, integrity or reliability of the research data.

4.6.1.4 They can create serious situations that require immediate investigation by the IRB Chair/Human Research Protections Program and reporting to the IO and/or IO designee and appropriate external agencies, including the OHRP, when warranted.

4.7 Protocol Exceptions:

4.7.1 A protocol exception is a temporary protocol deviation or eligibility waiver that is granted by the Sponsor or funding agency, (and the FDA if applicable, for investigational device studies) and the IRB prior to implementation. Protocol exceptions are generally for a single subject or, occasionally, a small group of subjects. If under extraordinary circumstances such action is considered ethically, medically, and scientifically justified for a patient, prior approval from the Sponsor and the IRB, in accordance with the SOP, is required before the patient will be allowed to enter the study.

4.7.2 The Protocol Exception or eligibility waiver is usually evaluated by both the sponsor or funding agency (and FDA, if applicable) and the IRB to determine that it does not increase the risk to the subject(s), or jeopardize the integrity of the research data. Documentation of sponsor (or FDA) pre-approval and IRB approval of the exception should be maintained in the investigator's research study file.

4.7.3 If the Investigator becomes aware of a subject that is enrolled in the study who did not meet protocol eligibility criteria (a protocol violation), the investigator must immediately inform the sponsor and the IRB. Such subjects will be discontinued from the study, except in the rare instance following review and written approval by the sponsor and the IRB that it is in the best interest of the subject to remain in the study in accordance with this SOP.

4.7.4 Exceptions may not increase risk or decrease benefit, affect the subject's rights, safety, welfare, or affect the integrity of the resultant data. An example of a Protocol Exception or Eligibility Waiver is listed below: Enrollment of a research subject who fails to meet all the Protocol eligibility criteria (e.g., the subject may have been evaluated for all other parameters, and it was determined by the Sponsor and the IRB that not meeting this inclusion criteria or laboratory screening value would not cause harm to the subject or alter the validity of the study).

4.7.5 An exception request applies to a one-time event. Such a request should be rare and justified in terms of serving the best interests of the potential study subject. Any change or deviation from the protocol that does not receive prior IRB review and approval (except when the deviation is performed to eliminate apparent immediate hazards to the subject) will be evaluated according to the IRB's policies and procedures for handling non-compliance and considering whether the deviation constitutes an unanticipated problem involving risks to subjects or others. This is not intended for deviations from the protocol performed to eliminate

apparent immediate hazards to the subject in compliance with 45 CFR 46:103(b)(4) and 21 CFR 6108.(a)(3)and (a)(4).

4.7.6 Investigator requests for protocol exceptions or eligibility waivers must be submitted via a Reportable New Information along with documentation of Sponsor justification and approval. The IRB Staff will screen the submission for completeness and identify the appropriate level of review. The IRB staff will forward the submission to the IRB Chair or designee for review. The IRB will review the investigator's Reportable New Information and document the findings on the Reportable New Information Reviewer Checklist. The Chair may choose to place any exception request on the agenda of the next convened IRB meeting for discussion. The investigator may be asked to appear at that meeting to answer any questions or clarify issues for the IRB. The fully convened IRB discusses the event at the convened meeting and the IRB meeting minutes document the discussion and final determination of the fully convened IRB regarding the Protocol Exceptions.

4.8 The possible determinations IRB members can make regarding exceptions include:

4.8.1 Exception approved-no issues

4.8.2 Exception disapproved

4.8.3 Modifications required

4.8.4 Referred for Fully Convened IRB Review

4.8.5 Deferral-further justification or information required (only for Fully Convened IRB Review)

4.9 Once a determination is made by the IRB, the PI will receive a notification of determination from the IRB and documentation of review is placed in the IRB Protocol file. All determinations made by expedited procedures regarding any Protocol Exception Request will be reported to the convened board on the next meeting agenda.

5 MATERIALS

5.1 SOP: HRP-024 New Information

6 REFERENCES

6.1 45 CFR 46.103(b)(5); 45 CFR 46.108(a)

6.2 21 CFR 56.108(b)

6.3 AAHRPP I.4.A.; I.5.D.; I.9.; II.2.G.; II.4.A.; II.4.B.; III.1.G.; III.2.D.;

HRP-030 Designated Reviewers

1 PURPOSE

1.1 This procedure establishes the process for an IRB chair to designate or remove IRB members who can conduct Non-Committee Reviews.

1.2 The process begins when the IRB chair instructs IRB Director to designate an Experienced IRB Member to conduct Non-Committee Reviews.

1.3 The process ends when the IRB member has been noted in the IRB roster to conduct Non-Committee Reviews.

2 POLICY

2.1 IRB rosters are maintained using the “IRB Roster.”

3 RESPONSIBILITIES

3.1 IRB staff members carry out these procedures.

4 PROCEDURE

4.1 Obtain from the IRB chair the name of the IRB member designated to conduct Non-Committee Reviews.

4.2 Review list of IRB members designated to conduct Non-Committee Reviews in the “Assign Designated Reviewer” activity. Verify that the IRB member is an Experienced IRB Member who has been an IRB member for a period of at least one (1) year and the IRB chair considers the IRB member to have sufficient experience in and knowledge of the criteria for approval and conducting IRB reviews.

4.3 Update the “IRB Roster” to indicate that the IRB member is a Designated Reviewer.

4.4 Use the “Update Eligible Designated Reviewers” activity to indicate that the IRB member is a Designated Reviewer.

4.5 Notify the IRB member of the decision.

5 MATERIALS

5.1 IRB Roster

6 REFERENCES

6.1 45 CFR 46.110(b)

6.2 21 CFR 56.110(b)

6.3 AAHRPP II.2.E.; II.2.F.

HRP-031 Non-Committee Review Preparation

1 PURPOSE

1.1 This procedure establishes the process to assign a Designated Reviewer for a Non-Committee Review.

1.2 The process begins when the Pre-Review of a submission is complete and an IRB staff member or the IRB Chair identifies an application as being possibly eligible for Non-Committee Review.

1.3 The process ends when the IRB staff member provides the materials to the Designated Reviewer.

2 POLICY

2.1 IRB rosters are maintained using “IRB Roster.”

2.2 For individuals who access materials through an electronic system or are provided all submitted materials, those individuals are expected to review the materials listed in the HRP-301 - WORKSHEET - Review Materials according to their role: “Documents Provided to All IRB Members and Alternate IRB Members,” “Additional Items Provided to Primary Reviewer,” and “Additional Items Provided to Scientific/Scholarly Reviewer”. Reviewers are expected to review, as applicable, the materials according to their role as described in SOP: HRP-045 IRB Member Review Expectations.

3 RESPONSIBILITIES

3.1 IRB staff members carry out these procedures.

4 PROCEDURE

4.1 Refer to “IRB Roster” and select a Designated Reviewer.

4.1.1 If a Designated Reviewer is not available, schedule the protocol to be reviewed by the convened IRB.

4.2 Use the “Assign Designated Reviewer” activity and select a Designated Reviewer.

4.2.1 If a Designated Reviewer is not available, schedule the protocol to be reviewed by the convened IRB.

4.2.2 Execute the "Assign Designated Reviewer" activity

4.3 For individuals who are provided materials to review, prepare the review materials using the HRP-301 - WORKSHEET - Review Materials and include all materials listed under the columns according to the individual's role.

4.4 Use the following worksheets when needed to judge eligibility for Non-Committee Review: HRP-310 - WORKSHEET - Human Research Determination, HRP-311 - WORKSHEET - Engagement Determination, HRP-312 - WORKSHEET - Exemption Determination, HRP-313 - WORKSHEET - Expedited Review.

4.5 Execute the "Assign Designated Reviewer" activity to send to the Designated Reviewer.

4.6 For research that does not involve interaction with prisoners (e.g., existing data, record review) reviewed by the expedited procedure: Research that does not involve interaction with prisoners may be reviewed by the expedited procedure (Non-Committee Review), if a determination is made that the research involves no greater than minimal risk for the prison population being studied.

4.6.1 Review by a prisoner representative is not required.

4.6.2 The prisoner representative may review the research as a reviewer or consultant if designated by the IRB Chair.

5 MATERIALS

5.1 IRB Roster

5.2 SOP: HRP-045 IRB Member Review Expectations

5.3 HRP-301 - WORKSHEET - Review Materials

5.4 HRP-310 - WORKSHEET - Human Research Determination

5.5 HRP-311 - WORKSHEET - Engagement Determination

5.6 HRP-312 - WORKSHEET - Exemption Determination

5.7 HRP-313 - WORKSHEET - Expedited Review

6 REFERENCES

6.1 21 CFR 56.110(b)

6.2 45 CFR 46.110(b)

6.3 AAHRPP I.1.A.; I.1.F.; I.3.; II.2.E.; II.4.A.

HRP-032 Non-Committee Review Conduct

1 PURPOSE

1.1 This procedure establishes the process for a Designated Reviewer to conduct a Non-Committee Review.

1.2 The process begins when the Designated Reviewer has the provided materials.

1.3 The process ends when the Designated Reviewer completes the review and returns the completed materials to an IRB staff member.

2 POLICY

2.1 Designated Reviewers are to review the material described in SOP: HRP-045 IRB Member Review Expectations.

2.2 The Designated Reviewer may not disapprove research.

3 RESPONSIBILITIES

3.1 The Designated Reviewer carries out these procedures.

4 PROCEDURE

4.1 Review all materials.

4.2 Consider whether you have a Conflicting Interest. If not:

4.2.1 If the submission is a request to close the study and meets the study closure criteria, close the study, and notify the IRB staff.

4.2.2 If the submission does not meet the study closure criteria communicate with the investigator and stop processing until the investigator revises the submission.

4.2.3 If the investigator will not revise the submission, return to the IRB staff member handling the submission for assignment to Committee Review.

4.3 Determine the required level of review. (Not Human Research, Human Research not Engaged, exempt Human Research (including exempt Human Research that requires Limited IRB Review), Human Research approved using the expedited procedure, or Human Research that requires review by a convened IRB.

4.4 If there is missing information

4.4.1 Request Clarification by Designated Reviewer and execute activity; or

4.4.2 Contact IRB staff and follow the procedures in SOP: HRP-021 Pre-review.

4.5 Approve the initial, continuing or modification submission if meets either:

4.5.1 The criteria in HRP-312 - WORKSHEET - Exemption Determination

4.5.2 The criteria in HRP-313 - WORKSHEET - Expedited Review and HRP-314 - WORKSHEET - Criteria for Approval and other applicable worksheets and checklists as determined by the Pre-Review.

4.5.3 “Modifications Required to Secure Determination of Not Human Research”: The submission with changes can be determined “Not Human Research.”

4.5.4 “Modifications Required to Secure Approval”: The submission with changes can be given the action of “Approve.”

4.5.5 For Veterans Administration (VA) research the approval of minor conditions by the IRB chair or designated IRB voting member must be documented in the minutes of the first IRB meeting that takes place after the date of the approval of the minor conditions. VA projects that are determined to be exempt must be reviewed by the VA Research and Development Committee prior to initiation and then they must be included in its annual review of research projects. The exempt status means the research is exempt from the requirements of 38 CFR Part 16 including reviews by the IRB. It does not exempt the research 111 from other required reviews, such as by the RDC.

4.5.6 Use HRP-302 - WORKSHEET - Calculation of Approval Intervals to calculate approval period.

4.5.7 Document using the electronic form ‘Submit Designated Review’ or HRP-402 - CHECKLIST - Non-Committee Review.

4.5.8 The determination action:

4.5.8.1 If the determination is “Approve” or “Modifications Required to Secure Approval,” document whether the approval level was “Exempt” or “Expedited.”

4.5.8.2 For “Exempt,” document the category or categories allowing the exemption on the electronic form or in HRP-312 - WORKSHEET - Exemption Determination and document if there will be an end/termination date which cannot exceed a period of three (3) years.

4.6 Limited IRB review:

4.6.1.1 Must be performed by the IRB Chair or by an experienced IRB member. The review can occur on an expedited basis and does not require consideration by a convened board. The reviewer may require modifications to the proposal prior to approval. The reviewer conducting limited IRB review may not disapprove research. Disapprovals must be made by the convened board. If the limited IRB review does not result in approval under the exempt categories, then the IRB can evaluate whether or not approval is appropriate under the expedited categories. Expedited research must meet all the approval criteria under 45 CFR 46.111, including either informed consent or waiver of consent. Use “WORKSHEET: Limited IRB Review and Broad Consent (HRP-319)”.

4.6.1.2 Eligible research is deemed to be no more than minimal risk.

4.6.1.3 Eligible research meets one or more exempt categories 2, 3, 7, or 8.

4.6.1.4 Investigators must submit following materials/documents for limited IRB review, including:

4.6.1.4.1 The full protocol, application, or a protocol summary containing the relevant information to determine whether the proposed research fulfills the relevant criteria for approval required under limited IRB view.

4.6.1.4.2 Proposed consent document, if applicable.

4.6.1.4.3 Recruitment materials.

4.6.2 Following determinations must be made when conducting limited IRB review,

4.6.2.1 For exemption Categories 2 and 3, there are adequate protections for privacy interests of subjects and the confidentiality of identifiable data.

4.6.2.2 For exemption Category 7, broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained. (Broad Consent will not be used at this institution.)

4.6.2.3 For exemption Category 8, broad consent was appropriately documented or a waiver of documentation of consent was appropriate. (Broad Consent will not be used at this institution.)

4.6.3 The evaluation of exempt research under limited IRB review to whether it fulfills the organization's ethical standards. Use HRP-313 - WORKSHEET - Expedited Review.

4.6.4 Continuing review is not required for studies that qualify for a limited review.

4.6.5 LSUHS retains the authority to suspend or terminate IRB approval of research approved with a limited review.

4.6.6 If a secondary research study that involves human subjects does not qualify for any exemption, the study must comply with the criteria for IRB approval of research at 45 CFR 46.111 (which includes the requirement for seeking the informed consent from every prospective subject or legally authorized representative, unless informed consent is waived by the IRB).

4.6.7 For "Expedited," document the category or categories allowing review using the expedited procedure on the electronic form or in HRP-313 - WORKSHEET - Expedited Review and document the period of approval which cannot exceed one (1) year.

4.7 Under the revised Common Rule, continuing review is not required for:

4.7.1 Research complies with 2018 regulatory requirements,

4.7.2 Research that is eligible for expedited review,

4.7.3 Exempt research conditioned on limited IRB review,

4.7.4 Research that has completed all interventions and now only includes analyzing data, even if the information or biospecimens are identifiable,

4.7.5 Research that has completed all interventions and now only includes accessing follow-up clinical data from clinical care procedures.

4.7.6 The IRB staff will inform the investigator "While this project is exempt from the need of continuing review, please note it is the investigators responsibility to notify the IRB of any changes (via a Modification in SHIELDS) and annually report progress of the study (via a Reportable New Information in SHIELDS). At completion of the study, please report study findings and close the study (via a Continuing Review (Study closure) in SHIELDS)."

4.7.7 The IRB can override this default and still choose to require continuing review if the IRB documents the decision and the rationale for this decision.

4.7.8 Update Pre-Review findings as needed.

4.7.9 Execute the "Submit Designated Review" activity.

4.8 Notify the IRB staff member handling the submission when done.

4.9 If consultation is needed, follow SOP: HRP-051 Consultation.

4.10 Execute the "Submit Designated Review" activity.

4.11 Broad Consent will not be used at this institution.

4.12 When following DoD requirements:

a. Surveys performed on DoD personnel must be submitted, reviewed, and approved by the DoD after the research protocol is reviewed and approved by the IRB. When a survey crosses DoD Components, additional review is required.

b. For any DoD-supported investigator, the following must be promptly (within 30 days) reported to the DoD human research protection officer:

(i) When significant changes to the research protocol are approved by the IRB.

(a) The results of the IRB continuing review.

(b) Change of reviewing IRB.

c. When the organization is notified by any Federal department, agency, or national organization that any part of an HRPP is under investigation for cause involving a DoD-supported research protocol.

5 MATERIALS

5.1 SOP: HRP-021 Pre-review

5.2 SOP: HRP-040 IRB Meeting Preparation

5.3 SOP: HRP-045 IRB Member Review Expectations

5.4 SOP: HRP-051 Consultation

5.5 HRP-302 - WORKSHEET - Calculation of Approval Intervals

5.6 HRP-312 - WORKSHEET - Exemption Determination

5.7 HRP-313 - WORKSHEET - Expedited Review

5.8 HRP-314 - WORKSHEET - Criteria for Approval

5.9 HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent

5.10 HRP-402 - CHECKLIST - Non-Committee Review

6 REFERENCES

6.1 45 CFR 46.102; 45 CFR 46.104; 45 CFR 46.110(b)

6.2 21 CFR 56.110(b)

6.3 AAHRPP I.1.A.; I.1.C.; I.3.; II.1.D.; II.1.E.; II.2.A.; II.2.B.; II.2.C.; II.2.E.; II.2.F.; II.3.G.; II.4.; III.1.E.

HRP-040 IRB Meeting Preparation

1 PURPOSE

1.1 This procedure establishes the process to prepare for a convened IRB meeting (held in-person (face to face) or via electronic (virtual/remote/teleconference/videoconference) means).

1.2 The process begins when the agenda is closed, typically, if possible, approximately a week in advance before the meeting date.

1.3 The process ends when IRB meeting agenda materials have been sent or made available to IRB members.

2 POLICY

2.1 At least one IRB member or consultant is responsible for scientific/scholarly review of research.

2.2 Protocols are reviewed by IRB members and consultants with sufficient expertise.

2.3 When IRB members review research that involves vulnerable subjects, at least one individual who is knowledgeable about or experienced in working with such subjects will be present at the meeting.

2.4 IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.

2.5 Alternate IRB members serve the same function as other IRB members, except that if the alternate IRB member and the regular IRB member for whom the alternate member is substituting are both present only one member may vote.

2.6 Review materials are provided to all IRB members in advance of the meeting, providing as much time as possible for member review. Typically, if possible, approximately a week in advance before the meeting date.

2.7 Quorum and representation of membership is the same in person or virtually.

2.8 The regulations 45 CFR 46.111/21 CFR 56.111 will be followed regardless of in-person or virtual meetings.

3 RESPONSIBILITIES

3.1 IRB staff members carry out these procedures.

4 PROCEDURE

4.1 Confirm which IRB members (regular, alternate, and chairs) will be present at the meeting.

4.1.1 For VA Research - At least one (1) VA representative will be present during the review and approval of VA research.

4.1.2 When following DOE requirements:

4.1.2.1 When conducting classified research, the IRB must have a voting quorum of at least five members, which must include both a non-scientist and a non-affiliated/unaffiliated member.

4.1.2.2 The non-affiliated/unaffiliated member must be a non-governmental member with the appropriate security clearances. This individual cannot be a current federal employee or contractor.

4.1.2.3 Any IRB member can appeal a vote to approve research to the Institutional Official, Secretary of Energy, and Director of the Office of Science and Technology, in that order.

4.2 Consult the IRB Roster to be aware of the experience, expertise, and representational capacity of the IRB.

4.3 Review all submissions placed on the agenda for a convened IRB meeting.

4.4 Prepare an agenda for the meeting.

4.4.1 Execute the “Assign Reviewers” activity in the meeting workspace to assign a primary reviewer to each agenda item.

4.4.2 Execute the Assign Reviewers” activity in the meeting workspace to assign a scientific/scholarly reviewer to each initial submission item, who has scientific/scholarly expertise in the area of research. The primary reviewer and scientific/scholarly reviewer may be the same individual.

4.4.3 Execute the Assign Reviewers" activity in the meeting workspace to assign a literacy reviewer to each initial submission item (that includes consent form and materials that will be handed out to the subjects) who has expertise in the area of research.

4.4.4 If the scientific/scholarly reviewer is not an IRB member, determine whether the scientific/scholarly reviewer has a Conflicting Interest as defined in SOP: HRP-001 Definitions. If so, assign another scientific/scholarly reviewer.

4.4.5 Include list of protocols granted approval using the expedited procedure.

4.5 Use HRP-305 - WORKSHEET - Evaluation of Quorum and Expertise to ensure that the meeting will be appropriately convened and to ensure the IRB will have the appropriate expertise for each protocol.

4.5.1 If the meeting will not meet the quorum and expertise requirements, take steps to obtain the required attendance of members and consultants or cancel the meeting.

4.5.2 Follow the procedures in SOP: HRP-051 Consultation to obtain consultants. Note any consultants on the agenda.

4.6 For individuals who are provided materials (IRB members, scientific/scholarly reviewers, consultants):

4.6.1 Execute the "Send Agenda" activity in the meeting workspace to deliver review materials to reviewers.

4.7 Participation from Remote Locations for in-person (face to face) meetings

4.7.1 Members unable to attend an IRB meeting in person may participate via teleconference/videoconference.

4.7.2 Members participating by a remote mechanism will receive and have access to IRB submission materials and will be able to participate in the discussion as if they were physically present.

4.8 Electronic (Remote/Virtual/Videoconference) or Teleconference IRB Meeting

4.8.1 Meetings may be convened via teleconference/videoconference. Meeting calendar invitation for videoconferencing (for e.g. Using Zoom/WebEx platforms) will be sent out to all

IRB members and consultants, by the IRB staff, at least a week in advance of the IRB meeting date to confirm their availability.

4.8.2 Members participating by a remote mechanism will receive and have access to IRB submission materials and will be able to participate in the discussion as if they were physically present.

5 MATERIALS

5.1 IRB Roster

5.2 SOP: HRP-001 Definitions

5.3 SOP: HRP-051 Consultation

5.4 HRP-301 - WORKSHEET - Review Materials

5.5 HRP-305 - WORKSHEET - Evaluation of Quorum and Expertise

5.6 HRP-320 - WORKSHEET - Scientific or Scholarly Review

6 REFERENCES

6.1 45 CFR 46.108(b)

6.2 21 CFR 56.108(b)

6.3 AAHRPP I.1.F.; II.1.A.; II.1.D.; II.1.E.; II.2.C.; II.2.D.; II.2.E.; II.2.F.; II.4.A.

HRP-041 IRB Meeting Conduct

1 PURPOSE

1.1 This procedure establishes the process to conduct convened meetings.

1.2 The process begins when the IRB members gather for a convened meeting held in-person (face to face) or via electronic (virtual/remote/teleconference/videoconference) means.

1.3 The process ends when the meeting is adjourned.

2 POLICY

2.1 The IRB reviews research in accordance with the applicable regulatory criteria for approval.

2.2 The IRB chair votes as a regular member.

2.3 IRB attendance is captured by documenting in the IRB meeting minutes the IRB members and alternates in attendance, replacement of a voting member by an alternate, attendance of IRB members who participate through teleconference/videoconference, and IRB members who are recused due to a conflicting interest.

2.4 If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored, even if more than half of the members are still present.

2.5 Substantive changes or requirements (deferral), requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB.

2.6 Minor or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by the IRB chair or a designated individual.

2.7 The worksheets and checklists described in HRP-301 - WORKSHEET - Review Materials and listed below in “Section 6: MATERIALS” are provided to IRB members in advance of meetings per SOP: HRP-040 IRB Meeting Preparation to conduct meetings and meet regulatory requirements.

2.8 For Veterans Administration (VA) Research “Substantive Changes” are defined as that ineligible for “Modifications Required to Secure Approval” as defined in this SOP.

3 RESPONSIBILITIES

3.1 The IRB chair carries out these procedures, unless otherwise noted.

3.2 Primary reviewers lead IRB members through consideration of the regulatory criteria for approval.

4 PROCEDURE

4.1 Call the meeting to order.

4.2 Ask IRB members whether anyone has a Conflicting Interest in any item on the agenda and note the responses.

4.3 Ask IRB members if there are any questions about the report of completed non-committee reviews that was made available to the IRB prior to the meeting.

4.4 For each agenda item:

4.4.1 Table the item when notified by IRB staff that requirements for review of a specific item as defined in HRP-305 - WORKSHEET - Evaluation of Quorum and Expertise are not met.

4.4.2 If there are IRB members with a Conflicting Interest, invite the IRB to ask questions of those members and then ask those members to leave for discussion and voting or if present by teleconference/videoconference, be placed on hold or disconnect for discussion and voting.

4.4.2.1 For Veterans Administration (VA) research, members with a Conflicting Interest present by teleconference/videoconference are to disconnect for discussion and voting.

4.5 Participation from Remote Locations for in-person (face to face) meetings

4.5.1 Members unable to attend an IRB meeting in person may participate via teleconference/videoconference. They may vote and be counted towards the quorum.

4.5.2 Members participating by a remote mechanism will receive and have access to IRB submission materials and will be able to participate in the discussion as if they were physically present.

4.5.3 The meeting minutes will indicate which members attended via an alternate mechanism (e.g., teleconference/videoconference).

4.6 Electronic (Remote/Virtual/Videoconference) or Teleconference IRB Meeting

4.6.1 To allow for appropriate discussion, all members must be connected simultaneously for a conference call to take place. All members must be able to hear one another to allow for discussion.

4.6.2 Members participating will receive and have access to IRB submission materials and will be able to participate in the discussion as if they were physically present.

4.6.3 Members not present at the convened meeting, nor participating in the conference call may not vote and be counted towards the quorum. Voting by proxy is not permitted.

4.7 For each agenda item involving the initial review, modification, or continuing review of a protocol:

4.7.1 If there is a consultant present, ask the consultant to present his or her review to the IRB.

4.7.2 If a consultant provided written information to the IRB, ask the primary reviewer to present that information to the IRB.

4.7.3 Ask the scientific or scholarly reviewer or primary reviewer to present the scientific or scholarly review to the IRB.

4.7.4 Ask the primary reviewer to lead the IRB through a discussion of the criteria in the HRP-314 - WORKSHEET - Criteria for Approval and all referenced checklists (listed below) to have the convened IRB determine which regulatory criteria are met (or continue to be met), which are not met (or no longer met), and which would be met if the investigator modified the protocol as requested by the IRB.

4.7.4.1 Criteria for IRB Approval of Research: For the IRB to approve human subjects' research at the time of Initial and Continuing Review, it must determine that the following requirements are satisfied:

4.7.4.1.1 Risks to subjects are minimized: a) by using procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

4.7.4.1.2 Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) among those research risks that fall within the purview of its responsibility.

4.7.4.1.3 Selection of subjects is equitable. In making this assessment, the IRB should consider the purposes of the research, the setting in which the research will be conducted, and special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4.7.4.1.4 Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

4.7.4.1.5 Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

4.7.4.1.6 When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

4.7.4.1.7 When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

4.7.4.1.8 When some or all the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

4.7.4.1.9 The IRB must ensure that steps to manage, reduce, or eliminate potential or real conflicts of interest (financial, role (investigator/patient relationship), and or institutional) have been taken. All VA investigators must comply with VHA policies and procedures regarding conflict of interest. Specifically, a member with a conflict of interest cannot: (a)

contribute to quorum; (b) be present for the discussion of the issue for which they are conflicted, except to answer questions from the committee; or (c) be present for the vote on the issue. Also, concerning disclosing conflicts of interests, this means disclosing to the IRB any potential, actual, or perceived conflict of interest of a financial, professional, or personal nature that may affect any aspect of the research, and complying with all applicable VA and other Federal requirements regarding conflict of interest.

4.7.4.1.10 The IRB must determine that the PI and all other investigators of the proposed research activity have met all current educational requirements for the protection of human research subjects as mandated by the facility's Assurance, VA Office of Research and Development, funding institutions, and applicable OHRP requirements. The IRB must also determine that the investigator(s) is qualified through education, training, and experience to conduct the research.

4.7.4.1.11 For the IRB to approve human subjects research conducted or supported by the DoD, the IRB must determine that the following criteria are met:

1. Investigator and research staff are aware of the specific requirements of research under the addendum of the DoD and have been educated on these requirements.

2. The research does not involve prisoners of war as subjects. This includes any person captured, detained, held, or otherwise under the control of personnel of the DoD (military and civilian, or contractor employee). Such persons include: Enemy Prisoners, Civilian Internees, Retained Persons, and Lawful and Unlawful Enemy Consultants. Such persons do not include personnel of the DoD being held for law enforcement purposes.

3. Military personnel will not be provided payment for research conducted during duty hours.

4. If research involves interventions or interactions with subjects, the research does not involve a waiver of consent or parental permission unless a waiver is obtained from the Secretary of Defense.

5. If the research involves cognitively impaired adults, there is anticipated direct benefit to the subject.

6. For research involving more than minimal risk to subject confirm the following:

1) an independent medical monitor has been appointed by name,

2) the medical monitor is a physician, dentist, psychologist, nurse or other healthcare provider capable of overseeing the progress of the research protocol, especially issues of individual subject/patient management and safety

3) the medical monitor is independent of the investigative team

4) the medical monitor possessed sufficient education and professional experience to serve as the subject advocate

5) the medical monitor has the authority to stop a research study in progress, remove individual subjects from a study, and take whatever steps are necessary to protect the safety and well-being of research subjects until the IRB can assess the medical monitor's report.

7. For research involving more than minimal risk and involving military personnel

1) unit officers and non-commissioned officers will not influence the decisions of their subordinates to participate or not to participate as research subjects

2) unit officers and senior non-commissioned officers in the chain of command will not be present at the time of research subject solicitation and consent during any research recruitment sessions in which members of units under their command are afforded the opportunity to participate as research subjects

3) when applicable, officers and non-commissioned so excluded will be afforded the opportunity to participate as research subjects in a separate recruitment session and 4) during recruitment briefings to a unit where a percentage of the unit is being recruited to participate as a group, an ombudsman not connected in any way with the proposed research of the unit will be present to monitor that the voluntary nature of individual subjects is adequately stressed and the information provided about the research is adequate and accurate.

8. The disclosure regarding provisions for research-related injury follows the requirements of the DoD component.

9. When conducting multi-site research, a formal agreement is required to specify the roles and responsibilities of each party including a Statement of Work (SOW) and specific assignment of responsibilities.

10. If the research involves Human Subjects who are not U.S. Citizens or personnel of the DoD, and is conducted outside the United States, and its territories and possessions: the permission of the host country has been obtained, the laws, customs, and practices of the host country and the United States will be followed, and an ethics review by the host country, or local Naval IRB with host country representation, will take place.

4.7.4.2 Risk/Benefit Assessment

4.7.4.2.1 At the time of initial and continuing review, the IRB will make a determination regarding the risks associated with the research proposals. Risks associated with the research will be classified as either minimal or greater than minimal based on the absolute interpretation of minimal risk. The meeting minutes will reflect the Committee's determination regarding risk levels.

4.7.4.2.2 The goal of the assessment is to ensure that the risks to research subjects posed by participation in the research are justified by the anticipated benefits to the subjects or society. The IRB must:

1. Judge whether the anticipated benefit, either of new knowledge or of improved health for the research subjects, justifies asking any person to undertake the risks;

2. Disapprove research in which the risks are judged unreasonable in relation to the anticipated benefits.

4.7.4.2.3 The assessment of the risks and benefits of proposed research - one of the major responsibilities of the IRB - involves a series of steps:

1. Identify the risks associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in research

2. Determine whether the risks will be minimized to the extent possible; This can be done, for example by using procedures which are consistent with sound Research design and which do not unnecessarily expose subjects to risk. This also can be accomplished, as appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes

3. Identify the probable benefits to be derived from the research

4. Determine whether the risks are reasonable in relation to the benefits to subjects, if any, and assess the importance of the knowledge to be gained; In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the Research, as distinguished from risks and benefits of therapies subjects would receive even if not participating in the Research. The IRB should not consider possible long-range effects of applying knowledge gained in the Research (e.g., the possible effects of the Research on public policy) as among those Research risks that fall within the purview of its responsibility

5. Ensure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits

4.7.4.2.4 Based on this assessment, risk associated with the research will be classified as either Minimal Risk or Greater than Minimal Risk

4.7.4.3 Scientific Merit: To assess the risks and benefits of the proposed research, the IRB examines the research plan, including research design and methodology, to determine that there are no inherent flaws that would place research subjects at unnecessary risk.

1. The research uses procedures consistent with sound research design including an adequate data monitoring plan or protecting confidentiality by using coded data.

2. The research is not lacking in statistical power such that meaningful results cannot be obtained.

3. The research design is sound enough to reasonably expect the research to answer its proposed question; and

4. The knowledge expected to result from this research is sufficiently important to justify the risk.

5. The review of scientific validity must determine the available nonclinical and clinical information on an investigational product is adequate to support the proposed trial. Selection of subjects is equitable: By viewing the IRB proposal, the IRB will determine that the selection of subjects is equitable with respect to gender, age, class, etc. The IRB will not approve a study that does not provide adequately for the equitable selection of subjects or has not provided an appropriate scientific and ethical justification for excluding classes of persons who might benefit from the research. In making this determination, the IRB evaluates: the purposes of the research; the setting in which the research occurs; scientific and ethical justification for including vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons; the scientific and ethical justification for excluding classes of persons who might benefit from the research; and the inclusion/exclusion criteria. At the time of the continuing review the IRB will determine that the PI has followed the subject selection criteria that he/she/originally set forth at the time of the initial IRB review and approval.

4.7.4.3.1 In making this determination, the IRB may draw on its own knowledge and disciplinary expertise, or the IRB may draw on the knowledge and disciplinary expertise of others, such as reviews by a funding agency, or Department Chair/Section review.

4.7.4.3.2 When following DoD regulations, substantive amendments to approved research submitted to the IRB, must undergo scientific review prior to IRB review or be conducted by the IRB. Scientific review by the Department Chair is documented by the signature of the Department Chair responsible for the investigator's research on new protocol applications. The IRB may rely on outside experts to provide an evaluation of the scientific merit.

4.7.4.3.3 When a Department Chair is the PI for a research proposal the Departmental review is forwarded to the Department Chair's superior for review and approval.

4.7.4.3.4 Recruitment of Subjects

4.7.4.3.4.1 The investigator will provide the IRB with all recruiting materials to be used in identifying subjects including recruitment methods, advertisements, and payment arrangements.

1. The potential research subject may initiate the contact by responding to an IRB-approved advertisement or similar recruitment notice.

2. A treating physician who is also an investigator may talk directly to the patient about recruitment into a research trial.

3. If the treating physician is not the investigator, the treating physician must get an authorization to refer the patient to the investigator. The investigator may then rely on the authorization to contact the individual. The investigator will then obtain an additional authorization from the patient to participate in the research.

4. An investigator may contact potential research subjects if granted a partial waiver of authorization for recruitment purposes from the IRB/Privacy Board. Investigators outside the covered entity may use this option. The Privacy Rule requirements and conditions for a waiver apply.

4.7.4.3.4.2 An Investigator may contact potential research subjects for recruitment purposes using the following methods:

4.7.4.3.4.3 An investigator who is not a part of the covered entity may not use the preparatory research provision to contact prospective research subjects. However, the preparatory research provision of the HIPAA Privacy Rule at 45 CFR 164.512(i)(1)(ii) allows an investigator who is not a part of the covered entity to obtain contact information through a Partial Waiver of Authorization. Use HRP-502.3 - TEMPLATE - LSU Partial Waiver of Authorization for Recruitment .

4.7.4.3.4.4 The Partial Waiver must be approved the IRB or Privacy Board as permitted at 45 CFR 164.512(i)(1)(i). The IRB or Privacy Board waiver of authorization permits the partial waiver of authorization for the purposes of allowing an investigator to obtain protected health information (PHI) as necessary to recruit potential research subjects. For example, even if an IRB does not waive informed consent and individual authorization for the study itself, it may waive such authorization to permit the disclosure of protected health information as necessary for the investigator to be able to contact and recruit individuals into the study. The investigator must submit the research protocol and include the recruitment plan for IRB review and approval to obtain approval of the Partial Waiver of Authorization.

4.7.4.4 Informed Consent

4.7.4.4.1 Unless waived by the IRB, legally effective informed consent must be obtained from subjects or their LARs as a condition for protocol approval. All relevant requirements in OHRP in 45 CFR 46.111 and 46.116, and in the FDA regulations in 21 CFR 50.20, 50.25, 50.27 and 56.111 that are applicable to the consent

process and the consent document must be satisfied. The IRB may require revisions to the consent document prior to protocol approval.

4.7.4.4.2 To approve research, the IRB must determine that informed consent will be appropriately documented, unless the IRB waives documentation under OHRP or FDA regulations. If a subject lacks the capacity to consent, then consent for research must be obtained from their LAR.

4.7.4.4.3 Consent is documented through use of a written consent document signed and dated by the subject or their legally authorized representative that embodies all of the required eight basic required elements and the six additional elements specified in 45 CFR 46.116 and 21 CFR 50.25.

4.7.4.4.4 Only the IRB approved informed consent document may be used, and unless the requirement is waived by the IRB the document must be signed by the subject (or the subject's LAR), and a copy must be given to the person signing the form. FDA regulations and institutional policy requires that the signature be dated.

4.7.4.4.5 A copy of the informed consent must be placed on the LSUHSC-S patient medical record along with the HIPAA authorization form. The original document remains with the investigator. The evaluation of compliance is achieved by:

1. IRB review of the informed consent process information and document(s) provided by the investigator.

2. Periodic consent form audits comparing signed and dated consent forms with the IRB approved versions.

3. Observation of the consent process, performed either as a periodic audit function of the HRPP, or as requested by the convened IRB

4.7.4.5 Data and Safety Monitoring

4.7.4.5.1 All interventional studies involving more than Minimal Risk must include a Data and Safety Monitoring Plan. A DSMP is established to assure that each research study has a system for appropriate oversight and monitoring of the conduct of the study to ensure the safety of subjects and the validity and integrity of the data. The DSMP should specify whether there will be an independent Data and Safety Monitoring Board (DSMB). The primary purpose of an independent DSMB is to protect the research subjects through independent analysis of emerging data from the trial. This differs from adverse event reporting in that the DSMB can review aggregate and un-blinded data as the data accumulate, identify significant issues and trends during the study, and

recommend changes in the study including recommending early termination of the study. The DSMB reviews data for both safety and efficacy. The protections afforded by this review apply to both current subjects and future subjects if the DSMB identifies the need to modify or even halt the trial. In addition to the above, an independent DSMB protects the credibility of the trial by virtue of its independence from the study sponsors and helps to ensure the validity of study results by reviewing data on subject accrual and conducting interim reviews. Independent DSMBs are Required in the Following Situations:

4.7.4.5.1.1 All Phase III studies require a DSMB, except for most minimal risk studies.

4.7.4.5.1.2 The involvement of a DSMB may still be requested for minimal risk studies if the studies are exceptionally large, long term, and/or involve particularly vulnerable study subjects.

4.7.4.5.1.3 Phase II clinical trials which are multicenter and randomized require a DSMB, except for most minimal risk studies.

4.7.4.5.1.4 Phase II studies which are high risk require a DSMB.

4.7.4.5.1.5 High-risk refers to trials or interventions associated with substantial side effects to subjects (e.g., side effects that could result in serious morbidity or death, or are irreversible), trials of diseases associated with high mortality or morbidity, and trials of highly experimental therapies (e.g., gene therapy).

4.7.4.5.1.6 In general, DSMBs are required for clinical trials of diseases with high mortality or morbidity, for clinical trials involving high risks, and for large, multicenter clinical trials.

4.7.4.5.1.7 Single-center, open-label, Phase I and II clinical trials may not need an independent DSMB providing the local investigator/sponsor maintains access to all data and can demonstrate the ability to provide sufficient oversight. (However, investigator initiated single-center open-label Phase I and II clinical trials require an adequate Data and Safety Monitoring Plan). Information that must be included in Data Safety Monitoring Plan:

4.7.4.5.1.8 Composition: Describe who will monitor the safety of the data and their expertise. This may include individuals with expertise in biostatistics, bioethics clinical trials, and the disease and treatment being studied.

4.7.4.5.1.9 Independence: When a DSMB is required, the investigator must confirm that the DSMB members are independent of the study sponsor and will not participate in the study as investigators, nor will they have conflicts of interest regarding the study, the study sponsor, or any study drugs or devices being tested.

4.7.4.5.1.10 Data: A description of the data that will be reviewed, e.g., data for primary or secondary endpoints (safety and efficacy), data for early termination of trial (stopping rules), adverse events or unanticipated problems.

4.7.4.5.1.11 Frequency of Review: Description of how often the data will be reviewed, whether based on the calendar or accrual targets. If formal interim analyses are planned, description of when they will occur. If a DSMB is required, how often will it meet?

4.7.4.5.1.12 Authority: When a DSMB is required, a description of the actions the DSMB is authorized to take must be included. DSMBs should have authority to recommend changes in the study, including discontinuation, if significant trends in safety or efficacy are identified earlier than expected. Additional Requirements of a Data Safety Monitoring Plan:

4.7.4.5.1.13 Data Safety Monitoring Reports are required to be submitted to the IRB, promptly.

4.7.4.5.1.14 The IRB may require the appointment of an independent medical monitor where appropriate. It is not the role of the IRB to perform data monitoring, but to ensure that appropriate monitoring is taking place, and to review reports from the monitoring entities.

4.7.4.6 Privacy and Confidentiality: The IRB will determine whether adequate procedures are in place to protect the privacy of subjects and to maintain the confidentiality of the data.

4.7.4.6.1 Privacy: The IRB must determine whether the activities in the research constitute an invasion of privacy. To make that determination, the IRB must obtain information regarding how the investigators are getting access to subjects or subjects' private, identifiable information and the subjects' expectations of privacy in the situation. Investigators must have appropriate authorization to access the subjects' information.

4.7.4.6.1.1 In developing strategies for the protection of subjects' privacy, consideration should be given to:

1. Methods used to identify and contact potential subjects.

2. Settings in which an individual will be interacting with an investigator

3. Appropriateness of all personnel present for research activities

4. Methods used to obtain information about subjects and the nature of the requested information

5. Information that is obtained about individuals other than the target subjects, and whether such individuals meet the regulatory definition of human subject (e.g., a subject provides information about a family member for a survey)

6. How to access the minimum amount of information necessary to complete the study.

4.7.4.6.2 Confidentiality: Confidentiality and anonymity are not the same. If anyone, including the investigator, can readily ascertain the identity of the subjects from the data, then the research is not anonymous, and the IRB must determine if appropriate protections are in place to minimize the likelihood that the information will be inappropriately divulged. The level of confidentiality protections should be commensurate with the potential of harm from inappropriate disclosure. At the time of initial review, the IRB ensures that the privacy and confidentiality of research subjects is protected. The IRB assesses whether there are adequate provisions to protect subject privacy and maintain confidentiality. The IRB does this through the evaluation of the methods used to obtain information:

A. About subjects

B. About individuals who may be recruited to participate in studies

C. The use of personally identifiable records and

D. The methods to protect the confidentiality of research data The PI will provide the information regarding the privacy and confidentiality of research subjects at the time of initial review through the completion of the IRB proposal, HIPAA Form, and/or other submitted, applicable materials. The IRB will review all information received from the PI and determine whether the privacy and confidentiality of research subjects is sufficiently protected. In some cases, the IRB may also require that

a Certificate of Confidentiality be obtained to additionally protect research data.

4.7.4.6.3 In reviewing confidentiality protections, the IRB shall consider the nature, probability, and magnitude of harm that would be likely to result from a disclosure of collected information outside the research. It shall evaluate the effectiveness of proposed de-identification techniques, coding systems, encryption methods, storage facilities, access limitations, and other relevant factors in determining the adequacy of confidentiality protections.

4.7.4.7 Vulnerable Populations

4.7.4.7.1 At the time of initial review, the IRB will consider the scientific and ethical reasons for including vulnerable subjects in research. To approve research involving vulnerable populations, the IRB must determine, where appropriate, that additional safeguards have been included to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence, such as:

- Children (45 CFR 46 Subpart D; 21 CFR 50 Subpart D)
- Prisoners (45 CFR 46 Subpart C)
- Pregnant women, human fetuses, or neonates (45 CFR 46 Subpart B)
- Persons with mental disabilities, cognitively impaired, economically, or educationally disadvantaged persons Additional requirements might apply, depending on the source of support/funding (e.g., DoD or other Federal Agencies).

4.7.5 Restate the IRB's consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.

4.7.6 Make a motion for one of the following actions:

4.7.6.1 Approve (with a specific continuing review interval for initial or continuing review when applicable): Made when all criteria for approval are met. Include in motions for initial and continuing review the period of approval and the level of risk.

4.7.6.2 Modifications Required to Secure Approval (with a specific continuing review interval for initial or continuing review when applicable): Made when IRB members require specific modifications such that an IRB staff member can determine whether

an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval. When making this motion, the assigned primary reviewer restates the modifications required by the IRB members and the IRB member's reasons for those changes

4.7.6.3 Defer: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision and describes recommendations to make the research approvable.

4.7.6.4 Disapprove: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has no recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision.

4.7.6.5 Suspension or Termination: Made when current approved research does not qualify for Approval or Modifications Required to Secure Approval. When making this motion, have the primary reviewer use the HRP-321 - WORKSHEET - Review of Information Items to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects. The assigned primary reviewer describes the IRB member's reasons for the decision.

4.8 Review any deferral reasons to ensure that the IRB staff has recorded them.

4.9 Review any modifications required to secure approval to ensure that the IRB staff has recorded them.

4.9.1 Ensure that the required modifications include all final contingencies in the Pre-Review activity.

4.9.2 For a pending financial interest review indicate that a determination that the financial interest is not a conflict of interest or has been eliminated can be verified by the IRB staff, but if there is a management plan, it must return to the convened IRB for review.

4.10 For each agenda item that is new information (Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, or Terminations of IRB Approval):

4.10.1 Have the primary reviewer use the HRP-321 - WORKSHEET - Review of Information Items to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.

4.10.2 Restate the IRB's consensus regarding any actions that need to be taken to protect subjects.

4.10.3 Make a motion for the IRB's determination(s) regarding the action items (e.g. the motion is for the Principal Investigator to provide the IRB additional information regarding the status of currently enrolled subjects).

4.10.4 Open the floor for additional discussion.

4.10.5 Call for a vote.

4.10.5.1 Only IRB members may vote.

4.10.5.2 If a member and an alternate are both present, only one may vote.

4.10.5.3 Consultants may not vote.

4.10.5.4 For a motion to be approved, it needs the approval of more than half of the members present at the meeting. (If there are 10 or 11 members present at the meeting, 6 votes are required for approval, which is greater than 5 and 5.5, respectively.)

4.10.6 Re-invite IRB members with a Conflicting Interest back into the meeting.

4.10.7 Provide any written information provided by a member or consultant to the IRB staff.

4.11 Adjourn the meeting when notified by IRB staff that quorum has been lost or when there is no further business.

5 MATERIALS

5.1 SOP: HRP-040 IRB Meeting Preparation

5.2 HRP-301 - WORKSHEET - Review Materials

5.3 HRP-305 - WORKSHEET - Evaluation of Quorum and Expertise

5.4 HRP-308 - WORKSHEET - Pre-Review

5.5 HRP-314 - WORKSHEET - Criteria for Approval

5.6 HRP-315 - WORKSHEET - Advertisements

5.7 HRP-316 - WORKSHEET - Payments

5.8 HRP-317 - WORKSHEET - Short Form of Consent Documentation

5.9 HRP-318 - WORKSHEET - Additional Federal Agency Criteria

5.10 HRP-320 - WORKSHEET - Scientific or Scholarly Review

5.11 HRP-321 - WORKSHEET - Review of Information Items

5.12 HRP-323 - WORKSHEET - Criteria for Approval and Additional Considerations HUD

5.13 HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process

5.14 HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent

5.15 HRP-412 - CHECKLIST - Pregnant Women

5.16 HRP-413 - CHECKLIST - Non-Viable Neonates

5.17 HRP-414 - CHECKLIST - Neonates of Uncertain Viability

5.18 HRP-415 - CHECKLIST – Prisoners

5.19 HRP-416 - CHECKLIST – Children

5.20 HRP-417 - CHECKLIST - Cognitively Impaired Adults

5.21 HRP-418 - CHECKLIST - Non-Significant Risk Device

5.22 HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research

5.23 HRP-502.3 - TEMPLATE - LSU Partial Waiver of Authorization for Recruitment

6 REFERENCES

6.1 45 CFR 46.109; 45 CFR 46.116; 45 CFR 46.117

6.2 21 CFR 50.20; 21 CFR 50.25; 21 CFR 50.27; 21 CFR 56.109; 21 CFR 56.111

6.3 AAHRPP I.1.C.; I.1.E.; I.3.; I.7.A.; II.1.D.; II.1.E.; II.2.C.; II.2.D.; II.2.E.; II.2.F.; II.2.G.; II.2.H.; II.3.A.; II.3.B.; II.3.C.; II.3.D.; II.3.E.; II.3.F.; II.3.G.; II.4.A.; II.4.B.; III.1.E.;

HRP-042 IRB Meeting Attendance Monitoring

1 PURPOSE

1.1 This procedure establishes the process to monitor quorum at convened IRB meetings.

1.2 The process begins when the IRB staff member responsible for monitoring quorum notifies the IRB chair that quorum has been attained.

1.3 The process ends when the meeting is adjourned.

2 POLICY

2.1 IRB members should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, they should inform the IRB Chair, Vice-Chair, or an IRB staff member prior to the scheduled meeting. In the case of an emergency, members should notify the IRB as soon as possible. If the inability to attend will be prolonged, a request for an alternate to be assigned should be submitted to the IRB Chair or IRB Director.

3 RESPONSIBILITIES

3.1 IRB staff members carry out these procedures.

4 PROCEDURE

4.1 At meetings consult the HRP-305 - WORKSHEET - Evaluation of Quorum and Expertise to determine that the meeting is appropriately convened by meeting the quorum requirements and notify the IRB chair when the meeting is appropriately convened.

4.2 Before each protocol consult the HRP-305 - WORKSHEET - Evaluation of Quorum and Expertise to determine that the meeting is appropriately convened by meeting the “EXPERTISE REQUIREMENTS” and notify the IRB chair when the meeting is not appropriately constituted for the review of that protocol.

4.3 When a member leaves the meeting room for any reason (including a Conflicting Interest) consult the HRP-305 - WORKSHEET - Evaluation of Quorum and Expertise to determine that the meeting continues to be appropriately convened by meeting the quorum requirements and notify the IRB chair when the meeting is not appropriately convened.

4.4 An IRB member may also join the meeting via teleconference/videoconference to present their review if there is a circumstance precluding their attendance at the meeting.

5 MATERIALS

5.1 HRP-305 - WORKSHEET - Evaluation of Quorum and Expertise

6 REFERENCES

6.1 45 CFR 46.108(b)

6.2 21 CFR 56.108(c)

6.3 AAHRPP I.3.; II.1.; II.2.D.; II.2.E.;

HRP-043 IRB Meeting Minutes

1 PURPOSE

1.1 This procedure establishes the process to record minutes for convened meetings.

1.2 The process begins when the meeting is called to order.

1.3 The process ends when the minutes are approved by the IRB chair.

2 POLICY

2.1 Minutes are to comply with regulatory and guidance requirements.

2.2 Minutes are to record separate deliberations for each action.

2.3 Minutes are officially approved on behalf of the IRB by the IRB chair or Vice Chair when the IRB Chair is absent.

2.4 IRB members may make corrections to minutes.

2.5 The IRB writes minutes and makes them available for review within 21 days of the meeting date.

2.6 Minutes may not be altered by anyone including a higher authority once accepted by the convened IRB.

3 RESPONSIBILITIES

3.1 IRB staff members carry out these procedures.

4 PROCEDURE

4.1 Execute the “Convene Meeting” activity.

4.2 The IRB Chair conducts the meeting with the IRB Staff. IRB staff makes notes of all the items discussed during the meeting.

4.3 Execute the “Close Meeting” activity.

4.4 Use HRP-501 - TEMPLATE MINUTES, to create minutes document.

4.5 Record each voting member (regular members and alternates) present at the meeting at any time: (Do not record non-voting members under “Attendance Table.”)

4.5.1 Name.

4.5.2 Status: E.g., chair, vice chair, scientific member, non-scientific member, non-affiliated/unaffiliated member, representative of vulnerable population (specify), prisoner representative, VA representative, or alternate member.

4.5.3 For alternate members who are substituting for a regular member, indicate the name of the regular member for whom the alternate member is substituting.

4.5.4 Whether the member was present by teleconference/videoconference.

4.6 If a consultant is present at the convened meeting, record the name of the consultant, and a brief description of the consultant’s expertise, and documentation that the consultant did not vote with the IRB on the study.

4.7 Record the names of non-members and guests, such as IRB support staff, investigators, and study coordinators.

4.8 When an alternate member replaces a primary member, including the name of the alternate member.

4.9 Record the names of IRB members who leave the meeting because of a conflict of interest along with the fact that a conflict of interest is the reason for the absence.

4.10 Record the total number of members on “IRB Roster.” Exclude alternate members in this count.

4.11 Record the number of members required for quorum. Divide the number of members by two and select the next whole number. For example, if there are 10 IRB members on the “IRB Roster,” then 10/2 = 5 and the next whole number is 6. If there 11 IRB members on the “IRB Roster,” then 11/2=5.5 and the next whole number is 6.

4.12 Indicate whether members present by teleconference/videoconference received all pertinent material before the meeting and were able to participate in all discussions actively and equally. Delete if no members were present by teleconference/videoconference.

4.13 Record the meeting start time.

4.14 For each submission reviewed record in the "Submit Committee Review" activity or "Submit RNI Committee Review" activity, as appropriate:

4.14.1 Motion: Approved, Approved with Modifications, Deferred, Disapproved, Suspended, or Terminated. For initial or continuing review add the period of approval to the motion.

4.14.1.1 Discussions and Actions Taken by the IRB : Discussions and actions taken by the IRB, and the separate deliberations and basis for each action are documented in the minutes, such as:

- Discussion of protocol events — initial, continuing review, modifications, reports of unanticipated problems and events and reportable new information requiring prompt review
- Approval of research — including the approval period for research, at initial and 168 continuing review, (and if appropriate to the degree of risk determination of an approval period of less than one (1) year)
- Any modifications in the research that the IRB requires before the research can secure approval
- Suspensions and terminations of previously approved research
- Disapproval of research
- Discussion of controverted issues and their resolution or disposition
- Requests for consultant review or input from an expert in the field (e.g. requests made during a convened meeting)
- Actions resulting from review of reports of unanticipated problems involving risks to subjects or others, or other reportable events and information
- Actions resulting from determinations of serious or continuing non-compliance

- Identification of any research for which there is need for verification from sources other than the investigator that no material changes are made in the research (e.g., Cooperative Studies, or other collaborative research)

  - That the current consent document is still accurate and complete.

  - That any significant new findings that arise from the review process and that might relate to subjects' willingness to continue participation will be provided to subjects.

- If a protocol is using a DHHS-approved sample consent: The justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample consent document

4.14.2 Risk Level: Minimal Risk or more than Minimal Risk.

4.14.3 Last Day of Approval Period: Record the study expiration date.

4.14.4 Recommended Changes and Reasons: If the motion is Modifications required to secure approval or deferral/disapproval, complete the table with the required changes and corresponding reasons. If no recommended changes, indicate "None"

4.14.5 Controverted Issues and their Resolutions: Summarize the issues where IRB members expressed a difference of opinion. For each issue indicate the resolution or indicate that there was None If no controverted issues, indicate "None"

4.14.6 Determinations and findings that require documentation: If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, neonates, Prisoners, or cognitively impaired adults, enter "See attached Supporting Documents" and ensure that the corresponding completed checklist is uploaded as a supporting document. If no determinations that require documentation, indicate "None".

4.14.7 RNI Determinations: Record the determination of unanticipated problem involving risks to subjects or others, suspension or termination of IRB approval, serious non-compliance, continuing non-compliance, non-compliance that is neither serious nor continuing, allegation of non-compliance with no basis in fact, or none of the above.

4.14.8 RNI Considerations: Record requirements determined by the IRB, for example modification to the protocol or ask subjects to re-consent.

4.14.9 Additional Information and Notes: Summarize issues useful to understand the agenda item. For example, a brief history of recent IRB actions

4.14.10 Supporting documents: For any determinations that require documentation, upload the appropriate checklist(s), or any other appropriate supporting documents.

4.14.11 Vote: Record as the number of members for, against, abstaining, absent, or recused. List the names of IRB members who were absent or recused. Do not count votes of consultants. If both a regular IRB member and the alternate IRB member are present at the meeting record the vote of just one.

4.14.11.1 For: Voting for the motion.

4.14.11.2 Against: Voting against the motion.

4.14.11.3 Abstain: Present for the vote, but not voting “For” or “Against.”

4.14.11.4 Absent: Listed under “Members Present” but not present for the discussion and vote, on this protocol for reasons other than a Conflicting Interest. List the names of absent members in the vote. For example: “For: 7 Against: 3 Abstain: 2 Absent: 2 (Alice Baker, Charlie Delta) Recused: 0 Substitutions: 0”

4.14.11.5 Recused: Listed under “Members Present” but not present for the discussion and vote on this protocol for because of a Conflicting Interest. List the names of recused members in the vote. For example: “For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 2 (Evelyn Foxtrot, George India) Substitutions: 0”

4.14.11.6 Substitutions: Listed under “Members Present” When regular members and their alternate(s) are listed under “Members Present” and an alternate member substitute for the regulator member, identify the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions. For example: “For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 0 Substitutions: 1 (Evelyn Foxtrot substituted for George India)”.

4.14.12 For Veterans Administration (VA) research that involves an Unanticipated Problem Involving Risks to Subjects or Others, complete and attach HRP-611 - Template - VA Minutes Supplement.

4.14.13 For an Unanticipated Problem Involving Risks to Subjects or Others, in the “Submit RNI Committee Review,” document the IRB’s determination as to whether a protocol or consent document modification is warranted, and if so, document the IRB’s determination as

to whether previously enrolled subjects must be notified of the modification and, if so, when such notification must take place and how such notification must be documented.

4.15 When following FDA regulations or guidance: Document the rationale for significant risk/non-significant risk device determinations.

4.16 When following DHHS regulations: Document the rationale for conducting continuing review on research that otherwise would not require continuing review.

4.17 When following VA requirements:

4.17.1 Research involving stem cells shall be governed by the policy set by NIH.

4.17.2 Research involving the provision of in vitro fertilization services is not allowed.

4.17.3 Research in which the focus is either fetus, human fetal tissue, in-utero, or ex-utero, is not allowed.

4.17.4 Interventional research involving neonates is not allowed. Prospective observational or retrospective record review studies that involve neonates or neonatal outcomes are permitted.

4.17.5 Research involving pregnant women as subjects is not allowed unless the IRB determines the requirements in 45 CRR 46.204 are met, and the facility director certifies the facility has sufficient expertise in women's health to conduct the proposed research.

4.17.6 Research involving prisoners as subjects is not allowed unless a waiver has been granted by the chief research and development officer.

4.17.7 Research involving children as subjects is not allowed unless a waiver has been granted by the facility director. Research involving children may not pose greater than minimal risk to the child.

4.17.8 Biological specimens and data obtained from children is considered research involving children even if de-identified.

4.17.9 International research is not initiated unless permission is obtained from the facility director.

4.17.10 Research involving adults who are unable to consent may occur only when the IRB determines the proposed research:

4.17.10.1 Does not present greater than minimal risk, or

4.17.10.2 Presents a greater probability of direct benefit to the subject than harm to the subject, or

4.17.10.3 Poses greater than minimal risk and no prospect of direct benefit to individual subjects but is likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance to understanding or amelioration of the subject's disorder or condition.

4.17.10.4 In addition, the IRB determines the research cannot be performed solely on adults who can consent, and the focus of the research is the disorder leading to the lack of decision-making capacity, or

4.17.10.5 Where the subject of the research is not directly related to the subject's lack of decision-making capacity, the investigator has presented a compelling reason for including adults unable to consent.

4.18 When following DoD requirements:

4.18.1 Research involving pregnant women, prisoners, and children are subject to the DHHS Subparts B, C and D.

4.18.2 For purposes of applying Subpart B, the phrase "biomedical knowledge" must be replaced with "generalizable knowledge."

4.18.3 The applicability of Subpart B is limited to research involving pregnant women as subjects in research that is more than minimal risk and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as subjects.

4.18.4 Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.

4.18.5 Research involving prisoners cannot be reviewed by the expedited procedure.

4.18.6 When the IRB reviews research involving prisoners, at least one prisoner representative must be present for quorum. The prisoner representative may be a prisoner, an employee of the prison, or an individual not affiliated with the prison.

4.18.7 In addition to allowable categories of research on prisoners in Subpart C, epidemiological research is also allowable when:

4.18.8 The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.

4.18.9 The research presents no more than minimal risk.

4.18.10 The research presents no more than an inconvenience to the subject.

4.18.11 When a previously enrolled human subject becomes a prisoner, if the investigator asserts to the IRB that it is in the best interest of the prisoner-subject to continue to participate in the research while a prisoner, the IRB chair may determine that the prisoner-subject may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the organizational official and DoD Component office review the IRB's approval to change the research protocol. Otherwise, the IRB chair must require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol.

4.18.12 The convened IRB, upon receipt of notification that a previously enrolled human subject has become a prisoner, must promptly re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy. The IRB should consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative. If the prisoner-subject can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the prisoner-subject's confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human subjects from continuing as approved, the convened IRB may approve a change in the study to allow this prisoner-subject to continue to participate in the research. This approval is limited to the individual prisoner-subject and does not allow recruitment of prisoners as subjects.

4.18.13 Research involving a detainee as a human subject is prohibited. This prohibition does not apply to research involving investigational drugs and devices when the same products would be offered to US military personnel in the same location for the same condition.

4.18.14 The exemption for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

4.18.15 Policies and procedures prohibit research involving prisoners of war.

4.18.16 The IRB is aware of the definition of "prisoner of war" for the DoD component granting the addendum.

4.19 When following the ICH-GCP (E6) guideline:

4.19.1 When adults are unable to consent, the IRB must determine:

4.19.2 A non-therapeutic clinical trial (i.e., a trial in which there is no anticipated direct clinical benefit to the subject) should be conducted in subjects who personally give consent and who sign and date the written consent document.

4.19.3 Non-therapeutic clinical trials may be conducted in subjects with consent of a legally acceptable representative provided the following conditions are fulfilled:

4.19.3.1 The objectives of the clinical trial cannot be met by means of a trial in subjects who can give consent personally

4.19.3.2 The foreseeable risks to the subjects are low

4.19.3.3 The negative impact on the subject's well-being is minimized and low

4.19.3.4 The clinical trial is not prohibited by law; and

4.19.3.5 The opinion of the IRB is expressly sought on the inclusion of such subjects, and the written opinion covers this aspect. Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended.

4.19.3.6 Subjects in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

4.20 Record the meeting end time.

4.21 At the conclusion of each convened IRB meeting, the IRB Director prepares the minutes and verifies that the affiliations contained in the minutes are accurate and correct.

4.22 Within 7 business days revise minutes for accuracy and notify the IRB chair for review.

4.23 Execute the “Prepare Minutes” activity and combine the attendee information with the generated submission-specific determinations.

4.24 Include link to the minutes in the agenda of the next IRB meeting.

4.25 IRB members have 7 days to review the minutes.

4.26 During the next IRB meeting, the IRB members will vote on approval of the minutes if no errors have been found. If errors are found, IRB members will notify the IRB Staff to make corrections to the minutes. The IRB members will vote to approve the corrected minutes at the next meeting.

4.27 Once the IRB members vote on approval of the minutes, The IRB Chair or a qualified voting member of the IRB designated by the IRB chair sign the minutes.

4.27.1 For minutes of Veterans Administration (VA) research have the IRB chair or a qualified voting member of the IRB designated by the IRB chair sign the minutes

4.27.2 The IRB staff will upload signed version of the minutes into the meeting workspace

4.28 Email minutes to:

4.28.1 VA Research and Development Committee, OSPTT Office, Compliance Office and the IO Office

4.28.2 When an affiliate IRB is the IRB of Record, the affiliate may either:

4.28.2.1 Provide VA with unredacted copies of meeting minutes, or

4.28.2.2 Provide VA with redacted copies of meeting minutes and permit relevant VA personnel (including, but not limited to, ORO staff, local VA Research Office staff, local RCOs, and R&D Committee members) to review the unredacted meeting minutes within two business days of a written request from VA. Such review may occur at the affiliate site during normal business hours, or as otherwise mutually acceptable to VA and the affiliate.

4.28.2.3 Minutes must communicate the decision and expedited review category in the minutes of the next available meeting, and in written notification to the investigator and research and development committee.

4.29 Attach the following documents to the meeting workspace:

4.29.1 List of protocols granted approval using the expedited procedure (Initial review. (B) Continuing review, when required by law or regulation. (C) Review of modifications to previously approved research.). Studies determined to meet exemption criteria are communicated to the IRB through the IRB meeting agenda and/or IRB meeting minutes.

4.29.2 Determinations made by the IRB Determinations made by the IRB are recorded in the minutes with documentation of the protocol-specific findings justifying those determinations as appropriate, such as:

- Significant risk and non-significant risk device determinations, pursuant to: 21 CFR 812.2(b), 21 CFR 812.150(b)(9) and considering FDA Information Sheet Significant and Non-significant Risk Medical Device Studies at **https://www.fda.gov/media/75459/download**
- Approval of waiver or alteration of informed consent, pursuant to: 45 CFR 46.116(f)
- Waiver of informed consent documentation, pursuant to: 45 CFR 46.117(c) and 21 CFR 56.109(c)(1)
- Research involving adults unable to consent in VA research (VHA Handbook 1200.05)
- Waiver of HIPAA Authorization, pursuant to 45 CFR 164.512(i)(2)(ii)
- Waiver of HIPAA Authorization for recruitment or screening, pursuant to 45 CFR 164.512(i)(2)(ii) x Whether or not subjects need to be re-consented to changes or new information
- When research involves children, the following IRB decisions are documented: x Appropriate children finding applicable to research: -45 CFR 46.404, 45 CFR 46.405, 45 CFR 46.406, 45 CFR 46.407, 45 CFR 46.408 (OHRP) -21 CFR 50.51, 21 CFR 50.52, 21 CFR 50.53, 21 CFR 50.54, 21 CFR 50.55 (FDA)

- Whether the permission of one parent/guardian is sufficient or if permission from both parents/guardians is required.
- How assent is to be solicited or obtained, unless waived.
- The participation of children who are wards of the state is approved under: -45 CFR 46.406, 45 CFR 46.407 only if 45 CFR 46.409(a) is satisfied, or -21 CFR 50.53, 21 CFR 50.54 only if 21 CFR 50.56(a) is satisfied
- Appropriate involvement of pregnant women, fetuses, and neonates pursuant to: -45 CFR 46.204, 45 CFR 46.205, 45 CFR 46.206, and 45 CFR 46.207
- Approval of research involving prisoners as subjects under the following regulations: -45 CFR 46.305 and 45 CFR 46.306
- Determination of the level of risk x Determinations of serious or continuing non-compliance
- For VA research (see VHA Handbook 1200.05) determinations may address:
  - Research involving adults unable to consent
  - Waiver of requirement to maintain a master list of all subjects
  - If recruitment of non-Veterans is justified and appropriate
  - Whether medical record should be flagged to protect the subject's safety by indicating participation in the study and the source of more information on the study

5 MATERIALS

5.1 HRP-501 - TEMPLATE MINUTES

5.2 HRP-611 - Template - VA Minutes Supplement

6 REFERENCES

6.1 45 CFR 46; 45 CFR 164

6.2 21 CFR 50; 21 CFR 56; 21 CFR 812

6.3 AAHRPP I.1.C.; II.1.A.; II.2.E.; II.2.F.; II.2.G.; II.3.F.; II.3.G.; II.4.A.; II.4.B.; II.5.B.

HRP-045 IRB Member Review Expectations

1 PURPOSE

1.1 This policy establishes for the review of Human Research the expectations of IRB members in advance of a meeting or when serving as a Designated Reviewer (experienced reviewers designated by the chairperson from among members of the IRB).

2 POLICY

2.1 In this policy, “all IRB members” refers to all members of the committee who will be present with voting status.

2.1.1 For review using the expedited (non-committee) procedure, the Designated Reviewer fulfills the roles described for the primary reviewer, and the scientific/scholarly reviewer, or obtains consultation for these roles.

2.2 All IRB members are to treat all oral, written, and electronic information obtained as part of the review process as confidential. IRB members must not disclose, use, share or duplicate review documents or confidential information without prior authorization.

2.3 All IRB members are to know the definition of Conflicting Interest.

2.3.1.1 No IRB member may participate in any review (including discussion or voting) in which he or she has a Conflicting Interest, except to provide information requested by the IRB.

2.3.1.2 When reviewing an item each IRB member is to consider whether he or she has a Conflicting Interest and if so, self-identify that Conflicting Interest.

2.4 All IRB members are provided a user account in the electronic IRB submission system for access to review materials.

2.4.1 All IRB members are to access all review materials through the electronic system.

2.4.2 IRB members attending by teleconference/videoconference are to access all review materials through the electronic system.

2.4.3 Any IRB member may request review materials be delivered outside the electronic system by contacting the IRB staff.

2.5 All members assigned as a primary reviewer or scientific/scholarly reviewers are to consider whether they have sufficient expertise to review the submission. If additional expertise is required, follow SOP: HRP-051 Consultation. Sufficient expertise includes as applicable for the research:

2.5.1 Scientific or scholarly expertise

2.5.2 Knowledge of or experience working with vulnerable populations

2.5.3 Qualifications as a prisoner representative

2.5.4 Knowledge of the country in which the research is conducted

2.5.5 Medical licensure for FDA-regulated test articles

2.6 All IRB members review the Pre-Review findings for each submission, if any.

2.7 All IRB members consider the criteria in all applicable worksheets and checklists.

2.7.1 Worksheets and checklists are available in the IRB Library through the electronic system or can be available outside the electronic system by contacting the IRB staff.

2.7.2 The primary presenter for each submission is expected to use applicable worksheets and checklists for preliminary judgments as to whether each criterion is met and provide preliminary study-specific findings justifying determinations.

2.7.3 The primary presenter leads the discussion.

2.7.4 IRB members who are not the primary presenter for a submission do not need to complete any checklists.

2.7.5 HRP-314 - WORKSHEET - Criteria for Approval applies to all non-exempt research.

2.7.6 The IRB must approve any and all recruitment materials/advertisements prior to posting and/or distribution for studies that are conducted under the purview of the LSUHSC-S IRB. Use HRP-315 - WORKSHEET - Advertisements. The IRB will review:

2.7.6.1 The information contained in the advertisement.

2.7.6.2 The mode of its communication.

2.7.6.3 The final copy of printed advertisements prior to posting.

2.7.6.4 The final audio/video taped advertisements.

2.7.7 All advertisements are required to include the following information: IRB Project number, the date of original IRB approval of protocol, and the date of IRB approval of the advertisement. Once approved by the IRB, an Advertisement is not to be altered or manipulated in any way without prior IRB approval.

2.7.8 Advertisements and Recruitment Incentives. Although the IRB is responsible for approving advertisements associated with any research proposal involving VA research, the RDC will also review advertisements as part of its approval process. No public displayed recruitment methods may be used at this facility without the explicit approval of the RDC and Public Affairs Officer. This includes posting and distributing advertisements and recruitment documents for non-VA funded research not taking place at this VA facility. If approved for non-VA research by the RDC, the Public Affairs Officer will be notified.

2.7.8.1 VA has approved the use of different types of social media, such as VA blogs, Facebook, Twitter, Flickr, and Yammer, to promote the mission, goals, and objectives of VA. When VA is advertising a non-VA study on the VA Facebook pages, it is promoting an activity that is not a VA activity. Hundreds or even thousands of people, including those outside of the intended audience, may see this advertisement. These Facebook posts advertising non-VA research activities can be perceived in a different context than that which was intended. Use of the Facebook pages to promote recruitment into non-VA research activities is not consistent with VA Directive 6515: Use of Web-Based Collaboration Technologies and is not permitted.

2.7.9 Payment to research subjects may be an incentive for participation or a way to reimburse a subject for time, travel, parking, and other experiences incurred due to participation. However, payment for participation is not considered a research benefit. Rather, it should be considered compensation for time, travel and inconvenience. Regardless of the form of remuneration, investigators must take care to avoid coercion of subjects. Payments should reflect the degree of risk, inconvenience, or discomfort associated with participation. The amount of compensation must be proportional to the risks and inconveniences posed by participation in the study. Use HRP-316 - WORKSHEET - Payments.

2.7.9.1 Investigators who wish to pay research subjects must indicate in their research project application the justification for such payment. Such justification should:

1. Substantiate that proposed payments are reasonable and commensurate with the expected contributions of the subject

2. State the terms of the subject participation agreement and the amount of payment in the informed consent document Substantiate those subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure on the patient to volunteer for the research study.

2.7.9.2 The IRB must review both the amount of payment and the proposed method of disbursement to assure that neither entails problems of coercion or undue influence. Credit for payment should accrue and not be contingent upon the subject completing the entire study.

2.7.9.3 The IRB does not allow the entire payment to be contingent upon completion of the entire study. Any amount paid as bonus for completion of the entire study should not be so great that it becomes coercive.

2.7.9.4 The consent form must describe the terms of payment and the conditions under which subjects would receive partial payment or no payment (e.g., if they withdraw from the study before their participation is completed). Unless the study is confidential, the LSUHSC-S Office of Business and Finance requires identifying information to issue checks to subjects. The consent form must inform subjects that they will be asked to provide their Social Security Number to receive payment. For confidential studies, only names and addresses are required by Business and Finance, but the PI MUST keep an identity key in a secure place. Investigators must submit a completed "Request to Pay Subjects in a Research Protocol" form (Form: LSUHSC-S 1144) to the Office of Business and Finance along with a check requisition form S/N 1238N, for reimbursement.

2.7.9.5 For VA Research

1. VA policy prohibits paying human subjects to participate in research when the research is integrated with a patient's medical care and when it makes no special demands on the patient beyond those of usual medical care. Payment may be permitted, with IRB approval, in the following circumstances: a) No Direct Subject Benefit. When the study to be performed is not directly intended to enhance the diagnosis or treatment of the medical condition for which the volunteer subject is being treated, and when the standard of practice in affiliated non-VA institutions is to pay subjects in this situation. b) Others Being Paid. In multi-institutional studies, when human subjects at a collaborating non-VA institution are to be paid for the same participation in the same study, subjects may be paid at a rate comparable to that proposed at the other sites, if deemed reasonable by the IRB. c) Comparable Situations. In other comparable situations in which, in the opinion of the IRB, payments of subjects is appropriate. d) Transportation Expenses. When

transportation expenses are incurred by the subject that would not be incurred in the normal course of receiving treatment and which are not reimbursed by any other mechanism.

2. The IRB and R & D Committee must review all proposals for payment of subjects to ensure conformity with VA policies. The facility research office is responsible for ensuring that IRB-approved payments to subjects are made from a VA approved funding source for research activities. Prospective VA investigators who wish to pay research subjects must include in the protocol:

    1) Substantiation that proposed payments are reasonable and commensurate with the expected contributions of the subject;

    2) the terms of the payment and the amount of payment are in the informed consent document; and

    3) substantiation that subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure or influence on the prospective research subjects to volunteer for, or to continue to participate in the research study.

2.7.9.6 In addition, the payments do not constitute (or appear to constitute) coercion to participate in or continue to participate in the research study. LSUHSC-S Employees who participate in clinical research must be aware of the following:

1. Employees must disclose to the research staff their employment status.

2. Attendance of study visits must be during off time, during annual time or on lunch. Break time may not be used.

3. Disclosure of the employees' participation in a clinical trial may be made to your Business Manager or Department Manager.

4. A "Request to Pay Subjects in a Research Protocol" form must be completed and submitted with a PER 3 to Human Resources. Compensation will be provided as additional income in your LSUHSC-S payroll.

2.8 For initial review: In advance of the meeting, all IRB members review the following materials to a depth sufficient to determine whether the criteria in applicable worksheets and checklists are met:

2.8.1 Application form with local context, HRP-503 - TEMPLATE PROTOCOL

2.8.2 Study Protocol

2.8.3 Consent/Assent document(s) and script(s), when applicable

2.8.4 HIPAA Authorization

2.8.5 Recruitment materials, when applicable

2.9 For review of a modification: In advance of the meeting, all IRB members review the modification, determine which criteria in applicable worksheets and checklists are affected, and criteria are met:

2.9.1 Protocol

2.9.2 Consent document(s) and script(s) when they exist

2.9.3 HIPAA Authorization

2.9.4 Recruitment materials when they exist

2.9.5 When following DoD regulations, substantive amendments to approved research submitted to the IRB, must undergo scientific review prior to IRB review or be conducted by the IRB.

2.10 For continuing review: In advance of the meeting, all IRB members review continuing review progress report and attachments, determine which criteria in applicable worksheets and checklists are affected, and review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:

2.10.1 Protocol

2.10.2 Current consent document(s) and script(s) when they exist

2.10.3 Recruitment materials when they exist

2.10.4 The progress report on the progress of the research includes:

A. Number of subjects accrued.

B. A summary since the last IRB review of:

i. Adverse events, untoward events, and adverse outcomes experienced by subjects.

ii. Unanticipated problems involving risks to subjects or others.

iii. Subject withdrawals.

iv. The reasons for withdrawals.

v. Complaints about the research.

vi. Amendments or modifications.

vii. Any relevant recent literature.

C. Any interim findings.

D. Any relevant multi-center trial reports.

E. The investigator's current risk-potential benefit assessment based on study results.

2.11 For review of new information: In advance of the meeting, all IRB members review the new information and attachments, determine which criteria in applicable worksheets and checklists are affected, and review the relevant sections of the following materials to a depth sufficient to determine as necessary whether affected criteria are met:

2.11.1 Protocol

2.11.2 Previously submitted modifications or a summary thereof

2.11.3 Consent document(s) and script(s) when they exist

2.11.4 Written reports of consultants or auditors when they exist

2.12 The primary presenter reviews all submitted materials for consistency with the materials reviewed by all IRB members, including the following additional documents when they exist:

2.12.1 The complete research protocol including any previously approved protocol modifications

2.12.2 Investigator brochure

2.12.3 Contract or grant application

2.12.4 Model template consent document

2.12.5 New Information reported during the current period of approval for continuing review submissions.

2.13 If the DHHS supported research involves prisoners as subjects, the prisoner representative reviews the submitted information to determine whether the criteria in HRP-415 - CHECKLIST - Prisoners are met, be present when the research is reviewed, and provide a review either orally or in writing.

2.14 IRB members or consultants with scientific or scholarly expertise review the submitted information in enough depth to answer the questions in HRP-320 - WORKSHEET - Scientific or Scholarly Review.

2.15 All IRB members review written reports of consultants, if any.

2.16 Any IRB member who needs to access additional information in the IRB records can contact an IRB staff member for assistance.

2.17 A subset of materials that are to be made available for review include HRP-301 - WORKSHEET - Review Materials

2.17.1 List of protocols approved using the expedited procedure (For Veterans Administration (VA) Research, include the review category.) List of protocols approved after verification of Modifications Required to Secure Approval for VA Research.

2.17.2 Information for Other Business items

2.17.3 Educational Materials when applicable

3 MATERIALS

3.1 SOP: HRP-051 Consultation

3.2 HRP-301 - WORKSHEET - Review Materials

3.3 HRP-314 - WORKSHEET - Criteria for Approval

3.4 HRP-315 - WORKSHEET - Advertisements

3.5 HRP-316 - WORKSHEET - Payments

3.6 HRP-318 - WORKSHEET - Additional Federal Agency Criteria

3.7 HRP-320 - WORKSHEET - Scientific or Scholarly Review

3.8 HRP-321 - WORKSHEET - Review of Information Items

3.9 HRP-323 - WORKSHEET - Criteria for Approval and Additional Considerations HUD

3.10 HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process

3.11 HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent

3.12 HRP-412 - CHECKLIST - Pregnant Women

3.13 HRP-413 - CHECKLIST - Non-Viable Neonates

3.14 HRP-414 - CHECKLIST - Neonates of Uncertain Viability

3.15 HRP-415 - CHECKLIST - Prisoners

3.16 HRP-416 - CHECKLIST - Children

3.17 HRP-417 - CHECKLIST - Cognitively Impaired Adults

3.18 HRP-418 - CHECKLIST - Non-Significant Risk Device

3.19 HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research

3.20 HRP-441 - CHECKLIST - HIPAA Waiver of Authorization

3.21 HRP-503 - TEMPLATE PROTOCOL

4 REFERENCES

4.1 AAHRPP I.1.F.; I.3.; II.1.D.; II.2.C.; II.2.D.; II.2.E.; II.2.F.; II.3.; II.4.A.; III.1.E.;

HRP-050 Conflicting Interests of IRB Members

1 PURPOSE

1.1 This procedure establishes the process to identify and manage Conflicting Interest of IRB members.

1.2 The process begins when an IRB member is asked to review an IRB submission.

1.3 The process ends when an IRB member has either identified a Conflicting Interest and notified IRB staff, or when an IRB member has determined that he or she does not have a Conflicting Interest.

2 POLICY

2.1 IRB members are responsible for knowing the definition of Conflicting Interest and self-identify when they have a Conflicting Interest.

3 RESPONSIBILITIES

3.1 IRB members (regular and alternate) follow these procedures.

4 PROCEDURE

4.1 For all voting, alternate, and ex-officio members of the IRB matters of financial conflicts of interest are governed by the Institution’s policy contained in Chancellor's Memorandum-23 found on the LSU Health website.

4.2 Before reviewing research, IRB members are to determine whether they have a Conflicting Interest with research HRP-325 - WORKSHEET - IRB Member and Consultant COI

4.3 If an IRB member has a Conflicting Interest for review outside a meeting (e.g., the expedited procedure), he or she is to notify the IRB staff and return all materials.

4.4 If an IRB member has a Conflicting Interest for review of a submission for which he or she has been assigned as a primary or scientific reviewer, he or she is to notify the IRB staff so the submission can be re-assigned.

4.5 If an IRB member has a Conflicting Interest for review of research at a meeting, he or she is to notify the IRB chair, stay in the meeting room only to answer questions about the research, and to leave the meeting room for discussion and voting regarding that research. All recusals by members with COI are recorded in the minutes. If the Conflict-of-Interest status of an IRB member changes during the course of a study, the IRB member is required to declare this to the IRB Chairs and/or Administrator of the IRB Office.

4.6 Committee members may find themselves in any of the following conflicts of interest when reviewing research:

4.6.1 Where the member or consultant is involved in the design, conduct, and reporting of the research.

4.6.2 Where an immediate family member of the member or consultant is involved in the design, conduct, and reporting of the research.

4.6.3 Where the member holds significant financial interest in the research being reviewed; and/or

4.6.4 Any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol

5 MATERIALS

5.1 HRP-325 - WORKSHEET - IRB Member and Consultant COI

6 REFERENCES

6.1 45 CFR 46.107(e)

6.2 21 CFR 56.107(e)

6.3 AAHRPP I.6.B.; II.1.D.; II.2.A.; III.1.B.; III.1.C.;

HRP-051 Consultation

1 PURPOSE

1.1 This procedure establishes the process for the IRB to obtain consultants.

1.2 The process begins when the IRB staff or IRB member has identified the need for consultation.

1.3 The process ends when the consultant has provided additional expertise to the IRB.

2 POLICY

2.1 The IRB invites consultants with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.

2.2 Consultants with a Conflicting Interest may not provide information to the IRB.

3 RESPONSIBILITIES

3.1 For review by a convened IRB, IRB staff members carry out these procedures.

3.2 For Non-Committee Review, the Designated Reviewer carries out these procedures.

4 PROCEDURE

4.1 Identify a consultant with the required expertise who can provide a review. Identify individuals as follows:

4.1.1 IRB members from other committees

4.1.2 Other employees of the organization

4.1.3 External consultants

4.2 Contact the consultant and determine availability for review.

4.3 Determine whether the consultant has a Conflicting Interest as defined in SOP: HRP-001 Definitions. If so, obtain another consultant.

4.4 Use HRP-301 - WORKSHEET - Review Materials to determine which documents to make available to the consultant so the IRB can obtain the additional expertise needed and make these documents available to the consultant. If the additional expertise needed does not require review of any materials, no materials need be provided.

4.5 For review by the convened IRB:

4.5.1 Make the consultant's written comments, if any, available to the IRB members attending the meeting.

4.5.2 If the consultant did not provide a written report or if requested by an IRB member, invite the consultant to the IRB meeting.

4.6 For Non-Committee Review:

4.6.1 Directly obtain the information (oral or written) from the consultant.

4.6.2 Document information received with the name of the consultant.

5 MATERIALS

5.1 SOP: HRP-001 Definitions

5.2 HRP-301 - WORKSHEET - Review Materials

6 REFERENCES

6.1 45 CFR 46.107(f)

6.2 21 CFR 56.107(f)

6.3 AAHRPP I.6.B.; II.1.D.; II.1.E.; II.2.A.; II.2.E.; II.5.B.;

HRP-052 Post Review

1 PURPOSE

1.1 This procedure establishes the process for communications after a protocol is reviewed.

1.2 The process begins when:

1.2.1 A Designated Reviewer has completed a Non-Committee Review and provided completed materials to the IRB staff, OR

1.2.2 An IRB meeting is adjourned, and the IRB chair or IRB Director has approved the minutes, OR

1.2.3 An IRB staff member has verified that modifications required to secure approval have been made.

1.3 The process ends when all correspondence related to IRB determinations and actions have been sent and additional tasks have been completed.

2 POLICY

2.1 The IRB reports its findings and actions to the investigator.

2.2 The IRB reports its findings and actions to the institution.

2.3 When the IRB disapproves research, it provides the investigator with a statement of the reasons for the decision and gives the investigator an opportunity to respond in person or in writing.

2.4 Communication of review results to investigators are to be completed within 10 business days of the IRB meeting or receipt of the completed Non-Committee Review materials.

2.5 Reporting of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; and Unanticipated Problem Involving Risks to Subjects or Others to outside agencies is to take place within 30 business days from the determination of a reportable problem.

2.5.1 For Veterans Affairs (VA) research notification to the VA facility Director and the Associate Chief of Staff/R&D must occur within 5 business days of the convened IRB's determination(s).

2.5.1.1 If the apparent Serious Non-Compliance or Continuing Non-Compliance notification was from a Research Compliance Officer (RCO), also notify the RCO within 5 business days of the convened IRB's determination(s).

2.6 Appeal of IRB Decisions

2.6.1 If an investigator disagrees with a decision of the IRB, the investigator may submit a written appeal to the IRB Chair within 30 days of being notified of the decision.

2.6.1.1 The appeal should include information supporting any disagreement made in the appeal.

2.6.1.2 For appeals involving research conducted by designated review the appeal is reviewed by the designated reviewer, IRB Chair, and IRB Director.

2.6.1.3 For appeals involving research reviewed by the convened board, the appeal is reviewed by the convened board.

2.6.1.3.1 The investigator may request to address the board at the meeting to provide clarification or additional information to the IRB.

2.6.1.4 The investigator is notified in writing of the decision.

2.6.2 If the investigator does not agree with IRB's decision regarding the appeal, the investigator may submit a written appeal to the Institutional Official or designee within 30 days of being notified of the decision.

2.6.2.1 3.6.2.1 The IO may organize a meeting to help facilitate discussion between the IRB and the investigator.

2.6.2.2 3.6.2.2 The IO may provide input and make recommendations for a resolution of the matter.

2.6.2.3 3.6.3 The IO or other LSUHSC-S Senior Leadership may override the IRB's decision to approve research; however they may not approve the research if it has not been approved by the IRB or overrule other decisions made by the IRB.

3 RESPONSIBILITIES

3.1 IRB staff members carry out these procedures. The IRB Chair facilitates any appeal process.

3.2 When the IRB staff analyst is logged into the electronic IRB system using a valid username and password and uses the system to generate correspondence that communicates the results of IRB decisions, including approval determinations, the correspondence is considered to have been signed under the authority of the IRB chair or designee.

4 PROCEDURE

4.1 If the Non-Committee Review indicated a Conflicting Interest or a lack of expertise, follow SOP: HRP-031 Non-Committee Review Preparation.

4.2 Refer to HRP-302 - WORKSHEET - Calculation of Approval Intervals to calculate approval intervals (if applicable).

4.3 Execute the "Finalize Documents" to stamp and accept all changes for attached documents.

4.3.1 Execute the "Prepare Letter" activity, and modify the letter as needed.

4.3.2 Execute the "Send Letter" activity.

4.4 For determinations of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others:

4.4.1 Use HRP-520 - TEMPLATE LETTER - External Report to send to outside agencies within 30 business days from the determination of a reportable problem.

5 MATERIALS

5.1 SOP: HRP-031 Non-Committee Review Preparation

5.2 HRP-302 - WORKSHEET - Calculation of Approval Intervals

5.3 HRP-303 - WORKSHEET - Communication of Review Results

5.4 HRP-520 - TEMPLATE LETTER - External Report

6 REFERENCES

6.1 45 CFR 46.103(b)(4)(i); 45 CFR 46.207; 45 CFR 46.306(2)(C); 45 CFR 46.306(2)(D); 45 CFR 46.407; 45 CFR 46 Waiver of Informed Consent Requirements in Certain Emergency Research (November 1, 1996)

6.2 21 CFR 50.24(e); 21 CFR 50.54(b); 21 CFR 56.108(a)(1); 21 CFR 812.66

6.3 VHA Handbook 1058.01

6.4 AAHRPP I.1.C.; I.5.C.; II.1.D.; II.2.E.; II.2.G.; II.2.H.; II.4.C.

HRP-054 Institutional Conflicts of Interests

1 PURPOSE

1.1 This procedure establishes the process to identify institutional financial interests that may cause an institutional conflict of interests.

1.2 The process begins when the Organizational Official/Institutional Official (IO/OO) or designee is informed of a change in the institution's financial holdings outside of standard investments.

1.3 The process ends when the IRB staff are provided an updated list of the institution's financial holdings.

2 POLICY

2.1 See Chancellor's Memorandum – 23

2.2 An institutional financial conflict of interests exists when any of the following might affect the design, conduct, or reporting of research:

2.2.1 Licensing, technology transfer, patents

2.2.2 Investments of the organization

2.2.3 Gifts to the organization when the donor has an interest in the research

2.2.4 Financial interests of senior administrative officials

2.2.5 Other financial interests

2.3 Senior administrative officials are required to disclose their financial interests to the Conflict of Interests Officer:

2.3.1 Upon joining the organization

2.3.2 Every year

2.3.3 When there are changes to financial interests

2.4 For purposes of HRPP policy, the definition of Senior administrative leadership under this policy is as follows:

2.4.1 All individuals whose title includes Chancellor, Dean, Hospital Administrator, Counsel, and others determined by the Chancellor.

2.4.2 A faculty member or administrator who has direct authority over personnel appointments, salaries, promotions, and/or allocation of organizational resources (e.g., funding, space, assignment of graduate students, residents, fellows or other trainees) for individuals involved in the design, conduct, reporting, review, or oversight of human subjects research.

2.5 The Technology Transfer Office, Grants and Contracts Office, legal counsel, and the Conflict of Interests Officer are to notify the IO/OO or designee of any change in the institution's financial holdings not controlled by the institution's investment Directors related to:

2.5.1 Licensing (e.g., licensing or technology transfer agreements)

2.5.2 Investments of the organization

2.5.3 Gifts to the organization when the donor has an interest in the research

2.5.4 Financial interests of senior administrative officials

2.5.5 Other financial interests

2.6 Annual Disclosure Certifications and quarterly updates will be provided to the Project Manager COI and Compliance and Investigation Specialist within the Office of Compliance.

2.7 The fiduciary responsibility of the institution's investment Directors is to maintain a diversified portfolio of holdings that that meets the institution's goals in terms of capital appreciation, income, and risk. Institutional officials may not influence the decisions of the institution's investment Directors. This institution considers such investments to be like diversified mutual funds and not subject to disclosure under this policy.

2.8 The evaluation and management of an institutional conflict of interest may not vary by funding or regulatory oversight.

2.9 If an institutional financial holding related to prospective or ongoing Human Research is identified, it will be managed according to SOP: HRP-055 Financial Conflicts of Interests

3 RESPONSIBILITIES

3.1 The Project Manager COI and Compliance and Investigation Specialist within the Office of Compliance carries out these responsibilities.

4 PROCEDURE

4.1 Upon receipt of information of a change in financial interest update the list of investments that are not controlled by the institution's investment Directors. Include information about the name of the company, the names of related companies, and affected products or services.

4.2 Provide a copy of the updated list to the IRB staff.

5 MATERIALS

5.1 SOP: HRP-055 Financial Conflicts of Interests

5.2 Chancellor's Memorandum – 23

6 REFERENCES

6.1 42 CFR 50 7.1; 45 CFR 94 7.2

6.2 AAHRPP I.6.; II.1.D.; II.2.A.; III.1.B.; III.1.C.

HRP-055 Financial Conflicts of Interests

1 PURPOSE

1.1 This procedure establishes the process to evaluate a report of an individual financial interest of an investigator or research staff Related to the Research or an institutional financial interest Related to the Research.

1.2 The process begins when COI Office determines that an investigator or research staff has reported a financial interest Related to the Research or the IRB staff have detected an institution financial interest Related to the Research.

1.3 The process ends when the reported financial interest has been evaluated and the results of the evaluation have been communicated to the IRB to make the final decision as to whether any financial interest and any management plan allows the research to be approved.

2 POLICY

2.1 The Assistant Vice Chancellor for Legal Affairs serves as the Conflicts of Interests Officer.

2.2 This policy complies with 3.1

2.2.1 LSUHSC-S Chancellor's Memorandum – 23

2.2.2 Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought

2.2.3 Title 21 Code of Federal Regulations (CFR), Part 54, Financial Disclosure by Clinical Investigators

2.3 For any or all steps of this procedure, the Conflicts of Interests Officer may have the Conflicts of Interests Committee follow the procedure whenever the Conflicts of Interests Officer believes that institutional consensus is needed to make a decision.

2.4 Individuals are considered to have an institutional responsibility and are subject to this policy when they are involved in any of the following:

2.4.1 The design, conduct, or reporting of research

2.4.2 Research consultation

2.4.3 Teaching

2.4.4 Professional practice

2.4.5 Institutional committee memberships

2.4.6 Service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards

2.5 Individuals subject to this policy are required to complete financial conflicts of interest training initially, at least every four (4) years, and immediately when:

2.5.1 Joining the organization

2.5.2 Financial conflicts policies are revised in a manner that changes investigator requirements

2.5.3 Non-compliant with financial conflicts policies and procedures

2.6 Individuals subject to this policy are required to disclose their institutional responsibility to conduct research and the financial interests Related to the Research:

2.6.1 On submission of an initial review.

2.6.2 At least annually on submission of continuing review.

2.6.3 Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest

2.7 Travel disclosures are to include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.

2.8 Potential Conflict of Interest for IRB Members, Consultants, and Investigators: Financial Interest Related to the Research - is defined as financial interest in the sponsor, product or service being tested, or competitor of the sponsor.

2.8.1 Conflict of interest includes:

2.8.1.1 Involvement of you or your family in the design, conduct or reporting of the research

2.8.1.2 Ownership interest, stock options, or other financial interest related to the research unless it meets four (4) tests:

2.8.1.2.1 Does not exceed $5,000.00 when aggregated for you and your immediate family

2.8.1.2.2 Publicly traded on a stock exchange

2.8.1.2.2.1 With regards to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

2.8.1.2.2.2 With regards to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest))

2.8.1.2.3 Value will not be affected by the outcome of the research

2.8.1.2.4 Does not exceed 5% interest in any one single entity when aggregated for you and your immediate family

2.8.1.3 Compensation related to the research unless it meets two (2) tests:

2.8.1.3.1 Does not exceed $5,000.00 in the past year when aggregated for you and your immediate family

2.8.1.3.2 Amount will not be affected by the outcome of the research

2.8.1.4 Proprietary interest (intellectual property) related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement

2.8.1.5 Board or executive relationship related to the research, regardless of compensation

2.8.1.6 Any other reason for which you believe you cannot provide an independent review

2.9 Violations of this policy or proscribed management plans can lead to:

2.9.1 Loss or restriction of privileges to conduct research

2.9.2 Other employment actions as allow by Human Resources Policies and Procedures.

2.10 Records related to disclosures and management of financial conflicts of interest are to be retained for at least three (3) years from completion of the research.

3 RESPONSIBILITIES

3.1 The Project Manager COI and Compliance and Investigation Specialist within the Office of Compliance carries out these procedures or ensures that a committee follows these procedures.

4 PROCEDURE

4.1 "Project Manager COI and Compliance and Investigation Specialist" reviews researcher and research staff conflict-of interest disclosures filed with the Office for Compliance and Investigations pursuant to Permanent Memorandum #11 (PM-11).

4.2 "Project Manager COI and Compliance and Investigation Specialist" compares the above-referenced disclosures with Sponsor and study-related materials to determine whether a conflict of interest exists. If a conflict of interest is identified, "Project Manager COI and Compliance and Investigation Specialist" works with the researcher or research staff to develop a plan to manage and/or minimize the conflict of interest.

4.3 The IRB reviews the management plan to ensure that research participants are adequately protected and informed of the conflict of interest. Information related to the conflict of interest is disclosed in the informed consent form (ICF) which is provided to the research participant at the time of enrollment.

4.4 On a monthly basis, the Quality Assurance/Quality Improvement Coordinator reviews all studies with a management plan to verify compliance.

4.5 Ensure committee members do not participate in the review of any conflict of interests in which the member has Conflicting Interest.

4.6 Review the reported financial interest and the research protocol.

4.6.1 If the financial interest and research protocol has already been reviewed, and if needed, managed, notify the IRB staff of this determination in writing, and stop processing subsequent steps of this procedure.

4.7 Determine whether the reported financial interest is related to the research.

4.7.1 If the financial interest is not related to the research, notify the IRB staff of this determination in writing, and stop processing subsequent steps of this procedure.

4.8 Determine whether the reported financial interest could directly and significantly affect the design, conduct, or reporting (i.e., the reported financial interest is a conflict of interests) of the Human Research.

4.8.1 If there is no conflict of interests, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.

4.9 If a conflict of interests exists, determine under what circumstances, if any, should a conflicted individual (in the case of individual financial interest) or the organization (in case of institutional financial interest) be allowed to participate in:

4.9.1 Subject recruitment.

4.9.2 Prescreening for inclusion/exclusion criteria.

4.9.3 The consent process

4.9.4 The clinical treatment of subjects, separate from the research interventions or procedures.

4.9.5 Clinical evaluation of subjects during the research, separate from the research interventions or procedures, including adverse event evaluation and reporting.

4.10 Create a written management plan, considering the following options:

4.10.1 Public disclosure of the financial interests.

4.10.2 Disclosure of the financial interests to subjects.

4.10.3 Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest.

4.10.4 Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.

4.10.5 Reduction or elimination of the financial interest (e.g., sale of an equity interest).

4.10.6 Severance of relationships that create financial conflicts.

4.10.7 Modification of the research plan.

4.10.8 Involvement of external individuals in key portions of the protocol

4.10.9 Use of an external IRB.

4.10.10 A retrospective review.

4.10.11 A mitigation report.

4.10.12 A plan to monitor and enforce the implementation of the management plan.

4.11 Provide the written management plan to the involved individual or office for comment and review.

4.12 Finalize the written management plan.

4.13 Provide the IRB staff of the reviewing IRB with the written management plan so the IRB can make the final decision as to whether the financial interest and its management, if any, allows the research to be approved.

4.14 When required provide the final determination to the funding or regulatory agencies.

4.15 Maintain a copy of determinations and management plans in the records.

4.16 For National Science Foundation Research Note: Although current NSF regulations specify a higher threshold for SFI than PHS (NIH) the LSUHSC-S CM-23 policy identifies $5,000 as the monetary threshold.

4.17 For FDA regulated research follow INVESTIGATOR MANUAL (HRP-103) Appendix A-2 - Additional Requirements for FDA-Regulated Research.

4.18 The VA works with the LSUHSC IRB to identify, evaluate, and mitigate Conflicts of Interests, including both institutional and individual. VA investigators are subject to their Research and Development SOP's, part 7. The VA relies on the IRB to evaluate financial Conflicts of Interest and any management plan, in accordance with appropriate regulatory standards. VA personnel listed in an IRB application or engaged in research must submit the VA Conflict of Interest form for review by the RDC and the IRB. The ACOS/R&D is the designated Conflict of Interest

Administrator.VA facilities are not required to follow PHS requirements, even when research is funded by a PHS agency (e.g., NIH).Investigators must report conflicts of interests using the VA financial conflict of interest form; the IRB must use the VA conflict of interest form, and may not create, redraft, or change this form.VA SOP's also describe the process for identifying, evaluating, and mitigating institutional Conflicts of Interest. The IRB retains the authority for final approval of any management plan.

5 MATERIALS

5.1 LSUHSC-S Chancellors Memorandum – 23

5.2 INVESTIGATOR MANUAL (HRP-103)

6 REFERENCES

6.1 42 CFR 50; 45 CFR 94

6.2 NSF GPM Section 510 7.2

6.3 21 CFR 54 7.3

6.3 AAHRPP I.6.; II.1.D.; II.2.A.; III.1.B.; III.1.C.;

HRP-060 Annual Evaluations of the HRPP

1 PURPOSE

1.1 This procedure establishes the process to conduct annual evaluations of the human research protection program.

1.2 The process begins the first business day of each July.

1.3 The process ends when all evaluations have been completed and communicated to those evaluated.

2 POLICY

2.1 The human research protection program is evaluated annually.

2.2 The subject outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished by making the document HRP-104 - BROCHURE - Should I Take Part in Research available to the patient population.

3 RESPONSIBILITIES

3.1 IRB staff ensure completion of these procedures. Use the HRP-344 - WORKSHEET - Annual Evaluation of the HRPP.

4 PROCEDURE

4.1 Have the Institutional Official or designee evaluate the following resources provided to the human research protection program and make adjustments as part of the budgeting process.

4.1.1 Space

4.1.2 Employees

4.1.3 HRPP educational program

4.1.4 Legal counsel

4.1.5 Conflicts of interests

4.1.6 Quality improvement plan

4.2 Evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed.

4.2.1 Provide a copy of the evaluation to the Institutional Official or designee.

4.2.2 If the number of IRBs is not appropriate to the volume and types of research reviewed, work with the Institutional Official or designee to modify the IRB structure.

4.3 Have the IRB chair or IRB Director evaluate the knowledge, skills, and performance of each regular and alternate IRB member.

4.4 Have each IRB member complete HRP-345 - WORKSHEET - IRB Member Self-Evaluation

4.4.1 Provide a copy of the evaluation to the Institutional Official or designee.

4.4.2 Provide each IRB member with a copy of his or her evaluation.

4.4.3 Send a copy of the HRP-562 - TEMPLATE LETTER - IRB Member Appreciation to the IRB member's supervisor.

4.4.4 If needed, work with each IRB member to develop a plan to improve the individual's knowledge, skills, and performance.

4.5 Have the Institutional Official or designee evaluate the knowledge, skills, and performance of each IRB chair.

4.6 Have each IRB Chair complete HRP-345 - WORKSHEET - IRB Member Self-Evaluation

4.6.1 Provide a copy of the evaluation to the Institutional Official or designee.

4.6.2 Provide each IRB chair with a copy of his or her evaluation.

4.6.3 If needed, work with each IRB chair to develop a plan to improve the individual's knowledge, skills, and performance.

4.7 Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB staff.

4.7.1 Provide a copy of the evaluation to the Institutional Official or designee.

4.7.2 Provide each IRB staff with a copy of his or her evaluation.

4.7.3 If needed, work with each IRB staff person to develop a plan to improve the individual's knowledge, skills, and performance.

4.8 Use the HRP-304 - WORKSHEET - IRB Composition to evaluate whether the composition of the IRB meets regulatory and organizational requirements.

4.8.1 Provide a copy of the evaluation to the Institutional Official or designee.

4.8.2 If the composition of an IRB does not meet regulatory and organizational requirements, work with the Institutional Official or designee to modify the IRB composition.

4.9 Evaluate the subject outreach plan.

4.9.1 Consider the following areas when evaluating the outreach plan:

4.9.1.1 Whether the existing scope and content of HRPP outreach materials continue to be adequate.

4.9.1.2 Whether modifications to existing outreach materials are necessary.

4.9.1.3 Whether or not the HRPP's existing materials are being regularly utilized by the IRB Office or by members of the research community in their own interaction with the communities in which they conduct research.

4.9.1.4 Whether there are new opportunities to provide outreach activities to the community and

4.9.1.5 Whether additional information is needed from the research community to assess the extent to which outreach materials are used and outreach activities take place.

4.9.2 Provide a copy of the evaluation to the Organizational Official or designee.

4.9.3 If the subject outreach program is not meeting organizational goals, work with the Institutional Official or designee to modify the plan. Modifications may include, but are not limited to:

4.9.3.1 Modifying existing outreach materials.

4.9.3.2 Developing new materials.

4.9.3.3 Surveying the research community to identify and participate in additional outreach opportunities, and

4.9.3.4 Working directly with community organizations to identify and participate in additional outreach opportunities.

4.10 Check whether each member of a Veterans Administration (VA) IRB or Veterans Administration (VA) representative has been a member longer than three years, and if so, send the member a HRP-560 - TEMPLATE LETTER - IRB Member Appointment.

4.11 Review SOP: HRP-080 IRB Formation to determine if IRB registration requires updating.[7]

4.12 Check when the last time the Federalwide Assurance (FWA) was updated or renewed. If more than two (2) years, update/renew the Federalwide Assurance (FWA).[8]

5 MATERIALS

5.1 HRP-104 - BROCHURE - Should I Take Part in Research

5.2 SOP: HRP-080 IRB Formation

5.3 HRP-304 - WORKSHEET - IRB Composition

5.4 HRP-344 - WORKSHEET - Annual Evaluation of the HRPP

5.5 HRP-345 - WORKSHEET - IRB Member Self-Evaluation

5.6 HRP-560 - TEMPLATE LETTER - IRB Member Appointment

5.7 HRP-562 - TEMPLATE LETTER - IRB Member Appreciation

6 REFERENCES

6.1 AAHRPP I.2.; I.4.B.; II.1.

[7, 8] See **http://www.hhs.gov/ohrp/assurances/**. Use the Web site: **https://ohrp.cit.nih.gov/efile/.**

HRP-063 Expiration of IRB Approval

1 PURPOSE

1.1 This procedure establishes the process for a Designated Reviewer to determine whether current subjects may continue in expired research.

1.2 The process begins when the Designated Reviewer is notified of a request by an investigator of a request for current subjects to continue in expired research.

1.3 The process ends when the Designated Reviewer has communicated a decision and documented the decision in writing.

2 POLICY

2.1 If research is granted "Modifications Required to Secure Approval" and expires before responsive materials are reviewed and approved, these procedures are to be followed.

3 RESPONSIBILITIES

3.1 A Designated Reviewer is responsible to follow these procedures.

4 PROCEDURE

4.1 When continuing review is required by law or regulation, if an investigator does not provide continuing review information to the IRB or the IRB has not approved a protocol by the expiration date,

4.1.1 Have all research activities stop.

4.1.2 Have interventions and interactions on current subjects stop, unless the IRB finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual subjects to continue participating.

4.1.3 Do not allow new enrollment of subjects to occur.

4.2 When following VA requirements:

4.2.1 If an investigator does not provide continuing review information to the IRB or the IRB has not approved a protocol by the expiration date:

(i) Stop all research activities including, but not limited to, enrollment of new subjects, continuation of research interventions or interactions with currently enrolled subjects, and data analysis.

(ii) Immediately submit to the IRB chair a list of research subjects who could be harmed by stopping study procedures.

(iii) The IRB chair, with appropriate consultation with the chief of staff, determines whether subjects on the list may continue participating in the research interventions or interactions.

4.3 Determine from the investigator which subjects need to continue in the expired research, what procedures are being requested to continue, and why.

4.4 Do not allow new subjects to be enrolled under any circumstances.

4.5 Determine which subjects can continue in the research based on these principles:

4.5.1 In general, research procedures should be safely discontinued.

4.5.2 In general, the only research procedures that should continue are those that are not available outside of the research context. If the required procedures can be provided as standard of care, these should be provided as such.

4.5.3 In general, research procedures conducted to collect data with no direct benefit to the subject should not continue.

4.5.4 In some cases, an ethical issue may be raised where the above general principles may not be followed.

4.6 In the case of Veterans Administration (VA) research, have the IRB chair consult with the Veterans Administration (VA) Chief of Staff to make a final determination within 2 business days whether subjects may continue participating in the research interventions or interactions.

4.7 Communicate with the investigator using HRP-532 - TEMPLATE LETTER - Continuation of Subjects in Expired Research.

5 MATERIALS

5.1 HRP-532 - TEMPLATE LETTER - Continuation of Subjects in Expired Research

6 REFERENCES

6.1 45 CFR 46

6.2 AAHRPP I.1.C.; II.2.

HRP-064 NIH GDS Institutional Certification

1 PURPOSE

1.1 This procedure establishes the process to certify approval for investigator submission of large-scale human genomic data to an NIH-designated data repository.

1.2 The process begins when an investigator contacts IRB staff for certification of the genomic data sharing plan.

1.3 The process ends when the Organizational Official / Institutional Official (IO/OO) has certified and communicated to the investigator.

2 POLICY

2.1 Investigators must request certification from IRB staff prior to investigator submission of large-scale human genomic data or approval of funding.

3 RESPONSIBILITIES

3.1 The IRB Director or designee verifies for the IO/OO that all data meet criteria for submission to the data repository.

4 PROCEDURE

4.1 Use HRP-332 - WORKSHEET - NIH GDS Institutional Certification to evaluate and document whether the investigator's genomic data sharing plan meets the criteria for submission to an NIH-designated data repository.

4.2 Prepare letter for NIH GDS Institutional Certification with submission-specific information. Pass the letter to the IO/OO for review and certification.

4.3 Save a copy of the signed letter and worksheet in IRB Office records.

4.4 Communicate certification approval to the investigator and provide a copy of the signed GDS Institutional Certification letter for the investigator to forward to the NIH.

5 MATERIALS

5.1 HRP-332 - WORKSHEET - NIH GDS Institutional Certification

6 REFERENCES

6.1 National Institutes of Health Final Genomic Data Sharing Policy, ***https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing***

6.2 NIH Points to Consider for IRBs and Institutions in their Review of Data Submission Plans for Institutional Certifications Under NIH's Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS),

https://osp.od.nih.gov/wp-content/uploads/PTC_for_IRBs_and_Institutions.pdf

6.3 AAHRPP I.4.A.; I.5.C.; I.7.A.; I.9.; II.3.E.; II.5.A.;

HRP-065 Lapsed Study-Out of Compliance

1 Purpose

1.1 This procedure establishes the process when a study enters the "Lapsed" state by not submitting a continuing review before the approval end date of the study occurs.

1.2 The process begins when a study's "approval end date" expires and study enters the "Lapsed" state in SHIELDS.

1.3 The process ends when the study is administratively closed by the IRB, is brought back into compliance by going into the "Approved" state by the PI submitting a continuing review submission for the lapsed study, or the study is closed by the PI submitting a closure submission for the lapsed study.

2 POLICY

2.1 If a study expires and enters the "Lapsed" state in SHIELDS, these procedures are to be followed.

3 RESPONSIBILITIES

3.1 Ther IRB Director and staff are responsible for following these procedures.

4 PROCEDURE

4.1 When continuing review is required by law, regulation, or institutional policy and an investigator does not provide a continuing review submission to the IRB or the IRB has not approved a continuing review by the expiration date,

4.1.1 Have all research activities stop.

4.1.2 Have interventions and interactions on current subjects stop, unless the IRB finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual subjects to continue participating.

4.1.3 Do not allow new enrollment of subjects to occur.

4.1.4 Any new submissions (Studies and Modifications) by the PI will not be processed until the lapsed study is brought back into compliance or a closure submission has been approved.

4.2 Once the study has entered the "Lapsed" state, the IRB staff will fill out and email HRP-533 - TEMPLATE LETTER – Lapsed Study immediately to the PI, study staff, and the chair of the PI's department. This letter is also added to the study in SHIELDS using a comment.

4.3 If no continuing review/closure submission is submitted to the IRB for review after two weeks from sending the lapsed study letter to the PI and study team, the IRB staff or director will then fill out HRP-550 – TEMPLATE LETTER – Study Out of Compliance and have it signed by the IRB Chair.

4.3.1 Once HRP-550 has been signed by the chair, it will then be emailed to the PI, study team, the chair of the PI's department, and the IRB Director. It will also be posted to the study in SHIELDS using a comment.

4.4 If no continuing review/closure submission is submitted to the IRB for review after two weeks from sending the out of compliance letter to the PI and study team, the IRB staff or director will then fill out HRP-574 – TEMPLATE LETTER – Admin Closure and have it signed by the IRB Chair.

4.4.1 Once HRP-550 has been signed by the chair, it will then be emailed to the PI, study team, the chair of the PI's department, the IRB chair, the Institutional official, the HRPP Quality Assurance and Improvement coordinator, and the Chancellor. It will also be posted to the study in SHIELDS using a comment.

4.5 Once the Admin Closure letter has been sent via email and posted to the study in SHIELDS, the IRB Director will execute the "Close Study (Admin)" function on the study in SHIELDS.

4.6 Once the study has been administratively closed in SHIELDS, the HRPP Quality Assurance and Improvement coordinator will then perform an audit on the study to ensure that all stipulations under section 4.1 of this SOP have been followed.

4.7 When following VA requirements:

4.7.1 In the case of a lapse of a Continuing Review/Annual Progress Report the PI will be notified immediately of the lapse and that all research activities must stop immediately until continuing review can be approved.

(i) A notification letter to the PI from the ACOS/R will be generated promptly by the AO for Research explaining that all research activities must stop immediately.

(ii) If the investigator continues to have a project lapsed due to lapse of continuing review/annual progress report status for a period that exceeds 2 months without communication to the administrative staff, the investigator will be advised that the R&DC will administratively close the project and will require a new submission to re-open the project.

(iii) Study staff access to the study's folder located on the Research server will be locked when the study is lapsed or closed administratively. The AO for Research will remove study staff's access to the folder.

4.8 Special circumstances may occur that hinder the PI's or study team's capabilities for meeting any specific deadline throughout this procedure (including the initial lapse in study approval). The IRB may provide leniency with the PI and study team on a case-by-case basis if efforts are made by the PI to communicate with the IRB explaining the situation.

4.9 If the procedure above ends in the administrative closure of a study and that study's PI submits a new study:

4.9.1 The PI must submit a written response along with the new study clarifying why the previous study lapsed in approval and no actions were taken to bring it back into compliance. The written response must also include a pledge that the new study will remain in compliance for the lifespan of the study.

4.9.2 If the new study also lapses in approval, then the PI will be prohibited from participating in research on campus. This includes being a PI or study team member on any research studies for 365 days (I year).

5 MATERIALS

5.1 HRP-533 - TEMPLATE LETTER – Lapsed Study

5.2 HRP-550 – TEMPLATE LETTER – Study Out of Compliance

5.3 HRP-574 – TEMPLATE LETTER – Admin Closure

HRP-070 IRB Records

1 PURPOSE

1.1 This procedure establishes the process to maintain IRB records.

1.2 The process begins when records are received or created.

1.3 The process ends when records have been filed.

2 POLICY

2.1 IRB records are to include:

2.1.1 Protocol files.

2.1.2 Minutes of IRB meetings.

2.1.3 Copies of all correspondence between the IRB and the investigators.

2.1.4 Current and all previous IRB member rosters.

2.1.5 Current and all previous IRB member files.

2.1.6 Current and all previous policies and procedures.

2.2 Protocol files are to include, as applicable:

2.2.1 All submitted materials.

2.2.2 Protocols.

2.2.3 Investigator brochures.

2.2.4 Scientific evaluations.

2.2.5 Recruitment materials.

2.2.6 Consent documents.

2.2.7 DHHS-approved sample consent document and protocol when they exist.

2.2.8 Progress reports submitted by investigators.

2.2.9 Reports of injuries to subjects.

2.2.10 Records of continuing review activities, including the rationale for requiring continuing review of research that otherwise would not require continuing review when applicable under the 2018 Rule.

2.2.11 Data and safety monitoring board reports.

2.2.12 Amendments.

2.2.13 Reports of unanticipated problems involving risks to subjects or others.

2.2.14 Documentation of non-compliance.

2.2.15 Correspondence between the IRB and investigator related to the protocol.

2.2.16 Significant new findings and statements about them provided to subjects.

2.2.17 For initial and continuing review of research by the expedited procedure:

2.2.17.1 The specific permissible category.

2.2.17.2 Description of action taken by the reviewer.

2.2.17.3 Any findings required under the regulations.

2.2.17.4 The rationale for a determination that research that otherwise meets a category for expedited review is greater than Minimal Risk.

2.2.18 For exemption determinations the specific category of exemption.

2.2.19 Unless documented in the IRB minutes determinations required by the regulations and protocol-specific findings supporting those determinations for.

2.2.19.1 Waiver or alteration of the consent process.

2.2.19.2 Research involving pregnant women, fetuses, and neonates.

2.2.19.3 Research involving Prisoners.

2.2.19.4 Research involving children.

2.2.19.5 Research involving adults unable to consent.

2.2.19.6 Significant/non-significant device determinations.

2.2.20 For each protocol's initial and continuing review, the frequency for the next continuing review, including the rationale for requiring continuing review for protocols approved by expedited review that otherwise would not require continuing review.

2.2.21 For Veterans Administration (VA) research:

2.2.21.1 Correspondence between the IRB and the Veterans Administration (VA) Research and Development Committee.

2.2.21.2 Internal or local serious adverse events.

2.2.21.3 Documentation of protocol deviations.

2.2.21.4 Reports of complaints from subjects

2.2.21.5 Records of expedited review activities

2.2.21.6 HIPAA Authorization documents

2.2.21.7 Audit results and documentation of compliance with remediation requirements

2.2.22 Records for FDA-regulated research are to be accessible for inspection and copying by authorized representatives of FDA at reasonable times and in a reasonable manner.

2.2.23 Records for research conducted, supported, or otherwise subject to regulation by a federal department or agency are to be accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner.

2.2.23.1 Records maintained that document compliance or Noncompliance with DoD regulations shall be made accessible for inspection and copying by representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD component.

2.3 Policies and procedures include:

2.3.1 Checklists.

2.3.2 Forms.

2.3.3 SOPs.

2.3.4 Template letters.

2.3.5 Template minutes.

2.3.6 Worksheets.

2.4 IRB member files include a resume for each IRB member.

3 RESPONSIBILITIES

3.1 IRB staff members are responsible to carry out these procedures.

4 PROCEDURE

4.1 Ensure that the IRB Records and Protocol files are maintained in the electronic system. Paper records may be used as indicated below or as a back-up system:

4.1.1 Minutes of IRB meetings: File a paper copy in minutes binder and electronic meeting workspace.

4.1.2 Store all protocol-specific information (communications, documents, determinations) in the electronic system and make paper copy as needed.

4.2 File correspondence NOT related to a specific protocol in a file related to that person or topic in the electronic system.

4.3 IRB member rosters: File paper copies into the IRB shared drive for the corresponding year; add list of members to electronic system.

4.4 IRB membership records (e.g., curricula vita and resumes): File in IRB member files in the IRB shared drive.

4.5 Policies and procedures:

4.5.1 File paper copy of current policies and procedures in the policies and procedures binder and electronic equivalent in the IRB Library in the electronic system.

4.5.2 File copy of replaced policies and procedures in the policies and procedures file of the IRB shared drive.

5 REFERENCES

5.1 45 CFR 46.115 7.2

5.2 21 CFR 56.115 7.1

5.3 AAHRPP I.7.A.; II.2.G.; II.2.H.; II.4.A.; II.5.A.; II.5.B.

HRP-071 Standard Operating Procedures

1 PURPOSE

1.1 This procedure establishes the process to create and update standard operating procedures and associated checklists and worksheets.

1.2 The process begins when the IRB Director or Institutional Official / Organizational Official (IO/OO) or designee determines that a standard operating procedure needs to be created or modified.

1.3 The process ends when the new or revised standard operating procedure has been approved and filed.

2 RESPONSIBILITIES

2.1 The IRB Director carries out these procedures.

3 PROCEDURE

3.1 For a new standard operating procedure, assign a number.

3.2 Assign an author and approver.

3.3 Have the author create or update the standard operating procedure following the HRP-505 - TEMPLATE SOP or update the associated checklist or worksheet.

3.4 Have the approver review and approve the document.

3.5 Once approved by the approver:

3.5.1 Update the approval/effective date.

3.5.2 File and maintain the approved new or revised document in the standard operating procedure files.

3.5.3 Post the approved procedure on the Human Research Protection Program Web site.

3.5.4 File and retain the previous version in the standard operating procedure files.

3.5.5 Send an email to affected individuals informing them of the change.

4 MATERIALS

4.1 HRP-505 - TEMPLATE SOP

4.2 AAHRPP I.1.D.; III.1.A.

HRP-072 IRB Records Retention

1 PURPOSE

1.1 This procedure establishes the process to retain IRB records.

1.2 The process begins each year in June.

1.3 The process ends when records that no longer need to be retained are destroyed.

2 POLICY

2.1 In accordance with the Common Rule and FDA regulations (45 CFR 46.115(b) and 21 CFR 56.115(b)), IRB records are retained for at least three (3) years after the completion of the research, either electronically or as hard copy. Protocol files are to be retained as long as required by law or as stated in clinical trial agreement but no less than three (3) years after completion of the research and then destroyed.

2.2 Protocols in which there was no subject enrollment, or no research was conducted are to be retained the same as protocols where research was conducted.

2.3 In accordance with federal HIPAA privacy regulations, IRB records pertaining to records containing protected health information (PHI) are retained for at least six (6) years after the completion of the research. It is LSUHSC-S policy to retain records for the greatest amount of mandated time. Thus, the IRB retains all research records for at least six (6) years.

2.4 Sponsored grants and contracts may require additional periods for record retention.

2.5 All records not in protocol files are retained indefinitely.

2.6 Records may be maintained in printed form or electronically.

2.7 Records pertaining to the following are to be accessible for inspection and copying by authorized representatives of that agency at reasonable times and in a reasonable manner:

2.7.1 All records for research conducted or funded by a Common Rule department or agency

2.7.2 Records maintained that document compliance or non-compliance with DoD regulations,

2.7.3 Records for research subject to FDA regulations

2.7.4 VA records

2.8 Records maintained indefinitely in the HRPP office include: IRB approved meeting minutes, A resume or curriculum vitae for each IRB member, and current and previous versions of IRB member rosters.

2.9 VA required records, including the investigator's research records, must be retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS I0-1). Records pertaining to research must be stored securely in the IRB Office. After that time those records will be shredded or otherwise destroyed. When following VA regulations, required records, including the investigator's research records, must be kept for six (6) years. Codes/Keys linking subject data to identifiers must be kept as part of the research protocol for six (6) years. All records must be accessible for inspection and copying by authorized representatives of the OHRP, FDA, sponsors, and other authorized entities at reasonable times and in a reasonable manner. Records are maintained in locked file cabinets and/or locked offices within the main HRPP Office and are available only to IRB members and IRB office staff.

3 RESPONSIBILITIES

3.1 IRB staff members carry out these procedures.

4 PROCEDURE

4.1 Destroy protocol files for Veterans Administration (VA) research when approved by the National Archives and Records Administration.

4.2 Destroy protocol files for the DoD research when approved by the DoD. The agency may require submitting records to the DoD for archiving.

4.3 Destroy all other protocol files when the protocol has been closed, withdrawn, or terminated more than three (3) years unless otherwise required by law.

4.3.1 In the case of multi-center research, three (3) years is referenced to the organization's involvement in the research, not the entire study.

5 REFERENCES

5.1 45 CFR 46.115

5.2 21 CFR 56.115

5.3 AAHRPP II.5.A.; II.5.B.

HRP-080 IRB Formation

1 PURPOSE

1.1 This procedure establishes the process to form a new IRB or update the OHRP IRB registration of an existing IRB.

1.2 The process begins when the Institutional Official / Organizational Official (IO/OO) or designee determines the need for a new IRB or updated OHRP IRB registration.

1.3 The process ends when the IRB is registered, the Federalwide Assurance (FWA) is updated (if needed), and all members have completed training (if needed).

2 POLICY

2.1 IRB rosters are maintained using the "IRB Roster."

2.2 IRB registrations on file with OHRP will be made or updated as follows:

2.2.1 To register any additional IRB before it is designated under an FWA, and reviews research conducted or supported by HHS.

2.2.2 Within 90 days after changes regarding the contact person who provided the IRB registration information or the IRB chairperson,

2.2.3 Within 30 days of the change if an FDA-regulated IRB decides to review additional types of FDA-regulated products (e.g., to review device studies if it only reviewed drug studies previously) or to discontinue reviewing clinical investigations regulated by FDA.

3 RESPONSIBILITIES

3.1 IRB staff members carry out these procedures.

3.2 The IO/OO or designee appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.)

4 PROCEDURE

4.1 For new IRBs:

4.1.1 Determine from the IO/OO or designee whether the IRB will conduct all reviews without limitation or will be limited to certain types of reviews.

4.1.1.1 Select:

4.1.1.1.1 At least five individuals to serve as IRB members.

4.1.1.1.2 Additional individuals to serve as alternate IRB members, if needed.

4.1.1.1.3 At least one of the individuals to be the IRB chair.

4.1.1.2 Follow SOP: HRP-082 IRB Membership Addition for each IRB member.

4.1.1.3 Use HRP-304 - WORKSHEET - IRB Composition and revise the selected individuals as needed to ensure that the IRB is appropriately constituted.

4.1.1.4 Notify the IRB Director when all individuals have completed training.

4.1.1.5 Using the "Create Committee" Smart Form, create the new committee in the system.

4.1.1.6 Once training is completed, add committee members to the system with the Committee Member role.

4.1.1.7 Assign any designees eligible to conduct non-committee reviews using the "Update Eligible Designated Reviewers" activity.

4.2 Register the new IRB, or update an existing IRB's OHRP registration as required by this policy, by following the instructions available at the OHRP website, **https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-registration/new-irb-registration/index.html**

4.3 On an as needed basis, but no less than quarterly, the IRB Director reviews the IRB Roster for accuracy and completeness. Any additions or deletions to the IRB Roster are reported to OHRP.

5 MATERIALS

5.1 IRB Roster

5.2 HRP-202 - TEMPLATE/FORM - IRB Member Information

5.3 SOP: HRP-082 IRB Membership Addition

5.4 HRP-560 - TEMPLATE LETTER - IRB Member Appointment

5.5 HRP-304 - WORKSHEET - IRB Composition

6 REFERENCES

6.1 45 CFR 46.103; 45 CFR 46.107; 45 CFR 46.108; 45 CFR 46.115(a)(5)

6.2 21 CFR 56.107; 21 CFR 56.115(a)(5)

6.3 AAHRPP I.1.A.; II.1.

HRP-081 IRB Removal

1 PURPOSE

1.1 This procedure establishes the process to remove/deactivate an IRB.

1.2 The process begins when the Institutional Official / Organizational Official (IO/OO) or designee determines that an IRB is no longer needed.

1.3 The process ends when the IRB is unregistered with OHRP, and the Federalwide Assurance (FWA) is updated.

2 POLICY

2.1 IRB rosters are maintained using the "IRB Roster".

3 RESPONSIBILITIES

3.1 IRB staff members carry out these procedures.

4 PROCEDURE

4.1 For internal IRBs:

4.1.1 For each IRB member who will no longer serve as an IRB member prepare a HRP-561 - TEMPLATE LETTER - IRB Member Thank You have them signed by the IO/OO or designee and send to the former IRB members.

4.1.2 Unregister the IRB with OHRP[9].

4.1.3 Remove the IRB from the FWA.

4.1.4 Remove members from "IRB Roster."

4.1.5 Remove the individual's Committee Member role in the system.

4.1.6 File:

4.1.6.1 IRB Roster

4.1.6.2 FWA

4.1.6.3 HRP-561 - TEMPLATE LETTER - IRB Member Thank You

4.2 For external IRBs follow the requirements of the inter-institutional agreement or contract.

4.2.1 Update the roster of IRB(s).

5 MATERIALS

5.1 IRB Roster

5.2 HRP-561 - TEMPLATE LETTER - IRB Member Thank You

6 REFERENCES

[9] See **http://www.hhs.gov/ohrp/assurances/**. Use the Web site: **https://ohrp.cit.nih.gov/efile/.**

6.1 45 CFR 46.107; 45 CFR 46.103(b)(3); 45 CFR 46.115(a)(5)

6.2 21 CFR 56.107; 21 CFR 56.115(a)(5)

6.3 AAHRPP II.1.A.

HRP-082 IRB Membership Addition

1 PURPOSE

1.1 This procedure establishes the process to appoint and re-appoint an IRB member.

1.2 The process begins when an individual expresses interest, is nominated or applies to join the IRB IO/OO (This may be a completely new IRB member, or re-appointment of a previous member).

1.3 The process ends when the IRB roster is updated, and the new member has completed training.

2 POLICY

2.1 IRB rosters are maintained using the "IRB Roster."

2.2 IRB members /alternates are appointed by the IO/OO. Reappointment of members/alternates is at the discretion of the IO/OO.

3 RESPONSIBILITIES

3.1 IRB staff members carry out these procedures.

3.2 The Institutional Official / Organizational Official (IO/OO) or designee appoints/re-appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.).

3.2.1 IRB Chair and IRB Vice-Chair:

3.2.1.1 The IO/OO in consultation with the IRB members appoints a Chair for each IRB. Any change in appointment is at the discretion of the IO and requires written notification from the IO. The IRB Chair and IRB Vice-Chair must have previously served as members of the IRB.

3.2.1.2 The IRB Chair should be a highly respected individual, from within the Institution, fully capable of managing the IRB, and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of the Chair. The IRB must be perceived to be fair, impartial, and immune to pressure by the institution's administration, the investigators whose protocols are brought before it, and other professional and nonprofessional sources.

3.2.1.3 The criteria used to select an IRB Chair include experience with, and knowledge of, applicable Federal and State laws and regulations and Institutional

policies. This individual must be willing to commit to the IRB; must have past experience as an IRB member; and must demonstrate excellent communications skills, along with an understanding of clinical research. The IRB Chair must also be flexible and demonstrate a thorough understanding of ethical issues involved in clinical research.

3.2.1.4 The IRB Chair convenes and chairs the meetings of the IRB and is required to attend a majority of the convened meetings of the IRB. The IRB Chair may conduct or delegate Expedited Review of Research that qualifies for such review; review the responses of Investigators to contingencies of the IRB (to secure IRB approval); and review and approve minor changes in previously approved research during the period covered by the original approval. The IRB Chair may delegate such authority to the authorized IRB Vice Chair or designee as needed.

3.2.1.5 The IRB Chair plays a leadership role in establishing and implementing IRB policy. The IRB Chair shares authority over all IRB policy and procedures in collaboration with the IO and the AVCRM. The Chair will represent the Institution in discussions with federal authorities.

3.2.1.6 It is recommended that the Chair will communicate with other reviewers so that IRB issues are resolved or identified prior to the convened meeting.

3.2.1.7 The Chair directs the proceedings and discussions of the convened meeting. The Chair is a voting member of the IRB except in situations of declared conflict of interest. The Chair may not review for approval, studies submitted for exempt or expedited review from his/her assigned department.

3.2.1.8 The Chair should have an in-depth understanding of ethical issues, state law, Institutional policy and federal regulations related to the types of research reviewed by the IRB. The IRB Chair is responsible for conducting the meetings and is a signatory for correspondence generated by the IRB. The Chair should review all proposals presented to the full committee.

3.2.1.9 The IRB Chair may designate other IRB members to perform duties, as appropriate, for review, signature authority, and other IRB functions, (e.g., the IRB Vice-Chair or the IRB Director.) The IRB Chair advises the IO/IO designee about IRB member performance and competence. A review of the performance of the IRB Chair will be performed on an annual basis by the IO. Feedback from the evaluation will be provided to the IRB Chair, and their Department Chair if applicable. If the Chair is not acting in accordance with the IRB's mission, not following policies and procedures, has an undue number of absences, or not fulfilling the responsibilities of the Chair, he/she will be removed by the IO and replaced with a suitable alternative.

3.2.1.10 The IRB Committee has one (1) Vice-Chair appointed for the committee. In the absence of the Chair, the Vice-Chair serves as the Chair. The Vice-Chair has the same qualifications, authority, and duties listed above as the Chair.

3.3 For VA Research

3.3.1 VA facility research office staff including, but not limited to, the ACOS/R&D, the AO for R&D, and IRB administrative staff may not serve as voting members of the facility's IRB. They may serve as ex officio, non-voting members or attendees; however, they and the IRB must be sensitive to any potential, actual, apparent, or perceived conflicts of interest and appropriately manage such conflicts.

3.3.2 Research Compliance Officers (RCOs) may act as consultants to the facility's IRB but may not serve as members of the IRB. RCOs may attend IRB meetings when requested by the IRB or as specified by the IRB's SOPs. RCOs must be aware of and manage any potential, actual, apparent, or perceived conflicts of interest that arise because of their role. NOTE: RCOs are further discussed in VHA Handbook 1058.01.

3.3.3 The Privacy Officer (PO) and the Information System Security Officer (ISSO) serve in an advisory capacity to the facility's IRB as either non-voting members or as consultants.

3.3.4 Facility Directors, their administrative staff, COS, other facility senior administrators such as Associate or Assistant Directors or Chief Nurse, and NPC Administrative Staff may observe IRB meetings, but may not serve as members of the facility's IRB.

3.3.5 If alternate members are appointed to the facility's IRB, the IRB's written procedures must describe the appointment and function of alternate members, and the IRB membership roster must identify by name the primary member(s) for whom each alternate member may substitute. The alternate members must have similar member qualification(s) of the primary member they replace.

3.3.6 The IO appoints VA voting members to an IRB in writing. Appointment procedures for ex officio, non-voting members are made according to local SOPs and any other applicable VA requirements. Voting members of VA IRBs and VA representatives to external IRB(s) of Record and the VA Central IRB are appointed for a period of up to three (3) years. They may be re-appointed to new terms of up to three (3) years without a break in service at the end of each term. NOTE: There is not a maximum number of terms for IRB members as long as the composition of the IRB meets all requirements. VA representation on external IRBs, such as academic IRBs, is optional and at the discretion of the IO and the external IRB.

4 PROCEDURE

4.1 Have the individual complete the "FORM: IRB Member Information (HRP-202)."

4.2 Obtain a copy of the individual's résumé or curriculum vita.

4.3 Interview the individual to assess suitability and availability.

4.3.1 Determine from the IO/OO or designee whether the individual will be a regular IRB member, alternate IRB member, or IRB chair.

4.3.2 In any instance for which the scientific or non-scientific status or affiliation status of a newly appointed or re-appointed IRB member may be questionable, the Institutional Official or designee will be consulted before proceeding with the appointment.

4.3.3 For VA representatives, communicate with the VA Medical Center Director in writing to obtain confirmation of the appointment.

4.4 Add the individual to the "IRB Roster."

4.5 Complete HRP-304 - WORKSHEET - IRB Composition and revise the membership as needed to ensure that the IRB is appropriately constituted.

4.6 An appointment letter from the IO will be sent to the individual.

4.6.1 If the individual requires training, schedule the individual for training. Training includes IRB Orientation, completion of CITI (IRB Members Course) and completion of COI disclosure in SHIeLDS.

4.7 Update the registration of all affected IRBs at **https://ohrp.cit.nih.gov/efile/** within 90 days.

4.8 File:

4.8.1 IRB Roster

4.8.2 Signed IRB appointment/re-appointment letter

4.8.3 FORM: IRB Member Information (HRP-202).

4.8.4 Résumé or curriculum vita.

4.8.5 Any other signed agreements.

4.9 Notify the IRB Director when the individual has completed training.

4.9.1 Assign individual the "Committee Member" role in the system.

4.9.2 If the individual is designated to conduct non-committee reviews, update the “Update Eligible Designated Reviewers” activity.

5 MATERIALS

5.1 IRB Roster

5.2 HRP-304 - WORKSHEET - IRB Composition

5.3 HRP-560 - TEMPLATE LETTER - IRB Member Appointment

5.4 HRP-561 - TEMPLATE LETTER - IRB Member Thank You

5.5 HRP-202 - FORM - IRB Member Information

6 REFERENCES

6.1 45 CFR 46.107; 45 CFR 46.108(a)(2); 45 CFR 46.115(a)(5)

6.2 21 CFR 56.107; 21 CFR 56.115(a)(5)

6.3 AAHRPP II.1.A.; II.1.B.

HRP-083 IRB Membership Removal

1 PURPOSE

1.1 This procedure establishes the process to remove an IRB member.

1.2 The process begins when an IRB member resigns or is removed from one or more IRBs.

1.3 This procedure applies if an individual is a member of more than one IRB and is being removed from some but not all IRBs.

1.4 The process ends when the IRB registration is updated.

2 POLICY

2.1 The Institutional Official / Organizational Official (IO/OO) or designee may remove IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs) with consultation from the IRB Director and IRB chair(s).

2.2 IRB rosters are maintained using the "IRB Roster."

3 RESPONSIBILITIES

3.1 IRB staff members carry out these procedures.

4 PROCEDURE

4.1 Remove the individual from "IRB Roster."

4.2 Complete HRP-304 - WORKSHEET - IRB Composition to ensure that the IRB is appropriately constituted.

4.3 Revise membership as needed. Prepare a HRP-561 - TEMPLATE LETTER - IRB Member Thank You have it signed by the IO/OO or designee and send to the individual.

4.4 Update the registration of all affected IRBs.[10]

4.5 File:

4.5.1 IRB Roster

4.5.2 HRP-561 - TEMPLATE LETTER - IRB Member Thank You

4.6 Remove individual's "Committee Member" role in the system.

4.6.1 If applicable, update the "Update Eligible Designated Reviewers" activity.

5 MATERIALS

5.1 IRB Roster

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[10] See **http://www.hhs.gov/ohrp/assurances/**. Use the Web site: **https://ohrp.cit.nih.gov/efile/**.

5.2 SOP: HRP-082 IRB Membership Addition

5.3 HRP-561 - TEMPLATE LETTER - IRB Member Thank You

5.4 HRP-304 - WORKSHEET - IRB Composition

6 REFERENCES

6.1 45 CFR 46.107; 45 CFR 46.103(b)(3); 45 CFR 46.115(a)(5)

6.2 21 CFR 56.107; 21 CFR 56.115(a)(5)

6.3 AAHRPP II.1.A.

HRP-084 IRB Meeting Scheduling and Notification

1 PURPOSE

1.1 This procedure establishes the process to schedule and notify individuals of convened meetings.

1.2 The process begins when there are approximately fewer than 90 days of meetings on the current schedule.

1.3 The process ends when meetings are scheduled at least three months in advance and individuals in the organization are notified of the schedule.

2 POLICY

2.1 Whenever possible the IRB schedules meetings at least 90 days in advance.

2.2 Scheduled meetings are to occur at intervals appropriate for the quantity, complexity, and frequency of required actions, and to permit adequate oversight of the progress of approved research. At present the IRB meets twice a month, but meetings may vary due to holidays or lack of quorum.

2.3 Additional meetings may be scheduled on an ad hoc basis to deal with urgent issues provided members are given sufficient notification and materials.

3 RESPONSIBILITIES

3.1 The IRB staff carries out these procedures.

4 PROCEDURE

4.1 Create a schedule of meetings for each IRB.

4.1.1 Execute the “Create Meeting” Smart Form in the system for each scheduled meeting.

4.2 Post the schedule on the organization’s Web site.

4.3 Notify the following individuals of the updated schedule with an email providing a link to the IRB Web page with the schedule information:

4.3.1 IRB members.

4.3.2 Investigators and research staff on the IRB email list.

4.3.3 Institutional Official / Organizational Official (IO/OO) or designee.

4.4 Special meetings may be called by the IRB Chair/designee at any time to deal with urgent issues.

4.5 Under special circumstances, such as during the COVID-19 pandemic, when IRB board members and staff cannot meet in person, the IRB meetings can be scheduled and conducted remotely via teleconference/videoconference.

5 REFERENCES

5.1 ICH-GCP E6 3.3.2

5.2 AAHRPP II.2.C.; II.2.D.

HRP-090 Informed Consent Process for Research

1 PURPOSE

1.1 This procedure establishes the process to obtain informed consent from subjects, the Legally Authorized Representative (LAR) of adults unable to consent, or the parents or guardians of children and recommendations on the use of electronic systems and processes that may employ multiple electronic media to obtain informed consent for both HHS-regulated human subject research and FDA-regulated clinical investigations of medical products, including human drug and biological products, medical devices, and combinations thereof.

1.2 The process begins when an individual identifies a subject as a potential candidate for a research study.

1.3 The process ends when a subject or the subject's LAR provides legally effective informed consent or declines to do so.

1.4 Broad consent will not be implemented at this time.

1.5 Informed consent is a continuing process whereby the investigator and research subject have an ongoing dialogue about all aspects of a research study that might inform a subject's decision to take part in the study and their decision to continue their involvement as a subject. The purpose of the consent process is to assure knowledgeable decision making and voluntary participation. No investigator conducting research under the auspices of the Institution may involve a human being as a subject in research without obtaining the legally effective informed consent of the subject or the subject's legally authorized representative unless a waiver of consent has been approved by the IRB.

1.6 The informed consent process generally includes:

1.6.1 Bringing the research study to the notice of potential subjects

1.6.2 Presentation and explanation of the study activities to the subject or their legally authorized representative (LAR)

1.6.3 Documentation of the informed consent by means of a signed and dated written consent document

1.6.4 Ongoing discussions between the investigator and the subject regarding continued participation in the study

1.7 The informed consent process application must:

1.7.1 Include the person who will conduct the consent interview and the person who will provide consent or permission.

1.7.2 Provide sufficient opportunity for the subject, or the subject's legally authorized representative (LAR), to consider whether to participate

1.7.3 Minimize the possibility of coercion or undue influence

1.7.4 Not include exculpatory language

1.7.5 Be in language understandable to the subject or their representative

1.7.6 Be conducted with the subject face-to-face/remotely for remote consent, in a private and quiet setting

1.8 The IRB also requires that the circumstances of the consent process be culturally and linguistically appropriate for the intended subjects. The IRB will evaluate both the consent process and the procedures for documenting informed consent to ensure that adequate informed consent is obtained from subjects.

1.9 For VA Research: All VA research requiring written informed consent must use the VA Informed Consent and all required elements must be present and completed, and a separate VA HIPAA Document. The requirement to utilize the VA Informed Consent and VA HIPAA Document to document informed consent applies to all VA-approved research including, but not limited to, studies in which VA investigators working on VA research enroll subjects at an affiliate hospital or other sites outside VA (e.g., community centers or shopping malls). The most recent IRB-approved version of the informed consent form contains the IRB approval date on the consent document. All required elements of the Common Rule must be present and completed as well as any additional elements required by the IRB.

1.10 Evaluation of Compliance with Informed Consent Requirements is achieved by:

1.10.1 IRB review of the informed consent process information and documents provided by the principal investigator. The IRB will determine

1.10.1.1 The investigator will obtain the legally effective consent of the subject or the subject's legally authorized representative.

1.10.1.2 The circumstances of the consent process provide the prospective subject or the legally authorized representative sufficient opportunity to consider whether to participate.

1.10.1.3 The circumstances of the consent process minimize the possibility of coercion or undue influence.

1.10.1.4 The individuals communicating information to the subject or the legally authorized representative during the consent process will provide that information in language understandable to the subject or the representative.

1.10.1.5 The information being communicated to the subject or the representative during the consent process will not include exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights.

1.10.1.6 In order to approve research, the IRB will determine that in seeking consent, the required disclosures will be provided to each subject or a legally authorized representative in accordance with legal and regulatory requirements.

1.10.1.7 The IRB will consider whether additional disclosures are required for inclusion in the consent process. The IRB will ensure that the consent process will be documented according to legal and regulatory requirements.

1.10.2 Periodic consent form audits comparing signed and dated consent forms with the IRB approved versions.

1.10.3 Observation of the consent process performed either as a periodic audit function of the HRPP or as requested by the IRB.

2 POLICY

2.1 In this procedure "investigator" means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.

2.2 In this procedure "subject/LAR" means:

2.2.1 The subject when the subject is an adult capable of providing consent.

2.2.2 LAR when the subject is an adult unable to give consent.

2.2.3 One or both biologic or adoptive parents when the subject is a child or in the absence of a parent a person other than a parent authorized under applicable law to consent on behalf of the child to general medical care.

2.3 The exchange of information between the investigator and study subject can occur via one or more of the following modes of communication, among others: face to face contact, mail, telephone, fax or electronically. However, the most preferred methods to obtain informed consent must be face to face between the investigator and the potential study subject/study subject's legally authorized representative.

2.3.1 When appropriate, (retrospective chart reviews, electronic surveys, and questionnaires) a request for waiving or altering some or all required elements of informed consent is required for any consent process that is not conducted face-to-face.

2.4 If the subject/LAR understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/LAR.

2.5 If the subject is an adult unable to consent:

2.5.1 The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.

2.5.2 Permission is obtained from a LAR.

2.5.3 A LAR must be in the class or persons approved by institutional policy or the IRB. See SOP: HRP-013 LARs, Children, and Guardians.

2.6 If the subject is a child:

2.6.1 The IRB must have specifically approved the protocol to allow the enrollment of children.

2.6.2 Permission is obtained from both parents unless:

2.6.2.1 One parent is deceased, unknown, incompetent, not reasonably available.

2.6.2.2 Only one parent has legal responsibility for the care and custody of the child or

2.6.2.3 The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.

2.6.3 If investigators foresee that obtaining consent remotely from the second parent (by e.g., fax, mail, electronically) may be necessary for a study, the consenting plan submitted for IRB review and approval should include how this would be accomplished.

2.6.4 In the absence of parent, permission may be obtained from an individual authorized to consent under applicable law on behalf of a child to general medical care.

2.7 Generally, the IRB requires assent from children 7 or older but this may vary depending on other factors. Once the IRB has enough information about the assent process, the IRB determines whether assent is a requirement of all children, some of the children or none of the children

2.7.1 Provide an assent document to children that can provide assent when required by the IRB.

2.8 If the subject/LAR cannot speak English:

2.8.1 The IRB must have specifically approved the protocol to allow the enrollment of subjects able to speak language that the subject understands.

2.8.2 When non-English speaking subjects are expected to enroll in the research the non-English consent documents require a certificate of translation to verify the translations are accurate.

2.8.3 Those who translate the consent document are to provide a brief description of their qualifications, skill or experience or serving in this role and sign the certificate of translation form. HRP-225 - TEMPLATE/FORM - Translation Certificate.

2.8.4 The research investigator may wish to delay the initial translation of the consent documents until after the IRB has reviewed and approved the English versions.

2.8.5 Translation/Interpreting Services: Services are provided by the Institution using contracted professional resources that have been identified as able to provide multi-lingual translation/interpreting services. Nursing units shall have a princess phone stored on the unit with a splitter that will be used to access interpreting services. When interpretative services are needed, the extra phone with the splitter will be taken into the room and the phone in the room will be taken out of the wall jack, the splitter inserted into the wall jack and both lines connected to the splitter. This will allow the patient and another person to speak and hear responses without delay. A princess phone line with splitter can be obtained from Telecommunication. These services shall be made available upon request by contacting the Social Services Department. A list of employees that can provide interpretive services is also maintained by Social Services.

2.9 Conduct all discussions in a private and quiet setting.

2.10 Any knowledgeable individual may:

2.10.1 Review the study with subject/LAR to determine preliminary interest.

2.10.2 If the subject/LAR is interested, notify an investigator.

2.10.3 If the subject/LAR is not interested, take no further steps regarding recruitment or enrollment.

2.11 In Sponsored research, medical care for subjects is addressed by:

2.11.1 Including in its standard contract template a provision that the sponsor provides for the cost of diagnosis, care and treatment of any undesirable side effects, adverse reactions, illness, or injury to a subject, without regard as to the fault of the Sponsor. All Funding agreements will indicate who will provide care and who is responsible to pay for it.

2.11.2 Asking for an inclusion of such a provision in any proposed contract that does not use LSUHSC-S Institutional standard template.

2.11.3 Including the substance of any such provision in the consent form (See LSUHSC-S consent form template).

2.11.4 Including a statement in the consent form that subjects do not waive any liability rights for personal injury by signing consent form.

2.12 Remote Consent:

2.12.1 FDA's requirements for electronic records/electronic signatures, informed consent, and IRBs are set forth in 21 CFR parts 11, 50, and 56, respectively. HHS requirements regarding the protection of human subjects are set forth in 45 CFR part 46. The information presented to the subject, processes used for obtaining informed consent, and documentation of the electronic informed consent (eIC) must meet the requirements of these and other applicable regulations.

2.12.2 The purpose of remote consent is to allow the investigator/study team member and potential subject to engage in the informed consent process in a way that is like what would be conducted in-person under normal circumstances. These conversations may occur via telephone, conference call, video conferencing, or telemedicine. Since the subject/LAR and witness (if applicable as per 21 CFR 50.27) needs to reference the informed consent form during the conversation, the informed consent must be sent electronically or via mail to them prior to engaging in the informed consent conversation.

2.12.3 The consent process may take place at the study site or remotely. The electronic consent form may be provided for both on-site and remote access.

2.12.4 If the consent process takes place at the study site, the study personnel can personally verify the subject's identification, review the electronic consent, answer questions about the material, have follow-up discussions, and witness the signing of the electronic consent.

2.12.5 If any or part of the consent process takes place remotely, then the electronic consent process must include a method to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study or is the subject's LAR (see 21 CFR 11.100(b))

2.12.6 Under special circumstances, electronic signatures/digital signatures may be allowed in lieu of traditional “wet ink” or “handwritten” signatures on informed consent form by the subject/LAR, the witness (if applicable as per 21 CFR 50.27) and the investigator. An example of such a special circumstance would be the COVID-19 pandemic, during which the investigators and the subjects are facing challenges with the informed consent process as the subjects participating in IRB approved studies are restricted to visit the study sites/investigator clinics in order to minimize the exposure.

2.12.6.1 An “electronic signature” means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

2.12.6.2 For clinical investigations regulated by the FDA, the electronic signature must comply with 21 CFR Part 11. Research not subject to 21 CFR parts 50 and 56 is also not generally subject to 21 CFR part 11 (FDA regulations regarding electronic records and electronic signatures).

2.12.6.3 A valid electronic signature for consent and HIPAA authorization could be the subject's typed name or it could even be as simple as a check mark or an X or any other symbol in a box on a form. Any method is valid provided that the mark or symbol is "logically associated" with the individual making that mark or authorized by an individual to be the legally binding equivalent of the individual’s handwritten signature. To associate the individual to the mark, the subject/LAR could:

2.12.6.3.1 Type their name

2.12.6.3.2 Type a unique ID number provided via phone or email; or

2.12.6.3.3 Type an answer to a “secret question,” that the subject previously provided to the study team.

2.12.6.4 To satisfy the regulatory requirements for written consent and written HIPAA authorization, the following criteria must be incorporated into the electronic form:

2.12.6.4.1 A valid electronic signature must be obtained;

2.12.6.4.2 Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.

2.12.6.4.3 The electronic signature must be linked to the record to which it pertains to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.

2.12.6.4.4 The meaning of the signature (such as review, approval, responsibility or authorship) must be indicated.

2.12.6.4.5 The subject must receive a printed or emailed copy of the signed document; and

2.12.6.4.6 The electronic document (consent or authorization) must reside in a system with timestamped audit trail indicating dates, times, location, and the chain of custody.

2.13 If someone other than the principal investigator conducts the interview and obtains consent from a patient, the investigator needs to formally delegate this responsibility in writing in the protocol or the IRB application, and the person so delegated must have received appropriate training to perform this activity. The person so delegated must be knowledgeable about the research to be conducted and the consenting process and must be able to answer questions about the study. Prior to a subject's participation in a trial, the written consent document should be signed and personally dated by the person who conducted the informed consent discussion.

3 RESPONSIBILITIES

3.1 The principal investigator is responsible to ensure these procedures are carried out.

4 PROCEDURE

4.1 If the consent process will be documented in writing with the long form of consent documentation:

4.1.1 Obtain the current IRB approved consent form.

4.1.2 Verify that you are using the most current IRB-approved version of the study specific consent form and that the consent form is in language understandable to the subject/LARLAR.

4.1.3 Provide a copy of the consent form to the subject/LAR. Whenever possible provide the consent form to the subject/LAR in advance of the consent discussion.

4.1.4 Legally effective informed consent includes the basic required elements and the additional elements, if applicable to the study, as specified in 45 CFR 46.116 and 21 CFR 50.25. Basic Elements (must be provided to each subject):

4.1.4.1 A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed and identification of any procedures which are experimental.

4.1.4.2 A description of any reasonably foreseeable material risks or discomforts to the subject.

4.1.4.2.1 A material risk is a risk that if disclosed to a prospective subject, would have affected the decision of a reasonable person whether to participate. A description of any benefits to the subject or to others which may reasonably be expected from the research.

4.1.4.3 A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

4.1.4.4 A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. For FDA regulated studies, the possibility that the Food and Drug Administration may inspect the records.

4.1.4.5 For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

4.1.4.6 An explanation of whom to contact for answers to pertinent questions about the research subjects' rights, and whom to contact in the event of a research-related injury.

4.1.4.7 A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

4.1.5 When following ICH-GCP (E6), the IRB determines that the following disclosures are included in the consent document:

4.1.5.1 The alternative procedures or treatment that might be available to the subject, and their important potential benefits and risks.

4.1.5.2 That the monitor, the auditor, the IRB, and the regulatory authority will be granted direct access to the subject's original medical records for verification of clinical trial procedures or data without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written consent form, the subject or the subject's legally acceptable representative is authorizing such access.

4.1.5.3 The approval of the IRB.

4.1.5.4 For VA Research the following is required:

4.1.5.4.1 A statement that in the event of a research-related injury the VA has to provide necessary medical treatment to a subject injured by participation. This includes any research approved by a VA RDC and conducted under the supervision of one (1) or more VA employees. For research involving more than minimal risk, the consent process and document will disclose a statement that in the event of a research-related injury the VA has to provide necessary medical treatment to a subject injured by participation. VA regulations require the VA to provide care for all research-related injuries including those studies that are considered minimal risk even, if a statement is not included in the consent process or document for research involving no greater than minimal risk.

4.1.5.5 A statement that a veteran-subject does not have to pay for care received as a subject in a VA research study except in accordance with federal law.

4.1.5.6 An indication that all regulations pertaining to the participation of veterans as subjects, including requirements for indemnification in case of research-related injury, pertain to non-veterans subjects enrolled in VA-approved research.

4.1.5.7 This does not apply to: (a) treatment for injuries due to non-compliance by a subject with study procedures; or (b) research conducted for VA under a contract with an individual or a non-VA institution.

4.1.5.8 Consent for research must be obtained from each research subject before taking photographs or making voice or video recordings that will be used for research purposes. Unless the IRB grants a waiver of documentation of the consent process for research, the consent document for research must include a discussion of why photographs, or voice or video recordings are being taken for the research, who will have access to them, and what their disposition will be after the research is completed.

4.1.5.9 When the research subject is a patient (either an inpatient or outpatient), the subject must sign VA Form 10-3203 to permit photographs or video and voice recordings that will be used for research purposes even if the IRB has waived the requirement for documentation of consent for research. Photography or recordings cannot occur prior to the patient's granting such permission.

4.1.5.10 When the research subject is a patient, the subject's signed and dated VA Form 10- 3203 must be placed into the medical record along with, if applicable, the signed and dated VA informed consent document. The signed VA Form 10-3203 must be obtained and placed in the subject's medical record, even if the IRB has waived documentation of consent for research.

4.1.5.11 If someone other than the investigator conducts the interview and obtains consent, policies and procedures have the investigator formally and prospectively designate in writing in the protocol or the IRB application, the individual who will have this responsibility. The person so delegated must have received appropriate training to perform this activity. This person must be knowledgeable about the research to be conducted and the consenting process and must be able to answer questions about the study. This designee must be a member of the research team.

4.1.6 Additional Elements: When appropriate, one or more of the following elements of information must also be provided to each subject:

4.1.6.1 A statement that a treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

4.1.6.2 Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

4.1.6.3 Any additional costs to the subject that may result from participation in the research.

4.1.6.4 The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

4.1.6.5 A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

4.1.6.6 The approximate number of subjects involved in the study.

4.1.6.7 For applicable clinical trials, the following statement shall be provided in informed consent documents and processes: "A description of this clinical trial will be available at **http://www.ClinicalTrials.gov**, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

4.1.7 New section of consent – key information.

4.1.7.1 "Consent forms must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in research."

4.1.7.2 Begin with a concise and focused presentation of key information that is most likely to assist the subject/LAR to understand the reasons why one might or might

not want to participate in the research. Explain the details in such a way that the subject/LAR understands what it would be like to take part in the research study.

4.1.8 As per the revised common rule, New Elements of Informed Consent include,

4.1.8.1 One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

4.1.9 New additional elements of consent (optional):

4.1.9.1 A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

4.1.9.2 A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

4.1.9.3 For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

4.1.10 Posting of clinical trial consent form

4.1.10.1 Posting the clinical trial consent form is the responsibility of the awardee.

4.1.10.2 For federally funded projects where LSUHS is the only awardee, the LSUHS PI bears the responsibility of ensuring the requirement for posting of the consent form is met.

4.1.10.3 For multi-site research (federally or pharmaceutically funded), generally the prime awardee is considered the responsible party and must ensure compliance with the posting requirement.

4.1.10.4 The consent form must be posted on a publicly available website approved for such posting. As per OHRP guidance, issued on 8/28/2018, the two publicly

available federal websites that have been identified to satisfy the consent form posting requirement are,

4.1.10.4.1 ClinicalTrials.gov

4.1.10.4.2 A docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

4.1.10.5 For studies that are registered on ClinicalTrials.gov, the consent form must be posted on ClinicalTrials.gov.

4.1.10.6 The informed consent form must be posted on the federal website.

4.1.10.6.1 after the clinical trial is closed to recruitment, and

4.1.10.6.2 no later than 60 days after the last study visit by any subject, as required by the protocol.

4.1.10.7 As per the Revised Common Rule, the version of the consent form that is posted must.

4.1.10.7.1 be the most recent IRB-approved version and

4.1.10.7.2 have been used to enroll a subject in the clinical trial.

4.1.10.8 If the investigator wants to request an exception to the requirement to post the consent form and the process to redact confidential commercial information from the consent, they must follow guidance from the federal agency. Only the federal agency supporting the clinical trial may permit or require redactions to the information posted.

4.1.10.9 For more information, please visit the OHRP website, **https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html**

4.2 If the consent process will be documented in writing with the short form of consent documentation:

4.2.1 NOTE: The short form is used only when subjects cannot speak English.

4.2.1.1 Obtain the current IRB approved short consent form and summary (same as the English consent form used for long form of consent documentation).

4.2.1.2 Verify that you are using the most current IRB-approved version of the study specific short consent form and summary that the short consent form is in language understandable to the subject/LAR.

4.2.1.3 Provide copies to the subject/LAR. Whenever possible provide the short consent form and summary to the subject/LAR in advance of the consent discussion.

4.2.1.4 Obtain the services of an interpreter fluent in both English and the language understood by the subject/LAR. The interpreter may be a member of the research team, family member, or friend of the subject/LAR.

4.2.1.5 Obtain the services of an impartial witness (21 CFR 50.27(b)(2)) who is fluent in both English and the language spoken by the subject/LAR to be present during the entire consent discussion to attest that the information in the short consent form, summary, and any other information provided was accurately explained to, and apparently understood by, the subject/LAR, and that consent was freely given. The witness and the interpreter may be the same person. The witness may be a family member or friend. The witness may not be a person involved in the design, conduct, or reporting of the research study. The witness must be present physically or by some other means, for example, by phone or video conference, during the oral presentation, not just the signing of the consent form (21 CFR 50.27(b)(2)). The witness must sign both the short form and the summary, and the person obtaining consent must sign the summary (21 CFR 50.27(b)(2)).

4.2.1.6 Have the interpreter translate the summary (not the short consent form) to the subject/LAR. Begin with a concise and focused presentation of the key information that is most likely to assist the subject/LAR to understand the reasons why one might or might not want to participate in the research.

4.2.1.7 Through the interpreter explain the details in such a way that the subject/LAR understands what it would be like to take part in the research study. When necessary, provide a different or simpler explanation to make the information understandable.

4.2.1.8 Have the subject/LAR read the short consent form or have the interpreter read the short consent form to the subject/LAR.

4.2.1.9 Have the subject or the subject's LAR sign and date only the short form (21 CFR 50.27(a) and (b)(2)).

4.2.2 If the requirement for written documentation of the consent process has been waived by the IRB:

4.2.2.1 Obtain the current IRB approved script.

4.2.2.2 Verify that you are using the most current IRB-approved version of the study specific script and that the script language is understandable to the subject/LAR.

4.2.2.3 When possible, provide a copy of the script to the subject/LAR.

4.2.2.4 If the subject/LAR cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/LAR. The interpreter may be a member of the research team, a family member, or friend of the subject/LAR.

4.2.3 Read the script (or have an interpreter translated the script) with the subject/LAR. Begin with a concise and focused presentation of the key information that is most likely to assist the subject/LAR to understand the reasons why one might or might not want to participate in the research. Explain the details in such a way that the subject/LAR understands what it would be like to take part in the research study.

4.2.4 Invite and answer the subject/LAR's questions.

4.2.5 Give the subject/LAR time to discuss taking part in the research study with family members, friends, and other care providers as appropriate.

4.2.6 Invite and encourage the subject/LAR to take the written information home to consider the information and discuss the decision with family members and others before making a decision.

4.2.7 Ask the subject/LAR questions to determine whether all the following are true, and if not, either continue the explanation or determine that the subject/LAR is incapable of consent:

4.2.7.1 The subject/LAR understands the information provided.

4.2.7.2 The subject/LAR does not feel pressured by time or other factors to make a decision.

4.2.7.3 The subject/LAR understands that there is a voluntary choice to make.

4.2.7.4 The subject/LAR can make and communicate an informed choice.

4.2.8 If the subject/LAR has questions about treatments or compensation for injury, provide factual information and avoid statements that imply that compensation or treatment is never available.

4.2.9 Once a subject/LAR indicates that he or she does not want to take part in the research study, this process stops.

4.3 If the subject/LAR agrees to take part in the research study:

4.3.1 If the subject is a child:

4.3.1.1 Whenever possible explain the research to the extent compatible with the child's understanding.

4.3.1.2 Request the assent (affirmative agreement) of the child unless:

4.3.1.2.1 The capability of the child is so limited that the child cannot reasonably be consulted.

4.3.1.2.2 The IRB determined that assent was not a requirement.

4.3.1.3 Once a child indicates that he or she does not want to take part in the research study, this process stops.

4.3.2 If the subject is an adult unable to consent:

4.3.2.1 Whenever possible explain the research to the extent compatible with the adult's understanding.

4.3.2.2 Request the assent (affirmative agreement) of the adult unless:

4.3.2.2.1 The capability of the adult is so limited that the adult cannot reasonably be consulted.

4.3.2.2.2 The IRB determined that assent was not a requirement.

4.3.2.3 Once an adult unable to consent indicates that he or she does not want to take part in the research study, this process stops.

4.4 Obtain written documentation of the consent process according to HRP-091 Written Documentation of Consent.

4.5 For minimal risk research such as simple surveys and questionnaires, where the IRB is not likely to require written documentation of consent process, use Consent Letter Template for Surveys or Questionnaires Research.doc.

4.6 Remote Consent:

4.6.1 If the study is conducted or supported by HHS and involves an FDA-regulated product, the study is subject to both 45 CFR part 46 and 21 CFR parts 50 and 56, meaning that both sets of regulations must be followed. Where the regulations differ, the regulations

that offer greater protection to human subjects should be followed. Research not subject to 21 CFR parts 50 and 56 is also not generally subject to 21 CFR part 11 (FDA regulations regarding electronic records and electronic signatures).

4.6.2 Procedure:

4.6.2.1 Obtain the current IRB approved consent form.

4.6.2.2 Verify that you are using the most current IRB-approved version of the study specific consent form and that the consent form is in language understandable to the subject/LAR.

4.6.2.3 If the subject/LAR is unable to be available in person for the informed consent process due to a special circumstance such as the COVID-19 pandemic, provide a copy of the consent form to the subject/LAR in advance of the consent discussion either by mailing the consent form to the subject/LAR's physical address or by providing it to him electronically such as via email.

4.6.2.4 Setup a time with the subject/LAR to discuss the informed consent and answer any questions they may have about the study. The investigator/designee must implement a method to ensure the identity of the subject/LAR (e.g., verification of state issued ID or use of personal questions or visual methods).

4.6.2.5 Perform the informed consent process as a regular process.

4.6.2.6 A witness (if applicable as per 21 CFR 50.27) must be present during the telephone/videoconferencing consent process. This witness must not be a member of the research team and must be impartial. The witness must be able to hear both sides of the conversation (e.g., speaker phone, conference line). A witness is required to attest to the adequacy of the consent process and to the subject's voluntary consent. Therefore, the witness must be present during the entire consent interview, not just for signing the documents. Requirements for social distancing may dictate that the witness may be in a different location than both the potential subject and/or the investigator/designee obtaining consent. Any arrangement is acceptable if the witness can listen to both parties in the informed consent discussion. If the potential subject or LAR agrees to participation, they sign the consent form and return it to the investigator (e.g., via mail, fax or email). If postal mail is used, a pre-paid, self-addressed envelope should be provided to the subject or LAR to mail the signed consent form back to the investigator.

4.6.2.7 Once the research team receives the signed informed consent document from the subject or LAR, the investigator/designee who conducted the consent process must sign and date the document using the current date. Under the signature line, the investigator/designee must document whether consent was obtained over the telephone or video conferencing, the date of the telephone/video conference, and the date the signed

consent was received. For example, “Discussed with [subject or LAR name] via [telephone or videoconferencing] on [insert date] and received signed consent form on [insert date].” Include a brief reason for performing the informed consent discussion over the telephone/videoconferencing.

4.6.2.8 Electronic Consent

4.6.2.8.1 If an electronic consent will be used, it must contain all elements of informed consent required by HHS and/or FDA regulations (45 CFR 46.116 and 21 CFR 50.25). The information must be in language understandable to the potential subject or the subject’s LAR and conveyed in a manner that minimizes the possibility of coercion or undue influence regarding the subject’s decision to participate in a study (45 CFR 46.116 and 21 CFR 50.20). To ensure that the electronic consent is presented appropriately and that subjects will have enough time to dedicate to the electronic consent process, the subjects should be informed of approximately how long the process will take and what information will be presented to them.

4.6.2.8.2 Any electronic consent should be easy to navigate, allowing the user to proceed forward or backward within the system and to stop and continue later. Hyperlinks may be provided were helpful. The electronic consent may also incorporate electronic strategies to encourage subjects to access all of the consent material before documenting their consent.

4.6.2.8.3 Electronic consent may be used to either supplement or replace paper-based informed consent processes to best address the subject’s needs throughout the course of the study.

4.6.2.8.4 The investigator is responsible for ensuring that legally effective informed consent is obtained before that subject takes part in the study (see 45 CFR 46.116 and 21 CFR 50.20, 312.60, and 812.100).

4.6.2.8.5 The consent process may take place at the study site or remotely. The electronic consent form may be provided for both on-site and remote access.

4.6.2.8.6 If the consent process takes place at the study site, the study personnel can personally verify the subject’s identification, review the electronic consent, answer questions about the material, have follow-up discussions, and witness the signing of the electronic consent.

4.6.2.8.7 If any or part of the consent process takes place remotely, then the electronic consent process must include a method to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study or is the subject’s LAR (see 21 CFR 11.100(b))

4.6.2.9 Signatures:

4.6.2.9.1 The procedure for electronic informed consent may include an electronic method to capture the signature of the subject or the subject's LAR. OHRP and FDA regulations permit the use of electronic signatures when written informed consent is required. OHRP permits electronic signatures if such signatures are legally valid within the jurisdiction where the research is to be conducted.

4.6.2.9.2 Electronic signatures/digital signatures may be allowed in lieu of traditional "wet ink" or "handwritten" signatures on informed consent form by the subject/LAR, the witness (if applicable as per 21 CFR 50.27), and the investigator.

4.6.2.9.3 LSU Health Shreveport has an institutional Adobe Sign account. Investigators or research study staff that are approved to obtain informed consent must use institutional third-party document service. The investigators and research study staff wanting to utilize the service will need to contact Lamar Nunnery (**lamar.nunnery@lsuhs.edu**) or LSUHS IT for an account. Once the Adobe Sign account is established, the investigator and/or the research study staff can email the electronic consent form to the subject/LAR/witness. Then they should be able to provide their signatures through Adobe Sign.

4.6.2.9.4 For FDA-Regulated Clinical Investigations (Research not subject to 21 CFR parts 50 and 56 is also not generally subject to 21 CFR part 11 (FDA regulations regarding electronic records and electronic signatures)).

4.6.2.9.4.1 FDA regulations found at 21 CFR part 11 set forth the criteria under which FDA considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to a handwritten signature executed on paper (see 21 CFR 11.1(a)). To be considered equivalent to full handwritten signatures, electronic signatures must comply with all applicable requirements under 21 CFR part 11.[10] The electronic system must also capture and record the date that the subject or subject's LAR provides consent (see 21 CFR50.27(a)).

4.6.2.9.4.2 The regulations found at 21 CFR part 11 permit a wide variety of methods to create electronic signatures, including using computer-readable ID cards, biometrics, digital signatures, and username and password combinations. FDA does not mandate or specify any methods for electronic signatures, including any particular biometric method upon which an electronic signature may be based.

4.6.2.9.4.3 Electronic signatures based on biometrics must be designed to ensure that they cannot be used by anyone other than their genuine owners (21 CFR 11.200(b)). Therefore, suitable biometrics should be uniquely identified with

the individual and should not change with time. In addition, electronic signatures based upon biometrics are accepted provided they meet the requirements found in 21 CFR part 11 (i.e., they must contain pertinent information associated with the signing (see 21 CFR 11.50(a)); they are subject to the same controls as electronic records and must be included as part of any human readable form of the electronic record (see 21 CFR 11.50(b)); and they must be linked to their respective electronic records (see 21 CFR 11.70).

4.6.2.9.4.4 IRB, investigators, and sponsors should consider such issues as how the electronic signature is created and whether the informed consent or permission document can be produced in hard copy for review by the subject upon request. IRBs, investigators, and sponsors may rely on a statement from the vendor of the electronic system used for obtaining the electronic signature that describes how the signature is created and that the system meets the relevant requirements contained in 21 CFR part 11.

4.6.2.9.4.5 A copy of the informed consent must be provided to the person signing the form (see 21 CFR50.27(a)).

4.6.2.9.4.6 The electronic informed consent process can be used to obtain assent from pediatric subjects (when required) and parental permission from their parent(s) or guardian. The general requirements for informed consent, found in 45 CFR 46.116 and 46.117 and 21 CFR50.20, 50.25, and 50.27, apply to parental permission, in addition to the requirements for permission by parents or guardians and for assent by children found at 45 CFR 46.408 and 21 CFR 50.55. Therefore, parental permission may be obtained and documented using the same electronic informed consent procedures as would be used for informed consent.

4.6.2.9.4.7 Compliance with the requirements in Part 11 is meant in part to prevent fraudulent use. Therefore, the regulations found at 21 CFR part 11 require that an organization verify the identity of an individual before it establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature or any element of such electronic signature (see 21 CFR 11.100(b)).

4.6.2.9.4.8 FDA regulations do not specify any method for verifying the identity of an individual and accepts many different methods. For example, verifying someone's identity can be done by using information from some form of official identification, such as a birth certificate, government-issued passport, or a driver's license. In addition, use of security questions to confirm an individual's identity can also be considered.

4.6.2.9.4.9 For FDA-regulated clinical investigations, the electronic system that supports the electronic informed consent must be secure with restricted access (see 21 CFR 11.10 and 11.30) and should include methods to ensure confidentiality regarding the subject's identity, study participation, and personal

information after informed consent has been obtained. If the entity holding the subject's personal information is a covered entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Public Law No.104-191) or acting as a business associate of a HIPAA-covered entity, the requirements in the HIPAA Privacy, Security, and Breach Notification Rules apply (see 45 CFR parts 160 and 164). For example, the subject's information within an electronic system must be encrypted, unless the entity documents why encryption is not reasonable and appropriate in their specific circumstances and implements a reasonable and appropriate equivalent measure.

4.6.2.9.4.10 HIPAA authorizations may be obtained electronically, provided that the signature of the subject (or the subject's personal representative) is a valid electronic signature under applicable laws and regulations. The Electronic Signatures in Global and National Commerce Act (E-Sign Act) (Public Law 106-229) addresses what constitutes a valid electronic signature and provides that a signature may not be denied legal effect because it is in electronic form. The HIPAA Privacy Rule requires that when a covered entity seeks an authorization from a subject (or a subject's personal representative), the covered entity must provide the individual with a copy of the signed authorization; this requirement also applies where a HIPAA authorization is obtained electronically.

4.6.2.9.4.11 The investigator should submit to the IRB copies of all forms (electronic and paper forms) and informational materials, including any videos and Web-based presentations, which the subject will receive and view during the eIC process. The investigator must obtain IRB approval for any subsequent modifications to the study-related information, whether electronic or in hard copy (see 45 CFR 46.109 and 21 CFR 56.109). It is recommended that an investigator discuss plans for using electronic informed consent with the IRB before finalizing development of the electronic informed consent to ensure that the IRB agrees that such a format may be used for the applicable research for obtaining informed consent.

4.6.2.9.4.12 LSU Health Shreveport has an institutional Adobe Sign account. Investigators or research study staff that are approved to obtain informed consent must use institutional third-party document service. The investigators and research study staff wanting to utilize the service will need to contact Lamar Nunnery (**lamar.nunnery@lsuhs.edu**) or LSUHS IT for an account. Once the Adobe Sign account is established, the investigator and/or the research study staff can email the electronic consent form to the subject/LAR/witness. Then they should be able to provide their signatures through Adobe Sign.

4.6.3 The investigator must document the verbal consent of the subject/LAR after the informed consent discussion and prior to proceeding with the research activities.

4.6.4 The final informed consent document must be filed in the designated investigator/site regulatory file location. A copy of the final informed consent document, signed by the subject

or LAR, the investigator, and the witness (if applicable as per 21 CFR 50.27), must be sent back to the subject via email/scan, fax, or postal mail.

4.7 Verbal/Oral Consent

4.7.1 Verbal consent will be considered and allowed on a case-by-case basis.

4.7.2 Verbal consent means that the investigator obtaining consent reads and explains the consent form, a consent information letter. Use Consent Letter Template for Surveys or Questionnaires Research.doc and subjects give their verbal consent in place of written consent to participate. Subjects should be given the opportunity to ask questions and provided with a copy of the information sheet.

4.7.3 The investigator must document in the regulatory file when the consent discussion took place and if there were any issues.

4.7.4 IRB responsibilities

4.7.4.1 HHS and FDA regulations require that an IRB review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by the applicable regulations (see 45 CFR 46.109(a) and 21 CFR 56.109(a)). A critical part of this responsibility is for the IRB to ensure there is an adequate informed consent process that protects the rights and welfare of subjects participating in HHS-regulated research and FDA-regulated clinical investigations (see 45 CFR 46.109(b) and 21 CFR 56.109(b) and 56.111(a)(4)). Therefore, the IRB must review and approve the electronic informed consent and any amendments to it that the subject will receive and view (see 45 CFR 46.109(a) and 21 CFR 56.109(a)). The IRBs must maintain and retain copies of materials that have been reviewed in accordance with 45 CFR 46.115 and 21 CFR 56.115.

4.7.4.2 The IRB must ensure that the consent process is appropriate for the risk level of the proposed research. In some cases, the IRB may decide that informed consent must be obtained face-to-face, which may preclude the use of an electronic consent.

4.7.4.3 The IRB should also review any optional questions or methods used to gauge subject comprehension of key study elements. The IRB should also review the usability of the electronic informed consent materials to ensure that they are easy to navigate. If the program uses hyperlinks to convey study-related information, IRB should review the contents to which subjects are referred in order to determine if the study-related information that has been supplied is accurate and appropriate. Because Web sites are often modified over time, IRB must maintain the version of the Web site information that contains the study-related information that the IRB reviews and approves, either electronically or as a hard copy (see 45 CFR 46.115 and 21 CFR 56.115).

4.8 When following VA requirements:

4.8.1 The consent document must include all required disclosures but does not need to use a specific template.

4.8.2 The consent document must be signed and dated by the subject or legally authorized representative, and by the person obtaining consent. The IRB may waive the requirement for the signature of the person obtaining consent when there is no physical contact with the subject (e.g., where the only contact with the subject is through telephone or mail).

4.8.3 The consent document must indicate the date of IRB approval, but the date does not need to appear on each page of the consent document.

4.8.4 Consent may be obtained and documented electronically so long as there are appropriate authentication controls to provide assurance the consent is rendered by the appropriate individual, and the subject dates the consent, or software provides the current date when signed.

4.8.5 Consent to take photographs, video, or audio recording for research cannot be waived by the IRB.

4.8.6 Consent documents must include additional VA elements of disclosure.

5 MATERIALS

5.1 Long form of consent documentation:

5.1.1 HRP-502 - TEMPLATE LSU CONSENT DOCUMENT

5.1.2 HRP-500 - TEMPLATE - LSU ASSENT DOCUMENT

5.2 Short form of consent documentation:

5.2.1 HRP-507 - TEMPLATE Short Form CONSENT DOCUMENT

5.2.2 Summary (same information as the English consent form used for long form of consent documentation)

5.2.3 HRP-317 - WORKSHEET - Short Form of Consent Documentation

5.2.4 HRP-225 - FORM - Translation Certificate

5.3 HRP-318 - WORKSHEET - Additional Federal Agency Criteria

5.4 Requirement for written documentation of the consent process has been waived by the IRB: Consent script (same as consent form used for long form of consent documentation except that signature block is optional)

5.5 SOP: HRP-013 LARs, Children, and Guardians

5.6 SOP: HRP-091 Written Documentation of Consent

5.7 Consent Letter Template for Surveys or Questionnaires Research.doc

5.8 **electronic consent guidance from HHS**

5.9 **https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html**

6 REFERENCES

6.1 45 CFR 46.109; 45 CFR 46.116; 45 CFR 46.117

6.2 21 CFR 11; 21 CFR 50; 21 CFR 56

6.3 AAHRPP I.1.C.; I.8.A.; II.3.F.; II.3.G.; II.4.B.; III.1.F.

HRP-091 Written Documentation of Consent

1 PURPOSE

1.1 This procedure establishes the process to document the informed consent process in writing.

1.2 The process begins when a subject agrees to take part in a research study.

1.3 The process ends when the consent process is documented in writing, including in an electronic format, to the extent required by this procedure (As per revised common rule, informed consent shall be documented using a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.)

2 POLICY

2.1 In this procedure "investigator" means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.

2.2 In this procedure "subject/LAR" means:

2.2.1 The subject when the subject is an adult capable of providing consent.

2.2.2 The Legally Authorized Representative (LAR) when the subject is an adult unable to give consent.

2.2.3 One or both biologic or adoptive parents when the subject is a child or in the absence of a parent, a person authorized under applicable law to consent on behalf of the child to the child's general medical care.

2.2.4 When the subject is a child an assent document will be used for children capable of providing assent when required by the IRB.

3 RESPONSIBILITIES

3.1 The principal investigator is responsible to ensure these procedures are carried out.

4 PROCEDURE

4.1 If the consent process will be documented in writing with the long form of consent documentation (21 CFR 50.27(a)):

4.1.1 Verify that the consent form is in language understandable to the subject/LAR.

4.1.2 Print the name of the following individuals on the consent document:

4.1.2.1 Subject/LAR

4.1.2.2 Person obtaining consent

4.1.3 Have the following individuals personally sign and date the consent document:

4.1.3.1 Subject/LAR

4.1.3.2 Person obtaining consent

4.1.4 If the IRB required written documentation of assent, note on the signature block one of the following:

4.1.4.1 Assent of the child was obtained.

4.1.4.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

4.1.5 Have the person obtaining consent personally sign and date the consent document.

4.1.6 Provided copies of the signed and dated consent document to the subject/LAR. This may be accomplished either by making a photocopy or by having the above individuals sign and date two copies of the consent document.

4.1.7 Under special circumstances (such as for e.g., when a subject understands English, but is blind or has low visibility), if an oral presentation of the consent form is required to be given to the subject, then obtain witness signature, date and name on the consent form to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by the subject and that consent was given freely.

4.2 If the consent process will be documented in writing with the short form of consent documentation:

4.2.1 Verify that the short consent form is in language understandable to the subject/LAR.

4.2.2 Print the name of the following individuals on the short form consent document and the summary:

4.2.2.1 Subject/LARLAR

4.2.2.2 Person obtaining consent

4.2.2.3 Impartial witness to the oral presentation

4.2.3 Have the following individuals personally sign and date the short form consent document and/or the summary ((21 CFR 50.27(a) and (b)(2)))

4.2.3.1 Subject/LAR sign and date short form consent document

4.2.3.2 Person obtaining consent sign and date short form consent document and the summary

4.2.3.3 Impartial witness signs and dates both short form consent document and summary

4.2.4 If the IRB required written documentation of assent, note on the signature block on the short consent document one of the following:

4.2.4.1 Assent of the child was obtained.

4.2.4.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

4.2.5 Provide a copy of the signed and dated short consent document and a copy of the signed and dated summary to the subject/LAR. This may be accomplished either by making photocopies or by having the above individuals sign and date two copies of the short consent document and summary.

4.2.6 As allowed by 45 CFR 46.117 I and 21 CFR 56.109 I, the IRB may waive the requirement to obtain written documentation of informed consent. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either that the

(a) Only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality;

- Subjects must be asked whether they want documentation linking them with the research, and their wishes must govern. (Example: domestic violence research where the primary risk is discovery by the abuser that the subject is talking to investigators.)
- To waive written documentation of consent where the only record linking the subject and the research would be the consent document, the IRB must determine that the research was not FDA-regulated.

(b) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

- Procedures such as non-sensitive surveys, questionnaires and interviews generally do not require written consent.

4.2.7 If the requirement for written documentation of the consent process has been waived by the IRB and the IRB determined that the subject/LAR had to be offered the opportunity to document his or her consent is writing, offer the subject/LAR the option to document his or her consent is writing.

4.2.7.1 If the subject/LAR declines, take no further action.

4.2.8 If the subject/LAR accepts, follow the process to document consent in writing with the long or short form of consent documentation (VA Research - The IRB will document the reason when it waives the requirement to obtain written documentation of the consent process.)

4.2.9 Other Federal Agencies - Additional requirements might apply depending on the source of support/funding (e.g., DoD, DOJ, Bureau of Prisons).

4.3 Place the signed and dated documents in the subject's binder.

4.4 Place a copy of the signed and dated consent document along with the HIPAA Authorization with the subjects medical record also for drug studies, place a copy of the IDIR in the subjects medical record and for device studies place a copy of the label and instructions for use in the subjects medical record.

4.5 When following GCP requirements for clinical trials, the case history for each individual subject should document that informed consent was obtained prior to participation in the study.

5 MATERIALS

5.1 Long form of consent documentation:

5.1.1 HRP-502 - TEMPLATE LSU CONSENT DOCUMENT

5.1.2 HRP-500 - TEMPLATE - LSU ASSENT DOCUMENT

5.2 Short form of consent documentation:

5.2.1 HRP-507 - TEMPLATE Short Form CONSENT DOCUMENT

5.2.2 Summary (same information as the English consent form used for long form of consent documentation)

5.2.3 HRP-317 - WORKSHEET - Short Form of Consent Documentation

5.2.4 HRP-225 - FORM - Translation Certificate

5.2.5 Short assent document

5.3 HRP-318 - WORKSHEET - Additional Federal Agency Criteria

5.4 Requirement for written documentation of the consent process has been waived by the IRB: Consent script (same as consent form used for long form of consent documentation except that signature block is optional)

5.5 SOP: HRP-013 LARs, Children, and Guardians

5.6 SOP: HRP-091 Written Documentation of Consent

5.7 Consent Letter Template for Surveys or Questionnaires Research.doc

5.8 HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent

5.9 **electronic consent guidance from HHS**

5.10 **https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html**

6 REFERENCES

6.1 45 CFR 46.117

6.2 21 CFR 50.27

6.3 AAHRPP II.3.E.; II.3.F.; II.3.G.; II.4.B.; III.1.F.

HRP-092 Humanitarian Use Devices (HUD)

1 PURPOSE

1.1 This procedure establishes the process for LSUHSC-S physicians to use Humanitarian Use Devices (HUDs) in a facility after the IRB has approved their use in that facility.

2 POLICY

2.1 A Humanitarian Use Device (HUD) is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in no more than 8,000 individuals in the United States per year. HUDs cannot be sold for profit except in narrow circumstances and they can only be used in a facility after an IRB has approved their use in that facility, except in emergencies where the physician determines that approval cannot be obtained in time to prevent serious harm or death to the patient. Although the use of a HUD within treatment does not constitute research, the FDA requires IRB approval to be obtained before a HUD can be used in a facility.

2.2 The FDA defines a device user facility as a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment, which is not a physician's office. The name of the facility where a device will be used must be stated in the SHIeLDS application and will be listed on the approval letter. Approval is for the facility listed on the letter.

2.3 If a HUD is used outside its approved indication(s), FDA recommends that the physician obtain informed consent from the patient and ensure that reasonable patient protection measures are followed, such as devising schedules to monitor the patient, taking into consideration the patient's specific needs and the limited information available about the risks and benefits of the device. FDA further recommends that the physician submit a follow-up report on the patient’s condition to the HDE holder.

3 RESPONSIBILITIES

3.1 Principal Investigator Responsibilities:

3.1.1 It is the primary physician’s responsibility to provide this institution with oversight of the HUD. The physician is responsible for regulatory requirements, local communications, and storage management of the HUD. The primary physician must obtain IRB approval prior to first use of the HUD and maintain IRB approval (continuing review) if the HUD continues to be used at the institution.

3.1.2 Informed Consent: HUD devices are not investigational, and their treatment use is not considered research, therefore, informed consent from individuals as research subjects is NOT applicable. This institution requires physician to obtain informed consent from each patient prior to use of the HUD utilizing the HUD Brochure, patient information packet (if available), standard procedural consent and the LSUHSC-S off-label informed consent addendum (if applicable).

3.1.3 An HDE holder may collect safety and effectiveness data in a clinical investigation for the HDE-approved indication(s) without an IDE. Clinical investigations of a HUD for a different indication must be conducted under IDE regulations.

3.1.4 Continuing Review: The treating physician must fulfill continuing review requirements at the designated IRB intervals.

3.1.5 Modifications: All modifications to the HUD submitted and approved by the FDA must be submitted as a modification. As applicable, the submission should be accompanied by 1) the FDA's approval of the modification; 2) the HDE holder's amendments to the HUD product labeling, HUD brochure and/or other pertinent materials corresponding to the requested modifications.

3.1.6 Whenever a HUD may have caused or contributed to a death or serious injury or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur [21 CFR 814.126(a) and [21 CFR 803], it must be reported to the HDE holder, FDA and to the IRB. This HDE regulation requires that MDR reports submitted to FDA, in accordance with 21 CFR Part 803 shall also be submitted to the IRB. Medical Device Reports (MDRs) must be submitted to FDA and to the IRB if the device may have caused or contributed to death or serious injury and for certain malfunctions (21 CFR 803). Only one medical device report from the user facility or manufacturer is required if the reporting entity becomes aware of information from multiple sources regarding the same patient and same event (21 CFR 803.22)

3.1.7 Emergency Use: The physician must report the emergency use within five days providing written notification of the use to the IRB Chair. The notification must include the following: the identification of the patient involved, the date of the use, and the reason for the use. Upon notification, the designated reviewer will use the HRP-322 - WORKSHEET - Emergency Use to determine whether the circumstances will meet the regulatory requirements or, if the report is received after the emergency use, if the circumstances met the regulatory requirements. The IRB will provide the results of this determination in writing to the physician. The Notification of Emergency Use will be documented in the IRB Emergency Use Log.

3.2 IRB Responsibilities: IRB approval is required before a HUD is used at this institution/facility. The only exception to prior IRB approval is an emergency use when IRB approval cannot be obtained in time to prevent serious harm or death to the patient.

3.2.1 For initial review of a HUD, the IRB is required to conduct a full board review. For continuing review, the IRB may use expedited review procedures if the IRB determines that full board review is not required.

3.2.1.1 At initial convened review, the IRB may provide review and approval for on-label and off-label use. The IRB may use its discretion to determine how to approve the use of a HUD.

3.2.2 Emergency Situations: If a physician in an emergency determines that IRB approval for the use of a HUD cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be used within the scope of its labeling or off-label without prior IRB approval. Emergency use situations are those in which:

3.2.2.1 The patient has a life-threatening condition that needs immediate treatment.

3.2.2.2 No generally acceptable alternative treatment for the condition exists.

3.2.2.3 Because of the immediate need to use the device, there is no time to obtain IRB approval.

3.2.2.4 Whenever possible, physicians should obtain informed consent from the patient or a legally authorized representative.

3.3 When HUD will be used outside its approved indication(s) (i.e. off-label use), the IRB will conduct a full board review during initial and continuing review.

4 PROCEDURES

4.1 Follow SOP: HRP-021 Pre-review.

4.2 When HUD is used as per approved indication, use standard procedural consent.

4.3 When HUD is used outside its approved indication(s) (i.e. off-label use), use HUD-Off Label Consent Addendum Template.

5 MATERIALS

5.1 SOP: HRP-021 Pre-reviewHRP-322 - WORKSHEET - Emergency UseHRP-323 - WORKSHEET - Criteria for Approval and Additional Considerations HUD

5.2 HUD-Off Label Consent Addendum Template

6 REFERENCES

6.1 21 CFR 814.126(a)

6.2 AAHRPP I.7.A. ; I.7.C.; I.8.A.; II.2.E.;

HRP-093 Activities that require IRB Review

1 PURPOSE

1.1 This policy establishes the process to determine whether an activity is human subjects research or not.

1.2 The policy begins when planning or preparing for any research activity or clinical investigation activity that involves human subjects.

1.3 The policy ends when IRB involvement in the LSUHSC-S research or clinical investigation activity is determined.

2 POLICY STATEMENT

2.1 This policy covers all human subjects research including preparatory to research activities that involve interventions or interactions with living individuals (e.g., advertising, recruitment, and/or screening of potential subjects for research) and/or accessing or obtaining identifiable, private information from or about living individuals for the purpose of conducting research (e.g., review of medical records).

2.2 In this policy, human research means any research or clinical investigation that involves human subjects as defined in SOP: HRP-001 Definitions.

2.3 Requests for Human Subjects Determinations must be submitted through the electronic submission system, SHIeLDS. Requests sent through other mechanisms (email, phone, fax) will not be processed.

3 RESPONSIBILITIES

3.1 Investigators, IRB staff and IRB reviewers perform these procedures.

4 PROCEDURE

4.1 Investigators should review the definitions of “Human Research”, “Human Subject” and “Research” to determine whether an activity is human subject research. See SOP: HRP-001 Definitions.

4.2 Determinations regarding activities that are clearly human subject research/clearly not human subject research/less clear, based on the OHRP definition, will be made by the IRB

Chair, IO/designee. If a clear determination cannot be made then, out of an abundance of caution, the activity should be deemed to constitute Human Subjects Research for further review (e.g., Exempt, Expedited or Full IRB Review).

4.3 Investigator must submit Determination of Human Subject Research Form via SHIeLDS along with HRP-220 - FORM - Administrative-Approval

4.4 The IRB will make the final determination if it is human subject research or not.

4.4.1 If the IRB determines the activity to be “Not Human Subject Research”, the investigator will receive a letter for “NOT HUMAN RESEARCH DETERMINATION”.

4.4.2 If the IRB determines the activity to be human subject research, then mandatory institutional CITI education and COI disclosure completion will be verified. If they are incomplete, then the investigator and study team members will be required to complete them. Additional documents may be requested depending on the human subject research.

4.4.3 Documentation of all determinations made will be maintained in SHIeLDS.

4.5 The Privacy Rule permits a covered entity to use or disclose protected health information to a investigator without authorization or waiver for the limited purpose of a “review preparatory to research.” Such reviews may be used to prepare a research protocol, or to determine whether a research site has a sufficient population of potential research subjects. Prior to permitting the investigator to access the protected health information, the covered entity must obtain representations from the investigator that the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purposes preparatory to research, that the investigator will not remove any protected health information from LSUHSC-S, and that protected health information for which access is sought is necessary for the research purpose. Investigators should consult the covered entity regarding any forms or applications necessary to conduct a review preparatory to research. Investigators conducting a review preparatory to research may not record information in identifiable form, nor may they use the information that they receive to contact potential subjects. Since the Privacy Rule permits a covered entity to disclose protected health information to the individual who is the subject of the information, covered health care providers and patients may continue to discuss the option of enrolling in a clinical trial without patient authorization. Even when permitted by the Privacy Rule, however, any use of patient information for recruitment must comply with IRB recruitment policies.

4.5.1 Reviews preparatory to research that are permitted under HIPAA may or may not be human subject research depending on the investigation being conducted. Investigators must submit Preparatory to Research Form to the IRB staff. The IRB Chair/designee will review and sign it. The form will be returned to the investigator by the IRB staff.

4.6 Self-Experimentation - Any research where the investigator/study team member is also a subject (investigator self-experimentation) requires IRB review and approval.

5 MATERIALS

5.1 SOP: HRP-001 Definitions

5.2 Preparatory to Research Form

5.3 Determination of Human Subject Research Form

5.4 HRP-220 - FORM - Administrative-Approval

6 REFERENCES

6.1 45 CFR §46.102

6.2 21 CFR §50.3; 21 CFR §56.102; 21 CFR §56.103; 21 CFR §312.3(b); 21 CFR §812.3(h)

6.3 AAHRPP I.1.A.; II.2.A.; III.1.E.

HRP-094 Repositories: Banking of Specimen and/or Data

1 PURPOSE

1.1 This policy establishes a process for the banking of specimens (human biological materials)/data by LSUHSC-S investigators. The banking of specimens/data refers to the creation of banks and/or databases (repositories) to collect, store, and distribute human biological materials (specimens) and data for future research purposes. Repository activities involve three components: (1) Collection of specimens/data; (2) storage and management of the specimens/data; and (3) distribution of specimens/data to "recipient" investigators for use in a future research project.

1.2 The policy begins when the Institutional Review Board (IRB) has determined that the banking of specimens/data is intended by an investigator, and/or research site designee.

1.3 The policy ends when the IRB determines that the policy should no longer be observed, or the repository is no longer in use and the IRB is notified.

2 POLICY STATEMENT

2.1 Non-Research Repositories:

2.1.1 If specimens or data were originally collected for non-research purposes (clinical care) AND were added to a non-research repository/database without any identifiable private data or information or links (codes, pathology numbers, medical record numbers) to identifiable private data or information, it is a "non-research" repository/database. If links are included, this policy section does not apply. Studies using specimens/data from non-research repositories or databases are generally considered Not Human Subjects Research.

2.2 Research Repositories:

2.2.1 If specimens or data were collected for research purposes, it is a research repository. Collection of specimens/data, repository storage or data management and use of specimens or disclosure of data are all considered "research activities" and require IRB review and approval.

2.2.2 Specimen/data repositories may include two kinds of specimens/data: a) those collected with the expressed purpose of distribution to other investigators, and b) those collected by individual investigators, and not originally intended to be shared with others, but which are subsequently shared as part of a repository.

2.2.3 Any collection which contains specimens/data that are potentially identifiable (i.e., directly or indirectly with a code or link) and are distributed to someone other than the original named investigator(s) making the collection, regardless of the original intent, may be considered to be a repository requiring IRB oversight.

2.2.4 If the original named investigator(s) wishes to use the potentially identifiable specimens or data for any future use that is not part of the original IRB approved protocol, then the subsequent use will also require IRB approval and oversight.

2.3 Collection of a Specimen/data for a Repository:

2.3.1 Investigators who collect directly or indirectly identifiable specimen/data must request IRB review and approval of the activity. Under most circumstances, written informed consent and HIPAA Authorization from the subject is required and should include information about the repository, the conditions under which the specimens/data will be shared with others and if the specimen/data will be stored for future use beyond the current research.

2.4 Confidentiality risks of research participation may extend beyond the duration of the subject's direct participation in research. This is common when records or samples with identifiers are retained by the investigator. These confidentiality risks and/or new disclosure concerns are important to consider.

2.5 The ability to re-test samples containing extractable DNA has made it possible that retained samples may contain information that cannot be foreseen at the time of initial collection, but that may eventually be of great importance or sensitivity. Investigators should destroy identifiers to their samples/data when possible.

2.6 Regarding storing data/ specimens outside of LSUHSC-S, if the repository is located at an external institution or organization, the investigator must submit (to the LSUHSC-S IRB) a copy of the external site's IRB approval letter for operation of the repository at that institution or organization.

2.7 The IRB at the institution where the repository is located must approve and maintain oversight of a protocol that: (a) specifies the conditions under which data and specimens may be accepted and shared with other investigators or designees and (b) ensures adequate privacy and confidentiality protections for subjects contributing to the repository.

2.8 Any "research" specimen/data repository that distributes materials/data requires IRB approval prior to the distribution. The investigator must follow the conditions under which the specimens/data will be shared as described in the IRB initial review application.

2.9 These conditions must consider the privacy of the individuals from whom the tissue came, what the informed consent permitted, and the intent of the person to whom the tissue is sent. The recipient of the tissue samples must abide by the conditions specified.

2.10 A gatekeeper or repository director, established under the IRB guidelines and pursuant to the IRB approval for the repository, should evaluate each request for samples to see if the request is consistent with the IRB's conditions for sharing samples and with the original informed consent and the repository's policies.

2.11 The transfer of data to outside collaborators or to external repositories requires a Data Use Agreement or other types of agreements/contracts between the parties involved. All agreements need to be signed by an authorized agent of LSUHSC-S.

2.12 The transfer of materials to outside collaborators requires the use of Material Transfer Agreements (MTAs). MTAs ensure LSUHSC-S rights are protected when specimens or reagents are shared with outside investigators or institutions. An MTA protects the intellectual and other property rights of the provider and generally addresses:

2.12.1 Limits on the use of the research materials, inventions, and results

2.12.2 Prohibitions on the redistribution of the material

2.12.3 Conditions of use, including prohibitions of use in animals or humans

2.12.4 Conditions for publication, usually with provisions that the manuscript must be seen by the donor before submission for publication

2.12.5 A hold-harmless cause, meaning that the donor has no liability resulting from the use of the material

2.12.6 The return of unused materials.

2.13 The Office of Sponsored Programs and Technology Transfer (OSPTT) coordinates the completion of MTAs. MTAs need to be signed by an authorized agent of LSUHSC-S.

3 RESPONSIBITIES

3.1 The investigator should ensure these procedures are carried out to ensure safe and proper usage of repositories and banking of specimens/data.

4 PROCEDURE

4.1 The following procedure should be followed when establishing a repository at LSUHSC-S.

4.2 The investigator is to develop written policies and procedures on operating and managing the repository. The policies and procedures are to be provided to the IRB as part of the initial application.

4.3 The following documents must be included with the HRP-503 - TEMPLATE PROTOCOL.

4.3.1 Purpose of the repository

4.3.2 Specimen and data collection procedures

4.3.3 Specimen and data storage/retention

4.3.4 Specimen derivation and processing

4.3.5 Specimen and data distribution

4.3.6 Obtaining informed consent

4.3.7 Procedures for protecting privacy and confidentiality (for example, anonymization of specimens/data, coding of specimens/data, encryption, limited access/secure storage)

4.3.8 Confidentiality measures

4.3.9 Procedures for return of research results (if and under what conditions)

4.3.10 Repository oversight

4.3.11 Model informed consents for subjects contributing to the repository

4.3.12 Model agreements for investigators collecting tissues for the repository and for investigators receiving tissues from the repository. These agreements should address use of specimens/data, human subject protections, sharing of specimens with third parties, commercial use of specimens, biohazards, and indemnification.

4.3.13 A plan for the disclosure of clinically relevant results/incidental findings including the mechanism for evaluating whether the results of research testing are clinically relevant and might warrant disclosure to the research subjects. A mechanism for disclosure to subjects of clinically relevant results/incidental findings to be included.

4.3.14 A Certificate of Confidentiality, if needed. Certificates of Confidentiality are issued by the National Institutes of Health to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research subjects in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. The certificate goes beyond the consent form in ensuring confidentiality and anonymity. Without the certificate, investigators can be required by a court-ordered subpoena to disclose research results (usually as part of a criminal investigation of the subjects). Any research project that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for a Certificate. Additional information is available at the NIH Certificate of Confidentiality Kiosk web site.

4.3.15 Statutory Basis for Protection: Protection against compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research is provided by the Public Health Service Act §301(d), 42 U.S.C. §241(d): "The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

4.3.16 Usage: Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting investigators and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to subjects. Any investigator engaged in research in which sensitive information is gathered from human subjects (or any person who intends to engage in such research) may apply for a Certificate of Confidentiality. Research can be considered sensitive if it involves the collection of:

1. Information about sexual attitudes, preferences, practices

2. Information about personal use of alcohol, drugs, or other addictive products

3. Information about illegal conduct

4. Information that could damage an individual's financial standing, employability, or reputation within the community

5. Information in a subject's medical record that could lead to social stigmatization or discrimination

6. Information about a subject's psychological well-being or mental health

4.3.17 Identifying information includes “name, address, social security or other identifying number, fingerprints, voiceprints, photographs, genetic information or tissue samples, or any other item or combination of data about a research subject which could reasonably lead, directly or indirectly by reference to other information, to identification of that research subject. This list is not exhaustive. Investigators contemplating research on a topic that might qualify as sensitive should contact the IRB Office for help in applying for a certificate. In the informed consent form, investigators should tell research subjects that a Certificate is in effect. Subjects should be given a fair and clear explanation of the protection that it affords, including the limitations and exceptions noted above. Every research project that includes human research subjects should explain how identifiable information will be used or disclosed, regardless of whether a Certificate is in effect.

4.3.18 Limitations: The protection offered by a Certificate of Confidentiality is not absolute. A Certificate protects research subjects only from legally compelled disclosure of their identity. It does not restrict voluntary disclosures. For example, a Certificate does not prevent investigators from voluntarily disclosing to appropriate authorities such matters as child abuse, a subject's threatened violence to self or others, or from reporting a communicable disease. However, if investigators intend to make such disclosures, this should be clearly stated in the informed consent form which research subjects are asked to sign. In addition, a Certificate of Confidentiality does not authorize the person to whom it is issued to refuse to reveal the name or other identifying characteristics of a research subject if:

1) The subject (or, if he or she is legally incompetent, his or her legal guardian) consents, in writing, to the disclosure of such information

2) Authorized personnel of the Department of Health and Human Services (DHHS) request such information for audit or program evaluation, or for investigation of DHHS grantees or contractors and their employees

3) Release of such information is required by the Federal Food, Drug, and Cosmetic Act or regulations implementing that Act

4.3.19 Application Procedures: Any person engaged in research collecting sensitive information from human research subjects may apply for a Certificate of Confidentiality. For most research, Certificates are obtained from NIH. If NIH funds the research project, the investigator may apply through the funding Institute. However, even if the research is not supported with NIH funding, the investigator may apply for a Certificate through the NIH Institute or Center funding research in a scientific area like the project. If the research is conducting a sensitive research project that is covered by the Agency for Healthcare Research and Quality (AHRQ) confidentiality statute (42 U.S.C. section299a-1(c) entitled "limitation on use of certain information") or the Department of Justice confidentiality statute (42USC section 3789g), then a CoC is not required. If there is an Investigational New Drug Application (IND) or an Investigational Drug Exemption (IDE), the sponsor can request a CoC from the FDA. For more information, see the NIH Certificates of Confidentiality Kiosk

4.3.20 When following DHHS regulations:

4.3.20.1 Research is automatically covered by a certificate of confidentiality whenever the study is funded in whole or in part by the NIH and involves identifiable, sensitive information.

4.3.20.2 Examples of research automatically covered by a certificate of confidentiality include:

(i) Biomedical, behavioral, clinical or other research, including exempt research, except where the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

(ii) The collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual.

(iii) The generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained.

(iv) Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical

methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

4.3.20.3 Investigators may also apply for a certificate of confidentiality for non-federally funded research.

4.3.20.4 When research is covered by a certificate of confidentiality, investigators:

(i) May not disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or

(ii) May not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

(iii) May disclose information only when:

(A) Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.

(B) Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

(C) Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

(D) Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

4.3.20.5 When research is covered by a certificate of confidentiality, investigators must inform subjects (for example, in the consent document) of the protections and limitations of certificates of confidentiality.

(i) For studies that were previously issued a Certificate and notified subjects of the protections provided by that Certificate, NIH does not expect subjects to be notified that the protections afforded by the Certificate have changed, although IRBs may determine whether it is appropriate to inform subjects.

(ii) If part of the study cohort was recruited prior to issuance of the Certificate, but are no longer activity participating in the study, NIH does not expect subjects consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that subjects who were previously consented to be re-contacted to be informed of the Certificate, although IRBs may determine whether it is appropriate to inform subjects. (g) Investigators conducting research covered by a certificate of confidentiality, even if the research is not federally funded, must ensure that if identifiable, sensitive information is provided to other investigators or organizations, the other investigator or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.

4.3.20.6 When following VA requirements where research involves a certificate of confidentiality:

(a) For studies that do not involve a medical intervention, no annotation may be made in the medical record.

(b) For studies involving a medical intervention, a progress note in the medical record should be made, indicating the individual has been enrolled in a research study, any details that would impact clinical care, and the name and contact information of the investigator conducting the study.

4.4 If the experimental design allows it, all identifiers should be stripped from the stored samples or data, such that they can never be traced to the individual

4.5 If the experimental design requires that the specimens/data be referable back to an individual subject, retention creates a durable confidentiality risk that must be both controlled and disclosed.

4.6 Storage with easily traceable identifiers such as patient names, initials, social security numbers, or medical record numbers is almost never appropriate. An additional safeguard for

maintaining confidentiality while retaining a link is to use a code in place of identifiers and retaining a master list that provides a key to the code.

5 MATERIALS

5.1 HRP-503 - TEMPLATE PROTOCOL

5.2 Repository-Protocol-Checklist

6 REFERENCES:

6.1 NIH Certificate of Confidentiality Kiosk web site

6.2 AAHRPP II.3.E.; II.3.F.

HRP-095 Contract/Budget Policy for Research Studies (CTO)

1 PURPOSE

1.1 This policy establishes the process to follow for the management, negotiation, implementation and finalization of the Confidentiality Disclosure Agreement (CDA), Clinical Trial Agreement (CTA) and Study Budget. The CTA and Budget are institutional agreements and require the oversight and sign off by the institutional official or designee.

2 POLICY

2.1 If required by the sponsor, a CDA will be completed.

2.2 A protocol will be supplied by the sponsor.

2.3 The Medical Director of Clinical Trials Management and the feasibility committee will approve the study based on the protocol.

2.4 If approved, the protocol will be used to create a Cost Analysis (CA).

2.5 The CA will be used by the institution to create a budget.

2.6 After the budget is approved by all parties a CTA will be created.

2.7 Once the CTA has been agreed upon, it will be signed by the appropriate parties and returned to the sponsor.

HRP-096 Monthly Financial Reconciliation (CTO)

1 PURPOSE

This policy is to outline the process for financial reports to ensure LSUHSC-S is recovering costs related to clinical trials. CTS will carry out the required procedures in conjunction with Accounting Services.

2 POLICY

2.1 Upon closure of the general ledger, a monthly review will be performed by Clinical Trial Services (CTS) to ensure that all institutional and study invoices have been generated and submitted for payment; all payables have been paid to the appropriate vendor; and all outstanding invoices have been paid or notices sent as appropriate to include per patient fees, variables, departmental fees and institutional fees (CTS, Pharmacy and IRB

2.2 At the end of each quarter, CTS will be responsible for verifying all revenue and ensuring that all revenues and expenses are posted correctly in both the CTMS and PeopleSoft.

2.3 Quarterly CTS will review and certify expenditures for sponsored projects for consistency with clinical trial agreements and university policies.

2.4 Quarterly CTS will conduct post reviews of transfers of payroll and non-payroll expenditures for conformance to university policies and procedures

HRP-097 Clinical Trial Closeout (CTO)

1 PURPOSE

1.1 The purpose of this policy is to standardize the process for closing clinical trials and to outline the treatment of residual balances.

1.2 CTS will carry out the required procedures in conjunction with the Accounting Services, Compliance Policy Committee, Principal Investigator, and Department Chair.

2 POLICY

2.1 All sponsored clinical trials must be audited to ensure that 1) all services and deliverables contained in the contract have been completed, (2) all revenues under the terms and conditions of the contract have been billed and collected, (3) all expenses of the contract have been paid and recorded in the general ledger within 120 days of closure approval by the IRB.

2.2 Residual balances resulting from completed Clinical Trial Agreements/Contracts may be transferred to appropriate accounts.

2.3 At the time of transfer, Indirect Costs (IDC) will be applied to any residual balance using the rates in effect for each individual contract.

2.4 Once residual balances are transferred, the study account will be closed in the general ledger and an end date will be added to the project to prevent any further transactions.

This policy is responsive to Finding Number 3 of the Internal Audit in establishing a policy for the closeout of sponsored research and the treatment of residual balance

HRP-098 Clinical Trial Startup (CTO)

1 PURPOSE

1.1 The purpose of this policy is to standardize the process for opening clinical trials and to define the process flow starting from the first point of contact with the sponsor to site activation in clinical trials.

2 PROCEDURE

2.1 Upon initial contact from a sponsor, Clinical Trials Management Team needs to be notified (Director, Business Manager, Project Manager Contract Agreements and Budgets).

2.2 If required by sponsor, the CDA should be sent to the Project Manager Contract Agreements and Budgets who will facilitate in getting it fully executed.

2.3 A protocol and all regulatory documents will be supplied by the sponsor.

2.4 The Medical Director of Clinical Trials Management and the feasibility committee will approve the study based on the protocol, feasibility questionnaire, and any other necessary documents. Principal Investigator will be notified of outcome.

2.5 If approved, the protocol will be used to create a Cost Analysis (CA). The Cost Analysis will be signed by the Principal Investigator and Department Chair.

2.6 The following procedures will take place simultaneously:

2.6.1 Contract and budgets negotiations will begin. All contract/budgets will be sent to the Project Manager Contract Agreements and Budgets to review and/or facilitate completion. The CA and CTMT Administrative fees (signed by Dr. Kevil) will be used to negotiate the budget. Budget will be sent to lead Clinical Research Coordinator (CRC) and Director of Clinical Trials Management after LSUHSC-Shreveport edits have been made.

2.6.2 Director of Clinical Trials Management will assign lead regulatory coordinator. Lead regulatory coordinator will create the study in SHIELDS and begin working on all regulatory documents. Research Pharmacist will be notified of study and provided a copy of the protocol and Pharmacy Manual (if a drug study). Lead regulatory will also create a channel in Microsoft Teams and invite Director, Business Manager, Project

Manager Contract Agreements and Budgets, Project Coordinator of Clinical Trials Management, Project Coordinator Invoicing, and study team members to channel.

2.6.3 Director of Clinical Trials Management will assign lead CRC and backup CRC(s). CRC will begin working on source documents using the protocol and CRF guidelines.

2.7 Once the Clinical Trials Agreement (CTA) has been agreed upon and in the signatory phase, full submission can be made in Shields.

2.7.1 Local IRB submission – Please refer to Worksheets HRP-338, HRP-339, & HRP-340 for required documents needed for submission

2.7.2 External IRB submission – Please see Worksheets HRP-335, HRP-339, & HRP-340 for required documents needed for submission. Reliance must be received for the local IRB prior to submitting to a central IRB. Once reliance is received, you may then submit to the central IRB. Once central IRB approval is obtained, all approved documents along with approval letter need to be submitted back to the local IRB.

2.8 Once IRB approval has been obtained, the following need to occur:

2.8.1 Notify Project Coordinator of Clinical Trials Management to have the study created in DDOTS and in EPIC.

2.8.2 Notify Project Coordinator Invoicing and Business Manager of study approval to have PeopleSoft account created for study.

2.8.2.1 Once PeopleSoft account is created, initial invoice to be sent for all study startup costs.

2.8.3 Notify Business Manager if Clincard is needed for participant reimbursement

HRP-099 Clinical Trial Closure (CTO)

1 PURPOSE

1.1 The purpose of this policy is to standardize the process for closing clinical trials and to define the process flow starting from clinical trial close out visit to IRB closure of clinical trial.

2 PROCEDURE

2.1 Once notified by sponsor of site closure, a close-out visit will be conducted.

2.2 After the close-out visit, the lead Regulatory Coordinator will notify Clinical Trials Management Business Manager and Project Coordinator Invoicing that final invoice needs to be sent.

2.2.1 The lead Regulatory Coordinator will be notified when the final invoice is sent.

2.3 Once final invoice is sent, study closure will be initiated with IRB.

2.3.1 If using an external IRB, study closure can be submitted.

2.3.1.1 When external IRB closure received, a modification will be submitted in SHIELDS for study closure. A comment will be made that final invoice has been sent. Once all invoices have been paid, a comment will be placed by the Project Coordinator Invoicing or Business Manager that all invoices have been paid.

2.3.2 If using a local IRB, a Modification/Continuing Review will be submitted for study closure. A comment will be made that the final invoice has been sent. Once all invoices have been paid, a comment will be placed by the Project Coordinator Invoicing or Business Manager that invoice has been paid.

2.3.3 Once study the study is closed in SHIELDS, lead Regulatory Coordinator will notify Project Coordinator Invoicing and Business Manager.

2.3.3.1 A reconciliation of study account will be completed.

2.3.3.2 Account closure form will be completed and sent to accounting.

HRP-100 Emergency Preparedness and Response

1 PURPOSE

1.1 This policy is designed to protect the rights and welfare of research participants during an emergency.

2 POLICY

2.1 The institution will ensure sustainability of the HRPP and continuing protection of participants in research during emergencies.

2.2 See and follow LSU HEALTH SCIENCES CENTER – SHREVEPORT Emergency Response Plan from LSUHSC-S Safety Manual, Policy Number: II.A.1.; Effective Date: 7/10/19, **https://inside.lsuhs.edu/departments/safety-services/emergency-information**

3 RESPONSIBILITIES

3.1 HRPP, IRB, investigators and research staff members are responsible to carry out these procedures.

4 PROCEDURE

4.1 HRPP will assess the type of emergency and prepare a response plan to address the emergency. Depending on the type of emergency, such as infectious disease pandemic or extreme weather events (for e.g., hurricane, earthquake, fire, flood), etc., the institution and the HRPP will follow the government orders such as stay at home or evacuate etc.

4.1.1 HRPP & IRB Responsibilities during public health emergencies:

4.1.1.1 The IRB will assess the current IRB operations and make necessary changes to them to protect the IRB staff and members.

4.1.1.2 Develop strategies to ensure continuity of IRB review if it becomes impossible to continue to meet in person

4.1.1.2.1 Replace in-person meetings with remote meetings

4.1.1.2.2 Consider relying on external IRBs for the review of research in situations where the local IRB is unavailable to perform reviews. Make arrangements for potential reliance in advance to enter into reliance agreements and transfer of research to external IRB and return to local IRB.

4.1.1.3 HURON periodically performs a backup of the IRB electronic system, SHIeLDS. The IRB will make arrangements with HURON, as the necessity arises, to ensure that the IRB records are maintained and stored securely in case the local IRB is unavailable to perform IRB operations and reviews in the electronic system due to a public health emergency, while maintaining the integrity of the data.

4.1.1.4 HRPP will consider alternate mechanisms for safety monitoring such as if trial subjects may not be able to come to the investigational site for protocol-specified visits, the IRB will evaluate whether alternative methods for consenting (e.g., remote consent), safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) could be implemented when necessary and feasible and would be sufficient to assure the safety of trial participants.

4.1.1.5 Develop education and training materials to address emergency preparedness and response in advance of the emergency, during the emergency and periodically update them.

4.1.2 Investigator Responsibilities:

4.1.2.1 The following criteria will be used to triage the research studies as type of research that can continue and that must be stopped/postponed as per following criteria,

4.1.2.1.1 Research that presents a likelihood of direct benefit to subjects.

4.1.2.1.2 Research that does not involve interaction or intervention that creates increased risks. Research that involves direct interaction or intervention but can manage risks by conducting study procedures via alternate mechanisms, including the use of remote study visits, conference calls, or videoconferencing, or by canceling in-person gatherings of people involving research activities and holding meetings such as focus groups and research-related activities, such as community advisory boards and participant and support groups for study participants.

4.1.2.1.3 Research that will have an adverse impact on resources required to address the emergency.

4.1.2.2 They will work with the IT department, research pharmacy and applicable laboratories to ensure the research data and/or specimens collected for the studies are stored and backed up appropriately to protect them in events such as loss of power or flooding or paper-record damage etc.

4.1.2.3 They will evaluate if there are emergency response plans in place for all their research locations.

- The need for response plans may be based on the type of research conducted and degree of risk in the event a study could not continue.
- Investigators must be knowledgeable that when planning to conduct research during emergencies, they should obtain IRB approval in advance where possible.

4.1.3 The research pharmacy will maintain storage, handling, and control of drugs and medical devices during the emergency. (See the US FDA's Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency (March 2020).)

4.1.4 The institution's security department and IT will ensure the security of research facilities.

4.1.5 During the COVID-19 pandemic, the following steps were taken to ensure the safety of the employees and research subjects while continuing as much research as possible,

4.1.5.1 The institution had ordered work from home for non-essential employees

4.1.5.2 IRB and research staff members were required to work from home

4.1.5.3 In-person business meetings were changed to conference calls or video conferencing

4.1.5.4 In-person IRB meetings were changed to video conference meetings while following all the applicable regulations

4.1.5.5 The HRPP, investigators and research staff members periodically evaluated the research studies,

4.1.5.5.1 That were stopped i.e., recruitment/enrollment was halted, but research activities continued on existing subjects

4.1.5.5.2 That could be postponed

4.1.5.5.3 That could be continued via alternate mechanisms, such as the use of remote study monitoring visits, audits, conference calls, or videoconferencing,

4.1.5.5.4 That could be continued at a satellite facility opened by the institution to ensure safe distance between people conducting and participating in research

4.1.5.6 The institution sent out communication to all the employees regarding the status of the pandemic, government orders and institutional orders

4.1.5.7 The IRB Director sent our communication to the IRB staff, IRB members, investigators, research staff members about changes to the IRB operations and documents etc.

5 REFERENCES

5.1 AAHRPP I.1.B.; I.1.E.; I.1.F.; I.1.H.; I.2.; I.9.; II.2.D.; II.3.B.; III.1.A.; III.1.D.; III.1.E.

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