

SOP: IRB Member Review Expectations

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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.

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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:

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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.

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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

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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.

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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

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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

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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.

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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

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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.;