



# RESIDENT RESEARCH HANDBOOK

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2021/2022 EDITION

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LSU HEALTH-SHREVEPORT GENERAL SURGERY RESIDENCY RESEARCH PROGRAM |

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## Research Management Team



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November 5, 2019

Good afternoon faculty and residents,

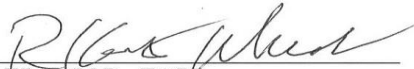
Due to the tremendous growth of our research activity, it is now imperative that we streamline and implement processes for the conduction of research that will ensure adherence to federal and state laws as well as compliance with institutional requirements. While these processes were previously recommended, they are now a requirement for all research conducted within the department of surgery. These processes will allow us to follow through on our obligation to protect the patient, the faculty and residents of our department, as well as our institution wholly.

**The principle investigator P.I. (i.e. faculty mentor) is ultimately responsible for compliance with ALL required regulatory components of the study and monitored by the IRB.** This includes overall design, conduct, and management of the study and study team. We cannot stress enough the importance of direct and proximate involvement of the P.I. on all aspects of the conduct of the study. Principle Investigators are faculty members only. Residents, students, and other team members can only be listed as sub-investigators on all research activities. It is a requirement to have all studies reviewed and approved by Dr. Lairmore and Wendy Chriss, prior to the IRB submission. Once approved by the research team, administrative approval may be sought. Once administrative approval has been granted, the study can be created in Shields for IRB review. The Research Coordinator must be listed on all studies submitted to the IRB when creating the study in Shields as well as, listed on the protocol as part of the study team. No data procurement, analysis, or study activity can occur prior to formal IRB approval. Failure to obtain IRB approval prior to conducting research violates federal and state laws associated with HRPP (Human Research Protection Program) as well as, a violation of institutional regulations.

We recognize that there remains a need for biostatistics support. While we have identified some key collaborators that have expertise in this area, this remains a limited resource. It is important to anticipate the need for assistance with statistics, and begin working early on identifying a suitable resource to complete your analysis. We can help you with this, but it is not possible to find help at the last minute. We strongly encourage you to identify the specific type of support you will need early in the study, involve the collaborator substantively in the study, and allow ample time to complete the statistical analysis. It is not possible to find someone to "run the numbers" at the last minute.

We are extremely excited about the newly developed research activities initiated in the department of surgery. We look forward to working with each of you throughout all of your research endeavors and are anxious to provide our unrelenting support in developing high value research projects and creating a culture that values research activity.

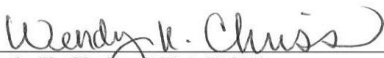
Respectfully,



**R. Keith White, M.D., FACS**  
Professor and Chairman | LSU Health Shreveport  
Department of Surgery  
John C. McDonald MD, Endowed Chair of Surgery



**Terry C. Lairmore, MD, FACS**  
Research Specialist | LSU Health Shreveport  
Department of Surgery



**Wendy K. Chriss, MBA-HCM**  
Project Manager | LSU Health Shreveport  
Department of Surgery

## ***Departmental Approval Process***

Submission of protocol by PI to Research Project Manager



Protocol review by Research Management Team  
(Protocol approval by research team required **prior to** administrative approval submission)



Submission of approved Protocol and Administrative Approval Request to  
Department Chair  
(Submitted by Research Project Manager)



Study Approval by Department Chair



Approval by Research Project Manager to Create Study in Shields (IRB)



**PI's Proceed to IRB Process**

## ***IRB Process***

### **Creation of Study in Shields by PI**

(Include Research Project Manager on the protocol and as part of the study team in Shields when creating study. Principal Investigators must consist of faculty members. Sub-investigators can include residents, students, and/or any other participants approved and appropriately trained to assist in conducting research.)



### **Documentation Review by Research Project Manager**

(See IRB tab in Shields - worksheets and templates. All required, completed documents must be approved by Research Project Manager prior to uploading into Shields)



**Upload all required documentation, specific to the type of research (retrospective vs prospective) being conducted, into Shields.**



**Obtain IRB Submission Approval from Research Project Manager**



## **Submit Study**

## **Purpose of this Handbook**

In recognition of the importance of resident scholarship, the Accreditation Council for Graduate Medical Education (ACGME) has issued that “residents should participate in scholarly activity”, and the program training curriculum “ must advance residents’ knowledge of basic principles of research, including how research is conducted, evaluated, explained to patients, and applied to patient care”. To this end, the General Surgery Residency Program at LSU Health-Shreveport has allocated resources and created the General Surgery Residency Research Program to facilitate residents’ involvement in scholarly activities. This handbook is intended to serve as a basic guide and reference as residents embark on their longitudinal, three years research curriculum. We anticipate that your participation in research during your residency training will:

- Provide you with the necessary mentorship and training experience encompassing successful research activities that promote future academic careers
- Promote your proficiency in critical appraisal of the literature
- Encourage you to pursue careers as clinical investigators

## **What Counts as Scholarly Activity**

- Clinical Research
- Translational Research
- Basic Science Research
- Quality Improvement Projects

The goal of the General Surgery Residency Research Program is to provide residents with opportunity to participate in scholarly activity and provide resources needed to conduct research. Residents will be introduced to available resources and support, and will learn basic research methodology through research training modules delivered monthly throughout PGY1. Additionally, there will be topics relevant to research or evidence based practice that will be covered during Tuesday morning conferences.

## **Expectations**

Residents will participate in a scholarly project with oversight provided by a faculty mentor. Residents will play a meaningful role in the project with continuous guidance and assistance provided by the faculty mentor throughout all phases of the research project. In order to be successful, residents will adhere to the following timeline and are required to report their progress as requested by the General Surgery Residency Research Program team. Mandatory meetings with the Research Program Management Team will occur throughout the life of each research project and will assess research progress, level of support provided/needed, as well as resource assessment to identify needed resources for project completion. Meeting dates will be provided to you in advance and confirmed via email. By the time of graduation, residents are required to have completed 3 scholarly projects with presentation of their work during Tuesday morning conference.

## **Research Timeline**

The timeline presented below represents an ideal timeline with flexibility to complete your annual research project during your first four years of training. In order to be successful, it requires you to start thinking of research as an integral part of your training beginning early during your internship. We believe residents armed with the right information can pace themselves along this suggested timeline without conflict with their clinical duties. We strive to provide you with the right information but keep in mind that it's only your commitment that is the cornerstone of your success. Be realistic and get started right away! The research timeline includes the following mandatory components and are discussed below. All components of the research timeline are mandatory and are assessed, evaluated, and reported to the Department Chair through Mid-point and Final Evaluations. These evaluations are utilized in combination with other evaluative measures to determine progression to the next PGY year. All components of the research timeline must be completed in order to meet ACGME guidelines surrounding scholarly activity.

- Submission of Study Documents
- Research Training
- Mandatory Meetings with Research Management Team
- Mid-Point Evaluations
- Final Evaluations
- Faculty Mentor Evaluations
- Mock Presentations
- Final Research Project Presentation

## **Submission of Study Documents**

Please submit all study documents, evaluations, surveys, and all other correspondence in an electronic format via email to Wendy Chriss on required due dates. Late submissions will be documented and reflected in resident evaluations. IRB templates must remain in their original format to avoid IRB clarification requests.

## **Research Training**

All research training sessions will be held in the Surgery Conference Room at 3:30PM on dates listed below. The Research Management Team will be available at 3PM on training days for one-on-one meeting sessions/discussion for your convenience. While the training sessions are only required for PGY1, all residents are welcome to attend. If you are interested in attending any of the following training sessions, located on the PGY1 timeline, please send a request to Wendy Chriss two weeks prior to training date via email. While we'll make every effort to accommodate all requests for training, late requests may not be accommodated in order to ensure compliance with governor's order for social distancing amidst the COVID 19 pandemic.

## **Mandatory Meetings with Research Management Team**

Research Management Team Meetings are scheduled throughout the academic year for all residents in order to assess current research progress, identify barriers hindering progress, and



implementation of a plan for successful completion. Please see your PGY calendar for meeting dates.

### **Mid-Point Evaluations / Final Evaluations**

Evaluations will be utilized to track resident progress on meeting the required components of the research timeline. Evaluations will assess timely completion and completion quality of all required deliverables, training, evaluations, and presentations as listed in the research timeline. Resident research evaluations are reviewed by the academic and research management teams and are utilized in combination with other evaluative measures/methods to determine progression to the next PGY year. All components of the research timeline must be completed in order to meet ACGME guidelines surrounding scholarly activity and program progression. See Appendices A thru D for evaluation templates.

### **Faculty Mentor Evaluation**

Faculty Mentorship is a critical component to research productivity and is essential to learning and success of all resident research endeavors during their time as a surgical residents. The Department of Surgery at LSU Health Shreveport recognizes the importance of the residents need for an excellent mentorship experience and strives to ensure that your experience encompasses professional growth in all areas.

For this reason, we want your feedback regarding your mentorship experience in order to ensure that you've been perfectly matched. Faculty mentorship surveys are completed biannually and are a required component of the research timeline.

### **Mock Presentations**

Mock Presentations are scheduled at different date/time intervals for each PGY cohort. Mock presentations are voluntary and are utilized to provide constructive feedback prior to formal presentation delivery.

## 2021-2022 Scheduled Due Dates

PGY1	
August 12, 2021	Research Orientation
August 19, 2021	Completion of CITI Training
August 23, 2021	Creation of Shields Account/COI Disclosure
September 2, 2021	<b>Research Training: Researching the Literature Study Design – Part I</b>
September 20, 2021	Identification of Research Topic and Faculty Mentor Due (See Letter of Intent)
September 30, 2021	<b>Research Training: Study Design – Part II</b>
November 4, 2021	<b>Research Training: Protocol Writing</b>
November 22, 2021	Protocol Due: First Draft
December 2, 2021	<b>Research Training: Protocol Feedback</b>
January 10, 2022	Protocol Revisions Due/Faculty Mentorship Evaluations Due
January 31, 2022	Mid-Point Evaluation Meeting with Research Management Team
February 28, 2022	<b>Research Training: Completion of Required IRB Documents for Study Submission; Data Collection Tool</b>
March 21, 2022	<ul style="list-style-type: none"> <li>➤ Finalize Project Details and IRB Documents with Faculty Mentor</li> <li>➤ IRB Documents Due</li> </ul>
March 30, 2022	<b>Research Training: Creating the Study in Shields for IRB Submission</b> <ul style="list-style-type: none"> <li>• Deliverables: IRB Documents - Final Revisions Due</li> </ul>
April 30, 2022	<ul style="list-style-type: none"> <li>➤ Due: Study Creation in Shields – ready for IRB submission</li> <li>➤ Due: Data Request</li> </ul>
May 30, 2022	<ul style="list-style-type: none"> <li>➤ <b>Research Training: Collecting the Data; Coding the Variables</b></li> <li>➤ Review IRB Status</li> </ul>
June 28, 2022	<ul style="list-style-type: none"> <li>➤ Project Review/Faculty Mentorship Evaluations Due</li> <li>➤ Final Evaluations Meeting with Research Management Team</li> </ul>

<b>PGY2</b>	
August 17, 2021	PGY2 Mandatory Meeting with Research Management Team
August 18, 2021	Identify Faculty Mentor Identify and Submit Research Topic (See Letter of Intent)
September 30, 2021	Protocol due (1st draft)
October 15, 2021	<ul style="list-style-type: none"> <li>➤ Final Protocol Revisions Due</li> <li>➤ Data Acquisition Requests and Data Collection Tools Due</li> <li>➤ All Other IRB Documents Needed for Study Submission Due.</li> </ul>
November 16, 2021	PGY2 Mandatory Meeting with Research Management Team
December 14, 2021	Faculty Mentorship Evaluations Due
February 1, 2022	PGY2 Mandatory Meeting with Research Management Team- Mid-Point Evaluation
March 01, 2022	<ul style="list-style-type: none"> <li>➤ Finalize Project with Faculty Mentor</li> <li>➤ PGY2 Mandatory Meeting with Research Management Team</li> </ul>
March 15, 2022	Abstract Due to Research Management Team
April 19, 2022	Mock Presentations
April 26, 2022	Mock Presentations
June 21, 2022	<ul style="list-style-type: none"> <li>➤ Faculty Mentorship Evaluations Due</li> <li>➤ Final Evaluation - Meeting with Research Management Team</li> </ul>

<b>PGY3</b>	
August 18, 2021	Identify Faculty Mentor Identify and Submit Research Topic (see Letter of Intent)
August 24, 2021	PGY3 Mandatory Meeting with Research Management Team
September 30, 2021	Protocol due (1st draft)
October 31, 2021	<ul style="list-style-type: none"> <li>➤ Final Protocol Revisions Due</li> <li>➤ All Other IRB Documents Needed for Study Submission Due.</li> <li>➤ Data Acquisition Requests and Data Collection Tools Due</li> </ul>
November 09, 2021	PGY3 Mandatory Meeting with Research Management Team
December 14, 2021	Faculty Mentorship Evaluations Due.
February 08, 2022	PGY3 Mandatory Meeting with Research Management Team – Mid-Point Review
March 1, 2022	Finalize Project with Faculty Mentor
March 15, 2022	Abstract Due to Research Management Team
March 29, 2022	PGY3 Mandatory Meeting with Research Management Team
April 12, 2022	Mock Presentations
April 26, 2022	Mock Presentations
June 14, 2022	<ul style="list-style-type: none"> <li>➤ Faculty Mentorship Evaluations Due</li> <li>➤ Final Evaluation - Meeting with Research Management Team</li> </ul>

<b>PGY4</b>	
August 18, 2021	Identify Faculty Mentor Identify and Submit Research Topic (see Letter of Intent)
August 24, 2021	PGY4 Mandatory Meeting with Research Management Team
September 30, 2021	Protocol due (1st draft)
October 31, 2021	<ul style="list-style-type: none"> <li>➤ Final Protocol Revisions Due</li> <li>➤ Data Acquisition Requests and Data Collection Tools Due</li> <li>➤ All Other IRB Documents Needed for Study Submission Due.</li> </ul>
November 09, 2021	PGY4 Mandatory Meeting with Research Management Team
December 14, 2021	Faculty Mentorship Evaluations Due
February 08, 2022	PGY4 Mandatory Meeting with Research Management Team Mid-Point Evaluation
March 1, 2022	Finalize Project with Faculty Mentor
March 15, 2022	Abstract Due to Research Management Team
March 29, 2022	Mandatory Meeting with Research Management Team
April 12, 2022	Mock Presentations
April 19, 2022	Mock Presentations
June 14, 2022	<ul style="list-style-type: none"> <li>➤ Faculty Mentorship Evaluations Due</li> <li>➤ Final Evaluation - Meeting with Research Management Team</li> </ul>

## **Faculty Mentorship and Research Topics**

### **Department of Surgery Research Team**

The success of the Department of Surgery's Residency Research Program at LSU Health Shreveport is dependent on four key players: the resident, the faculty mentor, the Research Management Team, and the Residency Research Program departmental committee.

#### **Resident**

The resident has the major responsibility to carry out the research project in a satisfactory manner. The resident is highly encouraged to submit the prepared report for publications in peer-reviewed journals as well as, present their research in national and international conferences.

#### **Faculty Mentor**

Any faculty member at LSU Health Shreveport – Department of Surgery could be eligible to be a faculty mentor to one or more residents at any given time. The major responsibility of the faculty mentor is guiding and supervising the resident during the research process. The faculty mentor has to ensure that the resident is carrying out the resident research project in a satisfactory manner by holding regular meetings.

#### **Research Management Team**

The primary role of the Research Management Team is to provide support and oversight for all aspects of the conduct of research within the Department of Surgery. This includes administrative functions such as verification of required research training, assistance with submission and required revisions for IRB research protocols, and monitoring compliance with all institutional and federal regulations. In addition to these administrative functions, the Research team also provides a structured didactic training program for each of the elements required for a productive and successful research project. These elements include, but are not limited to, training in performance of current literature searches, study design, computer analytics and data mining from administrative databases, human studies ethics, basic biostatistics and data analysis, abstract preparation, and "mock" oral presentation practice sessions with constructive feedback. The Research Team has also developed a structured calendar of milestones that will be required for each trainee to meet to ensure satisfactory progression of the project and to avoid last minute deficiencies that cannot be rectified. The Research team encourages residents to reach out for support and assistance, with an "open access" policy. The resources provided by the Research team are intended to supplement and complement the direct primary supervision of the research project by the Faculty mentor.

#### **Residency Research Program Departmental Committee**

The Residency Research Program departmental committee is comprised of the Department of Surgery Chairman, the Research Management Team, as well as faculty members who have research expertise in different fields within the Department of Surgery. This committee is responsible for evaluating the residents' work (completion of

all required work as listed in each PGY schedule of assignments and due dates, completion of research training, as well as progress evaluation during each phase of the resident research project).

## **Selecting a Faculty Mentor**

An important feature of the Department of Surgery's Research Training Program is the pairing of each trainee with a designated faculty mentor. According to this model, each resident will select a faculty member via self-match and/or committee assignment to provide guidance, oversight, and intellectual input into developing a research question, designing the research plan, and performing data analysis and interpretation. As part of the structured research curriculum, you will receive specific instruction for submitting an IRB research plan application, performing a literature review, and the basics of biostatistics. Importantly however, it will be this interaction with your designated faculty mentor that plays the primary role in generating an important research question to study, guiding the selection of the appropriate study design and feasibility, and data analysis and interpretation of the results. Additional support and guidance from the Research Management Team (Dr. Lairmore/Wendy Chriss) are available with open access. The Department of Surgery academic faculty are also charged with establishing and promoting a "culture" that values research.

Choosing an appropriate faculty mentor best suited to your individual research goals and career development is an important initial step. Here are some general guidelines, and available resources, to help you with this important decision. It is strongly recommended that align your research interests with your anticipated ultimate area of clinical expertise or focus. Although many trainees refine this early preference, or even change their specialization goals completely, there are many reasons to choose to focus scholarly activity within your area of interest. The advantages include not only maximizing your genuine interest in the clinical problem, but also allowing for the best support of your career advancement. Developing a publication track record and/or making contributions to specific clinical problems within your anticipated clinical area of specialization provides strong additions to applications for competitive fellowship training positions or academic appointments.

If you feel you share common clinical goals and philosophies with a faculty member, or perhaps identify them as a positive role model that you wish to emulate, that may be the important initial spark. Try to do some background work to determine the types of research projects, productivity, and prior success in mentoring previous trainees for a specific faculty member. Once you have identified a potential research mentor, it is strongly recommended that you take the initiative to approach them directly and discuss your goals as well as their interests and specific expertise. Tell them what your interests are, how you arrived in a surgical residency training program. What is your background and prior research experience, where do you want to be in 10 years?

Specific attributes that you may want to determine for a potential mentor include: How much time do they have to supervise me and what other associated staff do they have that can help me get established or show me new techniques (APPs, statistical expertise, relationships with cancer center or internal/external collaborators)? How successful are they in terms of grants and publications and do they have a regional or national reputation in their field of expertise?

Do they have any other associated indicators of performance such as journal editor, local/national leadership positions? It is important to remember that research experience does not always equate directly with clinical seniority. A very important metric to attempt to discern is do they have time to devote to my development and the project, are they the best person to supervise me? Most academic faculty understand the rigorous nature of surgical training and how difficult it can be to incorporate research into the mix. They have been there, but they understand the critical importance of a research experience in your overall training. It will teach you the process of research, how to critically read the scientific literature, and how to ask and answer critical clinical questions with an appropriately designed study.

From a practical standpoint, a strong research background is crucial to career advancement and is truly an integral and necessary component of a surgeon's training. The surgical discipline is a lifelong process that involves, service, teaching, and discovery. If you have found the right mentor, he/she will understand and address these principles, and actively assist you in getting your research effort off the ground. The process of identifying and securing your mentor will come very early in the structured timeline of the research curriculum. As always, the research Director, the research team, and the Chairman of Surgery are available to assist in this important decision.

### **Resident/Faculty Mentor Matching**

The matching process involves mutual agreement of the resident and faculty mentor to work on a specific research project. This matching is done either through self-matching or through the departmental research committee. During self-matching, residents identify a faculty mentor for the specific research question in mind based on similar interests and personal communication. For residents who fail to identify a potential match, the departmental research committee carries out the matching based on mutual interest and agreement.

### **Selecting a Research Topic**

Young surgical trainees have some very important attributes that may prove very valuable in developing a meaningful research question. Keep an inquisitive mind and do not be afraid to question the current practices and paradigms that exist in surgical practice. It is estimated that a very large proportion of the things we do in medicine are not evidenced-based and cannot be supported specifically by high level evidence. You have the advantage of just beginning your clinical experience and are likely more malleable in your thinking. If you see a significant clinical problem, think of ways it might be addressed better. Many good ideas come from the common experience of being confronted with a difficult problem or outcome and having an idea for a better way when looking at a problem with a fresh vision. The current techniques and technology utilized in surgical practice were developed by persons no smarter than you! We all have the potential to conceive of new approaches to commonly encountered problems.

Study the problems that you are seeing. Take advantage of those patients for which a large patient population is seen at LSU Health Shreveport. Specifically, we have a very large experience with trauma, burns, complex surgical oncology, and cardiovascular diseases at our center, among many others. "Defining important questions is best done by those who till the fertile soil of a busy clinical ward" - From Dr. S.A. Wells, Jr. Presidential address to the American



Surgical Association, 1996.

Surgical training has historically been based on a solid basic science background, innovative thinking, and the “technical courage” to implement novel ideas into surgical practice. There are some excellent resources online to assist a surgical trainee in identifying a research project. The Association for Academic Surgery promotes young developing surgical investigators and provides up-to-date practical information and guidance for young investigators (see below). Simply speaking, the best projects are ones that you believe in and are genuinely interested in. Think about the difficulties or unanswered questions that underlie a specific clinical problem. In what ways can the outcomes or clinical course be impacted? What is the value of studying the problem and will the answers be expected to lead to improved patient care or outcomes? What will be the next question to answer? A project that potentially leads to a new understanding or change in treatment outcomes is more valuable than a yes or no question.

A good starting point is to try to understand your own personal goals. How do you perceive the value of research and its impact on your personal, career, and clinical development? Your leadership and mentors have obviously identified scholarly activity as a crucial part of your training, so there must be a good reason.

Many people who go into research unsure, and later, come out passionate and engaged. In my experience it is rare for people to have a miserable time in research and I think everyone can learn something valuable from the experience. The amount of time that people spend in structured research may vary depending on their level of engagement, interest and aspirations and this is entirely appropriate.

“At the very minimum, a period of dedicated research should offer you training in research methodology, design and analysis. This in itself, is valuable but the project should also lead to a higher degree and ideally give rise to publishable material”.-Prof. S. Wigmore (see citation below). Some excellent current resources that address these issues are provided below. Dr. Lairmore and the Research Team are available to guide and assist you with this process. Please do not hesitate to take advantage of our open access policy. Your academic and clinical success is our top priority. We strive to be a premier training program for Surgeons, and we want you to develop and incorporate these ideals and be proud of your training program.

RESOURCES:

<https://www.aasurg.org/blog/creating-a-unique-research-plan-during-surgery-residency/>

<https://profstevewigmore.wordpress.com/2012/04/30/how-to-choose-a-research-project-for-surgery-trainees-2/>

## **Letter of Intent**

The research topic can be resident-initiated, where the residents identify the research topic, or faculty-initiated in which the faculty member is the one who provides a project for the resident to work on, which is mainly appropriate to residents who do not have a specific research question in mind. All resident research topics must be submitted to the Research Program Project Manager ([wendy.chriss@lsuhs.edu](mailto:wendy.chriss@lsuhs.edu)) via a Letter of Intent. The resident

prepares the letter of intent, which includes information regarding the resident and faculty mentor, and a brief description of the project (such as title, objectives, methodology and significance). Utilization of the letter of intent is required for research topic submission and committee review. All research topics will be reviewed and approved by the Research Committee. The letter of intent template will be located on the research website as well as, in the appendices of the Resident Research Handbook. This process will greatly assist in ensuring that every resident is embarking on a quality research project endeavor.

## Research Training Requirements: Getting Started

Investigators and staff involved in the design, conduct, or reporting of research are required to complete CITI training as identified below. IRB approval will not be granted for proposed research in which all members of the research team have not completed human research protections training, and any other required education or training. You may have additional training imposed by other federal, state, or institutional policies. See SOP: Education (HRP-002).

All members of the research team involved in the design, conduct, or reporting of the research 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. Investigators and staff conducting research involving human subjects must complete the Collaborative Institutional Training Initiative (CITI) human subjects online training program. The CITI site can be accessed at <http://www.citiprogram.org>.

## Creating a CITI Account

Use your name as it is listed in Outlook or your full legal name.

Register as a new user, typing **Louisiana State University Health Sciences Center-Shreveport** as your affiliation. DO NOT abbreviate Louisiana State University Health Sciences Center-Shreveport (LSUHSC-S). If you use another institution, you may not receive credit for training modules completed. The office of Legal Affairs cannot verify CITI records that are not associated with **Louisiana State University Health Sciences Center-Shreveport**. If possible, enter two (2) email addresses with your LSU email address listed as primary. Ochsner LSU Health Shreveport Employees must also use this affiliation for projects approved by the LSU Health Shreveport IRB. If you already have a CITI account, you do not need to create a new one. Following completion of your training modules, please email LeShonda Lindsey (leshonda.lindsey@lsuhs.edu) in Legal Affairs and Organizational Integrity in order to **create your Shields Account** needed for conducting research. You may also reach her by phone, extension 5-8439 for additional instructions. She will also provide assistance with user name retrieval and/or affiliating your CITI account with LSU.

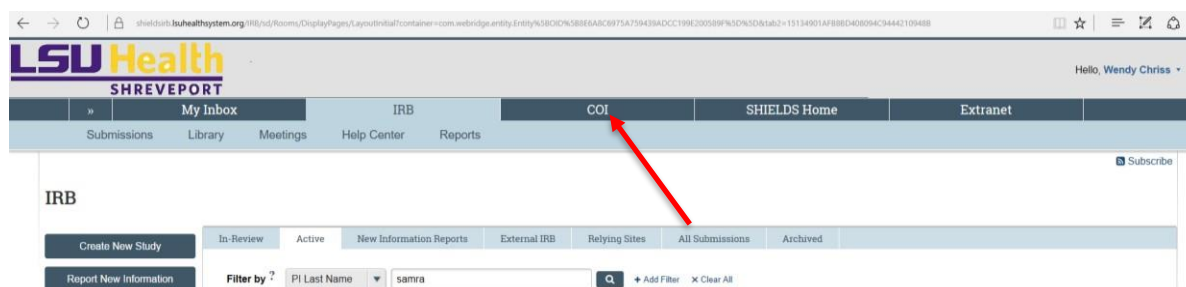
## Undue Foreign Influence: Risks and Mitigations

Investigator and Research Staff involved in <b>Clinical Studies</b> (drugs, devices, biologics, invasive procedures) Required Training		
	Course	Timeline
Initial Training	CITI Biomedical Research Basic	Prior to IRB Submission
	CITI Conflict of Interest	Prior to IRB Submission
	CITI Good Clinical Practice	Prior to IRB Submission
	CITI Health Information Privacy and Security	Prior to IRB Submission
	Undue Foreign Influence: Risks and	Prior to IRB Submission
Refresher Courses	CITI Biomedical Research Refresher	Every 3 years
	CITI Conflict of Interest	Every 4 years or upon change
Investigator and Research Staff involved in <b>Non-Clinical Studies</b> (drugs, devices, biologics, invasive procedures) Required Training		
	Course	Timeline
Initial Training	CITI Biomedical Research Basic	Prior to IRB Submission
	CITI Conflict of Interest	Prior to IRB Submission
	CITI Health Information Privacy and Security	Prior to IRB Submission
Refresher Courses	CITI Biomedical Research Refresher	Every 3 years
	CITI Conflict of Interest	Every 4 years or upon change

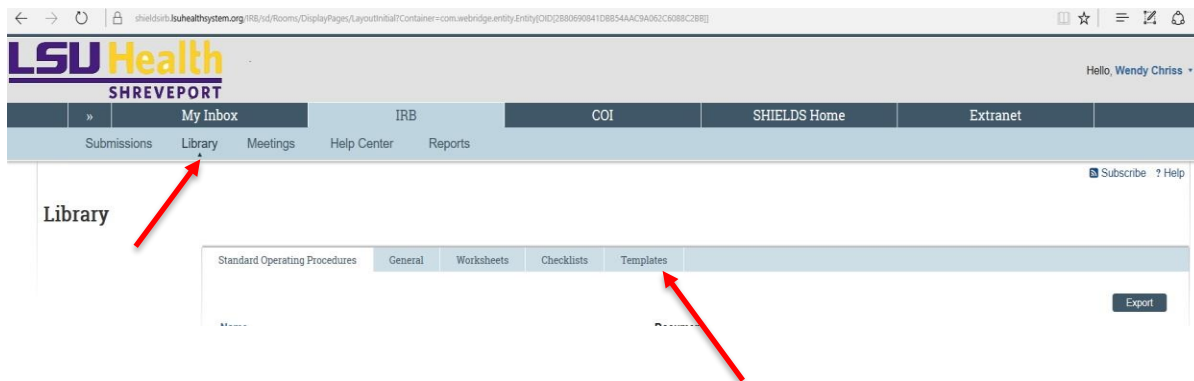
## Shields Account

Your Shields account will greatly assist you with obtaining the resources needed to create a study for IRB review. <https://shields.lsuhealthsystem.org/SHIELDS>

Upon creation of your Shields account, you will need to login and complete the COI disclosure. This process involves answering several questions pertaining to Conflicts of Interest and takes only 3 minutes to complete. COI disclosures must be completed annually.



The library (located under the IRB tab), provides all IRB required templates for your study. This includes protocol templates as well as all other documentation that will be required for submission of your study.



The worksheets and checklists are utilized by IRB reviewers and board members to ensure proper completion and documentation of each required form for study submission. You should use the worksheets and checklists as a guide when completing the required IRB templates for your study as this will prevent IRB clarification requests that delay study approvals. The **general** information tab contains the **HRP-101** – Human Research Program Protection Plan and **HRP-103** - Investigator Manual. You should be familiar with the information contained within these manuals prior to participating in research activity.

## Human Research Protection Program

### HRPP SOP's

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."

### HRP 101- Human Research Program Protection Plan

This Organization is committed to protecting the rights and welfare of subjects in Human Research. The purpose of this plan is to describe this Organization's plan to comply with ethical and legal requirements for the conduct and oversight of Human Research.

This Organization's Human Research Protection Program is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The Human Research Protection Program is based on all individuals in this Organization along with key individuals and committees fulfilling their roles and responsibilities described in this plan.

### HRP 103- Investigator Manual

This manual "Investigator Manual (HRP-103)" is designed to be an abbreviated guide to LSUHSC-S policies, procedures, guidances, and resources related to the conduct of human research at LSUHSC-S. All human research related activities must be in full compliance with the LSUHSC-S Human Research Protection Program (HRPP), the LSUHSC-S Institutional Review Board (IRB) policies and guidances, and federal regulations to ensure the protection of human research participants.

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 HRPP website at:

**<http://www.lsuhsershreveport.edu/Research/HRPPHome/index>**

The “Investigator Manual (HRP-103)” is designed to be an abbreviated guide to LSUHSC-S policies, procedures, guidances, and resources related to the conduct of human research at LSUHSC-S. All human research related activities must be in full compliance with the LSUHSC-S Human Research Protection Program (HRPP), the LSUHSC-S Institutional Review Board (IRB) policies and guidances, and federal regulations to ensure the protection of human research participants.

You, the researcher, are bound by state and federal laws, as well as institutional policy, that govern the conduction of research. You are held accountable for all standards and applicable laws pertaining to the conduction of research. The HRPP plan and SOP as well as the Investigator Manual will greatly assist you in understanding the IRB process, research conduct, federal and state laws surrounding the conduction of research, institutional policies, and your role as a researcher.

**PLEASE NOTE: PLEASE NOTE: ALL research activity MUST be sent to the IRB for review, determination, and/or study approval. This includes but is not limited to case studies, outside de-identified data banks, de-identified data from any source, non-human research, etc. LSUHSC-S Institutional policies require that all research activity be reviewed by the IRB for determination.**

## **Researcher Resources**

This following information is located in the LSU Health HRPP Investigator’s Manual (HRP-103) <https://shieldsirb.lsuhealthsystem.org/IRB/sd/Doc/0/RENKQGF0R5CK90GJSULBOJQ15F/HRP-103%20-%20INVESTIGATOR%20MANUAL%20revised%209.28.16.pdf>



## **Human Research Protection Program (HRPP)**

# **Investigator Manual**

**Version 1  
June 1, 2016**

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## Institutional Review Board Meeting Dates 2021


<b>Louisiana State University Health Sciences Center-Shreveport</b> <b>Institutional Review Board</b> <b>2021 Calendar</b> 1501 Kings Hwy, Shreveport, LA. 71103 FWA: 00000653    IRB: 00000178    Phone: 318-813-1350    Fax: 318-813-1360 <i>Meeting Dates Twice Monthly (11:45 AM)</i> Completed submissions submitted by Tuesday of the prior week will be placed on the Monday following's meeting date					
<b>January</b> (1 New Year's Day 18 MLK Jr.)	1/4/2021	1/11/2021 No Meeting	1/18/2021 Holiday No Meeting	1/25/2021	
<b>February</b> (15 President's Day)	2/1/2021 No Meeting	2/8/2021	2/15/2021 Holiday No Meeting	2/22/2021	
<b>March</b>	3/1/2021 No Meeting	3/8/2021	3/15/2021 No Meeting	3/22/2021	3/29/2021 No Meeting
<b>April</b> (2 & 5 Easter)	4/5/2021 Holiday No Meeting	4/12/2021	4/19/2021 No Meeting	4/26/2021	
<b>May</b> (31 Memorial Day)	5/3/2021 No Meeting	5/10/2021	5/17/2021 No Meeting	5/24/2021	5/31/2021 Holiday No Meeting
<b>June</b>	6/7/2021	6/14/2021 No Meeting	6/21/2021	6/28/2021 No Meeting	
<b>July</b> (5 Observed Independence Day)	7/5/2021 Holiday No Meeting	7/12/2021	7/19/2021 No Meeting	7/26/2021	
<b>August</b>	8/2/2021 No Meeting	8/9/2021	8/16/2021 No Meeting	8/23/2021	8/30/2021 No Meeting
<b>September</b> (6 Labor Day)	9/6/2021 Holiday No Meeting	9/13/2021	9/20/2021 No Meeting	9/27/2021	
<b>October</b>	10/4/2021 No Meeting	10/11/2021	10/18/2021 No Meeting	10/25/2021	
<b>November</b> (25 & 26 Thanksgiving)	11/1/2021 No Meeting	11/8/2021	11/15/2021 No Meeting	11/22/2021	11/29/2021 No Meeting
<b>December</b> (23, 24 & 27 Christmas 31 New Year's)	12/6/2021	12/13/2021 No Meeting	12/20/2021	12/27/2021 Holiday No Meeting	

<https://resources.finalsite.net/images/v1610738540/lshscshreveportedurwhpfo9ws2veuujpaqku/2021IRBMeetingCalendar.pdf>


## Study Submission

Prior to completion of additional required IRB documents listed below, please refer to the departmental approval process on page 4 of this handbook. Protocols should be reviewed by the Research Management Team and revised by the study team to reflect requested revisions by the Research Management Team prior to completion of all other required IRB documents. Completion of required IRB documents prior to protocol review and revision will result in additional revision requests to all other required study documents since these documents must reflect the information provided in the protocol. Once the Departmental Approval Process is complete, you are ready to move forward to the IRB process identified on page 5 of this handbook.

## What Do I Need for a Retrospective Study?

	<b>WORKSHEET: Documents Required for Research on Existing Data, Records or Specimens</b>		
	NUMBER	DATE	PAGE
	HRP – 337	12.14.2015	25 of 57
<b>IRB Study ID Number:</b>			
The purpose of this worksheet is to provide support for Investigators or IRB Staff when processing research submissions.			
<b>1 The Submission is complete with the following documents as applicable;</b>			
<input type="checkbox"/>	Protocol Template – <b>503.10 – Research Involving Existing Data, Documents, Records or Specimens</b>		
<input type="checkbox"/>	Cost Analysis – (Abbreviated Version – Chart Review Cost Analysis) contact <a href="mailto:ctmt@lsuhsc.edu">ctmt@lsuhsc.edu</a> when pre-review of protocol is complete		
<input type="checkbox"/>	Request for waiver of consent – Check ‘Yes’ on item #21 on the 503.10 Protocol Template		
<input type="checkbox"/>	HIPAA Waiver of Authorization Form; click on link: <a href="https://shields.lsuhealthsystem.org/">https://shields.lsuhealthsystem.org/</a>		
<input type="checkbox"/>	FORM: Administrative Approval (HRP-220) completed by Department Chair		
<input type="checkbox"/>	Investigator and research staff are up to date on human research and COI education and training (CITI) prior to submitting study;		
<input type="checkbox"/>	Investigator and research staff have completed COI disclosures prior to submitting study;		
<input type="checkbox"/>	Valid agreement with any third party participating in the research; (Data Use Agreement; Material Transfer Agreement; Contract)		
<input type="checkbox"/>	The principal investigator is NOT a student, resident or fellow. (Only senior staff and faculty members can be principal investigators).		

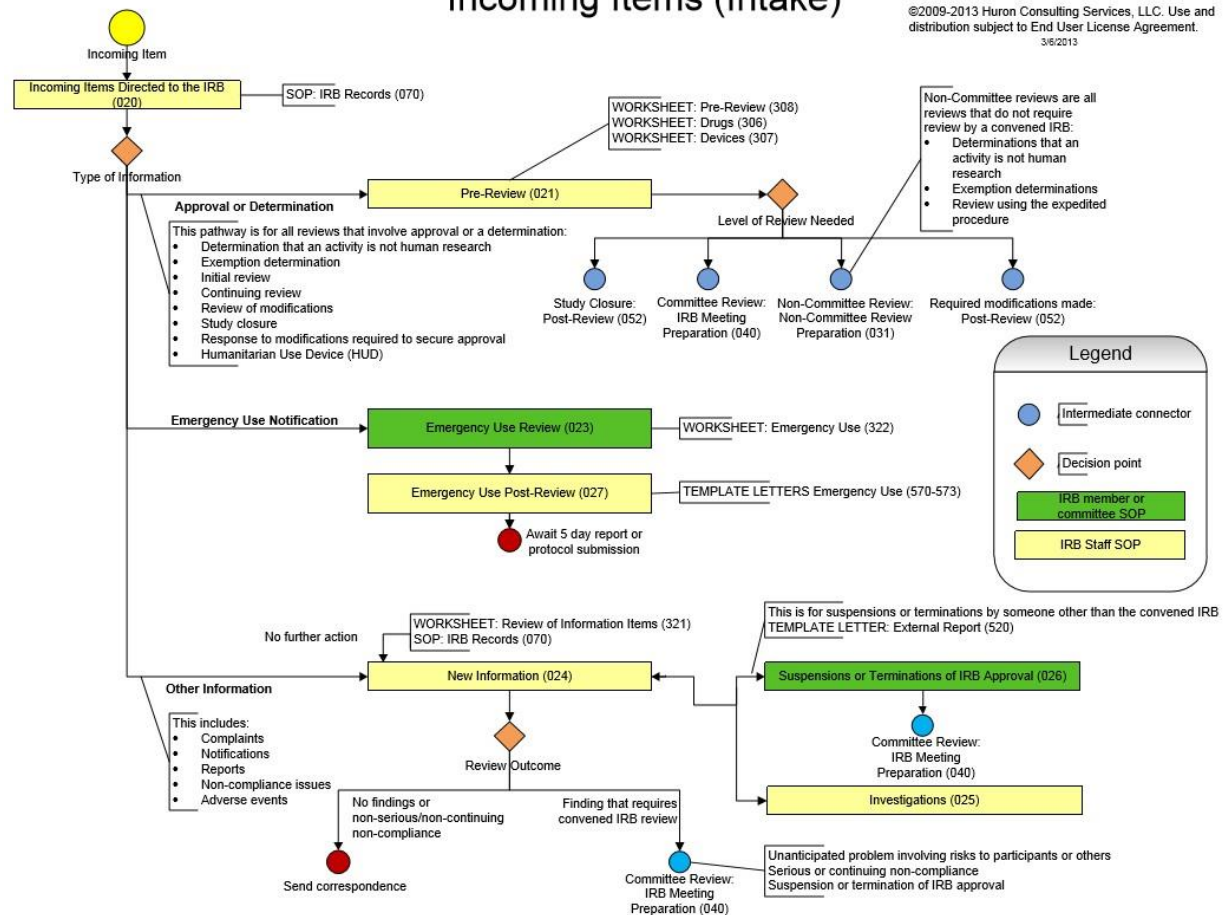
## What Do I Need for a Prospective Study?

	<b>WORKSHEET: Documents Required for Investigator Initiated – Minimal Risk Research</b>		
	NUMBER	DATE	PAGE
	HRP – 338	7/9/2015	26 of 57
<b>IRB Study ID Number:</b>			
The purpose of this worksheet is to provide support for Investigators or IRB Staff when processing research submissions.			
<b>1 The Submission is complete with the following documents as applicable;</b>			
<input type="checkbox"/>	Protocol – 503 Protocol Template		
<input type="checkbox"/>	Case Report Forms or Data Collection Tool		
<input type="checkbox"/>	Cost Analysis for LSU research (contact <a href="mailto:ctmt@lsuhsc.edu">ctmt@lsuhsc.edu</a> after pre-review of protocol is complete)		
<input type="checkbox"/>	Contract in signature phase or entire grant application when applicable for funded research		
<input type="checkbox"/>	Surveys or Questionnaires when applicable to protocol		
<input type="checkbox"/>	Research Administrative Record - required when patients/subjects are signing a consent document		
<input type="checkbox"/>	Consent document when applicable; or request for waiver of consent in the 503 Protocol Template		
<input type="checkbox"/>	HIPAA Authorization Form; or HIPAA Waiver of Authorization Form (click on link: <a href="https://shields.lsuhealthsystem.org/">https://shields.lsuhealthsystem.org/</a> )		
<input type="checkbox"/>	Advertisements (Flyers, etc.)		
<input type="checkbox"/>	Delegation Log		
<input type="checkbox"/>	FORM: Administrative Approval (HRP-220) completed by Department Chair		
<input type="checkbox"/>	Investigator and research staff are up to date on human research and COI education and training (CITI) prior to submitting study;		
<input type="checkbox"/>	Investigator and research staff have completed COI disclosures prior to submitting study;		
<input type="checkbox"/>	Valid agreement with any third party participating in the research; (Data Use Agreement; Material Transfer Agreement; Contract)		

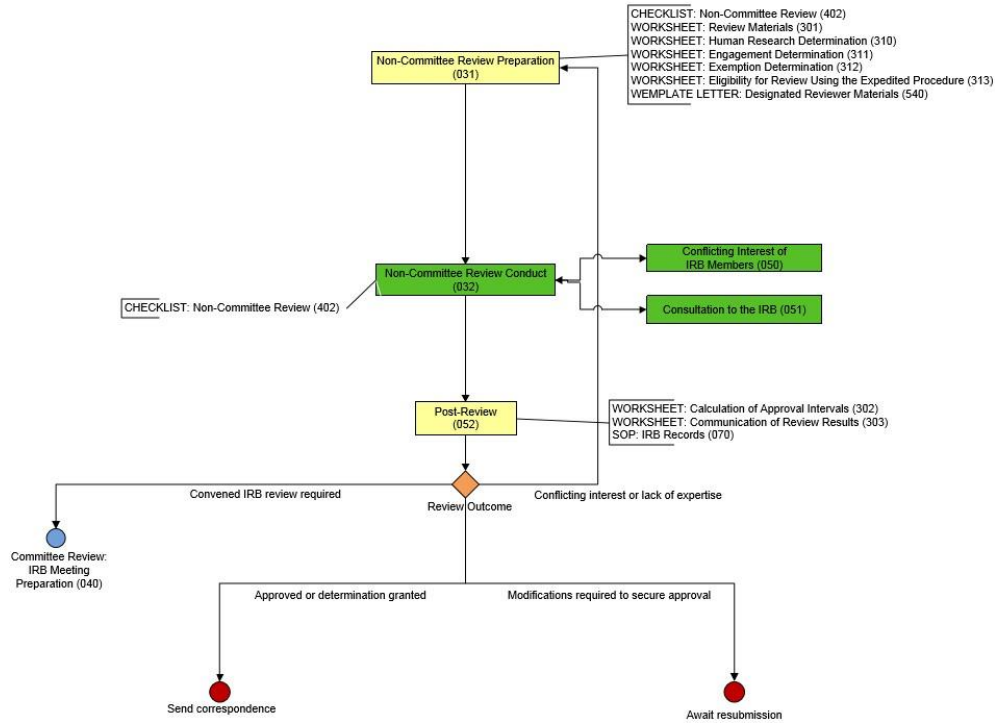
# IRB PROCESS

## Incoming Items (Intake)

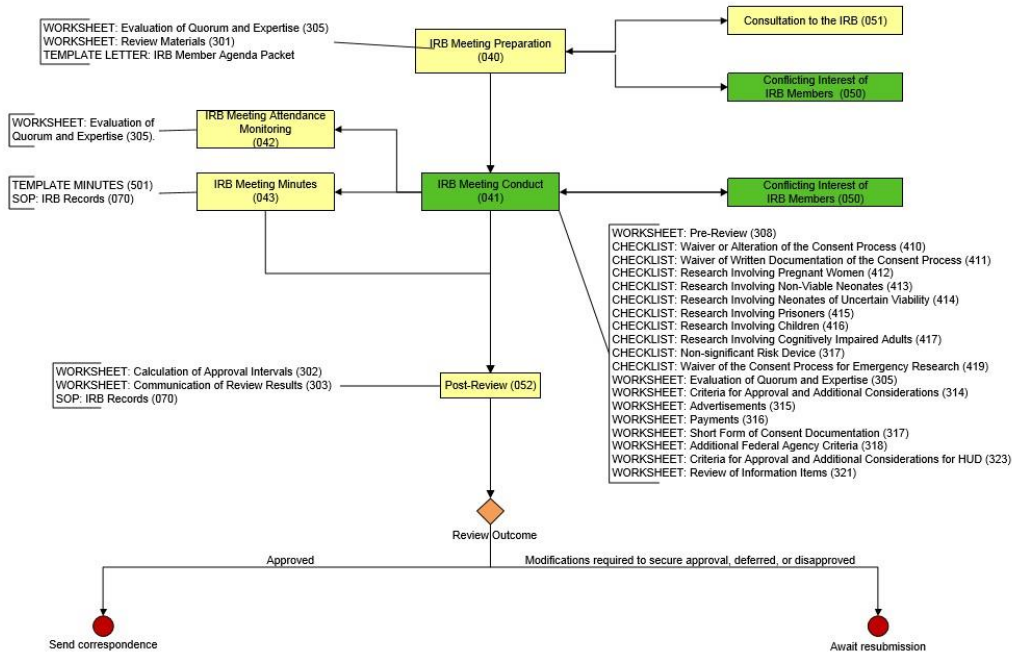
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3/6/2013



## Non-Committee Review



## Convended IRB Review



## **Data Reports and Retrieval**

Following IRB approval of your research project, you are, now, ready to begin collecting your data!!! This section pertains to data requests that include information from LSU Health Shreveport, OLSU Shreveport - Monroe Medical Center, OLSU Shreveport Academic Medical Center, Trauma Database, and the Cancer Registry.

Initial data collection will most likely begin with a data report that includes all patients and/or information that meets your inclusion criteria listed in your IRB approved protocol. An official request must be submitted by utilizing the Data Acquisition request form located in Appendix F of this handbook. Turn-around time for data requests is certainly not an expeditious process and may take 6-8 weeks for completion. While we are working diligently to improve this process, it is imperative that you plan accordingly and avoid last-minute data requests in order to complete your research project on time. Please review due dates listed in your PGY schedule for data acquisition requests. Due dates for each cohort have been staggered to avoid numerous data request submissions at one time in turn, preventing data request overload on the EPIC team and avoiding creation of major barriers to timely data retrieval. You are more than welcome to submit your data requests sooner. However, if you fail to submit your data request by the due date given for your cohort, your request will not be submitted until all other data requests, submitted on time, are completed.

## **Data Collection Tool**

In addition to the Data Acquisition Request Form, you will need to submit your Data Collection Tool. Your Data Collection Tool is an Excel document that includes all information listed in the “Data Fields” section of your protocol. Each data field should be listed as a column name in your Excel file. The name of your data collection tool should be the same name listed in your protocol and/or Waiver of Authorization template. (See Appendix G for Data Collection Tool)

All information utilized and listed in your required IRB templates must EXACTLY match the information in the protocol. Failure to do so will result in multiple clarification requests from the IRB and, in turn, significant delays in IRB approval of your research project.

## Research Collaboration

Establishing relationships with allied colleagues can facilitate the design and completion of an impactful research project. Research collaborations allow the investigator to engage with interdisciplinary science, learn innovative approaches to problem solving, and access expertise beyond that available in the Department of Surgery. A clinical surgeon has the important advantage of insight and a keen understanding of a specific disease process and problem. However, it is frequently necessary to rely on expert assistance from others to design the project, complete data mining, or analyze the results. Examples of such collaborations include associations with basic scientists for molecular or translational studies, physicians from other specialties (e.g. critical care, medicine, psychiatry) or collaborators that have expertise in biomedical engineering, computer data analytics, or biostatistics. The faculty mentor should take the leadership role in establishing collaborations needed for a specific research project. The research team can also provide advice and assistance in identifying the resources available within LSU Health Science Center or associated institutions. If it is anticipated that the expertise of others will be required for a specific research project, it is strongly recommended that you begin work early on establishing the necessary collaborations. To obtain “buy-in” and the necessary level of commitment from collaborators, it is appropriate to offer shared authorship for contributions that support this recognition. The faculty mentor and mentee also represent a collaboration, and shared or complementary skills may be potentiated by this pairing.

Along with the development and implementation of a structured Research Program for General Surgery residents, there are plans to establish an annual Department of Surgery Research Symposium to showcase the research work that is ongoing, and also provide a forum for multidisciplinary interaction. We will solicit judges from within and outside the Department, and the symposium will involve awards to recognize the best presentations and projects.

## Obtaining Biostatistical Support

A basic knowledge of statistics is a prerequisite to conducting scientific research. This basic familiarity includes understanding the different study design types (e.g. case-control, cohort, randomized controlled trial), the strengths and limitations of each type of study design, power of the study, and sources of bias. Importantly, the trainee will need to understand the basic statistical tests used to determine significance, and when each test is used. There are multiple resources available online or in print that do a good job of explaining basic statistics (such as “Statistics for Dummies” and similar summaries). In addition, a SCORE lecture presents some information that is especially pertinent to interpreting or designing clinical studies (Biostatistics and Evaluation of Evidence). Finally, the Research Program is incorporating some didactic modules focusing on the information needed to address a research problem or establish the appropriate collaboration to assist with the analysis. Importantly, a recent survey monkey given the residents identified availability of adequate biostatistical support as a critical need. The Research Team understands these limitations and is working diligently to close this gap.



## Venues to Present Scholarly Work

There are many local, regional, and national meetings that are appropriate for submissions by surgical residents. The faculty mentor and Research Team will provide guidance in selecting the appropriate venue to present the project. A schedule of deadlines for submission to the major surgical meetings will be provided to the residents. Throughout the year, there are research symposiums sponsored by the Medical School that feature work by junior investigators. A poster or short oral presentation may be appropriate for presentation of succinct studies, or preliminary results for studies in progress. However, it should be emphasized that a brief poster or oral presentation should not be the goal for completion of the research project, rather an intermediate milestone along the way. We are encouraging surgical residents to complete projects that will result in podium presentations at regional or national meetings, and ideally, a submission for a peer-reviewed original scientific publication. This achievement is not only a critical element of the surgical education training experience, but also an important competitive advantage when applying for specialty fellowship training.

A regional meeting that is very well suited for resident-initiated research studies and presentations is the Louisiana Chapter of the American College of Surgeons, which meets on an annual basis in New Orleans in January. The Surgical Forum is a research platform at national Clinical Congress of the American College of Surgeons that is often represented largely by resident presentations, and is divided into specialty areas such as Endocrine/Oncology, Cardiovascular, Trauma/Critical Care, GI, etc. Studies with a more basic science or translational basis are particularly well suited for this forum. The Association for Academic Surgery and Society of University Surgeons support submissions by developing surgical scientists, and there are multiple regional meetings that tend to accept high quality and current clinical studies, such as the Central Surgical Association, the Southeastern Surgical Association, The Western Surgical Association, the Southwest Surgical Congress, and the Southern Surgical Association. The suitability of these individual meetings will be driven in part by memberships and connections associated with your Faculty Mentor.

## LSU Health Shreveport Annual Poster Presentations

The 6<sup>th</sup> Annual Regional Poster Presentation hosted by LSU Health Shreveport is an event that the Department of Surgery participates in annually. This event allows our department to showcase the hard work and commitment that our residents display throughout the year for their selected research project endeavors. The event is hosted in May of each year and offers a cash prize for 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> place. Surgery resident research projects are nominated by the Department Chair, Research Committee, and Research Management Team to attend and represent the Department of Surgery's research efforts. Information regarding the Annual Regional Poster Presentation will be forwarded to all residents and faculty upon receipt of event information from the GME office. Please see the abstract template that must be utilized for your presentation (Appendix I).



## Selecting Journal to Publish Your Research Paper

The premier journals for Surgeons and surgical research are the Journal of the American College of Surgeons (JACS), the Annals of Surgery, Surgery, The American Journal of Surgery, and specialty Journals such as Annals of Surgical Oncology Journal of Thoracic and Cardiovascular Surgery, Annals of Thoracic Surgery, Journal of Trauma and Acute Care Surgery, etc. Presentations at national meetings are submitted to a designated Journal for the meeting. The impact factor is a measure of the frequency with which the average article in a journal has been cited in a particular year. It is used to measure the importance or rank of a journal by calculating the times its articles are cited. For example, the IF of JACS for 2018 was 4.45, as compared with an IF of 20.57 for Science, and 2.12 for the American Journal of Surgery. Your faculty mentor and the Research Team will provide guidance for the most appropriate journal for you to submit your work to.

## Poster Templates and Printing

Upon completion of your poster template for research presentations, you will need to send a request to Ginny Hammock, Academic Coordinator, with your poster template attached. You will need to include a Powerpoint and PDF version. Please note that your posters are not reviewed prior to printing so please be sure that all templates are free from error. Once departmental approval has been granted, you will be notified via email. The poster template that you will need to utilize is available through LSU Health Shreveport's Medical Communication's department and can be accessed at the link below:

<https://inside.lsuhs.edu/departments/communications-public-affairs/medical-communications-medcom/templates-for-poster-design>

## Software and Data Management Tools

### SPSS – Statistical Analysis and Data Management Software

LSU Health Shreveport offers SPSS (IBM Statistical Software). The license was expanded in 2020 to include ALL machines (laptops or regular computers) LSUHS owned or PERSONAL! In order to obtain the codes needed, individuals will need to submit a request to <https://inside.lsuhs.edu/departments/information-technology/software/scientific-mathematical-software> IBM requires verification of an LSUHS account via your LSU email in order to verify affiliation prior to software license codes being distributed. The request to the link above should include your name, email, and your request for access to SPSS software. This should be done several days in advance. This process only takes a few minutes.

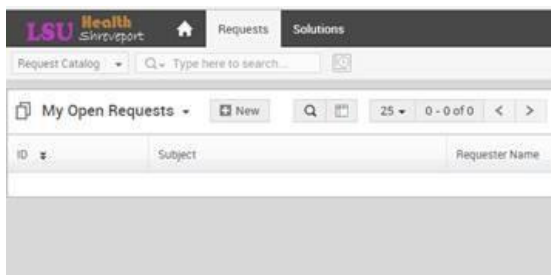
**As with any software license codes, sharing them with non-affiliated LSUHS (those without an LSUHS email) will result in access to the software being terminated.**

1. Navigate to <http://shv-ms-mesd.lsuhs-scshv.org:8080/WOListView.do>
2. Enter your LSUHSC-Shreveport user id and password (first part of your email address and email password)

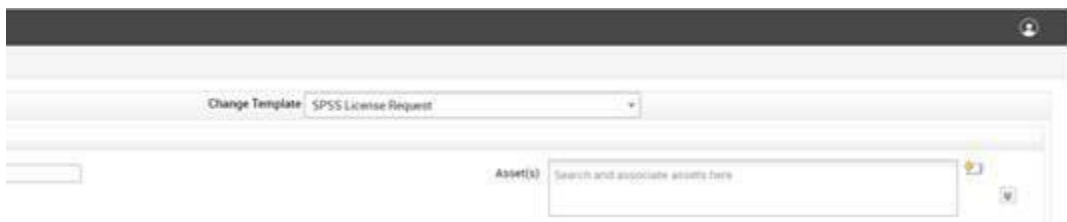
3. Select LSUMC-MASTER for the Log on to



4. Click **New**



5. Select the **SPSS License Request** from the **Change Template** dropdown



6. Fill in the requested information.

New Issue Change Template SPSS License Request

Requester Details

Name:

Asset(s)

1 Building:

2 Room #:

Serial #:

3 Service Category:

4 Affiliation:

5 Installation Type:

6 On Campus:

Subject:

Description

**B** **I** **U** **Text** **Link** **Image** **Table** **Code** **Quote** **Indent** **Outdent** **Undo** **Redo** **Print** **Fullscreen**

Please send me the license code for SPSS.

Site:

7

7. Click **Add Request** at the bottom of the page

Once your request has been processed you will receive an email containing the installation instructions and a product key to activate the software within 2-3 business days.

## Medical Student Participation in the Department of Surgery Research Program

The Department of Surgery at LSUH Shreveport recognizes that research experience is required for medical students to be competitive applicants across numerous specialties. In addition, research training in medical programs is essential to a medical student's professional development and establishment of a professional career pathway. Most importantly, research activity promotes innovative and improved outcomes, with the final common goal of improving the health of the patients and communities they serve. Research experience greatly benefits residents and medical students alike, by encouraging critical thinking through understanding of the scientific method. This process requires continuous receptive thinking, reflecting, analyzing, and the ability to deduce the potential causes for observations made. Experience with manuscript preparation also requires acquisition of good writing skills, which are required to prepare and submit quality research projects for publication. Because research achievements are rarely made in isolation, the Department of Surgery at LSUH Shreveport supports and encourages medical student engagement in discovery and learning, through active participation in the Department's research endeavors.

To ensure excellent research experiences that promote quality learning opportunity, the Department of Surgery at LSUH Shreveport has implemented the following processes and guidelines required to implement medical student participation in research projects overseen and administratively approved by LSUH Shreveport Department of Surgery. The goals of the Residency Research Program's inclusion of medical students are to:

- Provide surgical residents with a learning opportunity to teach, mentor, and engage undergraduate students in research activity. These skills will possibly incentive more residents to pursue academic teaching career
- Provide medical students with a learning experience surrounding the conduct of research.
- Optimize the chances for a productive research experience through appropriate assignment of research project tasks.
- Ensure consistent and quality participatory efforts by the medical student throughout the life of the research project

## Approval Process and Guidelines for Medical Student Participation in Research

It is the responsibility of faculty mentor and resident to provide guidance as well as intellectual and material support for research projects that involve medical students. Medical students should not be utilized to complete research project tasks that deliver non valuable research experiences or require development of new methodologies. Research projects involving medical students should be thoroughly discussed by the faculty mentor, resident, and student so that they agree upon the project goals, a realistic timetable, and division of responsibilities, all of which should be described in the **Medical Student Research Request** (see Appendix L) for involving a medical student on research activity. Considerations such as clearance of the project by the Institutional Review Board (IRB) are the responsibility of the faculty mentor and resident, however, student participation will provide a valuable learning experience. Involving medical students in such processes is appropriate. However, medical students should not be assigned tasks independently that involve necessary documentation required for IRB approval.

The Department of Surgery's Research Management Team and Research Committee have established the following process and guidelines for approval/continued approval of Medical

Student participation on any and all research projects associated and/or managed by LSUHS Department of Surgery.

- PGY 2 -5 may collaborate and conduct research with medical students who have completed all training requirements needed for the conduction of research. Residents are not permitted to involve and/or oversee medical students on any research projects/endeavors conducted during the PGY 1 year.
- Residents wishing to involve medical students on research projects must submit a request via email to the research management team. All requests will be reviewed by the research committee prior to determination and approval. Medical students who have not completed CITI training prior to email requests for research involvement will not be reviewed and/or denied. The **Medical student Research Request Form** (appendix L) must be completed in its entirety. Detailed information outlining project goals, task assignments, and timeline for completion must be provided to avoid denial by the research committee. This information will assist in appropriate assignment of research tasks to the medical student.
- Requests for inclusion of more than one medical student on an annual research project will be considered if the volume of project data and amount of time for project completion warrants additional study team members.
- Upon approval by the research committee, incorporation of routine checks for understanding are required throughout each phase of the research project. Meetings with study team members that include the medical students must occur at minimum once per month and must include meeting minutes that include objectives, plan, and descriptive summary of action items and to whom each action item is assigned.
- Medical students must submit a **Research Progress Note** (see Appendix K) monthly for committee review to ensure a quality learning experience. Please see Research Progress Note below. Failure to do so will result in removal of the medical student from the study team and removal of EHR access.

Prior to assigning medical students to a research project, the Medical Student Research guidelines, discussed here, must be reviewed and acknowledged (signed) by all medical students wishing to participate in research within the Department of Surgery (see Appendix M – **Medical Student Research Participation Guidelines and Process Receipt and Acknowledgement**). Since the Department of Surgery is responsible for all research administratively approved within our department, we are also responsible for all study team members participating within those projects and ALL research activities assigned to study team members. This includes the medical student, medical student access to EPIC O2, and medical student activities associated with data extraction from patient medical records for research purposes. It is imperative that all faculty, residents, and medical students review and completely understand the Medical Student Research guidelines. Medical students who fail to follow the guidelines set forth by the Department of Surgery for medical student research participation will result in immediate termination of research activity and IRB removal from the study team.

Prior to being considered for Research Committee review, all medical students wishing to participate in research within the Department of Surgery must have completed the following requirements:

- ALL CITI training requirements
- Medical Student Research Guidelines Receipt and Acknowledgment
- Submission of "Research Area of Interest" to [wchris@lsuhsc.edu](mailto:wchris@lsuhsc.edu)

Medical Students who have completed all requirements will be given priority for research project requests.

## Website

All information contained in this handbook is available on the surgery website <https://inside.lsuhs.edu/departments/surgery/research>.

The research website will allow our department to showcase the work and commitment by our residents and faculty in research, provide up-to-date information on research news and events, provide information regarding research collaboration opportunities, and consistently provide up-to-date information regarding resources available to our residents and faculty.

## Research Misconduct

**Principal investigators (PI)** have the primary responsibility for the design, implementation and management of the research projects they direct. They are responsible for ensuring that standards of professional and ethical conduct are maintained throughout all phases of their projects. In addition, they are responsible for the sound management of their resources. It cannot be overemphasized that there are substantial penalties at the individual and institutional level for failure to maintain strict compliance with all regulatory requirements for human subject research. The resources listed below provide additional information regarding regulatory requirements and penalties.

LSU Health Shreveport has primary responsibility for prevention, detection and investigation of research misconduct. This is accomplished through the diligence of **all administrative officials**. The funding agencies require our institution to actively ensure the integrity of research, the protection of the rights of research subjects and the public, and the observance of legal requirements related to research funding.

Examples of research misconduct are:

- Fabrication, falsification, plagiarism, distortion, or other serious deviation from accepted practices in proposing, carrying out and reporting research;
- Misappropriation of the work of others;
- Failure to comply with requirements for the protection of human or animal subjects or the public;

- Misappropriation of the Institution's and/or sponsors' property or resources;
- Intentional breach of law, Institutional rules or sponsors' regulations; and
- Failure to follow financial disclosure regulations as required under LSU Health Shreveport's Conflict of Interest policies.

LSU Health Shreveport may invoke academic, staff and/or student disciplinary procedures when allegations of misconduct in research arise. Federal or other sponsors may also initiate investigatory actions following allegations of misconduct. Confirmed research misconduct can result in the loss of federal funding for the PI and the Institution. Serious allegations may lead to criminal or civil suits which, if substantiated, may lead to the imposition of criminal and/or civil penalties. Suspected research misconduct should be reported to the Research Integrity Officer.

**John Maloy, J.D.**

Research Integrity Officer

Assistant Vice Chancellor for Research Management

LSU Health Sciences Center – Shreveport

1501 Kings Highway

Room F1-29B

Shreveport, LA. 71130

Office: 318-675.3464

Fax: 318-675-4144

Email: John Maloy, Assistant Vice Chancellor for Research Management

Information regarding policy and procedure as well as, research standards and regulations can be found by accessing the links below.

**LSU Health Shreveport Policy and Procedure for Allegations of Research Fraud**

<https://inside.lsuhs.edu/Departments/ResearchAdministration/Documents/Research%20Integrity/Policies%20and%20Procedures%20for%20Dealing%20with%20Alleged%20Research%20Misconduct.pdf>

**LSU Health Shreveport Policy and Procedure/Research Standards and Regulations**

<https://inside.lsuhs.edu/Departments/ResearchAdministration/Pages/default.aspx?tab=Pages&active=12&title=Responsible%20Conduct%20in%20Research>

Other research links – Research Standards and Regulation:

**"The Common Rule" (45 CFR 46)** - Code of Federal Regulations

[https://www.ecfr.gov/cgi-bin/text-](https://www.ecfr.gov/cgi-bin/text-idx?SID=8580b6878945c64fb3f4721592180170&mc=true&tpl=/ecfrbrowse/Title45/45cfr46_main_02.tpl)

[idx?SID=8580b6878945c64fb3f4721592180170&mc=true&tpl=/ecfrbrowse/Title45/45cfr46\\_main\\_02.tpl](https://www.ecfr.gov/cgi-bin/text-idx?SID=8580b6878945c64fb3f4721592180170&mc=true&tpl=/ecfrbrowse/Title45/45cfr46_main_02.tpl)

**21 CFR 50 and 21 CFR 56**

[https://www.ecfr.gov/cgi-bin/text-](https://www.ecfr.gov/cgi-bin/text-idx?SID=8580b6878945c64fb3f4721592180170&mc=true&tpl=/ecfrbrowse/Title21/21cfr50_main_02.tpl)

[idx?SID=8580b6878945c64fb3f4721592180170&mc=true&tpl=/ecfrbrowse/Title21/21cfr50\\_main\\_02.tpl](https://www.ecfr.gov/cgi-bin/text-idx?SID=8580b6878945c64fb3f4721592180170&mc=true&tpl=/ecfrbrowse/Title21/21cfr50_main_02.tpl)

**21 CFR 312**

[https://www.ecfr.gov/cgi-bin/text-](https://www.ecfr.gov/cgi-bin/text-idx?SID=8580b6878945c64fb3f4721592180170&mc=true&tpl=/ecfrbrowse/Title21/21cfr312_main_02.tpl)

[idx?SID=8580b6878945c64fb3f4721592180170&mc=true&tpl=/ecfrbrowse/Title21/21cfr312\\_main\\_02.tpl](https://www.ecfr.gov/cgi-bin/text-idx?SID=8580b6878945c64fb3f4721592180170&mc=true&tpl=/ecfrbrowse/Title21/21cfr312_main_02.tpl)

**21 CFR 812**

[https://www.ecfr.gov/cgi-bin/text-](https://www.ecfr.gov/cgi-bin/text-idx?SID=8580b6878945c64fb3f4721592180170&mc=true&tpl=/ecfrbrowse/Title21/21cfr812_main_02.tpl)

[idx?SID=8580b6878945c64fb3f4721592180170&mc=true&tpl=/ecfrbrowse/Title21/21cfr812\\_main\\_02.tpl](https://www.ecfr.gov/cgi-bin/text-idx?SID=8580b6878945c64fb3f4721592180170&mc=true&tpl=/ecfrbrowse/Title21/21cfr812_main_02.tpl)

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

**Declaration of Helsinki** - Recommendations guiding physicians in biomedical research involving human subject <http://www.cirp.org/library/ethics/helsinki/>



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LSUHSC – SHREVEPORT  
DEPARTMENT OF SURGERY  
RESIDENCY RESEARCH PROGRAM

**PGY1 Resident Research Mid-Point Evaluation**

Resident Name \_\_\_\_\_ Date of Evaluation: \_\_\_\_\_

Faculty Mentor: \_\_\_\_\_

Assigned Tasks/Deliverables	Due Date	Date of Completion
<b>Completion of Research Training Modules</b>		
Research Training: Researching the Literature	08/10/2020	
Research Training: Study Design	09/14/2020	
Research Training: Protocol Writing	10/05/2020	
Research Training: Protocol Feedback	11/23/2020	
<b>Deliverables</b>		
Completion of CITI Training	06/28/2020	
Creation of Shields Account/COI Disclosure	07/02/2020	
Identification of Research Topic and Faculty Mentor	08/24/2020	
Protocol Due: First Draft	11/09/2020	
Protocol Revisions and Faculty Mentorship Evals Due	12/14/2020	
Mandatory Meeting with Research Management Team Mid-Point Evaluation	12/17/2020	
<b>Comments:</b>		
<b>Action Plan:</b>		
<b>Resident Signature:</b>	<b>Date:</b>	
<b>Department Chair Signature:</b>	<b>Date:</b>	



LSUHSC – SHREVEPORT  
DEPARTMENT OF SURGERY  
RESIDENCY RESEARCH PROGRAM

**PGY1 Resident Research Final Evaluation**

Resident Name \_\_\_\_\_ Date of Evaluation: \_\_\_\_\_

Faculty Mentor: \_\_\_\_\_

Assigned Tasks/Deliverables	Due Date	Date of Completion
<b>Completion of Research Training Modules</b>		
Research Training: Completion of Required IRB Documents for Study Submission; Data Collection Tool	01/11/2021	
Research Training: Creating the Study in Shields	02/15/2021	
Research Training: Collecting the Data; Coding Variables	03/15/2021	
Research Training: Data Mining – Part I	04/13/2021	
Research Training: Data Mining – Part II	05/17/2021	
<b>Deliverables</b>		
Finalize Project Details and IRB Documents with Faculty Mentor/ IRB Documents Due	02/08/2021	
IRB Documents - Final Revisions	02/15/2021	
Study Creation in Shields/Data Request	02/22/2021	
Faculty Mentorship Evaluations Due	06/14/2021	
Mandatory Meeting with Research Management Team Final Evaluation	06/21/2021	
<b>Comments:</b>		
<b>Action Plan:</b>		
<b>Resident Signature:</b>	<b>Date:</b>	
<b>Department Chair Signature:</b>	<b>Date:</b>	



LSUHSC – SHREVEPORT  
DEPARTMENT OF SURGERY  
RESIDENCY RESEARCH PROGRAM

**PGY2-4 Resident Research Mid-Point Evaluation**

Resident Name \_\_\_\_\_ Date of Evaluation: See PGY Calendar

Faculty Mentor: \_\_\_\_\_

Assigned Tasks/Deliverables	Due Date	Date of Completion
<b>Completion of Research Project Deliverables</b>		
Identify Faculty Mentor Research Topic Submission via Letter of Intent	08/24/2020	
Mandatory Meeting with Research Management Team	See calendar	
Protocol due (1st draft)	See calendar	
Final Protocol Revisions Due	See calendar	
All other IRB Documents Needed for Study Submission	See calendar	
Data Acquisition Requests and Data Collection Tools Due	See calendar	
Mandatory Meeting with Research Management Team	See calendar	
Faculty Mentorship Evaluations Due	12/14/2020	
Mandatory Meeting with Research Management Team Mid-Point Evaluation	See calendar	
<b>Comments:</b>          		
<b>Action Plan:</b>          		
<b>Resident Signature:</b>		<b>Date:</b>
<b>Department Chair Signature:</b>		<b>Date:</b>



LSUHSC – SHREVEPORT  
DEPARTMENT OF SURGERY  
RESIDENCY RESEARCH PROGRAM

**PGY2-4 Resident Research Final Evaluation**

Resident Name \_\_\_\_\_ Date of Evaluation: See PGY Calendar

Faculty Mentor: \_\_\_\_\_

Assigned Tasks/Deliverables	Due Date	Date of Completion
<b>Completion of Research Project Deliverables</b>		
Identify Faculty Mentor	08/24/2020	
Research topic submission via Letter of Intent		
Mandatory Meeting with Research Management Team	See calendar	
Protocol due (1st draft)	See calendar	
Final Protocol Revisions Due	See calendar	
All other IRB Documents Needed for Study Submission		
Mandatory Meeting with Research Management Team	See calendar	
Data Acquisition Requests and Data Collection Tools Due		
Faculty Mentorship Evaluations Due	12/14/2020	
Mandatory Meeting with Research Management Team	See calendar	
Mid-Point Evaluation		
Finalize Project with Faculty Mentor	03/04/2021	
Abstract Due to Research Management Team	03/16/2021	
Mandatory Meeting with Research Management Team	See calendar	
Mock Presentations	See calendar	
Mock Presentations	See calendar	
Faculty Mentorship Evaluations Due	06/14/2021	
Final Evaluation Meeting with Research Management Team	See calendar	
<b>Comments:</b>		
<b>Action Plan:</b>		
<b>Resident Signature:</b>		<b>Date:</b>
<b>Department Chair Signature:</b>		<b>Date:</b>



**LSUHSC – SHREVEPORT  
DEPARTMENT OF SURGERY  
RESIDENCY RESEARCH  
PROGRAM**

**FACULTY MENTOR  
EVALUATION**

Date of Evaluation \_\_\_\_\_

Research Project Title \_\_\_\_\_ IRB# \_\_\_\_\_

Name of Mentor \_\_\_\_\_

Circle One: 1=Strongly Disagree    2=Disagree    3=Agree    4=Agree strongly

Topic	Rating	Comments
<b>Intellectual Growth and Development</b>		
Encourages my inventiveness including identification of new research topics and discovery of new methodologies	1    2    3    4	
Helps me develop my capacity for theoretical reasoning and data interpretation	1    2    3    4	
Helps me to be critical and objective concerning my own results and ideas	1    2    3    4	
Helps me become increasingly independent in identifying research questions and conducting and publishing my research	1    2    3    4	
Provides constructive feedback on my experimental designs	1    2    3    4	
Provides thoughtful advice on my research progress and results	1    2    3    4	
<b>Academic Guidance</b>		
Provides advice on my research work and project goals	1    2    3    4	

Ensures that I am firmly grounded in rules regarding ethical behavior and scientific responsibility	1    2    3    4	
Leads and attends regular research meetings throughout each phase of research project as listed on PGY schedule.	1    2    3    4	
Consistently and readily available to discuss research project concerns.	1    2    3    4	
Provides constructive feedback on my research mock presentation	1    2    3    4	
Encourages me to present my work at scientific meetings	1    2    3    4	
Provides support and access to resources needed for data analysis and interpretation	1    2    3    4	
Provides constructive feedback on my research mock presentation	1    2    3    4	
Encourages me to present my work at scientific meetings	1    2    3    4	
Provides support and access to resources needed for data analysis and interpretation	1    2    3    4	
<b>Personal Communication</b>		
Listens carefully to my concerns	1    2    3    4	
Routinely monitors my progress and reviews proposed timelines and milestones with me	1    2    3    4	
Provides timely feedback	1    2    3    4	
Is appropriately accessible to me	1    2    3    4	
<b>Serves as Role Model</b>		

Conveys high ethical standards and concern for research subjects	1   2   3   4	
Illustrates active teamwork and collaboration	1   2   3   4	
Illustrates good mentoring skills	1   2   3   4	
Illustrates good work habits	1   2   3   4	
Illustrates good work/life balance	1   2   3   4	
Would recommend this mentor to future trainees	1   2   3   4	





LSUHSC – SHREVEPORT  
DEPARTMENT OF SURGERY  
RESIDENCY RESEARCH PROGRAM

**Resident Research Data Report Request**

Date of Request \_\_\_\_\_ IRB# \_\_\_\_\_

Study Title \_\_\_\_\_

Resident Name \_\_\_\_\_ Faculty Mentor \_\_\_\_\_

Date Range (as listed in the protocol) \_\_\_\_\_

Inclusion Criteria (as listed in protocol)

--

Exclusion Criteria (as listed in protocol)

--

Data Collection Fields (as listed in the protocol)

--

\_\_\_\_\_  
Date Received

\_\_\_\_\_  
Research Management Team Signature

Excel ribbon interface for the "Data Collection Tool - Excel" workbook. The ribbon is set to the "HOME" tab, showing options for Font, Alignment, Number, Styles, and Cells. The active cell is P1.

The spreadsheet contains the following data:

	A	B	C	D	E	F	G	H	I	J	K
1		Type of Insuran	Length of Stay	Standard length of stay	Co-morbidities	Behavioral Health Issues	Discharge equipment	Treatment	City	Parish	Zip Code
2		Patient 1									
3		Patient 2									
4		Patient 3									
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											
15											
16											
17											
18											
19											
20											
21											
22											

The status bar at the bottom indicates "Data Collection Tool" and "READY".



LSUHSC – SHREVEPORT  
DEPARTMENT OF SURGERY  
RESIDENCY RESEARCH PROGRAM

**Resident Research Letter of Intent**

RESIDENT NAME \_\_\_\_\_ FACULTY MENTOR \_\_\_\_\_

DATE \_\_\_\_\_ STUDY TITLE \_\_\_\_\_

**BRIEF DESCRIPTION OF PROJECT**

OBJECTIVES

METHODOLOGY

SIGNIFICANCE

APPENDIX I

**TITLE (14 PT FONT)**  
Primary Author  
Other Contributing Participants

*Abstract should include the following elements in 12 pt size font*

Introduction:

Objectives/Purpose:

Methodology:

Results:

References:



LSU HEALTH – SHREVEPORT  
DEPARTMENT OF SURGERY  
RESIDENCY RESEARCH PROGRAM

**Resident Research Handbook Receipt and Acknowledgement**

The Resident Research Handbook describes important information about the Department of Surgery's Residency Research Program. I understand that I should consult the Research Management Team regarding any questions not answered in this handbook.

Since the information, policies, and research training curriculum described here are necessarily subject to change, I acknowledge that revisions to the handbook may occur. All such changes will be communicated through official notices, and I understand that the revised information will supersede, modify, or eliminate existing policies. All revisions to policies described in this handbook must be reviewed and adopted by the Department of Surgery Chairman.

I acknowledge that I have received this handbook and am responsible for all information, policies, and completion of required research training curriculum and deadlines described. I understand that it is my responsibility to read and comply with policies contained in this handbook and any revisions made to it.

---

Resident/Faculty Signature

Date

---

Resident/Faculty Name

APPENDIX K



LSU HEALTH – SHREVEPORT  
DEPARTMENT OF SURGERY  
RESIDENCY RESEARCH PROGRAM

MEDICAL STUDENT RESEARCH PROGRESS NOTE

MEDICAL STUDENT NAME \_\_\_\_\_ RESIDENT NAME \_\_\_\_\_

FACULTY MENTOR \_\_\_\_\_ RESEARCH PROJECT TITLE \_\_\_\_\_

DATE \_\_\_\_\_

IDENTIFY ACTION ITEMS ASSIGNED TO YOU THIS MONTH.

PROVIDE SUMMARY OF WHAT YOU LEARNED DURING THIS PHASE OF THE RESEARCH PROJECT.

WERE THERE ANY OBSTACLES THAT WERE ENCOUNTERED CREATING BARRIERS TO RESEARCH PROGRESSION?

HOW MANY TIMES WERE YOU ABLE TO MEET WITH THE STUDY TEAM THIS MONTH? WERE THE MEETING SESSIONS PRODUCTIVE? EXPLAIN WHY OR WHY NOT.

DID YOU UTILIZE PATIENT MEDICAL RECORDS (EHR) FOR RESEARCH PURPOSES THIS MONTH? IF SO, DESCRIBE REASONS FOR USE.

PLEASE LIST ACTION ITEMS ASSIGNED TO YOU FOR THE UPCOMING MONTH.

MEDICAL STUDENT SIGNATURE

DATE

RESIDENT SIGNATURE

DATE

FACULTY MENTOR SIGNATURE

DATE

APPENDIX L



LSU HEALTH – SHREVEPORT  
DEPARTMENT OF SURGERY  
RESIDENCY RESEARCH PROGRAM

MEDICAL STUDENT RESEARCH REQUEST  
(TO BE COMPLETED BY THE RESIDENT)

MEDICAL STUDENT NAME \_\_\_\_\_ RESIDENT NAME \_\_\_\_\_

FACULTY MENTOR \_\_\_\_\_ RESEARCH PROJECT TITLE \_\_\_\_\_

DATE \_\_\_\_\_

RESEARCH PROJECT GOALS.

--

TIMETABLE FOR PROJECT COMPLETION

--

PROJECTED NUMBER OF RESEARCH SUBJECTS AND/OR CHARTS TO BE REVIEWED.

--

ANTICIPATED SUMMARY OF TASKS TO BE ASSIGNED TO THE MEDICAL STUDENT

--

PROJECTED MEETING DATES, TIMES, AND LOCATION.

--



COMPLETION DATE OF CITI TRAINING FOR EACH MEDICAL STUDENT

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LSU HEALTH – SHREVEPORT  
DEPARTMENT OF SURGERY  
RESIDENCY RESEARCH PROGRAM

MEDICAL STUDENT RESEARCH PARTICIPATION GUIDELINES AND PROCESSES RECEIPT AND  
ACKNOWLEDGEMENT

MY SIGNATURE BELOW INDICATES THAT I HAVE READ AND UNDERSTAND THE GUIDELINES, REQUIRED PROCESSES, AND MEDICAL STUDENT/RESIDENT/FACULTY MENTOR ROLES ASSOCIATED WITH MEDICAL STUDENT PARTICIPATION IN RESEARCH CONDUCTED AND MANAGED BY THE DEPARTMENT OF SURGERY AT LSUH SHREVEPORT.

THE GUIDELINES AND PROCESS DESCRIBED ABOVE IS IMPORTANT INFORMATION ABOUT THE DEPARTMENT OF SURGERY'S RESIDENCY RESEARCH PROGRAM INVOLVING MEDICAL STUDENT PARTICIPATION. I UNDERSTAND THAT I SHOULD CONSULT THE RESEARCH MANAGEMENT TEAM REGARDING ANY QUESTIONS NOT ANSWERED IN THIS DOCUMENT.

SINCE THE INFORMATION, POLICIES, AND GUIDELINES DESCRIBED HERE ARE NECESSARILY SUBJECT TO CHANGE, I ACKNOWLEDGE THAT REVISIONS TO THE MEDICAL STUDENT RESEARCH PARTICIPATION GUIDELINES AND PROCESS MAY OCCUR. ALL SUCH CHANGES WILL BE COMMUNICATED THROUGH OFFICIAL NOTICES, AND I UNDERSTAND THAT THE REVISED INFORMATION WILL SUPERSEDE, MODIFY, OR ELIMINATE EXISTING POLICIES. ALL REVISIONS TO POLICIES DESCRIBED IN THIS HERE MUST BE REVIEWED AND ADOPTED BY THE DEPARTMENT OF SURGERY CHAIRMAN.

I ACKNOWLEDGE THAT I HAVE RECEIVED THESE GUIDELINES AND PROCESSES ASSOCIATED WITH THE DEPARTMENT OF SURGERY'S MEDICAL STUDENT PARTICIPATION IN RESEARCH AND AM RESPONSIBLE FOR ALL INFORMATION, POLICIES, AND COMPLETION OF REQUIRED RESEARCH DOCUMENTATION AND DEADLINES DESCRIBED. I UNDERSTAND THAT IT IS MY RESPONSIBILITY TO READ AND COMPLY WITH POLICIES CONTAINED IN THIS DOCUMENT AND ANY REVISIONS MADE TO IT.

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MEDICAL STUDENT SIGNATURE

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DATE

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RESIDENT SIGNATURE

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DATE

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FACULTY MENTOR SIGNATURE

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DATE