Research Standard Operating Procedure

LSUHSC-NO encourages faculty, staff, students, house officers, and other employees to participate in meaningful professional relationships with industry, government, and private entities. These relationships are established for mutually beneficial reasons and often produce knowledge and intellectual property that will help the community at large.

The Department of Orthopaedic Surgery supports both undergraduate and graduate medical students as primary participants in research. This requires software knowledge and skills in Kuali Research, including the Negotiation function for multi-site studies, Research Electronic Data Capture (REDCap) and Microsoft Teams.

Research Roles (https://www.lsuhsc.edu/administration/academic/ors/irb/docs/P&P5.03_%20Research%20Personnel_V12.09.21.pdf Principal Investigator (PI)

The PI is the faculty researcher. The primary role of the PI is to assure the quality of the study design. The PI also assists in obtaining access to appropriate databases and that data collection and analysis supports the research question. Ensures compliance with Chancellor's Memorandum #35 (CM-35) by all other Investigators and study team members participating in a Research Project, including any new Investigators or study team members who later join an ongoing Research Project. From NIH:

> Principal investigator (PI) refers to the person(s) in charge of a clinical trial or a scientific research grant. The principal investigator prepares and carries out the clinical trial protocol (plan for the study) or research paid for by the grant. The principal investigator also analyzes the data and reports the results of the trial or grant research.

Sub-Investigator

The sub-investigator is a faculty-level team member.

Student Researcher

Students may not serve as PIs on a human subjects research project. Their engagement in research must be supervised by an LSUHSC-NO faculty mentor who will function as the PI of the project. They may participate in any aspect of the research as deemed appropriate by the PI. Processes include performing a literature review and obtaining IRB approval via the Kuali system. Responsibilities are to manage all submission functions, renew the study if required and close the study. The student is encouraged to work in partnership with a resident.

Trainee Researcher

The trainee researcher is a fellow, resident, and others in training without a faculty appointment with the same restrictions and responsibilities as a Student Researcher. Processes include performing a literature review and obtaining IRB approval via the Kuali system. Responsibilities are to manage all submission functions, renew the study if required and close the study.

Data Manager

The data manager is the biostatistician. The primary role is to analyze research data in REDCap. The data manager also advises the sub-investigator and student researchers in all matters involving data collection and analysis.

Research Coordinator

Oversees and coordinates the daily activities of clinical research studies. He/She works closely with the clinical teams and investigators to ensure that all protocol required procedures and visits occur according to protocol specified guidelines. He/She typically manages participant enrollment including obtaining informed consent.

Kuali assistance is available via irboffice@lsuhsc.edu

Comprehensive literature reviews are required to determine knowledge gaps where they exist. New studies must demonstrate that the work is not redundant. Literature review assistance is provided by the research coordinator and Ische Library librarians.

While research is not a requirement of undergraduate medical education (e.g. not in the ACGME guidelines), a best practice is to become involved in research early in medical school to assure that you

a. have a published peer-reviewed article at the point you begin applying for a residency and
b. are able to speak confidently about it in an interview.

One way to assure authorship is to perform a significant amount of work either by initiating a study or joining one in progress. The following processes apply to all research efforts:

1. Become qualified to conduct research.
2. Gain access to medical records at the local partner hospital.
3. Participate in the IRB conversation.
4. Join a study.
5. Initiate a study.

1. Become qualified to conduct research

Participation in research requires certificates which demonstrate knowledge in research ethics, compliance, safety, etc. LSUHSC research training includes courses offered by the CITI Program and LSUHSC's Compliance and Training System (CATS).

CITI training

The Collaborative Institutional Training Initiative (CITI Program) is dedicated to serving the training needs of colleges and universities, healthcare institutions, technology and research organizations, and governmental agencies, as they foster integrity and professional advancement of their learners. Their focus areas include courses in ethics, research, meeting regulatory requirements, responsible conduct of research, research administration and other topics pertinent to the interests of member organizations, individual learners, and society.

Courses

a. Biomedical Research Basic -Initial & Refresher for Biomedical research

b. Good Clinical Practice - Initial & Refresher for NIH-funded clinical trials or FDA-regulated drug or device studies

Please review this module if you are using Data Use Agreements. The goal of the RecordsBased Research module (ID-5) is to assure that each person conducting scientific research based on records (e.g. retrospective chart reviews) should

- Understand specific risks to human subjects
- Ensure that the research plan specifies procedures that minimize the risks

OR

i. Social and Behavioral Research

AND

ii. One Good Clinical Practices (GCP) module

- GCP- Drug Development
- GCP- Device Development OR
- GCP- Social and Behavioral Research Best Practices for Clinical Research

LSUHSC Office of Compliance Programs (Institution-Required Training & Disclosure) https://www.lsuhsc.edu/administration/academic/ors/irb/training_lsuhsc.aspx

LSUHSC-NO, under the purview of the Office of Compliance Programs and the Office of Research, requires additional training for individuals involved in research. The Office of Research is responsible for confirming compliance with the training and disclosure requirements for all HSC investigators including those listed in the initial application and those added after study approval through an amendment request.

The required areas of training and disclosure relevant to the conduct of HSR are listed in the table below

- Annual COI disclosures
- Compliance and Training System ("CATS")
- Institutional Biosafety Committee (IBC) Oversight? HSR studies involving the manipulation of biological specimens or the use of biohazardous materials and/or recombinant or synthetic nucleic acids for research, require IBC approval.

You are responsible for being in compliance with LSUHSC's policy on **Protecting Patient Health Information (PHI) for Clinical Staff and Students: https://www.lsuhsc.edu/administration/ocp/docs/HIPA/HIPAPP/HIPA_HIPAPP.html 1. CATS training https://www.lsuhsc.edu/admin/it/email/docs/MM-2023-01-06-SELF_ASSIGN_USER_GUIDE_CATS_(Final).pdf**

My Learning – Bridge (bridgeapp.com): Access your training modules
LSUHSC-NO's HIPAA Research Authorization Policy
Account access
Send request to: nocompliance@lsuhsc.edu
Subject line: CATS Module Request Email
message:

- "Good afternoon, I am requesting modules pertaining to research compliance be added to my CATS account.
- Name:
- Username:
- Student Requested Training: Conflict of Interest in Research Training; HIPAA Privacy – Research
- Thank you!"

Unaffiliated Persons

Conflict of Interest in Research (COI)
Research relationships may create financial or non-financial interests that have the potential to create a bias in decisions. Chancellor's Memorandum #35 (CM-35) Updated May 3, 2023 - The COI policy seeks to maintain a reasonable balance between competing interests, gives LSUHSC-NO the ability to identify and manage financial and non-financial interests, and minimizes the reporting and other burdens on investigators. This policy meets the federal regulations governing the disclosure and reporting of financial conflicts of interest (FCOI).

This Policy applies to and requires compliance by all LSUHSC-NO administrators, faculty members (including part-time, gratis, and visiting faculty), students (including post-doctoral fellows), house officers, staff and other employees, as well as immediate family members of these persons, who propose, conduct, report, or approve of the results of research, regardless of funding source.

COI in Research training is completed in CATS and is required every four years and immediately when any of the following circumstances apply: (i) LSUHSC-NO revises this Policy to substantially change the requirements of Investigators; or (ii) an Investigator is new to LSUHSC-NO; or (iii) an Investigator is in noncompliance with this Policy or with a COI management plan.

An annual COI Disclosure is required to participate in research activities. By submitting it, the individual automatically becomes registered as a Kuali user. Instructions for submitting the annual COI Disclosure in Kuali are found at the COI in Research website.

Kuali Access
Bookmark the **Kuali link**

LSUHSC-NO IRB ListServ
Join the LSUHSC-NO IRB ListServ to receive new information concerning the IRB process and updates.

2. Gain access to medical records

You can only have access to electronic medical records systems (e.g. EPIC) at the hospitals in which we conduct research if you are associated with an IRB approved protocol. Each area hospital has their own EMR version.

UMC EPIC

Send request to: Ms. Melanie Brown (mbro15@lsuhsc.edu)

Subject line: UMC EPIC Access Request Email message:

"I am a L1 or L2 who is working on a research project *insert Name of project, IRB, & the associated Faculty Member*. I need access to the EPIC EMR for UMC. Thanks, *your name*" She will send you the UMC credentialing application which requires documentation listed below. After this, UMC will process your application and notify you when you have been approved.

Notes Pertaining to UMC's Credentialing Application

- **Immunization Record**- Mrs. [redacted] will submit a letter of good academic standing to fulfill this requirement. However, you must submit a copy of your immunization record to Mrs. [redacted]
- **Background and drug screening documents:** Mrs. Hebert will submit a letter of good academic standing to fulfill this requirement.
- **Annual TB results -** Must submit a copy with your application.
- **Annual Flu vaccination**- Must submit a copy with your application. Per UMC's policy, UMC cannot allow affiliates onto its campus once their flu shots have expired.
- **Proof of Covid-19 vaccination-** Must submit a copy with your application.
- **BLS Cert**- Submit a copy if working directly with patients. If your study does not require you to work directly with patients, please indicate this on your application.
- **Job description:** Does not apply to students.
- **Curriculum vitae/resume':** The student **must** provide a copy. **Include your signature + date in the top right corner of the CV.**
- **IATA Training:** Not needed.
- **Professional License Verification:** Not needed.
- **Good Clinical Practice and Biomedical Researchers CITI training completion certificates are required.**
- **IRB approval letter or equivalent to show proof of participation in research (if the IRB is pending, please provide the IRB number, title, and the PI's name).**

***** Dates/expiration dates must be entered on the checklist.**

*****Incomplete applications will not be accepted. Therefore, please do not leave any sections blank.**

LSU HealthCare Network EPIC
Instructions are in the document, 'How to Conduct Research and Access EPIC for Research at LSU Heathcare Network v12.22.2022.'

CHNOLA
LSUHSC IRB is the lead IRB. For studies where the lead PI is affiliated with Tulane, Tulane IRB is the lead IRB.

Ochsner EPIC: THIS CAN ONLY OCCUR AFTER YOUR PROJECT HAS BEEN APPROVED BY THE OCHSNER IRB. Please email the MSK Chair-Elect for all required documents. The Ochsner Director of Clinical Research approves and sponsors access requests. Send an email with all required documents and the following information to Mrs. Connie Catha. (ccatha@ochsner.org <ccatha@ochsner.org>).

1. Legal name of each person requiring access (middle initial is optional)
2. External company name or affiliation: LSU Health Sciences Center
3. Job Title (LSUHSC School of Medicine Student)
4. Last 4 digits of SSN:
5. Start Date:
6. Termination Date if less than 6 months
    - Maximum length of 6 months if not provided, see below for more details regarding Attestations)
7. Ochsner Sponsor Name: Ansley Hammons
8. Previous AD ID (If applicable): NA
9. Other access needed:
    - Departmental File share (list full network path or user to emulate), AD Groups and/or Ochsner email (web version):

3. Participate in the IRB conversation

Join the LSUHSC-NO IRB ListServ so that the IRB staff can more effectively communicate new information concerning the IRB process and updates

- *You must be on campus or connected through Citrix*
- Go to http://www.listserv.lsuhsc.edu/scripts/wa.exe?INDEX
- Join IRB_UPDATES_AND_ANNOUNCEMENTS

4. Join a study

Email the MSK Chair-elect requesting a list of active studies which you could join.

- Once a study is found, email the resident or project leader and copy the MSK Chair, Chairelect, and Senior Advisor to the Chair to learn about the study
- Determine if you could make a significant contribution
- State that, in exchange for making a significant contribution, you would like to be an author. If approval is received, ask the project member to add you to the Kuali protocol in the role of Student Researcher with read-only access.

5. Initiate a study

When developing a study, it is required that you work with 2 other classmates. Suggested combinations are

1. 2 L1/2s
2. 1 L3/4
3. 1 Resident

This ensures a good distribution of the workload and provides the L1/2s with upper-level students and residents as a point of contact to help guide you through the research process. Of Note: If you don't know any L3/4s to add, contact the MSK Chair-Elect and they will help find someone. Ideally, a resident would not be added until the IRB is ready to submit in Kuali since most of the legwork is to be done by the students. If you know of a resident that would like to be added before this point, then go ahead and add them.

This Standardized Operating Procedure has been established for initiating research: a.

Select a topic

b. Conduct a literature review
c. Write an abstract
d. Complete a Research Project Process Form
e. Establish a REDCap project
f. Develop a procotol
g. Conduct study
h. Enter data in REDCap
i. Review the data analysis
j. Publish findings
k. Present findings

a. Select a topic

1. Browse topics in the Research Idea Database
2. Browse the topic in a health science database (PubMed) using the Clinical Queries feature (e.g. total knee arthroplasty pain management). Notice that the default search is Therapy and the search is Broad. You can select Clinical Prediction Guides, Diagnosis, Etiology or Prognosis-and limit to Narrow. Read some abstracts. Read the articles associated with interesting abstracts. Review the Discussion section. Many times, authors will state what needs further investigation.
3. Inform the Chair-elect of your topic choice.
4. Request a meeting a faculty member who shares an interest in the topic and will serve as the PI. Copy the MSK Chairman, Chair-elect, and Senior Advisor to the Chair.
    i. If the PI has knowledge of the topic, request an article which is especially important to the topic
    ii. If the PI does not have knowledge of the topic, bring a gap statement and abstract to facilitate productive communication.

iii. *FYI: just discussing the idea does not require you to complete the project.* b. Obtain a literature review

The literature review functions to show Dr. Dasa that you have an idea about what the project plan is and that you have researched the topic. Initial literature review before faculty meeting may be completed by students. Ensure that you have extensively searched the topic in which your project is on.

Following topic refinement by PI during initial meeting, further lit review may be required. Ms. Hicks is available for further literature review, as she has a Master's degree in information science.

c. Write an abstract
    1. Write a 300-word abstract using EXAMPLES given on the MSK Committee webpage.
    2. Use the citation manager to format the Reference Section of the literature review. Do Not Do the Reference Section Manually. Tell the citation manager the citation style you require and let it populate your Word document.

        Refworks

        The Ische Library provides RefWorks. Create an account. Export all relevant articles from a database (PubMed) to it. Use the Create a Bibliography function in Refworks to download the citations to a Word document.

        Zotero

        This is an open source citation manager with a chrome extension and desktop app available. When finding new citations, the chrome extension will automatically add the journal to your Zotero library (after clicking). You can use the Zotero tab plugin in Word to insert citations and a bibliography that automatically updates as well as sync your citations to an account.

d. Complete a Research Project Process Form located on the MSK Committee webpage 1. *Download the Research Project Process Form
    2. Review requirements.
    3. Request assistance from the Faculty member
    4. Place the abstract in the PROJECT ABSTRACT portion of the form
    5. Click the link at the top of the form which submits it to Dr. Leonardi for methodological review with medical writer Amy Bronstone and the Principal Investigator (PI)
e. Enter study in Research Electronic Data Capture (REDCap)

REDCap is a secure, HIPAA compliant, web-based application for building and managing online surveys and databases. Administered by Biostatistician Claudia Leonardi, PhD, LSUHSC-New Orleans School of Public Health Analytic Center, REDCap is used for research and quality/performance improvement by the entire LSUHSC community, including external affiliates. Data collection is customized for each project by the research team with guidance from the SPH Analytic Center REDCap System Administrators. Dr. Leonardi (cleon1@lsuhsc.edu) will put your name in the system. Then by searching "redcap" on the LSUHSC web page, you can access the webpage using your LSUHSC ID & password

f. Develop a procotol
    1. Use Protocol Builder and the retrospective study template found on the website
    2. Create a protocol in Kuali*
        i. The research personnel section includes the PI, Data Manager, Research Coordinator, Trainee Researcher (Resident) and/or Student Researcher. Each team member needs full access. ii. Cut and paste parts of the protocol into Kuali
        iii. Submit protocol for IRB consideration iv. Store the protocol in the study Teams channel
        v. Manage the protocol by renewing or amending as needed
    3. Multi-site studies involving data transfer require a contract between organizations called a Data Use Agreement. Benjamin C. "Ben" Davis, JD, Contract Analyst, Clinical Trials Office, manages this function.
    4. OCHSNER STUDY PROTOCOLS
        i. Following Kuali submission and LSU IRB approval, all Ochsner studies MUST be submitted to the Ochsner eIRB portal for approval of LSUHSC as the external IRB of record.
g. Conduct study.
    1. Once data is collected, submit to Dr. Leonardi for data analysis
h. Review the data analysis
i. Publish your findings
    1. Write a paper
        i. Create a structured abstract and build out each section
            1. Begin results and discussion section of manuscript based on data analysis
            2. Use the citation manager to create the reference section ii. Find a journal that will accept your paper. Consult the Where to Publish (Journal Metrics) box on the Open Access and Scholarly Communication libguide. A popular product is the Journal/Author Name Estimator (JANE) Journal / Author Name Estimator (biosemantics.org)
                1. A PDF of orthopedic journals that are ranked in order of impact factor to submit to, are listed on the orthopedic research website
        iii. The Authorship section on journal websites provides format specifications
    2. Submit to faculty for review
    3. Submit to department medical writer, Dr. Amy Browstone, for editing
    4. Submit final manuscript for publication
j. Close the protocol
    1. The study is considered closed when a paper has been accepted for publication. Close the protocol at that point.
k. Present your findings
    1. Submit abstract for meeting (podium/poster)
        i. If POSTER is accepted
            1. use poster template on department website
            2. The library provides very good instruction about poster design and prints posters for free. https://libguides.lsuhsc.edu/posterprinting

ii. If PODIUM is accepted
    1. Use dept PPT template on dept research website
    2. Travel

i. Information about travel policy found on main research website under: "Resident/Student Travel Policy" *ii.* Get approval before purchasing anything via email to Dr. Dasa and faculty on study (provide proposed cost in email)

iii. Contact Edwina Jackson (ejack9@lsuhsc.edu) for reimbursement and coordination

***Kuali resources**

Kuali Support Documents
Creating a Protocol
Complete and Submit COI Form
COI in Research Training

File Sharing Resources

LSU Health FileS

Contacts

Dr. Vinod Dasa (Orthopedics Research Chairmen) vdasa@lsuhsc.edu)
Ms. Edwina Jackson (Administrative Assistant) ejack9@lsuhsc.edu
Tara Korbal (Senior Advisor to the MSK Chair) tmakar@lsuhsc.edu
Robby Branstetter (Committee MSK Chairman) rbran5@lsuhsc.edu
Erik Piedy (MSK Chair-Elect) epiedy@lsuhsc.edu
Dr. Claudia Leonardi (Faculty Statistician) cleon1@lsuhsc.edu

****If you have an issue please let us know*