

RESEARCH ONBOARDING CHECKLIST

Pre-Award Actions When Proposing to Conduct Research

Do you need assistance finding grant opportunities?

□ Search for Federal Grant Funding Opportunities: <u>Grants.gov</u>

- \Box Search for Government or Foundation Funding Opportunities: GrantForward
- □ Search for NIH-specific Funding Opportunities: <u>NIH.gov</u>
- □ Search for NSF-Specific Funding Opportunities: <u>NSF.gov</u>
- Search the LSUHSC Intramural Research Program Opportunities
- □ To identify industry-sponsored clinical trial opportunities, please visit product manufacturer websites or reach out to the <u>Clinical Trials Office</u> for assistance.

The Office of Research Services is in the process of establishing a Research Information Services division that will be able to assist researchers with identifying funding opportunities specific to their area of research focus.

Contact: Coming Soon

Are you planning to submit proposals to an external sponsor?

All extramural funded research and training grant applications should be reviewed and submitted through the <u>Office of Grants Compliance</u>.

 \Box To begin the process please contact Ann Clesi.

Contact: Ann Clesi, aclesi@lsuhsc.edu

Does your research require negotiation of a contract?

<u>Research-related contracts</u> are classified into multiple categories:

- 1) Confidential/Non-Disclosure Agreements (CDA or NDA)
- 2) Clinical Trial/Study Agreements (CTA)
- 3) Research Agreements
- 4) Subcontracts, when LSUHSC is receiving funds (*different from subaward*)
- □ To begin negotiation of a CDA or NDA, please contact the Office of Innovation and Partnership.
- □ To begin negotiation of a CTA, Research Agreement, or Subcontract that is Cancer-related please contact David Whaley.
- □ To begin negotiation of a CTA, Research Agreement, or Subcontract that is not Cancer-related please contact the Clinical Trials Office.

Contact: Marcus Brown (IP), <u>mbro60@lsuhsc.edu</u>

David Whaley, dwhal1@lsuhsc.edu

Clinical Trials Office, CTO@lsuhsc.edu



Are there awards transferring with you to LSU Health Sciences Center?

With incoming faculty, the research offices at the outgoing institution and LSUHSC will work together to transfer the award.

- □ Notify agency sponsors to begin transfer process. Request instructions for transferring the project to LSUHSC.
- □ Complete appropriate transfer materials/relinquishment forms depending on agency requirements.
- □ Submit a transfer application if required by the funding agency.

□ For NIH Awards: Request to change your eRA Commons affiliation to LSUHSC.

Contact: Ann Clesi, aclesi@lsuhsc.edu

Will materials be transferred to or from LSU Health Sciences Center?

Material Transfer Agreements (MTAs) are contracts governing the transfer of tangible research property from one entity to another. A <u>Material Transfer Initiation Form</u> must be completed and returned to the Office of Innovation & Partnerships.

□ To begin negotiation for a new MTA, please contact the Office of Innovation and Partnerships.

 \Box To organize the transfer of equipment, please contact Asset Management

Contact: Marcus Brown, Office of Innovation and Partnerships, mbro60@lsuhsc.edu

Asset Management, <u>noinv@lsuhsc.edu</u>

Will data be transferred to or from LSU Health Sciences Center?

Data use agreements (DUA) are classified into two categories:

- 1) Non-human subject data or de-identified, coded, or limited human subject data sets.
- 2) Identifiable human subject data, which includes one or more of the 18 protected health information (PHI) categories defined by HIPAA.
- □ Transfers of human subject data that is de-identified, coded, limited, or identifiable may require IRB approval. Questions about IRB approval, guidelines and policies should be directed to IRBOffice@lsuhsc.edu.
- □ If you are transferring data to LSUHSC, you may need to establish a DUA between the provider institution and LSUHSC. Verify with the provider institution if one is required.
- □ If you are transferring data to another institution, LSUHSC requires establishment of a DUA with the receiving institution.
- □ To begin negotiation of a new DUA for sending or receiving data, please contact the Clinical Trials Office.

Contact: Clinical Trials Office, <u>CTO@lsuhsc.edu</u>

Are you proposing research activities to be conducted at a local hospital or clinic?



- □ To conduct research activities at **University Medical Center New Orleans** (UMC), please contact <u>umcofficeofresearch@lcmchealth.org</u>
- □ To conduct research activities at **Children's Hospital New Orleans** (CHNOLA), please contact <u>CHResearch@lcmchealth.org</u>
- □ To conduct research activities at **East Jefferson General Hospital** (EJGH), please contact <u>ej_clinicalresearchtrial@lcmchealth.org</u>
- □ To conduct research activities at **West Jefferson Medical Center** (WJMC), please contact wjmcofficeofresearch@lcmchealth.org
- □ To conduct research activities at **Touro Infirmary**, please contact <u>medstaffoffice@lcmchealth.org</u>
- □ To conduct research activities at the LSU Healthcare Network, please contact Stephanie Sonnier, <u>ssonn7@lsuhsc.edu</u>

Regulatory Actions Prior to Conducting Research

Have you submitted an Annual Conflict of Interest Disclosure?

A COI disclosure form is required for anyone participating in LSUHSC-NO research. The COI disclosure form must be completed annually and updated within 30 days of discovering or acquiring any new or previously undisclosed actual or potential COI. You will not be approved to participate in LSUHSC-NO research without a completed COI disclosure form on file.

Information regarding the COI policy and instructions to complete a COI disclosure form are available on the <u>Office of Research Services COI website</u>.

 \Box Complete a COI disclosure form.

Note: After you complete your COI disclosure form, your form will be sent automatically to the Office of Research Services. You will be contacted if additional information is needed.

Contact: Anissa Patrick, amdo5@lsuhsc.edu

Will your research involve human subjects?

It is the policy of LSUHSC-NO that all activities involving human beings and/or information or specimens collected from human beings must be presented to the <u>HRPP</u> for a determination as to whether <u>the activity is human subjects research (HSR)</u>.

□ If your project is human subjects research and requires IRB review, a submission though the Kuali Research (KR) electronic submission system is required.

Contact: IRBOffice@lsuhsc.edu

Will your research involve animal subjects?

The Institutional Animal Care and Use Committee (IACUC) has the primary responsibility for ethical oversight of all activities involving the care and use of live vertebrate animals including,



but not limited to, establishing policies and procedures, inspecting facilities, reviewing and approving research protocols, and monitoring adherence to approved protocols.

□ Please review the <u>Compliance Flowchart for Starting A Research Lab At LSUHSC-NO</u> for additional information.

Contact: <u>IACUCOffice@lsuhsc.edu</u>

Will your research involve use of recombinant or synthetic nucleic acid molecules (r/sNAs) or genetically modified organisms, pathogens, potentially infectious materials, parasitic agents, biological agents, toxins, dual use research of concern (DURC) agents, or other biohazards?

The Institutional Biosafety Committee (IBC) acts as the framework for risk management associated with research-related, biosafety issues. The primary objectives of this risk management program are several-fold:

- 1. to protect individuals, research animals, facilities and the community from potential dangers in the use of, or exposure to, actual and potential biohazardous material;
- 2. to assure that LSUHSC-NO is in compliance with all biosafety requirements of state and federal regulatory agencies;
- 3. to review research involving the use of biological select agents and toxins under the oversight of the Federal Select Agents Program which have the potential to pose a severe threat to public, animal or plant health or to animal or plant products; and
- 4. to review Dual Use Research of Concern (DURC), life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.
- □ Any LSUHSC employee doing lab work on LSUHSC property will likely need an IBC approval prior to conducting research. Please visit the IBC website to learn about <u>Research Requiring</u> <u>IBC Review</u>.
- □ Please review the <u>Compliance Flowchart for Starting A Research Lab At LSUHSC-NO</u> for additional information.

Contact: <u>IBCOffice@lsuhsc.edu</u>

Will you be involved in laboratory-based research?

*Only applicable to LSU School of Dentistry and LSU Health Sciences Center Downtown Campuses

- Complete the EH&S Laboratory Precommissioning Consultation Form.
- Review the EH&S webpage, including policies and procedures.
- □ Register for the EH&S compliance system, SafetyStratus.
- Laboratory Pre-Commissioning Consultation Form
- Environmental Health and Safety (lsuhsc.edu)
- Safety Stratus Resources (lsuhsc.edu)



Review the PI Onboarding Checklist for more details on PI responsibilities and laboratory safety items. PI Onboarding Checklist.pdf (lsuhsc.edu)

Contact: Environmental Health & Safety, <u>safety@lsuhsc.edu</u> or 504.568.6585

Will your research be subject to export control regulations (i.e., ITAR, EAR), or does your research have restrictions on publication and foreign national participation?

□ To confirm if you are engaged in any research projects subject to the export control regulations, please contact the Office of Innovation and Partnerships.

Contact: Marcus Brown, Office of Innovation and Partnership, mbro60@lsuhsc.edu

Post-Award Actions

Project Award and Beginning Research

Do you need a PeopleSoft Account for your research?

The process for setting up a people soft project:

The departmental business manager will complete the sponsored project number request form (attached); ensuring that all applicable attachments on the request form which pertain to the award/grant are included. The departmental business manager will also ensure that signatures of the business manager and department head are obtained on the form. Once the packet is complete, the departmental business manager will email it to Sponsored Projects at <u>nosponproj@lsuhsc.edu</u> and request that a sponsored project number is established.

□ Please contact your department business manager for <u>Project Setup Requests</u>.

Contact: Department Business Manager

Do you need to issue a subaward to an outside institution?

Once a grant, contract, or clinical trial agreement is finalized/awarded, Departments may proceed with submitting a proposed subcontract/subaward to the <u>Office of Contract</u> <u>Management's contract database</u>.

Departments must upload:

- Award document (i.e., Notice of Grant Award or entire CTA file)
- In-House budget spreadsheet
- Completed subcontract/subaward template
- Medicare Coverage Analysis, if clinical trial
- Any other relevant emails/documentation/communication regarding the subcontract/ subaward, *if necessary*
- □ Please contact you department business manager for assistance with submitting a proposed subcontract/subaward to Contracts Management.
- □ Review Sponsored Project's information about <u>subrecipient monitoring</u>.



Contact: Department Business Manager

Contracts Management, <u>lsuhsccmteam@lsuhsc.edu</u> Sponsored Projects, <u>Nosponproj@lsuhsc.edu</u>

Could your work lead to a potentially patentable invention, or if you have copyrightable materials or software that you have developed?

At the Office of Innovation & Partnerships (<u>OIP</u>), we manage LSU Health's innovative technologies. We work with you to protect the new innovations you've created and get them to the marketplace for the public's benefit. The first step in this process is telling us about the innovation (i.e., "disclosure").

□ If you have previously filed patents, have been involved in commercialization activities, and/or plan on continuing work with pre-existing intellectual property, please contact the Office of Innovation and Partnerships to discuss these relationships.

□ If you have work that could lead to potentially patentable technology or copyrightable materials, consider submitting a <u>Disclosure Form</u> to OIP **BEFORE** a public disclosure (manuscript, presentation, etc.).

If you're interested in learning more about protecting intellectual property and commercializing technology, please contact the Office of Innovation and Partnerships for a meeting.

Contact: Marcus Brown, Office of Innovation and Partnership, mbro60@lsuhsc.edu

Do you need to purchase items to conduct your research?

□ Please contact your department business manager for <u>assistance with purchasing</u>.

Contact: Department Business Manager

Do you need to submit a bill or invoice to a sponsor for work performed?

Funded research usually requires LSUHSC bill the sponsor for activities performed. The details of the invoicing requirements including what information should be included on the invoice and how frequently invoicing must occur can be found within the award document.

- □ For assistance with creating and submitting invoices, please contact your department business manager.
- □ Some invoices may be processed through Sponsored Projects Administration or Billing/Accounts Receivable, please contact your department business manager to confirm responsibility.

Contact: Department Business Manager

Are personnel charged to a sponsored agreement?

Time and Effort Reporting are produced to certify federal effort per the Uniform Guidance (200.430i). Other sponsored agencies also require us to maintain time and effort certifications. Effort reporting ensures compliance with Uniform Guidance, validates cost sharing, validates



effort on other sponsored programs, and is used to ensure state unrestricted funds are used properly.

□ Please review the <u>Policy and Procedure</u> related to Time and Effort.

Contact: Department Business Manager

Do you need access to Core Facilities?

LSU Health Sciences Center in New Orleans has numerous core facilities that are available to our investigators. These core facilities are available to all LSUHSC faculty and staff on a fee per use basis.

- Analytic Center (School of Public Health): provides biostatistical, epidemiologic, study design, and program evaluation support for health-related research and policy projects.
- Animal Care Core: provides high quality laboratory animals, ensures humane care and use of all laboratory animals, provides expert technical knowledge, and provides training of all faculty and staff in accordance with related laws and guidelines of all federal and state agencies.
- <u>Biospecimen Core Laboratory</u>: collects and makes available to researchers high quality samples of normal and diseased human material (e.g., whole blood, cellular blood components, bone marrow, plasma, serum, urine, benign and malignant tissue) with appropriate pathological data.
- Cellular Immunology and Immune Metabolism Core: provides state-of-the-art instrumentation and expertise in flow cytometry and cell sorting, and immune cell function; and houses advanced analyzers such as BD LSRII, Auto MACS cell sorter, BioRad Bio-plex system, Elispot reader and Luminoscan. The Core will also provide consulting services on experimental design technical assistance, trouble shooting, and data analysis. To schedule the equipment, please register with iLab and contact Dorota Wyczechowska or Timothy Kayes.
- <u>Center for Bioinformatics Services</u>: provides bioinformatics and data analytics solutions and support services to the research community from experimental design, through all analyses to publication.
- Clinical Trials and Translational Research Core: A list of services offered by this core can be found on the <u>CTRC brochure</u> or on <u>SPARC</u>.
- HIV-Clinical/Tumor Biorepository Core: assists with patient enrollment and subsequent collection, storage, and retrieval of linked clinical data and biospecimens for laboratory analyses.
- Molecular Histopathology and Analytical Microscopy Core (MHAM): The Molecular Histopathology and Analytical Microscopy Core (MHAM) is a state-of-the-art facility created to provide advanced histopathology and microscopy services to investigators



and clinicians conducting research at LSU LCMC Health Cancer Center, including promising junior investigators of the Center for Translational Viral Oncology (CTVO).

The MHAM provides researchers with access to archival clinical samples, experimental planning design, and imaging studies on the histology and pathology of tissues, the expression of cell surface, and intracellular molecules including viral proteins, using bright field and confocal microscopy, immunohistochemistry, immunohistofluorescence, multiplexing, in situ hybridization, and in situ proximity ligation (DuoLink). These multiple methods are used to determine protein expression patterns and localization, mRNA levels, their subcellular localization, and protein-protein and RNA-protein interactions in the cells and tissues. Moreover, the MHAM Core assists investigators in developing the necessary imaging and data for the submission of manuscripts and grants.

- Morphology and Imaging Core: assist investigators requiring detection, imaging, and morphometric analysis of gene and protein expression in any type of cell and tissue.
- Proteomics and Metabolomics Core: services offered by Core facilities include sample extraction, high throughput screening, deep metabolomics and proteomics profiling using LC- and GC-MS techniques, targeted analysis, data analysis, pathway analysis, and flux analysis. In addition, molecular imaging is also available.
- <u>Translational Genomics Core</u>: The LSU LCMC Health Cancer Center Translational Genomics Core (TGC) functions as a genetic analysis "wet-lab" resource for LSU Health New Orleans and affiliated entities, as well as contracting users from outside the university. The TGC is committed to providing quality service by fulfilling the needs of the research community in a consistently rapid, dependable, and economical fashion.

Are there any other resources available to me?

The LSUHSC Libraries offer the following services to researchers:

- Data Management
- <u>Systematic Reviews</u>

The Library also has the following agreements with publishers:

- <u>BMJ Case Reports</u> Publish case reports without paying a fee (contact library for reference code)
- <u>Rockefeller University Press</u> Publish open access articles with no publishing fee for Journal of Cell Biology, Journal of Experimental Medicine, and Journal of General Physiology

Contact: Isché Library, reference@lsuhsc.edu

Dental Library, <u>dentlib@lsuhsc.edu</u>

Baton Rouge Campus Library, mdefoe@lsuhsc.edu

REDCap is a secure, HIPAA compliant, web-based application for building and managing online surveys and databases. Administered by LSUHSC-New Orleans, School of Public Health Analytic



Center, REDCap may be 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. Investigators can request a REDCap database here.

Contact: <u>REDCap@lsuhsc.edu</u>

The Office of Research Services offers the following Education series:

- ORS Lunch & Learn (first Wednesday of every month at 12pm via Zoom)
- IRB Lunch & Learn (recordings)
- <u>Coordinator Competencies</u> (live sessions coming soon)