Conflicts of Interest in Research
October 19, 2026

Managing Potential Financial and Non-Financial Conflicts of Interest

LSUHSC-NO strives to provide the highest quality patient care, an excellent teaching environment for future health care professionals, and a vibrant climate for cutting-edge basic and clinical research. All research activities at LSUHSC-NO must adhere to the highest standards of ethical conduct, protect the rights of human subjects, minimize conflicts of interest, and ensure the public's continued trust.

All research activities at LSUHSC-NO must:

- Adhere to the highest ethical standards
- Protect the rights of human subjects
- Minimize conflicts of interest
- Ensure the public's continued trust

LSUHSC-NO encourages its personnel to participate in meaningful professional research relationships with industry, government, and private entities. These mutually beneficial relationships may generate vital biomedical knowledge or intellectual property that may benefit the public.

Despite their benefits, these relationships may create potential financial or non-financial conflicts of interest that could appear to threaten:

- The integrity of the design, conduct, or reporting of the research, or
- The welfare of human research participants.

All potential or actual conflicts related to research must be disclosed in advance of initiating the research Please note that capitalized terms are terms that have specific definitions in the policy. Please refer to Campus Memorandum-35 for detailed definitions and guidance.

What is a Conflict of Interest? A Conflict of Interest (COI) is any interest, financial or otherwise, of an individual or the institution which may have a potential or actual adverse impact on the objective conduct of a Research Project or Institutional Responsibilities.

What is a Significant Financial Interest (SFI)
One or more of the following Financial Interests of the Investigator, or his/her Immediate Family Member(s), that reasonably appear to be related to the Investigator's Institutional Responsibilities, including the design, conduct, or reporting of Research Projects which may be sponsored either by an Entity or by the Institution.

1. Any payment, in cash or in kind, received directly from any publicly traded OR nonpublicly traded Entity in the twelve (12) months preceding the disclosure, or the ownership of any equity interest in the Entity as of the date of disclosure; or
2. Income from intellectual property rights and interests (e.g. patents, copyrights) personally held by the Investigator or his/her Immediate Family Member and not owned or managed by LSUHSC-NO; or
3. Any travel costs received in the twelve (12) months preceding the disclosure by the Investigator or his/her Immediate Family Member(s), related to the Investigator's Institutional Responsibilities, which is reimbursed and/or sponsored by an Entity. Disclosure must include purpose of the trip, identity of the sponsor, destination, and duration of travel.

Important Note
LSUHSC-NO does not set a minimum dollar amount for disclosure of a Financial Interest in an Entity.

Significant Financial Interest DOES NOT MEAN any of the following:

1. Salary, royalties, or other remuneration paid by Institution to the Investigator, if the Investigator is currently employed or otherwise appointed by the Institution; or
2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the mutual fund's investment decisions; or
3. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, a US institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education; or
4. Income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.
5. Any reimbursed or sponsored travel costs received in the twelve (12) months preceding the disclosure by the Investigator or his/her Immediate Family Member(s), related to the Investigator's Institutional Responsibilities, which is reimbursed and/or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

Your Responsibilities as a Research Team Member

The Principal Investigator must:

1. Take responsibility for ensuring compliance with this Policy by all Investigators and study team members involved in a Research Project, including any new Investigators or study team members who later join an ongoing Research Project.

2. Take responsibility for implementing the Conflict of Interest Management Plans developed by the Conflict of Interest Committee (CIC).

Procedures for Disclosure of Individual Conflicts of Interest

1. Research projects must be submitted to ORS using the current electronic submission platform. Ensure to include a list of study team members. At the time of submission, each team member must have a current COI disclosure form on file or must complete a COI Disclosure Form within thirty (30) days of notification by ORS. (See #1 and #2 under "What are my responsibilities as a team member of a research project . . ." above.)
2. Approval of new Research Projects, or annual re-approval of existing Projects, will not be granted until reviews of all COI disclosure forms have been concluded and, where necessary, a COI management plan has been developed and approved by the CIC. The Principal Investigator must accept responsibility for implementing all terms of the COI Management Plan.

Disclosure of Institutional Conflicts of Interest

Senior Leadership of the Institution shall disclose annually, to the Director, any equity interest valued over $100,000 which they personally hold in an Entity.

For each Research Project submitted to the IRB, the Chair of the IRB shall request the Director to determine whether any potential or actual Institutional Conflict of Interest exists related to the Research Project.

At the time of continuing review of a Research Project, the Director or his/her designee shall determine whether any new Institutional Conflicts of Interest may have developed since the last review, and shall require CIC review and management as appropriate.

Please refer to CM-35 for additional details on Institutional Conflicts of Interest.

Management of Conflicts of Interest

If the Director determines that there may be a COI which must be managed, his/her review and all relevant disclosure information will be transmitted to the COI Committee (CIC), which will be responsible for evaluating all pertinent factors to determine whether a COI exists.

- Upon a determination that an Individual or Institutional Conflict of Interest exists, the COI Committee will develop a written COI Management Plan to reduce, manage, or eliminate that conflict.
- A COI Management Plan is a written plan developed by the Conflict of Interest Committee and approved by the Vice Chancellor for Academic Affairs to manage an identified Conflict of Interest. The plan may include, but is not limited to the following actions:
    - Allowing the Research Project to proceed with the Investigator's involvement despite the presence of a Conflict of Interest with restrictions and/or additional oversight in place to reduce and manage the conflict.
    - Formal recusal of a conflicted member of the Senior Leadership from the chain of authority over the project or administrative decisions affecting the Investigator.
    - Disqualification of the conflicted Investigator from participating in all or a portion of a Research Project.
- A COI Management Plan must be signed by the Principal Investigator, the Investigator with the Conflict of Interest, the Chairperson of the CIC, the Department Head and Dean

of the School of the Investigator with the Conflict of Interest, and the Vice Chancellor for Academic Affairs.

- Whenever:
    - a new Investigator or study team member joins an ongoing Research Project and discloses a potential Conflict of Interest, or
    - an existing Investigator or study team member discloses a new potential Conflict of Interest or a potential Conflict of Interest was not previously reviewed for whatever reason, or
    - the Institution identifies a previously undisclosed potential Conflict of Interest, the Director shall, within sixty (60) days of disclosure, administratively review to assess the particular circumstances and determine whether there may be a Conflict of Interest which must be Managed. If the Director determines that a potential Conflict of Interest may exist, he/she may implement, on an interim basis prior to the CIC's action, a Plan which may include measures regarding participation in the Research Project between the date of disclosure and completion of CIC review.

Management of COIs Related to Start-up Companies

In some instances, creation of a new company may be the most effective mechanism to commercialize LSUHSC- NO innovations. A startup company, launched by an LSUHSC-NO employee who invented the technology ("Employee Innovator"), may need to conduct additional research to advance the technology, and may determine that the Employee Innovator is best able to conduct that research.

In such instances, disclosure and development of a COI Management Plan is imperative to clarify allowable research activities and to ensure that such activities occur within the boundaries of institutional policy, applicable law, and public expectation of research integrity. The Employee Innovator must always operate from the principle that his/her primary duties and obligations are to LSUHSC-NO.

For pre-clinical research activities sponsored at LSUHSC-NO by the Employee Innovator's company, the results will be adjudicated in the wider research field through the peer review process. However, clinical research activities sponsored at LSUHSC-NO by the Employee Innovator's company require a more rigorous Plan to ensure the Employee Innovator is adequately and appropriately removed from influencing analysis of research results.

- In addition to meeting disclosure requirements outlined above, each Employee Innovator also must disclose potential Conflicts of Interest to all members of his/her laboratory research group if a Research Project will be sponsored by his/her start-up company in his/her laboratory.
- If students or postdoctoral fellows supervised by the Employee Innovator will be working on a Research Project sponsored by the Employee Innovator's start-up company, an ombudsman must be appointed to oversee such activities.
- Results of research not funded by the Employee Innovator's startup company may not be shared with that company unless those results are:
    - publicly available, or
    - provided under a specific written agreement between LSUHSC-NO and that company.

- All contracts for Research Projects between LSUHSC-NO and an Employee Innovator's startup company **MUST:**
    - be negotiated and approved through standard Institutional processes,
    - include appropriate indirect cost charges and other standard terms and conditions,
    - include clear statements of work,
    - appropriately address intellectual property issues, and
    - not involve the Employee Innovator in negotiations on behalf of either party.
- LSUHSC-NO facilities may not be used for the purposes of the Employee Innovator's startup company portion of the Research Project:
    - without prior written approval of LSUHSC-NO authorized officials and
    - without appropriate compensation for use of Institution's state facilities at market rates as authorized under a separate written agreement.

Subcontractors
If Research Projects are conducted through a collaborator, sub-grantee, sub-recipient, or subcontractor, LSUHSC- NO shall, by written agreement, ensure that such entity either:

- complies with this Policy or
- provides written certification that its financial conflict of interest policies comply with applicable federal rules and regulations.

Additional Requirements for PHS-Funded Research Projects

- Prior to LSUHSC-NO's expenditure of any funds under a PHS-funded Research Project, the Director or his/her designee shall provide to the PHS Awarding Component an FCOI report, according to federal guidelines, regarding any Investigator's COI that has been found by the COI Committee to require management.
- If any COI is identified subsequent to the initial FCOI report, the Director or his/her designee shall provide to the PHS Awarding Component, within sixty (60) days, a FCOI report regarding that COI, according to federal guidelines.
- FCOI reports are updated at the time of an annual progress report.
- During the course of PHS-funded Research Projects only, if the Institution determines that a Conflict of Interest was not disclosed, identified, or managed in a timely manner, the Director shall, within one-hundred and twenty (120) days from such determination, direct the CIC to conduct a retrospective review of the Investigator's activities in any such PHS-funded Research Projects to assess the potential for bias in the design, conduct, or reporting of that Research Project. If appropriate, based upon the documented results of this retrospective review, the Director or his/her designee shall update the FCOI Report previously submitted to the PHS Awarding Component with information on the Conflict of Interest Management Plan. If the CIC's retrospective review finds evidence of bias in the Research Project as a result of the Conflict of Interest, the Director or his/her designee shall promptly notify and submit a mitigation report to the PHS Awarding Component, according to federal guidelines.
- Subcontractors of LSUHSC-NO under PHS-funded grants must report to the Institution any FCOI of their investigators, as determined through applicable policy, in sufficient time and at least thirty (30) days prior to the deadline required for LSUHSC-NO's submission of an annual report to allow LSUHSC-NO to provide timely FCOI Reports to the PHS Awarding Component.

Records
LSUHSC-NO will ensure public accessibility to certain information concerning a SFI disclosed to the Institution which is:

- still held by the Investigator; and
- determined to be related to a Research Project; and
- determined to be a Financial COI which must be Managed according to a written Plan.

Within five business days of receipt of a written request for information concerning a SFI, LSUHSC-NO, through its Office of Research Services, will provide such information as required by applicable law or regulation.

Violations and Sanctions
Violations of this Policy and implementing procedures, including, but not limited to the failure to file timely disclosures, filing incomplete, erroneous or inaccurate disclosures; or failure to comply with prescribed procedures for managing or resolving Conflicts of Interest, will be handled in accordance with applicable LSUHSC-NO policies.

Sanctions may include disciplinary action up to and including termination of employment. Violations may also result in civil or criminal liability.

Summary: Conflict of Interest (COI) Requirements

- Each study team member must have a current COI disclosure form on file or must complete a COI disclosure form within thirty (30) days of notification by ORS (Collaborators from other institutions must document that they are in compliance with their institutions COI policy.)
- COI forms must be updated annually and within 30 days of discovering or acquiring any new or previously undisclosed SFI or potential COI for themselves or for their immediate family members.
- There is no minimum threshold for disclosure of individual COIs or SFIs.
- A research project may not begin until the Principal Investigator acknowledges responsibility for implementing any Conflict of Interest Management Plans required by the CIC.
- Institutional COIs are handled administratively.

Important
All research team members are expected to be familiar with all the provisions of CM-35, not just those highlighted in this training. Read the policy in its entirety for complete details! Each member of a research study team must follow LSUHSC-NO's COI policies to ensure transparency and compliance.

Visit the COI website for resources, forms, and guidance.

Have Questions?
Contact the Office of Research Services:
433 Bolivar Street,
Suite 206 504-568-4970