

Chancellor's Memorandum

CM-35 – Managing Conflicts of Interest in Research

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Monitoring Unit: Office of Research Services

I. PURPOSE

LSU Health Sciences Center at New Orleans (“LSUHSC-NO”) strives to assure integrity, transparency, and objectivity in all research conducted at LSUHSC-NO. All research activities at LSUHSC-NO must adhere to the highest standards of ethical conduct, protect the rights of human subjects, manage and minimize conflicts of interest, and ensure continued trust of the public. This CM addresses disclosure and management of both financial and non-financial conflicts of interest that may arise in research conducted at LSUHSC-NO to ensure that these values and standards are consistently upheld.

II. DEFINITIONS

1. **“Conflict(s) of Interest”** or **“COI”** means any Financial Conflict of Interest, Non-Financial Conflict of Interest, or Institutional Conflict of Interest that may, depending on particular circumstances, have a potential or actual adverse impact on the objective conduct of a Research Project or Institutional Responsibilities.
2. **“Conflict of Interest Committee”** or **“CIC”** is a committee appointed by the LSUHSC-NO Vice Chancellor for Academic Affairs (VCAA) that determines whether specific potential or actual Institutional or Investigator COI exist and, if so, develops an appropriate Plan.
3. **“Conflict of Interest Management Plan”** or **“Plan”** is a written plan developed by the CIC and approved by the VCAA to Manage an identified COI.
4. **“Director”** means the Executive Director of the LSUHSC-NO Office of Research Services (ORS), or other person as designated by the VCAA, who is responsible for implementing this CM.
5. **“Entity”** means a company, association, organization, institution, or agency with a separate legal identity, whether domestic or foreign, public or private, profit or non-profit.
6. **“Financial Conflict of Interest”** or **“FCOI”** means a Significant Financial Interest of an Investigator or Immediate Family Member that could affect, or could have the appearance of affecting, directly and significantly the design, conduct, supervision, or reporting of a Research Project
7. **“FCOI Report”** means LSUHSC-NO’s report of an identified FCOI to PHS, as required under applicable federal regulations.
8. **“Financial Interest”** means anything of monetary value, whether or not that value is readily ascertainable.

9. **“Immediate Family Member”** means (a) an Investigator’s children, spouses of children, siblings, spouses of siblings, parents, spouse, and parents of spouse *and* (b) other individuals whose close personal relationship to the Investigator by blood, adoption, marriage, domestic partnership, sexual/romantic partnership, or business arrangement may give rise to a COI in a Research Project.

10. **“Institutional Conflict of Interest”** means a Financial Interest of LSUHSC-NO or its Senior Leadership that conflicts with, or may have the appearance of conflicting with, LSUHSC-NO’s duty to ensure the integrity and objectivity of its processes for the design, conduct, reporting, review, and oversight of research, including human subjects research. Such Financial Interests may include receipt of LSUHSC-NO revenue greater than \$100,000 annually: (a) generated from a license to LSUHSC-NO-owned intellectual property, or (b) received from investments, gifts, or sponsorships, or (c) other financial interests held by LSUHSC-NO or personally by its Senior Leadership.

11. **“Institutional Responsibilities”** means an Investigator’s professional responsibilities on behalf of LSUHSC-NO, which may include but are not limited to research, teaching, consultation, professional practice /clinical duties, and service on internal or external boards, committees, or panels.

12. **“Investigator”** means any LSUHSC-NO employee (whether faculty or staff), student, house officer, key personnel as defined by the NIH Grants Policy Statement, or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of a Research Project.

13. **“Manage”** means taking action to address, reduce, or eliminate a COI, to provide a reasonable expectation that the Research Project will be conducted with integrity and objectivity.

14. **“Non-Financial Conflict of Interest”** means conduct by an Investigator or an Immediate Family Member of either internal or outside activities which may compromise, or have the appearance of compromising, the objective and ethical conduct of the Investigator’s Institutional Responsibilities or of a Research Project, including, but not limited to (a) conflicts of commitment regarding time and effort or (b) using a student to perform services for an Entity in which the Investigator or Immediate Family Member has an ownership or management role when (i) the student is currently enrolled in a class taught by the Investigator or Immediate Family Member, or (ii) the Investigator or Immediate Family Member supervises the student in an academic capacity, or (iii) the Investigator or Immediate Family Member otherwise can influence the student’s academic progress.

15. **“Public Health Service”** or **“PHS”** means the Public Health Service of the U.S. Department of Health and Human Services (HHS), and any components to which its authority may be delegated, including the eight agencies designated as PHS Awarding Components: (a) Agency for Healthcare Research and Quality (AHRQ), (b) Agency for Toxic Substances and Disease Registry (ATSDR), (c) Centers for Disease Control and Prevention (CDC), (d) Food and Drug Administration (FDA), (e) Health Resources and Services Administration (HRSA), (f) Indian Health Service (IHS), (g) National Institutes of Health (NIH), and (h) Substance Abuse and Mental Health Services Administration (SAMHSA).

16. **“Research Project”** means any systematic investigation, study, scholarly activity, or experiment conducted at LSUHSC-NO, regardless of funding source, which is designed to develop or contribute to generalizable knowledge, including basic, applied, clinical, behavioral, biomedical, product development, or social-sciences research.

17. **“Senior Leadership”** means all LSUHSC-NO employees, whether permanent, interim, or acting, with the title Chancellor, Vice Chancellor, Associate Vice Chancellor, Assistant Vice Chancellor, Dean, or anyone else so

designated by the Chancellor.

18. **"Significant Financial Interest"** or **"SFI"** MEANS one or more of the following Financial Interests of the Investigator or an 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 sponsored either by an Entity or by LSUHSC-NO:

- a. With regard to any publicly traded OR non-publicly traded Entity, *any* remuneration received directly from the 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. Remuneration is defined as salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship), and equity interest is defined as any stock, stock option, unit/membership interests, profit interests, unit appreciation rights, or other form of ownership interest; **or**
- b. Intellectual property rights and interests (e.g., patents, copyrights, trademarks/service marks, etc.) *personally held* by the Investigator or an Immediate Family Member and *not* owned or managed by LSUHSC-NO, upon receipt of income related to such rights and interests; **or**
- c. Any reimbursed or sponsored travel costs received in the twelve (12) months preceding the disclosure by the Investigator or an Immediate Family Member(s), related to the Investigator's Institutional Responsibilities, which is reimbursed and/or sponsored by an entity other than a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education. Disclosure required under this section shall include purpose of the trip, identity of the sponsor, destination, and duration of travel.

HOWEVER, **"Significant Financial Interest"** or **"SFI"** *DOES NOT MEAN* any of the following:

- d. Salary, royalties, or other remuneration paid by LSUHSC-NO to the Investigator, if the Investigator is currently employed or otherwise appointed by LSUHSC-NO, including intellectual property rights assigned to LSUHSC-NO and agreements to share in royalties related to such rights; **or**
- e. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made therein; or
- f. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, a US institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education; **or**
- g. Income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

III. GENERAL POLICY GUIDELINES

1. This CM applies to and requires compliance by all LSUHSC-NO administrators, faculty members (including part-time and visiting faculty), students (including post-doctoral fellows), house officers, staff and other employees who propose, conduct, report, or approve results, of research, regardless of funding source. It meets applicable federal rules and regulations governing disclosure and reporting of FCOI, and does not replace or supersede general LSUHSC-NO or LSU System or LSU Board policies, rules, regulations, or bylaws, including those permanent memoranda governing disclosure of activities and financial interests relating to outside employment (PM-11) or state employees contracting with LSUHSC-NO or other institutions within the LSU System (PM-67).

2. LSUHSC-NO must meet certain reporting requirements for the management of potential COI for PHS-funded Research Projects as follows:

a. Initial Report: 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 the CIC deems must be Managed. However, if the CIC eliminates an identified COI prior to the expenditure of PHS-awarded funds, no FCOI Report is required.

b. Subsequent Report: 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.

c. Mitigation Report: If a retrospective review by the CIC, as described above, finds evidence of bias in the conduct of the Research Project, the Director or his/her designee will notify and submit a mitigation report to the PHS Awarding Component, according to federal guidelines.

d. Annual Report: At the time an annual progress report on the Research Project is due to the PHS Awarding Component, the Director or his/her designee shall also provide an annual FCOI Report that addresses (i) the status of the FCOI, (ii) any changes to the Plan for the duration of the project, (iii) whether the FCOI is still being Managed, or (iv) why the FCOI no longer exists.

3. 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 CM or provides written certification that its financial conflict of interest policies comply with applicable federal rules and regulations. Subcontractors of LSUHSC-NO under PHS-funded grants must report to LSUHSC-NO 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.

4. LSUHSC-NO shall take appropriate steps to protect confidentiality of disclosures required by this CM. However, when required by law or regulation, mandated by research sponsors, or necessary to administer this CM, LSUHSC-NO shall make certain information available upon written request, including the existence of any Plan. Records relating to disclosures of SFI, disclosures of actual or potential COI, Plans, and retrospective reviews of the CIC shall be maintained by ORS for at least three (3) years after the date of the final expenditure report, termination, or completion of the Research Project, or the resolution of any government action or litigation, or to comply with other applicable records retention requirements, whichever is later.

5. LSUHSC-NO will ensure public accessibility to certain information concerning an SFI disclosed to it that (a) is still held by the Investigator, *and* (b) is determined to be related to a Research Project, *and* (c) is determined to be an FCOI that must be Managed according to a Plan. Within five (5) business days of receipt of a written request for information concerning an SFI, LSUHSC-NO, through ORS, will provide such information as required by applicable law or regulation.

6. Training on all matters related to this CM will be conducted through the online training system of the LSUHSC-NO Office of Compliance Programs, which will notify Investigators when training is required. Investigators shall complete training regarding this CM at least every four (4) years, and immediately when any of the following circumstances apply: (a) LSUHSC-NO revises this CM to substantially change the requirements of Investigators, *or* (b) an Investigator is new to LSUHSC-NO, *or* (c) an Investigator is in non-compliance with this CM or with a Plan.

IV. PROCEDURES FOR DISCLOSURE OF INVESTIGATOR CONFLICTS OF INTEREST

1. Each Investigator must disclose **annually** all SFI and all actual or potential COI, for themselves or for their Immediate Family Members, which have occurred in the preceding twelve (12) months or which are expected to occur in the next twelve (12) months. Further, each Investigator must update their COI disclosure **within thirty (30) days** of discovering or acquiring any new or previously undisclosed SFI or actual or potential COI for themselves or for their Immediate Family Members. All disclosures include documentation sufficient to allow full evaluation of any reported potential COI.
2. At the time of submission to ORS of each proposed Research Project, each study team member listed as participating in the Research Project must have a current COI disclosure on file or must complete a disclosure within thirty (30) days of notification by ORS.
3. Each principal Investigator shall be responsible for ensuring compliance with this CM 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.
4. Proposed Research Projects *may not begin* until reviews of all COI disclosures have been concluded and, if necessary, (a) Plans developed by the CIC have been transmitted from the VCAA to the Investigator *and* (b) the Investigator has accepted responsibility for implementing those Plans.
5. While Investigators employed by LSUHSC-NO may launch start-up companies that seek to sponsor Research Projects, such situations require additional compliance, as outlined below in Section VII.

V. PROCEDURES FOR DISCLOSURE OF INSTITUTIONAL CONFLICTS OF INTEREST

1. To ensure that LSUHSC-NO maintains the highest level of public trust in its research, it will seek to minimize Institutional Conflicts of Interest related to Research Projects. Should a potential or actual Institutional COI be identified, the Director shall transmit the information to the CIC for evaluation and management according to its standard procedures.
2. Senior Leadership of the LSUHSC-NO shall disclose annually, to the Director, any personally-held equity interest in an Entity valued over \$100,000.
3. For each Research Project submitted to the Institutional Review Board (IRB), the Chair of the IRB shall request the Director to determine whether any potential or actual Institutional COI related to the Research Project may exist in the following categories:
 - a. Income over \$100,000 received by LSUHSC-NO pursuant to a license of LSUHSC-NO intellectual property to the sponsor of the Research Project (contact the Office of Innovation & Partnerships); or
 - b. Equity interest valued at more than \$100,000 directly held by LSUHSC-NO in the sponsor of the Research Project (contact the Vice Chancellor for Administration and Finance); or
 - c. Donations in the last year from the sponsor of the Research Project to LSUHSC-NO of more than \$100,000 (contact the Office of Sponsored Projects and the LSUHSC-NO Foundation).
4. At the time of continuing review of a Research Project, the Director or his/her designee shall determine whether any new Institutional COI may have developed since the last review, and shall require CIC review and

management as appropriate.

VI. PROCEDURES FOR MANAGEMENT OF CONFLICTS OF INTEREST

1. Within sixty (60) days of receipt of a disclosure of a potential Investigator or Institutional COI, the Director will administratively review to determine whether there may be a COI that must be Managed. Investigators may be required to provide additional information for this review.
2. In determining whether or not an Investigator COI exists, as a general rule, the Director will apply the definitions for SFI as established in the PHS regulations on Financial Conflict of Interest. The Director, in consultation with the CIC, retains the authority to establish a lower *de minimis* threshold on a case by case basis.
 - a. With regard to any publicly traded Entity, an SFI exists if the *cumulative* value of any remuneration received from the Entity in the twelve (12) months preceding the disclosure and any equity interest held in the entity as of the date of disclosure exceeds \$5,000.
 - b. With regard to any non-publicly traded Entity other than a start-up company launched by an LSUHSC-NO employee, an SFI exists if the aggregated value of any remuneration received from the Entity in the twelve (12) months preceding the disclosure exceeds \$5,000, or when the Investigator (or the Investigator's Immediate Family Members) holds any equity interest (e.g., stock, stock option, or other ownership interest). The \$5,000 *de minimis* threshold shall NOT apply to start-up companies launched by LSUHSC-NO employees and disclosure must follow the guidelines set forth in Section VIII below.
 - c. With regard to any reimbursed or sponsored travel, an SFI exists if the value of such remuneration received from an Entity in the twelve (12) months preceding the disclosure exceeds \$5,000.
3. If the Director determines that there may be a COI that must be Managed, their review and all relevant disclosure information will be transmitted to the CIC, which will be responsible for evaluating all pertinent factors to determine whether a COI exists that must be Managed.
4. Upon a determination that an Investigator or Institutional COI exists, the CIC will develop a Plan to reduce, manage, or eliminate that conflict. In certain circumstances, the CIC may determine that the Investigator has presented compelling circumstances to justify allowing the Research Project to proceed with his/her involvement despite the presence of a COI. In no instance will "compelling circumstances" be approved that may violate federal regulations or result in actions detrimental to LSUHSC-NO or the goals of this CM. The Plan developed by the CIC will define the compelling circumstances and will specify restrictions under which the Investigator may participate in the Research Project.
5. If the CIC determines that the Plan requires disqualification of the conflicted Investigator from participating in all or a portion of a Research Project, and/or formal recusal of a conflicted member of the Senior Leadership from the chain of authority over the Research Project or administrative decisions affecting the Investigator, then the Plan also shall designate a "safe-haven" (i.e., a non-conflicted senior Investigator) with whom the Investigator can address COI concerns.
6. The CIC shall submit Plans for Research Projects involving human subjects to the LSUHSC-NO IRB, which shall have the sole authority to determine whether the Plan satisfactorily protects the safety and welfare of human subjects and to require appropriate modifications to the Plan to ensure such protection. In no instance may a Research Project involving human subjects and requiring a Plan begin without prior IRB approval.

7. Each Plan must be signed by the principal Investigator, the Investigator with the COI, the Chairperson of the CIC, the Department Head and Dean of the School of the Investigator with the COI, and the VCAA. In cases where an Institutional Conflict of Interest involves the VCAA, the Chancellor must approve the Plan in his/her place. An Investigator *may not begin* a Research Project until the Plan has been signed by all parties and transmitted from the VCAA to the Investigator. The Director or his/her designee shall monitor the Investigator's compliance with the Plan and shall have the authority to enforce all its provisions.

8. Whenever a new Investigator or study team member joins an ongoing Research Project and discloses a potential COI, or when an existing Investigator or study team member discloses a new potential COI or a potential COI was not previously reviewed for whatever reason, or when the LSUHSC-NO identifies a previously undisclosed potential COI, the Director shall, within sixty (60) days of disclosure, administratively review to assess the particular circumstances and determine whether there may be a COI that must be Managed. If the Director determines that a potential COI may exist, he/she may implement a Plan on an interim basis prior to the CIC's action which may include measures regarding participation in the Research Project between the date of disclosure and completion of CIC review.

9. During the course of PHS-funded Research Projects only, if the LSUHSC-NO determines that a COI 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 Plan. If the CIC's retrospective review finds evidence of bias in the Research Project as a result of the COI, the Director or his/her designee shall promptly notify and submit a mitigation report pursuant to federal guidelines.

VII. MANAGEMENT OF CONFLICTS OF INTERESTS RELATED TO START-UP COMPANIES

1. In some instances, creation of a new company may be the most effective mechanism to commercialize LSUHSC-NO innovations. A startup company may be launched by an LSUHSC-NO employee who invented or developed the innovation ("Employee Innovator"), may need to conduct additional research to advance the innovation, and may determine that the Employee Innovator is best able to conduct that research. In such instances, disclosure and development of a 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 their primary duties and obligations are to LSUHSC-NO.

2. For preclinical research activities sponsored at LSUHSC-NO by the Employee Innovator's company it is expected that results will be evaluated appropriately through the external scientific 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.

3. In addition to meeting disclosure requirements outlined above, each Employee Innovator also must disclose potential COI to all members of their laboratory research group if a Research Project will be sponsored by their start-up company in their laboratory.

4. 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 independent observer must be appointed to oversee such activities and ensure fair treatment.

5. Results of research not funded by the Employee Innovator's startup company *may not be shared* with that startup company unless those results are publicly available or are provided under a specific written agreement between LSUHSC-NO and that company.

6. All contracts for Research Projects between LSUHSC-NO and an Employee Innovator's startup company (a) must be negotiated and approved through standard LSUHSC-NO processes, (b) must include appropriate indirect cost charges and other standard terms and conditions, (c) must include clear statements of work, (d) must appropriately address intellectual property issues, (e) must not involve the Employee Innovator in negotiations on behalf of either party, and (f) must be reviewed by the LSU PM-67 Standing Committee. No such contract may proceed without the approval of the LSU PM-67 Standing Committee and the President of LSU.

7. 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 LSUHSC-NO facilities at market rates as authorized under a separate written agreement.

VIII. COMPLIANCE, VIOLATIONS, AND SANCTIONS

1. All LSUHSC-NO personnel are required to comply with this CM and with any Plan. LSUHSC-NO will monitor such compliance during the term of all Research Projects.

2. Violations of this CM, including, but not limited to the failure to file timely disclosures, failure to file complete and accurate disclosures, or failure to comply with a Plan, will be handled in accordance with applicable LSUHSC-NO policies and may also result in civil or criminal liability. Sanctions may include disciplinary action up to and including termination of employment.

3. If failure to comply with this CM may have led to biased research, LSUHSC-NO (a) will promptly notify the sponsor of the Research Project, (b) will provide information on the conflicting interests, and (c) will specify a Plan to manage, reduce, or eliminate the conflicts leading to potential bias.

4. If the PHS determines that a PHS-funded Research Project involving clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an Investigator with a conflicting interest that was not previously disclosed or managed by the LSUHSC-NO, then the Investigator shall be required to disclose the conflicting interest in each public presentation of the results of the Research Project and shall be required to request an addendum to any previously published work related to the project, noting such COI.

IX. REFERENCES

PM-11 Outside Employment

PM-67 Contracts between the University and its Faculty Members