

Chancellor's Memorandum

CM-35 – Conflicts of Interest in Research:

Managing Potential Financial and Non-Financial Conflicts of Interest of Individuals and the Institution

To: Vice Chancellors, Deans, Administrative Staff, Department Heads, and Students.

From: LSU Health Sciences Center New Orleans Chancellor

February 26, 2018

I. Purpose

This Policy addresses disclosure and management of both financial and non-financial conflicts of interest which may arise in research conducted at the Louisiana State University Health Sciences Center at New Orleans ("LSUHSC-NO" or "Institution"). 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.

This Policy promotes and assures integrity, transparency, and objectivity in all research conducted at the Institution. It meets applicable federal rules and regulations governing disclosure and reporting of financial conflicts of interest, and does not replace or supersede general institutional or LSU system policies, including those permanent memoranda governing disclosure of activities and financial interests relating to outside employment (PM-11) or state employees contracting with the Institution (PM-67).

II. Scope

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.

III. General Statement of Policy

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; however, they also may create potential financial or non-financial conflicts of interest, on the part of either individuals or the Institution, that could be perceived to threaten the integrity of the design, conduct, or reporting of the research, or the welfare of human research participants. All such potential or actual conflicts of interest related to research must be disclosed in advance of initiation of that research.

This Policy allows LSUHSC-NO to identify and manage potential research conflicts of interests while minimizing reporting and other burdens placed on investigators. It is important to note that while federal guidelines establish certain minimum financial levels for required disclosure, LSUHSC-NO has no minimum financial thresholds for disclosure. It is also important to note that any potential conflicts of interest which may arise in the conduct of research are judged upon the particular circumstances of each situation and do not reflect upon the character of individuals conducting that research.

IV. Definitions:

1. **"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.

2. **"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.

3. **"Immediate Family Member"** means the spouse, significant other, and dependent children of an Investigator.

4. **"Senior Leadership"** means all individuals with the title Chancellor, Vice Chancellor, Dean, and any other individual designated by the Chancellor.

5. **"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 institutional or non-institutional boards, committees, or panels.

6. **"Entity"** means a company, association, organization, institution, agency, or other with a separate legal identity, whether domestic or foreign, public or private, profit or non-profit.

7. **"Financial Interest"** means anything of monetary value, whether or not that value is readily ascertainable.

8. **"Significant Financial Interest" or "SFI"**

A. MEANS 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. Note that LSUHSC-NO establishes *no minimum thresholds* for disclosure of a Financial Interest in an Entity:

- i. 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, or other form of ownership interest; or
- ii. 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, upon receipt of income related to such rights and interests; or
- iii. 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 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.

B. DOES NOT MEAN any of the following:

- i. Salary, royalties, or other remuneration paid by Institution to the Investigator, if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; or

- ii. 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
- iii. 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
- iv. 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.

9. **"Financial Conflict of Interest"** or **"FCOI"** means a Significant Financial Interest of an Investigator or Immediate Family Member which could, or could have the appearance of, directly and significantly affecting design, conduct, supervision, or reporting of a Research Project

10. **"Non-Financial Conflict of Interest"** means conduct by an Investigator or an Immediate Family Member of either institutional 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 (i) conflicts of commitment regarding time and effort; or (ii) using a student to perform services for an Entity in which the Investigator or Immediate Family Member has an ownership or management role when (a) the student is currently enrolled in a class taught by the Investigator or Immediate Family Member; or (b) the Investigator or Immediate Family Member supervises the student in an academic capacity; or (c) the Investigator or Immediate Family Member otherwise can influence the student's academic progress.

11. **"Institutional Conflict of Interest"** means a Financial Interest of the Institution or its Senior Leadership that conflicts with, or may have the appearance of conflicting with, the Institution'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 Institutional revenue greater than \$100,000 annually: (i) generated from a license to LSUHSC-NO-owned intellectual property, or (ii) received from investments, gifts, or sponsorships, or (iii) other financial interests held by LSUHSC-NO or individually by its Senior Leadership.

12. **"Conflict of Interest"** means any Financial Conflict of Interest, Non-Financial Conflict of Interest, or Institutional Conflict of Interest which may, depending on particular circumstances, have a potential or actual adverse impact on the objective conduct of a Research Project or Institutional Responsibilities.

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

14. **"Conflict of Interest Committee"** or **"CIC"** is a committee appointed by the LSUHSC-NO Vice Chancellor for Academic Affairs which determines whether specific potential or actual Institutional or Investigator Conflicts of Interest exist and, if so, develops an appropriate management plan.

15. **"Conflict of Interest Management Plan"** or **"Plan"** is a written plan developed by the CIC and approved by the Vice Chancellor for Academic Affairs to Manage an identified Conflict of Interest.

16. **"FCOI Report"** means the Institution's report of an identified FCOI to PHS, as required under applicable federal regulations.

17. **"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: (1) Agency for Healthcare Research and Quality (AHRQ), (2) Agency for Toxic Substances and Disease Registry (ATSDR), (3) Centers for Disease Control and Prevention (CDC), (4) Food and Drug Administration (FDA), (5) Health Resources and Services Administration (HRSA), (6) Indian Health Service (IHS), (7) National Institutes of Health (NIH), and (8) Substance Abuse and Mental Health Services Administration (SAMHSA).

18. "**Director**" means the Executive Director of the LSUHSC-NO Office of Research Services, or other person as designated by the Vice Chancellor for Academic Affairs, who shall be the designated institutional official responsible for implementing this Policy.

V. Procedures for Disclosure of Individual Conflicts of Interest

1. Each Investigator, as defined herein, must disclose **annually**, via the COI Risk Manager electronic form, all Significant Financial Interests and all actual or potential Conflicts of Interest, 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 such person must update their COI Risk Manager form **within thirty (30) days** of discovering or acquiring any new or previously undisclosed Significant Financial Interest or actual or potential Conflict of Interest for themselves or for their Immediate Family Members. All such disclosures must be accompanied by documentation sufficient to allow full evaluation of any reported potential conflicts of interest.

2. At the time of submission to ORS of each proposed Research Project the Principal Investigator must submit a *COI Team Member Form* which identifies each person who will be involved in any conduct or reporting of the proposed Research Project. Each person identified on the *COI Team Member Form* must have a current COI Risk Manager form on file or must complete a form in the COI Risk Manager system within thirty (30) days of notification by ORS.

3. Each Principal Investigator shall be responsible 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.

4. Proposed Research Projects *may not begin* until reviews of all COI Risk Manager disclosure forms have been concluded and, if necessary, (a) Conflict of Interest Management Plans developed by the CIC have been transmitted from the Vice Chancellor for Academic Affairs to the Investigator, *and* (b) the Investigator has accepted responsibility for implementing said Plan.

5. Individuals 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 VIII.

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

3. 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 related to the Research Project may exist in the following categories:

(i) Income over \$100,000 received by Institution pursuant to a license of LSUHSC-NO intellectual property to the sponsor of the Research Project (Contact the Office of Technology Management);

(ii) Equity interest valued at more than \$100,000 directly held by the Institution in the sponsor of the Research Project (Contact the Vice Chancellor for Administration and Finance); or

(iii) Donations in the last year from the sponsor of the Research Project to the Institution 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 Conflicts of Interest may have developed since the last review, and shall require CIC review and management as appropriate.

VII. Procedures for Management of Conflicts of Interest

1. Within sixty (60) days of receipt of a disclosure of a potential Individual or Institutional Conflict of Interest, the Director will administratively review to determine whether there may be a Conflict of Interest which must be Managed. Investigators may be required to provide additional information for this review.

2. If the Director determines that there may be a Conflict of Interest which must be Managed, his/her 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 Conflict of Interest exists.

3. Upon a determination that an Individual or Institutional Conflict of Interest exists, the CIC will develop a written Conflict of Interest Management Plan to reduce, manage, or eliminate that conflict.

4. 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 Conflict of Interest. 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 Policy. 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 project or administrative decisions affecting the Investigator, then the Plan also shall designate a "safe-haven" (e.g. a non-conflicted senior individual) with whom the Investigator can address Conflict of Interest concerns.

6. The CIC shall submit Conflict of Interest Management Plans for Research Projects involving human subject research studies to the LSUHSC-NO Institutional Review Board (IRB), which shall have the sole authority (i) to determine whether the Plan satisfactorily protects the safety and welfare of human subjects and (ii) to require appropriate modifications to the Plan to ensure such protection. No Research Project involving human subjects which requires a Plan may begin without prior IRB approval.

7. Each Conflict of Interest 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. In cases where an Institutional Conflict of Interest involves the Vice Chancellor for Academic Affairs, 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 Vice Chancellor for Academic Affairs 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 (i) a new Investigator or study team member joins an ongoing Research Project and discloses a potential Conflict of Interest, or (ii) 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 (iii) 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.

9. 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.

VIII. 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 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 Conflict of Interest 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.

2. For preclinical 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.

3. 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.

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 ombudsman must be appointed to oversee such activities.

5. Results of research not funded by the Employee Innovator's startup company *may not be shared* with that company unless those results (i) are publicly available or (ii) 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 (i) must be negotiated and approved through standard Institutional processes, (ii) must include appropriate indirect cost charges and other standard terms and conditions, (iii) must include clear statements of work, (iv) must appropriately address intellectual property issues, and (v) must not involve the Employee Innovator in negotiations on behalf of either party.

7. LSUHSC-NO facilities may not be used for the purposes of the Employee Innovator's startup company portion of the Research Project (i) without prior written approval of LSUHSC-NO authorized officials and (ii) without appropriate compensation for use of Institution's state facilities at market rates as authorized under a separate written agreement.

IX. Reporting Requirements for PHS-Funded Research Projects

1. 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 Conflict of Interest that has been found by the CIC to require Management. However, if the CIC eliminates an identified Conflict of Interest prior to the expenditure of PHS-awarded funds, no FCOI Report is required.
2. Subsequent Report: If any Conflict of Interest 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 Conflict of Interest, according to federal guidelines.
3. 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.
4. 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.

X. Subcontracting Obligations

1. 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 (i) complies with this Policy or (ii) provides written certification that its financial conflict of interest policies comply with applicable federal rules and regulations.
2. 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.

XI. Records Confidentiality & Retention

1. LSUHSC-NO shall take appropriate steps to protect confidentiality of disclosures required by this Policy. However, when required by law or regulation, mandated by research sponsors, or necessary to administer this Policy, LSUHSC-NO shall make certain information available upon written request, including the existence of any Plan.
2. Records relating to disclosures of Significant Financial Interests, disclosures of actual or potential Conflicts of Interest, Conflict of Interest Management Plans, and retrospective reviews of the Conflict of Interest Committee shall be maintained by the Vice Chancellor for Academic Affairs 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.

XII. Public Accessibility

1. LSUHSC-NO will ensure public accessibility to certain information concerning a Significant Financial Interest disclosed to the Institution which (i) is still held by the Investigator; and (ii) which is determined to be related to a Research Project; and (iii) which is determined to be a Financial Conflict of Interest which must be Managed according to a written Plan:

2. Within five (5) business days of receipt of a written request for information concerning a Significant Financial Interest, LSUHSC-NO, through its Office of Research Services, will provide such information as required by applicable law or regulation.

XIII. Compliance, Violations and Sanctions

1. All LSUHSC-NO personnel are required to comply with this Policy and with any Conflict of Interest Management Plan. The Institution will monitor such compliance during the term of all Research Projects.

2. Violations of this Policy, including, but not limited to the failure to file timely disclosures, failure to file complete and accurate disclosures, or failure to comply with a Conflict of Interest Management 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 Policy may have led to biased research, LSUHSC-NO (i) will promptly notify the sponsor of the Research Project, (ii) will provide information on the conflicting interests, and (iii) will specify the Plan developed 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 Institution, 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 Conflict of Interest.

XIV. Training Requirements

1. Training on this Policy will be conducted through the online KDS system of the LSUHSC-NO Office of Compliance Programs, which will notify Investigators when training is required.

2. Investigators shall complete training regarding this Policy at least every four (4) 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 non-compliance with this Policy or with a Conflict of Interest Management Plan.

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