Individual and Institutional Conflicts of Interest in Sponsored Projects

Updated 4/26/2017
An Investigator shall not be permitted to begin any research activity (e.g. design, conduct or reporting of research, educational, or service activities) when an actual or potential Conflict of Interest (Col) exists until a written review of the disclosure has been conducted and, if necessary, a Conflict of Interest Resolution Plan has been developed and has been received by the Investigator from the Vice-Chancellor for Academic Affairs.
Definitions

• “Conflict of Interest” means any “Financial Conflict of Interest” and/or any “Non-Financial Conflict of Interest.” A potential or actual Conflict of Interest occurs in the context of research if:
  – there is a chance that an Interest could reasonably appear to affect research; or
  – there is a chance that research or other LSUHSC-NO activities could reasonably appear to affect the interests of an external entity in which the Investigator (or Immediate Family Member) or the Institution has an Interest.
Definitions (cont.)

• “Immediate Family Member” is defined as the spouse or dependent children of the Investigator, and any other individual that the Investigator knows or should know maintains an interest that may be impacted by research or projects the Investigator is proposing or conducting.
  
  – Any other relationship that a reasonably prudent person might consider as an appearance of a Conflict of Interest should also be disclosed.
Definitions (cont.)

• “Financial Conflict of Interest” means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research and occurs when an Investigator’s or Immediate Family Member(s)’ Financial Interests compromise or have the appearance of compromising, an Investigator’s professional judgment in proposing, conducting, supervising, or reporting research.

  – A Financial Conflict of Interest depends on the situation and not on the character of the individual.
Definitions (cont.)

• “Investigator” means any LSUHSC-NO Principal Investigator, Co-Principal Investigator, Project Director, and any other research personnel, including but not limited to any other LSUHSC-NO employee (whether faculty or staff), student, or house officer who is responsible for the design, conduct or reporting of the research activity, regardless of funding, and/or status (e.g. key personnel (as defined by the NIH Grants Policy Statement), research associates, technicians, nurse coordinators, administrators, collaborators, consultants and students).
Individual Conflicts of Interest

• Procedures for Disclosure (All applications and agreements):
  - Note that LSUHSC-NO has no minimal threshold for Individual Conflicts of Interest.
  - Investigators must provide completed and signed Conflict of Interest Attestation forms at the time of submission of any research agreement, grant proposal, clinical trial agreement, or IRB application.
  - Conflict of Interest Attestation Forms must be updated to reflect any new or previously undisclosed Conflicts of Interest within thirty (30) days of discovering or acquiring a new Interest. New study team members must submit forms within 60 days of joining the project.
Conflict of Interest Attestation

Title of project as submitted on the sponsored project application/agreement or IRB application:

Name of Principal Investigator

The following items must be addressed by each member of the study team. This includes, but is not necessarily limited to, principal investigator, co-investigators, research/nurse coordinators, technicians, post-docs/fellows/residents, and other students working on the project. These attestations must be submitted with all sponsored project applications/agreements or non-sponsored IRB applications at the time of submission to the Office of Research Services or to the IRB.

Do you or does any member of your immediate family (see CM35 for definition of “immediate family member”):

1. Have an equity interest in the company that is sponsoring this project, or in a company with similar or competing products? Mark "No" if there is no commercial sponsor for this study.
   - No [ ] Yes [ ]

2. Receive honoraria or gifts from the sponsor of this project? Mark "No" if there is no commercial sponsor for this project.
   - No [ ] Yes [ ]

3. Have an equity interest in a “start-up” company in your field of research?
   - No [ ] Yes [ ]

4. Serve on the Board of Directors or an Advisory Board for the sponsor or any other company in your field of research? Mark “No” if there is no financial sponsor for this project.
   - No [ ] Yes [ ]

5. Hold an interest in or have applied to hold an interest in a patent, license or copyright related to any aspect of this project?
   - No [ ] Yes [ ]

6. Receive any royalties or compensation related to any aspect of this project?
   - No [ ] Yes [ ]

7. Have any other non-financial Conflicts of Interest (e.g., commitment or time and effort) related to this project?
   - No [ ] Yes [ ]

If you answered “yes” to any of these questions, you must provide full disclosure as required by LSUHSC-NO CM 35.

To the best of my understanding the above statements have been answered truthfully.

Printed name of study team member

Role in project

Signature ___________________________ Date ___________________________

Please note: If any changes in this attestation occur during the project they must be reported through this same process. Also, if additional personnel are added to this project, they must also complete and submit this document to the Office of Research Services.
If the Attestation Form indicates that a Conflict of Interest or potential Conflict of Interest exists, the Investigator must also submit descriptions and associated documentation of the Interest that is in sufficient detail to allow evaluation of the Interest.

This disclosure must be submitted to the Office of Research Services with the COI Attestation Form and must include, but is not limited to PM-11 and/or PM-67 disclosure forms. The disclosure must include a description of the nature of the activity, amounts of money received and the time frame of related activities and remuneration.
At the time of submission of the grant application,

In addition to the Conflict of Interest Attestation form, and any applicable documentation, a disclosure of all Significant Financial Interests on the SFI Disclosure form must be submitted for each study team member. All Significant Financial Interests related to any of the Investigator’s Institutional Responsibilities must be reported.
Institutional Responsibilities

• An Investigator’s professional responsibilities on behalf of LSUHSC-NO and the LSU System. Institutional responsibilities include but are not limited to the following: research, teaching, consultation, professional practice (clinical duties), and service on boards, committees, or panels (institutional or non-institutional).”
“Significant Financial Interest” (SFI) means one or more of the following interests of the Investigator and those of the Investigator’s Immediate Family Member(s) that reasonably appears to be related to the Investigator’s institutional responsibilities.

- With regard to any publicly traded entity, a significant financial interest exists
  - If any remuneration is received from the entity in the twelve (12) months preceding the disclosure, or
  - Holding any equity interest (e.g. stock, stock options, or other ownership interest) as of the date of disclosure.
  - For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship), equity interest includes any stock, stock option or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value.
• With regard to any non-publicly traded entity, a significant financial interest exists
  – If any remuneration is received from the entity in the past twelve (12) months preceding the disclosure, or
  – Holding any equity interest (e.g. stock, stock options, or other ownership interest)

• Intellectual property rights and interests (e.g. patents, copyrights) held by the investigator, shared with an institution, or held by an institution and related to the Investigator’s work or ideas (Note: This does not include provisional patents.); and

• Any reimbursed and/or sponsored travel (i.e., that which is paid to or on behalf of the Investigator) related to the Investigator’s institutional responsibilities. This includes immediate family members and covers a period over the previous 12 months from the disclosure. However, this does not include travel that is reimbursed or sponsored by 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 that is affiliated with an Institution of higher education.
Louisiana State University Health Sciences Center-New Orleans

U.S. Public Health Service Grant Application
Significant Financial Interests (SFIs) Disclosure

Application title: 

Principal investigator of project: 

All SFIs as defined in CM35 must be disclosed to the LSUHSC-NO Office of Research Services (ORS) prior to the time of submission of any grant application to a U.S. Public Health Services agency such as NIH, HRSA, CDC, AHRQ, or SAMHSA. Disclosures must be submitted for all study team personnel and their immediate family members (spouse and dependent children). Examples of SFIs include, but are not limited to: consulting contracts, book contracts, honoraria for speaking engagements, and reimbursed or sponsored travel. These activities need not necessarily be related to the current grant application. See CM35 for a complete description of SFIs.

***SELECT ONE RESPONSE***

☐ Neither I nor any of my immediate family members have SFIs as described in CM35.

OR

☐ I and/or my immediate family members have the following SFIs (Describe on a separate page attached to this document).

Should this project be funded by the PHS, an update of this disclosure is required each year of the award at the time of submission of the annual progress report to the ORS. In addition, any new SFIs must be reported to the ORS within 30 days of acquisition and SFIs must be disclosed within 60 days by any new personnel added to the project.

To the best of my understanding the above statements and information have been provided truthfully.

Printed name of study team member

Role in project

Signature ____________________________ Date ____________________________

Revised 8/24/12
The term “Significant Financial Interest” does not include the following types of financial interests:

- Salary, or other remuneration (except for royalties) paid by LSUHSC-NO to the Investigator;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures, or teaching engagements 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 that is affiliated with an Institution of higher education; or
- 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 that is affiliated with an institution of higher education; or
- Income from professional organizations.
• Investigators are required to submit annually an updated SFI Disclosure form (at the time of progress report submission) and must report an updated SFI Disclosure form within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.

• New investigators joining a study must file SFI forms within 60 days of joining the project.
Institutional Conflicts of Interest

Procedures for Disclosing -

• For each sponsored, human subjects research application submitted to the IRB, the Chair of the IRB shall request the Director, Office of Research Services to make inquiries as to whether any potential or actual Institutional Conflicts of Interest exist (note that there is a threshold of at least $100,000 for such Interests).
Review of Individual and Institutional Conflicts of Interest

If the CoI Committee determines that an actual or potential Individual or Institutional Conflict of Interest exists, then the Committee shall develop a Conflict of Interest Resolution Management Plan which may impose but not necessarily be limited to any of the following mitigation steps:

- Public disclosure of Conflicts of Interest;
- Disclosure to subjects through the consent process;
- Review of Research protocol by independent reviewers;
- Monitoring of the Research project by independent reviewers;
- Reduction of equity holdings;
- Clear separation of Research from paid activities
- Modification or disapproval of the Research plan;
- Divestiture of Conflicts of Interest, complete or partial;
- Appointment of a non-conflicted Principal Investigator;
- Severance of relationships that create actual or potential Conflicts of Interest;
Institutional Reporting Requirements—
PHS funded research only

• Prior to LSUHSC’s expenditure of any funds under a PHS-funded research project, the Director of Research Services or his/her designee, shall provide to the PHS Awarding Component a FCOI report regarding any Investigator’s Significant Financial Interest that is found by LSUHSC-NO’s CIC to be conflicting and ensure that a Conflict of Interest Resolution Management Plan has been implemented. This report must be updated on a yearly basis.
Sub-Contracts

• If federally funded research is conducted through collaborators, sub-grantees, or subcontractors, the LSUHSC-NO shall ensure that such entities comply with this policy or provide written certification that their entities comply with federal regulations and PHS conflict of interest requirements. Subcontractors of federally funded grants received by LSUHSC-NO must agree to report to LSUHSC-NO any FCOI of their investigators as determined through the sub-contracting entities CoI policy. These reports must be provided in sufficient time to allow LSUHSC-NO to meet PHS FCOI reporting requirements.
Public Accessibility — PHS funded research only

- LSUHSC-NO through the Office of Research Services will provide information concerning any Significant Financial Interest disclosed to LSUHSC-NO within five (5) days of written request if the following criteria are met:
  - The Significant Financial Interest was disclosed and is still held by the Investigator;
  - LSUHSC-NO has determined that the Significant Financial Interest is related to the PHS-funded research; and
  - LSUHSC-NO determined that there is a Financial Conflict of Interest.
Training

Training on this policy will be conducted through the LSUHSC-NO Office of Compliance Programs’ (OCP) online, KDS system. Investigators will be notified by OCP when training is required.
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

- **For all sponsored projects** -- Submit CoI Attestation forms for all study team members to ORS.
- **For PHS grant applications** -- Submit CoI and SFI forms for all study team members to ORS.
- **Non-sponsored IRB applications** -- Submit CoI Attestation forms for all study team members to the IRB.

  - All of the above must be updated yearly (if awarded or initiated).
  - Any newly acquired CoI and/or SFI must be disclosed within 30 days.
  - Disclosures of new investigators must be made within 60 days.
  - No threshold for individual CoI or SFI.
  - Institutional CoI handled administratively.
Important
You must read CM35 in its entirety for complete details!

CM-35:
http://www.lsuhsc.edu/administration/cm/cm-35.pdf

Conflicts of Interest Website:
http://www.lsuhsc.edu/administration/academic/ors/conflict_of_interest.aspx