



Louisiana State University Health Sciences Center at Shreveport

Chancellors Memorandum CM-23- Conflict of Interest Policy

EFFECTIVE DATE: May 2, 2016¹

PURPOSE

The mission of Louisiana State University Health Sciences Center at Shreveport (LSUHSC-S) is to provide excellence in patient care, to foster the development of future medical, biomedical, and allied health professionals, and to advance medical and scientific research. LSUHSC-S must ensure that service, education and research are conducted under the highest ethical standards and in an environment that supports sound and transparent research, ultimately protecting the rights and welfare of research subjects and providing the assurance of ethically conducted biomedical research.

LSUHSC-S encourages faculty, students, house officers, and other employees to participate in meaningful professional relationships with industry, government and private entities to achieve various scientific goals. These relationships are established for mutually beneficial reasons and many times produce knowledge and intellectual property beneficial to the community at large. However, these relationships also have the ability to influence the Institution or the Investigator by possibly creating financial or non-financial conflicts of interest. The value of research results to the advancement of health care and the biomedical sciences must not be compromised by conflicts that could bias the design, conduct, or reporting of the research.

This policy outlines the LSUHSC-S procedure for maintaining a reasonable balance between these academic endeavors and any potentially competing interests, by describing how to identify, evaluate and manage financial Conflicts of Interest (COI) in research. This policy further describes other types of Conflicts of Interest, *e.g.* conflicts of time or commitment or other nonfinancial conflicts that may interfere with institutional obligations. Any potential conflict of interest (real or perceived) should be disclosed so it can be managed, reduced or eliminated in accordance with Federal regulations, state laws², and the terms of this policy to

¹ Supersedes LSUHSC-S CM-23 dated 25 February 2013.

² Louisiana Code of Ethics, Sections 1111A and 1115

Section 111A – No public servant (public employee) shall receive anything of economic value (money or any other thing having economic value), other than the compensation and benefits to which he is entitled from his governmental employer, for the performance of the duties and responsibilities of his office or position.

Section 1115 – No public servant (public employee) shall solicit or accept, directly or indirectly, anything of economic value as a gift or gratuity from any person or from any officer, director, agent, or employee of such person: 1) has or is seeking to obtain a contractual, business or financial relationship with the public servant's agency, or 2) has substantial economic interests which may be substantially affected by the performance or nonperformance of the public employee's official duty.

ensure academic pursuits are conducted in an open and transparent manner and with a high level of scientific integrity.

This policy is in compliance with:

Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought;

Title 45 Code of Federal Regulations (CFR), Part 94, Responsible Prospective Contractors; and, National Science Foundation, Grant Policy Manual, Ch. 510, Conflict of Interests Policy (“NSF 510)

SCOPE

This policy applies to all research personnel, regardless of title or position, who are responsible for the design, conduct, or reporting of research at LSUHSC-S, regardless of funding source. This includes LSUHSC-S faculty members (including part-time, gratis, and visiting faculty), staff and other employees, house officers and students (including post-doctoral fellows) engaged in research or academic pursuits.

This policy also applies to all senior leadership of the Institution and any individual indirectly involved in research oversight. Research oversight includes, but is not limited to, Institutional Review Board, IACUC, and Conflict of Interest committee membership.

Subcontractors, sub-grantees or collaborators from other institutions engaged in LSUHSC-S research must provide written certification to LSUHSC-S that their Institution(s) are in full compliance with 42 CFR 50, *Conflicts of Interest Regulation*³, or comply with this policy. Written certification must be provided by subcontractor, sub-grantee or collaborator prior to submission of application for grant or protocol approval. LSUHSC- S reserves the right to review their COI policy for compliance with Federal regulations and, if necessary, require compliance with the LSUHSC-S COI policy.

RESPONSIBILITY FOR DISCLOSURE REVIEW

The Office of Legal Affairs and Organizational Integrity reviews all Individual and Institutional *Annual Disclosure Certifications* and *Disclosure Updates*. If an SFI is disclosed related to research, or if there appears to be a potential for conflict of interest, all information will be forwarded to the Conflict of Interest Committee for review and management plan implementation, as necessary.

DEFINITIONS

Academic Pursuits: Academic pursuits include research at any stage; teaching of trainees or colleagues; and management of resources in support of academic pursuits.

³ 42 CFR Part 50: *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and responsible Prospective Contractors.*

Annual Certification: Annual disclosure of potential financial conflicts of interest by Individuals and the Institution which is completed at the beginning of the fiscal year (July 1), or when a person is new to LSUHSC-S and is covered by this policy.

COI Xpress/SHIELDS: Electronic COI disclosure management system located at <https://shields.lsuhealthsystem.org>.

Conflict of Commitment: A conflict of commitment arises when professional activities apart from LSUHSC-S interfere with the individual's paramount full-time obligations to students, colleagues, patients and the fundamental mission of LSUHSC-S. Conflict of commitment only involves questions of obligation and time effort.

Conflict of Interest (COI): A situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity, and could undermine the integrity of an academic pursuit. An apparent conflict of interest is one in which a reasonable person would think that the professional's judgment is likely to be compromised. A potential conflict of interest involves a situation that may develop into an actual conflict of interest.

Disclosure Update: Modification/update of the *Individual Annual Certification* which must be completed within 30 days of the discovery or acquisition (*e.g.* through purchase, marriage or inheritance) of a new significant financial interest (42 CFR 50.604(3)). Modification/update of the Institutional Annual Certification which must be completed quarterly indicating any changes resulting in new Significant Financial Interest(s) held by the Institution.

Financial Conflict of Interest: Refers to any financial interest that competes with an individual's obligation to protect the integrity of the academic pursuit and especially the rights and welfare of research subjects. While financial interests may not compromise intellectual honesty or institutional integrity, they must not have the appearance of compromising LSUHSC-S values and missions of teaching, research and public service.

Significant Financial Interest (SFI): A significant financial interest consists of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities.

- With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. 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 the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- *Travel Disclosures:* Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e. that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities. Travel reimbursed 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 need not be disclosed (42 CFR 50.603(2)). Travel to Investigator meetings for training and education of investigative study staff relative to the research need not be disclosed.

Institutional Conflict of Interest: Institutional conflicts of interest arise when the institution or its senior leadership have interests, financial or otherwise, that conflict with, or may have the appearance of conflicting with, their duty to ensure the integrity of institutional processes for the design, conduct, reporting, review, or oversight of human subjects research. Such interests may include, but are not limited to publicly and non-publicly traded equity, royalties, licenses, technology transfers, patent interests, investments, certain gifts when the donor has an interest in the research, or other financial interests held either by the institution or by its senior leadership (all individuals whose title includes Chancellor, Dean, Vice Chancellors, Counsel, and others determined by the Chancellor).

Institutional Responsibility: Investigator's professional responsibilities on behalf of LSUHSC-S, examples of which include teaching, research, service activities, and institutional committee memberships.

Investigator: Project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research.

Management Plan (MP): A written agreement between a discloser and the Institution defining the actions to be taken to manage, monitor, reduce and/or eliminate a potential or real conflict of interest.

Non-Financial Conflict of Interest: Non-financial conflicts of interest may exist when an individual serves dual roles, such as healthcare provider and Investigator. Other interests such as publication, promotion or tenure, can also become conflicts of interest that may affect an individual's judgment. Membership in oversight committees such as the IRB as well as positions of authority may pose actual, perceived or potential conflicts of interest. Any position that includes responsibilities for the review and approval of research projects or contracts may potentially affect the design of, decisions made and/or action taken surrounding a specific study.

Senior Leadership: All individuals whose title includes Chancellor, Dean, Vice Chancellors, Counsel, and others determined by the Chancellor. Senior leadership of the institution is additionally covered by the institutional conflict of interest disclosure procedure.

PROCEDURE FOR DISCLOSING FINANCIAL CONFLICTS OF INTEREST

All persons within the scope of this policy must submit an *Annual Certification* at the beginning of each fiscal year (July 1) using the electronic disclosure system COI Xpress/SHIELDS located at <https://shields.lsuhealthsystem.org> to disclose all financial conflicts of interest occurring within the 12 months preceding the date of the *Annual Certification* submission. This annual process shall be completed no later than two months after the start of the new fiscal year. Persons new to the Institution and within the scope of this policy who have not submitted an *Annual Certification* at the beginning of the fiscal year must do so before engaging in research.

All persons within the scope of this policy are additionally required to update/modify their *Annual Certification* within 30 days of discovery or acquisition (*e.g.* through purchase, marriage, or inheritance) of a new significant financial interest 42 CFR 50.604(3). This is completed with the COI Xpress/SHIELDS system as a *Disclosure Update* at the following site: <https://shields.lsuhealthsystem.org>. Instructions detailing the disclosure process can be found within the LSUHSC-S Legal Affairs and Organizational Integrity Standard Operating Procedure (SOP) LA101, *Financial Conflicts of Interest (FCOI) Management* located on the Legal Affairs website: <http://www.lsuhschreveport.edu/legal>.

Additionally, at the time of each initial application for either an Institutional Review Board (IRB) study application or a research proposal submitted to the Office of Sponsored Projects and Technology Transfer (OSPTT), an initial conflict of interest attestation will be conducted within the electronic IRB Xpress system: <https://shields.lsuhealthsystem.org> or at the: [OSPTT website](#), respectively, to determine the COI relationship, if any, to the proposed project.

Each principal Investigator is responsible for ensuring all study personnel under his or her supervision involved in designing, conducting, or reporting of the research, comply with this policy and complete COI training prior to the disclosure.

DISCLOSURE REVIEW PROCESS

Review and Evaluation

Upon submission of the *Annual Certification or Disclosure Update*, the Office of Legal Affairs and Organizational Integrity will conduct an initial review of all disclosures involving Significant Financial Interests per 42 CFR 50.604(d). The determination of whether a potential SFI relates to Investigator research includes *e.g.* investigating value and type of all equity interests, remuneration, and intellectual property disclosures. If initial reviews determine the existence of a potential COI covered by this policy, it will be referred to the Conflicts of Interest Committee (COIC) for further review. The implementation and monitoring of any required Management Plan will be determined by the COIC. Additional information from the discloser regarding the SFI may be requested by the COIC at any time. The committee review process is detailed in SOP LA101, *Financial Conflicts of Interest FCOI Management* located on the Legal Affairs website: <http://www.lsuhschshreveport.edu/legal>.

In certain circumstances, the COIC may determine that the Investigator has presented compelling circumstances to justify allowing research to proceed despite the presence of a Conflict of Interest. Whether the circumstances are deemed compelling shall depend upon the following:

- the nature of the science;
- the nature of the Conflict of Interest;
- the amount of the Financial Interest;
- how closely the Conflict of Interest is related to the research;
- the degree to which the Conflict of Interest may be affected by the research; and
- the degree to which the Conflict of Interest can be effectively managed.

No “compelling circumstances” will be approved which may violate Federal regulations or result in actions detrimental to LSUHSC-S and the goals of this policy.

If the COI Committee determines that there are compelling circumstances, and the research should go forward despite the Conflict of Interest, then the COI Committee may allow the research to go forward and must include in any Management Plan the following:

- The compelling circumstances which support including the conflicted Investigator in the project;
- The stages of the research and the specific activities for which there are compelling reasons for the Investigator’s involvement;
- The activities the Investigator will be allowed to perform; and

- Any management imposed to prevent the conflict from influencing or appearing to influence the outcome of the project and disposition to restrict the time of involvement to a minimum.

Management of COI

In the event the COI Committee determines a Conflict of Interest exists, the conflict shall be addressed in a Management Plan. Potential ways to manage the conflict include, but are not limited to:

- Public disclosure of the FCOI;
- Disclosure of the FCOI directly to research subjects;
- Appointment of independent reviewers capable of taking measures to protect the design, conduct, and reporting of research;
- Reduction or elimination of the financial interest;
- Severance of the relationship(s) that create financial conflicts; or
- Other means to be determined by the COI Committee.

The Management Plan will be prepared by the COI Committee and a monitoring interval determined. All Management Plans will be signed by the COI monitor and then submitted to the Vice-Chancellor for Research or designee within 10 working days of completion of the proposed Plan, and a decision will be made to approve or disapprove the recommendations of the COI Committee.

If the proposed Plan is approved by the Vice-Chancellor for Research, or designee, it will further route for approval to the discloser, the discloser's department head and Dean of the School of the Investigator, the IRB if the plan involves human subjects research, the IACUC if the plan involves animal research, and lastly the Chancellor. If fully approved, the proposed academic pursuit will be permitted to move forward in the review process, as appropriate, and a monitoring interval will begin. Ultimately, in regards to human subject's research, the IRB retains final authority to decide whether the Management Plan satisfactorily protects human subjects, the IACUC retains final authority to decide whether the Management Plan satisfactorily protects research animals, and to allow for Plan approval. The Chancellor may decide to disapprove the Plan or research; however, if the IRB or IACUC disapproves, the Chancellor may not approve the research.

If the committee and/or the Vice-Chancellor for Research, or designee, decide not to approve the Management Plan, the disclosing individual will have the option to appeal this decision to the Vice-Chancellor for Research, or designee. The second level of appeal of an adverse decision will be to the Chancellor. The Chancellor will make the final decision to grant or deny the appeal of the Plan.

PROCEDURE FOR DISCLOSING INSTITUTIONAL FINANCIAL CONFLICTS OF INTEREST

Institutional COI

Institutional interests requiring annual disclosure include:

- Patent and royalty payments: including royalty payments and licensing fees, resulting from technology transfer, licensing, and similar business activities that, for each arrangement, exceed \$100,000 in the preceding twelve (12) month period;
- Non-publicly traded equity: equity and ownership interests of any amount in any for-profit entity that is not publicly traded;
- Publicly-traded equity: equity and ownership interests valued at greater than \$100,000.00 in the preceding twelve (12) month period in any publicly-traded, for-profit entity; and
- Gifts greater than \$100,000.00 when the donor has an interest in the research; and Financial Interests of Senior Leadership that exceed \$100,000.00.

Offices of Sponsored Programs and Technology Transfer, Legal Affairs and Organizational Integrity and Administration and Finance in cooperation with each other are responsible for completing an Annual Certification on behalf of the Institution, to determine if LSUHSC-S holds any patents or licenses or other financial interests related to human subjects research projects and to determine whether LSUHSC-S holds any interest in the sponsoring company or investment revenue. Disclosure Updates will be completed quarterly. These disclosures will be made utilizing COI Express/SHIELDS or equivalent form.

Institutional Significant Financial Interests will be reviewed and Conflicts of Interest managed, if necessary, in the same manner as Individual Conflicts of Interest.

Non-Compliance

If an Investigator fails to disclose a conflict of interest or comply with this policy, it will result in Legal Affairs, in conjunction with the COI Committee, performing a *Retrospective Review* to determine if noncompliance created bias in research. This review is outlined in SOP LA101, *Financial Conflicts of Interest (FCOI) Management* located on the Legal Affairs website: <http://www.lsuhschreveport.edu/legal>. If bias is found, a *Mitigation Report* will duly be completed to determine the impact on the research and to initiate corrective and preventive action.

Retrospective Reviews and *Mitigation Reports* are reviewed and approved by Legal Affairs, the discloser, the department head, dean of the relevant school, the Vice-Chancellor, or designee, the IRB for human subject research, and the Chancellor. Both the *Retrospective Report* and *Mitigation Report* will contain, but not necessarily be limited to, the necessary elements required per 42 CFR 50.605(a)(3)(B)(1-9).

PHS Funded Research Reporting Requirements

Actual or potential conflicts of interest in PHS funded research must be resolved in accordance with this policy prior to application submission to the PHS and prior to accepting any award or commencing any research activity. Additionally, before expenditure of any funds under a PHS-funded research project, the Director of OSPTT, or designee, shall attest to the PHS Awarding Component any FCOI report regarding any Investigator's Significant Financial Interest and that a Management Plan, as necessary, has been implemented. If it is determined that a FCOI is discovered within an ongoing project (*e.g.* a new Investigator is added to a project or was not disclosed or reviewed timely), LSUHSC-S will report (*Retrospective Review*) the FCOI with supporting documentation to the PHS within 60 days (42 CFR 50.605(g)(3)).

NSF Funded Research Reporting Requirements

In the event the Institution is unable to satisfactorily manage a conflict of interest related to NSF funded research, OSPTT will notify NSF via the NFS FastLane System.

Training

All individuals engaged in research, independent of funding source, must complete Conflicts of Interest training prior to engaging in research and prior to completion of an *Annual Certification*. Training must be completed once every four years, and immediately when any of the following circumstances apply:

- LSUHSC-S revises the conflict of interest policy or procedures in any way that affects investigator responsibilities.
- An investigator is new to LSUHSC-Shreveport.
- An investigator is non-compliant with LSUHSC-Shreveport COI policy or a Management Plan.

COI training is further detailed in SOP LA103, *Conflicts of Interest Training* located on the Legal Affairs website: <http://www.lsuhsreshreveport.edu/legal>.

Confidentiality

Appropriate steps shall be taken by LSUHSC-S to protect the confidentiality of the disclosures required by this policy. However, LSUHSC-S can make available, within 5 business days of a written request, identified FCOIs held by senior/key personnel per 42 CFR 50.605(5)(i)-(iv) on the LSUHSC-S website. Additionally, LSUHSC-S shall make COI information available when required by law, mandated by sponsoring entities, or when necessary to carry out the purpose and administration of this policy.

Records

All FCOI records will be maintained for a minimum of 3 years, from final expenditure report date submitted to the Public Health Service, from study termination or completion date, or the resolution of any government action or litigation, whichever is later.

These records include all interest disclosure of financial interests and the Institution's review of, and response to, such disclosures (whether or not disclosure resulted in a FCOI), and all actions under the Institution's policy of retrospective review, if applicable.

Contact for Questions

You may contact the Department of Legal Affairs and Organizational Integrity with any questions and concerns regarding this policy.

Signature Approval:



G. E. Ghali, DDS, MD, FACS, FRCS(Ed)
Interim Chancellor & Dean