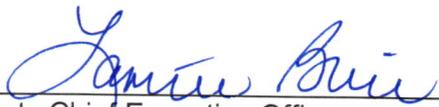


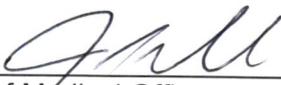
**Louisiana State University Health System
Health Care Services Division
Baton Rouge, LA**

Policy Number: 10002-17
Category: Sponsored Projects and Research
Content: Conflict of Interest in Research
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Inquiries to: Disease Management, Office of Sponsored Projects
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Deputy Chief Executive Officer
LSU Health Care Services Division

6/12/17
Date



Chief Medical Officer
LSU Health Care Services Division

6-12-17
Date

INTRODUCTION

Louisiana State University Health System, Health Care Services Division (LSU HCSD) and its employees are committed to the principle of free, open, and objective inquiry in the conduct of its service mission and research. Accordingly, it is crucial that LSU HCSD activities be conducted in an atmosphere that is free of conflicts of interest compromising this principle. To comply with federal regulations, LSU HCSD must manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an investigator.

SCOPE

This policy sets forth procedures and guidelines to be followed in resolving actual and potential employees and staff conflicts of interest and commitment pertaining to management of financial conflicts of interest that could bias the outcome of sponsored projects involving research, education and the services of LSU HCSD. This policy applies to all sponsored projects funded by (a) commercial sponsors, (b) those federal agencies having specific conflict of interest requirements, and (c) purchase orders and subcontracts issued by LSU HCSD under its sponsored projects irrespective of the source of funds

POLICY

It is the policy of LSU HCSD and pursuant to LSU HSC CM 35 and CM 21, that an Investigator shall not be permitted to begin 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 Management Plan has been developed and has been received by the Research Oversight Committee, LSU HCSD Chief Medical Officer, facility Compliance Officer and the Institutional official or his/her designee.

CONFLICT OF INTEREST IN RESEARCH

Conflict of interest in research involves situations in which an Investigator or Investigator's Immediate Family Member(s)' Financial Interests compromise, or have the appearance of compromising, professional judgment in the design, conduct, or reporting of research. A Financial Conflict of Interest depends on the situation and not the character of the individual.

Investigators conducting research funded by federal agencies such as the Public Health Service (including National Institutes of Health), the Department of Health and Human Services, the National Science Foundation, as well as those conducting studies regulated by the Food and Drug Administration, are subject to agency specific regulations. These regulations set forth the obligations of investigators, sponsors and institutions for research involving significant financial or other conflicts of interest, and affected parties are advised to review the relevant regulations prior to submission of a research proposal or application.

a. "Investigator" means the principal investigator, co-investigator and any other research person, whether faculty, staff, research associate, technicians, nurse coordinators, administrators, collaborators, consultants or student, who is responsible for the design, conduct, or reporting of research or educational activity proposed for funding. "Investigator" also includes the investigator's spouse, domestic partner, and dependent children.

b. "Institutional official" means the Chief Executive Officer, Chief Medical Director, Deputy Chief Executive Officer, Chief Information Officer, Chief Financial Officer, Medical Director, Hospital Administrator, Compliance Director, Unit Heads, Department Heads, Heads of Centers and programs

c. "Outside obligations/activities" involves work, either professional or non-professional, for a non-LSU HCSD facility or for oneself. Outside professional obligations involve the use of employees' expertise, the practice of their profession, or any activity that contributes to the employees' professional competence and development

d. "Non-Financial Conflict of Interest" occurs when an Investigator's or Immediate Family Member's role in the University or other outside activities compromise or have the appearance of compromising an Investigator's professional judgment in proposing, conducting, supervising, or reporting research or come into conflict with an Investigator's primary commitment to maintain scientific objectivity.

Non-Financial Interest includes, but is not limited to:

- Conflicts of Commitment regarding Time and Effort; and
- Using a student to perform services for a company in which the Investigator or Immediate Family Member has an ownership or management role when (1) the student is currently enrolled in the Investigator's or Immediate Family Member's class or (2) the Investigator or Immediate Family Member currently supervises the student in an academic capacity; or (3) the Investigator or Immediate Family Member otherwise has the ability to influence the academic progress of the student.

e. "Significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (patents, copyrights, and royalties from such rights) held by an investigator or the investigator's immediate family, individually or in aggregate, when such interest involves:

- 1) Payments in excess of \$10,000 (including salary, consulting fees, royalty or licensing payments from intellectual property, and honoraria and/or gifts) received within the past 12 months or anticipated for the next 12 months (excluding salary and other payments for services from LSU HCSD);
- 2) An equity interest in a publicly traded company worth more than \$10,000 or more than 5 percent of the business entity as determined by reference to its publicly listed price (excluding mutual funds);

- 3) Any equity interest if the value cannot be determined by reference to publicly listed prices (i.e., an equity interest in a privately held company, such as a start-up company);
- 4) A position giving rise to a fiduciary duty, such as director, officer, partner, trustee, employee, or any other position of management; or
- 5) Intellectual property rights (patents or copyrights) or royalties from such rights whose value may be affected by the outcome of the research, including royalties distributable under LSU HCSD policy, LSU HSC policy or any royalty-sharing agreements involving LSU HCSD.

DISCLOSURE OF SIGNIFICANT FINANCIAL INTEREST IN RESEARCH

LSU HCSD investigators holding a significant financial interest as defined above must disclose this interest *in writing prior to submission of a grant application or contract or, for non-sponsored research, prior to initiation of the activity*. The research may not begin until LSU HCSD Institutional officials have reviewed the disclosure and all parties have agreed to any necessary management strategies. If a new significant financial interest is created or if a new investigator with a significant financial interest is hired to work on the research project, HCSD Significant Financial Interest disclosure form must be completed and that interest must be disclosed within 60 days.

When a significant financial interest exists:

- 1) The investigator must submit a PM 11 form, Significant Financial Interest Disclosure Form, and all supporting documentation attached to the Research Oversight Committee (ROC) of the Investigator's facility with a copy to the Chief Medical Officer, LSU HCSD Executive Administration when submitting a grant or contract proposal.
- 2) Disclosures for non-sponsored research shall be made to the ROC and the Chief Medical Officer HCSD LSU HCSD Executive Administration prior to initiating the research.
- 3) Any change in the nature or amount of the interest must be reported within 30 days.
- 4) Investigators who have submitted an initial disclosure will receive an annual request to update or confirm the status of their financial interest.
- 5) All conflicts of interest arising from a significant financial interest must be reviewed and a management strategy fully developed and in place prior to initiation of the research or expenditure of funds.

REVIEW AND MANAGEMENT PROCESS

LSU HCSD the Chief Medical Officer, HCSD facility Compliance Officer and the Institutional official or his/her designee, shall conduct an initial review of all financial disclosures to determine whether or not a potential conflict of interest exists. If the initial determination is made that there may be a potential for conflict of interest covered by this policy, then the Disclosure packet will be referred to ROC and the Institutional official of the relevant HCSD facility. The LSU HCSD the Chief Medical Officer, the Principal Investigator and disclosing investigators will be informed whether any disclosures have been forwarded for review.

If a disclosure is forwarded to the LSU HCSD the Chief Medical Officer, the Investigator, in cooperation with the ROC, HCSD facility Institutional officials, shall promptly develop and present to LSU HCSD the Chief Medical Officer a Conflict of Interest Management Plan that details proposed steps that will be taken to manage, reduce, or eliminate actual or potential conflict of interest presented by a significant financial interest. At a minimum the Management Plan shall address such issues as:

- a. Public disclosure of significant financial interests
- b. Review of research protocol by independent reviewers
- c. Monitoring of research by independent reviewers

The ROC shall review the Management Plan and as appropriate, approve it, disapprove it, add conditions or restrictions, including, but not limited to the following.

- a. Modification of the research plan
- b. Disqualification of the investigator with the conflict from participation in all or a portion of the research
- c. Divestiture of significant financial interests
- d. Severance of relationships that create actual or potential conflicts of interest
- e. Disclosure of the conflict to the sponsor

If the ROC determines that imposing specific conditions or restrictions would be inequitable, or that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the ROC may, in exceptional circumstances, recommend that, to the extent permitted by federal regulations, the research go forward without imposing such conditions or restrictions.

Collaborators from other institutions must either comply with this policy or provide a certification that their institutions are in compliance with federal policies regarding investigator significant financial interest disclosure and that their portion of the project is in compliance with their institutional policies.

REPORTING REQUIREMENTS-PHS funded research only

Prior to LSU HCSDs expenditure of any funds under a PHS-funded research project, the LSU HCSD Chief Medical Officer 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 the facility ROC to be conflicting and ensure that a Conflict of Interest Resolution Management Plan has been implemented.

For any Significant Financial Interest identified by LSU HCSD as a conflict subsequent to the initial FCOI report, the LSU HCSD Chief Medical Officer shall provide to the PHS Awarding Component, within sixty (60) days, a FCOI report regarding the Financial Conflict of Interest and ensure that a Conflict of Interest Resolution Management Plan has been implemented.

CONSEQUENCES

It is critical that all parties involved in conducting research activities in HCSD facilities understand that a violation of this policy could result in research being interrupted until the conflict of interest is resolved. Any violation of this policy will subject the employee to appropriate disciplinary action, up to and including termination of employment. Because a violation of this policy could be a violation of the Code of Ethics for Public Employees, a referral to the Ethics Board will be warranted as well.