I. Purpose and Policy Statement

Ochsner Health System ("Ochsner") recognizes that productive synergies and partnerships between its investigators and outside entities, when undertaken responsibly, can further scientific innovation and translate it to improved clinical care. Ochsner is also committed to conducting research with integrity and free from outside interests that might compromise or influence the judgment of the investigators, potentially undermining the objectivity of the research. This policy informs Covered individuals of requirements to disclose certain financial interests that might create a conflict for their research and establishes procedures for Ochsner to ensure that such interests are appropriately reviewed, any identified financial conflicts of interest managed, and any obligations to report to the government met.

II. Scope

This policy applies to anyone who meets the definition of “covered individual” and applies to all Ochsner activities meeting the definition of research regardless of funding and regardless of whether or not the research involves human subjects. Designated provisions of the policy apply only to those investigators applying for or conducting research funded by the Public Health Service (PHS) (including the National Institutes of Health). Covered individuals who conduct studies funded by the Food and Drug Administration or other agencies, including the National Science Foundation, should review the agency-specific regulations relating to financial conflicts of interest prior to submission of a research proposal or application and are required to be in compliance with all applicable regulations and requirements.

III. Definitions

A. Covered individual: a covered individual includes investigators for all research conducted under the auspices of Ochsner, including research that is funded through Ochsner or conducted under the aegis of the Ochsner IRB.

B. Disclosure: an investigator’s disclosure to Ochsner of those financial interests related to his or her institutional responsibilities and identified on the Ochsner Research Conflict of Interest Disclosure Form.

C. Entity: a for-profit or non-profit organization, whether private or governmental.

D. Financial conflict of interest: a significant financial interest that is related to proposed Ochsner research (i.e. the interest reasonably appears to be affected by the research or is an entity whose financial interest reasonably appears to be affected by
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the research) and that reasonably could be determined to directly and significantly affect the design, conduct, or reporting of the research.

E. Human subjects research: research conducted with a living individual about whom an investigator obtains data through intervention or interaction with the individual or identifiable private information.

F. Institution: Ochsner, its divisions, centers and institutes and any other constituent parts.

G. Institutional responsibilities: the responsibilities and roles investigators are assigned in the course of their employment at Ochsner. This includes, for example, clinical practice, teaching, research, administrative roles, and committee service.

H. Investigator: the project director or principal investigator and any other person responsible for the design, conduct or reporting of research. This definition includes collaborators and consultants, and study team members identified on IRB applications. This definition is independent of whether one is employed by Ochsner.

I. Manage: take action to address a financial conflict of interest, which includes reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research are free from bias.

J. Research: a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge and encompasses basic and applied research and product development.

K. Senior/key personnel: a PHS project director or principal investigator and any other individual who contributes to the scientific development or execution of a project in a substantive, measurable way, and who is included in the grant application, progress report, or any other report submitted by the institution, whether or not they receive salaries or compensation under the grant.

L. Significant financial interest: any financial interest held by an investigator (and by the investigator’s spouse and dependent children) that reasonably appears to be related to the investigator’s institutional responsibilities, and that consists of one or more of the following interests:

1. With regard to any publicly traded entity, remuneration received from the entity in the rolling twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5000. This includes salary and any payment for services not otherwise identified as salary (honoraria, consulting fees, paid authorship). Equity includes stock, stock option, or other ownership interest as determined through reference to public prices or other fair market value measures;
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2. With regard to any non-publicly traded entity, the value of any remuneration received from the entity in the rolling twelve months preceding the disclosure, when aggregated, exceeds $5000, or any equity interest (stock, stock option, or other ownership interest);

3. Intellectual property rights and interest, upon receipt of income related to such rights and interests, to the extent the income (alone or when aggregated with other disclosed SFIs in the same company) exceeds $5000; or

4. For investigators applying for or conducting research funded by the PHS, any reimbursed or sponsored travel (i.e. travel 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 the investigator’s institutional responsibilities. Disclosure of this interest will include the purpose and duration of the trip, the identity of the sponsor/organizer, and the travel destination. Only those travel payments that exceed $5,000, to the extent the value is known or knowable, will constitute a significant financial interest.

5. The term “significant financial interest” does not include: salary, royalties or other remuneration paid by Ochsner to the investigator if the investigator is currently employed or working at Ochsner, including intellectual property rights assigned to Ochsner and agreements to share in royalties related to such rights; any ownership interest in the institution receiving the federal funds held by the investigator, if the institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions; income from seminars, lectures, teaching engagements sponsored by, or travel sponsored or reimbursed by, a federal, state or local government agency, institution of higher education, or academic teaching hospital, medical center, or 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, institution of higher education, academic teaching hospital, medical center, or a research institute that is affiliated with an institution of higher education.

IV. Procedures/Standards and Roles & Responsibilities

A. Obligations of Covered Individuals to Disclose Information to Ochsner

1. Covered individuals must make disclosures to Ochsner of significant financial interests in accordance with the instructions and questions on the annual Research Conflict of Interest Disclosure Form, which is a subsection of the annual Conflict of
Interest Disclosure Form. The annual disclosure is due by July 30 of each year and seeks information from all covered individuals related to their interests and roles in various external organizations; a subset of that information will be relevant to a covered individual’s conduct of research under this policy. The project-specific disclosure form is included in the funding or research application and is due prior to the earliest of (i) submission of a grant application or (ii) application to the IRB to conduct human subjects research or (iii) execution of a sponsored research contract for research that is neither federally funded or human subjects research and covered by (i) or (ii). The Conflict of Interest Committee and the Compliance and Privacy Department will review any financial interest disclosed through the annual or project-specific forms as further described below but before the expenditure of any sponsored research funds or the commencement of departmentally funded research.

2. Each investigator who submits a Research Conflict of Interest Disclosure Form is required to update the disclosure annually during the period of the award or, for non-sponsored research, annually during the conduct of the project. Annual updates must be submitted by July 30 of each year.

3. When an investigator discovers or acquires a new significant financial interest in an ongoing research project, the investigator is required to update the disclosure describing that interest within 30 days.

4. When a new investigator is added to an existing project, the investigator is required to disclose within 30 days any financial interests that are not already on file with the institution through the Research Conflict of Interest Disclosure Form and may not commence work on the project until cleared to do so.

B. Review by the Compliance and Privacy Department and the Research Conflict of Interest Committee

1. Prior to the investigator’s expenditure of any sponsored research funds, or prior to the initiation of the research in the case of research with no external funding, Ochsner will review disclosed financial interests and make the following determinations.

   a. Determination of significant financial interest: The AVP for Research Compliance, in consultation with the Research Conflict of Interest Committee as necessary, will review the investigator’s disclosures to confirm which ones constitute significant financial interests.

   b. Determination of relatedness: For any significant financial interests identified, the AVP for Research Compliance, in consultation with the Research Conflict of Interest Committee as necessary, will evaluate the significant financial interest to reasonably determine whether it (i) could be affected by the investigator’s
proposed research; or (ii) is in an entity whose financial interest could be affected by the research.

c. Determination of financial conflict of interest: Upon concluding that one or more disclosed financial interests constitutes a significant financial interest that is related to the investigator’s proposed research, the AVP for Research Compliance, in consultation with the Research Conflict of Interest Committee, will determine whether a financial conflict of interest exists and thus further review and management is required.

2. No member of the Research Conflict of Interest Committee or the Compliance and Privacy Department who holds a significant financial interest related to a project may participate in the review of an investigator’s interests, determination of whether any financial conflict of interests exist, or development of a management plan for the project.

3. Research Conflict of Interest Committee meetings are closed to the public.

C. Management of Identified Financial Conflicts of Interest

1. Where a financial conflict of interest is determined to exist, the AVP for Research Compliance and the Research Conflict of Interest Committee will, prior to the investigator’s expenditure of any sponsored research funds, or prior to the initiation of the research in the case of research with no external funding, develop a management plan that specifies the actions that have been or will be taken to manage the financial conflict of interest.

2. Management strategies may include:
   a. Public disclosures of financial conflicts of interest (when publishing or presenting the research);
   b. For human subjects research, disclosure of financial conflicts directly to participants;
   c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
   d. Modification of the research plan;
   e. Change of personnel or personnel responsibilities or disqualification of personnel from participation in all or a portion of the research;
   f. Reduction or elimination of the financial interest; and
   g. Severance of relationships that cause actual or potential financial conflicts.
3. In cases where Ochsner has determined that a financial conflict of interest exists, no research funds may be expended and no research may begin until the investigator has agreed in writing to a management plan.

4. Where a determination is made that a financial conflict of interest does not exist (either because a disclosed financial interest is not a significant financial interest, an identified significant financial interest is not related to the research, and/or an identified related significant financial interest does not rise to the level of creating a financial conflict of interest) Ochsner nonetheless retains the authority to evaluate disclosed financial interests and other information available through the Conflict of Interest Disclosure Form on a case-by-case basis and impose any conditions on the conduct of the research (for example, transparency obligations or other additional protections related to the conduct of the research) that it deems are warranted by the circumstances.

D. PHS funded research: for research sponsored by the PHS, Ochsner will apply the following specific provisions:

1. Reporting to PHS Funding Agency: prior to the expenditure of PHS-awarded funds, if a financial conflict of interest is determined to exist and is not eliminated Ochsner will report to the relevant funding agency with sufficient information to enable the agency to understand the nature and extent of the financial conflict and to assess the appropriateness of Ochsner’s management plan. Elements of the financial conflicts of interest report should include at least the following:
   a. Project number;
   b. Project director/principal investigator;
   c. Name of the investigator with the financial conflict of interest;
   d. Name of the entity with which the investigator has a financial conflict of interest;
   e. Nature of the financial interest;
   f. Value of the financial interest using dollar ranges or a statement that the interest is one whose value cannot readily be determined through reference to public prices or other reasonable measures of fair market value;
   g. A description of how the financial interest relates to the PHS-funded research and the basis for Ochsner’s determination that a financial conflict of interest exists; and
   h. A description of the key elements of the management plan.

2. Monitoring: the investigator’s management plan will be monitored on an ongoing basis until the completion of the research.
3. Subrecipients: Ochsner will incorporate as part of a written agreement with the subrecipient terms that establish whether the subrecipient or Ochsner’s conflict of interest policy will apply to the subrecipients. If the subrecipient’s policy applies, the subrecipient will certify that the policy complies with PHS regulations on Objectivity in Research.

4. Retrospective review: in the event Ochsner identifies a significant financial interest that was not disclosed in a timely manner by an investigator or was not previously reviewed by Ochsner during an ongoing research project, the Research Conflict of Interest Committee will, within 60 days of identifying the significant financial interest: review the interest to determine whether it is related to the PHS-funded research and whether it constitutes a financial conflict of interest and, if so, implement a management plan for the project. In addition, within 120 days of its determination of noncompliance, Ochsner will complete a retrospective review of the investigator’s research activities associated with the project to determine whether the research conducted during the period of noncompliance was biased in the design, conduct or reporting of such research.

5. Mitigation plan: during the retrospective review described above, if Ochsner determines that any part of the research was biased, the Research Conflict of Interest Committee will recommend a mitigation plan to the Vice President for Research to address any such issues. Ochsner will notify the PHS Awarding component of its determination and subsequently follow up with the mitigation report for the project.

6. Public Access of disclosed significant financial interest: upon written request to the AVP for Research Compliance, Ochsner will make available to the requestor within 5 business days of the AVP’s receipt of the request information concerning any significant financial interest that meets the following criteria:
   a. The disclosed significant financial interest is still held by the senior/key personnel of the active PHS project;
   b. Ochsner determines that the significant financial interest is related to the PHS funded research; and
   c. Ochsner determines that the significant financial interest is a financial conflict of interest.

E. Appeal: any investigator may appeal the decision of the AVP of Research Compliance regarding a financial conflict of interest in writing to the Vice President of Research and Academics and thereafter to the Chief Executive Officer of Ochsner. The decision of the Chief Executive Officer with respect to a financial conflict of interest is final and may not be challenged by the investigator.
F. Completion of Conflict of Interest Training:

1. Covered individuals must complete Ochsner Conflict of interest training.
   a. When training must be completed:
      i. Prior to engaging in research at Ochsner.
      ii. At least every four years.
   b. Training also must be completed when:
      i. Ochsner revises the conflict of interest policy in a significant way.
      ii. A covered individual is new to Ochsner.
      iii. Ochsner determines that a covered individual is not in compliance with this policy or his/her assigned management plan.
   c. How training should be completed:
      i. Via OLN or as specified.

G. Administration of the Policy; Records

1. The Chief Executive Officer will appoint a designated conflict officer who is responsible for overseeing implementation of this policy and who may implement additional procedures and complementary forms, as appropriate.

2. Records regarding disclosure and management of conflicts will be retained for the longer of three years after:
   a. The date of creation;
   b. The date of termination or completion of a research award or contract, or the submission of the final expenditures report, for research identified in a disclosure statement; or
   c. The date of final resolution of any investigation, audit or similar action involving the records.

3. Ochsner will provide for a central repository for financial interest statements, management plans, and related records.

4. This policy will be available on the Ochsner website or by request.

V. Enforcement and Exceptions

Noncompliance: failure to file a complete and truthful disclosure as required by this policy or to comply with conditions and restrictions imposed in the resolution,
management or elimination of financial conflicts of interest constitutes a violation of Ochsner policy and may violate state or federal law. In such cases, Ochsner may impose sanctions upon the investigator, consistent with Ochsner policies. In addition, Ochsner may suspend an ongoing research policy, halt the expenditure of funds, or suspend technology transfer activity to prevent continued violation of this policy. In any case in which the investigator does not comply with any applicable conditions or restrictions imposed pursuant to this policy, Ochsner will withdraw any affected applications for funding if the project cannot otherwise be completed without the services of the investigator. In the event Ochsner determines that the failure to comply with this policy has biased the design, conduct or reporting of the research, Ochsner will promptly notify the sponsor as required by applicable law and describe the corrective actions to be taken.

VI. Internal References

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VII. External References

42 CFR Part 50, Subpart F 45
CFR part 94

VIII. Policy History

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IX. Approved

Warner Thomas, President and Chief Executive Officer
Michael Hulefeld, Executive Vice President and System Chief Operating Officer
Pete November, General Counsel and Senior Vice President of Corporate Compliance

Reviewers

Research Conflict of Interest Committee