

	Policy	
	APPROVAL DATE: 02/23/2021	APPROVER: Tracey Schiro, Warner Thomas
APPLICABLE TO: Ochsner Baptist, Ochsner Health, Ochsner St. Anne, Ochsner St. Mary, OLG - Abrom Kaplan, OLG - Acadia General, OLG - American Legion, OLG - Lafayette General Medical Center, OLG - St. Martin Hospital, OLG - University Hospital and Clinics, OMC Baton Rouge, OMC Hancock, OMC Kenner, OMC New Orleans, OMC West Bank		

Research Conflict of Interest

I. Purpose

This policy informs Covered Individuals of requirements to disclose certain financial interests that may create a conflict for their research and establishes procedures for Ochsner Health to appropriately review such interests, manage any identified Financial Conflicts of Interest, and meet any obligations to report to the government and other research sponsors.

II. Scope

This policy applies to (i) Ochsner Health, (ii) Ochsner Clinic Foundation, and/or (iii) all facilities and entities wholly-owned and/or leased by Ochsner Clinic Foundation (“Ochsner”).

III. Definitions

- A. Conducting Research - includes designing Research, directing or serving as an Investigator, performing laboratory experiments, having a role in soliciting consent from Research subjects or making decisions related to eligibility of patients to participate in Research, analyzing or reporting research data, or submitting manuscripts or abstracts concerning the research for publication. Examples include, but are not limited to, projects for which outside support is requested and projects for which approval of an Institutional Review Board (IRB) is required. For purposes of this policy, the determination of what constitutes Research and what constitutes the Conduct of Research will be made by the appropriate Research Conflict of Interest committee.
- B. Covered Individual - includes Investigators for all Research conducted under the auspices of Ochsner, including Research that is funded through Ochsner or conducted under the supervision of the Ochsner IRB.
- C. 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.
- D. Entity - a for-profit or non-profit organization, whether private or governmental.

- E. 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 the Research) and that reasonably could be determined to directly and significantly affect the design, conduct, or reporting of the Research.
- F. Human Subjects Research - includes all Research meeting the definition of research performed with human subjects as these terms are defined in the Federal Common Rule and subsequent amendments, regardless of the source of research funding or whether the research is otherwise subject to federal regulation.
- G. Institution - means Ochsner and all its divisions, units, and constituent entities.
- H. Institutional Responsibilities - the responsibilities and roles Investigators are assigned in the course of their employment or contract at Ochsner. This includes, for example, clinical practice, teaching, Research, administrative roles, and committee service.
- I. Institutional Review Board (IRB) - An independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects
- J. Investigator - the project director or principal investigator and any other person responsible for the design, conduct or reporting of research, including collaborators and consultants, and study team members identified on IRB applications. This definition is independent of whether one is employed by Ochsner.
- K. Research - a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The definition encompasses basic and applied research and product development.
- L. Significant Financial Interest (SFI) - 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 last calendar year up to the time of Disclosure and the value of any equity interest in the Entity as of the date of Disclosure, when aggregated, exceeds \$5,000. 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;
 - 2. With regard to any non-publicly traded Entity, the value of any remuneration received from the entity in the last calendar year up to the time of Disclosure, when aggregated, exceeds \$5,000, 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 Significant Financial Interests (SFIs) in the same company) exceeds \$5,000; or
4. For Covered Individuals applying for or Conducting Research funded by the Public Health Service (PHS), any reimbursed or sponsored travel (i.e. travel is paid on behalf of the Covered Individual and not reimbursed to the Covered Individual so that the exact monetary value may not be readily available) related to the Covered Individual'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. Further, the disclosure requirement does not apply to travel reimbursed or sponsored by a government agency, and Institute of Higher Education as defined at 20 U.S.C. 1001(a), or an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.
5. Significant Financial Interest does not include: salary, royalties or other remuneration paid by Ochsner to the Covered Individual if the Covered Individual 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 Covered Individual, 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 Covered Individual 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. Policy Statements

Ochsner recognizes that productive interactions and partnerships between its Covered Individuals 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 Covered Individuals, potentially undermining the objectivity of the research.

This policy applies to Covered Individuals as defined in this policy and applies to all Ochsner activities of Research as defined in this policy 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 PHS (including the National Institutes of Health). Covered Individuals who conduct studies funded by the Food and Drug Administration, or other federal agencies or sponsors, should review the award terms and sponsor-specific policies and 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.

V. Policy Implementation

A. Obligations of Covered Individuals to Disclose Information to Ochsner

1. By July 31st of each year, Covered Individuals must certify compliance with Ochsner's Conflict of Interest policies and, if applicable, disclose Significant Financial Interests through a designated secure database (eCOI), which will provide instructions for completion of the process. The annual certification and Disclosure procedure 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.
2. Covered Individuals who conduct Research at Ochsner must also submit project-specific financial Disclosures in accordance with and as prescribed by the Research funding and IRB application processes. These Disclosures are 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 does not constitute federally funded research or Human Subjects Research covered by (i) or (ii). When a new Covered Individual is added to an existing project, the Covered Individual must Disclose, in accordance with and as prescribed by the Research application and IRB amendment processes, any financial interests that are not already on file with the Institution. The new Covered Individual must make these Disclosures within 30 days of being added and may not commence work on the project until cleared to do so.
3. Each Covered Individual is required to update project-specific financial Disclosures annually during the period of the award or, for non-sponsored Research, annually during the conduct of the project. Annual updates will be submitted through the eCOI database by July 31st of each year.
4. When a Covered Individual discovers or acquires a new Significant Financial Interest in an ongoing Research project, the Covered Individual must update the Disclosure describing that interest through the eCOI database within 30 days.
5. The Compliance and Privacy department, in consultation with the Research Conflict of Interest Committee as necessary, will review any financial interest Disclosed through the annual or project-specific processes, as further described below, but before the expenditure of any sponsored Research funds or the commencement of departmentally funded Research.

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

1. The Chair of the Research Conflict of Interest Committee is the designated official responsible for soliciting and reviewing disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities.

2. Prior to the Covered Individual'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: Compliance and Privacy, in consultation with the Research Conflict of Interest Committee as necessary, will review the Covered Individual's Disclosures to confirm which ones constitute Significant Financial Interests.
 - b. Determination of relatedness: For any Significant Financial Interests identified, Compliance and Privacy, 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 Covered Individual'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 Covered Individual's proposed Research, Compliance and Privacy, in consultation with the Research Conflict of Interest Committee, will determine whether a Financial Conflict of Interest exists, requiring further review and management.
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 Covered Individual's interests, determination of whether any Financial Conflicts of Interest 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, Compliance and Privacy and the Research Conflict of Interest Committee will, prior to the Covered Individual'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 plan 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 Covered Individual 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

1. If a Financial Conflict of Interest is determined to exist and is not eliminated, Ochsner will report to the relevant PHS funding agency with sufficient information to enable the agency to understand the nature and extent of the Financial Conflict of Interest and to assess the appropriateness of Ochsner's management plan in the following scenarios:
 - a. Prior to the expenditure of funds
 - b. Within 60 days of identification for an Investigator who is newly participating in the project
 - c. Within 60 days for new, or newly identified, FCOIs for existing Investigators
 - d. At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
 - e. Following a retrospective review to update a previously submitted report, if appropriate.
2. Elements of the Financial Conflicts of Interest report should include at least the following:
 - a. Project number;
 - b. Project Title;

- c. Project director/principal Covered Individual;
 - d. Name of the Covered Individual with the Financial Conflict of Interest;
 - e. Name of the entity with which the Covered Individual has a Financial Conflict of Interest;
 - f. Nature of the financial interest;
 - g. Value of the financial interest using dollar ranges or a statement that the interest is one, the value of which cannot readily be determined through reference to public prices or other reasonable measures of fair market value;
 - h. 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
 - i. A description of the key elements of the management plan.
3. Monitoring: The Covered Individual's management plan will be monitored on an ongoing basis until the completion of the Research.
 4. Subrecipients: Ochsner will incorporate as part of a written agreement with the subrecipient terms that establish whether the subrecipient's or Ochsner's Research 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.
 5. Retrospective Review: in the event that the Covered Individual fails to comply with a management plan or if Ochsner identifies a Significant Financial Interest that was not Disclosed in a timely manner by an Covered Individual 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. At the discretion of the Research Conflict of Interest Committee, Ochsner will complete, within 120 days of its determination of noncompliance, a retrospective review of the Covered Individual'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. Retrospective review should include at least the following:
 - a. Project number;
 - b. Project title;
 - c. Investigator or contact Investigator if a multiple Investigator model is used;
 - d. Name of the Covered Individual with the Financial Conflict of Interest;
 - e. Name of the entity with which the Covered Individual has a Financial Conflict of Interest;

- f. Reason(s) for the retrospective review;
 - g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - h. Findings of the review; and
 - i. Conclusions of the review.
6. 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 Ochsner IRB 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.
7. Public Access of Disclosed Significant Financial Interest: Ochsner will disclose in each public presentation of the results of the research, and request an addendum to previously published presentations when there is any Significant Financial Interest that meets the following criteria:
- a. The Disclosed Significant Financial Interest is still held by the Covered Individual 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 Covered Individual may appeal the decision of Compliance & Privacy regarding a Financial Conflict of Interest in writing to the Vice President and Chief Compliance Officer and thereafter to the Executive Vice President and Chief Administrative Officer of Ochsner. The decision of the Chief Executive Vice President and Administrative Officer with respect to a Financial Conflict of Interest is final and may not be challenged by the Covered Individual.
- F. Completion of Conflict of Interest Training:
- 1. Covered Individuals will complete Ochsner Conflict of Interest training.
 - a. Training will be complete prior to engaging in Research at Ochsner, in compliance with federal regulation;
 - b. At least every four years;
 - c. Training also will be completed when:
 - i. Ochsner revises the Conflict of Interest policies 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.

d. How training should be completed:

i. Via the Organization's Learning Management System or as specified.

G. Administration of the Policy; Records:

1. Compliance and Privacy is responsible for overseeing implementation of this policy and 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 internal policy database or by request.

H. In addition, Ochsner may suspend an ongoing Research protocol, halt the expenditure of funds, or suspend technology transfer activity to prevent continued violation of this policy.

I. In any case in which the Covered Individual 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 Covered Individual. 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. Enforcement

Failure to comply with this policy may result in progressive discipline up to and including termination of employment for employees or termination of contract or service for third-party personnel, students or volunteers. Additionally, Ochsner is required to notify PHS, if applicable, and take corrective action for noncompliance with this policy or related management plans.

VII. Attachments

This section intentionally left blank.

VIII. References

42 CFR Part 50, Subpart F 45

42 CFR part 94

45 C.F.R. Part 46 and 21 C.F.R. Part 56

IX. Policy History

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