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UNIVERSITY POLICIES & PROCEDURES

Category:	Compliance Administration
Title:	**CONFLICTS OF INTEREST POLICY FOR EMPLOYEES**
Applicability:	Thomas Jefferson University
Contributors/Contributing Departments:	

POLICY[1]

One of the primary responsibilities of the Board of Trustees and the Senior Officers is to safeguard the tangible and intangible assets of Thomas Jefferson University ("TJU"). In this regard, systems of internal review are established to ensure that the University's objectives are not compromised by the actions of any employee or faculty member. As part of a system of internal review, the Statement of Principles Regarding Avoidance of Conflicts of Interest for Employees of Thomas Jefferson University (Attachment 1) (the "Statement") was developed.

In order to ensure understanding of the Statement and the corresponding policies and procedures, all newly hired employees will be provided with, and shall read, a copy of the Statement. The Statement is intended to serve as a guide for all "covered individuals" (See definition in Attachment 2) in structuring their relationships with industry and other outside ventures in view of their academic responsibilities for teaching, research, and patient care, as well as relevant federal regulations, including 42 CFR Part 50, Subpart F-Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and 45 CFR, Subtitle A, Part 94-Responsible Prospective Contractors. All covered individuals are expected to make reasonable inquiry as to whether their relationships and activities fall within the provisions of the Statement and the corresponding policies and procedures. It is the intent of the University to enable covered individuals to recognize situations that may be subject to question and ensure that such situations are properly reviewed and, if necessary, eliminated, reduced, or managed.

1. The following Policy and Procedure should be read in light of the Operating Definitions set forth in Attachment 2.

PROCEDURE

Initial and Annual Disclosure
An integral part of this Policy is a disclosure mechanism whereby covered individuals regularly review and disclose to the University their financial interests that would appear to be reasonably related to their institutional responsibilities (See definition in Attachment 2). At the time of hiring or appointment and thereafter on an annual basis, all covered individuals must submit a Disclosure of Conflicts of Interest ("Disclosure") disclosing any such financial interests.

Covered individuals may submit required Disclosures via JEFF-COI-SMART, a web-based application that enables users to quickly and conveniently submit Jefferson's required Financial Conflicts of Interest Disclosure Forms. COI-SMART maintains electronic copies of all Conflict of Interest submissions, and, for your convenience, COI-SMART will auto-populate previously submitted information to minimize the need for reentry of the same information year after year. Most importantly, COI-SMART's security controls ensure that the information disclosed is maintained securely and privately. The Institutional Conflicts of Interest Officer and her/his delegates will utilize the Jeff-COI-Smart system to support the advancement of innovation while protecting the integrity of Jefferson's research processes and activities.

Jefferson community members with campus keys: Click here to access the secure COI-Smart platform to review or update your disclosure.

Jefferson Board members and external researchers: Click here to access the secure COI-Smart platform to review or update your disclosure.

Continuing Obligation to Disclose
If at any time between disclosure periods, an individual becomes aware of a change in his/her financial circumstances that would appear to be reasonably related to their institutional responsibilities, the situation must be disclosed to the person's supervisor and through Jeff-COI-Smart at the earliest possible time. When an individual is uncertain whether a particular situation might present a potential conflict, disclosure should occur to enable the COI Officer to evaluate the relationship or interest.

Standing Committee on Conflicts of Interest and Commitment
The President has appointed a standing University committee responsible for implementation and oversight of this Policy, including developing procedures for implementing the disclosure and approval process and the establishment of oversight protocols, and to assure that the Policy is applied consistently to all covered individuals. The COI Committee ("Committee") is also charged with the handling of cases involving noncompliance and breach, and determination of subsequent disciplinary actions.

The President shall appoint members of the Committee. The Committee shall be comprised of individuals who actively conduct clinical and/or basic research; two University lay members; one non-University lay member; the COI Officer (who will serve *ex officio* with voting privileges); and the University's Research Compliance Officer, (who will serve *ex officio* without voting privileges). With the exception of the COI Officer and the Vice President for Research, Committee members will serve staggered terms of two (2) to five (5) years, with reappointment at the discretion of the President. The Committee will meet at least twice annually and additionally on an interim basis as required, and may conduct business electronically when deemed appropriate.

Disclosure Review Process

COI Officer Review

The COI Officer is responsible for overseeing the implementation of the Policy by the Committee and the process and mechanism for disclosure, confirming compliance by all covered individuals with the University's Conflicts of Interest policies. The COI Officer reviews all breaches of the disclosure process, including but not limited to (a) failures to comply with the process, whether by virtue of a covered individual's refusal to respond or by his/her responding with incomplete, or knowingly inaccurate, information; and (b) failures to comply with the Committee's determinations. The COI Officer refers such cases to the Committee in accordance with the University's Policy on Enforcement and Sanctions for Non-Compliance (No. 107.18).

Following the disclosure period, the COI Officer reviews each Disclosure in order to determine whether any reported financial interests constitute a significant financial interest (See definition in Attachment 2). In such cases, the COI Officer shall further determine whether the significant financial interest may constitute a financial conflict of interest (See definition in Attachment 2). In such cases, the COI Officer will refer the matter to the Committee for further review and to determine if, indeed, a financial conflict of interest exists. As necessary, the COI Officer (or his/her designee) may request, and the covered individual is required to provide, additional information to clarify certain conflict situations. If an individual has any questions concerning the Disclosure, the Statement, or any requested additional information, s/he should discuss these questions with the COI Officer. Disclosures will be considered strictly confidential and the information disclosed therein will be made available only to those individuals duly charged with the responsibility for review and oversight of the implementation of the University's Conflicts of Interest policies, or as otherwise stated in this Policy or other University policies.

COI Committee Review
The Committee will review all potential conflicts that are brought to its attention by the COI Officer and make determinations as to whether an actual financial conflict of interest exists and if so, whether and how it may be eliminated, reduced or managed. In conducting its review, the Committee will presume that, in the absence of compelling circumstances, an individual having a significant financial interest that is determined to be a financial conflict of interest ("conflicted individual") may not engage in the research or activity in question ("the rebuttable presumption against financial conflict of interest"). This presumption does not suggest that every financial interest jeopardizes the integrity of research or the welfare of human subjects or an individual's fidelity in the performance of his/her job responsibilities, but rather ensures the systematic disclosure, review and treatment of any financial interest that might give rise to the perception of a conflict of interest.

If the Committee determines that an individual with a significant financial interest is deemed to have a financial conflict of interest, and thus is presumptively prohibited from conducting the research or engaging in the activity in question, the conflicted individual will be afforded the opportunity to rebut the presumption, either in writing or in-person, by demonstrating compelling circumstances for conducting the research or engaging in the activity despite the conflict. The Committee will review any request by a conflicted individual to rebut the presumption that s/he may not participate in a particular activity.

Exception for Compelling Circumstances
If the Committee determines that compelling circumstances exist based on the conflicted individual's rebuttal, the individual may be permitted to conduct the research or engage in the activity subject to conditions and/or restrictions discussed below. Whether the circumstances are deemed compelling will depend, in each case, upon the nature and magnitude of the interest, the degree to which the

interest is related to the research or activity, the extent to which the interest may be directly and substantially affected by the research or activity, whether the individual holding an interest is uniquely qualified by virtue of expertise and experience to perform the research or engage in the activity, as well as other facts that would justify allowing him/her to conduct the research or engage in the activity in question, despite the existence of the conflict.

The individual may also suggest procedures, protocols, or other measures designed to manage, reduce, or eliminate the conflict, and the extent to which the interest is amenable to effective oversight and management. In the research context, the circumstances to be considered also include the nature of the science, the degree of risk to any human subjects involved in the research protocol, and whether the research could not be conducted as safely or effectively without the conflicted individual. When the financial interest is directly related to the research or activity and may be substantially affected by it, (e.g., an equity interest in a start-up company that manufactures the investigational product being studied), the risk is greatest and the standard must be high; however, even a direct and potentially lucrative financial interest may be justified in some circumstances.

Management and Oversight

After reviewing the relevant facts and documenting the compelling circumstances, the Committee may recommend that the research or activity may be conducted subject to conditions and/or restrictions (a “conflicts management plan”) that ensure effective management of the conflict and credible oversight of the research or activity. The President must review and approve any recommendations made by the Committee, including the compelling circumstances, and any conditions or restrictions imposed to manage the conflict.

The following management and oversight procedures serve only as a guideline and are not binding on the Committee. These procedures apply to research-related conflicts, but may be relevant for other activities:

1) Public disclosure: The conflicted individual must disclose his/her relationship with the financially interested company when s/he publishes, gives lectures and submits human subject protocols or grant applications involving research by, or benefiting the financially interested entity;

2) Monitoring of the research or other activity either internally or by independent reviewers. For clinical research, a neutral third party Contract Review Organization (“CRO”) may be engaged and paid for by the Sponsor to monitor the trial. The CRO must submit reports to the COI Officer and the IRB on a quarterly basis. The COI Officer will summarize the CRO findings and report at least annually, or as needed, to the Committee, which will review these matters and decide whether additional conditions or restrictions should be implemented. The IRB concurrently will review the CRO reports and make immediate recommendations for the protection of human subjects arising from the results of the CRO reports, if necessary. Additional oversight measures could include regular audits of the informed consent and enrollment process and/or the use of a patient representative or ombudsman at the time of recruitment and provision of informed consent. Both the COI Officer and the IRB may mandate interim corrective actions before the meeting of the Committee if warranted under the circumstances;

3) Modification of the research plan or other activity, including a requirement for clinical trials that informed consent is obtained by a clinician or other individual with no financial ties to the research;

4) Disqualification from participation in all or a portion of the research or other activity;

5) Escrow or reduction of the financial interest. If the financial interest is of an equity nature and is deemed to create a financial conflict of interest, , the conflicted individual may be requested to place his/her ownership interest in an escrow account for a period of time as specified by the Committee. If the financial interest is of an income nature and is deemed to create a financial conflict of interest, the conflicted individual may be requested to reduce the financial interest by either limiting the amount s/he receives or by placing certain monies s/he earns in a Special Purpose Account within his/her department;

6) Divestiture of significant financial interests; or

7) Severance of relationships that create conflicts.

Institutional Conflict of Interest

The Directors of the University’s Office of Technology Transfer (“OTT”), ORA, Division of Human Subjects Protection (“DHSP”), Office of Legal Affairs, and Treasurer's Office will inform the COI Officer whenever the University acquires an investment interest in any entity conducting business with the University. Such interests may include, but are not limited to, sponsorship of a clinical trial or basic science research, licensee of intellectual property owned by the University, or other interests. In general, when the University's ownership interest is equal to or greater than a 10% equity ownership interest or greater than $100,000 investment or other financial interest in any entity supporting research, the management options outlined above will be instituted for basic science and clinical trials.University Policy 102.42 “Institutional Conflicts of Interest Policy” addresses pertinent policies and procedures related to such issues.

Notification of Conditions and/or Restrictions
The COI Officer and/or the Committee will provide written notice of the Committee's determination to the conflicted individual with a copy sent to the individual's Department chairperson or supervisor. The individual must indicate, in writing, his or her willingness to comply with the Committee's determination and any conditions or restrictions. If the individual is a Department chairperson, the appropriate Dean shall be responsible for enforcing the recommended conditions or restrictions. For all other conflicted individuals, the appropriate senior officer and/or Department chairperson shall be responsible for enforcing the recommendations. If the conflict involves a clinical trial or basic science research, enforcement shall also reside with the Department of Human Subjects Protection ("DHSP") and/or the Office of Research Administration ("ORA") which shall receive copies of the Committee's written determination. In each instance, the individual responsible for enforcing the recommendations of the Committee, (including the Directors of DHSP or ORA, as applicable), must certify in writing that the recommendations of the Committee have been imposed. Copies of the Committee's summary report, the individual's agreement to comply, and the enforcing individual's certification will be kept on file in the Office of University Counsel with the COI Officer.

Appeal of the COI Committee's Determination
Any determination made by the Committee, including any condition or restriction imposed pursuant to this Policy, may be appealed to the President in writing within five (5) days of the conflicted individual's receipt of the Committee's written notice and/or determination. The President shall review the conflict and the recommendation of the Committee and affirm, reject, or remand the matter back to the Committee for further consideration. The decision of the President shall be final.

COI Committee Annual Summary Report The Committee will prepare an annual summary report that documents its determinations, including the nature and amount of the financial interest, if any, and any recommendations. The summary report is forwarded to the President for approval and to the Deans for review. Once the President has approved the report, it is forwarded to the Audit, Risk, and Compliance Committee of the University's Board of Trustees for informational purposes. All reports of the Committee are maintained in accordance with applicable record retention and litigation hold policies.

Other Required Disclosures

Disclosure to and by the IRBs / DHSP
When a research proposal is submitted to the IRB for initial or continuing review, any Principal Investigator, Co-investigator, or Key Personnel must complete a Disclosure and the appropriate IRB forms, disclosing any financial interest in the sponsor or any other entity whose financial interests might reasonably be affected by the outcome of the research. The Director of DHSP will forward to the COI Officer any information the Director receives concerning an individual's conflict related to human subjects research. The COI Officer will refer potential or actual conflicts to the Committee for review and the IRB will withhold any review until the financial interest has been evaluated and, if there is an actual conflict of interest, until the Committee has approved a management plan. The Committee's determinations will be submitted to the Director of DHSP for review by the convened IRB, including any determination that the circumstances do not compel allowing a conflicted individual to conduct research. The IRB must consider the report of the Committee prior to its final review of the research, whether for initial or continuing review. In its discretion, the IRB may require additional safeguards or demand reduction or elimination of the financial interest before approving the research. Moreover, despite the Committee's finding that compelling circumstances warrant allowing a conflicted individual to conduct research, the IRB has the authority to disapprove the research. The IRB may not, however, remove or weaken the conditions and/or restrictions imposed by the Committee.

The Director of DHSP will ensure that disclosed conflicts are made known to research subjects via a statement in the informed consent document, and upon request, to the study sponsor and the IRBs of other institutions participating in the relevant trial.

If the failure of a covered individual to comply with this Policy has biased the design, conduct, or reporting of research, the Director of DHSP will promptly notify the sponsor of the research, as appropriate, of the corrective action taken or to be taken. In addition, the Director of DHSP shall make information available regarding identified conflicts as required by law to ensure that reporting requirements for funding or regulatory agencies are met.

Disclosure to and by ORA
When a research or grant proposal is submitted to ORA, each covered individual who will conduct the research will sign a Proposal Transmittal Form disclosing any financial interest in the sponsor or any other entity whose financial interests might reasonably be affected by the outcome of the research. The Director of ORA will forward to the COI Officer any information regarding a covered individual's financial interest related to research. The COI Officer will refer such financial interests to the Committee. When a research or grant award

involves a subgrantee, a subcontract, or collaborators, individuals working for these entities who will be conducting the research must comply with this Policy by completing a Disclosure or by otherwise providing acceptable evidence of compliance with these policies.

With respect to sponsored research, prior to the expenditure of any funds under an award and on an ongoing basis as required, the University, through ORA, will report to the sponsor information regarding the identification, nature, and management of financial conflicts of interest as required by this Policy, by the sponsor's policy, and as required by law, to ensure that reporting requirements for funding or regulatory agencies are met.

Upon request, the Director of ORA will make information available regarding identified conflicts to those entities funding research or sponsors, as required by law.

Technology Licensing Agreements
Prior to executing a technology licensing agreement, the Director of OTT must notify the COI Officer of the proposed terms of the agreement. The COI Officer will review the terms of the agreement in light of the covered individual's Disclosure and determine whether the agreement would create a significant individual financial interest in ongoing or proposed research, be it human subjects research or otherwise. The COI Officer will notify the Director of OTT of the existence of any potential conflict and forward the matter to the Committee for review and make determinations as set forth above.

Policy Provisions Specifically Applicable to PHS-Sponsored Research The above policy elements are applicable to employee and faculty activities related to all institutional responsibilities. The following elements of this Policy specifically pertain to research activities sponsored by the PHS (Public Health Service) (See definition in Attachment 2).

Training
Investigators must complete training prior to engaging in research related to any PHS-funded grant or contract and at least every four years. In addition, immediate training is required under the following circumstances: when the University's COI policies change in a manner that affects Investigator requirements, when an Investigator is new to the University, and if the University finds an Investigator noncompliant with the University's COI policy or management plan.

Monitoring
Research that is conducted under provisions of a conflict management plan will be subject to ongoing monitoring until the research project is completed.

Public Disclosure
Upon receipt of a specific written request to the University, the University will make available to the public certain information related to financial conflicts of interest associated with senior and key personnel engaged in research activities sponsored by the PHS. Disclosure of information will include the investigator's name, title and role on the project; the name of the entity in which the financial interest is held; and the nature and approximate value (if it can be determined) of the financial interest. Information concerning the significant financial interests of senior and key personnel engaged in PHS-funded research activities shall remain available for responses to written requests for information for three (3) years from the date of the most recent PHS-related financial disclosure.

Release of public information will be made if the following circumstances apply:

- The financial interest was disclosed and is still held by project personnel;
- The Committee has determined that the financial interest is related to the research;
- The request for information is made prior to the expiration of the University's applicable record retention period; and
- The Committee has determined that the financial interest constitutes a financial conflict of interest.

The University will respond to properly submitted written requests for information meeting these criteria within five (5) business days after receipt of the written request. (See the Public Disclosure Request Form at Attachment 5).

Travel
Investigators who are funded or proposed to be funded by the Public Health Service or other sponsor designated by the University, must disclose the occurrence of any reimbursed or sponsored travel (i.e., travel 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 the Investigator's Institutional responsibilities during the previous 12 months. Investigators are NOT required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, a University 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 a University of higher education.

Travel disclosures must include the purpose of the trip, the identity of the trip's sponsor or organizer, the trip's origin and destination, and the duration of the trip. In addition, the University or *Investigator*'s School or Department may request other information about the trip to evaluate whether the travel may constitute a financial conflict of interest (FCOI).

Each University Department or School is responsible for obtaining travel-related information from employees and transmitting to the Conflicts of Interest Committee any travel-related abnormalities or concerns. The Conflicts of Interest Committee will determine whether travel-related concerns or abnormalities require investigation.

Subrecipients

For research projects carried out through subrecipients, the University will incorporate as part of a written agreement terms that establish whether the COI policy of the University or that of the subrecipient will apply to subrecipient investigators and include time periods to meet disclosure and/or FCOI reporting requirements. Subrecipient Institutions who rely on their own policy must report identified financial conflicts of interest to the University in sufficient time to allow the University to report the matter to the PHS Awarding Component to meet reporting obligations.

Enforcement

The COI Officer reviews all breaches of this Policy, including but not limited to (a) failures to comply with the disclosure and review process, whether by virtue of a covered individual's refusal to respond or by his/her responding with incomplete, or knowingly inaccurate, information; and (b) failures to comply with the Committee's determinations. The COI Officer refers such cases to the Committee in accordance with the University's Policy on Enforcement and Sanctions for Non-Compliance (No. 107.18).

Retrospective Reviews and Mitigation Plans

The University will conduct a retrospective review of all identified cases of non-compliance with this policy involving PHS-sponsored research and where the COI Officer and the Committee determine that a financial conflict of interest exists. In such cases, a conflict management plan will be established within 60 days of identification of the non-compliance, and within 120 days, a retrospective review will be completed to determine if the research conducted during the period of non-compliance is found to have been biased with respect to its design, conduct or reporting.

If an Investigator's failure to comply with this Policy or the terms and conditions of an active financial conflicts of interest management plan governed by this Policy, appears to have biased the design, conduct, or reporting of PHS-funded research, the Committee will (1) recommend to the University a corrective action plan to address the bias (2) notify the PHS awarding component of the planned or completed corrective action taken by the University; and (3) Submit a mitigation report to the PHS Awarding Component to ensure that reporting requirements for funding or regulatory agencies are met

In any case in which the U.S. Department of Health and Human Services determines that a PHS-funded clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator(s) with a financial conflict of interest that was not managed or reported by the Institution as required by PHS regulations, the University will require the Investigator(s) involved to disclose the financial interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Records Retention

The University will maintain all records relating to Investigator disclosures of financial interests and the University's review of and response to such disclosures, for a period of at least three years from the date the final expenditures report is submitted to the PHS. If retention of such records is required by law, regulation, or additional applicable University policies, the retention period may be greater than three years. See the University's Records Retention and Destruction Policy No. 102.39 for retention requirements applicable to non-PHS-related financial disclosures.

Attachment 1: Statement of Principles (PDF)
Attachment 2: Operating Definitions (PDF)

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Responsibility for maintenance of policy: Office of University Counsel, CIO Officer

(Signature on File)

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