

ENTERPRISE-WIDE CORPORATE POLICIES

Category:	Compliance Administration
Title:	CONFLICTS OF INTEREST POLICY FOR EMPLOYEES
Applicability:	TJU and Its Affiliates
Contributors/Contributing Departments:	Institutional Conflicts of Interest Officer, University Conflicts of Interest Committee, Office of Legal Affairs.

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¹ Consolidating:

(1) Policy 107.03 – Conflicts of Interest Policy for Employees

(2) Policy 107.03 – Attachment 1 – Statement of Principles Regarding Avoidance of Conflicts of Interest for Employees of Thomas Jefferson University

(3) Policy 107.03 – Attachment 2 – Operating Definitions

(4) Policy 107.18 – Conflicts of Interest Policy – Enforcement and Sanctions for Non-Compliance

STATEMENT OF PRINCIPLES REGARDING AVOIDANCE OF CONFLICTS OF INTEREST FOR EMPLOYEES OF THOMAS JEFFERSON UNIVERSITY

Thomas Jefferson University is a nonprofit corporation organized under the laws of the Commonwealth of Pennsylvania. As a nonprofit organization, it is prohibited from engaging in any activity the primary purpose of which is to financially benefit any individual. Moreover, the tax-exempt status of the University further prohibits any corporate income to benefit any individual or group of individuals.

An important goal of Thomas Jefferson University is the advancement of scientific knowledge particularly that designed to improve the health of our citizenry. In order to preserve the continued growth of biomedical research and the delivery of quality healthcare, a principled partnership between academia and industry is essential. To facilitate the collaboration between academia and industry, Congress enacted the Bayh-Dole Act, which explicitly encourages academic institutions to seek private investment to facilitate the translation of academic biomedical research into medically useful products through commercialization of products arising from federally-sponsored research.

The resultant increase in academic involvement in commercially-sponsored research increases the occurrence of potential and actual financial conflicts of interest related to academic research. Such conflicts of interest arise in a variety of circumstances, including but not limited to, a University employee's opportunities to benefit financially either from the outcome of his/her research or from the legitimate activities conducted in the course of his/her responsibilities as an employee of the University.

Actual or perceived financial conflicts of interest may threaten public support for the research mission of academic institutions. Thus, the University is dedicated to fostering the public's continued confidence in the judgment of its employees and its dedication to the integrity of academic medicine and biomedical research.

Consequently, it is the policy of the University that all faculty, employees, students, and other persons covered under its policies avoid conflicts, or the appearance of conflicts, between their personal interests and the interests of the University when dealing with any organization or individual having, or seeking to have, any business relationship with the University.

In connection with the restrictions encompassed in the foregoing, this statement of principles has been prepared to offer broad guidance to the employees of the University.

Conflict of interest is not a precise term, and it is subject to interpretation and degree. The provision of state-of-the-art, compassionate and cost effective healthcare services; the education of students; the collection, analysis and interpretation of research data; and the hiring of staff, acquisition of materials and other administrative tasks at Thomas Jefferson University must be free of the undue influence of outside interests. It is recognized that certain situations or issues involving ethical judgment may not always be free from ambiguity.

As a general rule, therefore, a person should consider not only the actual fact of conflict but also the appearance of conflict to an unknowing third party who might have occasion to judge or interpret the transaction. Perceived conflicts will be evaluated and managed the same as known conflicts. The highest standards of honorable and ethical conduct must be observed in all relationships.

- All individuals employed by or providing services to Thomas Jefferson University are charged with fidelity in the performance of their functional duties and should conduct such duties for the purpose, benefit, and interest of the University.
- Individuals shall be aware that their positions should not be used to gain favorable treatment or self-enhancement unless such occurs as a result of a primary effort to benefit the University and its patients, students, and the public.
- In supporting or protecting political and legal causes or issues, the use of one's title is not considered inappropriate; however, careful judgment should be exercised to preclude any inference that one is using his position or speaking on behalf of the University in such instances unless proper authorization has been obtained.
- On ethical as well as legal grounds, individuals should only have direct dealings with vendors that are consistent with the University's purchasing policies. No employee, officer, or agent must participate in the selection, award or administration of a contract supported by a Federal award if he or she has an actual or apparent conflict of interest. Such a conflict of interest would arise when the employee, officer, or agent, any member of his or her immediate family; his or her partner, or organization which employs or is about to employ any of the parties identified in this policy, has a financial or other interest in or tangible personal benefit from a firm considered for a contract.
- Information acquired in the course of service at Thomas Jefferson University that is known to be confidential or privileged should be used only for University purposes.

- All employees should be aware that they are expected to devote their best efforts in furtherance of the University's mission during the course of their service. Outside employment or personal commitments, if such activities would tend to impair an individual's ability to effectively fulfill his regular responsibilities, are not appropriate.
- Thomas Jefferson University, a health care and academic institution, encourages faculty and employee participation in various extramural organizations, government agencies and/or professional associations that are of service to the general public, the University, or the individual. If the nature of the association is such that the University's name may be identified with the outside organization, however, the individual must exercise caution and sensitivity to avoid any participation or affiliation that could be detrimental to the University. While recognizing the benefits of such activities, the University is committed to ensuring that they are conducted properly and consistently with the principles of openness, trust, and free inquiry that are fundamental to the well-being of the University. Individuals are expected to seek advice from the appropriate chairman, department head, administrator or University Counsel before making any commitments that may be potentially compromising to the University's interests.
- A conflict of interest occurs when University resources - including time of University personnel, funds, facilities, reputation, or other assets - are diverted from their intended purpose by virtue of an individual's outside activities, associations, or appointments. Therefore, any outside activities utilizing University resources, in whole or in part, should be cleared through the individual's department chairman, department head, or administrator. In certain cases, such outside activity may be approved.
- A conflict of interest may exist when individuals or members of their families acquire or hold investments in real estate or property in which the University may have an interest, or have a financial relationship with or an executive position in biotechnology companies or any entity engaged in the delivery of health care services or health care supplies.
- A conflict of interest also may occur when individuals or members of their families accept compensation, gifts, gratuities, or favors from any person or organization doing business or seeking to do business with the University or make clinical referrals to any entity in which the individual or a member of his/her family has a financial interest.

The mere existence of a conflict of interest does not necessarily imply wrongdoing on anyone's part. However, when the question of conflict of interest arises, it must be recognized, disclosed, and either eliminated or properly managed. In order to encourage full disclosure of potential conflicts, disclosures will be treated as confidential and will not be disclosed, except as is required by law or as may be necessary under the University's Conflicts of Interest Policy for Employees.

All faculty, administrators, and other designated employees are required to complete a Disclosure of Conflicts of Interest and disclose any existing conflicts of interest or potential conflicts of interest in accordance with the University's Conflicts of Interest Policy for Employees. If, at any time, any employee becomes aware of a situation that may present an actual, perceived, or potential conflict of interest, s/he should report that situation to the Conflicts of Interest Officer and the person to whom s/he reports at the earliest practicable time. It will be the responsibility of the Conflicts of Interest Officer to review and evaluate potential conflicts of interest in accordance with the procedures for the management, reduction or elimination of conflicts of interest set forth in the University's Conflicts of Interest Policy for Employees. All identified significant conflicts of interest will be referred to the Standing Committee on Conflicts of Interest and Commitment for review and management.

Thomas Jefferson University expects its faculty members, officers, students, other employees, and agents to comply fully, promptly, and in a timely manner with the University's Conflicts of Interest Policy for Employees (No. 107.03).

OPERATING DEFINITIONS

An **associated entity** means any trust, organization or enterprise other than the University over which the covered individual, alone or together with his/her family, exercises a controlling interest.

Compelling circumstances are those facts that convince the Standing Committee on Conflicts of Interest and Commitment that a financially interested individual should be permitted to engage in the conduct in question. Such circumstances include, but are not limited to, 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 in question, and the extent to which the interest is amenable to effective oversight and management. In the research context, such circumstances also include the nature of the science, the degree of risk to any human subjects involved that is inherent in the research protocol, and whether the research could not be conducted as safely or effectively without the interested individual.

Conducting research means, with respect to a research protocol, designing research, directing research or serving as the principal, co-investigator or key personnel, enrolling research subjects (including obtaining subjects' informed consent) or making decisions related to eligibility to participate in research, analyzing or reporting research data, or submitting manuscripts concerning the research for publication. This term does not apply to covered individuals who primarily provide technical support and/or who are purely advisory, with no direct access to the data (e.g., control over its collection or analysis or, in the case of clinical research, to the trial participants),

unless they are in a position to influence the study's results or have privileged information as to the outcome.

Covered individual includes any faculty (full-time, part-time, or non-salaried), key personnel, or administrator who is an investigator; has a management position or above; whose job responsibilities affect purchasing, operating and/or financial decisions of the University or Jefferson University Physicians; and/or who has a significant responsibility with respect to sponsored or non-sponsored research projects. A covered individual further includes any faculty, key personnel, or administrator who, under the aegis of the University or pursuant to the review and approval of the University's IRBs, conducts research.

A **covered individual's family members** include his/her spouse, dependent children, and all other persons living in the same household.

Disclosure means the provision of information about financial interests by a covered individual to responsible institutional officials and to the Standing Committee on Conflicts of Interest and Commitment or the transmission of such information within institutional channels (e.g., from the Standing Committee on Conflicts of Interest and Commitment to the IRB).

Entity means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

Equity Interest means any ownership interest in a company or business, including, but not limited to, stocks, stock options or warrants, membership or partnership interests or rights, or other ownership interests, as determined through reference to public prices or other reasonable measure of fair market value.

Financial Conflicts of Interest means situations where an Employee's Financial Interest (including an Investigator's Significant Financial Interest, where applicable) compromises, or could appear to compromise, his or her judgment or ability to carry out the Institutional Responsibilities associated with his or her appointment or employment. A Financial Conflict of Interest may take many forms, but in general arises when an Employee in a relationship with an outside person or organization is in a position to influence the University's business, research or decisions in ways that could lead directly or indirectly to financial gain for the Employee or the Employee's Dependents or could give an improper advantage to others to the detriment of the University.

When applied to an Investigator, Financial Conflicts of Interest occur in situations in which such Investigator's Financial Interest (including Significant Financial Interest) compromises, or could appear to compromise, his or her professional judgment regarding the design, conduct or reporting of research or if such Financial Interest (including Significant Financial Interest) could directly and significantly affect the design, conduct or reporting of research. The bias such conflicts may conceivably impart not only affects collection, analysis and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants and the use of statistical methods.

Financial Interest means any interest that will, may, or is intended to lead to a profit or an increase in the income or net worth of an Employee, Investigator, Dependent, or other covered persons under this policy. Such a profit or increase in income or net worth could be realized through the receipt of anything of monetary or potential monetary value, including, but not limited to, payments of any kind (e.g., salary, consulting fees, honoraria, gifts, dividends, distributions, rent, paid authorship, etc.), Equity Interests, an increase in the value of real estate or Equity Interests, or Intellectual Property Rights.

Financially interested company means a commercial entity with financial interests that would reasonably appear to be affected by the conduct or outcome of the activity in question. With regards to research this term includes companies that compete with the sponsor of the research or the manufacturer of an investigational product, if the covered individual actually knows that the financial interests of such a company would reasonably appear to be affected by the research. This term also includes any entity acting as the agent of a financially interested company (e.g., a contract research organization).

Financially interested individual means a covered individual or family member holding a significant financial interest that could reasonably appear to be affected by the individual's activities in the scope of his/her employment.

Institutional Responsibilities means an Employee or Investigator's professional responsibilities discharged on behalf of Thomas Jefferson University (or his/her primary employer), including, but not limited to, research, research consultation, teaching, professional practice, institutional committee memberships and service on panels such as institutional review boards or data and safety monitoring boards.

Institutional Responsibilities include:

- Externally sponsored research or scholarly activities (including proposing, conducting, and analyzing research and disseminating results);
- Departmental/University research (includes participation in study sections, peer review of manuscripts, or effort on non-sponsored research);
- Instruction/University Supported Academic activities (including preparation for and presentations of formal and informal courses to students/trainee groups, mentoring students and trainees, and participation in resident training);
- Clinical service activities such as performing services for Jefferson University Physicians;

- Administrative activities including serving as Department Chair, Program Director, or service on institutional committees, participation in department activities or faculty advisory boards.

Institutional responsibilities do not include:

- Volunteer community or public service unrelated to one's primary employment responsibilities.

Investigator means the principal investigator, co-investigator, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research.

Public Disclosure means the University's provision of information related to financial conflicts of interest involving senior and key personnel engaged in research on active PHS-sponsored research projects to persons or entities that transmit to the University formal written requests to receive such information.

Public Health Service ("PHS") means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the NIH.

Rebuttable presumption against financial interests means the University will presume, in order to assure that all potentially problematic circumstances are reviewed, that a financially interested individual may not conduct or engage in the research or activity in question. This rule is not intended to be absolute: a financially interested individual may rebut the presumption by demonstrating facts that, in the opinion of the Standing Committee on Conflicts of Interest and Commitment, constitute compelling circumstances. The individual would then be allowed to conduct the research or engage in the activity, subject to final approval by the President and the Institutional Review Boards for research involving human subjects.

Remuneration means 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.

Research means a systematic investigation designed to develop or contribute to generalized knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development.

Senior/Key Personnel means the Principal Investigator ("PI") and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution under current PHS regulations.

Significant Financial Interest means a Financial Interest held by an Investigator and/or an Investigator's Dependent that reasonably appears to be related to the Investigator's Institutional Responsibilities and that consists of one or more of the following:

- Remuneration (including salary, consulting fees, honoraria, paid authorship and travel reimbursement) received from a publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, and/or an Equity Interest held in such publicly traded company, if the aggregate value of such remuneration, plus the value of the Equity Interest as of the date of disclosure, exceeds
- \$5,000.
- Remuneration (including, but not limited to, salary, consulting fees, honoraria, paid authorship and travel reimbursement) received from a non-publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, if the remuneration exceeds \$5,000.
- Any Equity Interest in a non-publicly traded company or business, regardless of value.
- Any Intellectual Property Rights, regardless of value, upon receipt of income related to such rights and interests.
- When applied to sponsored project applications (proposals) submitted to and/or awards received from PHS agencies, any reimbursed or sponsored travel (i.e., travel that is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), provided that the travel is not reimbursed or sponsored by a federal, state or local government agency, an institution 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 an institution of higher education.

Significant Financial Interest does not include:

- An Employee's salary, royalties or other remuneration received from the University and/or Jefferson University Physicians. Covered persons who are not University or JUP employees should not include salary or other remuneration from their primary employee in a calculation of reportable income.
- Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency or an institution 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 an institution of higher education.
- Income from service on advisory committees or review panels for a federal, state or local government agency or institution of higher education as defined at 20 U.S.C. 1001(a), academic teaching hospital, medical center or research institute that is affiliated with an institution of higher education.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

- For Investigators who are not University Employees, any ownership interest in their primary employer held by the Investigator.

Small Business Innovation Research (SBIR) Program and Small Business Technology Transfer (STTR) Program mean the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97219, the Small Business Innovation Development Act, as amended, Pub. L. 102564, respectively.

Sponsored Travel means travel related to a covered person's work on PHS-sponsored research and his or her institutional responsibilities. Travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution 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 an Institution of higher education is excluded from this definition.

POLICY²

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 preceding Statement of Principles Regarding Avoidance of Conflicts of Interest for Employees of Thomas Jefferson University (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 [Operating Definitions](#)) 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.

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 [Operating Definitions](#)). 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.

² The following Policy and Procedure should be read in light of the [Operating Definitions](#) and [Statement of Principles](#) set forth above.

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 (see [Enforcement and Sanctions for Non-Compliance](#)).

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 [Operating Definitions](#)). In such cases, the COI Officer shall further determine whether the significant financial interest may constitute a financial conflict of interest (See definition in [Operating Definitions](#)). 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 [Operating Definitions](#)).

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.

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.

ENFORCEMENT AND SANCTIONS FOR NON-COMPLIANCE

Thomas Jefferson University ("TJU"), and its controlled affiliates, expects its faculty members, officers, students, employees, and agents to comply fully, promptly, and in a timely manner with the Thomas Jefferson University's Conflicts of Interest Policy for Employees and all relevant federal regulations, including but not limited to 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.

Accordingly, TJU expects those individuals responsible for enforcing the decisions of the Standing Committee on Conflicts of Interest and Commitment ("COI Committee") to be vigilant in their oversight and enforcement of the Policy and to report promptly to the Institutional Conflicts of Interest Officer ("COI Officer") all alleged, suspected, and actual violations or instances of non-compliance with the Policy.

The COI Committee is responsible for overseeing the implementation of the Policy, including the process and mechanisms for disclosure. Working in collaboration with the COI Committee, the COI Officer will review 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. Covered individuals are required to cooperate with the COI Officer's investigation of alleged noncompliance with the Policy.

Investigation of Allegations of Noncompliance

The COI Officer (or his/her delegate) shall investigate any alleged violations or instances of non-compliance with the Policy through document collection, document review, interviews, and other appropriate investigatory techniques. The COI Officer shall determine the validity and veracity of all alleged violations and report findings to the COI Committee. Violations and instances of non-compliance may include but are not limited to the following: (1) failure to submit timely COI disclosure information in compliance with the Policy; (2) failure to provide timely all requested information in connection with a disclosure; (3) knowingly filing incomplete, erroneous, or misleading COI disclosures; (4) failure to seek prior approval of activities governed by the Policy; (5) failure to comply with prescribed conditions or restrictions that have been imposed pursuant to the Policy; (6) failure to make interim disclosures of activities and changed circumstances in compliance with the Policy; or (7) failure to comply with any other provision of the Policy.

Review of Investigatory Findings

The COI Officer will present all investigatory findings to the COI Committee. The COI Committee will review and evaluate the findings presented by the COI Officer (or his/her delegate) and recommend appropriate actions designed to address noncompliance with the Policy. The COI Officer will offer the covered individual an opportunity to provide information relevant to the issue under investigation and will include all such information in materials transmitted to the COI Committee for consideration.

Disciplinary or other actions

Disciplinary or other actions recommended by the COI Committee shall be transmitted to the Jefferson leader (e.g. academic dean, senior officer, department chairperson) with responsibility for oversight and evaluation of the covered individual's Jefferson responsibilities. Actions taken to address noncompliance with the Policy shall align with all relevant policies, including but not limited to applicable bylaws, employment-related policies, and other policies and guidelines governing the covered individual's relationship with Jefferson.

Research Impact

Referral of matters involving research activities

If the outcome of the investigation confirms or reveals potential issues related to the design, conduct, or reporting of activities associated with research conducted at or in connection with TJU or its controlled affiliates, the COI Committee shall promptly refer the matter to the TJU Research Compliance Officer for further review and action.

Mandatory Notification and Disclosure Requirements

Upon review of the investigatory findings and referral information provided in connection with the alleged breach of the Policy, the TJU's Research Compliance Officer, or her/his designee, shall promptly notify the appropriate individuals, publications, and/or agencies of the incident and the corrective action taken.

All regulatory reports and mandatory actions taken in connection with violations of the Policy shall adhere to reporting requirements set forth in relevant statutes, regulations, and internal policies. The Research Compliance Officer shall transmit notice of activities that may require regulatory reporting to the appropriate TJU Departments, including but not limited to the Office of Research Administration,

Office of Human Research, Office of Legal Affairs, and the Office of the Provost.

All clinical research projects involving covered persons who engaged in research activities in the presence of an undisclosed and unmanaged financial conflict of interest, as defined by the Policy, shall be subject to review to identify bias and other issues that might impact negatively the reported results, participant impact, or other relevant matters requiring prompt remediation.

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

(Signature on File)

Approved by:
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