

TEMPLE UNIVERSITY

POLICIES AND PROCEDURES MANUAL

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TEMPLE UNIVERSITY POLICY ON INSTITUTIONAL CONFLICT OF INTEREST IN RESEARCH

A. INTRODUCTION AND RATIONALE

This Policy is intended to protect against risks to Research integrity, Research participants and the academic mission that may result from certain conflicts of interest in Research. An Institutional Conflict of Interest in Research (an "Institutional COI" or an "ICOI") is of concern when such financial interests create the potential for inappropriate influence over the institution's Research activities. An Institutional COI is a situation in which the significant financial interests of an institution, an institutional official, or a duly authorized employee of an institution (acting within his or her authority and/or on behalf of such institution), may unduly affect or appear to affect the conduct or activities of the institution.

This policy applies to all Institutional COIs arising out of Research conducted at, or on behalf of, Temple University, including any Research activity of individuals holding an appointment at a subsidiary or affiliate of Temple University (hereinafter, the "University") as well as all Covered Officials, as defined below. This Policy does not address the potential or actual conflicts of interest of individual researchers who are not Covered Officials, as defined below. Such conflicts are addressed by separate University policies, namely: Conflict of Interest - Faculty ([04.16.02](#)), Conflict of Interest - All Employees ([04.16.01](#)), and Conflict of Interest - Trustees ([01.35.01](#)).

B. DEFINITIONS

1. **Institutional Conflict of Interest in Research:** An ICOI may occur whenever a Significant Financial Interest of the institution (as defined below), or of a Covered Official (as defined below), might affect - or reasonably appear to affect - institutional processes for the design, conduct, reporting, review, or oversight of Research.
2. **Business or Outside Entity:** (a) any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, limited liability company, trust or other for-profit commercial entity; and (b) any not-for-profit entity acting, directly or indirectly, as an agent for, or on behalf of, a commercial entity, or controlled by a commercial entity, i.e., where a commercial entity owns or funds 50% or more of the not-for-profit entity or otherwise controls the not-for-profit entity's activities.
3. **Covered Officials:** The President, Provost and Vice Presidents, other executive and senior officers and administrators, deans and vice-deans, associate deans and other institutional

administrators who have responsibility for oversight of Research. Covered Officials also include department chairs, division chiefs, institute and center directors, and chairs and members of Research regulatory review committees (“Regulatory Review Committees”) such as the Institutional Review Board, the Conflict of Interest Committee, the Institutional Animal Care and Use Committee, the Institutional Biosafety Committee, and other similar committees.

4. **Oversight of Research:** Responsibility for approval of Research proposals, Research regulatory approvals, and/or the supervision of faculty and staff participating in Research conducted at or under the auspices of the University.
5. **Research:** Includes but is not limited to any detailed study of a subject designed to produce new information or understandings on a topic or systematic investigation designed to develop or contribute to generalizable knowledge. Research includes basic, applied, demonstration Research and other types of studies in all fields of knowledge, sponsored by the University. Research sponsored by the University includes any Research: (a) conducted pursuant to an agreement between the University and a third party; (b) supported by funding that is administered through the University, the Office of the Vice President for Research (“OVPR”), the Office of Technology Commercialization and Business Development (“OTCBD”), The Clinical Research Institute (“TCRI”), Institutional Advancement, or through an individual school, center, institute or department; (c) supported by in-kind resources from the University including work load assignments, study leaves, support for facilities used in Research, support for personnel or students engaged in Research or other in-kind supports; or (d) requiring review by a Regulatory Review Committee.
6. **Significant Financial Interest (Covered Official):** A financial interest that relates to Research subject to the Covered Official’s Oversight of Research, as specified below:
 - A. Royalty payments, including those received under a University agreement, that in the aggregate have or are expected to exceed \$25,000 over a rolling 12 month period, and that are from the licensing or sales of a product or service that is the subject of the Research¹;
 - B. An ownership interest or entitlement to equity (including options, warrants or convertible debt securities) in a publicly-traded Business that represents ownership in excess of 5%, or has a value that exceeds \$100,000, where such Business is the sponsor of Research, manufactures or distributes products that are the subject of such Research, or holds the Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) for such products. This does not include indirect financial holdings that are not controlled, influenced or managed by the Covered Official (e.g., mutual funds).
 - C. Any ownership interest or entitlement to equity (including options, warrants or convertible debt securities) in a privately held Business, where such Business is the sponsor of Research, manufactures or distributes products that are the subject of such Research, holds the IND or IDE for such products, or holds a license or other contractual interest in the technology that is the subject of such Research;
 - D. Compensation from a Business for consulting, service on an advisory board, or for any other reason, that in the aggregate has or is expected to exceed \$25,000 over a rolling 12 month period, where the Business is the sponsor of Research, manufactures or distributes products that are the subject of such Research, holds the IND or IDE for such products, or holds a license or other contractual interest in the technology that is the subject of such Research;
 - E. Service as an officer, manager, member of the board of directors, or in any other fiduciary or managerial role for a Business, whether or not remunerated, where the Business is the sponsor of Research, manufactures or distributes products that are the

- subject of such Research, or holds the IND or IDE for such products; or
- F. A financial interest that relates to Research and is identified as a Significant Financial Interest by the Office of the Vice President for Research or the University Counsel.
7. **Significant Financial Interest (Institutional)**: A financial interest related to Research that meets any of the following criteria:
- A. Royalty payments: Royalties, milestone payments, license fees, or other payments associated with intellectual property that have or are expected to exceed \$100,000 over a rolling 12 month period that are from the licensing or sales of a product or service that is the subject of the Research.
 - B. Publicly traded equity: Ownership interest or an entitlement to equity (including options, warrants or convertible debt securities) exceeding \$100,000 in value, in a *publicly-traded* Business, obtained through the University's technology licensing activities or investments related to such activities.
 - C. Non-publicly traded equity: Ownership interest or an entitlement to equity (including options, warrants or convertible debt securities) in a privately-held Business, obtained through the University's technology licensing activities or investments related to such activities.
 - D. Gifts from corporate sponsors: A gift (including a gift in kind) valued in excess of \$500,000 from a Business that owns or controls products being studied or tested in Research. In such circumstances, the following circumstances should be evaluated.
 - 1. Whether a gift is of sufficient magnitude that even when held in the general endowment for the benefit of the entire University, it might affect, or reasonably appear to affect, Oversight of Research at the University;
 - 2. Whether a gift is held for the express benefit of the college, school, department, institute or other unit where the Research is to be conducted; or
 - 3. Whether any Covered Official who has the authority, by virtue of his or her position, to affect or appear to affect the conduct, review or oversight of the proposed Research has been involved in solicitation of the gift.

C. IDENTIFICATION OF POTENTIAL INSTITUTIONAL CONFLICTS OF INTEREST

1. **Covered Official Significant Financial Interests (SFIs)**: Covered Officials are required to disclose any Significant Financial Interest that relates to the Covered Official's Oversight of Research.
2. **Institutional SFIs**: Institutional SFIs that relate to Research may be identified through intake forms submitted by relevant administrative offices, e.g., the Office of Technology Commercialization and Business Development (OTCBD) or Institutional Advancement, as cross-referenced against information routinely collected through Research administration processes and University databases.

D. INSTITUTIONAL CONFLICT OF INTEREST COMMITTEE ("ICOI COMMITTEE")

An ICOI Committee shall be established by the University to review and manage potential Institutional COIs. The ICOI Committee shall include senior officers of the University and at least one senior representative from the University's schools and colleges, as identified by the OVPR. The ICOI

Committee will be staffed by the Office of Research Compliance. Non-voting participants shall include representatives from OTCBD; Institutional Advancement; and other Research administration offices as appropriate. The Office of University Counsel shall attend as counsel to the committee.

E. ICOI COMMITTEE REVIEW

Institutional and Covered Official SFIs must be reviewed by the ICOI Committee, with the exception of those SFIs set forth in Section F (“SPECIAL REQUIREMENTS: REGULATORY REVIEW COMMITTEES”) below. The ICOI Committee must assess the potential risks to Research integrity and human subjects presented by an institutional SFI to determine whether the SFI constitutes an ICOI. In keeping with recommendations by leading university associations, including the American Association of Universities and the American Association of Medical Colleges, this Policy reflects that the presence of an SFI is presumed to weigh against conducting the Research in question, until a decision by the ICOI committee determines otherwise. The presumption may be rebutted by a reasonable determination that the risks can be mitigated through the appropriate management or elimination of the ICOI, as follows:

1. Where the University itself holds the SFI, the ICOI Committee may determine that one or more of the following actions is appropriate:
 - a. Divestment of the SFI, if feasible;
 - b. Disclosure of the ICOI in informed consent processes;
 - c. Use of an external IRB;
 - d. Independent monitoring of the study, particularly endpoint assessments;
 - e. Use of an external Data Safety Monitoring Board (“DSMB”) or similar review board to evaluate the design, analytical protocols, and primary and secondary end- point assessments, and to provide ongoing evaluation of the study for safety, performance issues and the reporting of results;
 - f. Disclosure of the ICOI in public presentations and publications, and to all individuals, including (but not limited to) graduate students and other trainees, engaged in the design, conduct or reporting of the Research;
 - g. Disclosure of the ICOI to other centers in a multi-center trial;
 - h. Disclosure to the sponsors of the Research as required by the sponsor and all applicable regulations and laws;
 - i. Such other actions that the Committee deems to be appropriate, consistent with the principles articulated in this Policy.
2. Where a Covered Official holds the SFI, the ICOI Committee may determine that one or more of the following actions is appropriate:
 - a. Designation of an “Ombudsperson” (e.g. a non-conflicted senior individual) with whom the investigator can address ICOI-related concerns;
 - b. Modification of the role of a conflicted Covered Official, to minimize involvement with the Research at issue;
 - c. Such other actions that the Committee deems to be appropriate and consistent with the principles articulated in this Policy, including but not limited to any actions identified in paragraph E.1.

Any management plan for a project involving human subjects Research must explicitly address how any risks to human subjects are being mitigated.

The ICOI Committee and the University should make every attempt to resolve institutional conflicts in a manner that enables Research to proceed at the University. However, if the ICOI Committee finds that an ICOI cannot be managed, and divestment is not feasible, then the affected Research should not proceed at the University.

The ICOI Committee may develop precedents and standard operating procedures for handling particular ICOI issues, and may expedite review for subsequent cases involving those issues. The ICOI Committee will document its findings and the basis for its decision with respect to any Research. If such Research involves human subjects, such documentation will be made available to the IRB. The IRB may impose more, but not less, stringent requirements than the ICOI Committee.

F. SPECIAL REQUIREMENTS: REGULATORY REVIEW COMMITTEES

Where an individual is a Covered Official solely because of their institutional role as the chair or member of a Regulatory Review Committee (e.g. the University's IRB Committee) and the Covered Official holds an SFI that relates to Research subject to review by the Covered Official's Regulatory Review Committee, the Covered Official must recuse him or herself from any deliberations or review of the related Research. No ICOI Committee review is required in such cases.

G. ENFORCEMENT

Violations of the requirements of this Policy by any employee or officer shall, if not resolved, subject the employee to review and, where appropriate, imposition of corrective action and/or sanctions permitted by University policy.

H. POLICY REVIEW

The President of the University may, in consultation with the Vice President for Research, require reviews of this Policy and its implementation.