



Policy No: **107.18**
 Revision No: **3**
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UNIVERSITY POLICIES & PROCEDURES

Category:	Compliance Administration
Title:	CONFLICTS OF INTEREST POLICY - ENFORCEMENT AND SANCTIONS FOR NON-COMPLIANCE
Applicability:	Thomas Jefferson University
Contributors/Contributing Departments:	

POLICY

Thomas Jefferson University ("TJU") 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) (the "Policy") 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. 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 promptly report any violations or instances of non-compliance with the Policy to the Conflicts of Interest Officer ("COI Officer").

The COI Officer in conjunction with the COI Committee is responsible for overseeing the implementation of the Policy, including the process and mechanism for disclosure. The COI Officer will review all breaches of the disclosure process, including but not limited to (a) failures to comply with such process, whether by virtue of a covered individual's refusal to respond or by his/her responding with incomplete or knowingly inaccurate information; (b) failures to appropriately disclose activities or interests; (c) failures to remedy conflicts; and (d) failures to comply with a prescribed oversight plan. Covered individuals are required to cooperate with the COI Officer's inquiry into the matter. Such cases will be forwarded to the COI Committee for review. Based on its review, the Committee will make recommendations to the appropriate management level official for further action. In all cases, covered individuals will be provided the explicit opportunity to respond in person and in writing to the issues raised in the course of such review.

PROCEDURE

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 techniques. The COI Officer shall determine the validity and veracity of all alleged violations and report any adverse findings to the

COI Committee. Violations and instances of non-compliance may include but are not limited to the following: (1) failure to submit required disclosure forms or updates in a timely manner; (2) failure to provide requested additional information in connection with a disclosure; (3) knowingly filing incomplete, erroneous, or misleading disclosure forms; (4) failure to seek prior approval of any outside activity that implicates University resources as required 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 conflicts that occur during the year; or (7) failure to comply with any other provision of the Policy. The COI Committee will review and evaluate the findings presented by the COI Officer (or his/her delegate) and recommend the appropriate sanctions, if any, to be imposed. In all cases, the covered individual will be provided the explicit opportunity to respond in person and in writing to the issues raised in the course of such review. Any such written response will be appended to the COI Committee's report.

For faculty, sanctions recommended by the COI Committee will be presented to the appropriate academic Dean, who shall review and evaluate the findings and recommendations of the COI Committee. In addition, The COI Committee's report will be presented to the President as well as to Audit/Compliance Committee of the Board of Trustees and Academic Affairs Committee of the Board of Trustees for informational purposes. The determination of the appropriate disciplinary action to be imposed, however, shall be at the discretion of the appropriate Dean, taking into account the COI Committee's recommendations. If the financially interested individual is a department chairperson, the appropriate academic Dean shall enforce the sanction in accordance with any applicable organizational bylaws. For all other covered individuals, the appropriate senior officer and/or department chairperson shall enforce the sanction as permitted under the disciplinary policies and procedures of the University and the Bylaws of the appropriate College.

Possible sanctions include those listed under the Corporate Compliance Program Section of the appropriate College Bylaws. Appeal rights shall be those as stated therein.

If the failure of an employee or faculty member to comply with the Policy has biased the design, conduct, or reporting of any research, the University promptly

will notify the appropriate individuals, publications, and/or agencies of the incident and the corrective action taken. In addition, if the Department of Health and Human Services determines that a Public Health Service-funded project of clinical research 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 with a conflicting interest that was not disclosed or managed as required, the University shall require the investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

Revision Date(s):08/01/2000,06/07/2002,09/30/2003,12/11/2014

Review Date(s): 10/27/2004,12/10/2014

Responsibility for maintenance of policy: Office of University Counsel, Conflicts of Interest Officer

(Signature on File)

Approved by:

Cristina G. Cavalieri, Esq.

Sr. Vice President, Chief Legal and
Governance Officer, Secretary, TJU