

TEMPLE UNIVERSITY HEALTH SYSTEM ADMINISTRATIVE POLICIES AND PROCEDURES

NUMBER	230.00
TITLE	FINANCIAL CONFLICTS OF INTEREST IN RESEARCH
EFFECTIVE DATE	August 24, 2012
LAST REVIEWED	August 24, 2012
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REFERENCES	A. 42 C.F.R. PART 50, SUBPART F B. 45 C.F.R. PART 94 C. CONFLICT OF INTEREST AND RECEIPT OF GIFTS POLICY-ALL EMPLOYEES (POLICY #115)
ATTACHMENTS	A. RETENTION AND ACCESS REQUIREMENTS FOR RECORDS (45 C.F.R. 74.53(B) AND 92.42(B))
ISSUING AUTHORITY	CHIEF EXECUTIVE OFFICER

SCOPE

This policy shall apply to Temple University Health System, Inc. ("TUHS") and all TUHS subsidiary corporations. This policy replaces all prior TUHS and TUHS subsidiary corporation policies regarding the subject matter contained herein. Any reference to TUHS shall mean TUHS and its subsidiaries.

PURPOSE

The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research occurring at Temple University Health System is free from bias resulting from individual conflicts of interest.

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This policy draws upon regulations regarding financial conflicts of interest (“FCOI”) for Public Health Service (“PHS”) funded research¹, (the “Regulations”). Individual TUHS subsidiary corporations may implement more specific procedures hereunder as long as those procedures do not conflict with this policy. This policy is intended to be in compliance with the Regulations. In the event of any conflict between this policy, or any TUHS subsidiary corporation policy or procedure, and the Regulations, the most stringent standard shall apply.

This policy applies to each Investigator² who is planning to or is participating in research. The defined terms used in this policy are those used in the Regulations, 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94.

DEFINITIONS

1. Disclosure of Significant Financial Interest means an Investigator’s disclosure of significant financial interests to Institution.
2. Financial Conflict of Interest (or “FCOI”) means a significant financial interest that could directly and significantly affect the design, conduct or reporting of the research.
3. FCOI report means Institution’s report of a Financial Conflict of Interest to a PHS Awarding Component.
4. Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.
5. Immediate Family means spouse or spousal equivalent and dependent children.
6. Institution means Temple University Health System, Inc., (sometimes referred to as “TUHS”) including its subsidiary corporations.
7. Institutional Official (sometimes also referred to as “Authorized Institutional Official”) for the purpose of this policy means that person designated by the Institution, or TUHS subsidiary corporation, as the person responsible for administration of financial conflicts

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42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94.

2

42 C.F.R. 50.603 and 45 C.F.R. 94.3.

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of interest pursuant to this policy, or the more specific policy or procedures of the applicable school or college.

8. Institutional Responsibilities means an Investigator's professional responsibilities on behalf of Institution, and as may be defined by Institution in its policies on conflicts of interest. Such Institutional Responsibilities may include, for example, research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data Monitoring Committees.
9. Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research or proposed for such funding, which may include, for example, collaborators or consultants. For the purposes of this policy, the term "individual" shall be synonymous with "Investigator."
10. Manage or management of FCOI means taking action to address the FCOI, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.
11. PD/PI means a project director or principal Investigator of a research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this policy.
12. PHS Awarding Component means the unit of the PHS funding the research.
13. Research means a systematic investigation, study or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). For purposes of this policy, research is limited to the above activities when funded by PHS.
14. Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report under this FCOI Policy.
15. SFI Disclosure Form means the disclosure form and accompanying documentation that an Investigator or individual must submit to Institution disclosing any SFI.

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16. Significant Financial Interest or SFI means:

- (A) A Financial Interest consisting of one or more of the following interests of the Investigator and the Investigator's Immediate Family that **reasonably appears to be related to the Investigator's Institutional Responsibilities**, including but not limited to:
 - (i) With regard to any **publicly traded entity**, if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. This includes:
 - (a) Remuneration for salary and services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship); and
 - (b) Equity interest including any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
 - (ii) With regard to any **non-publicly traded entity**, if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or if the Investigator or his/her Immediate Family holds any equity interest (e.g. stock, stock ownership interest) in the entity; or
 - (iii) Intellectual property rights and interests (e.g. patents and copyrights), upon receipt of income related to such rights and interests.
- (B) Any **reimbursed sponsor travel** (i.e. that 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, other than travel that is reimbursed or sponsored by:
 - (i) A federal, state or local government agency ("Public Agency");
 - (ii) An institution of higher education as defined at 20 U.S.C. 1001(a); or
 - (iii) An academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education.
- (C) Significant Financial Interest **does not include**:
 - (i) Salary or other remuneration paid by Institution, if the Investigator is employed by Institution, including intellectual property rights assigned to the Institution and agreements to share royalties related to those rights;
 - (ii) 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;

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- (iii) Income from seminars, lectures or teaching engagements sponsored by a Public Agency, institution of higher education, academic teaching hospital, medical center or research institute that is affiliated with an institution of higher education; or
- (iv) Income from service on advisory committees or review panels for a Public Agency, institution of higher education, academic teaching hospital, medical center or research institute that is affiliated with an institution of higher education.

PROCEDURES

I. Training Requirements

- A. The authorized Institutional Official shall inform each Investigator of:
 - 1. This policy;
 - 2. Investigator's disclosure responsibilities; and
 - 3. Federal regulations.
- B. The authorized Institutional Official shall require each Investigator to complete FCOI training:
 - 1. Prior to engaging in research;
 - 2. At least every 4 years; and
 - 3. Immediately, if:
 - a. Institution revises this policy that affects requirements of Investigators;
 - b. An Investigator is new to an Institution; or
 - c. An Investigator is not in compliance with this policy or Management Plan.

II. Disclosure, Review and Monitoring Requirements

- A. An SFI disclosure form is required from all Investigators involved in or proposing to participate in research. This includes but is not limited to physicians, post doctoral fellows, graduate students and research nurses.
- B. The authorized Institutional Official shall require each Investigator to disclose SFIs (and those of the Investigator's immediate family) related to the Investigator's institutional responsibilities:

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1. No later than at the time of application for research;
 2. At least annually during the period of the award or research project; and
 3. Within 30 days of discovering or acquiring a new SFI.
- C. Institution shall designate one or more Institutional Official(s), to solicit and review disclosures of SFIs of the Investigator (and those of the Investigator's immediate family) related to an Investigator's institutional responsibilities.
- D. Institution shall provide adequate guidelines for the designated Institutional Official(s) to determine whether an Investigator's SFI is related to the research and, if so related, whether the SFI is an FCOI.
- E. The authorized Institutional Official shall require its designees, prior to Institution's expenditure of research funds, to:
1. Review all Investigator SFI disclosures;
 2. Determine if any SFIs relate to the research;
 3. Determine if an FCOI exists; and
 4. Develop and implement Management Plans, as needed to manage FCOIs.
- F. The authorized Institutional Official shall review disclosures of SFIs, make determination of FCOIs, and implement a Management Plan, when required, within 60 days for an Investigator who is new to participating in the research project or for an existing Investigator who discloses a new SFI.
- G. The authorized Institutional Official shall review disclosures of SFIs, make determination of FCOIs, and implement a Management Plan, when required, within 60 days whenever an Institution identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by the Institution.
- H. The authorized Institutional Official shall take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with Management Plans until completion of the project.

III. Reporting Requirements to NIH for PHS-funded Research

- A. The authorized Institutional Official shall send initial, annual (i.e., ongoing) and revised FCOI reports, including all reporting elements required by the Regulation,

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to the PHS Awarding Component for the Institution and its subrecipients, if applicable, as required by the Regulation:

1. Prior to the expenditure of funds;
2. Within 60 days of identification for an Investigator who is newly participating in a project;
3. Within 60 days for new, or newly identified, FCOIs for existing Investigators;
4. At least annually (at the same time the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the Management Plan, if applicable, until completion of the project; and
5. Following Retrospective Review to update a previously submitted report, if appropriate.

B. The authorized Institutional Official shall notify the PHS Awarding Component promptly if, during a Retrospective Review, bias is found with the design, conduct or reporting of PHS-funded research and to include the requirement to submit a Mitigation Report in accordance with the Regulation.

1. The procedures must include all Mitigation Report reporting elements as required by the Regulation.

C. The authorized Institutional Official shall notify the PHS Awarding Component promptly if an Investigator fails to comply with this policy or a FCOI Management Plan that appears to have biased the design, conduct or reporting of the PHS-funded research.

1. The Institution shall notify the PHS Awarding Component promptly and take any corrective action for noncompliance with this policy or the Management Plan.

IV. Maintenance of Records

- A. The authorized Institutional Official shall maintain all FCOI-related records for:
1. At least 3 years from the date the final expenditures report is submitted to the PHS Awarding Component, if applicable;
 2. At least 3 years from the date the final expenditure is made for research funded from all sources, except the PHS; and
 3. From other dates specified in 45 C.F.R. 74.53(b) and 92.42(b), where applicable and reproduced in Exhibit A attached hereto, and as may be amended from time to time.

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V. Enforcement Mechanisms, Remedies and Noncompliance

- A. The authorized Institutional Official shall adequately enforce and provide for employee sanctions or other administrative actions to ensure Investigator compliance.
- B. The authorized Institutional Official shall complete and document Retrospective Reviews within 120 days of the Institutional Official's determination of noncompliance for SFIs not disclosed timely or previously reviewed, or whenever an FCOI is not identified or managed in a timely manner, and shall document the reviews consistent with the Regulation.
- C. The purpose of a PHS-funded clinical research project may be to evaluate the safety or effectiveness of a drug, medical device or treatment. In certain circumstances, the Department of Health and Human Services may determine that such PHS-funded research project was designed, conducted or reported by an Investigator with a FCOI that was not managed or reported by the Institution as required by the Regulation. In such instance, the authorized Institutional Official shall require the Investigator involved to:
 - 1. Disclose the FCOI in each public presentation of the results of the research; and
 - 2. Request an addendum to previously published presentations.
 - 3. Institution may require similar disclosures for non-PHS-funded research.

VI. Subrecipient Requirements for PHS-funded Research

- A. Where applicable, the authorized Institutional Official shall establish, via a written agreement, whether the subrecipient will follow this policy or the FCOI policy of the subrecipient.
- B. If applicable, the authorized Institutional Official shall obtain a certification from the subrecipient that its FCOI policy complies with the Regulation.
- C. If applicable, the Institution shall include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the awardee Institution to report identified FCOIs to the PHS Awarding Component as required by the Regulation.

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- D. Alternatively, if applicable, Institution shall include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable Institution to identify, manage and report identified FCOIs to the PHS Awarding Component.

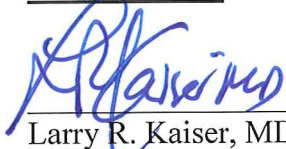
VII. Public Accessibility Requirements

- A. The authorized Institutional Official shall make this policy publicly accessible by posting it on its website.
- B. For PHS-funded research only, the authorized Institutional Official shall make available information concerning identified FCOIs held by senior/key personnel publicly accessible prior to the expenditure of funds. The information will:
1. Include the minimum elements as provided in the Regulation;
 2. Be posted on a public website or made available within 5 calendar days of written request;
 3. Be updated, at least annually (website only but any response to a written request should include the updated information);
 4. Be updated, within 60 days of a newly identified FCOI (website only but any response to a written request should include the updated information); and
 5. Remain available for 3 years from the date the information was most recently updated.

NOTES:

The policy was enacted to reflect changes in regulation regarding the disclosure and management of financial conflicts of interest related to research.

APPROVALS



Larry R. Kaiser, MD, FACS

President and Chief Executive Officer, Temple University Health System, Inc.

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ATTACHMENT A

45 C.F.R. 74.53(b)

§ 74.53 Retention and access requirements for records.

- (b) Financial records, supporting documents, statistical records, and all other records pertinent to an award shall be retained for a period of three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report. The only exceptions are the following:
 - (1) If any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.
 - (2) Records for real property and equipment acquired with Federal funds shall be retained for 3 years after final disposition.
 - (3) When records are transferred to or maintained by the HHS awarding agency, the 3-year retention requirement is not applicable to the recipient.
 - (4) Indirect cost rate proposals, cost allocations plans, etc., as specified in § 74.53(g).

45 C.F.R. 92.42(b)

§ 92.42 Retention and access requirement for records.

- (a) Applicability.
 - (1) This section applies to all financial and programmatic records, supporting documents, statistical records, and other records of grantees or subgrantees which are:
 - (i) Required to be maintained by the terms of this part, program regulations or the grant agreement, or
 - (ii) Otherwise reasonably considered as pertinent to program regulations or the grant agreement.

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- (2) This section does not apply to records maintained by contractors or subcontractors. For a requirement to place a provision concerning records in certain kinds of contracts, see § 92.36(i)(10).
- (b) Length of retention period.
 - (1) Except as otherwise provided, records must be retained for three years from the starting date specified in paragraph (c) of this section.
 - (2) If any litigation, claim, negotiation, audit or other action involving the records has been started before the expiration of the 3-year period, the records must be retained until completion of the action and resolution of all issues which arise from it, or until the end of the regular 3-year period, whichever is later.
 - (3) To avoid duplicate recordkeeping, awarding agencies may make special arrangements with grantees and subgrantees to retain any records which are continuously needed for joint use. The awarding agency will request transfer of records to its custody when it determines that the records possess long-term retention value. When the records are transferred to or maintained by the Federal agency, the 3-year retention requirement is not applicable to the grantee or subgrantee.

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