| System-wide Policy:<br>GE0002 - Procedure: Public Health Service FCOI Requirements | |
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Public Health Service (PHS) promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. **The University of Tennessee (University) adopts, implements, and enforces PHS requirements through GE0002. This GE0002 Policy Document is designed to supplement and support those efforts.**

No matter the outside interest, activity, or circumstances involved, each University employee and researcher must understand and comply with applicable state and federal requirements. The following is intended to help the University and its investigators understand, implement, and enforce PHS financial conflict of interest (FCOI) requirements:

## Definitions

A. "Financial Interest" means anything of monetary value, whether or not the value is readily ascertainable.
B. "Financial Conflict of Interest (FCOI)" means a financial conflict of interest the exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a PHS-funded research project (i.e., the Significant Financial Interest could be affected by the research or the Significant Financial Interest is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct or reporting of the PHS-funded research.
C. "Institutional Responsibilities" means an individual's professional responsibilities on behalf of the University. Such responsibilities include, but are not limited to: research, research consultation, teaching, general and scholarly publications and public presentations, professional practice, institutional committee memberships, and service on committees or panels such as research ethics committees (e.g. Institutional Review Boards) and other bodies monitoring the conduct of research.
D. "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 funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants.

E. "PD/PI" means a project director or principal Investigator of a PHS-funded research project. PD/PI is included within the definition of Senior/Key Personnel.

F. "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.

G. "Research" means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The 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). As used in this Policy Procedure, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

H. "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 submitted to the PHS.

I. "Significant Financial Interest" means the regulatory definition of SFI including NIH's FAQs D.8., E.9. and E.20.

**Training Requirements** (42 CFR 50.604(b))

A. The University's Campus conflicts officer (its designated official) establishes processes to comply with 42 CFR 50.604(b) and inform all investigators involved in any PHS-funded research of: (1) the University's policy on financial conflicts of interest described herein and GE0002; (2) the investigator's responsibilities regarding disclosure of all foreign and domestic significant financial interests; and (3) the PHS regulations.

B. The Campus conflicts officer establishes processes requiring each investigator to complete training regarding the same (which may also utilize FCOI Training resources) ***prior to*** engaging in any PHS-funded research and at least every four years, and immediately when any of the following circumstances apply:

1. The University revises its policies or procedures in any manner that affects the requirements of investigators;
2. An investigator is new to the University; or
3. The University finds that an investigator is not in compliance or with any management plan implemented under with PHS requirements.

C. Documentation that each investigator has completed the required training will be maintained in the investigator's personnel file or in the office of the Campus conflicts officer.

**Disclosure, Review and Monitoring Requirements** (42 CFR 50.603; 42 CFR 50.604; 42 CFR 50.605)

A. Each current Campus conflicts officer will be named as the designated official in GE0002.

B. The Campus conflicts officer, consistent with PHS regulations and GE0002, will require that:
   1. Each investigator who is planning to participate in the PHS-funded research use the University's outside interest disclosure system to disclose significant financial interests (and those of the investigator's spouse and dependent children) no later than the time of application for PHS-funded research.
   2. Each investigator who is participating in the PHS-funded research submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by GE0002, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the University pursuant to the above paragraph, or in a subsequent disclosure of significant financial interests (e.g., any FCOI identified on a PHS-funded project that was transferred from another institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).
   3. Each investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest. Investigators must also disclose reimbursed or sponsored travel within thirty (30) days of each occurrence.

C. Prior to the expenditure of any funds under a PHS-funded research project, the Campus conflicts officer shall review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research (in accordance with the standards

described in F below); determine whether a FCOI exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI. The management plan for a FCOI may include, but is not limited to, the following examples of conditions and restrictions:

1. Public announcement of financial conflicts of interest (e.g., when presenting or publishing the PHS-funded research to research personnel working on the study, to the Institution's Institutional Review Board, to the Institution's Institutional Animal Care and Use Committee, to a Data Safety and Monitoring Board, etc., as applicable);
2. For PHS-funded research projects involving human subjects research, announcement of financial conflicts of interest directly to participants;
3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the PHS-funded research against bias, resulting from the FCOI;
4. Modification of the research plan;
5. Change of investigator or investigator's institutional responsibilities, or disqualification of investigator from participation in all or a portion of the research;
6. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
7. Severance of relationships that create financial conflicts of interest.

D. Whenever, in the course of an ongoing PHS-funded research project, an investigator who is new to participating in the project discloses a significant financial interest or an existing investigator discloses a new significant financial interest, the Campus conflicts officer shall, within 60 days: review the disclosure of significant financial interest; determine whether it is related to PHS-funded research; determine whether a FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward. Depending on the nature of the significant financial interest, the Campus conflicts officer may determine that additional interim measures are necessary with regard to the investigator's participation in the PHS-funded research project between the date of the disclosure and the completion of the University's review.

E. Whenever Campus conflicts officer identifies a significant financial interest that was not disclosed timely by an investigator or, for whatever reason, was not previously reviewed by the University during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the Campus conflicts officer shall, within 60 days, review the significant financial

interest, determine whether it is related to PHS-funded research; determine whether a FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward.

F. The following guidelines are provided for the Campus conflicts officer to determine whether a significant financial interest is related to PHS-funded research and, if so, whether the significant financial interest is a FCOI.

1. The Campus conflicts officer shall refer to the PHS regulations 42 CFR 50.604(f), the Frequently Asked Questions, and other guidance provided on the NIH FCOI website when making determinations as to whether a significant financial interest is related to PHS-funded research and, if so, whether the significant financial interest is a FCOI. Upon request, the Institutional Review Board, Institutional Animal Care and Use Committee, and other relevant committees shall cooperate with the Campus conflicts officer in making the required determinations. The Campus conflicts officer shall consult with the University's Office of the General Counsel as needed with respect to the interpretation of the PHS regulations and NIH guidance.
2. A significant financial interest is related to PHS-funded research when the University, through its Campus conflicts officer, reasonably determines that the significant financial interest (1) could be affected by the PHS-funded research, (2) or is in an entity whose financial interest could be affected by the PHS-funded research. The Campus conflicts officer may involve the investigator in the determination of whether a significant financial interest is related to the PHS-funded research.
3. A FCOI exists when the University, through its Campus conflicts officer, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

G. Whenever the Campus conflicts officer implements a management plan, the Campus conflicts officer shall monitor investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project. The Campus conflicts officer shall use best efforts to ensure investigators comply and cooperate with any conditions or restrictions imposed by the University, through the Campus conflicts officer, to manage a FCOI.

**Reporting Requirements; Maintenance of Records** (42 CFR 50.604; 42 CFR 50.605)

The Campus conflicts officer shall ensure that all financial conflicts of interest are reported in compliance with the following requirements:

A. Prior to the expenditure of any funds under a PHS-funded research project, the University shall submit to the PHS awarding component an FCOI report of any investigator's significant financial interest determined to be a FCOI and ensure that a management plan has been implemented. If a FCOI is eliminated prior to the expenditure of PHS-awarded funds, the University shall not submit an FCOI report to the PHS awarding component.

B. For any significant financial interest the University determines to be a financial conflicts of interest subsequent to the University's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an investigator who is new to the research project), the University shall submit to the PHS awarding component, within 60 days, an FCOI report the FCOI and ensure that a management plan has been implemented. In addition, whenever an FCOI is not identified or managed in a timely manner including failure by the investigator to disclose a significant financial interest that is determined by the University to constitute a financial conflict of interest; failure by the University to review or manage such a financial conflict of interest; or failure by the investigator to comply with a financial conflict of interest management plan, the University shall, within 120 days of the University's determination of noncompliance, complete a retrospective review of the investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

    1. The University is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

        A. Project number;
        B. Project title;
        C. PD/PI or contact PD/PI if a multiple PD/PI model is used;
        D. Name of the Investigator with the FCOI;
        E. Name of the entity with which the Investigator has a financial conflict of interest;
        F. Reason(s) for the retrospective review;

G. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

H. Findings of the review; and

I. Conclusions of the review.

2. Based on the results of the retrospective review, if appropriate, the University shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the University is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the University's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the University will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, the University may determine that additional interim measures are necessary with regard to the investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the investigator's noncompliance is determined and the completion of the University's retrospective review.

C. If, in compliance with PHS regulations, the University completes a retrospective review and determines that any PHS-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or report of such research, the University shall notify the PHS awarding component promptly and submit a mitigation report.

D. FCOI reports shall include sufficient information to enable the PHS awarding component to understand the nature and extent of the FCOI and to assess the appropriateness of the University's management plan, such information to include but not be limited to at least the following key elements:

1. Project number;
2. PD/PI or contact PD/PI if a multiple PD/PI model is used;
3. Name of the investigator with the FCOI;
4. Name of the entity with which the investigator has a FCOI;
5. Nature of the investigator's financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
6. Value of the investigator's financial interest (dollar ranges are permissible: $0 - $4,999; $5,000 - $9,999; $10,000 - $19,999; amounts between $20,000 - $100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
7. Description of how the financial interest relates to the PHS-funded research and the basis for the University's determination that the financial interest conflicts with such research; and
8. Description of the key elements of the University's management plan, including:
   (a) Role and principal duties of the conflicted investigator in the research project;

   (b) Conditions of the management plan;

   (c) How the management plan is designed to safeguard objectivity in the research project;

   (d) Confirmation of the investigator's agreement to the management plan;

   (e) How the management plan will be monitored to ensure investigator compliance; and

   (f) Other information as needed.

E. For any FCOI previously reported by the University with regard to an ongoing PHS-funded research project, the Campus conflicts officer shall provide to the PHS awarding component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the FCOI is still being managed or explain why the

FCOI no longer exists. The Campus conflicts officer shall provide annual FCOI reports to the PHS awarding component for the duration of the research project period (including extensions with or without funds) in the time and manner specified by the PHS awarding component.

F. All FCOI reports shall be submitted using the electronic FCOI module, accessed via eRA Commons on the Electronic Research Administration portion of the NIH's website, or by another method provided or required by NIH from time-to-time.

G. Maintenance of Records (42 CFR 50.604). The University shall maintain records relating to all investigator disclosures of financial interests, the University's review of, and response to, such disclosures (whether or not a disclosure resulted in the determination of a FCOI), and all actions or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in a grant agreement or applicable law or regulation.

**University and Federal Enforcement Mechanisms** (42 CFR 50.604; 42 CFR 50.605; 42 CFR 50.606)

A. Consistent with GE0002, compliance with PHS requirements is a condition of employment and/or participation for all applicable investigators and such investigators who fail to comply are subject to discipline, including termination of employment, and may be disqualified from further participation in any PHS-funded research. For investigators who are not University employees, compliance with PHS requirements is a condition of participating in a PHS-funded research project with the University, and such investigators who fail to comply may be disqualified from further participation in any PHS-funded research. In addition, such investigators who are University students (including residents and fellows) are subject to disciplinary action under applicable student conduct rules.

B. As outlined above, the Campus compliance officer must perform a retrospective review in accordance with PHS requirements. Upon request by the PHS awarding component, the University shall submit, or permit on site review of, all records pertinent to compliance with the PHS regulations.

C. If the failure of an investigator to comply with PHS requirements or with a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the

University shall promptly notify the PHS awarding component of the corrective action taken or to be taken. The PHS awarding component may take appropriate action or refer the matter to the University for further action, which may include directions on how to maintain appropriate objectivity in the PHS-funded research project.

D. If the Department of Health and Human Services determines that a PHS-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 FCOI that was not managed or reported by the University as required by the PHS regulations, the University shall require the investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

**Subrecipient Requirements** (42 CFR 50.604)

A. If the University carries out PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Campus conflicts officer will ensure that the University takes reasonable steps to ensure that any subrecipient investigator complies with the PHS regulations by:
    1. Incorporating as part of a written agreement with the subrecipient terms that establish University's Conflicts of Interest & Commitment Policy or the financial conflicts of interest policy of the subrecipient will apply to the subrecipient's investigators.
    2. Except as provided below, the agreement shall provide that the subrecipient's investigators must comply with the subrecipient's financial conflicts of interest policy, and the subrecipient shall certify as part of the agreement that its policy complies with the PHS regulations. The agreement shall also specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the University. Such time period(s) shall be sufficient to enable the University to provide timely FCOI reports, as necessary, to the PHS awarding component as required by the PHS regulations.
    3. If the subrecipient cannot certify that its financial conflicts of interest policy complies with the PHS regulations, or if the subrecipient does not have a financial conflicts of interest policy, the agreement shall state that subrecipient investigators are subject to the requirements of GE0002 for disclosing significant financial interests that are directly related to the subrecipient's work for the University. The agreement shall also specify time period(s) for the subrecipient to submit all investigator disclosures of significant financial

interests to the University. Such time period(s) shall be sufficient to enable the University to comply timely with its review, management, and reporting obligations under the PHS regulations.

B. Providing FCOI reports to the PHS awarding component regarding all financial conflicts of interest of all subrecipient investigators consistent with the PHS regulations, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

**Public Accessibility Requirements** (42 CFR 50.604; 42 CFR 50.605)

A. The University's Conflicts of Interest & Commitment Policy (GE0002) shall be posted on the University's public website.

B. Prior to the University's expenditure of any funds under a PHS-funded research project, the University shall ensure public accessibility, via written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the University that meets the following three criteria:
   1. The significant financial interest was disclosed and is still held by senior/key personnel as defined by PHS regulation;
   2. The University determines that the significant financial interest is related to the PHS-funded research; and
   3. The University determines that the significant financial interest is a FCOI.

C. The information the University makes available via written response to any requestor within five business days of a request, shall include, at a minimum, the following: The investigator's name; the investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

D. The University will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60

days of Campus conflicts officer's identification of a new FCOI, which should be requested subsequently by the requestor.

E. Information concerning the significant financial interests of investigators, as applicable pursuant to PHS requirements, shall remain available, for responses to written requests for at least three years from the date the information was most recently updated.

**Certification Requirements**

In each application for PHS-funded research, the Campus compliance officer shall help ensure the University includes a certification that the University:

1. Has in effect at the University an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS;
2. Shall promote and enforce investigator compliance with the PHS regulations, including those pertaining to disclosure of significant financial interests;
3. Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS awarding component consistent with the PHS regulations;
4. Agrees to make information available, promptly upon request, to the HHS relating to any disclosure of financial interests by an investigator and the University 's review of, and response to, such disclosure, whether or not the disclosure resulted in the University's determination of a FCOI; and
5. Shall fully comply with the requirements of the PHS regulations.