

<b>System-wide Policy: FI0125 - Conflict of Interests</b>	
<b>Version: 3</b>	<b>Effective Date: 10/01/2017</b>

## FI0125 – Conflict of Interests

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### Objective:

Objectivity and integrity are essential qualities for employees and others engaged with any organization in carrying out its mission, and particularly for those who are engaged in the service of a comprehensive public university like The University of Tennessee (University). If the University is to carry out its mission in the areas of instruction, research, and public service with unquestioned credibility, the highest standards of objectivity and integrity must be maintained. The purpose of this policy is to promote those high standards.

### Policy:

## APPLICATION

This Conflicts of Interest Policy is divided into Part I and Part II for the purpose of addressing the change in federal regulations governing research funded by the Public Health Service (PHS) or one of its components, including the National Institutes of Health.

**Application of Part I, General Conflicts of Interest Policy:** Part I of this policy applies to the following individuals who will be referred to as a "covered individual" except where a provision applies only to University employees:

1. All University employees, except student employees who do not qualify as investigators as defined in Section 1 of Part 1; and

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2. All investigators, as defined in Section 1 of Part I, who are responsible for the design, conduct, or reporting of research at the University, except that with respect to PHS-funded research, Part I shall apply only to research with an award date (including a noncompeting continuation) before August 24, 2012.

Part I of this policy, and the PHS regulatory requirements in effect before August 24, 2012, will continue to govern the disclosure, review, management, and reporting of financial conflicts of interest in PHS-funded research grants, cooperative agreements, and contracts with an award date (including a noncompeting continuation) before August 24, 2012 **only until the grant, cooperative agreement, or contract becomes subject to Part II of this policy (e.g, when a PHS-funded research grant existing before August 24, 2012 receives a Notice of Award or incremental funding on or after August 24, 2012).**

**Application of Part II, PHS-Funded Research:** Part II of this policy applies only to investigators (as defined in Part II) involved in research grants and cooperative agreements funded in whole or in part by PHS with an award date (including a noncompeting continuation) **on or after August 24, 2012** and to solicitations issued and contracts awarded (including a noncompeting continuation) **on or after August 24, 2012.**

An investigator subject to Part II who is an employee of the University is also subject to Part I this policy (except that the requirements of Part II shall be controlling with respect to PHS-funded research) and must file the disclosure forms required by both Part I and Part II.

**IMPORTANT NOTICE:** When a PHS-funded research grant, cooperative agreement, or contract becomes subject to Part II of this policy, all investigators (as defined in Part II) must complete the mandatory training required by Section 4 of Part II and must make the disclosure of significant financial interests required by Section 5 of Part II *prior to engaging in any research* related to such grant, cooperative agreement, or contract. This is required so that the University can fulfill its obligations under Part II *prior to the expenditure of any funds* related to such PHS-funded research grant, cooperative agreement, or contract.

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## PART I: GENERAL CONFLICTS OF INTEREST POLICY

### Section 1. Definitions

- a. For the purpose of Part I, a financial interest means anything of monetary value, whether or not the value is readily ascertainable and includes the interest of the covered individual's spouse (whether or not they commingle assets), parents, and children (both dependent and nondependent and including stepchildren and foster children).
- b. For the purpose of Part I, an investigator means any person (including but not limited to a student, resident, fellow, post-doctoral appointee, and affiliate, volunteer, and adjunct faculty appointee), regardless of title or position and regardless of whether compensated or not, who is responsible for the design, conduct, or reporting of research at the University.

### Section 2. General Principles

Covered individuals are expected to take all reasonable precautions to ensure that their outside financial interests do not place them in conflict with carrying out their duties and responsibilities as employees of the University or as investigators. Generally, a conflict of interests exists in the following circumstances:

- a. A covered individual allows outside financial interests to interfere with or compromise judgment and objectivity with respect to duties and responsibilities to the University or sponsoring organizations.
- b. A covered individual makes University or University-related decisions or uses university resources in a manner that results in or is expected to result in:
  - Personal financial gain or financial gain for his or her relatives; or
  - An unfair advantage to or favored treatment for a third party outside the university.
- c. A covered individual allows outside financial interests to affect the design, conduct, or reporting of research.

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### Section 3. Examples of Conflicts of Interests

In accordance with the principles stated above, the following situations are examples of prohibited conflicts of interests and **do not constitute an all-inclusive list of prohibited conflicts**.

- a. Serving as a member of the board of directors for, serving as a consultant to, or holding an office or a management position in an outside entity **and**:
  - The covered individual procures or influences the procurement of goods or services from that entity for the University; **or**
  - The covered individual uses his or her University position to obtain favored treatment for or to provide an unfair advantage to that entity.
- b. Holding more than a 5 percent financial interest (or 5 percent combined interest of the covered individual, spouse, and dependent child) in an outside venture **and**:
  - The covered individual procures or influences the procurement of goods or services from that venture for the University; **or**
  - The covered individual uses his or her University position to obtain favored treatment for or to provide an unfair advantage to that venture.
- c. Soliciting or accepting gifts, gratuities, benefits, or favors of monetary value from a person or an entity:
  - In return for influencing a covered individual in the discharge of his or her University or University-related duties and responsibilities; **or**
  - While being in a position to obtain favored treatment for or provide an unfair advantage to that person or entity.
- d. Selling any products or services to the University or other state agency while an employee or within six months after termination of active employment with the University.

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**This prohibition applies to sales by:**

- The employee,
- A business in which the employee is the sole proprietor,
- A business in which the employee is a partner, or
- A business in which the employee has a controlling interest (owns or controls the largest number of outstanding shares owned by any single individual or business).

**This prohibition does *not* apply to:**

- The purchase of textbooks, stage plays, and other copyrighted literary property for which the employee receives royalties from a distributor in which the employee does not own a controlling interest.
- Sole-source suppliers, unless the employee-supplier also procures or influences the procurement of the particular product or service for the University.

**Note:** If the sole-source exception allows an employee to sell products or services to the University, the employee's interest must be publicly acknowledged at the time of the sale.

- e. Using confidential or official University information in any manner that results in or is expected to result in personal financial gain or financial gain for the covered individual's relatives or that provides financial gain or an unfair advantage to a third party.

#### **Section 4. State Law**

Certain conflicts of interest violate state law and may result in criminal and civil penalties [State-Laws-on-Conflicts-of-Interest-20120821](#) .

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## **Section 5. Enforcement**

Compliance with Part I is a condition of employment for all University employees, and employees who fail to comply with Part I are subject to discipline, including termination of employment. For all covered individuals who are investigators subject to Part I, compliance with Part I is a condition of participating in a research project at the University, and such investigators who fail to comply with Part I may be disqualified from further participation in any research at the University. In addition, such investigators who are University students (including residents and fellows) are subject to disciplinary action under applicable student conduct rules.

## **Section 6. Disclosure Requirements**

All employees are required to take the initiative and report in writing (e.g., memo) to their immediate supervisor any conflicts of interest between their University duties and responsibilities and their outside interests. In addition, all covered individuals (except term employees) will be notified annually to disclose outside interests on the form provided by the University. This form requires the disclosure of specific outside interests that may or may not represent conflicts of interests. Covered individuals may also be required periodically to complete a disclosure form whether or not they have interests or activities to disclose. Requirements for filing a disclosure form are as follows:

- a. All faculty and exempt staff must have a completed disclosure form on file whether or not they have interests or activities to disclose.
- b. All covered individuals (except term employees) will receive an annual notification to disclose outside interests and activities. Once a covered individual discloses any outside interests or activities, he or she must file a disclosure form annually as long as the interest or activity exists.
- c. New employees (except term employees and student employees who are not investigators as defined in Section 1 above) are required to complete and file a disclosure form within 30 days of their effective employment date whether or not they have interests or activities to disclose.

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- d. Senior administrators designated by the president or the chief financial officer (or designee) are required to file a disclosure form by July 31 each year.
- e. Covered individuals involved in research (i.e., investigators as defined in Section 1 above) must have disclosed outside interests that may be affected by the research before proposals are submitted to funding agencies. Such covered individuals must keep their disclosures updated for the duration of the project. Examples of such interests include, but are not limited to, receiving payments for services exceeding \$10,000, having equity interest exceeding 5 percent **or** \$10,000, and holding intellectual property rights.
- f. Although not necessarily prohibited, certain outside interests or activities may be conflicts and must be disclosed, such as:
  - Engaging in a partnership, consulting relationship, employment relationship, or other outside venture with University employees or students. **Note:** [HR0122 - Employment of University Employees by Other University Personnel](#) prohibits University supervisory staff from hiring employees in their line of authority for personal services.
  - Engaging in University research sponsored by an organization in which the covered individual has more than a 5 percent **or** \$10,000 financial interest.
  - Having a financial interest (including, but not limited to, receiving payments for services exceeding \$10,000, having equity interest exceeding 5% **or** \$10,000, and holding intellectual property rights) in an outside venture that would reasonably appear to be affected by any research conducted by the covered individual.

### **Section 7. Campus or Institute Requirements**

Chief business officers are responsible for ensuring that their campuses or institutes:

- a. Present and discuss this policy with new employees during their orientation.
- b. Require all faculty and exempt staff to have an outside interests disclosure form on file whether or not they have interests or activities to disclose.

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- c. Notify covered individuals (except term employees) annually of their obligation to disclose outside interests and activities and of where to file the disclosure form.
- d. Provide instructions to department heads and supervisors to ensure that they understand their responsibilities in reviewing and identifying conflicts of interests.
- e. Establish a committee(s) to review the information disclosed by covered individuals; determine whether a conflict of interests exists; and notify covered individuals of the results of the review.
- f. Maintain the disclosure forms of employees in their personnel files and the disclosure forms of other covered individuals in the chief business officers' office.
- g. Work with covered individuals to prevent or resolve conflicts. Resolution can include eliminating such conflicts or managing conflicts that cannot be eliminated. Conflicts can be managed through independent reviewers, reassignment of responsibilities, modifying the research plan, or other methods to reduce or minimize the effects of a conflict.
- h. Inform the chief financial officer (or designee) of conflicts of interests in the following ways: (1) report annually any conflicts of interests that were disclosed or became known over the past twelve months and their resolution and (2) report immediately any conflicts of interests that cannot be resolved.
- i. Document the review of information disclosed by covered individuals and the actions taken to resolve any conflicts. For sponsored programs, all documentation related to disclosures and the elimination or management of conflicts must be maintained for three years either after the close of the related awards or any government action involving these records.
- j. Report immediately any conflicts of interests that cannot be resolved to sponsoring organizations according to their requirements.
- k. Provide sponsoring organizations with required certifications that, for example, the University's conflicts of interest policy was implemented, disclosures were made, and identified conflicts are being managed satisfactorily, etc.

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## **PART II: POLICY GOVERNING FINANCIAL CONFLICTS OF INTEREST IN PHS-FUNDED RESEARCH AS OF AUGUST 24, 2012**

### **Section 1. Effective Date and Application**

Part II of the University's Conflicts of Interest Policy is effective August 24, 2012 and governs the disclosure, review, management, and reporting of financial conflicts of interest in research funded by the Public Health Service (PHS) of the U. S. Department of Health and Human Services and its components, including the National Institutes of Health.

Part II applies only to research grants and cooperative agreements funded in whole or in part by PHS with an award date (including a noncompeting continuation) on or after August 24, 2012 and to solicitations issued and contracts awarded (including a noncompeting continuation) on or after August 24, 2012.

Investigators (as defined in Section 2 of Part II) who are University employees are also subject to the requirements of Part II in addition to the requirements of Part I of the University's Conflicts of Interest Policy (except that the requirements of Part II shall be controlling with respect to PHS-funded research) and must file the disclosure forms required by both Part I and Part II.

**IMPORTANT NOTICE: When a PHS-funded research grant, cooperative agreement, or contract becomes subject to Part II of this policy, all investigators (as defined in Part II) must complete the mandatory training required by Section 4 of Part II and must make the disclosure of significant financial interests required by Section 5 of Part II *prior to engaging in any research* related to the grant, cooperative agreement, or contract. This is required so that the University can fulfill its obligations under Part II *prior to the expenditure of any funds* related to the grant, cooperative agreement, or contract.**

### **Section 2. Definitions**

The following terms used in Part II shall have the meaning described below.

**"Designated Official"** means the chief research officer or the chief business officer of the campus or institute, as designated by the chief executive officer of the campus or

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institute, who shall have primary responsibility for implementing Part II of the University's Conflict of Interest Policy and overseeing the compliance with its requirements.

**"Disclosure of significant financial interests"** means an investigator's disclosure of significant financial interests to the University.

**"Financial conflict of interest (FCOI)"** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

**"FCOI report"** means the University's report of a financial conflict of interest to a PHS awarding component.

**"Financial interest"** means anything of monetary value, whether or not the value is readily ascertainable.

**"HHS"** means the United States Department of Health and Human Services and any components of the Department to which the authority involved may be delegated.

**"Institutional responsibilities"** mean an investigator's professional responsibilities on behalf of the University, which include the following and similar activities: research, research consultation, teaching, professional practice, University committee memberships, service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards, and other internal or external service activities.

**"Investigator"** means the project director ("PD") or principal investigator ("PI") and any other person (including but not limited to a student, resident, fellow, post-doctoral appointee, and affiliate, volunteer, and adjunct faculty appointee), regardless of title or position and regardless of whether compensated or not, who is responsible for the design, conduct, or reporting of PHS-funded research, or proposed for such funding, which may include, for example, collaborators or consultants.

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**"Manage"** means taking action to address a financial conflict of interest, 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.

**"PD/PI"** means a project director or principal investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and investigator under Part II.

**"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 National Institutes of Health (NIH).

**"PHS awarding component"** means the organizational unit of the PHS that funds the research subject to Part II.

**"PHS regulations"** means the federal regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought (42 C.F.R. Part 50 Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94).

**"PHS-funded research"** means research funded in whole or in part under a PHS grant or cooperative agreement with a Notice of Award issue date or other award date (including a noncompeting continuation) on or after August 24, 2012 and to solicitations issued and contracts awarded (including a noncompeting continuation) on or after August 24, 2012.

**"Public Health Service Act" or "PHS Act"** means the statute codified at [42 U.S.C. 201 et seq.](#)

**"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

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(e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from a PHS awarding component through a grant, cooperative agreement, or contract 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, University training grant, program project, or research resources award.

**"Senior/key personnel"** means the project director (PD) and principal investigator (PI) and any other person identified as senior/key personnel by the University in the grant application, progress report, or any other report submitted to the PHS by the University.

**"Significant financial interest"** means:

(1) A financial interest consisting of one or more of the following interests of the investigator, and those of the investigator's spouse and dependent children, that are, or could reasonably appear to a non-expert to be, related to the investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, speaker fees); equity interest includes any stock, stock option, partnership share, member interest, sole proprietorship, 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, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator (or the investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock

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option, partnership share, member interest, sole proprietorship, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, pending patent applications, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored 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 their institutional responsibilities; **provided, however, that this disclosure requirement does not apply to 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.** The disclosure shall include the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and any other information, including a determination or disclosure of monetary value, determined by the Designated Official to be necessary to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term significant financial interest does **not** include the following types of financial interests:

- salary, royalties, or other remuneration paid by the University to the investigator if the investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
- 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;
- income from seminars, lectures, or teaching engagements 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;

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- or income from service on advisory committees or review panels for 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.

### **Section 3. Responsibilities of the Designated Official**

The chief executive officer of each campus or institute shall designate either the chief research officer or the chief business officer of the campus or institute to serve as the Designated Official with primary responsibility for implementing Part II and for overseeing the University's compliance with its requirements. The Designated Official shall establish one or more committees to assist in carrying out these responsibilities.

### **Section 4. Training Requirements**

- A. The Designated Official shall establish a process to inform all investigators involved in any PHS-funded research of: (1) Part II of the University's Conflicts of Interest Policy; (2) the investigator's responsibilities regarding disclosure of significant financial interests; and (3) the PHS regulations.
- B. The Designated Official shall establish a process to require each investigator to complete training regarding Part II, the investigator's responsibilities regarding disclosure of significant financial interests, and the PHS regulations **prior to** engaging in 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 related to conflicts of interest 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 with Part II or with any management plan implemented under Part II.
- C. The training of each investigator required by this Section 4 of Part II shall be consistent with the training guidance set forth on the National Institutes of Health (NIH) Financial Conflict of Interest website located at: <http://grants.nih.gov/grants/policy/coi/>, as it may be updated from time-to-

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time, and may include the training tutorial located on the NIH website (which includes a certificate of completion of such tutorial) or other appropriate online training. Documentation that each investigator has completed the required training shall be maintained in the investigator's personnel file or in the office of the Designated Official.

### **Section 5. Disclosure Requirements**

- A. Each investigator planning to participate in any PHS-funded research shall disclose significant financial interests (see the definition in Section 2 of Part II) of the investigator, and those of the investigator's spouse and dependent children, **no later than at the time of application for PHS-funded research**; provided, however, that an investigator who is new to the University and is planning to participate in an on-going PHS-funded research project shall make the disclosure no later than 30 days after initial employment with the University;
- B. Each investigator participating in PHS-funded research shall submit an updated disclosure of significant financial interests not later than July 31 annually during the period of the award, and shall include any information that was not disclosed initially to the University pursuant to paragraph A. of this Section 5, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded research 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); and
- C. Each investigator participating in PHS-funded research shall submit an updated disclosure of significant financial interests within 30 days after discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest of the investigator and of the investigator's spouse and dependent child(ren). Specifically, the following new financial interests must be disclosed: (1) any equity interest in a non-publicly traded entity; (2) an equity interest in a publicly traded entity that, alone or aggregated with remuneration from or equity interest in the same entity within the 12 months preceding the

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updated disclosure, is valued at more than \$5,000; (3) remuneration from a single external entity (publicly traded or non-publicly traded) that, alone or aggregated with remuneration from the same entity within the 12 months preceding the updated disclosure, exceeds \$5,000; and (4) any income related to intellectual property rights and interests.

- D. Each investigator participating in PHS-funded research shall disclose any reimbursed or sponsored travel related to, or that could reasonably appear to a non-expert to be, related to the investigator's institutional responsibility within 30 days of the travel return date using the **Disclosure Form for Reimbursed and Sponsored Travel**.
- E. In disclosing significant financial interests, the interest of a legal entity, including but not limited to a foundation or a trust, that is controlled or directed by the investigator and/or the investigator's spouse and/or dependent children is considered to be the interest of the investigator or the investigator's spouse or dependent children as if the legal entity did not exist.
- F. In disclosing significant financial interests, the investigator should resolve doubt in favor of disclosure.
- G. To enable the University to fulfill its obligation under the PHS regulations to determine if the investigator has a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research, thereby constituting a financial conflict of interest that must be managed, the investigator shall comply with the disclosure requirements of this Section 5 by completing the [Financial-Interest-Disclosure-Form-for-PHS-Investigators](#). The investigator shall provide any additional information necessary for the University to fulfill its obligations under the PHS regulations.

## **Section 6. Review, Management, and Monitoring Requirements**

- A. Prior to the University's expenditure of any funds under a PHS-funded research project, the Designated Official shall, consistent with the PHS regulations, review all disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; and determine whether a

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financial conflict of interest exists; and, if so, develop and implement a management plan specifying the actions that have been, and shall be, taken to manage the financial conflict of interest.

- B. 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 Designated Official shall, within 60 days: review the disclosure of significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest 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 financial conflict of interest going forward. Depending on the nature of the significant financial interest, the Designated Official 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.
- C. Whenever Designated Official 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 Designated Official shall, within 60 days, review the significant financial interest, determine whether it is related to PHS-funded research; determine whether a financial conflict of interest 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 financial conflict of interest going forward.
- D. The following guidelines are provided for the Designated Official to determine whether a significant financial interest is related to PHS-funded research and, if so, whether the significant financial interest is a financial conflict of interest.
1. The Designated Official shall refer to the PHS regulations, the Frequently Asked Questions, and other guidance provided on the NIH FCOI website located at <http://grants.nih.gov/grants/policy/coi/> when making determinations as to whether a significant financial interest is related to

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PHS-funded research and, if so, whether the significant financial interest is a financial conflict of interest. Upon request, the Institutional Review Board, Institutional Animal Care and Use Committee, and other relevant committees shall cooperate with the Designated Official in making the required determinations. The Designated Official 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 Designated Official, 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 Designated Official may involve the investigator in the determination of whether a significant financial interest is related to the PHS-funded research.
  3. A financial conflict of interest exists when the University, through its Designated Official, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
- E. The management plan for a financial conflict of interest may include, but is not limited to, the following conditions and restrictions:
1. Public announcement of financial conflicts of interest (e.g., when presenting or publishing the PHS-funded research);
  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 financial conflict of interest;
  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;

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- 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.
- F. Investigators shall comply with any conditions or restrictions imposed by the University, through the Designated Official, to manage a potential or actual financial conflict of interest and shall cooperate with the Designated Official to ensure that the University is able to manage potential or actual financial conflicts of interest.
- G. Whenever the Designated Official implements a management plan pursuant to this Part II, the Designated Official shall monitor investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

### **Section 7. Retrospective Review and Mitigation Requirements**

- A. Whenever a financial conflict of interest 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 Designated Official 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 Designated Official shall, within 120 days of the 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.
- B. The Designated Official shall document all retrospective reviews, and the documentation shall include, but not necessarily be limited to, all of the following key elements:
- 1. Project number;
  - 2. Project title;
  - 3. PD/PI or contact PD/PI if a multiple PD/PI model is used;

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4. Name of the investigator with the FCOI;
  5. Name of the entity with which the investigator has a financial conflict of interest;
  6. Reason(s) for the retrospective review;
  7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
  8. Findings of the review; and
  9. Conclusions of the review.
- C. Based on the results of a retrospective review, if appropriate, the Designated Official shall update the previously submitted FCOI report (see Section 9 of Part II), specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Designated Official shall 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 Designated Official will submit FCOI reports annually, as specified elsewhere in Part II. Depending on the nature of the financial conflict of interest, the Designated Official 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 Designated Official's retrospective review.

### **Section 8. Maintenance of Records**

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 financial conflict of interest), and all actions

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under this Part II 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 [45 C.F.R. 74.53\(b\)](#) and [92.42 \(b\)](#) for different situations.

### **Section 9. Reporting Requirements**

The Designated Official 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 financial conflict of interest and ensure that a management plan has been implemented. If a financial conflict of interest 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 financial conflict of interest and ensure that a management plan has been implemented.
- C. If the University completes a retrospective review pursuant to Section 7 of Part II and determines that any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest 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 financial conflict of interest 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;

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3. Name of the investigator with the financial conflict of interest;
4. Name of the entity with which the investigator has a financial conflict of interest;
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.

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- E. For any financial conflict of interest previously reported by the University with regard to an ongoing PHS-funded research project, the Designated Official shall provide to the PHS awarding component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict of interest is still being managed or explain why the financial conflict of interest no longer exists. The Designated Official 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 located at: [http://era.nih.gov/services\\_for\\_applicants/other/fcoi.cfm](http://era.nih.gov/services_for_applicants/other/fcoi.cfm), or at another website or by another method provided or required by NIH from time-to-time.

### **Section 10. Subrecipient Requirements**

If the University carries out PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Designated Official 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 whether this Part II of the University's Conflict of Interest Policy or the financial conflicts of interest policy of the subrecipient will apply to the subrecipient's investigators.
  - a. Except as provided in subsection (1)(b) 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

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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.

- b. 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 this Part II of the University's Conflicts of Interest Policy 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.
2. 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.

### **Section 11. Certification Requirements**

In each application for PHS-funded research, the University shall include 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;

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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 financial conflict of interest; and
5. Shall fully comply with the requirements of the PHS regulations.

### **Section 12. University Enforcement Mechanisms**

- A. Compliance with this Part II is a condition of employment for all investigators who are University employees, and such investigators who fail to comply with this Part II are subject to discipline, including termination of employment, and may be disqualified from further participation in any PHS-funded research.
- B. For investigators who are not University employees, compliance with this Part II is a condition of participating in a PHS-funded research project with the University, and such investigators who fail to comply with this Part II 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.

### **Section 13. Federal Enforcement**

- A. Upon request by the PHS awarding component and/or HHS, the University shall submit, or permit on site review of, all records pertinent to compliance with the PHS regulations.
- B. If the failure of an investigator to comply with this Part II or with a financial conflict of interest 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.

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C. If HHS 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 financial conflict of interest 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 financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

#### **Section 14. Public Accessibility Requirements**

- A. The University's Conflicts of Interest Policy 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 in Section 2 of Part II;
  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 financial conflict of interest.
- 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

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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 Designated Official's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.
- E. Information concerning the significant financial interests of investigators to which the provisions of this Section 14 apply shall remain available, for responses to written requests for at least three years from the date the information was most recently updated.

#### **FORMS:**

- [Part 1 - Outside Interest Disclosure Form - Faculty and Staff](#)
- [Part 2 - Financial Interest Disclosure Form for PHS Investigators](#)
- [Disclosure-Form-for-Reimbursed-and-Sponsored-Travel-20120821 \(PDF\)](#)
- [Outside-Interest-Disclosure-Form-Faculty-and-Staff-2019 \(PDF\)](#)
- [Financial-Interest-Disclosure-Form-for-PHS-Investigators-20120821](#)

#### **PROCEDURES:**

To view links to campus policies and procedures, click here:

<https://policy.tennessee.edu/campus-policies-procedures/>

#### **FOR MORE INFORMATION:**

Ron Maples (865) 974-2493 [maples00@tennessee.edu](mailto:maples00@tennessee.edu)

**Related Policies:** [FI0420 - Contracts](#), [HR0122 - Employment of University Employees by Other University Personnel](#)