

**A RESOLUTION TO ENDORSE AMENDMENTS TO THE GEORGE WASHINGTON
UNIVERSITY POLICY ON CONFLICTS OF INTEREST AND COMMITMENT FOR
FACULTY AND INVESTIGATORS (12/1)**

WHEREAS, the Faculty Senate has previously adopted resolutions endorsing the original adoption of the University's Policy on Conflicts of Interest and Commitment for Faculty and Investigators (the "University Policy"), including its attached disclosure forms (Appendices A and B), as well as subsequent amendments thereto; and

WHEREAS, the University Administration has advised the Faculty Senate that the Department of Health and Human Services ("DHHS") has recently issued revised conflict of interest requirements for Investigators who conduct research sponsored by the National Institutes of Health and other agencies administered by the Public Health Service ("PHS"); and

WHEREAS, a joint committee composed of administration and faculty representatives has proposed amendments to the University Policy, including a new Appendix C to be completed by Investigators conducting research sponsored by PHS-administered agencies; and

WHEREAS, the University Administration has advised the Faculty Senate that the proposed amendments to the University Policy, in the form attached to this Resolution as Exhibit A (unmarked) and Exhibit B (marked to show changes from the current University Policy), are necessary to enable the University to comply with the revised conflict of interest requirements issued by DHHS for Investigators who conduct research sponsored by PHS-administered agencies; and

WHEREAS, the Faculty Senate Committee on Professional Ethics and Academic Freedom has reviewed and endorsed the proposed amendments to the University Policy, including the new Appendix C thereto, in the form attached to this Resolution as Exhibits A and B; and

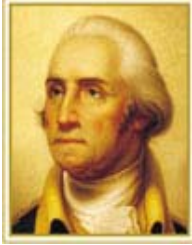
WHEREAS, the Faculty Senate believes that the proposed amendments to the University Policy, as shown on Exhibits A and B attached to this Resolution, are consistent with the best interests of the University and its faculty; **NOW, THEREFORE**,

**BE IT RESOLVED BY THE FACULTY SENATE OF THE GEORGE WASHINGTON
UNIVERSITY:**

- (1) That the Faculty Senate hereby endorses amendments to the University's Policy on Conflicts of Interest and Commitment for Faculty and Investigators (the "University Policy"), including a new Appendix C thereto, in the form attached to this Resolution as Exhibit A (unmarked) and Exhibit B (marked to show changes from the current University Policy); and
- (2) That the Faculty Senate understands and expects that future proposed amendments to the University Policy (including its Appendices) will be presented to the Faculty Senate for its review and recommendations in accordance with the procedures followed in connection with the adoption of this Resolution.

Faculty Senate Committee on Professional Ethics and Academic Freedom
April 9, 2012

Adopted May 11, 2012



THE GEORGE
WASHINGTON
UNIVERSITY
WASHINGTON DC

Responsible University Official:
Provost and Executive Vice President
for Academic Affairs
Responsible Office: Office of the
Provost and Executive Vice President
for Academic Affairs

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT FOR FACULTY AND INVESTIGATORS

Policy Statement

Faculty and investigator activities shall be conducted in a manner that avoids inappropriate conflicts of interest and commitment. Conflicts of interest may occur when there is a divergence between a Faculty Member's private interests and professional service to the University. The goal of the University is to establish boundaries within which conflicts of interest are tolerable and beyond which they are intolerable; processes for review of actual and apparent conflicts of interest; and appropriate mechanisms for management of tolerable conflicts of interest.

Reason for Policy/Purpose

This Policy is designed to assist faculty and investigators and the University in the identification of potential and actual conflicts of interest and to support compliance with applicable government regulations. For purposes of this Policy, the terms "Faculty" and "Faculty Member" mean those individuals defined in the Faculty Code, pages 1 and 2, section I, subsection B, items 1, 3, and 4, and the term Investigator refers to any person responsible for the design, conduct or reporting of externally sponsored University research, including without limitation Research Scientists, Senior Research Scientists and Lead Research Scientists.

Who Needs to Know This Policy

Faculty and investigators

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Policy/Procedures

I. GENERAL STATEMENT

A. Purpose and scope of policy.

This Policy is designed to assist faculty and the University in the identification of potential and actual conflicts of interest and to support compliance with applicable government regulations. For purposes of this Policy, the terms "Faculty" and "Faculty Member" mean those individuals defined in the Faculty Code, pages 1 and 2, section I, subsection B, items 1, 3, and 4, and the term Investigator refers to any person responsible for the design, conduct or reporting of externally sponsored University research, including without limitation Research Scientists, Senior Research Scientists and Lead Research Scientists.

B. Underlying principles.

The Faculty Code states, "faculty shall have a primary responsibility of devoting their time, thought, and energy to service of the University." Of no less importance is a Faculty Member's responsibility to further his or her own professional development and the goals of his or her professional discipline. Normally a Faculty Member's participation in activities of governmental, industrial, and professional institutions is consistent with academic interests of the University and the Faculty Member.

Conflicts of interest may occur when there is a divergence between a Faculty Member's private interests and professional service to the University. Conflicts of interest differ in nature and degree. The goal of any institution cannot be to eliminate all conflicts of interest. Rather it should be to establish boundaries within which conflicts of interest are tolerable and beyond which they are intolerable; processes for review of actual and apparent conflicts of interest; and appropriate mechanisms for management of tolerable conflicts of interest.

Faculty activities shall be conducted in a manner that avoids inappropriate conflicts of interest. As specifically described in Sections II and III, conflicts of interest may require review and oversight when:

1. the University is deprived of appropriate (compensated) time and effort of the Faculty Member due to external commitments (for example, when a Faculty Member exceeds the limitations of the "one-day-a-week" rule set forth in Section

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II.B.; or accepts obligations that may frequently conflict with scheduled classes or other academic responsibilities);

2. substantial use is made of human and material resources of the University for non-University purposes (for example, when a Faculty Member or Investigator inappropriately uses University equipment, supplies, personnel, and other facilities and resources for activities that yield financial benefit to the Faculty Member, Investigator or a third party; or receives outside financial incentives that distort scholarly activity or the shaping of academic goals; or facilitates the erroneous impression that the University endorses or is connected to an outside activity);
3. the Faculty Member's or Investigator's extra-University financial involvements affect, or reasonably appear to have a significant potential to affect, his or her academic responsibilities, or compromise basic scholarly activity or freedom of action (for example, when a Faculty Member or Investigator hires a family member; or enters into an agreement to limit or delay the free publication, or access to the results, of sponsored research, other than according to normal University practice (as in the case of patents); or has a reportable interest in a transaction described in Section III.B.; or when a Faculty Member, Investigator or his or her immediate family member is a founder, board member or equity stakeholder in a company sponsoring the Faculty Member's or Investigator's research); or
4. the University is deprived of appropriate potential financial gain (for example, when a Faculty Member or Investigator inappropriately seeks to obtain research support in a manner that substantially undermines responsibilities of the Office of the Vice President for Research; or has an outside commitment that provides an individual or organization, other than the University, intellectual or tangible property rights, such as patent ownership or license rights, that ought to accrue to the University).

C. Nature of policy.

Because precise boundaries are difficult to establish without reference to specific facts, it is prudent to establish a flexible, not formulaic, approach based on principles of fairness and trust. Fairness is advanced by policies firm enough to provide clear guidance and consistency, yet sufficiently flexible to accommodate diversity of discipline and unique circumstance. Trust is advanced by appropriate disclosure and discussion. In light of these principles, this Policy has two essential elements: (1) Faculty are provided a mechanism to report and seek guidance concerning significant actual, potential, and apparent conflicts of interest, thus to ensure appropriate disclosure and that the interests of the Faculty Member and the University are well served. To promote fairness, all faculty are required to report, as set forth in this Policy. (2) Each school shall administer in accordance with this Policy: a procedure for annual Faculty disclosure of reportable actual, potential, and apparent conflicts of interest; disclosure by Faculty of

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information pertinent to such conflicts; and a procedure for review and resolution of any lack of agreement arising from disclosure of such conflicts.

D. Obligation of University.

In its promotion and administration of research and otherwise, the University shall be sensitive to prospective conflicts of interest involving Faculty and Investigators, including, for example, with respect to (1) the independence of Faculty and Investigators to determine subjects of research and scholarship and (2) enabling Faculty and Investigators to report accurately their time and effort.

II. CONSULTING, OTHER PROFESSIONAL ACTIVITIES, AND RESEARCH SUPPORT FROM OUTSIDE ENTITIES

A. The merit of external involvements.

Increasingly, industry and government rely on university faculties for advice. Such practical contributions from higher education institutions to the nonacademic world have provided many Faculty Members the opportunity to use their knowledge and talents constructively, to strengthen their competence through a greater variety of professional experiences, to enhance the Faculty Member's and the University's scholarly reputation, and to serve the public interest.

B. "One-day-a-week" rule.

A full-time Faculty Member may spend the equivalent of up to one working day a week on average during the academic year on outside consulting and other professional activities, provided such commitments do not interfere with University obligations. Payments for such activities are negotiated by the Faculty Member directly and do not involve the University. This privilege is not extended to research Faculty Members paid wholly from research grants or contracts, or other physician Faculty Members whose University contracts preclude such activities.

C. Administration of the rule.

The department chair (or, where applicable, head of other pertinent academic unit) and the dean are responsible for ensuring compliance with this Policy and that no Faculty Member abuses this privilege. In particular, Faculty involved in private income-producing activities shall not, absent prior written approval by the Provost and Executive Vice President for Academic Affairs ("Provost and Executive Vice President"), for such purposes substantially utilize University space or resources or the services of secretaries or other University staff, provided that this Policy does not prohibit incidental use of personal office space, local telephone, library resources, and personal computer equipment.

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D. Need for written sponsored-research agreements.

Before the University enters into any arrangement in which an entity outside the University provides support for research, a clearly stated written agreement should be negotiated that sets forth the Faculty Member's, the Investigator's, the University's, and the external entity's expectations. Funding amounts and other financial arrangements, realistic timetables for mutually agreed objectives, and intellectual property agreements should be in writing before work begins. If the research project involves or may potentially involve a product or service with commercial potential, that prospect must be made known to all parties in advance.

III. REPORTABLE INTERESTS

A. Reportable interests (i.e., "significant financial interests") defined.

This Section III and the disclosure requirements contained in Section IV apply only to transactions and relationships, described in Section III.B, that involve a Faculty Member,¹ Investigator or immediate family member, the University, and an outside entity. For purposes of this Policy:

- "Immediate family member" means spouse/domestic partner and dependent children.
- "Significant financial interest" means (1) any stock, stock option, or similar ownership interest in the outside entity by the Faculty Member or Investigator that, alone or together with interests of immediate family members, is valued at least at the lesser of \$10,000 or five percent of the total ownership interests in the outside entity, excluding any interest arising solely by reason of investment by a mutual, pension, or other institutional investment fund over which neither the Faculty Member, Investigator nor an immediate family member exercises control; or (2) receipt, individually or collectively by a Faculty Member, Investigator and immediate family members, of, or the right or expectation to receive, income, whether in the form of a fee (e.g., consulting), salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing of technology or other processes or products, rent, capital gain, real or personal property, or any other form of compensation, or any combination thereof, that over the last 12 months exceeded or over the next 12 months is expected to exceed \$10,000 in income of all types; or (3) that the Faculty Member, Investigator or immediate family member provides services as a principal investigator for, or holds a management position in, an outside entity.²

¹ Principal investigators should take the lead in identifying those individuals in their organizations who are "responsible for the design, conduct or reporting" of externally sponsored University research and therefore are Investigators potentially subject to conflict of interest disclosure requirements. Such individuals may not be limited to the PI and/or co-PI, but could include, depending on the circumstances, persons such as technicians, other staff members and unpaid lab workers.

² "Significant financial interest" does not include: (1) salary, royalties or other remuneration from the University; (2) income from seminars, lectures or teaching engagements sponsored by public or non-profit entities; or (3) income from service on advisory committees or review panels for public or non-profit entities.

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B. Transactions covered.

Before the University enters into any transaction potentially presenting an apparent or actual conflict of interest, and annually thereafter, a Faculty Member or Investigator must submit to the school dean a written disclosure of any current or pending relationship of such Faculty Member, Investigator or immediate family member with the outside entity, the relationship of the proposed University activity to the entity, and, if desired, means by which the Faculty Member or Investigator will manage his or her University role in relation to the Faculty Member's, Investigator's or immediate family member's role or interest in the entity. The Disclosure Forms annexed to this Policy pursuant to Part IV.A.1. provide descriptions of covered transactions for which Faculty Members and Investigators must make disclosure. Some examples of such covered transactions are:

1. Gifts to the University of cash or property that will be under the control, or will directly support the teaching or research activities, of a Faculty Member or Investigator from an outside entity in which the Faculty Member, Investigator or immediate family member has a significant financial interest;
2. Sponsored-project proposals as to which the involved Faculty Member, Investigator or immediate family member has a significant financial interest in the proposed sponsor or in a proposed subcontractor, vendor or collaborator;
3. University technology-licensing arrangements with an outside entity in which the Faculty Member, Investigator or immediate family member has a significant financial interest;
4. Procurement of materials or services from an outside entity in which the Faculty Member, Investigator or immediate family member has a significant financial interest, if the Faculty Member or Investigator is personally involved in or has the ability to influence the formation or implementation of the procurement transaction; and
5. Submission to an external sponsor of an application for funding of University research in the design, conduct or reporting of which a Faculty Member or Investigator plans to participate that would reasonably appear to affect the Faculty Member's, Investigator's or immediate family member's interest in an outside entity or would reasonably appear to affect the entity's financial interests.

A Faculty Member or Investigator who seeks funding from or who works on a project funded by an external sponsor must comply with that sponsor's additional requirements, if any, related to disclosure, management, and avoidance of conflicts of interest. (See Section III.D regarding sponsored research and Appendix C regarding Public Health Service ("PHS") research proposals and awards.)

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C. Ongoing and elective disclosures.

In addition to disclosures required under Section III.B., Faculty members and Investigators shall disclose to the department chair (or, where applicable, head of other pertinent academic unit) or dean on an ad hoc basis current or prospective situations that are likely to raise questions of reportable conflict of interest under this Policy, including any new reportable significant financial interests, as soon as such situations become known to the Faculty Member or Investigator. In addition, a Faculty Member or Investigator may elect to disclose voluntarily other financial benefit to the Faculty Member, Investigator or immediate family member, related to an existing or contemplated relationship between the University and an outside entity with which the Faculty Member, Investigator or immediate family member is or expects to be involved, if the Faculty Member or Investigator deems it desirable to seek review in accordance with the procedures specified in Section IV.

D. Additional reporting procedures for research.

Consistent with the requirements of external sponsors, including federal government agencies, this Policy is designed to identify potential, actual and apparent conflicts of interest and support compliance with applicable rules and regulations. A number of external organizations, in particular PHS and the National Science Foundation (“NSF”), have developed policies requiring the disclosure of financial conflicts of interest.

1. PHS requirements

Appendix C of this Policy sets forth additional requirements that apply to PHS research proposals and awards. Investigators who plan to participate in PHS-funded research or who are engaged in PHS-funded research must comply not only with this Policy but also with Appendix C.

2. NSF requirements

Under NSF rules,³ a Faculty Member or Investigator utilizing or seeking NSF funding has a potential conflict of interest if the Faculty Member, Investigator or his/her immediate family member has a “significant financial interest” (as defined in paragraph III.A, above) that could directly and significantly affect the design, conduct or reporting of NSF-funded research. NSF requires the University to report any conflict the University is unable to manage satisfactorily. As part of the NSF grant proposal process, the University additionally must certify that actual or potential conflicts were, or prior to funding will be, managed, reduced, or eliminated, or disclosed to NSF.

³ NSF conflict of interest rules are incorporated into the NSF Award & Administration Guide, Ch. IV.A, “Conflict of Interest Policies,” NSF Proposal and Award Policies and Procedures Guide. See Section V of this Policy for a list of resources providing information on financial conflicts of interest.

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In order to manage conflicts of interest, the University may impose conditions or restrictions on itself, on the design and conduct of research, and on Faculty Members and Investigators, such as requiring:

- 1) public disclosure of significant financial interests;
- 2) monitoring of research by independent reviewers;
- 3) modification of the research plan;
- 4) disqualification from participation in all or part of the funded research;
- 5) divestiture of the significant financial interest; and/or
- 6) severance of relationships that create actual, potential or reasonably apparent conflicts of interest.

In accordance with NSF requirements, the University will maintain all records of financial disclosures made by Faculty Members and Investigators and actions taken by the University with respect to conflicts of interest for at least three years from the termination or completion of the relevant grant, and will make such records available in appropriate circumstances for inspection and review upon request by the agency.

3. Food and Drug Administration requirements

Faculty Members and Investigators also should be aware of Food and Drug Administration (FDA) regulations (21 CFR Part 54) regarding conflicts of interest, which apply to any applicant who submits a marketing application for a human drug, biological product or device, and who submits clinical studies covered by the regulation. The regulations require the disclosure of conflicts or a certification that no financial conflicts exist.

4. Other requirements

Other sponsors may have specific requirements regarding the disclosure of financial interests. For more information, contact the sponsor or the Office of the Vice President for Research.

IV. PROCEDURES FOR REVIEW

A. Review of disclosure form; management of disclosed conflicts.

1. Faculty Members and Investigators shall supply the annual and ad hoc disclosures required by Section III on the annexed Disclosure Forms, for confidential review by the Administration. Each dean shall forward to the Provost and Executive Vice President a copy of each Disclosure Form submitted by a Faculty Member or Investigator, any related material submitted by a Faculty Member or Investigator, and the dean's recommendation for action.
2. If the dean, with the concurrence of the Provost and Executive Vice President, determines that the conduct disclosed is permissible under this Policy, the Faculty Member or Investigator shall be so informed in writing. Guidance on types of

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conduct approved shall be provided the Faculty from time to time, without identifying Faculty Members or Investigators who received approval.

3. If the dean or the Provost and Executive Vice President determines that the conduct may present an actual conflict of interest, or reasonably appears to present a significant potential for such a conflict of interest, within the scope of this Policy, conditions or restrictions to manage or prohibit the conflict, agreeable to the Provost and Executive Vice President, may be imposed. Such conditions or restrictions may include, but are not limited to: Public disclosure of significant financial interests; monitoring of research by independent reviewers; modification of the research plan; disqualification from participation in all or part of an externally funded research project; divestiture of significant financial interests; and severance of relationships that create actual or reasonably apparent conflicts of interest.
4. It is not the object of this Policy to discourage outside activities by Faculty and Investigators that present no actual or reasonably apparent conflict of interest within the scope of this Policy. Instead, the review process is designed to allow Faculty Members and Investigators to undertake permissible activities without concern about later criticism, to provide the University accurate information about those Faculty and Investigator activities, and to be fair to all involved.

B. Procedures for resolving disputes about conflicts.

1. If a dean learns from a Faculty Member, Investigator or otherwise of conduct the dean believes presents a significant question under this Policy, the dean should discuss the conduct with the Faculty Member or Investigator; shall relate his or her findings to the Provost and Executive Vice President, and subject to the concurrence of the Provost and Executive Vice President shall advise the Faculty Member or Investigator whether (a) the conduct is permissible under this Policy without conditions or restrictions; (b) may be undertaken subject to conditions or restrictions as described in Section A.3 above; (c) or should cease, subject to further review. If the dean or Provost and Executive Vice President determines that conditions or restrictions should be imposed, the Faculty Member or Investigator shall, as the case may be, cease the conduct, accept the conditions or restrictions agreeable to the Provost and Executive Vice President, or seek review of the matter by the school's Conflicts Consultation Committee.
2. Any member of the University community ("Complainant") may bring directly to the attention of a school's Committee a probative and not frivolous matter alleged to be reportable under this Policy. A Faculty Member or Investigator whose activity has been questioned shall be entitled to know the identity of the person or persons bringing such allegations to the Committee and the full extent of the allegations.
3. A school's Conflicts Consultation Committee, unless otherwise authorized

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by the Provost and Executive Vice President, shall be composed of at least five Faculty Members of the school, elected, ordinarily annually, by the Faculty of the school. The Committee's function shall be to conduct a hearing if necessary, to make written findings about any disputed facts, and to write a reasoned recommendation as to whether the conduct entails a reportable conflict of interest under this Policy and whether the conduct may be undertaken subject to conditions or restrictions.

4. The dean, the Provost and Executive Vice President, the Complainant, the Faculty Member or the Investigator may consult a member of the Conflicts Consultation Committee informally, with that member's consent, before the matter is referred to it, to discuss whether a given activity would entail a reportable conflict of interest under this Policy and/or what if any conditions or restrictions would be appropriate, but no such informal advice should bind any party to the process described above. The Committee member who has provided such consultation shall not participate in the hearing or decision.
5. The Provost and Executive Vice President shall review the Committee's recommendation, confer with the Dean, and render a formal decision.
6. A Faculty Member or Investigator dissatisfied with the Provost and Executive Vice President's decision may appeal it to the University Conflicts Resolution Panel ("Panel"), which shall be composed of five Faculty Members nominated by the Faculty Senate Executive Committee in consultation with the Provost and Executive Vice President and elected by the Faculty Senate. Members of the Panel shall ordinarily serve for staggered three-year terms.
7. The Panel shall be bound by the factual findings of the school Conflicts Consultation Committee unless in the judgment of the Panel the school Committee clearly failed to consider important facts submitted to it. Ordinarily there should be no need for a hearing before the University Panel and no augmenting of the factual record.
8. A member of the Panel from the school from whose Committee the appeal is taken may not participate in the appeal. No informal or other ex parte communication with members of the Panel shall be permitted as to a matter that has been or may be brought before the Panel.
9. The Panel shall render its report to the affected Faculty Member or Investigator, the dean, and the Provost and Executive Vice President. The conclusion of the Panel shall be forwarded to the Administration for final disposition.
10. To the extent that conduct of Faculty or Investigators who are identified in Section I.D.1. is ultimately determined to be impermissible under this Policy, the Provost and Executive Vice President (or other supervisors, for Investigators)

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may impose sanctions not inconsistent with the substantive and procedural requirements of the Faculty Code (or other applicable procedures).

11. A Faculty Member or Investigator whose conduct has been ultimately determined to be permissible under this Policy shall be insulated from school or University sanction for that conduct. However, another Faculty Member or Investigator may not rely on an approval that addressed a different Faculty Member's or Investigator's conduct, as it may have been based on unique circumstances.

Website Addresses for This Policy

[GW University Policies](#)

Contacts

Subject	Contact	Telephone
Conflicts of Interest and Commitment	Office of the Provost and Executive Vice President for Academic Affairs	202-994-6510
Sponsored Research Requirements	Office of the Vice President for Research	202-994-6255

Related Information

RESOURCES FOR INFORMATION ON FINANCIAL CONFLICTS OF INTEREST

NSF home page:
www.nsf.gov

NSF "Award & Administration Guide, Chapter IV – Grantee Standards":
http://www.nsf.gov/publications/pub_summ.jsp?ods_key=aag

FDA home page:
www.fda.gov

FDA "IDE Financial Disclosure":
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051337.htm>

DHHS final guidance "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection":
<http://www.hhs.gov/ohrp/policy/fguid.pdf>

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National Bioethics Advisory Committee publication: “Ethical and Policy Issues in Research Involving Human Participants”:

<http://bioethics.georgetown.edu/nbac/pubs.html>

Association of American Medical Colleges and Association of American Universities report “Protecting Patients, Preserving Integrity, Advancing Health – Accelerating the Implementation of COI Policies in Human Subjects Research”:

<https://www.aamc.org/advocacy/research/coi/>

Council on Governmental Relations, “Recognizing and Managing Personal Financial Conflicts of Interest” (2002) (available in hard copy from the University Office of the Vice President for Research)

http://www.cogr.edu/Pubs_Conflicts.cfm

See Appendix C for resources regarding conflicts of interest in PHS-funded research.

Appendices

Appendix A Annual Faculty Member and Investigator Financial Interest Disclosure Form

Appendix B Proposal-Specific Investigator Financial Interest Disclosure Form

Appendix C Additional Requirements for PHS Research Proposals and Awards

Who Approved This Policy

The George Washington University Board of Trustees
Faculty Senate of The George Washington University
Steven Lerman, Provost and Executive Vice President for Academic Affairs
Beth Nolan, Senior Vice President and General Counsel
Leo Chalupa, Vice President for Research

History/Revision Dates

Origination Date: February 13, 1998

Originally adopted by the George Washington University Board of Trustees February 13, 1998.

Last Amended Date: March 31, 2005

Revisions approved by the Faculty Senate of The George Washington University February 13, 2004, and by the George Washington University Board of Trustees May 14, 2004.

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT
FOR FACULTY AND INVESTIGATORS

Revisions approved by the Faculty Senate of The George Washington University January 21, 2005, and by The George Washington University Board of Trustees February 11, 2005.

Next Review Date: **April 30, 2012**

DRAFT

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT
FOR FACULTY AND INVESTIGATORS

Appendix C

Additional Requirements for PHS Research Proposals and Awards

This Appendix C to the Policy sets forth certain requirements that apply to PHS research proposals and awards (including grants, cooperative agreements, and contracts).⁴ These requirements supplement any Investigator or University obligations under the Policy itself. To the extent of any conflict between a provision of the Policy and a provision of this Appendix C, the provision of this Appendix C shall govern.

Definitions

For purposes of this Appendix C, the following definitions apply.

“Institutional Responsibilities” means an Investigator’s professional responsibilities on behalf of the University, which may include for example: activities such as research, research consultation, teaching, professional practice, University committee memberships, and service on panels such as Institutional Review Boards or data and safety monitoring boards.

“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 PHS, or proposed for funding by PHS, which may include, for example, consultants or collaborators.

“PHS Awarding Component” means the organizational unit within PHS that funds the research that is subject to this Appendix C.

“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). 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, institutional training grant, program project, or research resources award.

“Significant Financial Interest”⁵ means, in addition to the interests described in Section III.A of the Policy, a financial interest⁶ consisting of one or more of the following interests of the

⁴ See 42 CFR Part 50, Subpart F, “Promoting Objectivity in Research,” and 45 CFR Part 94, “Responsible Prospective Contractors.” Appendix C does not apply to Small Business Innovation Research Program (including Small Business Technology Transfer Program) Phase I applications.

⁵ Nothing in this Appendix C imposes an obligation beyond that required by the Policy to disclose the following types of financial interests: (1) 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; (2) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly

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Investigator (and those of the Investigator's spouse/domestic partner and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

(a) With regard to any *publicly traded entity*, a Significant Financial Interest exists 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 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); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(b) 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 twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse/domestic partner or dependent children) holds any equity interest (*e.g.*, stock, stock option, or other ownership interest);

(c) Intellectual property rights and interests (*e.g.*, patents, copyrights), upon receipt of income related to such rights and interests; or

(d) the occurrence of any reimbursed or sponsored travel.⁷

Financial Disclosures by Investigators

In addition to the disclosure obligations set forth in Section III.B and C of the Policy, each Investigator planning to participate in PHS-funded research must disclose to the dean or the dean's designee the Investigator's Significant Financial Interests (and those of the Investigator's spouse/domestic partner and dependent children) no later than the time of application for the PHS-funded research.

Each Investigator participating in PHS-funded research must update his or her disclosure annually during the period of the award to reflect any information not disclosed initially or updates to any previously-disclosed Significant Financial Interests (*e.g.*, the updated value of previously disclosed equity interests). Investigators are also required to report a new Significant Financial Interest within 30 days of discovering or acquiring the interest.

control the investment decisions made in these vehicles; (3) income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; (4) income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or (5) travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

⁶ A financial interest is anything of monetary value, whether or not the value is readily ascertainable.

⁷ Sponsored travel means travel that is paid on behalf of the Investigator and not reimbursed to the Investigator (so that the exact monetary amount may not be readily determined). The disclosure of reimbursed or sponsored travel must include, at a minimum, the purpose of the trip, the identity of the sponsor/organization, the destination, and the duration.

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT FOR FACULTY AND INVESTIGATORS

Review and Management of Financial Disclosures

Investigators' disclosures of Significant Financial Interests under this Appendix C must be reviewed by the dean or the dean's designee. Such review shall include a determination of whether an Investigator's Significant Financial Interest is related to a PHS-funded research project at the University and, if so, whether the Significant Financial Interest constitutes a financial conflict of interest.

An Investigator's Significant Financial Interest is related to PHS-funded research when (a) the Significant Financial Interest could be affected by the PHS-funded research or (b) the Significant Financial Interest is in an entity whose financial interest could be affected by the research.

A financial conflict of interest exists when an Investigator's Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research. The University will take such actions as are necessary to manage financial conflicts of interest in PHS-funded research, including, prior to the expenditure of PHS award funds, development and implementation of a management plan that specifies the actions that have been or will be taken to manage, reduce or eliminate the financial conflict of interest.⁸ Management plans must be approved by the dean (or designee) and the Provost and Executive Vice President.

Whenever, in the course of an ongoing PHS-funded research project, a Significant Financial Interest is disclosed by a new Investigator or an existing Investigator discloses a Significant Financial Interest not previously reported, or it comes to the attention of University officials that a Significant Financial Interest related to the PHS-funded research was not disclosed in a timely manner by an Investigator, the interest shall be reviewed within 60 days and a decision shall be made as to whether the Significant Financial Interest constitutes a financial conflict of interest. If the University determines that a financial conflict of interest exists, the University shall implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be taken, to manage the Financial Conflict of Interest.

Financial Conflict of Interest Reports by the University

Prior to the expenditure of any funds under a PHS-funded research award, the University is required to submit to the PHS Awarding Component a financial conflict of interest report ("Report") regarding any Significant Financial Interests related to the PHS-funded research that the University finds to be conflicting and implement a management plan as set forth in this Appendix C. In addition, during the course of a PHS-funded research project, the University will provide the PHS Awarding Component with a Report, and implement a management plan,

⁸ Examples of management strategies include but are not limited to: (i) Public disclosure of financial conflicts of interest (*e.g.*, when presenting or publishing the research); (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants; (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest; (iv) Modification of the research plan; (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; (vi) Reduction or elimination of the financial interest (*e.g.*, sale of an equity interest); or (vii) Severance of relationships that create financial conflicts.

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT FOR FACULTY AND INVESTIGATORS

within 60 days of identifying any Significant Financial Interest that the University identifies as conflicting subsequent to its initial Report.⁹

For any financial conflict of interest previously reported by the University to PHS, the University shall provide updated Reports annually for the duration of the PHS-funded research project (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

Any required Reports shall be submitted to the PHS Awarding Component by the Office of the Vice President for Research.

Retrospective Reviews

If the University identifies a Significant Financial Interest that was not disclosed timely by the 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 University shall, within sixty 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.

In addition, whenever a financial conflict of interest in PHS-funded research is not identified or managed in a timely manner, the University must, 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 noncompliance, was biased in the design, conduct, or reporting of such research. The University is required to document the review in accordance with PHS requirements.

Based on the results of the retrospective review, the University will, if appropriate, update the previously submitted Reports affected by the review, specifying the actions that will be taken to manage the financial conflict of interest going forward. If the retrospective review determines that the research was biased in its design, conduct or reporting, the University, through the Office of the Vice President for Research, will promptly notify and submit a mitigation report to PHS.

Furthermore, in any case in which the U.S. Department of Health and Human Services determines that a PHS-funded project of clinical research evaluating the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with a conflicting interest that was not managed or reported by the University as required by this Appendix C, the University shall require the Investigator to disclose the conflicting interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

⁹ The University is not required to submit a financial conflict of interest report to PHS if it identifies and eliminates a financial conflict of interest prior to the expenditure of PHS-awarded funds.

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT FOR FACULTY AND INVESTIGATORS

Maintenance and Disclosure of Records

In accordance with PHS requirements, the University must maintain records relating to all financial disclosures made by Investigators engaged in PHS-funded research, as well as the University's review of, and response to, such disclosures (whether or not a disclosure resulted in the University's determination of a financial conflict of interest) and all actions taken under the Policy and this Appendix C (including any retrospective review, if applicable) for at least three years from submission of the final expenditures report for a grant or cooperative agreement and three years after final payment for a contract, or for such longer periods as prescribed in applicable regulations, and will make such records available in appropriate circumstances for inspection and review upon request by duly authorized agencies.

In addition, the University, through the Office of the Provost and Executive Vice President, will provide a written response to a requestor within five business days of a request for information concerning a Significant Financial Interest held by a Project Director/Principal Investigator and any other person identified by the University to PHS as senior/key personnel if the University has determined that the Significant Financial Interest constitutes a financial conflict of interest in PHS-funded research.

Subgrantees, Contractors, and Collaborators

If the University carries out PHS-funded research through a subrecipient (e.g., subgrantees, contractors, or collaborators), the University, through the Office of the Vice President for Research, will include in its written agreement with the subrecipient a statement as to whether the financial conflicts of interest policy of the University or that of the subrecipient applies to the subrecipient's Investigators.

If the subrecipient's financial conflicts of interest policy applies to subrecipient Investigators, the subrecipient shall certify as part of the agreement that its policy complies with the PHS regulations. If the subrecipient cannot make such a certification, the University's policy and this Appendix C will apply to subrecipient Investigators to the extent necessary for compliance with the PHS regulations.

If the subrecipient's financial conflict of interest policy applies, the University, through the Office of the Vice President for Research, will include in the subrecipient agreement time periods for the subrecipient to report all identified financial conflicts of interests to the University. Such time periods must provide the University with sufficient time to review the reports and make timely reports to PHS, as necessary.

If subrecipient Investigators are subject to the University's policy, the subrecipient agreement will specify time periods for the subrecipient to submit subrecipient Investigators' disclosures of Significant Financial Interests to the University so that the University has sufficient time to review the disclosures and comply timely with its review, management, and reporting obligations under this Policy.

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT FOR FACULTY AND INVESTIGATORS

Notification to PHS

The University, through the Office of the Vice President for Research, will promptly notify the PHS Awarding Component if failure of an Investigator to comply with the Policy or this Appendix C or with a management plan provided for hereunder has biased the design, conduct or reporting of PHS-funded research.

Training

Investigators engaged in PHS-funded research are required to complete training regarding their responsibilities under the Policy and this Appendix C prior to engaging in any PHS-funded research project and at least every four years. Investigators must complete such training immediately if they are new to the University, if the University revises the Policy, Appendix C, or its conflict of interest procedures in a manner that affects the requirements of Investigators, or if the University finds that the Investigator is not in compliance with the Policy or this Appendix C or a management plan adopted thereunder.

Resources

NIH home page:

www.nih.gov

NIH conflict of interest requirements:

<http://www.grants.nih.gov/grants/policy/coi/>

NIH list of conflict of interest information resources available on the Web:

<http://grants1.nih.gov/grants/policy/coi/resources.htm>



THE GEORGE
WASHINGTON
UNIVERSITY
WASHINGTON DC

Responsible University Official:
Provost and Executive Vice President
for Academic Affairs
Responsible Office: Office of the
Provost and Executive Vice President
for Academic Affairs

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT FOR FACULTY AND INVESTIGATORS

Policy Statement

Faculty and investigator activities shall be conducted in a manner that avoids inappropriate conflicts of interest and commitment. Conflicts of interest may occur when there is a divergence between a Faculty Member's private interests and professional service to the University. The goal of the University is to establish boundaries within which conflicts of interest are tolerable and beyond which they are intolerable; processes for review of actual and apparent conflicts of interest; and appropriate mechanisms for management of tolerable conflicts of interest.

Reason for Policy/Purpose

This Policy is designed to assist faculty and investigators and the University in the identification of potential and actual conflicts of interest and to support compliance with applicable government regulations. For purposes of this Policy, the terms "Faculty" and "Faculty Member" mean those individuals defined in the Faculty Code, pages 1 and 2, section I, subsection B, items 1, 3, and 4, and the term Investigator refers to any person responsible for the design, conduct or reporting of externally sponsored University research, including without limitation Research Scientists, Senior Research Scientists, and Lead Research Scientists.

Who Needs to Know This Policy

Faculty and investigators

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Policy/Procedures

I. GENERAL STATEMENT

A. Purpose and scope of policy.

This Policy is designed to assist faculty and the University in the identification of potential and actual conflicts of interest and to support compliance with applicable government regulations. For purposes of this Policy, the terms "Faculty" and "Faculty Member" mean those individuals defined in the Faculty Code, pages 1 and 2, section I, subsection B, items 1, 3, and 4, and the term Investigator refers to any person responsible for the design, conduct or reporting of externally sponsored University research, including without limitation Research Scientists, Senior Research Scientists and Lead Research Scientists.

B. Underlying principles.

The Faculty Code states, "faculty shall have a primary responsibility of devoting their time, thought, and energy to service of the University." Of no less importance is a Faculty Member's responsibility to further his or her own professional development and the goals of his or her professional discipline. Normally a Faculty Member's participation in activities of governmental, industrial, and professional institutions is consistent with academic interests of the University and the Faculty Member.

Conflicts of interest may occur when there is a divergence between a Faculty Member's private interests and professional service to the University. Conflicts of interest differ in nature and degree. The goal of any institution cannot be to eliminate all conflicts of interest. Rather it should be to establish boundaries within which conflicts of interest are tolerable and beyond which they are intolerable; processes for review of actual and apparent conflicts of interest; and appropriate mechanisms for management of tolerable conflicts of interest.

Faculty activities shall be conducted in a manner that avoids inappropriate conflicts of interest. As specifically described in Sections II and III, conflicts of interest may require review and oversight when:

1. the University is deprived of appropriate (compensated) time and effort of the Faculty Member due to external commitments (for example, when a Faculty Member exceeds the limitations of the "one-day-a-week" rule set forth in Section

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT
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II.B.; or accepts obligations that may frequently conflict with scheduled classes or other academic responsibilities);

2. substantial use is made of human and material resources of the University for non-University purposes (for example, when a Faculty Member or Investigator inappropriately uses University equipment, supplies, personnel, and other facilities and resources for activities that yield financial benefit to the Faculty Member, Investigator or a third party; or receives outside financial incentives that distort scholarly activity or the shaping of academic goals; or facilitates the erroneous impression that the University endorses or is connected to an outside activity);
3. the Faculty Member's or Investigator's extra-University financial involvements affect, or reasonably appear to have a significant potential to affect, his or her academic responsibilities, or compromise basic scholarly activity or freedom of action (for example, when a Faculty Member or Investigator hires a family member; or enters into an agreement to limit or delay the free publication, or access to the results, of sponsored research, other than according to normal University practice (as in the case of patents); or has a reportable interest in a transaction described in Section III.B.; or when a Faculty Member, Investigator or his or her immediate family member is a founder, board member or equity stakeholder in a company sponsoring the Faculty Member's or Investigator's research); or
4. the University is deprived of appropriate potential financial gain (for example, when a Faculty Member or Investigator inappropriately seeks to obtain research support in a manner that substantially undermines responsibilities of the Office of **the Vice President for Research Services**; or has an outside commitment that provides an individual or organization, other than the University, intellectual or tangible property rights, such as patent ownership or license rights, that ought to accrue to the University).

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C. Nature of policy.

Because precise boundaries are difficult to establish without reference to specific facts, it is prudent to establish a flexible, not formulaic, approach based on principles of fairness and trust. Fairness is advanced by policies firm enough to provide clear guidance and consistency, yet sufficiently flexible to accommodate diversity of discipline and unique circumstance. Trust is advanced by appropriate disclosure and discussion. In light of these principles, this Policy has two essential elements: (1) Faculty are provided a mechanism to report and seek guidance concerning significant actual, potential, and apparent conflicts of interest, thus to ensure appropriate disclosure and that the interests of the Faculty Member and the University are well served. To promote fairness, all faculty are required to report, as set forth in this Policy. (2) Each school shall administer in accordance with this Policy: a procedure for annual Faculty disclosure of reportable actual, potential, and apparent conflicts of interest; disclosure by Faculty of

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information pertinent to such conflicts; and a procedure for review and resolution of any lack of agreement arising from disclosure of such conflicts.

D. Obligation of University.

In its promotion and administration of research and otherwise, the University shall be sensitive to prospective conflicts of interest involving Faculty and Investigators, including, for example, with respect to (1) the independence of Faculty and Investigators to determine subjects of research and scholarship and (2) enabling Faculty and Investigators to report accurately their time and effort.

II. CONSULTING, OTHER PROFESSIONAL ACTIVITIES, AND RESEARCH SUPPORT FROM OUTSIDE ENTITIES

A. The merit of external involvements.

Increasingly, industry and government rely on university faculties for advice. Such practical contributions from higher education institutions to the nonacademic world have provided many Faculty Members the opportunity to use their knowledge and talents constructively, to strengthen their competence through a greater variety of professional experiences, to enhance the Faculty Member's and the University's scholarly reputation, and to serve the public interest.

B. "One-day-a-week" rule.

A full-time Faculty Member may spend the equivalent of up to one working day a week on average during the academic year on outside consulting and other professional activities, provided such commitments do not interfere with University obligations. Payments for such activities are negotiated by the Faculty Member directly and do not involve the University. This privilege is not extended to research Faculty Members paid wholly from research grants or contracts, or other physician Faculty Members whose University contracts preclude such activities.

C. Administration of the rule.

The department chair (or, where applicable, head of other pertinent academic unit) and the dean are responsible for ensuring compliance with this Policy and that no Faculty Member abuses this privilege. In particular, Faculty involved in private income-producing activities shall not, absent prior written approval by the Provost and Executive Vice President for Academic Affairs ("Provost and Executive Vice President"), for such purposes substantially utilize University space or resources or the services of secretaries or other University staff, provided that this Policy does not prohibit incidental use of personal office space, local telephone, library resources, and personal computer equipment.

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT
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D. Need for written sponsored-research agreements.

Before the University enters into any arrangement in which an entity outside the University provides support for research, a clearly stated written agreement should be negotiated that sets forth the Faculty Member's, the Investigator's, the University's, and the external entity's expectations. Funding amounts and other financial arrangements, realistic timetables for mutually agreed objectives, and intellectual property agreements should be in writing before work begins. If the research project involves or may potentially involve a product or service with commercial potential, that prospect must be made known to all parties in advance.

III. REPORTABLE INTERESTS

A. Reportable interests (i.e., "significant financial interests") defined.

This Section III and the disclosure requirements contained in Section IV apply only to transactions and relationships, described in Section III.B, that involve a Faculty Member,¹ Investigator or immediate family member, the University, and an outside entity. For purposes of this Policy:

- "Immediate family member" means spouse/domestic partner and dependent children.
- "Significant financial interest" means (1) any stock, stock option, or similar ownership interest in the outside entity by the Faculty Member or Investigator that, alone or together with interests of immediate family members, is valued at least at the lesser of \$10,000 or five percent of the total ownership interests in the outside entity, excluding any interest arising solely by reason of investment by a mutual, pension, or other institutional investment fund over which neither the Faculty Member, Investigator nor an immediate family member exercises control; or (2) receipt, individually or collectively by a Faculty Member, Investigator and immediate family members, of, or the right or expectation to receive, income, whether in the form of a fee (e.g., consulting), salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing of technology or other processes or products, rent, capital gain, real or personal property, or any other form of compensation, or any combination thereof, that over the last 12 months exceeded or over the next 12 months is expected to exceed \$10,000 in income of all types; or (3) that the Faculty Member,

¹ Principal investigators should take the lead in identifying those individuals in their organizations who are "responsible for the design, conduct or reporting" of externally sponsored University research and therefore are Investigators potentially subject to conflict of interest disclosure requirements. Such individuals may not be limited to the PI and/or co-PI, but could include, depending on the circumstances, persons such as technicians, other staff members and unpaid lab workers.

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Investigator or immediate family member provides services as a principal investigator for, or holds a management position in, an outside entity.²

B. Transactions covered.

Before the University enters into any transaction potentially presenting an apparent or actual conflict of interest, and annually thereafter, a Faculty Member or Investigator must submit to the school dean a written disclosure of any current or pending relationship of such Faculty Member, Investigator or immediate family member with the outside entity, the relationship of the proposed University activity to the entity, and, if desired, means by which the Faculty Member or Investigator will manage his or her University role in relation to the Faculty Member's, Investigator's or immediate family member's role or interest in the entity. The Disclosure Forms annexed to this Policy pursuant to Part IV.A.1. provide descriptions of covered transactions for which Faculty Members and Investigators must make disclosure. Some examples of such covered transactions are:

1. Gifts to the University of cash or property that will be under the control, or will directly support the teaching or research activities, of a Faculty Member or Investigator from an outside entity in which the Faculty Member, Investigator or immediate family member has a significant financial interest;
2. Sponsored-project proposals as to which the involved Faculty Member, Investigator or immediate family member has a significant financial interest in the proposed sponsor or in a proposed subcontractor, vendor or collaborator;
3. University technology-licensing arrangements with an outside entity in which the Faculty Member, Investigator or immediate family member has a significant financial interest;
4. Procurement of materials or services from an outside entity in which the Faculty Member, Investigator or immediate family member has a significant financial interest, if the Faculty Member or Investigator is personally involved in or has the ability to influence the formation or implementation of the procurement transaction; and
5. Submission to an external sponsor of an application for funding of University research in the design, conduct or reporting of which a Faculty Member or Investigator plans to participate that would reasonably appear to affect the Faculty Member's, Investigator's or immediate family member's interest in an outside entity or would reasonably appear to affect the entity's financial interests.

² "Significant financial interest" does not include: (1) salary, royalties or other remuneration from the University; (2) income from seminars, lectures or teaching engagements sponsored by public or non-profit entities; or (3) income from service on advisory committees or review panels for public or non-profit entities.

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT
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A Faculty Member or Investigator who seeks funding from or who works on a project funded by an external sponsor must comply with that sponsor's additional requirements, if any, related to disclosure, management, and avoidance of conflicts of interest. (See Section III.D regarding sponsored research and Appendix C regarding Public Health Service ("PHS") research proposals and awards.)

C. Ongoing and elective disclosures.

In addition to disclosures required under Section III.B., Faculty members and Investigators shall disclose to the department chair (or, where applicable, head of other pertinent academic unit) or dean on an ad hoc basis current or prospective situations that are likely to raise questions of reportable conflict of interest under this Policy, including any new reportable significant financial interests, as soon as such situations become known to the Faculty Member or Investigator. In addition, a Faculty Member or Investigator may elect to disclose voluntarily other financial benefit to the Faculty Member, Investigator or immediate family member, related to an existing or contemplated relationship between the University and an outside entity with which the Faculty Member, Investigator or immediate family member is or expects to be involved, if the Faculty Member or Investigator deems it desirable to seek review in accordance with the procedures specified in Section IV.

D. Additional reporting procedures for research.

Consistent with the requirements of external sponsors, including federal government agencies, this Policy is designed to identify potential, actual and apparent conflicts of interest and support compliance with applicable rules and regulations. A number of external organizations, in particular ~~the Public Health Service~~ PHS and the National Science Foundation ("NSF"), have developed policies requiring the disclosure of financial conflicts of interest.

1. PHS requirements

Appendix C of this Policy sets forth additional requirements that apply to PHS research proposals and awards. Investigators who plan to participate in PHS-funded research or who are engaged in PHS-funded research must comply not only with this Policy but also with Appendix C.

2. NSF requirements

Under ~~PHS and~~ NSF rules ~~and regulations~~,³ a Faculty Member or Investigator utilizing or seeking ~~PHS or~~ NSF funding has a potential conflict of interest if the Faculty Member,

³ ~~See PHS 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought," and PHS 45 CFR Part 94, "Responsible Prospective Contractors." PHS excludes Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program Phase I applications from its regulations. NSF conflict of interest rules are incorporated into the NSF Grant Policy Manual Award & Administration~~

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Investigator or his/her immediate family member has a “significant financial interest” (as defined in paragraph III.A, above) that could directly and significantly affect the design, conduct or reporting of ~~the PHS or NSF funded research.~~⁴ ~~The University is required to report to PHS, prior to the expenditure of any funds under a PHS award, the existence (but not the nature) of any conflict and to assure PHS that the conflict has been managed, reduced or eliminated. For conflicting interests identified subsequent to the University’s initial report under a PHS award, the University is obligated to report the conflict and manage, reduce or eliminate it, at least on an interim basis, within 60 days of its identification. NSF also~~NSF-funded research. NSF requires the University to report any conflict the University is unable to manage satisfactorily. As part of the NSF grant proposal process, the University additionally must certify that actual or potential conflicts were, or prior to funding will be, managed, reduced, or eliminated, or disclosed to NSF.

In order to manage conflicts of interest, the University may impose conditions or restrictions on itself, on the design and conduct of research, and on Faculty Members and Investigators, such as requiring:

- 1) public disclosure of significant financial interests;
- 2) monitoring of research by independent reviewers;
- 3) modification of the research plan;
- 4) disqualification from participation in all or part of the funded research;
- 5) divestiture of the significant financial interest; and/or
- 6) severance of relationships that create actual, potential or reasonably apparent conflicts of interest.

~~If a Faculty Member or Investigator fails to comply with this Policy and, as a result, has biased the design, conduct or reporting of PHS funded research, the University will promptly notify PHS of the corrective action taken or to be taken. Furthermore, in any case where a PHS funded project of clinical research evaluating the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by a Faculty Member or Investigator with a conflicting interest that was not disclosed or managed as required by this Policy, the University will require the Faculty Member or Investigator to disclose the conflicting interest in each public presentation of the results of the research, and the Faculty Member or Investigator shall do so.~~

In accordance with ~~PHS and~~ NSF requirements, the University will maintain all records of financial disclosures made by Faculty Members and Investigators and actions taken by the University with respect to conflicts of interest for at least three years from the termination or

Guide, Ch. V, Sec. 540IV.A, “Conflict of Interest Policies,” NSF Grant General Conditions and NSF Grant Proposal and Award Policies and Procedures Guide. See Section V of this Policy for a list of resources providing information on financial conflicts of interest.

⁴~~PHS defines “research” as: “A systemic investigation 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 and product development. As used in [the PHS regulations], 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.”~~

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completion of the relevant grant, and will make such records available in appropriate circumstances for inspection and review upon request by ~~those agencies~~the agency.

3. Furthermore, pursuant to Food and Drug Administration requirements

~~PHS requirements, all subgrantees, contractors and collaborators on PHS funded research at the University must either comply with this Policy or provide assurances to the University that enable the University to satisfy PHS regulations.~~

Faculty Members and Investigators also should be aware of Food and Drug Administration (FDA) regulations (21 CFR Part 54) regarding conflicts of interest, which apply to any applicant who submits a marketing application for a human drug, biological product or device, and who submits clinical studies covered by the regulation. The regulations require the disclosure of conflicts or a certification that no financial conflicts exist.

4. Other requirements

Other sponsors may have specific requirements regarding the disclosure of financial interests. For more information, contact the sponsor or the Office of the Vice President for Research Services.

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IV. PROCEDURES FOR REVIEW

A. Review of disclosure form; management of disclosed conflicts.

1. Faculty Members and Investigators shall supply the annual and ad hoc disclosures required by Section III on the annexed Disclosure Forms, for confidential review by the Administration. Each dean shall forward to the Provost and Executive Vice President a copy of each Disclosure Form submitted by a Faculty Member or Investigator, any related material submitted by a Faculty Member or Investigator, and the dean's recommendation for action.
2. If the dean, with the concurrence of the Provost and Executive Vice President, determines that the conduct disclosed is permissible under this Policy, the Faculty Member or Investigator shall be so informed in writing. Guidance on types of conduct approved shall be provided the Faculty from time to time, without identifying Faculty Members or Investigators who received approval.
3. If the dean or the Provost and Executive Vice President determines that the conduct may present an actual conflict of interest, or reasonably appears to present a significant potential for such a conflict of interest, within the scope of this Policy, conditions or restrictions to manage or prohibit the conflict, agreeable to the Provost and Executive Vice President, may be imposed. Such conditions or restrictions may include, but are not limited to: Public disclosure of significant

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financial interests; monitoring of research by independent reviewers; modification of the research plan; disqualification from participation in all or part of an externally funded research project; divestiture of significant financial interests; and severance of relationships that create actual or reasonably apparent conflicts of interest.

4. It is not the object of this Policy to discourage outside activities by Faculty and Investigators that present no actual or reasonably apparent conflict of interest within the scope of this Policy. Instead, the review process is designed to allow Faculty Members and Investigators to undertake permissible activities without concern about later criticism, to provide the University accurate information about those Faculty and Investigator activities, and to be fair to all involved.

B. Procedures for resolving disputes about conflicts.

1. If a dean learns from a Faculty Member, Investigator or otherwise of conduct the dean believes presents a significant question under this Policy, the dean should discuss the conduct with the Faculty Member or Investigator; shall relate his or her findings to the Provost and Executive Vice President, and subject to the concurrence of the Provost and Executive Vice President shall advise the Faculty Member or Investigator whether (a) the conduct is permissible under this Policy without conditions or restrictions; (b) may be undertaken subject to conditions or restrictions as described in Section A.3 above; (c) or should cease, subject to further review. If the dean or Provost and Executive Vice President determines that conditions or restrictions should be imposed, the Faculty Member or Investigator shall, as the case may be, cease the conduct, accept the conditions or restrictions agreeable to the Provost and Executive Vice President, or seek review of the matter by the school's Conflicts Consultation Committee.
2. Any member of the University community ("Complainant") may bring directly to the attention of a school's Committee a probative and not frivolous matter alleged to be reportable under this Policy. A Faculty Member or Investigator whose activity has been questioned shall be entitled to know the identity of the person or persons bringing such allegations to the Committee and the full extent of the allegations.
3. A school's Conflicts Consultation Committee, unless otherwise authorized by the Provost and Executive Vice President, shall be composed of at least five Faculty Members of the school, elected, ordinarily annually, by the Faculty of the school. The Committee's function shall be to conduct a hearing if necessary, to make written findings about any disputed facts, and to write a reasoned recommendation as to whether the conduct entails a reportable conflict of interest under this Policy and whether the conduct may be undertaken subject to conditions or restrictions.

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4. The dean, the Provost and Executive Vice President, the Complainant, the Faculty Member or the Investigator may consult a member of the Conflicts Consultation Committee informally, with that member's consent, before the matter is referred to it, to discuss whether a given activity would entail a reportable conflict of interest under this Policy and/or what if any conditions or restrictions would be appropriate, but no such informal advice should bind any party to the process described above. The Committee member who has provided such consultation shall not participate in the hearing or decision.
5. The Provost and Executive Vice President shall review the Committee's recommendation, confer with the Dean, and render a formal decision.
6. A Faculty Member or Investigator dissatisfied with the Provost and Executive Vice President's decision may appeal it to the University Conflicts Resolution Panel ("Panel"), which shall be composed of five Faculty Members nominated by the Faculty Senate Executive Committee in consultation with the Provost and Executive Vice President and elected by the Faculty Senate. Members of the Panel shall ordinarily serve for staggered three-year terms.
7. The Panel shall be bound by the factual findings of the school Conflicts Consultation Committee unless in the judgment of the Panel the school Committee clearly failed to consider important facts submitted to it. Ordinarily there should be no need for a hearing before the University Panel and no augmenting of the factual record.
8. A member of the Panel from the school from whose Committee the appeal is taken may not participate in the appeal. No informal or other ex parte communication with members of the Panel shall be permitted as to a matter that has been or may be brought before the Panel.
9. The Panel shall render its report to the affected Faculty Member or Investigator, the dean, and the Provost and Executive Vice President. The conclusion of the Panel shall be forwarded to the Administration for final disposition.
10. To the extent that conduct of Faculty or Investigators who are identified in Section I.D.1. is ultimately determined to be impermissible under this Policy, the Provost and Executive Vice President (or other supervisors, for Investigators) may impose sanctions not inconsistent with the substantive and procedural requirements of the Faculty Code (or other applicable procedures).
11. A Faculty Member or Investigator whose conduct has been ultimately determined to be permissible under this Policy shall be insulated from school or University sanction for that conduct. However, another Faculty Member or Investigator may not rely on an approval that addressed a different Faculty Member's or Investigator's conduct, as it may have been based on unique circumstances.

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Website Addresses for This Policy

[GW University Policies](#)

Contacts

Subject	Contact	Telephone
Conflicts of Interest and Commitment	Office of the Provost and Executive Vice President for Academic Affairs	202-994-6510
Sponsored Research Requirements	Office of the Vice President for Research	202-994-6255

Related Information

RESOURCES FOR INFORMATION ON FINANCIAL CONFLICTS OF INTEREST

NSF home page:
www.nsf.gov

NSF “~~Grant Policy Manual~~Award & Administration Guide, Chapter ~~IV~~ – Grantee Standards”:
<http://www.nsf.gov/pubs/manuals/gpm05-131/gpm5.jsp>

Frequently asked questions concerning PHS and NSF investigator conflicts of interest
www.nih.gov/grants/policy/coifaq.htm

http://www.nsf.gov/publications/pub_summ.jsp?ods_key=aag

FDA home page:
www.fda.gov

FDA “~~Device Advice-IDE~~ Financial Disclosure”:
www.fda.gov/oc/ide/financial.shtml

FDA guidance “Financial Disclosure by Clinical Investigators”:
www.fda.gov/oc/guidance/financialdis.html

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051337.htm>

DHHS ~~draft interim~~final guidance “Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators and IRBs to Consider When Dealing with Issues of Financial Interests and in Research Involving Human Subjects: Guidance for Human Subject Protection”:
<http://www.hhs.gov/ohrp/nhrpac/mtg12-00/finguid.htm><http://www.hhs.gov/ohrp/policy/fguid.pdf>

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National Bioethics Advisory Committee publication: “Ethical and Policy Issues in Research Involving Human Participants”:

<http://bioethics.georgetown.edu/nbac/pubs.html>

Association of American Medical Colleges ~~Task Force on Financial Conflicts of Interest in Clinical Research~~ and Association of American Universities report “Protecting ~~Subjects~~Patients, Preserving ~~Trusts, Promoting Progress~~—Policy and Guidelines forIntegrity, Advancing Health – Accelerating the ~~Oversight~~Implementation of ~~Individual Financial Interests~~COI Policies in Human Subjects Research”:

~~Financial Conflicts of Interest in Academic Medicine – Research – AAMC~~

Association of American Universities Task Force on Research Accountability “Report on Individual and Institutional Financial Conflict of Interest”:

<http://www.aau.edu/research/COI.01.pdf>

<https://www.aamc.org/advocacy/research/coi/>

Council on Governmental Relations, “Recognizing and Managing Personal Financial Conflicts of Interest” (2002) (available in hard copy from the University Office of ~~Research Services and the Medical Center Office of Health Research, Compliance and Technology Transfer~~the Vice President for Research)

http://www.cogr.edu/Pubs_Conflicts.cfm

See Appendix C for resources regarding conflicts of interest in PHS-funded research.

Appendices

Appendix A Annual Faculty Member and Investigator Financial Interest Disclosure Form

Appendix B Proposal-Specific Investigator Financial Interest Disclosure Form

Appendix C Additional Requirements for PHS Research Proposals and Awards

Who Approved This Policy

The George Washington University Board of Trustees
Faculty Senate of The George Washington University
Steven Lerman, Provost and Executive Vice President for Academic Affairs

Beth Nolan, **Senior Vice President and General Counsel**

Leo Chalupa, Vice President for Research

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History/Revision Dates

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT
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Origination Date: February 13, 1998

Originally adopted by the George Washington University Board of Trustees February 13, 1998.

Last Amended Date: March 31, 2005

Revisions approved by the Faculty Senate of The George Washington University February 13, 2004, and by the George Washington University Board of Trustees May 14, 2004.

Revisions approved by the Faculty Senate of The George Washington University January 21, 2005, and by The George Washington University Board of Trustees February 11, 2005.

Next Review Date: April 30, 2012

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Appendix C

Comment [JBS1]: Appendix C is new

Additional Requirements for PHS Research Proposals and Awards

This Appendix C to the Policy sets forth certain requirements that apply to PHS research proposals and awards (including grants, cooperative agreements, and contracts).⁵ These requirements supplement any Investigator or University obligations under the Policy itself. To the extent of any conflict between a provision of the Policy and a provision of this Appendix C, the provision of this Appendix C shall govern.

Definitions

For purposes of this Appendix C, the following definitions apply.

“Institutional Responsibilities” means an Investigator’s professional responsibilities on behalf of the University, which may include for example: activities such as research, research consultation, teaching, professional practice, University committee memberships, and service on panels such as Institutional Review Boards or data and safety monitoring boards.

“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 PHS, or proposed for funding by PHS, which may include, for example, consultants or collaborators.

“PHS Awarding Component” means the organizational unit within PHS that funds the research that is subject to this Appendix C.

“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). 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, institutional training grant, program project, or research resources award.

“Significant Financial Interest”⁶ means, in addition to the interests described in Section III.A of the Policy, a financial interest⁷ consisting of one or more of the following interests of the

⁴ See 42 CFR Part 50, Subpart F, “Promoting Objectivity in Research,” and 45 CFR Part 94, “Responsible Prospective Contractors.” Appendix C does not apply to Small Business Innovation Research Program (including Small Business Technology Transfer Program) Phase I applications.

⁵ Nothing in this Appendix C imposes an obligation beyond that required by the Policy to disclose the following types of financial interests: (1) 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; (2) income from

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Investigator (and those of the Investigator's spouse/domestic partner and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

(a) With regard to any *publicly traded entity*, a Significant Financial Interest exists 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 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); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(b) 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 twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse/domestic partner or dependent children) holds any equity interest (*e.g.*, stock, stock option, or other ownership interest);

(c) Intellectual property rights and interests (*e.g.*, patents, copyrights), upon receipt of income related to such rights and interests; or

(d) the occurrence of any reimbursed or sponsored travel.⁸

Financial Disclosures by Investigators

In addition to the disclosure obligations set forth in Section III.B and C of the Policy, each Investigator planning to participate in PHS-funded research must disclose to the dean or the dean's designee the Investigator's Significant Financial Interests (and those of the Investigator's spouse/domestic partner and dependent children) no later than the time of application for the PHS-funded research.

Each Investigator participating in PHS-funded research must update his or her disclosure annually during the period of the award to reflect any information not disclosed initially or updates to any previously-disclosed Significant Financial Interests (*e.g.*, the updated value of

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; (3) income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; (4) income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or (5) travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

⁶ A financial interest is anything of monetary value, whether or not the value is readily ascertainable.

⁷ Sponsored travel means travel that is paid on behalf of the Investigator and not reimbursed to the Investigator (so that the exact monetary amount may not be readily determined). The disclosure of reimbursed or sponsored travel must include, at a minimum, the purpose of the trip, the identity of the sponsor/organization, the destination, and the duration.

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previously disclosed equity interests). Investigators are also required to report a new Significant Financial Interest within 30 days of discovering or acquiring the interest.

Review and Management of Financial Disclosures

Investigators' disclosures of Significant Financial Interests under this Appendix C must be reviewed by the dean or the dean's designee. Such review shall include a determination of whether an Investigator's Significant Financial Interest is related to a PHS-funded research project at the University and, if so, whether the Significant Financial Interest constitutes a financial conflict of interest.

An Investigator's Significant Financial Interest is related to PHS-funded research when (a) the Significant Financial Interest could be affected by the PHS-funded research or (b) the Significant Financial Interest is in an entity whose financial interest could be affected by the research.

A financial conflict of interest exists when an Investigator's Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research. The University will take such actions as are necessary to manage financial conflicts of interest in PHS-funded research, including, prior to the expenditure of PHS award funds, development and implementation of a management plan that specifies the actions that have been or will be taken to manage, reduce or eliminate the financial conflict of interest.⁹ Management plans must be approved by the dean (or designee) and the Provost and Executive Vice President.

Whenever, in the course of an ongoing PHS-funded research project, a Significant Financial Interest is disclosed by a new Investigator or an existing Investigator discloses a Significant Financial Interest not previously reported, or it comes to the attention of University officials that a Significant Financial Interest related to the PHS-funded research was not disclosed in a timely manner by an Investigator, the interest shall be reviewed within 60 days and a decision shall be made as to whether the Significant Financial Interest constitutes a financial conflict of interest. If the University determines that a financial conflict of interest exists, the University shall implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be taken, to manage the Financial Conflict of Interest.

Financial Conflict of Interest Reports by the University

Prior to the expenditure of any funds under a PHS-funded research award, the University is required to submit to the PHS Awarding Component a financial conflict of interest report ("Report") regarding any Significant Financial Interests related to the PHS-funded research that

⁸ Examples of management strategies include but are not limited to: (i) Public disclosure of financial conflicts of interest (*e.g.*, when presenting or publishing the research); (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants; (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest; (iv) Modification of the research plan; (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; (vi) Reduction or elimination of the financial interest (*e.g.*, sale of an equity interest); or (vii) Severance of relationships that create financial conflicts.

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the University finds to be conflicting and implement a management plan as set forth in this Appendix C. In addition, during the course of a PHS-funded research project, the University will provide the PHS Awarding Component with a Report, and implement a management plan, within 60 days of identifying any Significant Financial Interest that the University identifies as conflicting subsequent to its initial Report.¹⁰

For any financial conflict of interest previously reported by the University to PHS, the University shall provide updated Reports annually for the duration of the PHS-funded research project (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

Any required Reports shall be submitted to the PHS Awarding Component by the Office of the Vice President for Research.

Retrospective Reviews

If the University identifies a Significant Financial Interest that was not disclosed timely by the 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 University shall, within sixty 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.

In addition, whenever a financial conflict of interest in PHS-funded research is not identified or managed in a timely manner, the University must, 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 noncompliance, was biased in the design, conduct, or reporting of such research. The University is required to document the review in accordance with PHS requirements.

Based on the results of the retrospective review, the University will, if appropriate, update the previously submitted Reports affected by the review, specifying the actions that will be taken to manage the financial conflict of interest going forward. If the retrospective review determines that the research was biased in its design, conduct or reporting, the University, through the Office of the Vice President for Research, will promptly notify and submit a mitigation report to PHS.

Furthermore, in any case in which the U.S. Department of Health and Human Services determines that a PHS-funded project of clinical research evaluating the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with a conflicting interest that was not managed or reported by the University as

⁹ The University is not required to submit a financial conflict of interest report to PHS if it identifies and eliminates a financial conflict of interest prior to the expenditure of PHS-awarded funds.

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required by this Appendix C, the University shall require the Investigator to disclose the conflicting interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Maintenance and Disclosure of Records

In accordance with PHS requirements, the University must maintain records relating to all financial disclosures made by Investigators engaged in PHS-funded research, as well as the University's review of, and response to, such disclosures (whether or not a disclosure resulted in the University's determination of a financial conflict of interest) and all actions taken under the Policy and this Appendix C (including any retrospective review, if applicable) for at least three years from submission of the final expenditures report for a grant or cooperative agreement and three years after final payment for a contract, or for such longer periods as prescribed in applicable regulations, and will make such records available in appropriate circumstances for inspection and review upon request by duly authorized agencies.

In addition, the University, through the Office of the Provost and Executive Vice President, will provide a written response to a requestor within five business days of a request for information concerning a Significant Financial Interest held by a Project Director/Principal Investigator and any other person identified by the University to PHS as senior/key personnel if the University has determined that the Significant Financial Interest constitutes a financial conflict of interest in PHS-funded research.

Subgrantees, Contractors, and Collaborators

If the University carries out PHS-funded research through a subrecipient (e.g., subgrantees, contractors, or collaborators), the University, through the Office of the Vice President for Research, will include in its written agreement with the subrecipient a statement as to whether the financial conflicts of interest policy of the University or that of the subrecipient applies to the subrecipient's Investigators.

If the subrecipient's financial conflicts of interest policy applies to subrecipient Investigators, the subrecipient shall certify as part of the agreement that its policy complies with the PHS regulations. If the subrecipient cannot make such a certification, the University's policy and this Appendix C will apply to subrecipient Investigators to the extent necessary for compliance with the PHS regulations.

If the subrecipient's financial conflict of interest policy applies, the University, through the Office of the Vice President for Research, will include in the subrecipient agreement time periods for the subrecipient to report all identified financial conflicts of interests to the University. Such time periods must provide the University with sufficient time to review the reports and make timely reports to PHS, as necessary.

If subrecipient Investigators are subject to the University's policy, the subrecipient agreement will specify time periods for the subrecipient to submit subrecipient Investigators' disclosures of Significant Financial Interests to the University so that the University has sufficient time to

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review the disclosures and comply timely with its review, management, and reporting obligations under this Policy.

Notification to PHS

The University, through the Office of the Vice President for Research, will promptly notify the PHS Awarding Component if failure of an Investigator to comply with the Policy or this Appendix C or with a management plan provided for hereunder has biased the design, conduct or reporting of PHS-funded research.

Training

Investigators engaged in PHS-funded research are required to complete training regarding their responsibilities under the Policy and this Appendix C prior to engaging in any PHS-funded research project and at least every four years. Investigators must complete such training immediately if they are new to the University, if the University revises the Policy, Appendix C, or its conflict of interest procedures in a manner that affects the requirements of Investigators, or if the University finds that the Investigator is not in compliance with the Policy or this Appendix C or a management plan adopted thereunder.

Resources

NIH home page:

www.nih.gov

NIH conflict of interest requirements:

<http://www.grants.nih.gov/grants/policy/coi/>

NIH list of conflict of interest information resources available on the Web:

<http://grants1.nih.gov/grants/policy/coi/resources.htm>