

**A RESOLUTION TO ENDORSE REVISED DISCLOSURE FORMS AND CONFORMING CHANGES TO THE GEORGE WASHINGTON UNIVERSITY POLICY ON CONFLICTS OF INTEREST AND COMMITMENT (04/6)**

**WHEREAS**, federal requirements regarding conflicts of interest pertaining to federally-sponsored research were first addressed in The George Washington University Policy on Conflicts of Interest in Federally Funded Research (1995); and

**WHEREAS**, this policy was superseded by The George Washington University Policy on Conflicts of Interest and Commitment (1998) (hereinafter the “Policy on Conflicts of Interest”), whose scope included not only research conflicts of interest but other conflicts of interest and commitment involving faculty members and persons responsible for the design, conduct, or reporting of externally funded programs (hereinafter “Investigators”); and

**WHEREAS**, the Policy on Conflicts of Interest was amended in May 2004, in order to bring the Policy into compliance with applicable federal regulations concerning conflicts of interest in externally-sponsored research; and

**WHEREAS**, the University Administration has proposed two revised disclosure forms, pursuant to the Policy on Conflicts of Interest, to be completed by (1) faculty members and Investigators in connection with their annual reports to the University, and (2) faculty members and Investigators in connection with proposals for external funding (hereinafter “Disclosure Forms”); and

**WHEREAS**, representatives of the Faculty Senate Committee on Professional Ethics and Academic Freedom and the Faculty Senate Committee on Research have met with Administration representatives and, after making modifications, have agreed to the contents of the revised Disclosure Forms; and

**WHEREAS**, representatives of the foregoing Senate Committees and the Administration have also agreed on technical changes to the Policy on Conflicts of Interest in order to make appropriate references to the revised Disclosure Forms; and

**WHEREAS**, the Policy on Conflicts of Interest, marked to show the agreed technical changes, is attached to this Resolution as Exhibit A; and

**WHEREAS**, the revised Disclosure Forms agreed to by representatives of the foregoing Senate Committees and the Administration are attached hereto as Exhibits B and C; and

**WHEREAS**, the Faculty Senate believes that the technical changes to the Policy on Conflicts of Interest and the revised Disclosure Forms 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 the proposed technical changes to the Policy on Conflicts of Interest, as shown on Exhibit A attached to this Resolution; and
- (2) That the Faculty Senate hereby endorses the revised Disclosure Forms as referenced in Part IV.A. of the Policy on Conflicts of Interest and attached to this Resolution as Exhibits B and C; and
- (3) That the Faculty Senate expects that, consistent with the procedures described above, future amendments to the Policy on Conflicts of Interest and the Disclosure Forms will be presented to the Faculty Senate for its review and recommendations prior to the adoption thereof by the University.

Faculty Senate Committee on Professional Ethics and Academic Freedom  
Faculty Senate Committee on Research  
January 13, 2005

Adopted, with the underlying documents as amended, January 21, 2005

# Exhibit A

Changes Submitted for Endorsement by Faculty Senate 1/21/05

## POLICY ON CONFLICTS OF INTEREST AND COMMITMENT FOR FACULTY AND INVESTIGATORS

The George Washington University

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### Disclosure Forms

#### 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 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 Sponsored 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 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 Executive Vice President for Academic Affairs ("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.

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,<sup>1</sup> 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

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<sup>1</sup> 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.

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

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.

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

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<sup>2</sup> "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.

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 and the National Science Foundation, have developed policies requiring the disclosure of financial conflicts of interest. Under PHS and NSF rules and regulations,<sup>3</sup> a Faculty Member or Investigator utilizing or seeking PHS or 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 the PHS- or NSF-funded research.<sup>4</sup> 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 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 completion of the relevant grant, and will make such records available in appropriate circumstances for inspection and review upon request by those agencies.

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<sup>3</sup> 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, Ch. V, Sec. 510, “Conflict of Interest Policies,” NSF Grant General Conditions and NSF Grant Proposal Guide. See Section V of this Policy for a list of resources providing information on financial conflicts of interest.

<sup>4</sup> 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.”

Furthermore, pursuant to 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 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.

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

#### 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 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 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 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 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 Executive Vice President, and subject to the concurrence of the Executive Vice President shall advise the Faculty Member or Investigator whether the conduct is permissible under this Policy without conditions or restrictions; (b) may be undertaken subject to conditions or restrictions as described in Section IV.A.3 above; (c) or should cease, subject to

further review. If the dean or 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 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 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 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 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 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 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 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 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.

## V. RESOURCES FOR INFORMATION ON FINANCIAL CONFLICTS OF INTEREST

NIH home page:

[www.nih.gov](http://www.nih.gov)

NIH conflict of interest requirements:

<http://grants1.nih.gov/grants/policy/emprograms/overview/ep-coi.htm>

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

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

NSF home page:

[www.nsf.gov](http://www.nsf.gov)

NSF "Grant Policy Manual, Chapter V – Grantee Standards":

<http://www.nsf.gov/pubs/2002/nsf02151/gpm5.htm>

Frequently asked questions concerning PHS and NSF investigator conflicts of interest

[www.nih.gov/grants/policy/coifaq.htm](http://www.nih.gov/grants/policy/coifaq.htm)

FDA home page:

[www.fda.gov](http://www.fda.gov)

FDA "Device Advice: Financial Disclosure":

[www.fda.gov/cdrh/devadvice/ide/financial.shtml](http://www.fda.gov/cdrh/devadvice/ide/financial.shtml)

FDA guidance "Financial Disclosure by Clinical Investigators":

[www.fda.gov/oc/guidance/financialdis.html](http://www.fda.gov/oc/guidance/financialdis.html)

DHHS draft interim guidance "Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators and IRBs to Consider When Dealing with Issues of Financial Interests and Human Subject Protection":

<http://ohrp.osophs.dhhs.gov/humansubjects/finreltn/finguid.htm>

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 report "Protecting Subjects, Preserving Trusts, Promoting Progress – Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research":

<http://www.aamc.org/members/coitf/firstreport.pdf>

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>

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)

Adopted by the Faculty Senate of The George Washington University, 13 February 2004

Adopted by The George Washington University Board of Trustees, 14 May 2004

## Exhibit B

Submitted for Endorsement by the Faculty Senate on 1/21/05

Annual Faculty Member and Investigator Financial Interest Disclosure Form

Pursuant to The George Washington University Policy on Conflicts of Interest and Commitment for Faculty and Investigators (May 14, 2004)

The Faculty Senate and the Board of Trustees approved an updated University-wide *Policy on Conflicts of Interest and Commitment for Faculty and Investigators* in May 2004. The full policy is available at [my.gwu.edu/files/policies/ConflictofInterestandcommitment.pdf](http://my.gwu.edu/files/policies/ConflictofInterestandcommitment.pdf). The policy requires that each faculty member and investigator complete this form yearly.

The purpose of this form is to assist faculty, investigators, and the University in the identification of potential and actual conflicts of interest and to support compliance with applicable government regulations. Because of the complexities of The George Washington University, it is not unusual for an employee to respond affirmatively to one or more of the following questions. An affirmative response in no way implies that a conflict of interest necessarily exists or, if it does, that it cannot be managed.. Please be assured that responses to this questionnaire may be submitted on a confidential basis and will be held strictly in confidence. ~~and that~~ Responses requiring further clarification will be brought to your immediate attention.

Faculty Member or Investigator Name: \_\_\_\_\_

Department/Unit: \_\_\_\_\_

College/Unit: \_\_\_\_\_

### **PART I (To be completed by all Faculty and Investigators)**

#### **A. Definitions**

The term *significant financial interest* means

(1) any stock, stock option, or similar ownership interest in an 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 any 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, immediate family member or close family member provides services as a principal investigator for, or holds a management position in, an outside entity; or

(4) that a close family member holds an ownership interest in an outside entity or has a right to receive income from an outside entity, if such ownership interest or right to receive income would be treated as a “significant financial interest” with respect to a Faculty Member or Investigator under (1) or (2), above.

*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 income from service on advisory committees or review panels for public or non-profit entities.

*The George Washington University (and University)* means The George Washington University and any entity owned in whole or in part, directly or indirectly, or controlled by the University, including the Medical Faculty Associates (MFA) and any joint venture.

*Gifts* do not include honoraria (e.g., remuneration or gifts-in-kind) received in connection with (1) participation in seminars, lectures, or teaching engagements sponsored by public or non-profit entities or (2) service on advisory committees or review panels for public or non-profit entities.

*Immediate family member* includes an employee’s spouse/domestic partner and dependent children.

*Close family member* includes an employee’s non-dependent children, as well as father, mother, sisters and brothers of the employee and the employee’s spouse/domestic partner.

*Material conflict of interest* means a conflict of interest that has the potential (i) to influence a person’s decisions or conduct or (ii) to have a non-trivial impact on the financial situation of a person or an entity in which that person or an immediate family member has a significant financial interest.

*To your knowledge* means your actual knowledge or knowledge that you should reasonably be expected to have based on information that has been provided to you or is in your possession. *To your knowledge* does not imply a duty to make inquiries to discover facts that are not known to you or to obtain information that has not been provided to you or is not in your possession.

**B. Certification as to Employee and Immediate Family Members**

1. Do you have, or does any immediate family member have, any of the relationships, transactions, activities, or financial interests described below in subparagraphs (a) through (h)?

(a) An outside entity in which you have or an immediate family member has a significant financial interest has made, or will make, a gift to The George Washington University of cash or property that will be under your control or will directly support your teaching or research activities.

(b) You have or an immediate family member has a significant financial interest in the proposed or current sponsor of, or a proposed or current subcontractor, vendor, or collaborator for, a sponsored project involving The George Washington University.

(c) You have an actual or proposed technology licensing or commercialization arrangements with an outside entity in which you have or an immediate family member has a significant financial interest and where those arrangements might reasonably be perceived as involving or creating the appearance of a material conflict of interest with your appointment at The George Washington University.

(d) You are or will be personally involved in, or you have or will have the ability to influence the formation or implementation of, a transaction in which The George Washington University, directly or indirectly, is procuring or will procure property, goods or services from an outside entity in which you have or an immediate family member has a significant financial interest.

(e) The design, conduct or reporting of your current or proposed externally funded research at The George Washington University does impact or will impact a significant financial interest that you hold or an immediate family member holds in an outside entity.

(f) You are or an immediate family member is a director, officer, sole owner, partner, employee, agent, consultant, or advisor of a business enterprise that to your knowledge supplies The George Washington University with any property, goods, or services.

(g) You have or an immediate family member has a significant financial interest in a business enterprise (excluding any investment representing less than 1 percent of the total equity of a publicly traded entity) that to your knowledge supplies The George Washington University with any property, goods, or services.

(h) You are a director, officer, sole owner, partner, employee, agent, consultant, or advisor of, or you have a significant financial interest in, a business

enterprise (other than The George Washington University) that to your knowledge engages in the business of higher education or the delivery of patient care services.

Yes \_\_\_\_\_ No \_\_\_\_\_

2. In the past 12 months, to the best of your knowledge, have you or has any immediate family member received a loan of money, property, or services in the amount of \$250 or more (excluding any loan from a bank or other financial institution), or received a gift of money, property, services, or out-of-home entertainment with a value exceeding \$100, from a business enterprise that to your knowledge supplies property, goods, or services to The George Washington University?

Yes \_\_\_\_\_ No \_\_\_\_\_

3. In the past 12 months, to the best of your knowledge, have you received a loan of money, property, or services in the amount of \$250 or more (excluding a loan from a bank or other financial institution), or received a gift of money, property, services, or out-of-home entertainment with a value exceeding \$100, from a business enterprise (other than The George Washington University) that engages in the business of higher education or patient care services?

Yes \_\_\_\_\_ No \_\_\_\_\_

4. Do you have, or does any immediate family member have, any other relationships, transactions, activities, or financial interests that might reasonably be perceived as involving, or creating the appearance of, a material conflict of interest with your appointment at The George Washington University?

Yes \_\_\_\_\_ No \_\_\_\_\_

If your answer to any of the above Questions 1-4 is Yes, please give details, including identifying the business enterprise(s) and describing your or your immediate family member's relationship to it, as well as the approximate value of any income or financial interest, loan or gift. (Where more space is required for your answers, please attach additional pages to this questionnaire.)

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**C. Certification as to Employee and Close Family Members**

1. To your knowledge, do you have or does any close family member have any of the relationships, transactions, activities, or financial interests described below in subparagraphs (a) through (g)?

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(a) An outside entity in which a close family member has a significant financial interest has made, or it will make, a gift to The George Washington University of cash or property that will be under your control or will directly support your teaching or research activities.

(b) A close family member has a significant financial interest in the proposed or current sponsor of, or a proposed or current subcontractor, vendor, or collaborator for, a sponsored project involving The George Washington University.

(c) You have an actual or proposed technology licensing or commercialization arrangements with an outside entity in which a close family member has a significant financial interest and where those arrangements might reasonably be perceived as involving or creating the appearance of a material conflict of interest with your appointment at The George Washington University.

(d) You are or will be personally involved in, or you have or will have the ability to influence the formation or implementation of, a transaction in which The George Washington University is procuring or will procure property, goods, or services from an outside entity in which a close family member has a significant financial interest.

(e) The design, conduct or reporting of your current or proposed externally funded research at The George Washington University does impact or will impact a significant financial interest that a close family member holds in an outside entity.

(f) A close family member is a director, officer, sole owner, partner, employee, agent, consultant, or advisor of a business enterprise that to your knowledge supplies The George Washington University with any property, goods, or services.

(g) A close family member has a significant financial interest in a business enterprise (excluding any investment representing less than 1 percent of the total equity of a publicly traded entity) that to your knowledge supplies The George Washington University with any property, goods, or services.

Yes \_\_\_\_\_ No \_\_\_\_\_

2. In the past 12 months, to your knowledge, has a close family member received a loan of money, property, or services in the amount of \$250 or more (excluding any loan from a bank or other financial institution), or received a gift of money, property, services, or out-of-

home entertainment with a value exceeding \$100, from a business enterprise that to your knowledge supplies The George Washington University with any property, goods, or services?

Yes \_\_\_\_\_ No \_\_\_\_\_

3. To your knowledge, does a close family member have any other relationships, transactions, activities, or financial interests connected to The George Washington University that might reasonably be perceived as involving, or creating the appearance of, a material conflict of interest with your appointment at The George Washington University?

Yes \_\_\_\_\_ No \_\_\_\_\_

If your answer to any of the above Questions 1-3 is Yes, please give details, including identifying the business enterprise(s) and describing your close family member's relationship to it, as well as the approximate value of any income or financial interest, loan or gift. (Where more space is required for your answers, please attach additional pages to this questionnaire.)

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I certify that all of the foregoing information in **PART I** is true and complete to the best of my knowledge.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Full Name (Printed)

\_\_\_\_\_  
Position Title

**PART II (To be completed by University officials)**

**Department Chair/Unit Head – Comments and Recommended Actions**

\_\_\_\_\_ To the best of my knowledge, there is no perceived or inappropriate activity or conflict.

\_\_\_\_\_ I have reviewed this disclosure and recommend the following actions be taken:

\_\_\_\_\_  
Printed Name and Signature

\_\_\_\_\_  
Date

**College Dean/Director – Comments and Recommended Actions**

\_\_\_\_\_ To the best of my knowledge, there is no perceived or inappropriate activity or conflict.

\_\_\_\_\_ I have reviewed this disclosure and recommend the following actions be taken:

\_\_\_\_\_  
Printed Name and Signature

\_\_\_\_\_  
Date

**Executive Vice President for Academic Affairs – Comments and Approval**

\_\_\_\_\_ To the best of my knowledge, there is no perceived or inappropriate activity or conflict.

\_\_\_\_\_ I have read the Financial Interest Disclosure and, if provided, the plan to manage, reduce or eliminate any actual, potential, or apparent conflict of interest. I approve of the Management Plan.

\_\_\_\_\_  
Printed Name and Signature

\_\_\_\_\_  
Date

# Exhibit C

Submitted for Endorsement by the Faculty Senate 1/21/05

## Proposal-Specific Investigator Financial Interest Disclosure Form

**Pursuant to The George Washington University Policy on Conflicts of Interest and Commitment for Faculty and Investigators (May 14, 2004)**

The Faculty Senate and the Board of Trustees approved an updated University-wide *Policy on Conflicts of Interest and Commitment for Faculty and Investigators* in May 2004. The full policy is available at [my.gwu.edu/files/policies/ConflictofInterestandcommitment.pdf](http://my.gwu.edu/files/policies/ConflictofInterestandcommitment.pdf). Pursuant to the policy, persons responsible for the design, conduct, or reporting of University sponsored programs (hereinafter "Investigators") must complete this form for each proposal submitted for external funding.

The purpose of this form is to assist faculty, Investigators, and the University in the identification and management of potential and actual conflicts of interest and to support compliance with applicable government regulations. Because of the complexities of The George Washington University, it is not unusual for an employee to respond affirmatively to one or more of the following questions. An affirmative response in no way implies that a conflict of interest necessarily exists or, if it does, that it cannot be managed. Please be assured that responses to this questionnaire may be submitted on a confidential basis and will be held strictly in confidence, ~~and that~~ Responses requiring further clarification will be brought to your immediate attention.

**Faculty Member or Investigator Name:** \_\_\_\_\_

**Department/Unit:** \_\_\_\_\_

**Sponsor:** \_\_\_\_\_

**Title:** \_\_\_\_\_

### **PART I (To be completed by all Investigators)**

#### **A. Definitions**

The term *significant financial interest* means

(1) any stock, stock option, or similar ownership interest in an 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, immediate family member or close family member provides services as a principal investigator for, or holds a management position in, an outside entity; or

(4) that a close family member holds an ownership interest in an outside entity or has a right to receive income from an outside entity, if such ownership interest or right to receive income would be treated as a “significant financial interest” with respect to a Faculty Member or Investigator under (1) or (2), above.

*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 income from service on advisory committees or review panels for public or non-profit entities.

*The George Washington University (and University)* means The George Washington University and any entity owned in whole or in part, directly or indirectly, or controlled by the University, including the Medical Faculty Associates (MFA) and any joint venture.

*Gifts* do not include honoraria (e.g., remuneration or gifts-in-kind) received in connection with (1) participation in seminars, lectures, or teaching engagements sponsored by public or non-profit entities or (2) service on advisory committees or review panels for public or non-profit entities.

*Immediate family member* includes an Investigator’s spouse/domestic partner and dependent children.

*Close family member* includes an Investigator’s non-dependent children, as well as father, mother, sisters and brothers of the Investigator and the Investigator’s spouse/domestic partner.

*To your knowledge* means your actual knowledge or knowledge that you should reasonably be expected to have based on information that has been provided to you or is in your possession. *To your knowledge* does not imply a duty to make inquiries to discover facts that are not known to you or to obtain information that has not been provided to you or is not in your possession.

**B. Certification as to Investigator and Immediate Family Members**

1. Do you have, or does any immediate family member have, any of the relationships, transactions, activities, or financial interests described below in subparagraphs (a) through (g)?

(a) An outside entity in which you have or an immediate family member has a significant financial interest has made, or will make, a gift to The George Washington University of cash or property that will be under your control or will directly support this sponsored project.

(b) You have or an immediate family member has a significant financial interest in the proposed or current sponsor of, or a proposed or current subcontractor, vendor, or collaborator for, this sponsored project.

(c) You have or an immediate family member has an actual or proposed technology licensing or commercialization arrangement with the proposed or current sponsor of, or a proposed or current subcontractor, vendor, or collaborator for, this sponsored project.

(d) You are or will be personally involved in, or you have or will have the ability to influence the formation or implementation of, a transaction to procure property, goods, or services for this sponsored project from an outside entity in which you have or an immediate family member has a significant financial interest.

(e) The design, conduct or reporting of this sponsored project does impact or will impact a significant financial interest that you hold or an immediate family member holds in an outside entity.

(f) You are or an immediate family member is a director, officer, sole owner, partner, employee, agent, consultant, or advisor of a business enterprise that to your knowledge supplies or will supply The George Washington University with any property, goods, or services for this sponsored project.

(g) You have or an immediate family member has a significant financial interest in a business enterprise that to your knowledge supplies or will supply The George Washington University with any property, goods, or services for this sponsored project.

Yes \_\_\_\_\_ No \_\_\_\_\_

2. In the past 12 months, to the best of your knowledge, have you or has any immediate family member received a loan of money, property, or services in the amount of \$250



(a) An outside entity in which a close family member has a significant financial interest has made, or will make, a gift to The George Washington University of cash or property that will be under your control or will directly support this sponsored project.

(b) A close family member has a significant financial interest in the proposed or current sponsor of, or a proposed or current subcontractor, vendor, or collaborator for, this sponsored project.

(c) You are or will be personally involved in, or you have or will have the ability to influence the formulation or implementation of, a transaction to procure property, goods, or services for this sponsored project from an outside entity in which a close family member has a significant financial interest.

(d) The design, conduct or reporting of this sponsored project does impact or will impact a significant financial interest that a close family member holds in an outside entity.

(e) A close family member has an actual or proposed technology licensing or commercialization arrangement with the proposed or current sponsor of, or a proposed or current subcontractor, vendor, or collaborator for, this sponsored project.

(f) A close family member is a director, officer, sole owner, partner, employee, agent, consultant, or advisor of, or has a significant financial interest in, a business enterprise that to your knowledge supplies or will supply The George Washington University with any property, goods, or services for this sponsored project.

Yes \_\_\_\_\_ No \_\_\_\_\_

2. In the past 12 months, to your knowledge, has a close family member received a loan of money, property, or services in the amount of \$250 or more (excluding any loan from a bank or other financial institution), or received a gift of money, property, services, or out-of-home entertainment with a value exceeding \$100, from: (a) a business enterprise that to your knowledge supplies property, goods, or services to the George Washington University, or (b) the sponsor of, or a subcontractor, vendor, or collaborator for, this sponsored project?

Yes \_\_\_\_\_ No \_\_\_\_\_

3. To your knowledge, does a close family member have any other relationships, transactions, activities, or financial interests that might reasonably be perceived as involving, or creating the appearance of, a conflict of interest with respect to your involvement in this sponsored project?

Yes \_\_\_\_\_ No \_\_\_\_\_



**PART II (To be completed by University officials)**

**Department Chair/Unit Head – Comments and Recommended Actions**

\_\_\_\_\_ To the best of my knowledge, there is no perceived or inappropriate activity or conflict.

\_\_\_\_\_ I have reviewed this disclosure and recommend the following actions be taken:

\_\_\_\_\_  
Printed Name and Signature

\_\_\_\_\_  
Date

**College Dean/Director – Comments and Recommended Actions**

\_\_\_\_\_ To the best of my knowledge, there is no perceived or inappropriate activity or conflict.

\_\_\_\_\_ I have reviewed this disclosure and recommend the following actions be taken:

\_\_\_\_\_  
Printed Name and Signature

\_\_\_\_\_  
Date