

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

The George Washington University

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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 solely of this Policy, the terms "Faculty" and "Faculty Member" mean those individuals are (1) as defined in the Faculty Code, pages 2 1 and 3 2, section I, subsection B, items 1, 3, and 4, and also the term Investigator refers to (2) any other person responsible for the design, conduct or reporting of externally sponsored University research, including without limitation Research Scientists and Senior Research Scientists.***

**AB. 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 **Ffaculty Mmember's** responsibility to further his or her own professional development and the goals of his or her professional discipline. Normally a **Ffaculty mMember's** participation in activities of governmental, industrial, and professional institutions is consistent with academic interests of the University and the **Ffaculty mMember**.

Conflicts of interest may occur when there is a divergence between a **Ffaculty Mmember'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 **Ffaculty Mmember** due to external commitments (for example, when a **fFaculty mMember** 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 **Ffaculty mMember** inappropriately uses University equipment, supplies, personnel, and other facilities and resources for activities that yield financial benefit to the **Ffaculty Mmember** 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 **F**aculty **m**ember'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 **F**aculty **m**ember 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
4. the University is deprived of appropriate potential financial gain (for example, when a **F**aculty **M**ember 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).

**BC.** 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 **F**aculty **m**ember and the University are well served. To promote fairness, all **F**aculty are required to report, as set forth in this Policy. (2) Each school shall administer in accordance with this Policy: a procedure for annual **F**aculty disclosure of reportable actual, potential, and apparent conflicts of interest; disclosure by **f**aculty of information pertinent to such conflicts; and a procedure for review and resolution of any lack of agreement arising from disclosure of such conflicts.

**CD.** Obligation of University.

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

~~D. "Faculty" defined.~~

~~For purposes solely of this Policy, the terms "faculty" and "faculty member" are (1) as defined in the Faculty Code, pages 2 and 3 section I, subsection B items 1, 3, and 4, and also refer to (2) any other person responsible for the design, conduct or reporting of externally sponsored University research.~~

**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 **f**aculty **m**embers the opportunity to use their knowledge and talents constructively, to strengthen their competence through a greater variety of professional experiences, to enhance the **f**aculty **m**ember's and the University's scholarly reputation, and to serve the public interest.

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

A full-time ~~f~~Faculty ~~M~~member may spend the equivalent of up to one working day a week 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 ~~f~~Faculty ~~m~~Member directly and do not involve the University. This privilege is not extended to research ~~f~~Faculty ~~M~~members paid wholly from research grants or contracts, ~~full-time physician-fFaculty-mMembers in the Medical Center who are participants in Medical Faculty Associates~~, or other physician ~~f~~Faculty ~~m~~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 ~~f~~Faculty ~~M~~member abuses this privilege. In particular, ~~f~~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 ~~F~~faculty ~~M~~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 ~~f~~Faculty ~~M~~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 and dependent children.,-**and**
- ~~"Significant financial interest"~~ means (1) any stock, stock option, or similar ownership interest in the outside entity by the ~~f~~Faculty ~~M~~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 ~~F~~faculty ~~M~~member, **Investigator** nor an immediate family member exercises control; or (2) receipt, individually or collectively by a ~~f~~Faculty ~~M~~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,

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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.**

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 **F**aculty **M**ember, **I**nvestigator 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 of the following arrangements, and annually thereafter, a **F**aculty **M**ember or **I**nvestigator described in paragraphs 1-5 below must submit to the school dean a written disclosure of any current or pending relationship of such **F**aculty **M**ember, **I**nvestigator 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 **F**aculty **M**ember or **I**nvestigator will ~~ensure separation of manage~~ his or her University role **in relation to** ~~from~~ the **F**aculty **M**ember's, **I**nvestigator's -or immediate family member's role or interest in the entity:

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 **F**aculty **M**ember or **I**nvestigator from an outside entity in which the **F**aculty **M**ember, **I**nvestigator or immediate family member has a significant financial interest;
2. Sponsored-project proposals as to which the involved **F**aculty **M**ember, **I**nvestigator 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 **F**aculty ~~inventor~~ **M**ember, **I**nvestigator or immediate family member has a significant financial interest;
4. Procurement of materials or services from an outside entity in which the **F**aculty **M**ember, **I**nvestigator or immediate family member has a significant financial interest, if the **F**aculty **M**ember or **I**nvestigator 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 **F**aculty **M**ember or **I**nvestigator plans to participate that would reasonably appear to affect the **F**aculty **M**ember's, **I**nvestigator's or immediate family member's interest in an outside entity or would reasonably appear to affect the entity's financial interests.

A **F**aculty **M**ember or **I**nvestigator 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.

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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.**

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.**

**Under Public Health Service and National Science Foundation 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.**

<sup>3</sup> PHS 42 CFR Part 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought.” PHS excludes Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program Phase I applications from the regulation. 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. Faculty members 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. 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 generalized 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 [42 CFR Part 50, Subpart F], 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.”

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.

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.

#### IV. PROCEDURES FOR REVIEW

- A. Review of disclosure form; management of disclosed conflicts.
  1. Faculty ~~m~~Members and Investigators shall supply the annual and ad hoc disclosures required by Section III on the annexed Disclosure Form, for confidential review by the Administration. Each dean shall forward to the ~~Vice President~~Executive Vice President a copy of the Faculty and Investigator disclosure forms, 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 ~~Vice President~~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 ~~Vice President~~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 ~~Vice President~~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 ~~F~~faculty ~~M~~member, ~~Investigator~~ or otherwise of conduct the dean believes presents a significant question under this Policy, the dean should discuss the conduct with the ~~f~~Faculty ~~M~~member or ~~Investigator~~; shall relate his or her findings to the ~~Vice President~~Executive Vice President, and subject to the concurrence of the ~~Vice President~~Executive Vice President shall advise the ~~f~~Faculty ~~M~~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 ~~Vice President~~Executive Vice President determines that conditions or restrictions should be imposed, the ~~f~~Faculty ~~M~~member or ~~Investigator~~ shall, as the case may be, cease the conduct, accept the conditions or restrictions agreeable to the ~~Vice President~~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 ~~F~~faculty ~~M~~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 shall be composed of at least five ~~F~~faculty ~~M~~members of the school, elected, ordinarily annually, by the ~~f~~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 ~~Vice President~~Executive Vice President, the Complainant, ~~or~~ the ~~f~~Faculty ~~M~~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 ~~Vice President~~Executive Vice President shall review the Committee's recommendation, confer with the Dean, and render a formal decision.

6. A ~~f~~Faculty ~~M~~member or ~~Investigator~~ dissatisfied with the ~~Vice President~~Executive Vice President's decision may appeal it to the University Conflicts Resolution Panel ("Panel"), which shall be composed of five ~~F~~faculty ~~M~~members nominated by the Faculty Senate Executive Committee in consultation with the ~~Vice President~~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 ~~F~~Faculty ~~M~~ember 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 ~~F~~Faculty or **Investigators** who are identified in Section I.D.1. is ultimately determined to be impermissible under this Policy, the ~~Vice President~~**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 ~~F~~Faculty ~~m~~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 ~~F~~faculty ~~M~~ember or **Investigator** may not rely on an approval that addressed a different ~~F~~Faculty ~~m~~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/COL01.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)**