

## INVESTIGATOR SIGNIFICANT FINANCIAL DISCLOSURE POLICY FOR SPONSORED PROJECTS

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These guidelines define general College policy and procedures regarding conflicts of interest in relationship to sponsored projects involving research, education, and college service. This policy is to protect the credibility and integrity of the College's faculty and staff, thereby ensuring public trust and confidence in the College's sponsored research activities.

In accordance with Federal regulations, the College has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an investigator. Thus, the College requires that investigators disclose any significant financial interest that may present an actual or potential conflict of interest in relationship with a sponsored project. This policy applies to all externally sponsored projects, regardless of funding source.

### Background

On June 28, 1994, the National Science Foundation (NSF) issued notice of its policy on financial disclosure by scientific investigators in sponsored research (59 Fed. Reg. 33308), which is designed to protect the integrity of NSF-funded research and at the same time to promote sharing and publication of results. The notice--titled *Investigator Financial Disclosure Policy*--was published in the *Congressional Register* on June 28, 1995.

Placing primary responsibility upon the institution (college, university, etc.) to develop information-gathering and reporting procedures, the National Science Foundation requires that grantee institutions employing more than 50 (fifty) persons maintain "an appropriate written and enforced policy on conflict of interests."

NSF has been coordinating its Policy with the Public Health Service of the Department of Health and Human Services (PHS-HHS), and on June 28, 1994, PHS published a proposed rulemaking entitled *Objectivity in Research*. Under its proposed rules, PHS would require that applicant institutions ensure there is no reasonable expectation that the design, conduct, and reporting of the research to be funded will be biased by any significant financial interest of the investigator responsible for the design, conduct, and reporting of research.

Both NSF and PHS-HHS policies become effective October 1, 1995. These policies are printed in the *Federal Register* (FR) with the most recent PHS-HHS and NSF policy changes published in FR, V.60, July 11, 1995, pp. 35810-35819 (for PHS-HHS), and 35820-35823 (for NSF).

These documents are available for review in Simmons College's Office of Sponsored Programs, Room C-208-MCB. Jon A. Kimball, the College's Director of Grants and Sponsored Programs, is also available to answer any questions pertaining to NSF and PHS-HHS policies, as well as the College's policy.

## Requirements

Federal regulations require institutions to have policies and procedures in place that ensure that investigators disclose:

1. any significant financial interests that would reasonably appear to be directly and significantly affected by the research or educational activities funded, or proposed for funding, by an external sponsor;
2. any significant financial interest of the investigator in an entity whose financial interests would reasonably appear to be directly and significantly affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

Such disclosures must be made prior to the submission of a proposal for funding. Furthermore, institutions must certify compliance on each proposal as well as develop specific mechanisms by which conflicts of interest will be satisfactorily managed, reduced, or eliminated prior to award or acceptance of an award. The institution must also maintain appropriate records. If a new reportable significant conflict of interest arises at any time during the period after submission of the proposal through the period of the award, the filing of a disclosure is also required.

## Definitions

The term *investigator* means the principal investigator/project director, co-principal investigator(s), and any other person at the College who is responsible for the design, conduct, or reporting of research or educational activities funded, or proposed for funding, by an external sponsor. In this context the term *investigator* includes the investigator's spouse and dependent children.

A conflict of interest may take many forms, but arises when a principal investigator is or may be in a position to influence the College, research, or other decisions in ways that could lead to any form of personal gain for the principal investigator (including her/his spouse and/or dependent children) or give improper advantage to others to the College's detriment.

A *potential* conflict of interest occurs when there is a divergence between an individual's private interests and her/his other professional obligations to the institution such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. An actual conflict of interest depends upon the situation, and not upon the character or actions of the individual.

An *actual or potential* conflict of interest exists when the reviewers reasonably determine that a significant financial interest could affect the design, conduct, or reporting of the research or educational activities funded, or proposed for funding, by an external sponsor.

*Significant financial interest* means anything of monetary value, including, but not limited to, salary or other payment (s) for services (e.g., consulting fees or honoraria); equity interests (e.g.,

stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

The term does not include: (a) salary, royalties, or other remuneration from Simmons College; (b) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; (c) income from service on advisory committees or review panels for public or nonprofit entities; (d) financial interests in business enterprises or entities if the value of such interests does not exceed \$5,000 (or \$5,000 per annum if such interests represent salary, fees, or other continuing payments) or represent more than 5% (five percent) ownership interest for any one enterprise or entity when aggregated for the investigator and the investigator's spouse and dependent children.

Significant financial interests that must be disclosed are:

1. any financial interests of the investigator (including those of the investigator's spouse and dependent children) that would reasonably appear to be directly and significantly affected by the research or educational activities funded, or proposed for funding, by an external sponsor;
2. interests in entities whose financial interests would reasonably appear to be directly or significantly affected by sponsored activities. Research funded under the Small Business Technology Transfer Program is excluded from this disclosure.

## **Policy**

1. Effective September 30, 1995, Simmons College requires each investigator submitting a proposal for external funding to submit all required financial disclosure at the time of proposal submission and to update this information annually or as new interests are obtained during the life of the award.

Disclosure of significant financial interests shall be made to Simmons College's Director of Grants and Sponsored Programs by means of a packet of information consisting of:

- Declaration for Significant Financial Interest Disclosure Policy (the Short Form A, or Form A & the longer Form B);
- if necessary, all required supporting documentation (in a sealed envelope and clearly marked *confidential*);
- the proposal; and
- the proposal approval form.

2. In accordance with Federal regulations, a complete disclosure must be made by the investigator prior to submission of the proposal.

3. The procedure to review disclosures, assess their potential for conflicts of interest, and develop resolution strategies to "manage, reduce or eliminate" such conflicts shall be

incorporated with the standard proposal signature process and integrated into the normal proposal submission process.

4. A conflict of interest review committee, its members appointed by the College President, shall be charged with responsibility for review of significant financial disclosures to determine whether an actual or potential conflict of interest exists; determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate such conflicts of interest; and, as necessary, recommend sanctions.
5. The Office of Sponsored Programs shall be responsible for appropriate follow-up reporting and records management procedures.

### **Reporting Guidelines**

1. Each investigator is required to disclose the following significant financial interests:
  - any significant financial interest of the investigator that would reasonably appear to be directly and significantly affected by the research or educational activities funded, or proposed for funding, by an external sponsor, or
  - any significant financial interest of the investigator in an entity whose financial interests would reasonably appear to be directly and significantly affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

Regardless of the above minimum requirement, a faculty or staff member, in her/his own best interest, may choose to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a very important factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

2. Each investigator shall fully complete a Significant Financial Interest Disclosure Form (Form A) and, if necessary, fully complete Form B and attach all required supporting documentation. The completed disclosure form(s) must be submitted with the proposal and proposal approval form to the Office of Sponsored Programs using normal College procedures.

Supporting documentation that identifies the business enterprise or entity involved and the nature and amount of the interest should be submitted in a sealed envelope marked *confidential* and accompany the disclosure form, the proposal, and the proposal approval form.

3. As required by Federal regulation, all significant financial interests must be disclosed prior to the time a proposal is submitted. Furthermore, all financial disclosures must be updated by investigators during the of the award period, either on an annual basis or as changes are made to previously reported significant financial interests. If a new reportable significant financial interest arises at any time during the period after the submission of the proposal through the entire period of any resulting award, the filing of a disclosure form is also required.

4. The Director of Grants and Sponsored Programs or official designee shall conduct an initial review of all financial disclosures to determine if any disclosed significant financial interest could affect the design, conduct, or reporting of the proposed sponsored project. If the initial determination is made that there may be a potential for conflict of interest covered by this policy, then the disclosure packet will be referred to the Conflict of Interest Review Committee.

Conflict of Interest Review Committee members are appointed by the College President. The Committee shall contain, at minimum, researchers representing a cross-section of disciplines and a research administrator. The Committee shall determine what conditions or restrictions, if any, should be imposed by the College to manage actual or potential conflicts of interest arising from disclosed significant financial interests. Recommendations for Committee members will be made to the College President.

5. Prior to consideration by the Conflict of Interest Review Committee, the investigator, in cooperation with the investigator's department and school, shall develop and present to the Committee a resolution plan that details proposed steps that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by a significant financial interest. At minimum, the resolution plan shall address such issues as public disclosure of significant financial interests, review of research protocol by independent reviewers, and monitoring of research by independent reviewers.

Where the Committee deems appropriate, the Committee shall review the resolution plan and approve it, add conditions or restrictions, including the following:

- modification of the research plan;
- disqualification from participation in all or a portion of the research funded;
- divestiture of significant financial interests; or
- severance of relationships that create actual or potential conflicts of interest.

If the Committee determines that imposing the above-referenced conditions or restrictions would be either ineffective or inequitable, or that potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or public health and welfare, then the Committee may recommend that the research go forward without imposing such conditions or restrictions. In these cases the Director of Grants and Sponsored Programs shall make the final decision regarding resolution.

6. The approved resolution plan shall be incorporated into a memorandum of understanding that details the conditions or restrictions imposed upon the investigator in the conduct of the project or in the relationship with the business enterprise or entity. The memorandum of understanding shall be developed by the Office of Sponsored Programs and signed by the investigator and the investigator's Chair and Dean. Actual or potential conflicts of interests will be satisfactorily managed, reduced, or eliminated in accordance with these guidelines prior to accepting any award, or they will be disclosed by the Office of Sponsored Programs to the sponsoring agency for action.

7. Records of investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest shall be retained by the Office of Sponsored Programs until 3 (three) years after the later of the termination or completion of the award to which they relate, or the resolution of any government action involving those records. All records, forms, correspondence, and all copies thereof shall be returned to the investigator at the determination of award or resolution of government action involving those records.

8. Whenever an investigator has violated this policy or the terms of the memorandum of understanding, the Conflict of Interest Review Committee shall recommend sanctions which may include disciplinary action ranging from a public letter of reprimand to dismissal and termination of employment. The Committee's recommendations on sanctions shall be presented to the investigator's Chair and Dean who, in consultation with the Director of Grants and Sponsored Programs, shall enforce any disciplinary action in accordance with strict professional standards.

9. The Director of Grants and Sponsored Programs or official designee shall report annually to the College President and to College Deans about the status and workings of this policy and the actions of the Conflict of Interest Review Committee.