Conflict of Interest Policy

INVESTIGATOR SIGNIFICANT FINANCIAL INTEREST DISCLOSURE POLICY FOR SPONSORED PROJECTS

These guidelines define general University of Scranton policy and procedures regarding conflicts of interest in relationship to research or educational sponsored projects. Their purpose is to protect the credibility and integrity of University's faculty and staff members and the University so that public trust and confidence in the University's sponsored research activities is ensued.

In accordance with Federal Regulations, the University 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 University requires that investigators disclose any significant financial interest that may present an actual or potential conflict of interest in relationship to a sponsored project. Necessary forms are available in the Office of Research Services, extension 6190.

A. BACKGROUND - Technology Transfer and Conflict of Interest

Effective interaction between universities conducting research and industry is essential to ensure the rapid application of scientific discoveries to the needs of the Nation and to maintain the international competitiveness of domestic industry. Nonetheless, prudent stewardship of public funds includes protecting sponsored research from being compromised by the conflicting financial interests of any investigator responsible for the design, conduct, or reporting of sponsored research.

Numerous statutes and programs demonstrate Federal interest in the promotion of interactions among Government, academia and industry. For example, the Stevenson-Wydler Technology Innovation Act of 1980 (Public Law (P.L.) 96-480) encourages technology transfer, particularly through industrial-academic collaborations. The Patent and Trademark Act Amendments of 1980 (P.L. 96-517) allow universities and other funding recipients to apply for patents developed with Federal funding, and expressly promote collaboration between commercial concerns and nonprofit organizations. The Economic Recovery Tax Act of 1981 (P.L. 97-34) is aimed at fostering research and development by small companies and associated Institution partners. The Federal Technology Transfer Act of 1986 (P.L. 99-502), which amended P.L. 96-480, and Executive Order 12592 provide similar patent and licensing authority to Federal laboratories, and encourage them to participate in cooperative research and development agreements with the private sector and nonprofit organizations, including universities.

These legal authorities facilitate the movement of intellectual capital between the Federal Government, academic institutions, and the private sector. This kind of cross-fertilization is critical to the development of U.S. industry. However, these and other inducements for collaboration have created a climate in which the stewardship of public funding for research is increasingly complex and challenging.

The value of the results of sponsored research to the health and the economy of the Nation must not be compromised by any financial interest that will, or may be reasonably expected to, bias the design, conduct or reporting of the research. This policy seeks to maintain a reasonable balance between these competing interests, give the University the ability to identify and manage financial interests that may bias the research, and minimize reporting and other burdens on the investigators.
B. DEFINITIONS

A potential Conflict of Interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to the University 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. Any significant financial interest will be presumed to represent at least a potential conflict of interest. An actual conflict of interest depends on the situation, and not on the character or actions of the individual.

Investigator means the principal investigator/project director, co-principal investigators, and any other person at the University 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.

Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments 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:

1. Salary, royalties, or other remuneration from the University of Scranton;
2. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
3. Income from service on advisory committees or review panels for public or nonprofit entities;
4. An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more that a five percent ownership interest in any single entity; or
5. Salary, royalties or other payments that when aggregated for the Investigator and the Investigator’s spouse and dependent children over the next twelve months, are not expected to exceed $10,000.

C. GUIDELINES

1. Each Investigator is required to disclose the following significant financial interests:
   a) 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
   b) Any Significant Financial Interest of the Investigator in an entity whose financial interest 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 requirements, a faculty or staff member, in his or her own best interest, may choose to disclose any other financial or related interest that could present a
conflict of interest. Disclosure if a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

2. Each Investigator who has a significant financial interest requiring disclosure shall complete a Significant Financial Interests Disclosure Form and attach all required supporting documentation. The completed Disclosure Form must be submitted with the proposal and Externally Funded Projects Approval Form to the Office of Research Services using normal University 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 and the Approval Form.

3. As required by Federal regulation, all Significant Financial Interests must be disclosed prior to the time a proposal is submitted. All financial disclosures must be updated by Investigators during the pendency of the award, 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 Research 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 the potential conflict of interest requires management, the Director of Research will form an ad hoc Conflict of Interest Review Committee (CIRC) to review the disclosure. The investigator will be informed of the formation of the CIRC. The CIRC will consist of the Investigator's Dean or cognizant University official, the Director of Research, and up to two (2) additional faculty members to act as consultants, as necessary. The faculty consultants will be given only those details of the significant financial interest necessary to provide appropriate advice. The investigator will be informed of the specific financial details that will be disclosed to the members of the CIRC. Members of the CIRC will be required to maintain the confidentiality of such information. In the event that the Director of Research Services has a conflict of interest with respect to a particular project, the Provost/Academic Vice-President shall designate an alternate Conflict of Interest Officer to review that project.

5. The CIRC, in cooperation with the Investigator, shall develop a Resolution Plan that details proposed steps that will be taken to manage, reduce, or eliminate any potential conflict of interest presented by a Significant Financial Interest. The Director of Research shall make the final decision regarding the content of the resolution plan. At a minimum the Resolution Plan shall address such issues as:
   a) Public disclosure of significant financial interests;
   b) Review of research protocol by independent reviewers; and
   c) Monitoring of research by independent reviewers.
Where the CIRC deems it appropriate, the CIRC shall review the Resolution Plan and make recommendations concerning it to the Director of Research. The resolution plan may include the following:

d) Modification of the research plan;
e) Disqualification from participation in all or a portion of the research funded;
f) Divestiture of significant financial interests; or
g) Severance of relationships that create potential conflicts of interest.

If the CIRC determines that imposing the above referenced conditions or restrictions would be inequitable, or that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the CIRC may recommend that, to the extent permitted by Federal regulations [PHS policy, for instance, does not permit such an action], the research go forward without imposing such conditions or restrictions. In these cases, the Director of Research shall make the final decision regarding resolution.

6. The approved Resolution Plan shall be incorporated into a Memorandum of Understanding (MOU) 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 signed by the Investigator and their Dean of cognizant University official. Potential conflicts of interests will be satisfactorily managed, reduced, or eliminated in accordance with these Guidelines and all required reports regarding the conflict of interest submitted to the sponsor prior to the expenditure of any funds under an award. [For example, the PHS requires the University to report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by the University and assure that the interest has been managed, reduced, or eliminated. NSF only requires the University to report conflicts which cannot be satisfactorily be managed, reduced, or eliminated.]

7. Records of investigator financial disclosures and of actions taken to manage potential conflicts of interest, shall be retained by the Office of Research Services, in locked storage, until 3 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.

8. Whenever an Investigator has violated this policy or the terms of the Memorandum of Understanding, the Director of Research shall recommend sanctions which may include disciplinary action ranging from a public letter of reprimand to dismissal and termination of employment. The Director of Research may consult with the CIRC regarding the recommendation for sanctions. If the violation results in a collateral proceeding under the University’s policies regarding misconduct in science, then the decision on sanctions will be deferred until the misconduct in science process is completed. The recommendations on sanctions shall be presented to the Investigator’s Dean or cognizant University official who, in
consultation with the Director of Research, shall enforce any disciplinary action. It is understood that individuals alleged to have violated this policy or the terms of an MOU will be accorded due process in any disciplinary proceeding. In addition, the University shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.

9. Collaborators/subrecipients/subcontractors from other academic or not-for-profit institutions must either comply with this policy or provide a certification from their institutions that they are in compliance with Federal policies regarding investigator significant financial interest disclosure and that their portion of the project is in compliance with their institutional policies. Subcontractors from commercial firms need not make a certification, except when the prime award is from the Public Health Service. The PHS requires a certification from any subcontractor, including commercial firms, stating that it is in compliance with Federal policies regarding investigator financial interest disclosure and that its portion of the project is in compliance with company policies.

The University of Scranton Significant Financial Interest Disclosure form
(Applicable to all Sponsored Project Proposals)