Significant Financial Disclosure Policy for Investigators

Disclosure Form in Microsoft Word Format

Introduction

Federal regulations require the University to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an investigator in covered federal programs. Thus, the University requires that investigators disclose any significant financial interest that may present an actual or potential conflict of interest in a sponsored project.

Definitions

**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 a covered federal agency.

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

**Significant financial interest** means anything of monetary value to the investigator, his or her spouse or his or her dependent children, 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);
- Intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

The term does not include:

- Salary, royalties, or other such remuneration from Radford University;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities; or
- Financial interests in business enterprises or entities if the value of such interests does not exceed $10,000 (or $10,000 per annum if salary, fees or other continuing payments) and if the value does not represent more than a 5% ownership interest for any one enterprise or entity when aggregated for the Investigator and the Investigator’s spouse and dependent children.
Requirements

1. Each Investigator is required to read this policy.
2. 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 Interest of the Investigator in any entity whose financial interest would reasonably appear to be directly and significantly affected by the research or educational activities funded, or proposed by funding, by an external sponsor.

Regardless of the above minimum requirements, an Investigator, in his or her 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 key factor in protecting one’s reputation and career from potentially embarrassing or harmful allegations of misconduct.

Procedures

1. Each Investigator must complete a Significant Financial Interests Disclosure Form and attach all required supporting documentation. The completed Disclosure Form must be submitted with the proposal and University Internal Review Form (Proposal Summary Form) to the Office of Sponsored Programs and Grants Management. 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 Proposal Summary Form.

2. As required by Federal regulation, all Significant Financial Interests must be disclosed prior to the time a proposal is submitted. If a new Significant Financial Interest arises at any time after the submission of the proposal through the entire period of any resulting award, the Investigator must file a new Disclosure Form within 14 days of becoming aware of a potential or actual conflict of interest.

3. If an Investigator indicates there may be a potential conflict of interest covered by this policy, the Disclosure Packet will be referred to the University Conflict of Interest Review Committee (CIRC). Committee members are appointed for staggered two-year terms as follows: one by each academic dean. The Director of Sponsored Programs and Grants Management will call the meeting together and serve as a non-voting member. The Investigator whose financial interests are to be discussed will be invited to the meeting, but will not vote. In the event of a tie, the Provost shall make the final decision.

4. Prior to consideration by the CIRC, the Investigator must develop and present to the CIRC a conflict of Interest Resolution Plan that details proposed steps that will be taken
to manage, reduce, or eliminate any actual potential conflict of interest presented by a Significant Financial Interest. Examples of conditions or restrictions that might be proposed include:

- Public disclosure of significant financial interests;
- Review of research protocol by independent reviews; and
- Monitoring of research by independent reviewers.

The CIRC must review the Resolution Plan for approval with several possible outcomes. The CIRC may approve the plan, reject the plan, or approve the plan with additional 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.

Investigators may revise and resubmit rejected Resolution Plans or may appeal the CIRC decision. The Provost will make the final decision regarding resolution of appeals.

If the CIRC determines that imposing the above referenced conditions or restrictions would be ineffective or 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 the research go forward without imposing such conditions or restrictions.

1. The approved Resolution Plan must detail the conditions or restrictions imposed upon the investigator in the conduct of the project or in the relationship with business enterprises or entities. It must be signed by the Investigator, the CIRC chairperson, and the Director of Sponsored Programs and Grants Management.

2. Actual or potential conflicts of interests must be satisfactorily managed, reduced, or eliminated in accordance with these guidelines prior to accepting any award, or they will be disclosed to the sponsoring agency. The Investigator must therefore notify the Director of Sponsored Programs and Grants Management in writing once all the conditions of the Resolution Plan have been met.
3. The Director of Sponsored Programs and Grants Management will notify the sponsoring agency if a resolution cannot be agreed upon or if a Resolution Plan has not been followed.

4. Records of investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest, must be retained by the Office of Sponsored Programs and Grants Management until three years after the latter of the termination or completion of the award to which they relate, or the resolution of any government action involving those records.

5. Whenever an Investigator has violated this policy of the terms of the Resolution Plan, the CIRC must recommend sanctions, which may include a disciplinary action ranging from a public letter of reprimand to dismissal and termination of employment. If the violation results in a collateral proceeding under University policies regarding misconduct in science, then the CIRC must defer a decision on sanctions until the misconduct in science process is completed. The CIRC’s recommendation on sanctions is presented to the Provost who will enforce any disciplinary action.

Effective Date

This policy comes into effect June 28, 1995, and will remain in effect until modified or rescinded. It may also be revised in response to modifications of the applicable federal regulations and guidelines.

Other Regulations

The Virginia State and Local Government Conflict of Interest Act (Code of Virginia, Section 2.1-639.1-.24) defines several prohibited conflicts of interests for state employees. Radford University has promulgated a University Conflict of Interest Policy that supplements the statutes of the Commonwealth of Virginia. The University Conflict of Interest Policy also requires disclosures of a potential conflict of interest and specifies penalties for willful violation of the policy. This Investigator Financial Disclosure Policy for Federally Funded Projects is unrelated to, and in no way supersedes, the Virginia State and Local Government Conflict of Interest Act or the University Conflict of Interest Policy.
SIGNIFICANT FINANCIAL INTEREST DISCLOSURE POLICY

(Applicable to all sponsored programs proposals/projects covered by relevant federal regulations)

What is required?

Federal regulations require institutions to have policies and procedures that ensure that Investigators disclose any significant financial interest that may present an actual or potential conflict of interest in relationship to externally sponsored projects. Such disclosures must be made prior to the submission of a proposal for funding*, and institutions must develop specific mechanisms by which conflicts of interest will be satisfactorily managed, reduced, or eliminated prior to award or acceptance of an award.

*If a new reportable significant financial conflict of interest arises at any time during the period after the submission of the proposal through the period of the award, the filing of a disclosure is also required. The new disclosure must be filed with the Office of Sponsored Programs and Grants Management within 14 days of the Investigator’s becoming aware of the potential conflict of interest.

Who is covered?

"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 a covered federal agency.

What must be disclosed?

Each Investigator shall disclose all significant financial interests (including those of the investigator’s spouse and dependent children):

1. 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
2. in entities whose financial interests would reasonably appear to be directly and significantly affected by such activities.

What is covered?

"Significant financial interests" means anything of monetary value, including, but not limited to, salary or other payments of 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 Radford University;
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; or
4. Financial interests in business enterprises or entities if the value of such interests does not exceed $10,000 (or $10,000 per year) and if the value does not represent more than 5% ownership interest for any one enterprise or entity when aggregated for the Investigator and the Investigator’s spouse and dependent children.

Disclosure Procedures:

1. All Investigators must disclose their significant interests using this form and attach all required supporting documentation. The completed form and packet must be submitted with the proposal and University’s Internal Review Form (Proposal Summary Form) to the Office of Sponsored Programs and Grants Management. Supporting documentation should be submitted in a sealed envelope marked confidential.
2. In accordance with federal regulations, a completed disclosure must be made by the Investigator(s) prior to submission of the proposal.