

CLARION UNIVERSITY OF PENNSYLVANIA
Clarion, Pennsylvania 16214

Conflict of Interest Policy
Research and Sponsored Projects

Objective/Purpose

This Conflict of Interest Policy for Research and Sponsored Projects at Clarion University of Pennsylvania was developed pursuant to and in accordance with applicable federal requirements of (1) the National Science Foundation, “Investigator Financial Disclosure Policy,” published at 60 Federal Register 35820 - 35823, July 11, 1995, and (2) the Public Health Service of the Department of Health and Human Services, published at 60 Federal Register 35810 - 35819, July 11, 1995.

The purposes of these guidelines are to: (1) ensure the credibility and integrity of Clarion University’s faculty and staff so that public trust and confidence in the University’s research and sponsored activities is also ensured; and (2) preserve the faculty’s freedom to participate in these activities while ensuring that faculty and staff exercise substantial responsibility to avoid conflicts of interest. In accordance with Federal regulations, Clarion 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. The opportunity for investigators to receive financial or other personal rewards for their endeavors is not intrinsically unacceptable, as long as it does not adversely influence the objectivity, integrity, or professional commitment of an investigator. [42 C.F.R. § 50.601] Thus, the university requires that investigators disclose any significant financial interest that may present an actual or potential conflict of interest with a sponsored project. [42 C.F.R § 50.602]

General Discussion

Interaction between university faculty and external organizations has grown in magnitude and complexity in recent years. In order to fulfill its teaching/research/community service orientated mission, Clarion University encourages its faculty to participate in appropriate relationships with governmental, industrial, and private partners, to obtain public and private support of research and innovative educational programs, through grants and contracts. Similarly, the University recognizes the value of faculty members serving as consultants for the academic and non-academic community. Such partnerships - grants, contracts, consultations - are established for mutually beneficial reasons and typically produce knowledge and/or technology that will help to meet societal and educational needs.

Potential conflicts of interest or the appearance of conflicts of interest may be complex and may involve many different considerations. These conflicts include ethical and financial considerations; priorities in distribution to time and effort; guidance of students' research; guidance of contractual research; consulting; contractual obligations to research sponsors, both governmental and private; and access to privileged information. Federal and state regulations also address the role of the spouse and of dependent children as potential sources of conflict of interest. Even when behavior itself is exemplary, the appearance of conflict of interest should be avoided.

A conflict of interest is a conflict of interest even if no wrongdoing actually occurs, and even those examples where no wrongdoing is intended should be avoided to preclude the perception of wrongdoing and to protect the reputation of the individual and the university. Generally, the State Adverse Interest Law, 71 P.S. §775.1 et seq., prohibits university employees (including faculty) from entering into contracts with the university, other than their contracts of employment, with some very narrow exceptions. It also prohibits them from being a stockholder, partner, member, agent, representative or employee of a corporate entity which enters into contracts with the university. The State Ethics Act, 65 P.S. §401 et seq., generally

exempts teaching faculty from its application. However, faculty who administer or monitor grants or subsidies are subject to the provisions of this Act. The Ethics Act prohibits a subject employee from using his employment or any confidential information received through his employment for the private pecuniary benefit of himself, a member of his immediate family or a business with which he or a member of his immediate family is associated. The Ethics Act also prohibits subject employees from accepting an honorarium, which is defined as “payment made in recognition of published works, appearances, speeches and presentations and which is not intended as consideration for the value of such services which are non public occupational or professional in nature.”

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, Clarion requires that investigators disclose any significant financial interest that may present an actual or potential conflict of interest with a sponsored project.

Conflicts of commitment usually involve issues of time allocation. The many diverse demands on an employee’s time necessitate setting priorities. The specific responsibilities and professional activities that constitute an appropriate and primary commitment will differ across colleges and departments, but they should be based on a general understanding between faculty members and their respective department chairs and/or deans.

Policy

Clarion University encourages and supports university faculty and staff in undertaking research, community service and other scholarly activities in the interest of the public. The University further supports the development of collaborative relationships with business entities for the benefit of the public and of the economic development of the State and the Nation.

In this collaborative environment, the University must ensure that both the occurrence and/or the appearance of conflict of interest is addressed. The integrity or objectivity of university personnel performing research and scholarly activity should not be influenced or affected as a result of any personal financial interest held by investigators, or their immediate family, in the business entities which are external sponsors, in full or in part, for the investigator's sponsored research, scholarly activity, or community service. Disclosure of financial interest is a key factor in protecting the University as well as the investigator's reputation and career from potentially embarrassing or harmful allegations of conflict of interest.

The university requires that all investigators submitting applications for external funding of sponsored research or scholarly activity disclose to the University any personal financial interests which the investigator or the investigator's immediate family hold, if these holdings could reasonably give the appearance of or actually involve a conflict of interest between the investigator and the external sponsor of the research. In the event that a significant financial interest is held by the spouse or dependent children of the investigator, the investigator is responsible for ensuring that disclosure of this interest is made to the university.

Disputes on matters regarding conflict of interest, including the interpretation of this policy, will be referred to the University President, or the Presidents' designee, for resolution.

All financial disclosure information will be kept confidential, except to the extent required by law, and except to the extent necessary to review, consider, and resolve any conflicts.

This conflict of interest policy applies to all investigators, and their immediate family, who are in a position to affect the design, conduct, or reporting of externally funded research or scholarly activity.

Definitions

For purposes of this policy the following definitions will be in effect and observed.

Business Entity - any person or entity or organization, or any combination of one or more of them. A business entity includes, but is not limited to, a sole proprietorship, partnership, association, joint venture, corporation, firm, trust, foundation or other organization or entity used in carrying on a business, including parent organizations of such entities or any other arrangement in which an entity operates through a subsidiary.

Conflicts of Interest - (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. (B) Actual conflict of interest depends on the situation and not on the character or actions of the individual. For purposes of this policy, a conflict of interest exists when the University, through procedures described herein, reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of research or sponsored projects. [42 C. F. R. § 50.605(a)]. (C) Conflict of commitment usually involves issues of time allocation. Clarion University acknowledges that while identifying commitments and in setting priorities the employee's first responsibility is to the university and its educational mission.

Immediate Family - spouse, dependent children, and independent children of the investigator.

Intellectual Property - any patentable invention, any copyrightable subject matter or trade secret. It also includes publications, compositions, discoveries, works of art and creations that might normally be developed on a proprietary basis.

Investigator - the principal investigator/project director, co-principal investigators, and any other person who is responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor.

Resolution Plan - a Memorandum of Understanding (MOU), agreed to by the University and the investigator, outlining the steps that must be taken by the investigator and/or the university to manage a potential conflict of interest situation.

Significant Financial Interest - 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);
- intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The phrase does not include:

- salary, royalties, or other remuneration from the 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.

- an equity interest that, when aggregated from the investigator and the investigator's spouse and dependent children, meets both 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 represents less than or equal to a five percent ownership interest in any single entity;

- salary, royalties, or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children over the academic year, are not expected to exceed \$10,000. [42 C. F. R. § 50.603]

Sponsor - any non-university entity providing partial or full support of research or scholarly activity performed by university members utilizing university resources.

Procedures

The Clarion University Proposal Transmittal Form for Grants and Contracts for all public and private sponsors will have a check box for the investigator to use in order to indicate whether a potential or actual conflict of interest exists involving the grant proposal that is being submitted. The definitions above should guide the investigator in this determination. A faculty or staff member, in his or her own best interests, may choose to disclose any 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. If the investigator identifies a potential or actual conflict of interest, the following procedure must be followed.

- I. Each investigator is required to disclose the following significant financial interests:
 1. Any significant financial interests of the investigator that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or,

2. Any significant financial interest of the investigator in a business entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

II. Each investigator who has a significant financial interest requiring disclosure will complete a Significant Financial Interests Disclosure Form and attach all required supporting documentation. The completed Disclosure Form must be submitted with the proposal and the Clarion University Proposal Transmittal Form for Grants and Contracts using standard 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 accompanying the Disclosure Form. This envelope will remain sealed until the grant is awarded. If the grant is not awarded, the sealed envelope will be returned to the proposed project director.

III. As required by federal regulation, all Significant Financial Interests must be disclosed during the time a proposal is being submitted for university review. All financial disclosures must be updated by investigators during the period of the award as new reportable significant financial interests are obtained.

IV. The Director of Faculty Research Development (Grants Officer) will conduct an initial review of any financial disclosure. 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 University Conflict of Interest Review Board (CIRB).

V. The CIRB will be composed of six faculty members representing a cross section of academic disciplines and an administrator. The faculty members will be recommended by the Senate and the Union. All appointments to the Board will be made by the President. Faculty members on the Board will serve 2 year rotating terms. Initial faculty appointments to the board would be 3 members with one year terms and 3 members with full 2 year terms.

VI. The CIRB will determine whether a significant financial interest exists that could directly and significantly affect the design, conduct, or reporting of the proposed project, thus creating a conflict of interest.

If a review indicates a potential conflict of interest, the Review Board will then determine what conditions or restrictions, if any, should be imposed by Clarion on the investigator to manage actual or potential conflicts or interest arising from disclosed significant financial interests; or the investigator will be notified and asked to develop and present to the CIRB a conflict of interest resolution plan that details proposed steps that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by significant financial interests. [42 C. F. R. § 50.604] At a minimum the resolution plan will address such issues as:

1. public disclosure of significant financial interests;
2. review of research or project protocol by independent reviewers;
3. Monitoring of research/project by independent reviewers.

Where the CIRB deems it appropriate, the CIRB will review the resolution plan and approve it, or suggest additional conditions or restrictions, including the following:

1. modification of the research or project plan;
2. disqualification from participation in all or a portion of the research/project funded;
3. divestiture of significant financial interests;

4. severance of relationships that create actual or potential conflicts of interests. [42 C. F. R § 50.605(a)]

Appeals of the decisions by the Conflict of Interest Review Board (CIRB) concerning the resolution plan must be made to the President, or the President's designee, within five (5) working days of receipt by the investigator of written notice of the decision of the CIRB. Final resolution of appeals and/or disputes will be communicated to the investigator and the CIRB within 15 working days of the receipt of the original appeal.

If the CIRB determines that imposing the above referenced conditions or restrictions would be either ineffective or inequitable, and 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 CIRB may recommend that the research or sponsored project go forward without imposing such conditions or restrictions, to the extent permitted by federal regulations (PHS policy, for instance, does not permit such an action). In these cases, the President or designee will make the final decision regarding resolution.

VII. The approved resolution plan will be incorporated into a Memorandum of Understanding (MOU) between Clarion University and the faculty member 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 MOU will be signed by the investigator and the Provost. Actual or potential conflicts in interest 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 expenditure of any funds under an award.

- Records of investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest will be retained by the Office of Faculty Research Development until three years after the termination or completion of the award to which they relate, or the resolution of any government action involving those records, whichever is later.
- VIII. If the University Grants Officer sees indications that this policy or the terms of the Memorandum of Understanding may have been violated, the Grants Officer will seek review of the matter with the CIRB. If the CIRB determines there has been a violation, the Grants Officer will notify the President or designee so that appropriate action may be taken. All actions taken will be in accordance with appropriate collective bargaining provisions. Additionally, the University will 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.
- X. Collaborators/subrecipients/subcontracts 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.
- XI. The disclosure of significant financial interests that are held by an author of a publication (journal article, presentation, poster session, etc.) is required to alert all readers of the potential for bias in the research or sponsored project results, even if such bias is unconscious and unintended. Disclosure in all presentations or publications is required whenever disseminating the results of scholarly activities.

- XII. Where research or a project at the university that is sponsored by a company which has a financial affiliation with an Investigator/Employee, a clear potential exists for the Investigator/Employee to bias the research or project to promote the business plan or product of the company. Even in the event no such bias exists, the very relationship subjects the employee, the company, and the university to potential criticism from third parties regarding the potential bias. This is particularly true with pharmaceutical or medical related technology, but also applies to other groups.
- XIII. To avoid the appearance of Conflict of Interest, if employees intend to use university equipment, facilities or staff (including clerical or other support staff) for their company, for projects not sponsored by the university, they must obtain the prior written approval of the Provost in the form of a letter of agreement. Often, this will require the creation of equipment usage charges which are similar to those the university charges to other non-university companies or entrepreneurs. Similarly, the employee or company must not receive preferential or unusual access to the facilities or equipment involved. Finally, it is important to list the physical location of the equipment for purposes of determining whether the facility in which the equipment is located, or the equipment itself, was financed by the university with tax exempt bonds. In that event, use by a for-profit company will probably be prohibited.

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SIGNIFICANT FINANCIAL INTEREST DISCLOSURE

Faculty/Staff Name: _____

Department/Unit: _____

College/Division: _____

Proposal/Project Title: _____

Proposal Submitted to: _____

I am disclosing the following significant financial interests (check all that apply) and attaching supporting documentation (in an envelope marked confidential) that identifies the business enterprise or entity involved and the nature and amount of the interest:

_____ Salary or other payment for services (e.g., consulting fees or honoraria).

_____ Equity interests (e.g., patents, copyrights, and royalties from such rights).

_____ Other significant financial interest of the Investigator that possibly could affect or be perceived to affect the results of the research or educational activities funded or proposed for funding.

Further I agree:

- To update as necessary or resubmit this disclosure during the period of the award, either on an annual basis, or as new reportable significant financial interests are obtained.
- To cooperate in the development of a Memorandum of Understanding (MOU) that constitutes a conflict of interest "resolution plan".
- To comply with any conditions or restrictions imposed by the University to manage, reduce, or eliminate actual or potential conflicts of interest or forfeit the award.

Signed: _____ Date: _____

original signature only - a "per" signature is not acceptable

Endorsements:

I have reviewed the significant financial interest disclosure and believe that it will be possible to develop and execute, prior to award, an MOU to manage, reduce or eliminate any actual or potential conflict or interest; and, therefore, I recommend that the proposal be submitted to the agency at this time.

Department/Unit Head: _____ Date: _____

College Dean/Division: _____ Date: _____

(See reverse side for summary of Financial Interest Disclosure Policy and Disclosure Procedures)

INVESTIGATOR FINANCIAL INTEREST DISCLOSURE POLICY (Applicable to all Sponsored Project Proposals)

What is required?

Federal regulations require institutions to have policies and procedures in place 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 disclosure 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 conflict or 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.

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, educational, or service activities funded, or proposed for funding, by an external sponsor. In this context, the “investigator” includes the Investigator’s spouse and dependent children.

What must be disclosed?

Each Investigator shall disclose all significant financial interests:

- i) that would reasonably appear to be affected by the research, educational, or service activities funded, by an external sponsor; or
- ii) in entities whose financial interests would reasonably appear to be affected by such activities.

What is covered?

“Significant financial interests” 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 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;
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 measure of fair market value, or constitute more than a five percent ownership interest in any single entity;
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. Provided, however, that the exclusions in items 1, 4, and 5 do not apply if the compensation or transfer of an equity interest is conditioned upon a particular outcome in a sponsored project.

Disclosure Procedures:

1. All Investigators must disclose their significant financial interests utilizing this form and attaching all required supporting documentation. The completed form and packet must be submitted with the proposal and Grant/Contract Cover Sheet to the Office of Faculty Research Development. Supporting documentation should be submitted in a sealed envelope marked confidential.
2. In accordance with Federal regulations, a complete disclosure must be made by Investigator(s) prior to the submission of a proposal.
3. Resolutions to conflicts of interest will be incorporated into a Memorandum of Understanding (MOU) between the Investigator(s) and the University, signed by Investigator(s), the department chair/unit head, and the dean or appropriate administrator prior to award or award acceptance.

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Resolution Plan Questionnaire

For the Development of a Conflict of Interest Resolution Plan
and Memorandum of Understanding

Name: _____ Signature: _____

Date Submitted: _____ Dept/Unit: _____

1. Please provide the University Documentation Form identifying the business enterprise or entity ("Company") involved and the nature and amount of the financial interest.

2. Does the Company plan to submit proposals for federal funding?

Yes No

3. If so, is it for research which could be performed in your laboratory at the University? (Please provide a brief description.)

Yes No

4. Do you intend to employ any undergraduate or graduate students at the Company?

Yes No

5. If so, for each student, please set forth: (a) the nature of the work to be performed; (b) how the work relates to the students' studies or thesis; and (c) the number of hours anticipated per month.

6. Does the Company intend to sponsor any work at the University?

Yes

No

7. If so, will it be necessary or preferable for the work to be performed in your laboratory?
(Please provide a brief description.)

Yes

No

8. Describe the significance of the research to any commercial product or service that the Company will sell or manufacture.

9. Will you agree to disclose your relationship in the Company in any publications, presentations and papers you submit regarding the research, and abide by all submission requirements from _____ journals or organizations?

Yes

No

10. In the event you or your Dean believe that research oversight is required, please list a colleague, preferably within your department, who would be willing to review your research protocol for objectivity.

11. In the event you or your Dean believe that research oversight is required, please list a colleague, preferably within your department, who would be willing to provide oversight during the duration of the research project to ensure adherence to protocol and other sound scientific practices.

12. Have you obtained the concurrence of the person(s) listed above to serve in the capacity of review/overseer?

Yes

No

13. Do you intend to use any University facilities on behalf of the Company?

Yes

No

14. If so, please list each piece of equipment which will be used, the nature and extent of the use, and the physical location of the equipment (i.e., name of the building and room number).

15. Please attach an equipment use charge obtained from your Dean.

16. Please list all University clerical and/or service staff support you intend to utilize for or on behalf of your Company.

17. Are you intending to or do you now serve as a consultant to the Company?

Yes

No

If so, please describe the general nature of your consultancy and where applicable attach a copy of the agreement or its provisions governing intellectual property.

Dean

Typed Name

Signature

Date