

# Conflict of Interest

## 1 Conflict of Interest

A conflict of interest arises from a situation in which commitments and obligations to the University or to widely recognized professional norms are likely to be compromised by a person's other interests or commitments, especially economic, particularly if those interests or commitments are not disclosed.

- Participation by a researcher in an activity that provides personal gain does not in itself constitute unacceptable behavior.
- Possible intrusions on research integrity could occur if the outside interests of a researcher, financial or otherwise, affect the design, conduct, or reporting of professional activity.
- Each instance of a researcher's involvement in outside activities must be examined on a case-by-case basis for the existence of a conflict of interest. (See Section [4.6.](#))
- This module deals with conflict of interest mainly with respect to research and teaching. Conflicts related to University business decisions, including purchasing, are dealt with in a separate University Policy #07-05-02, Conflict of Interest for Designated Administrators and Staff.
- Conflict of interest is the subject of a more detailed treatment in Module 4.

## 2 University Policies on Conflict of Interest

- University policies on conflict of interest are compatible with requirements of federal agencies sponsoring and regulating research.
- The policies are summarized in the Faculty Handbook and may be accessed as indicated in the [References](#) section for this chapter.
- In addition, participation by researchers in technology transfer, including formation of start-up companies to commercialize research, may give rise to special conflict of interest concerns. (See Section [4.9.](#))
- All researchers are required to make periodic disclosures, at least annually, of outside remunerative activities related to their University responsibilities. (See Sections [4.4](#) and [4.5.](#))

- There is a separate University policy on conflict of interest for consultants. This may be accessed as indicated in the [References](#) section for this chapter.
- University researchers who use outside consultants on their projects must call the attention of these consultants to the Policy for Consultants and arrange for the consultants to make the required disclosures called for in that Policy.

### **3 Examples of Potential Conflict**

- Accepting gratuities or special favors from companies doing business or sponsoring research at the University
- Accepting over-scale honoraria for lectures at companies
- Performing evaluative research for a company in which the investigator has a financial interest
- Accepting a paid consultancy with a company having an interest in the faculty's research
- Being a paid member of a speakers' bureau for a company
- Using students to perform company services
- Assigning as a required text a book for which the instructor receives royalties
- Accepting a research contract with a restricted publication clause
- Providing privileged access to information developed with University or independent sponsors to a favored company
- Purchasing materials from a company in which the investigator has an interest
- Influencing the negotiation of contracts, including research contracts or licensing contracts, between the University and a company in which the investigator has an interest

### **4 Required Disclosure, Part I**

Faculty members, administrators, and researchers are required to make regular, timely, and full confidential disclosures to their superiors (usually a department

chair or dean) of all outside remunerative activities related to their teaching, research, or administrative activities.

- The disclosure must be submitted electronically on the Conflict of Interest Superform , accessible on the web at <http://www.coi.pitt.edu>.
- The form should be submitted at the time of appointment and before April 15 of each subsequent year.
- A disclosure should also be made at other times of the year if new relevant facts develop.
- Disclosures submitted on the Conflict of Interest Superform are entered automatically onto a Conflict of Interest Database maintained by the Research Conduct and Compliance Office (RCCO).
- No grant or contract proposal will be processed through the Office of Research unless a current copy of the disclosure form of the investigator appears in the Conflict of Interest Database.
- Some categories of outside interests and activities to be disclosed pertain also to members of the declarer's immediate family (dependents, spouse, and members of the household).
- In the case of some special circumstance such as a potential conflict of interest on the part of a department chair, the initial disclosure may be submitted directly to the dean rather than to the chair.
- Investigators in clinical research or pre-clinical animal research must also declare any significant financial interest in the sponsor or technology of a protocol when submitting the protocol for approval by the Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) . (See Modules 2 and 3.)
- Research relations with a start-up company in which the researcher has an interest must be reviewed by the Entrepreneurial Oversight Committee (EOC). (See Section [4.9](#).)

#### **4.1.1 Required Disclosure, Part I - Outside Interests to be Declared**

The Superform requires researchers to answer Yes or No with respect to the following categories.

- Ownership interests in an organization in your field of research when aggregated for you and members of your immediate family exceeding \$10,000 or 5% of the organization's outstanding equity.

- Offices, board memberships, employee or management positions in such an outside organization held by you or a member of your immediate family
- Remuneration from any single outside organization exceeding 1% of your University salary or \$10,000 when aggregated for you, your spouse and dependent children
- Engagement in research that could affect a company in which you have a financial interest
- Employment by you of a University student or staff in an outside company
- Interest in a contract or sale to which the University was a party
- Interest in intellectual property by reason of your (or your spouse's or dependent child's) being inventor of a technology related to your research for which an invention disclosure has been filed or is being developed or evaluated

## 5 Required Disclosure, Part II

Part II is to be completed only if you responded positively to one of the categories listed in Part I.

- You are to list details of your relationships to outside organizations for which you indicated positive answers in Part I.
- In addition, you are to list research grants that might reasonably appear to affect the company in which you disclosed an interest.
- Generally, if you receive an economic benefit from a company with an interest in your research, you should disclose that benefit in any publications, presentations, or grant proposals related to the research. Examples of benefits to you might include:
  1. sponsorship of the research,
  2. a consulting or lecturing agreement you have with the company,
  3. a salary or stipend you receive as an officer, employee, or member of the board or scientific advisory committee of the company,
  4. stock you may own in the company, or
  5. royalties you receive from the company.

### **5.1.1 Required Disclosure, Part II - Examples of Conflicts**

#### **Examples of Conflicts That Require Management**

- Conflicts that must be eliminated or managed are those that place the researchers at risk of jeopardizing the integrity of the research, such as the following:
- Holding of an office in, or receipt of remuneration or equity from a company having an interest in your University research (See Section 4.9.)
- Conducting experiments that measure, test, or exploit the effectiveness of the product of a company in which you have an interest
- Sale to the University of a product or service of a company in which you have an interest

### **5.1.2 Examples of Situations Not Requiring Management**

- Aggregated ownership (by you and your immediate family) of less than 5% of the equity in an organization in your field of research, and less than \$10,000.
- Remuneration of less than \$10,000 per year from a company having an interest in your research.
- Ownership of equity in a publicly traded corporation whose only connection with your research is the manufacture of an instrument used in your work, if there is no other source of that type of instrument, unless one purpose of your research is to test the effectiveness of the instrument
- Remuneration from service on a panel or committee of a government agency or other non-profit entity

## **6 Procedures for Reviewing Disclosures**

**Aim:** to manage, reduce, or eliminate the conflicting interest

- After completing the Superform, you should print out the Detached Signature Page, sign it, and give it to your supervisor (e/g/, department chair, dean).
- If you were required to complete Part II, your supervisor will meet with you so as to determine whether any steps beyond disclosure are needed to

eliminate, reduce, or manage the potential or actual conflict and, if so to prepare a Management Reporting Form

- The supervisor shall forward to the dean or campus president for additional review all Detached Signature Pages from persons who were required to complete Part II. Each Detached Signature Page is to be accompanied by the corresponding Management Reporting Form.
- The dean or campus president shall forward to the Provost or Senior Vice Chancellor for Health Sciences, as appropriate, a copy of each reviewed Detached Signature Page with its accompanying Management Reporting Form.
- The Provost or Senior Vice Chancellor for Health Sciences will also review the material, modify the management plan if necessary, and forward a copy of each Detached Signature Page with its Management Reporting Form to the University Conflict of Interest Office.
- Sanctions may be applied for failure to follow a recommended procedure for dealing with the matter.
- A conflict that cannot be resolved may be referred to the Conflict of Interest Committee for recommendation of a resolution by the Provost or Senior Vice Chancellor for Health Sciences.

## **7 Managing Conflicting Interests - General Considerations**

- Researchers must make full and accurate disclosures to their supervisors, as required by University policy.
- Supervisors shall maintain confidentiality with respect to disclosures by investigators, and the contained information shall be disclosed only to the extent necessary for review, management of any conflicts, or compliance with requirements of reporting to a federal sponsoring or regulatory agency.
- All research results shall be published or publicly disclosed with reasonable promptness, whether the results are favorable or unfavorable to the interests of any sponsor or to the outside interests of the researcher.
- Students and postdoctoral fellows shall not be exploited or their training compromised in the service of sponsored research or the financial gain of the supervisor.

- \*A disclosure of outside interests impacting research should be provided to students and postdocs engaged in the research.
- In the case of a presentation or publication which deals at least in part with the evaluation of the effectiveness or risk of using a substance, device, or service sold or provided by a commercial organization with which the researcher has a connection or by a commercial organization competitive with one with which the researcher has a connection, that presentation or publication must contain a statement disclosing the researcher's connection.

## **8 Managing Conflicting Interests - Some Specific Management Tools**

- Disclosure of the potentially conflicting relationship
- Monitoring and oversight of research by an independent committee
- Modification of the research plan
- Disqualification from participation in all or part of the research
- Full or partial divestiture of significant financial interests
- Resignation from management or board positions
- Severance of the conflicting relationships

## **9 Special Requirements with Respect to Start-up Companies**

### **General Reference to University Policy:**

11-02-03 Commercialization of Inventions through Independent Companies

<http://www.pitt.edu/HOME/PP/policies/11/11-02-03.html>

### **Administration of the Policy:**

Chair of the Entrepreneurial Oversight Committee , 412-383-1774

- To help to address the economic, scientific, and technological development of the region and the nation, researchers are encouraged to explore options to commercialize inventions through licensing arrangements with existing companies or by formation of independent

(start-up) companies based on the science or technology that has been developed in their laboratories.

- Disclosures of inventions, applications for patents and arrangements for commercialization must be made through the Office of Technology Management.
- No more than 20% of stock in a start-up company may be held in the aggregate by all University faculty, staff, and students, and members of their immediate families. Exceptions may be considered for companies in a developmental stage that do not have products in clinical trials or products being sold.
- Faculty, staff, and students may not hold management, board, or operating positions in the company.
- Proposals for sponsorship of university research by start-up companies must be reviewed by the department chair or dean, and by the Entrepreneurial Oversight Committee (EOC), to whom regular reports must be made on the research methodologies and results.
- No faculty, staff, or student holding equity in, or receiving financial benefits from the success of a start-up company can be the principal investigator for a University research project sponsored by that company or be the attending physician or record patient data in a clinical study sponsored by the company. Such a faculty, staff, or student shall not negotiate the research grant or contract.
- Prior approval must be obtained from the department chair and dean on the use of students in projects sponsored by start-up companies.
- Investigators must disclose to students any significant financial interest related to the students' research.
- Stock in a start-up company may not be sold or traded by a University faculty, staff, or student, or by members of their immediate families unless general and specific guidelines established by the EOC are followed.
- University resources and facilities may not be used in the operation of start-up companies, including telephone, e-mail, and computers.

## **10 Conflict of Commitment**

- The University recognizes the value both to the institution and to the faculty of consulting and other outside professional activities by individual faculty members. The institutional constraints on such outside activities



are described in the policy, Outside Employment, summarized in the Faculty Handbook and accessed as:

<http://www.pitt.edu/HOME/PP/policies/02/02-06-01.html>

- The outside activities must not conflict with the individual's responsibilities to the University.
- The name, property, and facilities of the University may not be used in the work for which the individual receives personal payment.
- The time given to such activities should not exceed an average of one day per week.
- The fee for outside work must be commensurate with the individual's professional standing.
- The individual must receive permission from the department chair or dean to engage in such outside activities.
- Some professional schools have more restrictive requirements concerning the amount of time spent and the amount and distribution of fees earned, including the possibility that fees be shared or turned over completely to the academic unit.
- Pro bono professional service is encouraged, such as membership on advisory committees for government, non-governmental non-profit organizations, or for professional associations. Extensive activities of this type, however, should be cleared with department chairs or deans to insure that faculty responsibilities to the University are not compromised.
- Clinical activities in department- or school-approved practice plans are separately regulated and are not necessarily subject to the one-day-a-week limitation.