

**University of Pittsburgh  
Policy 11-01-03**

**Conflict of Interest Policy for Faculty, Scholars, Researchers,  
Research Staff/Coordinators**

**September 24, 2013**

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## I. INTRODUCTION

The mission of universities traditionally has focused on teaching, scholarship and research; but in recent years, faculty and researchers at many institutions of higher learning have taken on functions outside those customary domains, such as technology transfer and public service involvement of various kinds. These functions have been encouraged and supported by government as necessary for the public good with legislation such as the Bayh-Dole Act, passed by the U.S. Congress in 1980. The Act recognizes the public service mission of universities in the form of economic development for their region and the nation by accelerating the transfer of new technology to the market place or to clinical or diagnostic practice. Institutions and their faculties, staffs, and students have been encouraged to explore the means of commercializing the inventions developed in their laboratories through existing or new and independent companies.

As a result, academic researchers and their institutions have entered into a variety of relationships with industry, such as sponsored research agreements, cooperative research activities, and licensing agreements with established companies with royalty provisions for the exploitation of university-owned patents; equity in such companies for the researcher and/or the university; consultancies for university-based researchers; and formation of new and independent companies in which investigators and/or the university may have a financial stake.

The opportunity for University personnel to receive financial or other personal rewards from such endeavors, as well as from other types of relationships, such as speaking on behalf of commercial enterprises or consulting, is not intrinsically unacceptable, as long as they do not adversely affect the objectivity, integrity, or professional commitment of investigators and scholars. It is the potential for conflicts of interest that must be addressed to ensure that they do not threaten the integrity of the university's scholarship, research, instruction, evaluation, and administration.

For the above reasons, and in compliance with federal laws that deal with financial conflicts, the University of Pittsburgh has put in place this Conflict of Interest (COI) Policy, which requires disclosure and management of the outside relationships and organizational commitments of its faculty, scholars, investigators, and research staff/coordinators in order to assure itself and its various partners that the advantages of associations between academe and industry are being realized without the loss of the fundamental values of objectivity and freedom of inquiry in research and scholarship; that the University's research programs and reputation are not compromised by even the appearance of a lack of concern about this matter; and that no one will unfairly benefit from the University's public trust or reputation.

The University of Pittsburgh's Conflict of Interest Policy complies with federal regulations related to financial conflicts of interest in research<sup>1</sup> and shall be subject to any appropriate modifications in order to conform with regulations of any federal agency sponsoring the research in question. Because not all agencies follow the same regulations, however, those policies that apply to research for which Public Health Service (PHS) funding has been proposed or received in the preceding 12 months, or is expected to be received in the next 12 months, will be presented with the notation "PHS."

## II. DEFINITIONS

### A. Conflict of Interest (COI)

A potential or actual COI exists when commitments and obligations to the University or to widely recognized professional norms are likely to be compromised, or perceived to be compromised, by a

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<sup>1</sup> National Science Foundation Grant Policy Manual, Chapter 5, Grantee Standards, 510 COI Policy, and Public Health Service Regulations codified at 42 CFR Part 50, Subpart F, and 45 CFR Part 94. Additional conflict of interest disclosures are required by the FDA in clinical investigations that are subject to FDA oversight. Such additional disclosures, which are contained in 21 CFR Part 54, are discussed in more detail under Section IV.B.1.b.

person's outside interests or commitments, especially financial. Examples of common conflicts of interest are provided in Section VII of this policy.

B. Financial Conflict of Interest (FCOI)

A Financial Conflict of Interest is a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

C. Institutional Responsibilities

Institutional responsibilities refer to an Investigator's professional responsibilities on behalf of the University of Pittsburgh, including activities such as research, teaching, professional practice, institutional committee memberships, service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards, and other administrative activities.

D. Investigators

1. Principal Investigator (PI): Employee who is responsible for the design, conduct, and reporting of research.

Note: The PI for any research activity conducted at a University facility must be a University employee, or, under appropriate circumstances, a student.

2. Co-Investigator (Co-I): Employee who participates in the design, conduct, and reporting of research.

E. Licensed Start-up Company

A Licensed Start-up Company has the following characteristics: 1) it has a license or an option for a license for University intellectual property; 2) it is not publicly traded; and 3) equity or an equity option is held by the University, by a University employee or student, by a Member of the employee's or student's Immediate Family, or in trust for any employee's or student's Immediate Family. Excluded from this definition are companies which license only technology released by the University to the researcher/inventor, or technology to which the University has no claim.

F. Members of the Immediate Family

Spouse, dependents, and all members of the employee's household, including registered domestic partners.

G. Public Health Service (PHS)

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality.

H. Regulatory Committees/Specifically Regulated Research

The Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and any other University entity that regulates a particular area of research and requires the disclosure of COI information with the submission of a research protocol; Specifically Regulated Research refers to research thus regulated.

I. Research Staff/Coordinator

Employee classified as staff, who directs or can materially influence research, or who is responsible for the design, conduct, and reporting of research.

J. PHS: Senior/key personnel

The Project Director/Principal Investigator and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution.

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K. Significant Financial Interest (SFI)

An SFI is an external financial interest that would reasonably appear to be related to the individual's institutional responsibilities, including:

1. any equity interest, including stock options in a non-publicly-traded entity held by an individual and Members of the Immediate Family;
2. any equity interest, including stock options in a publicly-traded entity held by an individual or in the aggregate with Members of the Immediate Family, that exceeds 5% ownership interest or a current value of \$10,000<sup>2</sup>, as determined through reference to public prices, recent financing events, or other reasonable measures of fair market value;
3. salary, consulting fees, honoraria, royalties, and milestone fees and other licensing proceeds received directly from a single outside entity that, when aggregated for the individual and Members of the Immediate Family, are expected to exceed \$10,000<sup>2</sup> in a 12-month period;
4. being the inventor of a technology on which research is continuing that has been patented, optioned, or licensed to an external entity;
5. being the author of copyrighted technology on which research is continuing that has been optioned or licensed to an external entity;
6. holding a management or operating position in any outside entity.

The term SFI does not include

1. salary or supplementary payments from the University of Pittsburgh;
  2. salary or supplemental payments from the Veterans Administration Pittsburgh Healthcare System, the University of Pittsburgh Medical Center (UPMC), or University of Pittsburgh Physicians (UPP), except for supplemental payments that represent distribution of royalties from licensing;
  3. income from seminars, lectures, or non-promotional engagements sponsored by governmental or non-profit entities;
  4. income from service on advisory committees or review panels for governmental or non-profit entities;
  5. income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.
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PHS: SFI

A Significant Financial Interest is a financial interest (i.e., anything of monetary value, whether or not the value is readily ascertainable) consisting of one or more of the following interests of the Investigator (and Members of the Immediate Family) that reasonably appear to be related to the Investigator's institutional responsibilities:

1. the aggregation of remuneration received from any publicly traded entity in the 12 months preceding the disclosure (including salary, consulting fees, honoraria, and paid authorship) and the value of any equity interest in that entity as of the date of disclosure (including any stock,

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<sup>2</sup> This figure reflects the SFI threshold established by the National Science Foundation's Policy GPM 510 as of July 2005, and will change as the federal government's threshold changes.

- stock options, or other ownership interests, as determined through reference to public prices or other reasonable measures of fair market value) exceeding \$5,000<sup>3</sup>;
2. any remuneration received from a non-publicly traded entity in the 12 months preceding the disclosure exceeding \$5,000<sup>3</sup>, or any equity interest in such an entity (e.g., stock, stock option, or other ownership interest);
  3. being the inventor of a technology on which research is continuing that has been patented, optioned, or licensed to an external entity;
  4. being the author of copyrighted technology on which research is continuing that has been optioned or licensed to an external entity;
  5. holding a management or operating position in an outside; entity;
  6. any reimbursed or sponsored (i.e., that which is paid on behalf of the Investigator) travel expenses exceeding \$5,000 from a single external entity in a 12-month period, except travel that is reimbursed or sponsored by a federal, state, or local government agency; an Institution of higher education as defined in 20 U.S.C. 1001 (a); an academic teaching hospital; a medical center; or a research institute affiliated with an institution of higher education [Exempt Institutions].

The term SFI does not include

1. salary or supplementary payments from the University of Pittsburgh;
2. salary or supplemental payments from the Veterans Administration Pittsburgh Healthcare System, the University of Pittsburgh Medical Center (UPMC), or University of Pittsburgh Physicians (UPP), except for supplemental payments that represent distribution of royalties from licensing;
3. income from seminars, lectures, or non-promotional engagements sponsored by Exempt Institutions;
4. income from service on advisory committees or review panels for Exempt Institutions;
5. income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

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### III. GENERAL CONFLICT OF INTEREST POLICY AND COI MANAGEMENT<sup>4</sup>

This University of Pittsburgh Conflict of Interest Policy outlines the requirements for disclosure, oversight, and management of potential conflicts of interest and applies to all full-time and part-time<sup>5</sup> faculty members, researchers, and Research Staff/Coordinators with respect to their teaching and research – whether publicly, privately, or internally supported.

#### A. Responsibilities of Investigators and Scholars

##### 1. COI Policy

Full-time faculty members, researchers, scholars, or Research Staff/Coordinators must devote their primary professional efforts to the University to the extent required by their appointments. Other activities or commitments must be arranged so as not to conflict with or dilute this commitment. While

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<sup>3</sup> This figure reflects the SFI threshold established by the federal government's regulation 42 CFR Part 50, Subpart F and 45 CFR Part 94.

<sup>4</sup> Please note: this policy governs conflicts of interest related to research and teaching on the part of University personnel, as distinguished from policies that govern conflicts of interest for consultants (Policy 11-01-04), conflicts of interest related to designated administrators and staff (Policy 07-05-02), and conflicts of interest in procurement relationships (Policy 05-02-02).

<sup>5</sup> Part-time faculty members not conducting research are covered by this COI policy only to the extent that their outside financial interests would reasonably appear to be affected by their work for the University. The policy does not apply to employees on unpaid leave from the University or to adjunct faculty (who are not engaged in research).

time devoted to employment outside the contract period<sup>6</sup> (i.e., for those on less than 12-month appointments) may not represent a conflict of commitment, it can entail a COI.

Potential COIs must be disclosed fully and accurately in all formal communications that may be impacted by the financial interest, including abstracts, publications, presentations, press releases, and applications or proposals for research funding.

Faculty, investigators, and administrators must withdraw from decisions or the exertion of influence concerning any University relationship affecting a company in which they or Members of their Immediate Families have a financial interest.

Reasonably prompt collegial communication among colleagues involving scientific information (such as sharing preliminary and unconfirmed results) is to be encouraged in an academic setting; in those few cases where exceptions to such an approach are unavoidable, the scope of the project must be defined so as to permit the exchange of as much information as possible.

All research results must be submitted for publication or publicly disclosed. Delays of no more than 90 days may be permitted to allow for the filing of patent applications, as provided by the Patent Rights and Technology Transfer Policy.

Unpublished research results may not be disclosed to investors or investment analysts.

When consistent with the terms of their University appointments, students or fellows may be employed by companies in which their supervisors or advisers have an economic interest only with the prior approval of their chairs or deans. Faculty members must take all precautions necessary to ensure that their students' progress and academic standing are not jeopardized by violations of any professional norms in projects in which they participate, or by students' naiveté as to the circumstances surrounding industry-sponsored research.

Any faculty member, Investigator, or Research Staff/Coordinator who disagrees with the recommendations of his/her superior for managing, reducing, or eliminating COIs may appeal to the next higher level of administration. Instead of a direct appeal to the provost, the aggrieved individual may invoke either of the alternative grievance procedures as outlined in University Procedures 02-03-01 or 02-03-01A. This process applies, even if the individual is not a faculty member.

The Faculty Handbook addresses the issue of faculty leave of absence. The pursuit of entrepreneurial endeavors is an acceptable reason to be cited in a request for a faculty leave of absence. A faculty member on entrepreneurial leave may be exempted by the COIC from restrictions on holding equity or a management role only for the period of the entrepreneurial leave.

## 2. Disclosure

Disclosure by University employees of financial, personal, or professional relationships that raise a potential COI or its perception is at the heart of the University of Pittsburgh's COI policy and is a prerequisite for determining whether a conflict, once recognized, can be managed or reduced or, in some cases, eliminated. Moreover, the policy assures confidentiality in order to encourage full disclosure of potential conflicts without unduly intruding on the privacy of University personnel or their families.

All University faculty members, Senior/key personnel on PHS-supported research, and Research Staff/Coordinators must submit conflict of interest disclosures upon appointment, and annually thereafter, on or before April 15, and within 30 days of discovering or acquiring (for example, through a consultancy, purchase, marriage, or inheritance) a new Significant Financial Interest

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<sup>6</sup> See Policy 02-06-01 Outside Employment.



related to their institutional responsibilities, and submit them to their supervisors (e.g., department chairs, deans, or division heads, as appropriate).

These conflict of interest disclosures must be filed electronically through the Superform system (<https://coi.hs.pitt.edu/>) a centralized, confidential University of Pittsburgh database that stores the information; the system also allows supervisors and others with oversight responsibilities to review and manage SFIs that have been disclosed.

Employees must complete appropriate parts of the disclosure form, including, for example,<sup>7</sup>

- ownership constituting an SFI in an external entity;
- offices and positions in an entity whose interests would reasonably appear to be affected by their research;
- remunerative activities constituting an SFI in an external entity;
- outside employment of students and staff;
- technology transfer activities;
- other financial transactions;
- conflicts relating to federal or industry-supported research.

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#### PHS: Disclosure

Faculty who have applied for or received PHS funding in the previous 12 months, or expect to receive such funding in the next 12 months, will have a PHS-oriented form for making their COI disclosures that will require disclosure of the following information:

- ownership constituting an SFI in an external entity, and the value of the equity held;
- offices and positions in an entity whose interests would reasonably appear to be affected by their research;
- remunerative activities constituting an SFI in an external entity, and the amount of the remuneration;
- outside employment of students and staff;
- technology transfer activities, including patents awarded and copyrights optioned or licensed to an outside entity;
- other financial transactions;
- conflicts relating to federal or industry-supported research; and
- reimbursed or sponsored travel related to their institutional responsibilities exceeding \$5,000 in value from a single entity in a 12--month period, including: the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration of the trip, and the amount of reimbursement and/or value of the sponsored travel. Supervisors and the COI Committee have the right to request additional information in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

#### 3. Prior approval

As required by the University Policy on Outside Employment (02-06-01), faculty members, Investigators, or Research Staff/Coordinators must seek prior approval from their superiors for any planned outside interests and activities that are, or could appear to be, in conflict with their commitments to the University for the purpose of managing, reducing, or eliminating the potential or actual conflict. Consulting contracts shall not convey ownership of intellectual property that may be subject to the University's Patent Rights and Technology Transfer Policy (11-02-01), unless the Technology Transfer Committee has released the technology. Some schools have more formal review processes.<sup>8</sup>

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<sup>7</sup> Please see the Superform for actual questions and related examples.

<sup>8</sup> Industry Relationship Policy:

<http://www.coi.pitt.edu/IndustryRelationships/Policies/IndustryRelationshipsPolicy.pdf>

4. Training

All Investigators are required to complete a COI training module on appointment and/or prior to submission of a proposal for external funding.

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PHS: Training

Each Investigator is required to complete a COI training module prior to engaging in PHS-funded research, again at least every three years, and at the direction of the COIC (such as when s/he is found not to be in compliance with this policy or a conflict management plan).

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B. Responsibilities of Department Chairs, Division Heads, and Deans

1. Review

The enforcement of this policy rests with the academic unit where the research is conducted, and, if not the same, the unit where the researcher has his/her primary appointment. The immediate supervisor of the faculty member, scholar, or Research Staff/Coordinator should be cognizant of the activities taking place in the unit and should monitor the research as to potential and actual COIs.

For all disclosures, including those reporting PHS funding, the chairs, division heads, or deans, as appropriate, shall

- a. keep confidential all COI disclosures submitted to them by faculty members, researchers, or Research Staff/Coordinators, except to provide institutional or internal oversight as authorized by this COI policy, and to comply with requests from federal funding agencies as required under terms of a grant, contract, or cooperative agreement;
- b. review promptly the COI disclosures for existing or potential conflicts of interest, and request and document additional details, including precise dollar figures or percentages for ownership interests or remuneration, if such details appear necessary to determine whether there is an impermissible conflict of interest;
- c. in all cases notify their superiors of these outside interests disclosed when a COI has been determined to exist;
- d. notify employees that their superiors will be reviewing the disclosures of COIs submitted as a matter of routine;
- e. disqualify themselves and request that the review be done by their superiors if supervisors have a conflict of interest in reviewing disclosed information.

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PHS: Review

Department chairs shall review COI disclosures, and, for PHS SFIs in the \$5,001 to \$10,000 range, determine whether an FCOI exists. Department chairs must sign off on the review, either explaining why there is no FCOI or stating that there is an FCOI and indicating what level of management will be employed (e.g., use of a data steward, disclosure in publications, etc.) and inform the COI Office. The COI Committee (in consultation with department chairs and investigators) will review PHS SFIs greater than \$10,000 to determine whether they give rise to FCOIs and, if so, how they will be managed.

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2. COI Management

Upon review of the disclosures of their employees, first-line supervisors shall meet with them individually and, as appropriate, discuss how potential or actual conflicts will be managed, reduced, or eliminated, and recommend and initiate actions to do so; or refer the matter to the

next higher administrative level. Copies of the management plan shall be submitted to the senior vice chancellor for the health sciences or the provost, as appropriate, and then to the COI Office.

Examples of appropriate actions to resolve COIs include:

- a. public disclosure of SFIs in abstracts, publications, presentations, press releases, and applications or proposals for research funding;
- b. monitoring of research by independent reviewers or an oversight committee;
- c. selection of a non-conflicted PI;
- d. disqualification from participation in all or a portion of the funded research;
- e. divestiture of SFIs;
- f. severance of relationships that create actual or potential conflicts;
- g. prospective discussions with supervisors of the time involved in any planned outside activities that may have the potential to conflict with, or appear to conflict with, commitments to the University;
- h. refusal by the University to enter into a research agreement if a COI cannot be managed effectively;
- i. participation of one or more non-conflicted persons in the evaluation of research data and/or preparation of manuscripts;
- j. completion or repetition of the COI training module;
- k. participation in a research ethics course, seminar, or workshop.

### 3. Additional Actions by First-line Supervisors

- a. If investigators' conflicts involve federally supported research, supervisors must inform the Conflict of Interest Office prior to the expenditure of research funds, or, if the conflict is not disclosed prior to the beginning of research, no later than 30 days after learning of the conflict, that a management plan has been developed.
- b. For each individual who discloses outside conflicting interests, supervisors must submit for review by May 15 the Signature Page and management plan to the provost or senior vice chancellor for the health sciences, as appropriate.
- c. Possible additional actions:
  - i. recommend and initiate actions leading to sanctions for non-compliance with this policy or the approved management plan;
  - ii. seek the advice of the COIC.
- d. Monitoring  
Supervisors shall monitor Investigators' compliance with management plans on an ongoing basis until completion of the project and, for FCOIs, provide the chair of the COI Committee with their plans for monitoring compliance.

### 4. Annual Data Summary Report

- a. The department chairs, deans, or other administrators reporting to a senior vice chancellor, as the case may be, must submit to their respective superiors annual statistical reports for their units that will summarize the COI disclosures, including the number of department employees whose conflicts were resolved or were not managed, reduced, or eliminated.
- b. Each dean of a departmentalized school shall prepare an Annual Data Summary Report for the entire school and submit it to the provost or senior vice chancellor for the health sciences, as appropriate.

### 5. Disclosure of Outside Income

In some units, the supervisor may request more detailed disclosures, such as dollar amounts of financial interests, even for non-PHS-supported researchers.

## C. Responsibilities of the Senior Vice Chancellors

1. The senior vice chancellors receive the Signature Pages and related management plans that address reported outside interests, and the Annual Data Summary Reports from their deans.
  2. The senior vice chancellors have the discretionary authority to review plans to eliminate or manage COIs and to approve sanctions for non-compliance.
  3. They may request the assistance of the COIC in dealing with individual cases.
  4. Any decision by the COIC may be appealed to the provost.
  5. The provost's ruling on any COI issue will be final.
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D. PHS: Responsibilities of the Office of Research

1. Any subcontract of PHS-funded research shall specify whether the FCOI policy of the subrecipient or the University of Pittsburgh will apply to the subrecipient's investigators. If the subrecipient's policy will be applied, the agreement must include a certification that the policy complies with the PHS regulations. In either case, the contract must specify time periods for disclosures, management, and reporting of FCOIs.
  2. The Office of Research will notify the Principal Investigator's department and the COI Office upon receipt of notice that a PHS award will be made or is likely to be made when an SFI was identified at the proposal stage.
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E. Responsibilities of the Conflict of Interest Committee and the COI Office (see Section VI)

1. The chair of the COIC will make the required reports of management of COIs to federal agencies sponsoring the research.
  2. The COI Office may conduct random or for-cause audits assessing compliance with this policy or with COI management plans, on its own initiative, or as requested by a department chair, dean, a senior vice chancellor, a Regulatory Committee, or other parties, as appropriate. Alternatively, the COIC may request that an audit be performed by the Education and Compliance Office of the Research Conduct and Compliance Office (RCCO).
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3. PHS: FCOI

With the exception of SFIs in the \$5,001 to \$10,000 range, evaluation of which for the existence of an FCOI is the responsibility of the department chair, it is the COIC—in collaboration with the Investigator and his/her department chair—that will determine whether the disclosed financial interest gives rise to an FCOI that the COIC will manage and that the chair of the COIC will subsequently report to the PHS. Each FCOI report will include the name of the conflicted Investigator, the Investigator's title and role on the research project, the name of the entity in which the interest is held, the nature of the SFI, a description of the management plan, and the approximate dollar value of the SFI as defined in a set of ranges or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. Annual FCOI reports will be submitted for the duration of the PHS-funded research project addressing the status of the FCOI and any changes to the management plan.

4. PHS: FCOI Retrospective Review

In case of delay in identifying or managing an FCOI, or failure of the Investigator to comply with a plan to manage his or her FCOI, the COIC shall, within 120 days of the Institution's determination of non-compliance, complete a retrospective review to determine whether any PHS-funded research was biased in the design, conduct, or reporting of such research performed during the period of non-compliance.

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5. The COIC and the COI Office monitor potential conflicts of interest and provide assistance in their resolution to researchers and supervisors.

F. Sanctions

Sanctions may be applied for non-compliance with the requirements of this policy or with management plans, in the same way as for non-compliance with any other University policy, including a letter of reprimand, special monitoring of future work, removal from the particular project, probation, suspension, salary reduction, or initiation of steps leading to possible reduction in rank or termination of employment.

If the failure of a researcher to comply with the University's COI policy has biased the design, conduct, or reporting of federally-funded research, the University will promptly notify the sponsoring agency of the corrective action taken or to be taken.

G. Data Retention

Conflict of interest records relating to research activities, including disclosures and conflict management plans, must be retained for a period of seven years after submission of the investigator's filing of the final project report, or longer if required by the relevant funding agency.

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H. PHS: Public Accessibility

Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall ensure accessibility, via a publicly accessible Web site, of information concerning any SFI held by an investigator determined to be an FCOI, including the name of the conflicted Investigator, the Investigator's title and role on the research project, the name of the entity in which the interest is held, the nature of the SFI, and the approximate dollar value of the SFI as defined in a set of ranges; or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

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**IV. COI POLICY AND COI MANAGEMENT RELATED TO SPECIFICALLY REGULATED RESEARCH<sup>9</sup>**

A. COI Policy

Compensation arrangements for support of human research studies shall not affect the conduct or influence the outcome of such research.

For all cases involving researchers who have an SFI impacting specifically regulated research, the COI Committee, its designated subcommittee, or the COI Office operating under guidelines from the COI Committee, shall develop a conflict management plan, which it will report to the Regulatory Committee, the PI, the investigator with the SFI, and his/her department chair and dean.

This section does not apply to the overall PI of a multi-task project, such as one supported by a program project or a center grant, although it does apply to the PIs of the independent sections of such projects. There are two alternative ways of addressing a conflict related to an SFI held by the proposed PI:

1. In general, an investigator with an SFI related to Specifically Regulated Research should not serve as PI (this is known as the "PI exclusion rule"), and a non-conflicted PI should be sought to conduct the research. In the case of research involving an investigator whose only SFI is in

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<sup>9</sup> e.g., IRB, IACUC

intellectual property rights, however, the applicability of the PI exclusion rule is determined on a case-by-case basis.

Department chairs are responsible for developing conflict management plans for PHS FCOIs in the \$5,001 to \$10,000 range, which may not necessarily include application of the PI exclusion rule.

Any non-conflicted alternate PI should have the necessary background and skills to conduct the project and should be scientifically and administratively independent of the conflicted investigator. The conflicted individual may be a Co-Investigator on the project, subject to some restrictions on the research role detailed in a conflict management plan developed by the COIC.

2. If a suitable non-conflicted PI cannot be found, the conflicted investigator may ask for a waiver of the PI-exclusion rule if a case can be made for the existence of compelling circumstances. A request for such a waiver must be submitted, by way of the COI Committee, to the Authorized Institutional Official in the case of research overseen by the IRB or the IACUC.

#### B. COI Management Plan

Any management plan must include the following:

##### 1. Disclosure

- a. At the time of initial protocol submission, and at any time during the conduct of the research study when new interests are accrued, the PI must disclose to the relevant Regulatory Committee any SFIs of the PI or Co-Investigators or any Research Staff/Coordinator that may be affected, or perceived to be affected, by the outcome of the research study. Any SFIs that reasonably appear to be related to the PI's, Co-Investigator's, or Research Staff/Coordinator's institutional responsibilities must be disclosed.
- b. In the case of research that is considered a "clinical investigation" under the FDA regulations, investigators must also disclose: 1) any proprietary interest in the tested product (including, but not limited to, a patent, trademark, copyright, or a licensing agreement) and 2) all payments made by the sponsor of a covered study to the investigator or the institution to support activities of the investigator that have a monetary value of more than \$25,000 (exclusive of the costs of conducting the clinical study or other clinical studies – e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria) during the time the clinical investigator is carrying out the study and for one year following the completion of the study.
- c. An individual who has a financial interest in intellectual property (IP) rights that are being evaluated or developed in human subject research covered under an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application cannot serve as the Sponsor of the application if the IP rights have been optioned or licensed to an outside entity that is providing financial or other material support for that study.
- d. All participants in the project, including students, postdoctoral fellows, faculty, staff, and human subjects, must be informed of the existence of a conflict.
- e. The existence of the conflict must be disclosed in all abstracts, publications, presentations, press releases, and applications or proposals for research funding related to research in which an investigator has a financial interest.

##### 2. Exceptions

Requests for exceptions to a management plan not related to PI exclusion (e.g., to add/remove elements to/from the plan) shall be communicated to the COI Office. The request will then be forwarded to a subcommittee of the COIC for deliberation. The results of these deliberations will be reported to the appropriate Regulatory Committee and the investigator with the SFI within two weeks of receiving the request, and to the COIC at its next meeting.

If an exception is granted allowing a conflicted investigator to be PI, the management plan must include at least these additional elements:

- a. A data stewardship committee (referred to below as the Committee) must be formed, appointed by the PI's immediate academic superior together with the chair of the Conflict of Interest Committee. The chair of the Committee shall be an Associate Professor or Professor at the University of Pittsburgh or a person of comparable standing from outside the University, who has adequate knowledge to scrutinize the data issuing from the project. This person shall not have the same primary departmental affiliation (or divisional affiliation in the case of very large departments) as the PI, must not have a financial conflict with the research project, and may not have had joint publications or grant support with the PI within the previous five years. There shall be at least two additional members of the Committee, all free of financial conflicts with respect to the research in question. One of these persons shall be a voting member of the Conflict of Interest Committee. The major criteria for appointment to the Committee are independence from the PI and sufficient background to understand the data from the study. In the case of a University institutional conflict in the form of equity in the entity sponsoring the research, at least one member of the Committee shall be from outside the University.
- b. The Committee shall meet at least once a year and shall have the opportunity to meet individually with members of the research team. The Committee must have access to such information deemed sufficient and necessary to ensure that data are interpreted in accordance with standards appropriate to the discipline.
- c. After each of its meetings, the Committee shall report in writing to the chair of the PI's department and to the COI Committee, attesting to its opinion about the integrity and interpretation of the data.
- d. The PI may not be the only person involved in interpretation of study results but may be involved as part of a committee that evaluates study results. This committee, comprised of predominantly non-conflicted individuals, is not necessarily the same as the data stewardship committee.
- e. The following additional provisions shall apply in the case of human subject research:
  - i. The PI may identify possible subjects for the protocol but may not participate in enrollment.
  - ii. The PI may not administer the informed consent.
  - iii. The informed consent document shall include a disclosure of the existence of the PI's financial interest, in a form approved by the IRB.
  - iv. The PI will not be involved in subjective assessments of eligibility criteria and intervention outcomes.
  - v. There shall be an independent and conflict-free Data and Safety Monitoring Board for any study considered by the IRB to involve more than minimal risk. This Board shall function under general guidelines from the Office of Clinical Research, Health Sciences.
  - vi. In the unlikely event that the IRB is not in agreement with the proposed COI management plan, and an agreement cannot be reached following the above procedures, the decision to grant approval of the protocol remains with the IRB.
- f. The following additional provisions shall apply in the case of research using vertebrate animals:
  - i. A plan shall be devised in cooperation with the Attending Veterinarian for provision of "enhanced" veterinary oversight for the animals that serve as subjects for the project. A contract with the Division of Laboratory Animal Resources will be required to formalize this arrangement. As with all animal studies at the University, the Attending Veterinarian has the discretion to provide treatments to and/or humanely euthanize any research animals that may be deemed to be in pain or distress. Such actions shall be reported to the COI Committee by the Attending Veterinarian.
  - ii. The Committee defined in IV.B.2.a., above, shall meet at least semi-annually.<sup>10</sup>

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<sup>10</sup> The animal research data stewardship committee would meet semi-annually (as opposed to annually for human subject research) because animal studies tend to be shorter in duration.

- g. Any costs connected with the operation of the Committee, of a Data and Safety Monitoring Board, or of "enhanced" veterinary oversight must be budgeted to the research project.

C. Sanctions

The COIC will report any known violations of this policy to the appropriate Regulatory Committee that, in turn, is responsible for invoking any sanctions it determines appropriate (e.g., suspension of human subject or animal enrollment, suspension of the research study) for non-compliance with COI management plans. Sanctions are invoked in cooperation with the Investigator's department chair and dean for violations of this policy or for non-compliance with the management plan.

V. **COI POLICY AND COI MANAGEMENT RELATED TO LICENSED START-UP COMPANIES**

A. COI Policy

1. Disclosure and Approvals

- a. The relationship of all University faculty, staff, and students, and Members of their Immediate Families to the company, including the holding of equity, must be disclosed to, and reviewed and approved by, the department chair or dean, and the COIC.
- b. Faculty, staff, and students must submit their financial disclosures at least annually, and as relationships change, to their department chairs or deans and the COIC through the Superform system.
- c. The individual's conflict, potential or actual, must be disclosed in abstracts, publications, presentations, press releases, and applications or proposals for research funding when the described research involves matters that may be of interest to the Licensed Start-up Company.
- d. Involved faculty, staff, and students must sign a policy compliance statement (available on the COI Web site) that certifies that they understand applicable policies and agree to cooperate in their implementation.

2. Equity

a. Institutional Equity

The University may, in some circumstances, take stock in Licensed Start-up Companies that do not have the financial resources to make full license payments in cash. In such cases Licensed Start-up Companies should normally be required to pay for out-of-pocket patenting and related expenses. Equity shall not be held in sufficient amounts to confer management power, which generally would limit ownership to no more than 20% of voting stock. Review and approval of stock acquisitions shall be provided by the COIC as to COI matters and by the executive vice chancellor and the provost as to financial terms.

The Office of Technology Management determines the amount and form of equity to accept, subject to the approval of the Office of General Counsel, and the executive vice chancellor and the provost, as noted above. The Office of Finance merely holds the shares, once taken, and ensures that legal restrictions on transfer are observed up to and including the date when the shares are sold. When it receives equity security in exchange for intellectual property of the University, it is the policy of the Office of Finance to liquidate that security as soon as it is legally tradable and in a manner that allows for an orderly sale, consistent with market conditions. This policy holds regardless of the research activity that may be occurring at the University or elsewhere. By selling equity securities as soon as legal restrictions on transfer are lifted and market conditions permit, the Office of Finance makes no judgment whether to hold or sell an equity position in a company and is not influenced by other potential financial interests of the University or faculty who may be shareholders in the company.



Decisions on acquisition of company stocks for the University's endowment are made by a third party investment manager having no connection with research administration or oversight.

b. Individually Held Equity

With the prior approval of the COIC, equity may be issued to inventors whose technology is being licensed and to other faculty, staff, and students, provided that a 49% ownership cap is placed on the aggregated stock and/or stock options held by the University, its employees, students, and Members of their Immediate Families, so long as their aggregated ownership interests do not constitute a controlling interest in the company. With the approval of the individual's department chair, dean, and the COIC, and the implementation of a conflict management plan that includes any conditions of approval imposed by his/her supervisor, exceptions to the 49% cap may be made for Licensed Start-up Companies electing the Patent Cost-Only Option Agreement or an Express License Agreement. The exception will be in effect for up to two years or until the company reaches \$500,000 in dilutive capital, whichever comes first.

3. Offices and Positions

Faculty, staff, and students may not hold management or operating positions in the company (e.g., officer of the company, member of the board of directors, chief scientific or medical officer), although membership or chairmanship of the scientific advisory board is allowed. With the approval of the individual's department chair, dean, and the COIC, and the implementation of a conflict management plan that includes any conditions of approval imposed by his/her supervisor, exceptions to this general prohibition may be made for Licensed Start-up Companies electing the Patent Cost-Only Option Agreement. The exception will be in effect for up to two years, or until the exercise of the option, or until the company reaches \$500,000 in dilutive capital, whichever comes first. Individuals holding management or operating positions cannot serve as PIs of research sponsored by, or of commercial interest to, the company. They can serve as Co-Investigators with the implementation of a plan to manage their conflicts with this research.

4. Consulting for companies in which faculty, Investigators, and Research Staff/Coordinators have an interest

- a. Consulting, in accordance with the University's policy on Outside Employment, may be undertaken, provided there is prior approval from the department chair or dean, and the COIC.
- b. Consultants shall not use University resources for purposes other than University business.
- c. The University may claim rights to intellectual property developed by its employees in consulting arrangements in accordance with the Patent Rights and Technology Transfer Policy.
- d. Full-time University faculty may not provide any research effort to the company, whether compensated or not, other than through an SRA with the University.

5. Research Grants and Contracts

- a. Research grants and contracts, service agreements, and other contracts between the University and the Licensed Start-up Company shall be negotiated on behalf of the University by the Office of Research, in collaboration with the Office of Technology Management, or the Purchasing Department of the University (as appropriate), not by faculty, staff, or students.
- b. Financial relationships must be disclosed in applications and proposals for research funding.
- c. University personnel may not receive remuneration directly from a company for work subcontracted to that company by the University.

6. Research Sponsored by a Licensed Start-up Company

Research sponsored by a Licensed Start-up Company should generally be permitted in University laboratories, provided that:

- a. proposals are reviewed by the COIC prior to approval;
- b. reports to the COIC on the sponsored activity are provided at least annually;
- c. in general, an investigator with a Significant Financial Interest in the company may not serve as PI<sup>11</sup>;
- d. any exception to the PI exclusion rule or request for an exception must be approved by the provost or the senior vice chancellor for the health sciences upon the recommendation of the COIC; in case an exception is granted, the management plan indicated in section IV.B. applies. Exceptions will not be considered for Licensed Start-up Companies where the individual also holds a management or operating position;
- e. in the case of SBIR or STTR grants not involving research regulated by the IRB or IACUC, the Investigator with the outside interest can be the PI;
- f. participation as a researcher in a company's SBIR or STTR program is limited to the sub-contract to the University or to the portion of the award made directly to the University;
- g. University employees who participate in company research, whether at University or company facilities, do so under sponsored research agreements (SRAs), negotiated by the Office of Research, and not through consultancies;
- h. prior approval is obtained from the department chair or dean on the use of graduate and undergraduate students on such research;
- i. the study's budget includes application of the University's full indirect cost rate and all costs associated with the research study are borne by the company. The University will not cost share any work funded by a Licensed Start-up Company.

7. Other Affiliation Requirements between faculty, staff, or students and Licensed Start-up Companies

- a. Prior written approval is required for the use of the University name and logo by the company.
- b. The University name and logo may not be used in the marketing of commercial products and services.

8. Licensing of University Technology

The Office of Technology Management undertakes broad marketing and utilizes a common format for optioning or licensing a specified technology to either a Licensed Start-up Company or an existing company. A comprehensive grant of future rights to all technologies from a laboratory will not be allowed.

9. Product Liability

In order to control the risk of product liability, a disclaimer of warranties to the Licensed Start-up Company, along with comprehensive company insurance, is required. Automatic indemnification of the University by the Licensed Start-up Company also is required.

B. Review by the COIC

1. Initial Submission of Proposed Equity Ownership

The initial submission to the COIC shall be made on the Information Submission Form for Review by Conflict of Interest Committee of Entrepreneurial Endeavor, available (as are all forms

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<sup>11</sup> Department chairs are responsible for developing conflict management plans for SFIs in the \$5,001 to \$10,000 range, which may not necessarily include application of the PI exclusion rule. The PI-exclusion rule is considered on a case-by-case basis when the investigator's only financial interest is in intellectual property rights.

mentioned below) on the COI Web site at the following URL:

<http://www.coi.pitt.edu/COIforms.htm>. This form requests, among other items, identification of University employees and Members of their Immediate Families involved in the creation of the Licensed Start-up Company, the products or services to be developed, ownership interests, any intended sponsored research agreements between the Company and the University, and funding.

## 2. Initial Review

The initial review will consider the proposed relationships among the faculty/staff/student-entrepreneurs, administrative and other University personnel, the Licensed Start-up Company, and the University. The COIC may accept the proposed relationship with or without stated conditions, may request additional information, or may reject the proposed relationship.

Other forms required for an initial submission:

- a. Equity Holding in Entrepreneurial Endeavor Policy Compliance Statement
- b. Approval of Entrepreneurial Activities of Faculty Member by Department Chair or Dean
- c. Notification to Students/Staff of Financial Interest in a Company (if applicable)

## 3. Subsequent Review

Review will be required annually, upon the occurrence of changes in any elements of the initial submission, and upon the occurrence of specified triggering events. Changes in faculty relationships with the University or with the Licensed Start-up Company also will be reviewed.

## VI. CONFLICT OF INTEREST COMMITTEE AND COI OFFICE

The University has demonstrated its commitment to proper internal monitoring and management of conflicts of interest by establishing a Conflict of Interest Committee. The COIC is responsible for the oversight and management of potential conflicts of interest on the part of the University's employees and the institution itself related to this policy, and it reviews conflicts related to technology transfer activities involving Licensed Start-up Companies.

Committee members are appointed by the provost and the senior vice chancellor for the health sciences. The chair of the COIC is appointed by the chancellor. The membership of the COIC consists of a broad spectrum of University faculty, staff members, and students involved in a cross-section of research disciplines, including two members proposed by the president of the University Senate, and administrators responsible for purchasing. The COIC also includes representation from the University Office of Research, the Research Conduct and Compliance Office, and the non-University community. Representatives from the Office of Technology Management, Office of General Counsel, and the UPMC Corporate Legal Department serve as *ex officio*, non-voting members. Voting membership of the Committee shall not exceed 30, and a quorum shall consist of 50% of the total voting membership.

The COIC reports through its chair to the vice chancellor for research conduct and compliance, who reports directly to the chancellor.

A Conflict of Interest Office staff supports the functions and activities of the COIC. The director of the COI Office is accountable to the chair of the COIC and reports to the vice chancellor for research conduct and compliance.

To promote awareness and understanding of COI issues and their importance to the University's mission and research integrity, the COIC and the COI Office also fulfill an educational function, providing resources and training for the University community on these subjects. Examples of such resources include:

- the COI Web site <http://www.coi.pitt.edu>

- working with department chairs, deans, and division heads, as requested, encouraging them to:
  - disseminate COI information (policy, procedures, etc.) to their faculty, Investigators, and Research Staff/Coordinators at departmental meetings, at the time of annual performance reviews, and during orientation programs for new employees;
  - adhere to consistent and equitable COI policies and procedures;
- presentations to academic units upon request;
- providing the University community with policy updates;
- preparation of updates to the material contained in the online COI training modules.

## VII. EXAMPLES OF CONFLICTS OF INTEREST

The following examples illustrate potential or actual COIs. They are by no means exhaustive but are illustrative of potential COIs that must be disclosed, avoided, or otherwise managed, reduced, or eliminated.

- A. Accepting gifts, gratuities, or special favors related to University teaching, research, or administrative duties;
- B. Giving remunerated lectures for or on behalf of companies or organizations whose economic or political interests are affected or perceived to be affected by an investigator's scholarly work;
- C. Entering into a paid consultancy with an entity that has an interest in the consultant's University-based research;
- D. Commenting directly or indirectly to investors or investment analysts about unpublished research results that may affect the value of the shares of a for-profit company;
- E. Providing privileged access to information (particularly unpublished research results) developed with University resources or supported by independent sponsors to any external entity other than the sponsor;
- F. Engaging in the purchase or sale of securities of a company while possessing information on unpublished research results that may affect the value of the shares;
- G. Undertaking evaluative research when the Investigator or Members of the Investigator's Immediate Family have a financial, managerial, or ownership interest in the sponsoring company or in the company producing the product being tested;
- H. Using students or employees of the University to perform services for a company in which a faculty member has an ownership interest or from which he/she receives any type of remuneration;
- I. Assigning as a course-required text a book from the sale of which the instructor derives financial benefits, e.g., royalty payments;
- J. Accepting support for research under terms that require results to be held confidential, unpublished, or significantly delayed in publication;
- K. Purchasing equipment, instruments, or supplies for research or teaching, or contracting services from a firm in which the faculty member, Investigator, or Research Staff/Coordinator has a financial or other interest;
- L. Influencing the negotiation of contracts between the University and outside organizations in which a faculty member, Investigator, or Research Staff/Coordinator has a financial interest or other relationship;
- M. Influencing the sub-contracting of federally funded University research to an entity in which the faculty member has an interest;
- N. Receiving royalties or non-royalty payments related to ongoing research.

## VIII. APPENDICES

[Conflict of Interest Web Site](#)

[Guidelines for Responsible Conduct of Research](#)

[Faculty Handbook](#)

[COI-related Policies](#) The following policies and procedures may be useful resources in evaluating and managing COI issues at the University of Pittsburgh.

[02-04-02, Academic Responsibilities and Professional Conduct](#)

[02-04-03, Faculty-Student Relationships](#)

[02-06-01, Outside Employment](#)

[05-02-02, Conflict of Interest and Procurement Relationships](#)

[05-02-03, Code of Ethics](#) (dealing with purchasing activities)

[05-02-05, Department Purchasing Authority and Responsibilities](#)

[05-02-15, Required Use of Contracted Suppliers](#)

[05-02-16, Competitive Bidding](#)

[05-02-17, Directed or Sole Source Purchase Justification](#)

[05-02-18, Supplier Code of Conduct](#)

[05-08-01, Personal Use of University Resources](#)

[07-05-02, Conflict of Interest for Designated Administrators and Staff](#)

[07-05-03, Conflict of Interest for University of Pittsburgh Employees](#)

[08-01-01, Licensing and Use of University Name, Logos, Trademarks, and Service Marks](#)

[11-01-01, Research Integrity](#)

[11-01-02, Rights, Roles and Responsibilities of Sponsored Research Investigators](#)

[11-01-04, Consultant Conflict of Interest](#)

[11-02-01, Patent Rights and Technology Transfer](#)

[11-02-02, Copyrights](#)

[Industry Relationship Policy for the Schools of the Health Sciences and UPMC:](#)

Policy on Conflicts of Interest and Interactions between Representatives of Certain Industries and Faculty, Staff and Students of the School of the Health Sciences and Personnel Employed by UPMC at all Domestic Locations

### **Abbreviations**

COI – Conflict of Interest

COIC – Conflict of Interest Committee

Co-I – Co-Investigator

FCOI – Financial Conflict of Interest

IACUC – Institutional Animal Care and Use Committee

IDE – Investigational Device Exemption

University of Pittsburgh Policy 11-01-03

SUBJECT: Conflict of Interest Policy for Faculty, Scholars, Researchers, Research Staff/Coordinators

EFFECTIVE DATE:

IND – Investigational New Drug  
IRB – Institutional Review Board  
PI – Principal Investigator  
SBIR – Small Business Innovation Research  
SFI – Significant Financial Interest  
STTR – Small Business Technology Transfer