

University of Pittsburgh
Conflict of Interest Policy for Research
Policy #11-01-03

Category: Research Administration
Section: Research
Subject: Conflict of Interest Policy for Research

Responsible Executive: Senior Vice Chancellor for Research

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I. Policy Statement

The mission of the University of Pittsburgh, in part, is to “advance learning through the extension of the frontiers of knowledge and creative endeavor” and to “cooperate with industrial and governmental institutions to transfer knowledge in science, technology, and health care.”¹ Thus, University Members are encouraged to engage in outside activities consistent with this mission and which benefit society and are permitted to have management or officer positions in outside entities and receive financial benefit from their outside professional activities, so long as these interests do not interfere with their University duties or distort the judgements expected of them. To this end, faculty and staff are required to make the disclosures outlined below to facilitate effective identification and management of conflicts of interest (COIs).

The University will conduct a review of proposed sponsored research agreements, technology transfer agreements, and human subject research protocols when the University or University Members involved (or their family members) have related financial or Management Interests that could create conflicts of interest. The University will enter into such agreements and approve research protocols when the conflicts can be satisfactorily managed with appropriate oversight or eliminated. Such agreements will not be accepted if it is determined that the conflict compromises the integrity or objectivity of the proposed work or the investigators’ obligations to the University, sponsor, research subjects, or students.

¹https://provost.pitt.edu/faculty-handbook/ch1_mission_stmt.

II. Definitions

- A. Conflict of Commitment exists when a University Member's external relationships or activities have, or will have, a reasonable potential to interfere or compete with the University's educational, research, or service mission or with that individual's ability or willingness to perform the full range of responsibilities associated with his or her position.
- B. Conflict of Interest (COI) exists whenever personal, professional, commercial, or financial interests or activities outside of the University are, or have a reasonable potential of, (1) compromising a University Member's judgment; (2) biasing the nature or direction of scholarly research; or (3) influencing a faculty or staff member's decision or behavior with respect to teaching and student affairs, appointments and promotions, uses of University resources, interactions with human subjects, or other matters of interest to the University; or (4) resulting in personal or immediate family member's gain or advancement to the detriment of the University or in ways prohibited by University policy.
- C. Conflict of Interest Committee (COIC) is a standing committee responsible for the oversight and management of potential COIs and is authorized by the Senior Vice Chancellor for Research (SVC-R) to receive COI disclosures and to review and manage the risks associated with the disclosed interests.
- D. COI Management Plan (CMP) is a document that describes how COIs and conflicts of commitment will be managed, monitored, or avoided.
- E. Disclosure means the reporting of outside interest, activity, or relationship related to an individual's University responsibilities. The information disclosed includes, but is not limited to, "significant financial interests" as described in the Public Health Service (PHS) Financial Conflict of Interest (FCOI) Regulation. ([42 C.F.R. Part 50 § 50.603](#) and [45 C.F.R. Part 94 § 94.3.](#))
- F. Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- G. Immediate Family Member(s) refers to the spouse, domestic partner, dependents of the University Member.
- H. Incidental Use refers to the limited personal use of University equipment or services that the University is already providing and the University Member's use of such equipment or services will not result in any additional expense to

the University, or the use will result in only normal wear and tear, and uses only small amounts of power and expendable supplies, and such use complies with existing contractual obligations.

- I. Institutional Responsibilities refer to an individual's responsibilities on behalf of the University, 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.
- J. Intellectual Property (IP) refers to property created or developed by a University Member, including but not limited to, patents and inventions, copyrightable work, software, and trademarks.
- K. Investigator refers to an individual, regardless of title or position, who is independently responsible for, or significantly influences, the design, conduct, outcome, or reporting of University research.
- L. Licensed Start-up Company (LSC) means a company that: (1) is legally recognized in the State or Commonwealth of creation or incorporation; (2) is not publicly-traded; (3) has a license agreement or option agreement for a license covering University-owned Intellectual Property; and (4) has a portion of its equity or option for equity held by the University, a University Member, a member of the Immediate Family, or in trust for a member of the Immediate Family. This definition does not include companies that have licensed Intellectual Property that the University released and assigned back to the University Member consistent with the University's intellectual property policy.
- M. Management Interest refers to positions of responsibility held by a University Member within an outside organization, whether paid or unpaid, that have authority to make decisions bearing on hiring, finance, investment, research, production, marketing, sales, and any other strategic business decisions, and carry a fiduciary obligation to act in the best interest of that outside organization. Unless they hold other positions in the company, members of the scientific advisory board and the chair of the scientific advisory board would ordinarily not be considered to have a Management Interest.
- N. Management of COI means taking action to address an actual, potential, or perceived COI or conflict of commitment, to ensure, to the extent possible, that the design, conduct, and reporting of the research will be free from bias. Examples of management mechanisms include, but are not limited to:
- Institutional disclosure of the COI or conflict of commitment;

- Monitoring of the research or research management by non-conflicted individuals;
 - Assignment of independent mentors for students/trainees/junior faculty;
 - Modification of the research plan;
 - Limiting participation in some or all of the research;
 - Divestiture of the interest; or
 - Severance of the relationship that creates the COI or conflict of commitment.
- O. Outside interest, activity or relationship refers to an interest with an outside organization that relates to a University Member's institutional responsibilities. This also applies both to the individual and members of his or her immediate family.²
- P. Principal investigator (PI), for purposes of this policy, is the person so designated on the institutional record as the individual having the responsibility, including the necessary background and training in scientific and administrative oversight, to conduct and manage the research or sponsored project.³
- Q. Public Health Service (PHS) refers to the agencies of the Public Health Service of the U.S. Department of Health and Human Services, and any of their components. The National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC) are three PHS components that are often involved in academic research.

² See Policy 02-06-01 "Outside Employment" for further clarification on the conditions under which faculty members may perform professional services outside the University, or internally, but outside their department, school, or regional campus. Also, see Policy 07-05-02 "Conflict of Interest for Designated Administrators and Staff" and Policy 07-05-03 "Conflict of Interest for University of Pittsburgh Employees" for additional clarification on conditions governing such professional services performed by staff and employees.

³ See Policy No. 11-01-02, "Rights, Roles, and Responsibilities of Sponsored Research Investigators," for additional description of the PI's responsibilities.

- R. **Research Gifts** refers to an award of money, equipment, or other property of value given, with charitable or philanthropic intent, to the University by an individual or a non-governmental entity who may request that the award be used to support the general research efforts of the research laboratory, but does not expect anything significant of value in return. The award involves only general obligations on behalf of the University or its faculty, is irrevocable, and is not intended to result in award-specific deliverables.
- S. **Significant Financial Interest (SFI)**, as it relates to research not funded by a PHS agency⁴, 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 individual and Members of the Immediate Family that reasonably appears to be related to the individual's Institutional Responsibilities:
- a. the aggregation of remuneration received or anticipated from any publicly traded entity in a 12 month period (including salary, consulting fees, honoraria, and paid authorship) and the value, as determined through reference to public prices or other reasonable measures of fair market value, of any equity interest in that entity (including any stock, stock options, or other ownership interests) as of the date of disclosure exceeding \$10,000; or an equity interest in such an entity that exceeds 5% ownership interest;
 - b. remuneration received or anticipated from a non-publicly traded entity in a 12-month period exceeding \$10,000, or any equity interest in such an entity;
 - c. being the author or inventor of Intellectual Property when royalties, milestone fees, or other proceeds have been received in excess of \$10,000 in a 12-month period.
 - d. Holding a management or operating position or serving as an officer in any outside entity.

The term SFI does not include (1) salary or supplemental payments from the University of Pittsburgh, the Veterans Administration Pittsburgh Healthcare System, the University of Pittsburgh Medical Center (UPMC), or University of

⁴ For the definition of SFIs relating to PHS funded research see: ([42 C.F.R. Part 50 § 50.603](#) and [45 C.F.R. Part 94 § 94.3](#)). University Investigators who are engaged in PHS funded research must disclose (as explained below in Section IV) financial relationships included in the PHS definition and in the University's definition. For PHS funded research at the University, SFIs include management/operating/officer positions in outside entities, sponsored/reimbursed travel expenses from certain entities and/or royalties, milestone fees, and other proceeds from IP that exceed or are expected to exceed \$5,000 in a 12-month period.

Pittsburgh Physicians (UPP), except for supplemental payments that represent distribution of royalties, milestone fees, or other proceeds; (2) income from service on advisory committees or review panels and from seminars, lectures, or non-promotional engagements sponsored by governmental or non-profit entities; or (3) income from investment vehicles, such as mutual funds and retirement accounts, so long as the individual does not directly control the investment decisions made in these vehicles.

- T. Student refers to any undergraduate or graduate student enrolled and/or registered at the University of Pittsburgh for a course of study.
- U. University Member refers to all full-time faculty, as well as part-time faculty, staff, students, visitors, volunteers, fellows, trainees, and interns who are engaged in University research.⁵

III. Policy Overview

The University is committed to basic values of transparency, integrity of scholarship, and independence as it pursues its mission to create, preserve, and disseminate knowledge through teaching, research, and public service. Accordingly, the University encourages University Members to engage in outside activities and relationships that enhance the mission of the University. All faculty and staff members are to act with honesty, integrity, and in the best interest of the University when performing their duties, and to abide by the highest standards of research, educational, professional, and fiscal conduct.

Outside activities should not, however, interfere with an individual's University obligations. Faculty and staff must not use their official University positions or influence to further gain or advancement for themselves, immediate family, or other personal and business associates, at the expense of the University.⁶

Faculty members and staff members with half-time or greater appointments owe their primary professional commitment to the University. Accordingly, a commensurate commitment of time and intellectual energy should be used to support and enhance the mission of the University. Other part-time faculty members and staff members owe time and effort commitments to the University commensurate with their appointments.

All actual and potential conflicts of interest or commitment must be disclosed to a designated University official; evaluated; and, if found to be significant, eliminated or managed as described below.

⁵ The policy does not apply to employees on unpaid leave from the University or to adjunct faculty not engaged in research.

⁶ For additional clarification regarding the prohibition on using an official University position for further personal gain, including student involvement, see Policy 05-08-01 "Personal Use of University Resources" and the Faculty Handbook.

This Policy operates in addition to other University policies related to COIs and conflicts of commitment, which are available on the University's COI website (<http://www.coi.pitt.edu/>).

Below are the principles that shape this policy:

- A. **Outside Activities** – University Members may engage in outside professional activities consistent with the University's policies governing outside activity (Policy Nos. 02-06-01, 07-05-02, and 07-05-03). As a University Member's primary responsibility is to the University, such participation in external activities must not conflict with the Member's satisfactory fulfillment of their University duties or the University's over all interests.
- B. **Disclosure of Conflicts** – University Members must disclose real or apparent conflicts of interest or conflicts of commitments to the appropriate University individual or unit as such conflicts arise and are known or are identified. Supervisors may require additional information in order to evaluate and manage conflicts of interest or commitment.
- C. **Adherence to Conflict Management Plans** – If it is determined, after disclosure, that a conflict exists, the appropriately designated University body will decide whether the conflict must be eliminated or can be managed. When appropriate, a management plan will be put in place by the designated University body in consultation with the University Member. The University Member must abide by any such conflict management plan. The department chairs or persons holding an equivalent supervisory position are responsible for overseeing compliance with COI management plans.
- D. **Personal Gain or Advancement** – University Members must not use their University position to exploit their professional relationships for purposes of personal gain, or advancement for themselves, their family or their associates to the detriment of the University or in ways prohibited by University policy.
- E. **University Resources/Incidental Use** – For purposes of this Policy, unless authorized by University authority, a University Member may make only Incidental Use of university resources to support outside interests. Such resources include, but are not limited to, University facilities, personnel, students, and equipment. Incidental Use of these resources must not interfere with the University Member's official duties or the official duties of others employed by the University. The department chairs or persons holding an equivalent supervisory position over the

University Member are responsible for determining what constitutes Incidental Use.

- F. Knowledge of Applicable Law** – This policy incorporates elements of regulations promulgated by the Department of Health and Human Services to promote objectivity in research funded by the Public Health Service and other relevant Federal laws and regulations regarding COI which may be modified or replaced from time to time. To the extent University policy conflicts with these authorities, the applicable Federal laws or regulations govern. University Members are responsible for knowing and complying with such laws and regulations as well as all applicable University policies and procedures.

IV. Disclosures and Approvals

A. General Disclosure Requirements

Disclosure by University Members of financial, personal, or professional relationships that raise a potential COI or conflict of commitment, or their perception, is a prerequisite for determining whether a conflict, once recognized, can be managed or reduced or, in some cases, eliminated.

All University Members are required to submit financial disclosures using the University's designated system upon appointment, and

- annually, on or before April 15, and
- within 30 days of discovering or acquiring and becoming aware of (for example, through a new consultancy, purchase, marriage, or inheritance) a new Significant Financial Interest related to their institutional responsibilities.

An annual disclosure must be submitted even if the individual has no outside interest or there have been no changes to the prior disclosure. Each disclosure shall be reviewed by the submitter's supervisor for conflict of commitment and to determine if the University Member's outside interests give rise to any conflicts of interest that have not yet been managed. If any such conflicts are identified, the supervisor may contact the COI Office (a component of the Research Conduct and Compliance Office) for assistance in developing an appropriate management plan or for guidance on corrective action, if required.

B. Additional requirements in regard to PHS-funded Investigators

- a. All Investigators proposing or receiving grants, contracts or cooperative agreements from agencies of the PHS, or entities explicitly requiring compliance with the PHS FCOI Regulations, must disclose, at least annually, their outside interests related to any of their University

responsibilities as requested on the PHS version of the University's COI disclosure form.

- b. The University will confirm that the proposed Investigators have a current PHS-compliant disclosure on file prior to submitting a grant proposal to PHS or an entity requiring compliance with PHS FCOI Regulations.
- c. If an Investigator engaged in PHS-funded research has disclosed a SFI on his/her COI disclosure form the University will determine whether the SFI constitutes an FCOI. Department chairs are responsible for determining whether SFIs in the \$5,001-\$10,000 range give rise to FCOIs with PHS-funded research. The COIC is responsible for FCOI determinations in the case of SFIs exceeding \$10,000.
- d. Any subcontract to an external entity from a University of Pittsburgh PHS-funded research project shall specify whether the subrecipient will follow its own PHS-compliant FCOI policy or the University of Pittsburgh's policy. 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.
- e. The Office of Research will forward Notices of Award for PHS funding for review by the COI Office when any Investigator on the project has disclosed a SFI on his/her COI disclosure form.
- f. The University, through the COI Office, shall post on a publicly accessible website information required by the PHS regulations regarding managed conflicts of interest of Investigators engaged in PHS-funded research.
- g. 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.

C. Research proposals with other research sponsors

- a. When submitting a research proposal, the PI is responsible for following the instructions of the agency or sponsor regarding COI disclosures in the submission. Some agencies prohibit disclosure, and some agencies require disclosure. Therefore, if available instructions

from the agency are not clear, the PI should contact an agency representative for instructions.

- b. The declaration will pertain to any Investigator responsible for the design, conduct, or reporting of the proposed research, and will include information about the financial or Management Interests held by those individuals and/or their Immediate Family Members.
- c. At the time of award, the Office of Research will refer any projects on which it has identified or the PI has disclosed that one or more Investigators have a related outside interest to the COI Office for review.

D. Licensed Startup Companies

All the reviews and approvals by the COIC that are called for in this Section will be completed as expeditiously as possible and within a reasonable time frame.

- a. An Option or License agreement for University Intellectual Property with a non-publicly traded company must be prospectively approved by the COIC if the University, a University Member, or Members of their Immediate Families have or will be taking an equity interest in the company.
- b. The issuance of equity (including stock options or warrants) in a non-publicly traded company with an Option or License to University IP to University Members or their Immediate Family Members, or to the University, requires the prospective review and approval of the COIC.
- c. The COIC must review and prospectively approve transactions between the University and an LSC, including, but not limited to: new or additional issuance of equity to the University, new or amendments to existing IP agreements, sponsored research agreements, Material Transfer Agreements or other non-financial collaborative agreements, gifts, purchases of products or services, and research subcontracts.
 - i. Research in University facilities funded by an LSC may only be conducted under a properly executed agreement negotiated by the Office of Research and approved by the department and COIC. The budget for the project must cover all costs of the research, including application of the University's full Facilities and Administrative (F&A) cost rate (also known as the "indirect cost rate").

- d. University Members' relationships with LSCs are subject to the normal review and approval processes required by University policy and the individual's department and school. Additionally, the COIC must review and prospectively approve interactions between University Members and an LSC, including but not limited to: new or additional issuance of equity, employment, or consulting work.
 - i. Prior to entering into a consulting or employment relationship with an LSC, University Members must obtain the approval of their department chair or person holding an equivalent supervisory role, the Innovation Institute (with respect to Intellectual Property rights) and the COIC.
 - ii. A University Member may hold a management or officer position in a Licensed Startup Company with the approval of the department chair or person holding an equivalent supervisory role and with the implementation of a COIC-approved CMP. A University Member's supervisor is responsible for monitoring their University work and performance to ensure that holding the position does not result in a Conflict of Commitment. These relationships will be reviewed annually by the COIC.
 - iii. Individuals holding management or officer positions may serve as PIs of non-human subject research sponsored by or of commercial interest to the company with approval of the SVC-R after consideration of the recommendation of the COIC. (NB: Holding a management or officer position may affect a faculty member's eligibility for research support or salary through STTR (Small Business Technology Transfer) or SBIR (Small Business Innovation Research) programs, and other Federal support sources.)

- E. Research overseen by the Institutional Animal Care and Use Committee (IACUC)
 - a. The PI of a protocol submission to the Institutional Animal Care and Use Committee (IACUC) is responsible for disclosing all related Significant Financial Interests of any Investigator on the protocol. The IACUC will refer any protocol on which an Investigator has disclosed a related SFI to the COI Office for review. Any Investigator with a conflict of interest must agree to a CMP developed by the COI Office in accordance with direction from the COIC to participate in the research.

F. Human Subject Research

- a. IRB leadership, staff, and affiliated IRB members are required to disclose SFIs related to any protocols they review, as described in Human Research Protection Office Policies and Procedures.⁷
- b. The COI Office is required to review and submit ancillary COI approval for any study that is submitted for IRB review where the Principal Investigator indicates that any member of the study team who participates in the design, conduct, or reporting of the research protocol has an SFI related to the research covered by the protocol.
- c. The COI Office will develop a CMP for the University Member with a conflict of interest in accordance with guidance received from the COIC. The COI Office will notify the University Member's department chair or dean of the managed conflict of interest and seek their advice in developing the CMP. The decision to approve the experimental protocol remains with the IRB.
- d. The COIC shall determine which SFIs related to Human Subject Research may prohibit the Investigator with the SFI from serving as PI. This is known as the "PI-exclusion rule." In such cases, a scientifically-qualified faculty member who is independent of the Investigator with the COI must be identified to assume the role of PI for the project. The alternate PI must not have a COI in the research and must be approved prospectively by the COIC. The individual with the COI may be a Co-Investigator on the project, subject to terms defined in the CMP developed by the COIC.
 - i. If a suitable PI without a COI in the research project cannot be found, the Investigator may ask for a waiver of the PI-exclusion rule if a case can be made for the existence of compelling circumstances that justify the person with the conflict of interest serving as PI. A request for such a waiver must be submitted to the COIC, by way of the COI Office. The COIC will make a recommendation to the Authorized Institutional Official for Human Subject Research, who will make the final decision whether to grant approval; however, the final decision to approve the experimental protocol remains with the IRB.

⁷ Available at <http://www.irb.pitt.edu/content/policies-and-procedures>.

V. Research Gifts

To protect the objectivity of University research, oversight will be required whenever one or more members of a laboratory benefiting from a Research Gift have SFIs in the donor entity.

A. Use

Research Gifts may be used to pay for general utility equipment, generic reagents, personnel, and expendables used in support of the general research efforts of the research laboratory of the designated faculty member(s). Sponsored research agreements, not Research Gifts, are to be used as the source of funding for the conduct of defined research projects focused on the evaluation or further development of substances, products and/or processes that are currently owned by, or optioned or licensed to the donor entity.

B. Requirements

Immediate supervisors of faculty members who are the recipients of a Research Gift are responsible for establishing an accounting mechanism that will track the expenditures from the Research Gift funds. The accounting of expenditures from Research Gift funds must be maintained in such a manner so as to facilitate respective University audits. Additional information regarding the accounting for gifts is available in the Chief Financial Officer's Financial Guideline titled "Accounting For Sponsored Projects vs. Gifts".⁸

C. Prohibition on Disclosure

Research results not yet publicly disclosed may not be divulged to investors, investment analysts, or donors of Research Gifts. Reports to donors may account for funds expended and reports to donors, investors, and investment analysts may describe general areas of investigation, but must not disclose project information that would provide a competitive advantage to the recipient of the information

VI. Committee Review

A. Conflict of Interest Committee

The Senior Vice Chancellor for Research (SVC-R) is the designated University Official responsible for the COI policy as it relates to research and technology transfer agreements. The SVC-R has authorized a Conflict of Interest Committee

⁸ Available here: https://www.cfo.pitt.edu/policies/guideline/sponsored_projects_vs_gifts.pdf.

(COIC) to receive COI disclosures and to review and manage the risks associated with the disclosed interests.

The Chair of the COIC is appointed by the Chancellor and the COIC members are appointed by the SVC-R. The membership of the COIC represents the diverse interests of the University. There shall be no more than 30 voting members of the Committee, which shall include faculty, staff, Students, a representative from the non-University community, and two members proposed by the president of the University Senate.

The Chair, with the assistance of the COI Office, will report the management of COIs to federal agencies and other funding sources as required. The Chair or the COI Office, on behalf of the COIC, may at any time consult with Deans and Directors of impacted units.

The functions and activities of the COIC shall be supported by the COI Office, which is a component of the Research Conduct and Compliance Office (RCCO). The COI Office may conduct random or for cause audits assessing compliance with this policy or with CMPs, on its own initiative or as requested by an internal authority (including the COIC) or external party, as appropriate, and will report the results to the COIC. Alternatively, the COIC or the COI Office may request that the audit be conducted by other units within the RCCO.

The COIC is responsible for the oversight and management of potential COIs of the University's employees and the institution itself. Additional information on the COIC is available at <http://www.coi.pitt.edu/>.

B. Determinations

When a COI or potential COI is brought to the attention of the COIC or the COI Office they may require additional information from individuals as part of their review of the outside interest to determine whether one or more Investigators has a COI. If a COI exists, the COIC may (among other options):

- Require specific type of administrative oversight or management condition; or
- Recommend the withdrawal of the proposal or suspension of the technology transfer agreement.

The COIC will have the assistance of the COI Office in handling its responsibilities and the flow of paperwork, correspondence, record keeping and the development and implementation of management decisions made by the Committee.

The COI Office on behalf of the COIC, will, when appropriate, report managed conflicts of interest to funding agencies within 60 days (or as required by the funding agency) of identifying the COI and thereafter as required by the funding agency.

VII. Appeal

An individual may appeal a COIC decision in writing to the SVC-R within 30 days of receipt of the Committee's notification of the decision. Within 30 days of receipt for the written appeal, the SVC-R will decide to endorse, reverse, or modify the Committee's decision. The decision of the SVC-R shall be final and will be reflected in a writing that explains the reasons for the decision.

If the SVC-R has a COI himself or herself, the Chancellor (or another SVC, appointed by the Chancellor and having no relevant COI) will make the decision.

VIII. Training⁹

All Investigators are required to complete COI training on appointment. Investigators who are externally funded, regardless of sponsor, must complete COI training within four years prior to commencing or engaging in any externally funded research activity and must renew their training at least every four years. An Investigator found to be not in compliance with this policy or a CMP may be required to repeat COI training.

IX. Record Retention

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

X. Noncompliance

The COIC, and the COI Office on its behalf, will work cooperatively with Investigators, their supervisors, and others to resolve any minor noncompliance.

Flagrant or repeated noncompliance with this Policy, its related procedures, or management requirements will be handled through University disciplinary procedures, after notice is provided to the noncomplying individual. Failure by an Investigator to comply with this Policy for reporting a related outside interest that has been determined by the University to have biased the design, conduct, or reporting of funded research will be promptly reported by the University to the funding agency, as required, including the corrective action taken or to be taken.

XI. Governance

This Policy will be reviewed and updated as necessary, on a regular basis. The SVC-R may, at his discretion, appoint a committee to conduct this review. Any

⁹ Additional background on training requirements is available here: <http://rcco.pitt.edu/training-courses/required-training/all-investigators>.

substantive changes to this Policy recommended by the committee must be presented to the SVC-R for approval only after receiving appropriate stakeholder input and, if required, University Senate approval.

XII. Contact Information/Public Accessibility

This Policy is posted under “Research Administration” at the following website: <http://www.cfo.pitt.edu/policies/policies.html>

University members are encouraged to contact the COI Office (<http://www.coi.pitt.edu/>) for assistance with understanding their obligations related to compliance.

More information about the COIC and the COI Office can be found at the following website: <http://www.coi.pitt.edu/>.

Appendix – Related Authorities and Policies

- PHS Regulations – 42 C.F.R. Part 50 Subpart F and 45 C.F.R. Part 94.
- NSF Regulations – National Science Foundation Grant Policy Manual, Chapter V, Grantee Standards, 510 COI Policies.
- FDA Regulations – 21 C.F.R. Part 54.
- Outside Employment – 02-06-01 (<http://www.cfo.pitt.edu/policies/policy/02/02-06-01.html>).
- Personal Use of University Resources – 05-08-01 (<http://www.cfo.pitt.edu/policies/policy/05/05-08-01.html>).
- Conflict of Interest for Designated Administrators and Staff – 07-05-02 (<http://www.cfo.pitt.edu/policies/policy/07/07-05-02.html>).
- Conflict of Interest for University of Pittsburgh Employees – 07-05-03 (<http://www.cfo.pitt.edu/policies/policy/07/07-05-03.html>).
- Responsibilities of Sponsored Research Investigators – 11-01-02 (<http://www.cfo.pitt.edu/policies/policy/11/11-01-02.html>).
- Organization Conflict of Interest – 11-01-08 (<http://cfo.pitt.edu/policies/documents/policy11-01-08web.pdf>).
- Patent Rights and Technology Transfer – 11-02-01 (<http://www.cfo.pitt.edu/policies/policy/11/11-02-01.html>).
- 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 (<http://www.coi.pitt.edu/industryrelationships/Policies/IndustryRelationshipsPolicy.pdf>).
- Guidelines on Sponsored Projects and Gifts – University’s Financial Guideline

(https://www.cfo.pitt.edu/policies/guideline/sponsored_projects_vs_gifts.pdf).

- University of Pittsburgh Faculty Handbook (<https://provost.pitt.edu/faculty-handbook>).
- University of Pittsburgh Staff Handbook (<http://www.hr.pitt.edu/handbook>).

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