

## University of Pittsburgh Institutional Conflict of Interest Policy RI 11

Implementing Executive: Senior Vice Chancellor for Research

**Responsible Unit:** Office of Research Protections

**Category:** Research and Innovation

Effective Date: June 18, 2022

#### I. Purpose

The University of Pittsburgh ("University") is committed to the highest standards of conduct in its core missions: research, scholarship, and teaching. Relationships with external entities play an important role in supporting the University's core missions, and it is recognized that institutional financial interests arise in the normal course of the University's operations. However, these financial interests must not compromise the objectivity or integrity of or unduly influence the University's core missions or appear to have such effect. In addition, the external engagements of University officials must not influence or appear to influence the University's business decisions or integrity of its core missions. Such potential conflicts generated by financial interests of the University or the external engagements of its senior officials must be identified, reviewed, and managed.

The purpose of this Policy is to set forth the standards and procedures for identification, review, and formulation of strategies for management of potential Institutional Conflicts of Interest ("ICOIs").

#### II. Scope

This Policy applies to all University campuses.

#### III. Definitions

- A. <u>Conflict Management Plan:</u> A strategy to ameliorate the potential impact of a financial interest or relationship with an external entity on the integrity or objectivity of research, scholarship, or teaching, as well as the business transactions of the University.
- B. <u>Covered University Official:</u> Chancellor, Senior Vice Chancellors, Vice Chancellors, Assistant and Associate Vice Chancellors, Provost, Vice Provosts, Assistant and Associate Vice Provosts, Presidents, Vice Presidents, Deans, Vice Deans, Assistant and Associate Deans, Department Chairs.

Covered University Officials may also include additional individuals (such as a Departmental or School Division Director/Chief) with a substantial role in making major decisions for the University, who engage in activities that could generate an ICOI. These individuals may be identified by the Chancellor, Provost, a Senior Vice Chancellor, a Dean, their designates, or the ICOI Committee.

- C. <u>Gift:</u> A charitable contribution as defined by the Internal Revenue Service (IRS), which is generally a charitable contribution for the use of the University made voluntarily and for charitable purposes, without the donor receiving, or expecting to receive, anything of equal or greater value in return. In this Policy, a Gift may also include a monetary or non-monetary donation including goods, services, time and labor, or use of facilities and equipment at no or reduced cost.
- D. <u>Institutional Conflict of Interest ("ICOI"):</u> A situation in which the University's financial interests, its relationship with external entities, or the external engagements of Covered University Officials could reasonably be perceived as interfering with its business decisions or its core missions of research, scholarship, and teaching.
- E. <u>ICOI Committee:</u> A standing committee responsible for the review of Threshold University Transactions and provision of advice to the relevant Senior Decision Makers.
- F. <u>Senior Decision Makers:</u> Covered University Officials responsible for high-level decisions, who receive advice from the ICOI Committee. Senior Decision Makers include the Chancellor, Provost, Senior Vice Chancellor ("SVC") for Philanthropic and Alumni Engagement, SVC for Business and Operations, SVC for Research, SVC and Chief Financial Officer, SVC and Chief Legal Officer, SVC for the Health Sciences, and their designates.
- G. Significant External Activity: This term includes: (1) external engagements providing > \$25,000 in income (from one entity) in a 12-month period; (2) a fiduciary or other senior management role in an entity (such as president, CEO, COO, Treasurer, Chief Scientific Officer, Chief Medical Officer); (3) an ownership interest in a privately held entity regardless of value; (4) an ownership interest in a publicly held entity valued >\$25,000.

The term "Significant External Activity" does not include (1) salary or supplemental payments from the University of Pittsburgh, the Veterans Administration Pittsburgh Healthcare System, UPMC d/b/a University of Pittsburgh Medical Center ("UPMC"), or University of Pittsburgh Physicians (UPP), except for supplemental payments that represent distribution of royalties, milestone fees, or other proceeds; (2) service on advisory committees or review panels and from seminars, lectures, or non-promotional engagements sponsored by governmental 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.

- H. <u>Threshold University Transactions</u>: For the purposes of this Policy, the below items are defined as a Threshold University Transaction, requiring review as defined herein under section IV.B.:
  - i. Any Gift(s) in aggregate made to the University or the University and UPMC from a commercial entity or a philanthropic unit affiliated with a commercial entity in a 12-month period > \$500,000 in total cumulative value.
  - ii. Payments to the University (or the right to receive future payments) resulting from technology transfer licensing to an entity, including royalty payments, milestone payments and other fees, WHEN the licensed technology is tested or evaluated at the University:
    - o Using human subject research;
    - Using cells that are derived from or mimic human cells, or using tissues obtained from human subjects; and/or
    - o Using methodologies defined by the ICOI Committee.
  - iii. Any equity of the University in a non-publicly traded company WHEN that entity proposes to sponsor research, scholarly activities, or teaching at the University.
  - iv. Equity of the University in a publicly traded company (other than that through an independent investment vehicle) > \$100,000 WHEN that entity proposes to sponsor research, scholarly activities, or teaching at the University.
  - v. A Significant External Activity of a Covered University Official with an entity WHEN that entity:
    - Is sponsoring or proposes to sponsor research, scholarly activities, or teaching (directly or through their philanthropic unit) at the University;
    - Receives > \$100,000 from the University in revenue for purchases or other transactions over a 12-month period; and/or
    - Is licensing or proposes to license data or biological samples from the University.
  - vi. Referrals from other University committees, including the Conflict of Interest ("COI") Committee and Institutional Review Board ("IRB"), or other official University bodies such as the University Senate, when there are concerns about a potential ICOI.

# IV. Policy

As provided above, relationships with external entities play an important role in supporting the University's core missions. It is recognized that institutional financial interests arise in the normal course of the University's operations. However, these financial interests or the Significant External Activity of Covered University Officials must not influence or appear to influence the University's business decisions or integrity of its core missions.

To this end, this Policy authorizes the ICOI Committee to monitor for, and formulate Conflict Management Plans to address, actual or perceived incidents of ICOI by the University or a Covered University Official. These Conflict Management Plans will be transmitted as advice to Senior Decision Makers and their supervisors. Compliance with Conflict Management Plans accepted by Senior Decision Makers will be monitored by the ICOI Committee. To perform its function, the sections below provide for the ICOI Committee composition and operations.

## A. Core Policy Principles

The following core principles will guide the decision-making process of the ICOI Committee, and its formulation of Conflict Management Plans:

- Gifts from corporate entities must not influence, or appear to influence, the University's business decisions or the integrity of research, scholarship, or teaching.
- The University's potential to receive financial gain from intellectual property that it owns must not compromise, or appear to compromise, the evaluation or testing of that intellectual property by University personnel.
- The University's ownership interest in a company must not compromise, or appear to compromise, the testing or evaluation of the company's products by University personnel.
- Covered University Officials must not use their official University positions or influence to further gain advancement for themselves, immediate family, or other personal and business associates, at the expense of the University.
- Significant External Activities of Covered University Officials must not compromise the University's business decisions or the integrity of University research, scholarship, or teaching.
- University personnel must comply with Conflict Management Plans that are formulated by the ICOI Committee and accepted by Senior Decision Makers.

#### B. ICOI Committee

This Policy authorizes the ICOI Committee to formulate Conflict Management Plans for Threshold University Transactions, and to provide advice to Senior Decision Makers and their supervisors to mitigate ICOI. The ICOI Committee is empowered to monitor compliance with Conflict Management Plans that have been accepted by Senior Decision Makers, and to report noncompliance to an appropriate University authority for review.

Voting members of the ICOI Committee include:

- Chair of the Conflict of Interest Committee;
- Chair of the Institutional Review Board;

AND eleven (11) other individuals, eight (8) of whom are full-time University faculty members, one (1) of whom is a full-time University staff member, and two (2) of whom are not employees of the University (external members).

These eleven voting members are selected by the University Senate from nominations provided by a Senior Vice Chancellor ("SVC") of the University (e.g., Provost, SVC Research, SVC Health Sciences). An SVC will solicit input for nominees from Deans, the ICOI Committee and other stakeholders (e.g., the Staff Council for the staff representative). No nominee can be a Covered University Official.

The University faculty members serving on the ICOI Committee must have a rank of Associate Professor or higher, including but not limited to those with Research, Teaching, or Clinical in their titles (Research, Teaching or Clinical Associate Professors or Professors). The distribution of faculty membership from a University unit on the ICOI Committee should approximately follow its representation on the Faculty Assembly.

The external members of the ICOI Committee include:

- A community member with no affiliation with the University or UPMC; and
- A representative from UPMC.

ICOI Committee members serve a three-year renewable term. At the inception of the committee, the University Senate will designate staggered terms (3-5 years) for the initial members to ensure a continuity of expertise.

Two (2) Co-Chairs, who are in addition to the 13 members described above, will manage the activities of the ICOI Committee, but do not have voting rights. The Co-Chairs are selected by the University Senate from nominations provided by an SVC of the University. The Co-Chairs will be appointed for 3-year renewable terms, but at inception of the ICOI Committee, the University Senate will appoint one (1) Co-Chair for a 3-year term and the other for a 5-year term to assure continuity of expertise.

Non-voting ex-officio members from University offices/units designated by the ICOI Committee will participate in committee discussions and provide information relevant to the activities of the Committee. The offices/units represented by these members shall provide reports to the ICOI Committee on request, or regularly at a frequency chosen by the ICOI Committee, to support implementation of this Policy.

Non-voting consultants invited by the ICOI Committee may also engage in committee discussions, to provide advice on particular topics.

### C. Support for ICOI Committee

The Conflict of Interest Division ("COID") of the Office of Research Protections will support the activities of the ICOI Committee. The COID is empowered to establish procedures to acquire information from relevant University offices necessary to generate a database of Threshold University Transactions. New or altered Threshold University Transactions will be conveyed at least monthly to the ICOI Committee Co-Chairs. In addition, the COID will formulate procedures to monitor compliance with Conflict Management Plans developed by the ICOI Committee and approved by Senior Decision Makers.

## D. Conflict Management Plans

The ICOI Committee Co-Chairs, in consultation with the ICOI Committee, will determine whether each Threshold University Transaction could reasonably be perceived as generating an ICOI. If so, a Conflict Management Plan for the Threshold University Transaction will be developed. Possible Conflict Management Plan elements may include but are not limited to the following:

- Recusal of a Covered University Official from the chain of authority over a transaction or project (including a research study) and supervision of personnel conducting the activity, and appointment of a nonconflicted individual to assume this role.
- For research studies, disclosure of the ICOI to all stakeholders (including all investigators conducting the study, the sponsor, and the public in presentations and publications).
- For human subject studies, disclosure of the ICOI in consent forms and/or to applicable regulatory bodies, as well as the use of an external IRB, external biostatisticians, external contract research organizations and/or an external Data Safety Monitoring Board ("DSMB").
- Reduction or elimination of transactions or other engagements with an external entity.
- Declining Gifts or funding for sponsored research projects or other activities.
- Divestment of a financial interest.

Conflict Management Plans will be conveyed as advice by the Co-Chairs of the ICOI Committee to relevant Senior Decision Makers and their supervisor. If the ICOI is related to the external engagements of the Chancellor, the Conflict Management Plan will be conveyed to designated members of the Board of Trustees.

Senior Decision Makers must confirm whether they accept Conflict Management Plans formulated by the ICOI Committee as provided or in modified form. Subsequently, the ICOI Committee will monitor compliance with the final version of the Conflict Management Plan accepted by the Senior Decision Maker.

## V. Noncompliance

Covered University Officials are expected to provide complete and truthful information relating to their external engagements that may give rise to the involvement of the ICOI Committee or a Conflict Management Plan. Noncompliance with an executed Conflict Management Plan or the failure to disclose or the submission of erroneous, misleading, or incomplete information may be the subject of disciplinary procedures and sanctions. The ICOI Committee shall refer concerns relating to noncompliance or failure to disclose to an appropriate University authority for review.

### VI. Contact Information & Public Accessibility

This Policy is posted under Research & Innovation on the Office of Policy Development & Management's website and can be found at: <a href="https://www.policy.pitt.edu">https://www.policy.pitt.edu</a>.

For specific questions related to this Policy, please contact the Office of Research Protections at: <a href="mailto:icoi@pitt.edu">icoi@pitt.edu</a>.

### VII. Related Authorities

University Policy AO 25 (formerly 03-01-01), Non-Cash Gifts

University Policy AO 45, Gift Acceptance and Naming

University Policy AO 46, Gifts that Support Projects

University Policy CS 09 (formerly 02-06-01), Outside Employment

<u>University Policy FN 06 (formerly 05-02-02)</u>, Conflict of Interest and Procurement Relationships Policy

University Policy RI 01 (formerly 11-01-03), Conflict of Interest for Research