



University of Pittsburgh Institutional Conflict of Interest Policy Committee Charter

I. Preamble

This body is called the Institutional Conflict of Interest Policy Committee (“Committee”). It is authorized by the Chancellor and will serve at the Chancellor’s discretion. The Chancellor has authorized the Senior Vice Chancellor for Research (“SVC-R”) to direct the operations of this Committee, consistent with the terms of this Charter. This Charter outlines the purpose, relevant background, scope, responsibilities, composition, and operations of the Committee, as well as the review process for any proposals generated by this Committee.

This document should be read in conjunction with Policy AO 01, Establishing University Policies, and all other applicable University policies, protocols, and procedures.

II. Purpose

The Committee is created for the purpose of proposing a new University Policy, as well as documents that support its implementation, which will govern potential Institutional Conflicts of Interest (“ICOI”) at the University of Pittsburgh (“University”).

III. Background

Guidance from the Department of Health and Human Services Office of the Inspector General provides, “institutional conflict may arise when an institution’s own financial interests (e.g., royalties, equity, stockholdings, and gifts) or those of its senior officials pose a risk of undue influence on decisions involving the institution’s research.” An ICOI may also affect or appear to affect the education, clinical care, business transactions, or other activities of the institution. Currently, the University does not have a Policy governing ICOI.

As an accredited member of the Association for the Accreditation of Human Research Protection Programs (“AAHRPP”), the University follows rigorous standards for ethics, quality, and protections for human research. A new University Policy on ICOI would be consistent with these AAHRPP recommended standards and would reflect best practices among peer and aspirant institutions.

IV. Scope and Authority

The Committee will recommend a University Policy on ICOI, and supplemental documents (e.g., guidelines and procedures). In doing so, the Committee’s deliberations must address the following topics:

- **Definitions and Terms.** Define what constitutes an institutional conflict of interest, including financial interests that could affect research or decision-making at the institutional level.
- **Scope.** Review and consider the scope of other institutions' policies on ICOI, including the types of investments covered under such ICOI policies, and propose a recommended Policy scope for the University.
- **Guidelines and Implementation.** Establish a consistent and uniform process for the University to identify, document, and address institutional conflicts through case-specific conflict management plans, including establishing a process for reporting the conflict and conflict management plan in cases where reports are required by relevant federal regulations or contractual obligations.

V. Responsibilities

As provided above, the Committee is created to propose an ICOI Policy. To perform this function, the Committee has the responsibility to:

- Review and consider terms and procedures used in other University Policies that could inform the drafting of an ICOI Policy, including Policy RI 01, Conflict of Interest for Research; Policy RI 02, Consultant Conflict of Interest; Policy FN 06, Conflict of Interest and Procurement Interests; Policy ER 02, Conflict of Interest for Designated Administrators and Staff; Policy RI 04, Organizational Conflict of Interest; and Policy ER 03, Conflict of Interest for University of Pittsburgh Employees.
- Research and discuss best practices that govern ICOI at peer and aspirant institutions, including a benchmarking of relevant policies.
- Consult with relevant University stakeholders, including the Office of the Chief Financial Officer, in determining the scope of a proposed Policy on ICOI.
- Research and discuss relevant federal guidance, including guidance provided by the Department of Health and Human Services, as well as accreditation standards provided by the AAHRPP.
- Incorporate or address any applicable requirements imposed by local, state, and federal laws and regulations.
- Recommend a draft Policy for review pursuant to the process described in Section VIII below and consider feedback received during that review; and
- Recommend a draft procedure or other supporting documents for review pursuant to Section VIII below that is needed for the effective and efficient implementation of the proposed Policy.

It is expected that the Committee will work in confidence to have full and frank discussion of all options. Individual members should maintain the deliberations of the Committee confidential and are expected to not discuss the content of the Committee's deliberations outside of the

Committee, unless authorized to do so by the Committee. The broader community will have an opportunity to consider the Committee's proposals pursuant to the Process described in Section VIII below.

VI. Composition

This Committee, at the direction of the SVC-R, will be chaired by **Bill Yates**, Vice Chancellor for Research Protections. The Committee will include the following members:

1. **Mark Anderson**, Executive Director, Enterprise Risk Management
2. **Tim Billiar**, Distinguished Professor of Surgery; Executive Vice President and Chief Scientific Officer for UPMC; Associate Senior Vice Chancellor For Clinical Academics, University of Pittsburgh Health Sciences; Associate Medical Director, UPMC International and Commercial Services Division
3. **Alex Ducruet**, Director, Licensing and Intellectual Property
4. **Laurel Gift**, Assistant Vice Chancellor for Compliance, Investigations, and Ethics
5. **Carolyn Hoyt**, Vice Chancellor for Advancement Services
6. **Margaret Hsieh**, Associate Professor of Emergency Medicine; Associate Chief, ED Staffing, UPMC Presbyterian and UPMC Shadyside
7. **Michele P. Jegasothy**, Corporate Secretary & Senior Associate Counsel, UPMC
8. **Maureen Lichtveld**, Dean of Graduate School of Public Health
9. **Lisa Parker**, Professor of Human Genetics; Director, Center for Bioethics & Health Law
10. **Steve Reis**, Director, Clinical and Translational Science Institute; Associate Senior Vice Chancellor for Clinical and Translational Research, Health Sciences; Distinguished Service Professor of Medicine
11. **Shipla Sant**, Associate Professor, Dept. of Pharmaceutical Sciences and Bioengineering; Co-Chair, Senate Research Committee
12. **Lu-in Wang**, Vice Provost for Faculty Affairs
13. **Craig Wilcox**, Professor of Chemistry; Research Integrity Officer; Chairman, Conflict of Interest Committee

Tyler Tenney, Policy Specialist, will help facilitate and support the Committee on behalf of the Office of Policy Development and Management.

Jennifer Seng, Assistant Vice Chancellor and Deputy Chief Legal Officer, will support the Committee on behalf of the Office of University Counsel.

VII. Operations

The Committee will meet bi-weekly or more frequently as circumstances dictate, until the work set forth above is complete. The Committee's proposed Policy on ICOI will be submitted to the SVC-R by February 2022. The SVC-R may ask for interim status reports.

After the SVC-R's review is complete, the draft Policy will be submitted to the Policy Office to coordinate its review consistent with Policy AO 01.

VIII. Proposed Policy Review Process

The review process for the Committee's recommended Policy is as follows:

- University comment period;
- Council of Deans;
- University Senate Research Committee;
- Faculty Assembly;
- University Senate Council; and
- Administration Leadership.

The Committee will coordinate with the Policy Office to consider feedback provided throughout this process.

Once this review process is complete, the proposed Policy will be sent to the Policy Office for review and submission to the Chancellor in accordance with Policy AO 01.

IX. Amendment

Any amendments to this Charter must be made in accordance with Policy AO 01 and receive the approval of the Chancellor or designee.

The Committee shall expire on the publication of a new University Policy that governs ICOI, unless otherwise directed by the Chancellor.