

**UPMC
POLICY AND PROCEDURE MANUAL**

POLICY: HS-EC1701*
INDEX TITLE: Ethics & Compliance

SUBJECT: Conflicts of Interest in Clinical Research
DATE: February 14, 2022

I. POLICY

A. General

It is UPMC’s Policy to preserve integrity and independence in the exercise of professional and leadership judgment at UPMC. Conflicts of Interest can compromise such integrity and independence if not identified, assessed, and either eliminated or appropriately managed. Preserving such integrity and independence in clinical research studies conducted on UPMC premises or under UPMC oversight (“Research”) is essential to protect the safety and well-being of human subjects and the integrity of the study data and results. Therefore, all Research Team Members have a duty at all times to fulfill their obligations to UPMC and otherwise to conduct Research in an impartial and unbiased manner, in the best interests of UPMC and the human subjects, and in strict compliance with this Conflicts of Interest in Clinical Research Policy.

The Ethics and Compliance Committee of the UPMC Board of Directors (the “Committee”) has the ultimate responsibility for implementation, compliance monitoring, and enforcement of this Policy. The Committee may delegate responsibilities to the Chief Legal Officer, Chief Compliance Officer, UPMC Office of Sponsored Programs and Research Support (OSPARS), and such other staff as it deems appropriate. The Committee will also from time to time adopt changes to this Policy and adopt procedures and guidelines that supplement and are consistent with those set forth in or required by this Policy and related policies, as it considers necessary and appropriate to fulfill its charge.

All Research Team Members shall cooperate with the Committee and its delegates in the administration and enforcement of this Policy and such related policies, procedures, and guidelines.

Links to policies referenced within this policy can be found in Section VIII.

II. PURPOSE

The purpose of this Policy is to set forth the study-specific responsibilities of Research Team Members with respect to disclosing, identifying, and documenting

Interests in and with other organizations or individuals that fund or sponsor Research or are otherwise interested in or affected by the outcome of Research at UPMC. This Policy is intended to supplement (not replace) any applicable state laws governing Conflicts of Interest applicable to charitable, nonprofit corporations and it is to be read in conjunction with other related UPMC policies, including but not limited to the Policy on Conflicts of Interest and Commitment – General Obligations (HS-EC1700) and the Policy on Conflicts of Interest and Interactions between representatives of Certain Industries and Faculty, Staff and Students of the Schools of the Health Sciences, and Personnel Employed by UPMC at all United States based locations (HS-EC1702). To the extent that other federal or state laws may impose more restrictive conflicts of interest standards, those laws shall control.

III. SCOPE

A. Entities Covered by the Policy

For purposes of this Policy, “UPMC” includes UPMC and all of its integrated affiliates, specifically including those noted below. Affiliates not integrated with UPMC are covered under this policy only to the extent specifically adopted by such affiliates.

[Check all that apply]

- | | |
|--|--|
| <input checked="" type="checkbox"/> UPMC Children’s Hospital of Pittsburgh | <input checked="" type="checkbox"/> UPMC Pinnacle Hospitals |
| <input checked="" type="checkbox"/> UPMC Magee-Womens Hospital | <input checked="" type="checkbox"/> UPMC Carlisle |
| <input checked="" type="checkbox"/> UPMC Altoona | <input checked="" type="checkbox"/> UPMC Memorial |
| <input checked="" type="checkbox"/> UPMC Bedford | <input checked="" type="checkbox"/> UPMC Lititz |
| <input checked="" type="checkbox"/> UPMC Chautauqua | <input checked="" type="checkbox"/> UPMC Hanover |
| <input checked="" type="checkbox"/> UPMC East | <input checked="" type="checkbox"/> UPMC Muncy |
| <input checked="" type="checkbox"/> UPMC Hamot | <input checked="" type="checkbox"/> UPMC Wellsboro |
| <input checked="" type="checkbox"/> UPMC Horizon | <input checked="" type="checkbox"/> UPMC Williamsport |
| <input checked="" type="checkbox"/> UPMC Jameson | <input checked="" type="checkbox"/> Divine Providence Campus |
| <input checked="" type="checkbox"/> UPMC Kane | <input checked="" type="checkbox"/> UPMC Lock Haven |
| <input checked="" type="checkbox"/> UPMC McKeesport | <input checked="" type="checkbox"/> UPMC Cole |
| <input checked="" type="checkbox"/> UPMC Mercy | <input checked="" type="checkbox"/> UPMC Somerset |
| <input checked="" type="checkbox"/> UPMC Northwest | <input checked="" type="checkbox"/> UPMC Western Maryland |
| <input checked="" type="checkbox"/> UPMC Passavant | |
| <input checked="" type="checkbox"/> UPMC Presbyterian Shadyside | |
| <input checked="" type="checkbox"/> Presbyterian Campus | |
| <input checked="" type="checkbox"/> Shadyside Campus | |
| <input checked="" type="checkbox"/> UPMC Western Psychiatric Hospital | |
| <input checked="" type="checkbox"/> UPMC St. Margaret | |

Provider-based Ambulatory Surgery Centers

- UPMC Altoona Surgery Center
- UPMC Children’s Hospital of Pittsburgh North
- UPMC St. Margaret Harmar Surgery Center
- UPMC South Surgery Center
- UPMC Center for Reproductive Endocrinology and Infertility
- UPMC Digestive Health and Endoscopy Center
- UPMC Surgery Center – Carlisle
- UPMC Surgery Center Lewisburg
- UPMC Pinnacle Procedure Center
- UPMC West Mifflin Ambulatory Surgery Center
- UPMC Community Surgery Center

Free-Standing Ambulatory Surgery Facilities:

- UPMC Hamot Surgery Center (**JV**)
- Hanover Surgicenter
- UPMC Leader Surgery Center (**JV**)
- UPMC Specialty Care York Endoscopy
- Susquehanna Valley Surgery Center (**JV**)
- West Shore Surgery Center (**JV**)

B. Individuals Covered by the Policy

This Policy applies to Research Team Members, which includes all individuals who from time to time conduct or participate in any clinical research on UPMC’s premises or under the oversight of UPMC (“Research”), provided that they are in a position to materially influence research, whether or not such research team members are employed by UPMC.

IV. WHAT IS A CONFLICT OF INTEREST? (Please refer to Section IV of [HS-EC1700](#) for definitions of various Conflicts of Interests.

V. DISCLOSURE AND IDENTIFICATION OF INTERESTS

The following requirements and procedures have been developed to enable UPMC to identify, evaluate, eliminate, or manage financial or associational interests that can compromise or create the appearance of compromising integrity and independence in the exercise of professional and leadership judgment in the context of a Research study.

A. Disclosure Obligations

All information disclosed by Research Team Members during the disclosure and review process described herein will be confidential, except as necessary to implement this Policy or as otherwise required by law. The following sets forth the disclosure requirements for all Research Team Members:

1. Initial Disclosure - Upon becoming a Research Team Member and prior to engaging in any research, each Research Team Member must immediately disclose all Individual Interests that he/she holds, or expects to hold in the near future, by completing a Conflicts Disclosure Form which may be accessed at www.mydisclosures.pitt.edu.

2. Annual Disclosure - All Research Team Members must disclose by April 15th of each year any Individual Interests that they currently hold, or expect in the near future to hold, in or with an entity that is sponsoring or funding the Research study and/or other third parties interested in or affected by the outcome of the study, by completing a Conflicts Disclosure Form.
3. Continuing Disclosures - If during the course of any given year a Research Team Member becomes aware of a new actual or potential or otherwise undisclosed Individual Interest, the Research Team Member must promptly and no later than within 30 days appropriately update their Conflicts Disclosure Form.
4. Confirmation of Accuracy of Disclosures Prior to Commencement of New Research - Within 45 days of the commencement of new Research, each Research Team Member shall access their Conflicts Disclosure Form and either update it as appropriate or confirm its accuracy as of that time. The principal investigator on a Research study or their delegate shall be responsible for ensuring that each Research Team Member has confirmed the accuracy of his or her disclosures and shall certify such confirmation by the Research Team Members on the application to conduct a Research study.

B. Maintaining and Querying the Watchlist to Track and Identify Interests

When processing an application for a Research study, the UPMC OSPARS or any other UPMC office that may process an application for Research shall query the Watchlist as described in HS-EC1700 as well as any disclosures made related to a specific research study to identify whether Interests exist that could give rise to a Conflict of Interest with respect to the applicable study.

Interests identified through these queries will be reported to the Executive Administrator and Clinical Supervisor of the department proposing the research, with a description of the proposed Research study, for evaluation pursuant to the procedures set forth in this Policy and other applicable UPMC policies, procedures and guidelines. In the event the Clinical Supervisor is the individual with the potential conflict, the interest will be reported to that individual's Clinical Supervisor

VI. REVIEW AND EVALUATION PROCESS

Using the information from the Conflicts Disclosure Form or Watchlist query, any supplemental disclosures made pursuant to this Policy and related policies, procedures, and guidelines, and any other reliable source of information, the Department will, either directly or through its delegates, investigate and assess all Interests implicated by a Research study, and will determine whether any such Interest gives rise to a

Conflict of Interest. If the Department reports to the Committee or its delegee that a contemplated transaction or relationship gives rise to a Conflict of Interest, then the UPMC OSPARS or other office within UPMC that may process an application for Research may not approve the Research study unless and until the Department or its delegates have completed the review and assessment, the Committee or its delegee have granted final approval, established a conflict management plan (where appropriate), and taken all such other steps as required by this Policy and other applicable UPMC policies and procedures. Conflict Management Plans will be subject to standards and guidelines adopted by the Committee. The key purpose of a Conflict Management Plan will be to prevent decision-making with respect to the approval and implementation of a proposed Research study from being influenced by a Conflict of Interest.

OSPARS policies, procedures, and guidelines are designed to promote independence and objectivity in the conduct of research and are, to the extent practicable, consistent with those of the University of Pittsburgh, as well as national standards. Any individual with a financial interest of \$20,000 or more in or from a trial sponsor during the 12-month period before a trial is proposed or anticipated during the 12-month period following such date, including any pre-trial activities, will be subject to a conflict management plan, which may include preclusion from being the principal investigator, consenting or enrolling subjects, and participating in analysis of data from the local trial. Individuals with a financial interest between \$15,000 and \$19,999 may be subject to a conflict management plan depending on the nature of their conflict of interest.

Research Team Members who wish to proceed with a proposed relationship may be asked by the Committee or its delegates to produce evidence to support the Committee's consideration. Any Research Team Member or member of the Committee who has a Conflict of Interest with respect to a proposed Research study must not be present during any meeting in which the Committee conducts its evaluation, except to answer questions of the Committee and to provide information the Committee needs for its deliberations. Such conflicted individuals will in no event be present during the deliberations and vote of the Committee. If any member of the Committee holds the Interest being considered by the Committee, then the Chairman of the Board of Directors will appoint one or more qualified individuals to take the place of the affected Committee member(s) and to serve on the Committee for the purpose of reviewing the matter. Any such reconstituted Committee will have all rights, authority, and obligations of the Committee. The Committee or its delegates will communicate its findings and recommendations to the IRB.

VII. VIOLATIONS OF THIS POLICY

Each Research Team Member has an obligation to report to the Chief Compliance Officer, a member of the Committee, and/or the Department Executive Administrator or Clinical Supervisor any situation s/he believes to be a violation of this Policy.

If the Committee or its delegates have reasonable cause to believe that a Research Team Member has failed to make a disclosure required by this Policy, including completing an annual disclosure or promptly updating a disclosure after an interest becomes known, or has otherwise failed to comply with this Policy, it/they will inform the Research Team Member of the basis for such belief and afford such person an opportunity to make the disclosure. If, after hearing the response of the Research Team Member and making such further investigation as may be reasonable and warranted in the circumstances, the Committee or its delegates determine that the Research Team Member has in fact failed to make the disclosure, it/they may take appropriate disciplinary action (e.g., removal of a director or officer from his or her position, termination of employment, ineligibility to participate in research studies, and sanctions under applicable medical staff bylaws).

Research Team Members are encouraged to contact OSPARS, the Chief Compliance Officer, the Chief Legal Officer, or their designees (conflicts@upmc.edu), regarding any questions concerning their obligations under this Policy.

VIII. POLICIES REFERENCED WITHIN THIS POLICY

[HS-EC1700 Conflicts of Interest – General Obligations](#)

[HS-EC1702 Policy on Conflicts of Interest and Interactions between representatives of Certain Industries and Faculty, Staff and Students of the Schools of the Health Sciences and Personnel Employed by UPMC at all Domestic Locations](#)

[HS-EC1703 Gift](#)

SIGNED: W. Thomas McGough, Jr.
Executive Vice President, UPMC and Chief Legal Officer

ORIGINAL: April 1, 2009

APPROVALS:
Policy Review Subcommittee: January 20, 2022
Executive Staff: February 14, 2022

PRECEDE: July 28, 2020

SPONSOR: Chief Compliance Officer, Office of Ethics and Compliance

*** With respect to UPMC business units described in the Scope section, this policy is intended to replace individual business unit policies covering the same subject matter. In-Scope business unit policies covering the same subject matter should be pulled from all manuals.**