I. POLICY/SCOPE

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, Executive Director of the 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. To the extent that other federal or state laws may impose more restrictive conflict of interest standards, and it is to be read in conjunction with other related UPMC policies, including but not limited to the Policy on Conflicts of Interest – 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 Domestic Locations (HS-EC1702).

III. SCOPE

A. Entities Covered by the Policy

For purposes of this Policy, “UPMC” includes UPMC and all of its managed or controlled affiliates. Affiliates not managed or controlled by UPMC are covered under this policy only to the extent specifically adopted by such affiliates.

B. Individuals Covered by the Policy

This Policy applies to Research Team Members, who include 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?

In general, a potential for a Conflict of Interest arises when UPMC or a Research Team Member holds an Interest that may compromise or have the appearance of compromising the integrity or independence of a Research Team Member’s or UPMC’s professional or leadership judgment. An Interest may include a Financial Interest (e.g., a compensation arrangement, ownership interest) or an Associational Interest (e.g., an uncompensated position on the board of directors or the scientific advisory board of an entity). The mere existence of such an Interest does not necessarily result in a Conflict of Interest. However, it is important that any such Interest is disclosed by the Research Team Member and evaluated by the Committee or its delegates before UPMC or a Research Team Member holding the Interest becomes involved in a decision or activity that could be biased by the Interest.

Conflicts of Interest fall in three principal categories: Individual Conflicts of Interest, Institutional Conflicts of Interest and Imputed Conflicts of Interest. As they relate to Research, these Interests are described below:

1. Individual Conflicts of Interest arise from Financial or Associational Interests held personally by a Research Team Member or a Research Team Member’s
Family Member\(^1\) in or with an outside entity or individual that funds or sponsors Research or is otherwise interested in or affected by the outcome of Research at UPMC.

2. Institutional Conflicts of Interest arise from Financial or Associational Interests held by UPMC itself, directly or indirectly, in or with an outside entity that funds or sponsors Research or is otherwise interested in or affected by the outcome of Research at UPMC.

3. Imputed Conflicts of Interest arise from direct or indirect Individual Financial or Associational Interests held by an Institutional Official that funds or sponsors Research or is otherwise interested in or affected by the outcome of Research at UPMC. These Interests are imputed to UPMC by virtue of the Institutional Official’s responsibilities and duties within UPMC. Institutional Officials include individuals who hold positions of influence at UPMC. They include members of UPMC boards of directors, board and corporate officers, certain UPMC employees, and non-employed members of the UPMC medical staff who also either: hold paid or unpaid UPMC medical administrative positions such as chairs of UPMC clinical department, section and division chiefs, directors of special care units, directors of research or individuals who otherwise direct or materially influence research; have UPMC procurement responsibility or the authority effectively to recommend such procurement; have UPMC fundraising responsibility or the authority to influence fundraising; or have UPMC business responsibility or authority to influence business or investment transactions, for example. Depending on the circumstances, Research Team Members may qualify as Institutional Officials.

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. **Disclosures Obligations**

All information disclosed by Research Team Members during the disclosure and review process described herein will be confidential, except as necessary to

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\(^1\) Includes: (1) a Research Team Member’s spouse and children; and (2) the following persons if they live with the Research Team Member, the Research Team Member manages their financial affairs, or the Research Team Member is aware without inquiry that they hold the interest or position in question: (a) the Research Team Member’s parents, siblings, grandchildren, and their spouses; and (c) the Research Team Member’s spouse’s parents, siblings, children, grandchildren, and their spouses.
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, each
   Research Team Member must disclose all Individual Interests that he/she
   holds, or expects to hold in the future, in the manner outlined in UPMC’s
   on-line Conflict of Interest Disclosure Statement, which may be accessed
   through My Hub.

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, in the manner outlined in the
   Conflict of Interest Disclosure Statement, which may be accessed through
   the My Hub.

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 appropriately update the Conflict of Interest Disclosure
   Statement.

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 Conflict of Interest Disclosure
   Statement and either update it as appropriate or confirm its accuracy as of
   that time. The principal investigator on a Research study 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**

1. **Maintaining the Watchlist to Track Interests Established and Disclosed**

   All Individual Interests disclosed pursuant to this Policy will be input into
   or mapped to the electronic Watchlist that the UPMC Committee uses as
   the primary tool used to track and cross-check all types of Interests for
   purposes of identifying, assessing and managing potential Conflicts of
   Interest.

2. **Querying the Watchlist to Identify Interests**

   In the course of processing an application for a Research study, the
   UPMC OSPARS or such other office within UPMC that may process an
application for Research shall query the Watchlist of Interests maintained by the Committee and its delegates to identify whether Individual or Institutional Interests exist that could give rise to an Individual, Institutional or Imputed Conflict of Interest with respect to the applicable study. For purposes of illustration, the Watchlist is queried to (a) identify an Individual Interest held by the chair of the clinical department that will be involved in approving or conducting the research; or (b) identify an Institutional Interest held by UPMC itself in a commercial entity that is sponsoring or funding the study as a result of UPMC having received major charitable gift from the entity or UPMC being a co-investor in a joint ventures or other investment transactions.

Interests identified through this query will be reported to the Chief Compliance Officer 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.

VI. REVIEW AND EVALUATION PROCESS

Using the information from the Watchlist query and any supplemental disclosures made pursuant to this Policy and related policies, procedures and guidelines, the Committee 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 Committee or its delegates determine 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 Committee or its delegates has completed the review and assessment, granted final approval, established a conflicts management plan (where appropriate), and taken all such other steps, as required by this Policy and other applicable UPMC policies and procedures. Conflicts Management Plans will be subject to standards and guidelines adopted by the Committee from time to time. The key purpose of a Conflicts 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.

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 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 Director, the Chief Compliance Officer or a member of the Committee 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 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 the Executive Director of OSPARS, the Chief Compliance Officer, the Chief Legal Officer, or their designees, 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

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

ORIGINAL:  April 1, 2009

APPROVALS:
          Executive Staff:  October 26, 2012

PRECEDE:  October 10, 2011

SPONSOR:  Senior Vice President, UPMC and Chief Legal Officer

* 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.