

**Individual Conflict of Interest Oversight on the Penn State University College of  
Medicine/Penn State Milton S. Hershey Medical Center Campus**

POLICY'S INITIAL DATE: July 1, 2001

POLICY APPROVAL DATE: September 1, 2007

**THIS VERSION EFFECTIVE: June 27, 2014**

Purpose:

To create a single process for clarifying and strengthening the reporting, reviewing, managing or reducing significant financial or business interests (conflicts of interest) by faculty and staff on the unified campus.

Oversight:

The oversight process for individual conflicts of interest on the unified Penn State University College of Medicine/Penn State Milton S. Hershey Medical Center campus is described below:

1. Penn State University policies requiring disclosure of significant financial or business interests prevail. In order to establish a consistent definition of conflicts of interest, the College of Medicine (COM) and the Penn State Milton S. Hershey Medical Center (PSHMC) will both adhere to the definitions of Conflict of Interest and Significant Financial Interest as stated in Penn State Policy RA20.
2. Oversight of conflicts of interest at the Penn State COM and PSHMC is provided by the campus Conflict of Interest Review Committee (CIRC) per Penn State Policy RA20.
3. The Dean of the College of Medicine and the Executive Director of the PSHMC have ultimate responsibility for monitoring the activities of COM and PSHMC personnel, respectively.

CIRC Membership

1. The Conflict of Interest Review Committee (CIRC) membership will reflect representation of the Penn State COM and the PSHMC. Members are appointed by the Dean of the COM and Chief Executive Officer of the PSHMC and include:

Voting members

Committee Chair (a faculty member appointed by the Dean)

Committee Vice Chair

Six COM faculty members, three physicians and three basic scientists, with experience in clinical and basic science research and/or technology transfer.

Community Representative

Non voting members *ex officio*

Vice Dean for Research and Graduate Studies in the COM

The Treasurer of the PSHMC or delegate

The Associate Dean of Technology Development

The Associate Dean for Research  
A representative of the Human Subjects Protection Office (HSPO)  
The Chief Compliance Officer of the PSHMC  
The Campus Conflict of Interest Specialist

2. The faculty members and alternates are appointed to the CIRC for staggered three-year terms.
3. In order to provide continuity in CIRC decisions, voting members are expected to attend a majority of the scheduled CIRC meetings in each academic (fiscal) year.

Conflict of Interest Disclosure:

1. The following persons are required to submit a conflict of interest disclosure:
  - a. All persons holding paid faculty appointments in the COM, other than incidental, occasional, or emeritus appointments
  - b. Other persons who are in administrative positions within PSHMC or the COM who, by virtue of their position, may be at risk of financial conflict of interest. (see Appendix A)
  - c. Other persons, including students, who, as defined in RA-20 and designated by the study's principal investigator, have the ability to make independent decisions related to the design, conduct or reporting of a University research project, but not including individuals who perform only incidental or isolated tasks related to the project.
  - d. Undergraduate, medical student, or resident research projects which are not externally funded, are not published, and completed as part of their educational curriculum do not routinely require conflict of interest disclosure. However, if the student meets the definition of an "investigator", discloses a related financial interest on an IRB submission, or if the student, his/her faculty mentor, or the conflict of interest program knows of student financial interests related to the research, this exception does not apply and the financial interests should be disclosed and managed as required by RA 20.
2. These persons, regardless of their position, are required to submit a conflict of interest disclosure statement at least annually, and to update this disclosure when any significant changes (per Penn State University Policy definitions) occur during the year. All disclosures must be submitted to Penn State University via the University's electronic [Conflict of Interest System \("COINS"\)](#).
3. All research projects involving patients/human subjects require disclosure of **any relevant** financial or business interests, regardless of the amount of the interests and even if the project is not sponsored by a third party. No *de minimus* will apply for research involving human subjects performed at the College of Medicine.
4. Disclosure reports will be filed in accordance with Penn State Policy RA20 and PSHMC Policy A60 HAM, and review will be conducted according to this policy and Standard Operating Procedures established by CIRC.

### Conflict of Interest Review Process:

1. The CIRC will meet on a regularly scheduled basis, but at least monthly. The Chair may call additional meetings *ad hoc* as needed. Employees with issues coming before CIRC are invited, encouraged, but not required (except in cases of non-compliance) to attend meeting of CIRC to discuss potential FCOI issues with which they are involved.
2. CIRC Recommendations in any individual case will be by majority vote of all voting members present
3. One-half of the voting members (5) will constitute a quorum.
4. CIRC review and recommendations in an individual case may be made by email if there is no objection from any voting member. If there is an objection, the matter will be considered at the next regularly scheduled meeting.
5. If the person disclosing conflict of interest is a member of the CIRC, that person shall be recused from the committee's consideration of the conflict.
6. PSU policies prevail in the case of perceived discrepancies with other policies on the unified campus.
7. The Penn State COM and PSHMC supports the spirit of the Sarbanes-Oxley Act of 2002 through the establishment of independent audit policies and procedures for the PSHMC.

### **APPENDIX A**

The following individuals must disclose conflicts of interest on an annual basis or in "real-time" if their situation changes\*:

CEO and Dean of the College of Medicine

Executive Director of the PSHMC

All persons reporting directly to CEO and Dean of the College of Medicine and/or

Executive Director of the PSHMC, including Basic Science Academic Chairs, Clinical Academic Chairs, Institute and Center Directors

Associate Vice President for Finance and Business

Treasurer of the PSHMC

Chief Financial Officer of the PSHMC

Chief Compliance Officer for the PSHMC

Clinical department administrators, Clinical Division Directors, and Center Directors

All materials management/purchasing department employees

Associate Dean for Research

Associate Dean for Technology Development

All members, including members *ex officio* of the Conflict of Interest Review Committee

\* In addition to the annual COI disclosure statements, the above individuals must submit updated COI disclosure statements to reflect any significant changes that occur during the year