

Penn State College of Medicine
Standards of Practice Regarding Disclosure of Conflict of Interest

Updated November 6, 2015, Effective: August 24, 2012

These standards incorporate within them the requirements of Penn State University policies regarding Conflict of Interest, including policy RP 06. The intent of this document is to clarify and apply RP 06 to meet the needs of the College of Medicine. Standards established by the College of Medicine may modify, but do not replace, those established by Penn State University as a whole. The provisions **in bold** apply to the College of Medicine only, while the remainder of the provisions apply to all of Penn State University.

I. Conflict of Interest Disclosure

A. Who must disclose?

1. Investigators as defined by RP 06: “Any University faculty, employee, or student who has 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.”
 - a. Students include undergraduate, graduate, and postgraduate students, residents, and fellows
 - b. Any employee named as an investigator or co-investigator on the study protocol or grant application would be considered an “investigator” by definition for disclosure purposes
 - c. A study’s principal investigator would have the responsibility to identify and name as a co-investigator in COINS any additional employees or students who they believe meet the definition of “investigator” for conflict of interest purposes, for any funded or unfunded study conducted as part of their University employment
 - 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 RP 06.

- 2. IN ADDITION, all paid College of Medicine or Penn State Milton S. Hershey Medical Center employees with a College faculty appointment as determined by the Office of Faculty Affairs**
 - a. Including full time and part time employees**
 - b. Not including unpaid affiliate faculty members with prefix or suffix titles**
 - c. Not including occasional or PRN employees (< 0.1 FTE), or those who have a primary job elsewhere**
- 3. The following designated administrators:**
 - a. CEO and Dean of the College of Medicine**
 - b. Executive Director of the Penn State Milton S. Hershey Medical Center**
 - c. All persons reporting directly to CEO and Dean of the College of Medicine and/or**
 - d. Executive Director of the Penn State Milton S. Hershey Medical Center, including Basic Science Academic Chairs, Clinical Academic Chairs, Institute and Center Directors**
 - e. Treasurer of the Penn State Milton S. Hershey Medical Center**
 - f. Chief Financial Officer of the Penn State Milton S. Hershey Medical Center**
 - g. Chief Compliance Officer for the Penn State Milton S. Hershey Medical Center**
 - h. Clinical department administrators, Clinical Division Directors, and Center Directors**
 - i. All materials management/purchasing department employees**
 - j. Associate Dean for Research**
 - k. Associate Dean for Technology Development**
- 4. Retired Faculty Members or Faculty members who are no longer Penn State employees**
 - a. If a retired faculty member, or one who is no longer a Penn State employee, is listed as an investigator or co-investigator on a Penn State grant, or an investigator on a Penn State study protocol, they may**

be required to disclose their significant financial interests in COINS IF:

- i. The faculty member identifies that they have a related significant financial interest to disclose (SFID) on the study's PIAF or "blue sheet"
 - A. However, if the retired faculty member does not identify that they have an SFID on the PIAF or "blue sheet" then no further disclosure in COINS is required.

B. What must be disclosed?

1. All Significant Financial Interest (SFI) related to institutional responsibilities.
2. SFI is defined as financial interests consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or partner and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities.
 - a. Publicly Traded Entity – *a significant financial interest in a publicly traded entity exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure plus the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. For the purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;*
 - b. Non Publicly Traded Entity – *a significant financial interest exists when the Investigator (or the Investigator's spouse or partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest) in the entity or if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or.*
 - c. Intellectual Property (IP) Rights and Interest – upon receipt of income related to such rights and interests that exceed \$5,000 in the previous 12 months
 - d. **Human Subjects Research or Penn State related purchasing authority - Any financial interest in a for-profit entity or any intellectual property, regardless of income generated, if related to**

human subjects research conducted at Penn State or to Penn State purchasing authority.

- e. Travel – the occurrence of any travel of the investigator, their spouse/partner, or dependent children, for the last year from any one entity, exceeding \$5,000 in the 12 months preceding disclosure, which is reimbursed or sponsored (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available)
3. EXCEPTIONS: Financial interests that do not require disclosure include:
- a. Salary, royalties, or other remuneration paid by the University (this includes any intellectual property rights assigned to the University and any agreements to share in royalties or licensing revenue related to these intellectual property rights);
 - b. Income from investment vehicles, such as mutual funds and retirements accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
 - c. Additional EXCEPTIONS: for faculty members who are also investigators as defined above, all of the following are exempt from disclosure, as described in NIH 2011 regulations.
 - i. Income from seminars, lectures, or teaching engagements sponsored by a U.S. Federal, state, or local government agency, an Institution of higher education as defined at 20.U.S.C.1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
 - ii. Income from service on advisory committees or review panels for a U.S. Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
 - iii. For any faculty members who are also investigators as defined above, income or travel reimbursement from any not for profit entity not specified in i and ii above (including professional and 501(c)(3) organizations) does

need to be disclosed, though reimbursed travel costs for family members do not.

- d. **Additional EXCEPTIONS: for faculty members NOT considered investigators, all of the following are exempt from disclosure**
 - i. **Any income for services provided to, or travel expenses from, non-profit entities including**
 - 1. **a U.S. Federal, state, or local government agency**
 - 2. **an Institution of higher education as defined at 20.U.S.C.1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education**
 - 3. **A non-profit 501(c)(6) professional association which is not a subsidiary of a for profit entity**
 - 4. **A charitable 501(c)(3) organization**

C. When must disclosures be completed?

- 1. A new disclosure or an update of an existing disclosure is required for all investigators, faculty members, and designated administrators within 30 days of:
 - a. Beginning employment with the University **or the Penn State Milton S. Hershey Medical Center** in a job requiring disclosure
 - b. When an application for Research funding is submitted, whenever the proposed Research is related to any new or previously disclosed SFI.
 - c. When an SFI is acquired with a new entity not already included in the individual's current COINS disclosure
 - d. In cases of non-compliance
 - e. At least annually
- 2. In addition, for any employee who is defined as an investigator ,
 - a. Any significant financial interests must be disclosed within 30 days of the date they were acquired or discovered, or before the expenditure of any funds received from PHS, even if prior interests in that entity have been disclosed
 - b. For Travel, this would mean within 30 days of the date the travel is completed
- 3. For the College of Medicine, the period for required annual disclosures and annual conflict of interest training will ordinarily

be January 1 – April 30. Changes to this period may be made each year to accommodate Federal and Penn State policy changes or needs for COINS system changes. All disclosers will be notified of these changes by January 1 of each calendar year.

D. To whom must disclosures be submitted?

1. All College of Medicine disclosures should be submitted via the electronic COINS conflict of interest disclosure system. (coins.psu.edu)
2. Responsibility for Conflict of Interest policies, disclosures, reporting, and management at the College of Medicine rests with the College's Conflict of Interest Review Committee (CIRC)
3. Contact:
 1. Marisa Klein, Conflict of Interest Specialist C3520A, Phone Number 717-531-0003 ext. 283526, Email – mklein1@hmc.psu.edu

E. What ordinarily constitute "Institutional Responsibilities"?

1. Institutional Responsibility (ies) include an Investigator's professional responsibilities on behalf of the University. Examples include:
 - i. research (regardless if funded or not);
 - ii. research consultation;
 - iii. teaching;
 - iv. outreach;
 - v. professional practice (e.g. clinical medical practice, veterinarian practice, practice of law, etc.);
 - vi. University committee memberships (e.g. Faculty Senate, Purchasing Committees); and
 - vii. service on University panels, such as the Institutional Review Board ("IRB") or Data or Safety Monitoring Boards.

F. Penalties for Failure to Disclose

1. Additional COI Training may be required
2. Referral to the IRB if, as a result of the finding of noncompliance, any part of the noncompliance or remedial measures is/are related to the protection of human participants;
3. *Suspension of funds on sponsored research projects pending resolution of the noncompliance matter;*
4. Reporting of the noncompliance to external agencies where required, such as research sponsoring agencies.
5. If serious or continuing noncompliance is found to exist, it may rise to the level of research misconduct as defined in Penn State policy RP 02, and will be handled according to the requirements of policy RP 02 or any other pertinent policies.

6. If necessary, suspension of University **or the Penn State Milton S. Hershey Medical Center** employment without pay, or termination of University employment

II. Conflict of Interest Training

- A. Conflict of Interest training required by NIH Regulations shall inform each Investigator of Penn State Policy, the Investigator's responsibilities regarding disclosure of his/her SFI, and of the federal regulations pertaining to FCOI. FCOI Training is required of College of Medicine Investigators, faculty members, and designated administrators under the following circumstances:
 1. When hired into a position requiring disclosure by the institution
 2. Every three years thereafter
 3. When COI Policies change (does not include changes in these Standards of Practice)
 4. When the University finds that an Investigator is not in compliance with this Policy or with his/her FCOI Management Plan.
- B. This training is ordinarily included as part of the COINS Annual Disclosure process

III. Process for Public Disclosure of Conflicts of Interest Information (Applicable to PHS Investigators and PHS sponsored studies Only)

- A. Public disclosure of conflicts of interest of individual employees of the College of Medicine or **Penn State Milton S. Hershey Medical Center** will be made only, as required in Federal PHS regulations, for conflicts of interest involving studies funded by the Public Health Service (PHS)

Requests for Publicly Accessible information regarding Conflicts of Interest in PHS-sponsored Studies should specify the full name of the individual and/or the study for which information is requested and be made in writing either using the form available on the Office of Administration website or via email to:

COI Program – Public Accessibility Request
500 University Drive
PO Box 850
Mail Code: H162
Hershey, Pennsylvania 17033
COIProgram@hmc.psu.edu

The COI program may not be able to provide public information if the requestor does not request information regarding a specific employee or employees or a specific funded study or studies.

Answers to questions or further information can be obtained via e-mail at: COIProgram@hmc.psu.edu

COI Program website:

<http://www.pennstatehershey.org/web/administration/public-disclosure>

B. The Conflict of Interest staff will respond via e-mail or in writing to anyone requesting this information within 5 business days of receipt by the COI Program, for Financial Conflict of Interest involving PHS studies performed at PSHMC.

i. The requestor will receive a letter from the COI program either providing the public information or specifying one of the following reasons it could not be provided: 1) the individual for whom information is requested is not a current PSHMC/COM employee; 2) the individual for whom information is requested is not a PHS funded investigator or the study requested is not funded by PHS; and/or 3) the study for which information is requested was not performed at Penn State Hershey.

C. The information to be made public will include the following:

- ii. The Investigators' name
- iii. Investigators' title and role with respect to the research project;
- iv. Name of the entity in which the *significant financial interest* is held;
- v. Nature of the *significant financial interest*; and
- vi. Approximate dollar value of the *significant financial interest* or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

If the investigator has no applicable conflict of interest, that information will be provided as well.

D. The investigator will be copied on this response.

III. These standards are in compliance with:

[Title 42 Code of Federal Regulations \(CFR\), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought](#)

[Title 45 Code of Federal Regulations \(CFR\), Part 94, Responsible Prospective Contractors](#)

[Title 21 Code of Federal Regulations \(CFR\), Part 54, Financial Disclosure by Clinical Investigators](#)