

# Disclosure and Management of Significant Financial Interests at Penn State Training (“SFI Training”)



## Introduction

Research at Penn State is wide-ranging and multifaceted, and the benefits of that research are similarly diverse. In addition to advancing basic understanding and knowledge, research findings and ideas can often be used in development of products and applications that may directly benefit society. This kind of development can result in financial gain for the investigator and the institution, which in turn provides an incentive for further research and development. Because of this, these activities are encouraged by the University and the federal government. However, care must be taken to ensure that the multiple interests of the investigator (as a researcher, a teacher, a mentor, an employee, and a businessperson, for example) do not come into conflict.

Financial interests with or in entities outside the University are not inherently wrong, but must be managed in a way that ensures the objectivity of the University research and teaching process, the safety of human research participants, and protects the reputations of researchers, faculty, and Penn State itself. This brief training module will provide information to enable investigators to properly disclose financial interests as required by our federal sponsors and Penn State policy. More detail and additional resources can be found by using the links at the end of the module.

# SFI Training

## How does the process work?

Penn State has a policy (Policy RP06 Disclosure and Management of Significant Financial Interests), which requires disclosure of financial interests that meet the definition of “significant financial interests”. The policy is based on regulations implemented by the federal government in 1995 and revised in 2011. Penn State’s policy applies to all investigators, defined as any

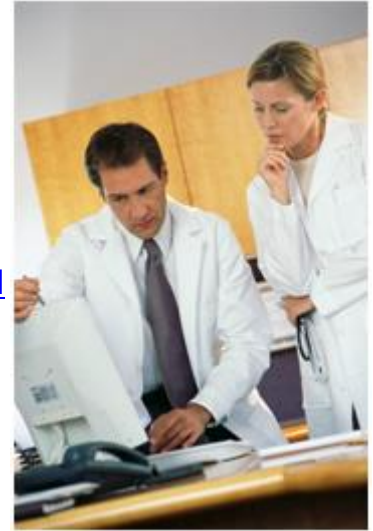


individual, regardless of title or position, who has the ability to make independent decisions related to the design, conduct, or reporting of University research, but not including individuals who perform only incidental or isolated tasks related to a University research project. The policy specifies that all investigators must disclose their significant financial interests to Penn State’s Conflict of Interest Official annually, and within 30 days of discovering or acquiring the financial interest. The Conflict of Interest Official will determine if those interests could directly and significantly affect the design conduct, or reporting of research. If so, the significant financial interest may present a conflict (or the appearance of a conflict). Sometimes additional information is needed from the investigator, and the Conflict of Interest Committee may become involved in making the determination. If a financial conflict of interest is found to exist, a management plan will be developed with the investigator to minimize the conflict. The following sections of this module describe what investigators need to know, and what actions they need to take, under Penn State’s policy.

## Special note for the Penn State Hershey College of Medicine

Because of the widely-publicized potential for conflicts of interest in medical practice and education, the Penn State Hershey College of Medicine has an additional requirement that all full-time and part-time College of Medicine faculty and designated administrators and staff disclose significant financial interests, regardless of whether or not they design, conduct, or report research. Therefore, the term “investigator,” used throughout this training module and on the COINS disclosure form, includes all faculty members and designated administrators at the College of Medicine, as well as students, fellows, and staff involved in research.

However, College of Medicine faculty members, administrators and investigators may have more or less disclosure requirements than the federal government or Penn State policy. Thus, before completing a financial disclosure, College of Medicine and M.S. Hershey Medical Center employees should consult the College's Standard Practices for Conflict of Interest Disclosure on the College's Conflict of Interest website at <http://www.pennstatehershey.org/web/administration/home/conflict/disclosure>.



## SFI Training

### What do I need to know?

As a Penn State investigator, you have a number of responsibilities regarding disclosure of significant financial interests.

- You should be aware of the relevant Penn State and federal policies regarding disclosure of significant financial interests. Penn State's policy is described in this training module, and federal policy can be found [here](#). Additional information can be obtained by contacting [coistaff@psu.edu](mailto:coistaff@psu.edu), or (for the College of Medicine) [COIProgram@hmc.psu.edu](mailto:COIProgram@hmc.psu.edu).



- You should know what is considered a Significant Financial Interest (SFI). A financial interest is anything of monetary value (whether that value can be easily determined or not), that belongs to the investigator, or the investigator's spouse or partner, or dependent children. The financial interest becomes significant if it meets ANY of the following definitions:
  - You received income from a publicly-traded entity during the 12 months prior to disclosure that (in combination with the value of any equity interest in the entity) exceeds \$5,000.



- You hold ANY equity interest in a non-publicly traded entity, OR you received more than \$5,000 income from a non-publicly traded entity during the 12 months prior to disclosure.
- You received income from intellectual property rights and interests (such as patents, copyrights, royalties, licensing fees) exceeding \$5,000 during the 12 months prior to disclosure.
- You received reimbursed or sponsored travel exceeding \$5,000 from an entity during the 12 months prior to disclosure.

- SFI does NOT include:
  - Travel that is reimbursed or sponsored by a federal, state, or local government agency in the United States, an American Institution of higher education as defined at 20 U.S.C. 1001(a), an American academic teaching hospital, an American Medical Center, or a research institute that is affiliated with an American Institution of higher education does not need to be disclosed as an SFI.
  - Income of travel paid by the University or covered by a sponsored award through the University.
  - Income received from Penn State or the Penn State Research Foundation (PSRF), or intellectual property owned by PSRF.
- You must disclose this SFI if it appears to be *related to your institutional responsibilities*, which are the professional activities that you undertake on behalf of the University. Institutional responsibilities include (but are not limited to) research, teaching, outreach, professional practice, administration, and University committee memberships.
- All SFI and reimbursed or sponsored travel, and its relationship to funded or unfunded research, must be disclosed prior to an application for funding (if required by the sponsor) or (at the latest) before funds for related research will be released. Disclosure prior to application for funding to any Public Health Service agency is mandatory.



- With regard to reimbursed or sponsored travel, many Investigators receive travel that is paid directly on their behalf (sponsored) and are never aware of the actual cost. However, there is a \$5,000 de minimis for all travel disclosures. Therefore, if the amount is unknown, you should obtain the information or err on the side of caution and disclose the travel in your annual financial disclosure if you think it *could* exceed \$5,000. For example, you could reasonably conclude that two nights in a hotel would not exceed \$5,000 and does not require

disclosure, whereas a week-long, all expenses-paid trip overseas *may* exceed \$5,000 and should be disclosed. The actual cost of a trip is not required information in your disclosure of sponsored or reimbursed travel.

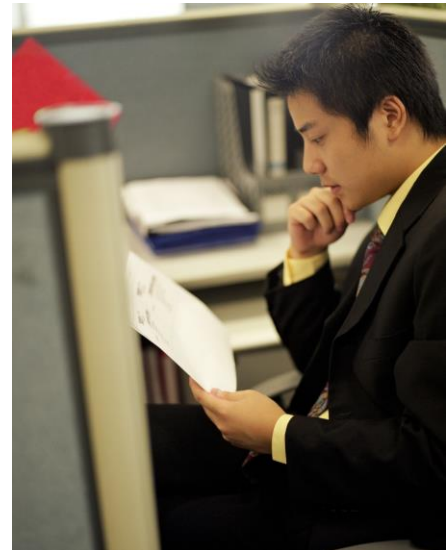
- More detailed information, including what is NOT considered an SFI, can be found in PSU Policy RP06. Some common examples of financial interests that do not need to be disclosed include: income from “pooled” investments (e.g. retirement accounts, mutual funds, and large brokerage accounts), and salary, royalties, or other remuneration paid by the University. [For College of Medicine employees: please see the “Special Note for the Penn State Hershey College of Medicine” on the previous page].
- If the Conflict of Interest Official or Committee finds noncompliance (either because you have failed to disclose as outlined in policy RP06 and in this training, or because you have failed to comply with the terms of your management plan), then you may be required to complete additional training; research funding can be withheld; and/or other appropriate enforcement mechanisms (including suspension/termination of employment) can be recommended to the proper University administrator.
- If your research involves human participants, your disclosure will also be evaluated to determine whether the SFI might adversely affect the participants. The Conflict of Interest Official will communicate its findings to the Institutional Review Board, who will not approve the research protocol until the financial interest review is complete and any necessary management plan has been implemented. The IRB has authority to add provisions to the management plan if deemed necessary for the protection of human participants.

## SFI Training

### What do I need to do?

Penn State requires you to complete a few simple steps in order to be compliant with University and federal regulations. By reviewing this training module, you're already part of the way there! The following steps may be completed through the COINS system:

- Complete this "*Disclosure and Management of Significant Financial Interests at Penn State*" training when you begin employment; at least once every four years; and on other occasions if specifically notified by University officials.
- Disclose any Significant Financial Interests within 30 days of acquiring or discovering the interest, by completing the financial disclosure form in COINS.
- Disclose any significant financial interests annually. Annual disclosures will be in addition to any disclosures within 30 days of new interests being acquired.
- Provide any additional information requested by Penn State's Conflict of Interest Official or Conflict of Interest Committee as they review your disclosure.
- If a Financial Conflict of Interest Management Plan is created for you, you may request changes to the plan within five days of receiving it. Once you have documented your agreement to the plan, any funding related to your SFI(s) will be released.
- If a management plan is in place, you are responsible for all its terms, conditions, and actions. You must respond to all requests for information and/or meetings regarding the University's responsibility to monitor compliance with the plan.
- Even if you have no financial interests that meet the definition of "significant financial interest", you still need to complete the required training and annual disclosure. In this case, you will only need to check the box on the disclosure form to certify that you have "no significant financial interest," and follow the submission instructions. (Note that College of Medicine investigators will need to answer a few additional questions before submission).





## Links

**COINS** Penn State's electronic Conflict of Interest System ([coins.psu.edu](http://coins.psu.edu))

### **Policies**

Penn State Policy RP06 Disclosure and Management of Significant Financial Interests:  
<http://guru.psu.edu/policies/RP06.html>

NIH regulations: [grants.nih.gov/grants/policy/coi/](http://grants.nih.gov/grants/policy/coi/)

### **Other Conflict of Interest training modules**

Office of Research Integrity: <http://ori.hhs.gov/ori-introduction-responsible-conduct-research>

Columbia University:  
[www.ccnmtl.columbia.edu/projects/rcr/rcr\\_conflicts/foundation/index.html](http://www.ccnmtl.columbia.edu/projects/rcr/rcr_conflicts/foundation/index.html)