

# Disclosure and Management of Significant Financial Interests at Penn State



## 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.

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## How does the process work?

Penn State has a [policy](#) (Policy RA20 Disclosure and Management of Significant Financial Interests), which requires disclosure of financial interests that meet the definition of “significant financial interests”. The policy based on regulations implemented by the federal government in 1995 and revised in 2011. Penn State’s policy applies to all investigators, defined as university



employees, regardless of title or position, who are responsible for the design, conduct, or reporting of research. 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 College of Medicine faculty and designated administrators and staff disclose significant financial interests as outlined above, 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.

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## 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 can be found [here](#). Additional information can be obtained by contacting [ORProtections@psu.edu](mailto:ORProtections@psu.edu), or (for the College of Medicine) [administrativeaffairs@hmc.psu.edu](mailto:administrativeaffairs@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 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 were reimbursed for travel or had ANY of your travel costs sponsored by an entity. Income and travel costs paid by other non-profit organizations, such as professional organizations, are considered an SFI.
- SFI does NOT include:

- Any income, reimbursement, or sponsorship of travel by a government agency, higher education institution, academic teaching hospital, medical center, or research institute affiliated with a higher education institution.
  - 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.



- More detailed information, including what is NOT considered an SFI, can be found in [PSU Policy RA20](#). Some common examples of financial interests that do not need to be disclosed include: income from “passive” investments (e.g. retirement accounts, mutual funds, and large brokerage accounts), and salary, royalties, or other remuneration paid by the University.
- If the Conflict of Interest Official or Committee finds noncompliance (either because you have failed to disclose as outlined in policy RA20 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 withholding wages or 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.

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## 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.
- Beginning in spring 2012, some investigators will begin annual disclosures, and by 2014 all investigators at Penn State will disclose annually. Annual disclosures will be in addition to any disclosures within 30 days of new interests being acquired. Please see the "Special Note on Implementation" below to determine when you need to begin annual reporting.
- 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 ([www.coins.psu.edu](http://www.coins.psu.edu))

## Policies

Penn State Policy RA20 Disclosure and Management of Significant Financial Interests: [www.research.psu.edu/policies/penn-state-policies/ra20](http://www.research.psu.edu/policies/penn-state-policies/ra20)

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: [ori.hhs.gov/education/products/RCRintro/c05/05c.html](http://ori.hhs.gov/education/products/RCRintro/c05/05c.html)

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)

## Special Note on Implementation for 2012-2014

Penn State is implementing the new annual disclosure requirement in stages, in order to manage the large number of investigators at the University. *Please note that immediate disclosure (within 30 days) of any newly acquired or discovered SFI is still required from all investigators.* The following schedule\* will be used to implement the annual disclosure requirements:

(2012) March and April: All investigators with active sponsored awards or pending proposals from a Public Health Service agency or the National Science Foundation must begin completing annual disclosures.

(2013) January - April: All investigators from the following colleges and units must begin making annual disclosures: College of Agricultural Sciences, College of Engineering, Eberly College of Science, College of Earth and Mineral Sciences, College of Health and Human development, and Applied Research Lab (including the Electro-Optics Center).

(2014) January – April: All investigators from the following colleges and units must begin making annual disclosures: College of Liberal Arts, College of Education, College of Arts and Architecture, College of Information Sciences and Technology, College of Communications, Smeal College of Business, School of Law, School of Nursing, School of International Affairs, and all investigators at Penn State Commonwealth Campuses.

\*Investigators at the Penn State Hershey College of Medicine are already required to make annual disclosures and so are not subject to this implementation schedule.