



A. Who

- A.1. Who is required to disclose?
- A.2. Who is an investigator?
- A.3. Do postdocs, graduate students, medical students, residents and fellows need to disclose?
- A.4. If I am an affiliated unpaid faculty member am I required to disclose?

B. When

- **B.1.** If information that I enter in my disclosure changes during the coming year, do I need to update it prior to next year's annual disclosure?
- **B.2.** When do disclosures need to be made?

C. What

- C.1 Is the disclosure of financial interest limited to research only?
- C.2. If I receive an honorarium or other payment from another university, does that need to be disclosed?
- C.3. I sit on a study section at NIH/NSF/etc. Does my income from that need to be disclosed?
- C.4. I sit on an editorial board for a journal. Does my income from that need to be disclosed?
- C.5. What about mutual funds or other investments, such as those through TIAA-CREF?
- C.6. What if someone from a business comes to Hershey and takes me to lunch to discuss my research? Must I disclose that?
- C.7. Does travel paid by a professional society need to be disclosed? What about honoraria from a professional society?
- C.8. If an individual has financial interest in a for profit entity that does not meet the \$5,000 threshold but is related to human subjects research is this required to be disclosed?

D. Travel

- D.1. Where does an individual go in order to make their travel disclosure?
- <u>D.2. When disclosing reimbursed or sponsored travel will the individual disclosing the travel have to know the cost of the travel?</u>
- <u>D.3.</u> For the disclosure of travel, is an individual required to disclose travel that is reimbursed or sponsored on behalf of their spouse and/or dependent children?
- <u>D.4.</u> When the regulations or policy say *sponsored travel*, does that include travel expenses covered on a *sponsored* award, such as a grant or contract?
- D.5. If travel is reimbursed or sponsored by a non-profit entity is it required to be disclosed?
- <u>D.6.</u> Is travel that is reimbursed to the University by a publicly or non-publicly traded entity on behalf of an investigator, required to be disclosed?

D.7. When do I need to update my reimbursed or sponsored travel – before the trip or after?
F. Fausian Futition
E. Foreign Entities
E.1. Is income from foreign institutions of higher education, teaching hospitals or governments considered
significant financial interest that would require disclosure?
E.2. Is income from a foreign for profit entity considered significant financial interest that would require
disclosure?
F. Intellectual Property and Royalties
F.1. I own Intellectual Property Rights and Interests that are related to human subjects' research but the
Intellectual Property Rights and Interests have not generated any income or do not meet the \$5,000 threshold,
does this still need to be disclosed?
F.2. I receive royalties or licensing income from a patent that is owned by the Penn State Research
Foundation ("PSRF"). Do I need to disclose that?
Touridation (1 5th). Do l'ileeu to disclose tilat:
O D LP A
G. Public Accessibility
G.1. What information is publicly accessible?
H. Definitions
H.1. What is an Entity as used with regard to the Conflict of Interest disclosure process?
H.2. What does Institutional Responsibilities mean?
H.3. What does SFI mean?
I. COINS Error Messages
I.1. What do I do if I get an error message as I am trying to submit my COINS disclosure?
The state of the s

A.1. Who is required to disclose?

At the College of Medicine, all investigators (as defined by RA20), faculty, and designated administrators are required to complete an annual disclosure.

A.2. Who is an Investigator?

Any University employee, 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. Since title and position are not indications of who is an "Investigator," it is possible for students and post docs to meet this definition.

A.3. Do postdocs, graduate students, medical student, residents and fellows need to disclose?

If a postdoctoral fellow, graduate student, medical student and/or resident meet the definition of Investigator, then they must comply with policy RA20 and all related regulations.

A.4. If I am an affiliated unpaid faculty member am I required to disclose?

No, if you are an affiliated unpaid faculty member or an occasional or PRN employee you are not required to disclose. Only full time and part time paid faculty members are required to disclose.

B.1. If information that I enter in my disclosure changes during the coming year, do I need to update it prior to next year's annual disclosure?

Yes. If you are an investigator you must update your disclosure within 30 days of acquiring or discovering a new SFI, including sponsored or reimbursed travel, and you must also ensure that your disclosure is up-to-date at the time of submitting any new proposal for sponsored funding. Failure to meet these deadlines can result in additional administrative requirements and delays to receiving your funds.

If you are not an investigator you must update your disclosure within 30 days of

- Beginning employment with the University or Milton S. Hershey Medical Center
- When an SFI is acquired with a new entity that has not previously been disclosed

B.2. When do disclosures need to be made?

All investigators, faculty and designated administrators are required to make a disclosure at least on an annual basis. For the College of Medicine the annual disclosure period will typically be from January 1^{st} to April 30^{th} . All disclosures are done electronically via COINS at www.coins.psu.edu.

In addition to annual disclosure, all investigators are required to update their disclosures within 30 days of acquiring or discovering a new SFI. This includes reimbursed or sponsored travel. Investigators are also required to disclose all SFI prior to the submission of an application for research funding.

For those that are not investigators, in addition to the annual disclosure you are required to update your disclosure within 30 days of the following instances;

- Beginning employment with the University or Milton S. Hershey Medical Center
- When an SFI is acquired with a new entity that has not previously been disclosed

C.1 Is the disclosure of financial interest limited to research only?

No, every investigator, faculty member and designated administrator is required to disclose all financial interest that is related to their institutional responsibilities. Common examples of institutional responsibilities could be the following:

- Research (regardless if funded or not);
- Research consultation;
- Teaching;
 - Example: You own stock in Merck and you lecture on a particular product manufactured by Merck
- Outreach;
- Professional practice (e.g. clinical medical practice, veterinarian practice, practice of law, etc.);
 - Example: You are a speaker for Medtronic devices and receive income for speaking. You also use Medtronic devices in your professional practice and makes purchasing decisions related to Medtronic devices
- University committee memberships (e.g. Faculty Senate, Purchasing Committees);
 - Example: You own stock in a medical device company and you are also on the purchasing committee and make purchasing decisions related to this particular medical device
- Service on University panels

C.2. If I receive an honorarium or other payment from another university, does that need to be disclosed?

No. Income from American institutions of higher education, teaching hospitals or research centers affiliated with the above, is not included in SFI and does not need to be disclosed. However, honoraria or payments from foreign institutions MUST be disclosed.

C.3. I sit on a study section at NIH/NSF/etc. Does my income from that need to be disclosed?

Income from service on a study section for an American government funding agency does not need to be disclosed because it is a government source. Please note, however, that if you are an investigator and you serve on a proposal review board for a non-profit Entity, such as a foundation, any income over \$5,000 is considered SFI and must be disclosed. If you are not an investigator you do not need to disclose income from service on a study section for an American government funding agency or a non-profit Entity.

C.4. I sit on an editorial board for a journal. Does my income from that need to be disclosed?

This depends on two things. First are you classified as an investigator? If so, then if the journal is published by a private organization, either for profit or non-profit, you need to disclose the income. However, if it is published by an American government agency or an American institution of higher education you do not need to disclose the income. If you are not an Investigator, and the journal is published by a non-profit entity, you do not need to disclose, but if it is published by a for-profit entity, you do need to disclose. Follow the same guidelines as for other income.

C.5. What about mutual funds or other investments, such as those through TIAA-CREF?

Investments such as mutual funds, in which an Investigator does not have control over the individual securities held, are excluded from SFI and do not need to be disclosed. If you own other investments, such as stock in an individual corporation, even if held in a retirement account, those investments can be bought or sold at your discretion, and you will need to evaluate each such investment in order to determine whether it is reasonably related to your Institutional Responsibilities (see H.2.).

C.6. What if someone from a business comes to Hershey and takes me to lunch to discuss my research? Must I disclose that?

The lunch would be considered a gift and could be disclosed if, in aggregate with other compensation or any equity in the company, you exceed the \$5,000 threshold for the past twelve months. However, if the lunch (gift) is the only financial interest you have in the company, then it would not need to be disclosed. Please note that this is not a travel expense, as the lunch occurred locally. If you receive meals while travelling, it is not required to be disclosed specifically, either, but can be included in the total expense of the trip if you know the expense.

C.7. Does travel paid by a professional society need to be disclosed? What about honoraria from a professional society?

Yes, professional societies are non-profit organizations, and IF YOU ARE AN INVESTIGATOR, travel and income from them is required to be disclosed.

IF YOU ARE NOT AN INVESTIGATOR, income and travel from non-profits, not affiliated or controlled by for-profit entities, does not need to be disclosed.

C.8. If an individual has financial interest in a for profit entity that does not meet the \$5,000 threshold but is related to human subjects research is this required to be disclosed? For example, Dr. X is a

speaker for Pfizer and has received \$3,000 in the previous calendar year. Dr. X is also working on a study sponsored by Pfizer that involves human subjects.

Yes, for the College of Medicine, any financial interest that you have in any for profit entity that is related to human subject research will require disclosure. The same is true for intellectual property rights and interest. Regardless of whether the intellectual property rights and interest have generated income if it is related to human subject research it is required to be disclosed.

D.1. Where does an individual go in order to make their travel disclosure?

Travel disclosure is incorporated into the electronic disclosure form (COINS) at www.coins.psu.edu

D.2. When disclosing reimbursed or sponsored travel will the individual disclosing the travel have to know the cost of the travel?

No, when making a disclosure for travel the individual disclosing will only be required to disclose the following information:

- The entity that has reimbursed or sponsored the travel
- The number of trips taken that have been reimbursed or sponsored by that entity
- The purpose of the travel
- The destination
- The duration of the trip

If the individual knows the cost of the travel it would be valuable to provide that information however, if the value is not known it is not required to be disclosed. (This question is asked in the disclosure form but is not required).

D.3. For the disclosure of travel, is an individual required to disclose travel that is reimbursed or sponsored on behalf of their spouse and/or dependent children?

Yes, for the disclosure of travel an investigator, faculty member and/or designated administrator will be required to disclose travel that is reimbursed or sponsored to them directly and travel that is reimbursed or sponsored to their spouse and/or dependent children.

D.4. When the regulations or policy say *sponsored travel*, does that include travel expenses covered on a *sponsored* award, such as a grant or contract?

No. Travel paid with funds from a sponsored award does not need to be disclosed. In the case of travel, the federal regulations use the word *sponsored* to refer to situations where travel has been arranged

and paid for by an Entity, such as where ABC Company directly pays an airline and/or hotel on an Investigator's behalf.

D.5. If travel is reimbursed or sponsored by a non-profit entity is it required to be disclosed?

Yes, if the individual that has received the reimbursed or sponsored travel is considered an investigator as defined by Penn State RA20, they are required to disclose any occurrence of reimbursed or sponsored travel by any for profit and/or non-profit entity within 30 days of the travel. However, if the individual is NOT an investigator as defined by Penn State RA20, they are NOT required to disclose travel that is reimbursed or sponsored by a non-profit entity. Rather individuals NOT considered as an investigator will only be required to disclose the occurrence of any reimbursed or sponsored travel by any for profit entity at least on an annual basis.

D.6. Is travel that is reimbursed to the University by a publicly or non-publicly traded entity on behalf of an investigator, required to be disclosed? For example, Merck would like Dr. X to come speak at a conference. The University or Dr. X's department pays for Dr. X's travel expenses and is later reimbursed by Merck as part of either a research or a unrestricted educational grant.

No, this would not constitute a significant financial interest and would not require disclosure, as the travel is being handled through the University. Under the NIH 2011 regulations, income which includes sponsored or reimbursed travel by an institution of higher education is excluded, and especially if it is paid by Penn State as your employer, it would not require disclosure.

D.7. When do I need to update my reimbursed or sponsored travel – before the trip or after?

If you are an Investigator, either before or after the trip, but at the latest 30 days after the trip

If you are not an investigator and have previously disclosed SFI with the same company, then with your next disclosure update.

E.1. Is income from foreign institutions of higher education, teaching hospitals or governments considered significant financial interest that would require disclosure?

Yes, all investigators are required to disclose income and travel received from any foreign institutions of higher education, teaching hospitals or governments that are related to their institutional responsibilities. However, those College of Medicine faculty that are not considered investigators would not be required to disclose financial interest from foreign non-profit entities just as they would not be required to disclose income from U.S. non-profit entities.

E.2. Is income from a foreign for profit entity considered significant financial interest that would require disclosure?

Yes, all investigators, faculty members and other designated administrators are required to disclose income and travel received from foreign entities that are related to their institutional responsibilities.

F.1. I own Intellectual Property Rights and Interests that are related to human subjects' research but the Intellectual Property Rights and Interests have not generated any income or do not meet the \$5,000 threshold, does this still need to be disclosed?

Yes. All College of Medicine Investigators and faculty that have intellectual property rights and interest (IP) related to human subjects' research must disclose that IP regardless whether the IP has generated income or meets the \$5,000 threshold.

F.2. I receive royalties or licensing income from a patent that is owned by the Penn State Research Foundation ("PSRF"). Do I need to disclose that?

No, royalties or other remuneration received from the University or PSRF is excluded from the definition of SFI and does not need to be disclosed.

G.1. What information is publicly accessible?

For Investigators who are not Senior or Key Personnel on a PHS-funded award with a Financial Conflict of Interest, none of the information disclosed to the University is publicly accessible. For Investigators who *are* Senior or Key Personnel on a PHS-funded award *and* for which a Financial Conflict of Interest has been identified in relation to one or more such awards, the following information will be available publicly, via a written response from the University to a requestor, within five business days of the Office for Research Protections receiving the request:

- i. The Investigator's name;
- ii. The title(s) of the affected project(s);
- iii. The Investigator's role on the affected project(s);
- iv. The name of the Entity in which the Investigator has an SFI/FCOI;
- v. The nature of the SFI, e.g., income, equity, etc.;
- vi. The approximate value of the SFI, in dollar ranges as set by the PHS.

H.1. What is an Entity as used with regard to the Conflict of Interest disclosure process?

An Entity is any domestic or foreign, public or private, for-profit or not for-profit, organization (excluding Federal, State, and Local governmental agencies). Examples include, but are not limited to: small or large businesses, corporations, sole proprietorships, LLC's, Ltds., 501(c)'s, and partnerships.

H.2. What does Institutional Responsibilities mean?

Institutional Responsibilities are your professional responsibilities on behalf of the University. Examples include, but are not limited to:

- research
- research consultation
- teaching
- outreach
- professional practice (e.g. clinical medical practice, veterinary practice, practice of law)
- committee membership (e.g. Faculty Senate, Purchasing Committees)
- service on panels, such as IRB or Data or Safety Monitoring Boards

H.3. What does SFI mean?

SFI stands for "significant financial interest" and is defined as:

anything of monetary value held by you, your spouse, or your dependent children, that reasonably appears to be related to your institutional responsibilities, including:

- Compensation or other payments (e.g., consulting fees or honoraria) exceeding \$5,000
 in a non-publicly traded entity or exceeding \$5,000 when aggregated with the value of
 any equity interests held in a publicly-traded entity;
- Equity interests (e.g., stocks, stock options or other ownership interests) exceeding \$5,000 when aggregated with any compensation received from a publicly-traded entity, or any equity interests in a non-publicly traded entity;
- Intellectual property rights and interests (e.g., patents, copyrights,) upon receipt of income exceeding \$5,000 related to such rights; and
- Sponsored or Reimbursed Travel exceeding \$5,000 from an entity in the 12 months preceding disclosure

I.1. What do I do if I get an error message as I am trying to submit my COINS disclosure?

Go to the following link for troubleshooting information

http://www.pennstatehershey.org/c/document_library/get_file?uuid=9438a0fa-4d91-45f3-b97d-d3b9f0f74d98&groupId=867743