

Office of the Vice Provost for Research

Financial Conflict of Interest (FCOI) Disclosure Process in Financial Interest Disclosure Electronic System (FIDES)

Overview. Unlike annual School-based extramural activities reporting, the financial disclosure requirement for individuals participating in research arises in connection with each individual research project that is conducted by Penn faculty, staff or that uses Penn resources. This requirement is meant to apply broadly. Research projects include, but are not limited to:

- Human subjects and animal research protocols
- Federal grants and contracts
- Sponsored research, clinical trial, and material transfer agreements

Why is Disclosure Required? Financial or other personal considerations have the potential to compromise or bias professional judgment or objectivity of researchers. An Investigator's judgment does not necessarily have to be biased in order to be problematic; even the appearance of bias in judgment is reason for concern. Because FCOIs are inherent to the research enterprise, the governing federal regulations and University and School policies require disclosure of relevant financial interests / relationships.

Note: You are disclosing financial interests and relationships - NOT conflicts of interest.

Whether a conflict of interest exists is a factual determination based on the type and monetary value of financial interests / relationships you disclosed, the nature of the research, your role in the research, and other factors.

See [Overview of Policy on Conflicts of Interest Related to Research](#) and [Useful Links -Federal Regulations Governing FCOI](#)

Italicized terms in the following summary are defined in the FCOI Policy.

Who Must Disclose in FIDES? You must disclose if:

- You are an *Investigator* (you have a role in the design, conduct, or reporting of the research, regardless of your title or position), and
- For the past 12 months through the next 12 months, you and/or your *Family Member* have relevant *Significant Financial Interests (SFIs)* that may affect or be affected by the research
 - personal *financial interests / relationships*; or
 - relationships in/with any *Outside Organization* whose interests may affect / be affected by the research (e.g., the research sponsor, manufacturer of the investigational item, or a competitor of the sponsor or the manufacturer if you know that the competitor's financial interests would reasonably appear to be affected by the research.

FIDES disclosure required for PHS-funded Research. In addition to the above, if you are an *Investigator* participating in a project to be funded / funded by the PHS, you may also be required to submit a disclosure in FIDES regarding any *SFI* related to this research that you disclosed in your PHS Financial Interest and Travel Statement (PHS-FITS) submitted to your School.

When to Disclose. You must submit your eDisclosure when:

- The research proposal is submitted to the Office of Research Services (ORS); or
- The human subjects research protocol is submitted to the IRB; or
- A transaction is initiated by the Center for Technology Transfer involving technology in which you have a financial interest (e.g., you are a named inventor on a patent application or your technology is being licensed to an *Outside Organization*); or
- There is a change regarding your previously disclosed *SFIs*; you have new *SFIs* relevant to ongoing research, or as required by a conflict of interest management plan or other communication from your School or the Office of the Vice Provost for Research (OVPR)
- You receive notice to disclose in FIDES based on your PHS Financial Interest and Travel Statement (PHS-FITS) submitted to your School.

Disclosures related to proposals linked to IRB protocols

If you submitted an eDisclosure in connection with a proposal submitted to the ORS, you may or may not be required to submit a separate eDisclosure for the IRB protocol, depending on how long ago your initial eDisclosure was submitted and how much information was provided about the protocol, including your role and participation. The same is true if you previously submitted an eDisclosure in connection with an IRB protocol and a sponsored agreement is now being submitted. For further guidance, contact the OVPR.

What must be disclosed? You are required to disclose your and/or your *Family Members' SFIs* for the past 12 months or anticipated during the next 12 months, that are relevant to the research project, including:

- Any *Fiduciary Responsibilities* for, *Equity Interests* in, or *Extramural Activities* provided to or on behalf of an *Outside Organization* with a financial interest in this research
- Any *Intellectual Property* (IP) rights or interests in an item being tested, evaluated, or developed in, or if its commercial value could be affected by, the research, if the IP is not assigned to Penn and you have received any income related to the IP during the past 12 months
- Any *interest in Intellectual Property* (that is the subject of a copyright, issued patent, or a patent application, regardless of whether or not licensed and whether or not assigned to Penn) if it is being tested, evaluated, or developed in, or if its commercial value could be affected by, a *Clinical trial*

Financial interests / relationships with more than one *Outside Organization*. Your eDisclosure must address financial interests / relationships for each *Outside Organization* that has an interest in the research. For example, if you consult for Pharma Company 1 (provides funding), and serve on an advisory board for Pharma Company 2 (provides the study drug), you must disclose your financial interests / relationships for both Pharma Company 1 and 2. Note that as long as your eDisclosure is being submitted for one identified research project, it may contain information about more than one *Outside Organization*.

How to Disclose in FIDES - Overview

FIDES is a transactional, web-based application for disclosure of financial interests and relationships related to participation in specific research projects. You may access FIDES at any time using any computer via the internet. You will need your PennKey and Password to enter the system. If you do not have a PennKey to log into the application, but you are required to submit a disclosure, you will need to obtain a Guest PennKey. Guests must be sponsored by a department. The process is usually initiated by a Business Administrator or Local Support Provider. For information about obtaining click [Guest PennKey](#)

eDisclosures are **not accepted** via phone, fax, e-mail, or written hard copy.

Access to [FIDES](#)

FIDES Disclosure in a Nutshell

Once you log into FIDES, you will arrive at your personal Investigator Dashboard page. From this page, you will be able to submit a new eDisclosure, view previously submitted eDisclosures, upload supporting documentation, and submit an Addendum to a previously submitted eDisclosure.

For new eDisclosures:

- You will be asked to identify the specific research project that is the subject of the eDisclosure, including IRB protocols and/or sponsored research proposals, and whether or not the proposal is funded by the PHS.
- You will be asked several screening questions about your and your *Family Members'* financial interests and relationships that are relevant to this research.
- Depending upon your responses to the screening questions, you may be asked:
 - More detailed questions about specific financial interests /relationships
 - To identify all *Outside Organizations* with an interest in this research
 - To describe the nature of the research (e.g., human subjects), your role (e.g., PI) and how you participate (e.g., data analysis)
 - To certify as to the accuracy of the information reported

Once you have submitted your eDisclosure, you will receive an e-mail confirming receipt. You will be able to print a copy of your eDisclosure once it has been submitted.

Information you will need to complete your eDisclosure. Before you begin your eDisclosure, you should have the following information available:

Identify the relevant research – proposals and protocols

An eDisclosure covers a specific research project which may consist of several components. For example, if you are disclosing in connection with a federal grant and you have submitted a protocol that will be funded under the grant, you should be able to identify in the drop down lists provided in the eDisclosure both the grant and protocol by title and by protocol number and/or institution number as they appear in PennERA or HS-ERA, as applicable.

Identify Financial Interests / Relationships (for the past 12 months and/or anticipated during the next 12 months). These may include *Intellectual Property Interests, Fiduciary Responsibilities, Equity Interests* and *Extramural Activities*. Be prepared to provide:

- Compensation amounts
- Information regarding assignment and licensure of your intellectual property
- Royalties or other license –related revenues
- Stock – number of shares, estimated % interest and estimated value
- Stock Options- number held

How and when to report changes to a previously submitted eDisclosure. FIDES gives you the ability to submit an Addendum to communicate changes to a previously submitted eDisclosure, including:

- Material changes in your research program (e.g., applications for new grants or a change from basic science to human subjects research)
- Changes in financial interests in relation to an *Outside Organization*, or changes regarding that entity's rights or interests
- Changes in your financial interests relative to new *Outside Organizations*
- Information to be reported as required under a management plan or other communication from the OVPR

How to submit an Addendum. Once you log into FIDES, you will be able to view all your previously submitted eDisclosures. Click on the Addendum Box next to the eDisclosure that you wish to update. You should submit an Addendum as soon as possible. If you have any questions regarding whether to report a change and what specific information to report, please contact the OVPR for guidance.

Depending on the information reported in an Addendum, you may be required to submit a new eDisclosure.

Other Things to Know about FIDES

InfoDots. InfoDot icons found throughout FIDES provide help text (including giving examples or providing further explanation regarding a question or required response).

Training. We offer individual training in the use of FIDES by request. Please contact the OVPR for Research at 215-898-3603 or email coi@exchange.upenn.edu