

MANAGING CONFLICTS OF INTEREST IN SPONSORED PROJECTS

Required Training

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2011 Revised Regulations

- Purpose of the regulations and links to more information
- Major changes to the regulations and Effective Date

Drexel's Policy on Managing Conflicts of Interest in Sponsored Projects (Drexel Policy)

- Summary of Drexel Policy and link to the full policy
- Who is covered by the policy
 - Definition of University Personnel/Investigators (UP/I)
- UP/I's two main responsibilities under the policy
 - Training
 - Significant Financial Interest Disclosures
- Subrecipients on PHS-funded sponsored projects
- New Public Accessibility Requirement for PHS-funded sponsored projects
- Brief overview of SFI disclosure review process

Contact Information

Purpose

- 42 C.F.R. Part 50, Subpart F promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from FCOIs of an Investigator, as defined in the regulations.

Additional Information

- [NIH FCOI Website](http://grants.nih.gov/grants/policy/coi/) (<http://grants.nih.gov/grants/policy/coi/>)
- [NIH FCOI Presentation with Case Studies \(06/22/2012\)](#)
- [2011 Revised Regulations \(42 C.F.R. Part 50, Subpart F\)](#)

Summary of Major Changes

- 42 C.F.R. Part 50, Subpart F has been revised to reflect the following changes:
 - Reduced financial interest disclosure threshold
 - New Financial Conflict of Interest (FCOI) training requirement
 - New requirements of Public Accessibility of information regarding FCOIs in Public Health Service (PHS)-funded sponsored projects
 - Increased transparency for sponsored or reimbursed travel

Effective Date

- August 24, 2012

Policy Summary

- Drexel Policy describes its commitment to manage conflicts of interest in sponsored projects supporting research, scholarly, and creative activities, where the sponsor may be any external sponsor or the University itself.
Reduced financial interest disclosure threshold
 - This policy supplements the University's general policy on [Conflicts of Interest and Commitment](#).

Full Policy

- [Managing Conflicts of Interest in Sponsored Projects](#)
<http://www.drexel.edu/research/administration/formsPolicies/Policies/fcoi/>

University Personnel/Investigators (UP/I) are defined in Drexel Policy as:

- Individuals, who are engaged in and are responsible for overseeing or managing sponsored projects at the University, including students, post-doctoral fellows, subcontractors, consultants, and scholars who contribute to the development or execution of a sponsored project.

All UP/Is must complete the REQUIRED TRAINING.

- **Why?**
 - **UP/I** must complete this training presentation to:
 - Understand **UP/Is** responsibilities; and
 - Be in compliance with the 2011 Revised Regulations and/or Drexel Policy.
- **When?**
 - Prior to proposal submission or the expenditure of funds, whichever is applicable (initial training);
 - At least every 4 years after initial training; AND
 - Immediately when:
 - Drexel Policy changes such that it affects **UP/I**'s responsibilities
 - **UP/I** are new to Drexel; or
 - **UP/I** are not in compliance with Drexel Policy or the management plan.

When should SFI Disclosure Forms be submitted.

- **By Whom?**
 - For PHS, all **UPI** whom the PI deems “responsible for the design, conduct, or reporting “ of the project
 - For Non-PHS, all **UPI** whom the PI deems Senior/Key Personnel
- **Which Forms?**
 - [Financial Interest Disclosure Form 1](#), completed by all **UPI**
 - [Financial Interest Disclosure Form 2](#), only if **UPI** answered “YES” to any question in Part B of Form 1.
 - A separate form must be completed for each identifiable SFI or disclosure.
- **To Whom?**
 - Submit Form(s) to Drexel University Office of Research (OR)
- **When?**
 - Prior to proposal submission or the expenditure of funds, whichever is applicable
 - For sponsored projects involving human or animal subjects, when the project is being designed for implementation
 - Within 30 days from the date that a new SFI arises in an active sponsored project
 - On an annual basis for each active sponsored project

SFI Disclosures

- What types of financial interests must be disclosed on the disclosure forms?
 - Financial Interest that are deemed Significant Financial Interests (SFIs) must be disclosed.
- What is deemed an SFI?
 - A SFI is a financial interest of a value exceeding a **Defined Threshold** that is reasonably related to your **Institutional Responsibilities** and/or could reasonably affect or be affected by the outcome of the sponsored project, and has been/will be possessed and/or received during a **12-month period prior to and/or after the disclosure**.

Three Key Components of the SFI Definition:

- **Defined Threshold:**
 - A \$5000 aggregate amount, on an entity-by-entity basis, for each of the following categories: 1) income from and equity in a publicly traded entity; 2) income from a non-publicly traded entity; 3) income from any intellectual property rights and interests; and 4) reimbursed or sponsored travel.
 - A \$0 aggregate amount, on an entity-by-entity basis, for: 1) equity in a non-publicly traded entity; and 2) income from managerial interest.
- **Institutional Responsibilities:**
 - University Personnel/Investigators' professional responsibilities on behalf of the University, which may include for example: current or proposed activities such as research, research consultation, research-related student supervision, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- **Time Frame:**
 - 12-month period prior to and/or after the disclosure

Financial Interests Excluded from the Definition of a SFI:

- Salary, royalties, reimbursements, or other remuneration paid by the University or affiliates, such as Tenet, to University Personnel/Investigators (UP/I) if UP/I are currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as UP/I do not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency (Government Agency), an Institution of higher education as defined in [20 U.S.C. 1001\(a\)](#) (Higher Education Institution), an academic teaching hospital, a medical center, or a research institute that is affiliated with a Higher Education Institution;
- Income from service on advisory committees or review panels for a Government Agency, a Higher Education Institution, an academic teaching hospital, a medical center, or a research institute that is affiliated with a Higher Education Institution;
- Travel reimbursed or sponsored by a Government Agency, a Higher Education Institution, an academic teaching hospital, a medical center, or a research institute that is affiliated with a Higher Education Institution; and
- Grants and contracts administered through the University.

Examples of Financial Interests that may be SFIs:

- **Sponsored or reimbursed TRAVEL**
 - New requirement created by the 2011 revised regulations
 - All travel that is related to UP/I's Institutional Responsibilities and is deemed an SFI must be disclosed.
- Gifts
- Favors for services that result in financial gain
- Vested or non-vested stock or stock options
- Ownership interest in publicly traded or non-publicly traded entities
- Intellectual property rights, such as patents
- Income from Honoraria or Consulting Fees
- Loans

Subrecipients (Subs) on PHS-funded Sponsored Projects:

OR will work with **UP/I** to ensure that Sub relationships are created in compliance with the 2011 revised regulations.

- For Subs with policies compliant with the 2011 revised regulations:
 - Ensure that the Sub has disclosed to Drexel all identified FCOIs **within 45 days from the date of identifying the FCOI and/or prior to the expenditure of funds.**
 - Ensure that the certification of Sub's policy compliance with the 2011 revised regulations is incorporated into the written subcontract agreement.
- For Subs without policies compliant with the 2011 revised regulations:
 - Collect all of the Sub's SFI disclosures that directly relate to the Sub's work for the University using the SFI disclosure forms provided on the [OR website](#) and submit the forms to the OR **prior to executing the agreement and/or in compliance with Drexel Policy.**
 - Work with the OR to ensure that the appropriate Sub language is incorporated into the written subcontract agreement.

New Public Accessibility Requirement for PHS-funded Sponsored Projects:

- Drexel is required to make the information below publicly accessible, if:
 - SFI is determined to be an FCOI;
 - **UPI** are designated as senior/key personnel; and
 - **UPI** still hold the SFI:
- Publicly accessible information:
 - **UPI**'s name
 - **UPI**'s title
 - **UPI**'s role with respect to the project
 - Name of the entity in which the SFI is held
 - Nature of the SFI
 - Approximate value of the SFI

Brief Overview of SFI Disclosure Review Process:

OR:

- Receives SFI disclosure form(s) from **UPI**;
- Performs initial review of the form(s) for potential financial conflicts of interest (FCOIs); and
- For projects with Form 2's
 - Records the initial determination;
 - Drafts a COI Memo detailing a management plan, if necessary; and
 - Escalates the initial determination and COI Memo, if applicable, to the Outside Interest Committee (OIC) for further review and a final determination.

If you have any questions or comments, please contact:

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