

DEPAUL UNIVERSITY



Conflict of Interest in Public Health Service (PHS) Funded Research

Category: Academic Affairs - Operational

Responsible Department: Office of Research Services

Responsible Officer: Associate Vice President for Research

Effective Date: 8/11/2015

Policy Summary

This policy helps to ensure that research at DePaul which is funded under Public Health Service (PHS) grants and cooperative agreements is free from bias resulting from Investigator financial conflicts of interest.

Scope

This policy affects the following groups of the University:

- Full-Time Faculty
- Deans
- Directors/Department Chairs

This policy applies to Investigators who are applying for or accepting research funding from the Public Health Service (PHS) of the U.S. Department of Health and Human Services, which includes the National Institutes of Health.

Those who are applying for or accepting funding from non-PHS sources are required to follow the *Conflicts of Interest in Externally Sponsored Projects* policy in lieu of this one.

Policy

INTRODUCTION

This policy implements Title 42, Part 50, Subpart F of the Code of Federal Regulations as published in the *Federal Register*, Vol 75, No 165, on August 25, 2011. This section of the Code of Federal Regulations, which focuses on promoting objectivity in research, is referred to in this policy as "Subpart F."

Subpart F applies to each institution that is applying for, or that receives, PHS research funding by means of a grant or cooperative agreement, and to each Investigator who is planning to participate in, or is participating in, such research, with the exception of those Investigators submitting to the Phase I component of the Small Business Innovation Research (SBIR) Program.

DEFINITIONS

Following are definitions of the key terms in this policy:

Subpart F: A section of the Code of Federal Regulations that establishes standards which help to ensure that the design, conduct, and reporting of research funded under Public Health Services (PHS) grants or cooperative agreements is free from bias resulting from Investigator financial conflicts of interest.

PHS: The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component: The organizational unit of the PHS that funds the research that is subject to Subpart F.

Investigator: The project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding. Such persons may include, for example, collaborators or consultants.

Research: A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-science research. The term encompasses basic and applied research and product development.

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

Significant Financial Interest (SFI): A financial interest that reasonably appears to be related to the Investigator's institutional responsibilities and that meets one of more of the disclosure requirements established in Subpart F. Such SFIs include those of the Investigator, and of the Investigator's spouse and dependent children.

Institutional responsibilities: An Investigator's professional responsibilities on behalf of the University, including activities such as research, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Financial Conflict of Interest (FCOI): A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report: The University's report of a financial conflict of interest to a PHS Awarding Component.

Manage: Taking action to address a financial conflict of interest, which can include reducing or eliminating the conflict.

Management Plan: A plan that specifies the actions to be taken to address a financial conflict of interest.

KEY RESPONSIBILITIES

Subpart F describes a number of responsibilities that Investigators and the University are expected to fulfill to help ensure that the design, conduct, and reporting of PHS-funded research will be free from bias resulting from Investigator conflicts of interest.

Investigator Responsibilities

Investigators on PHS-funded research projects that are proposed by or awarded to DePaul have the following responsibilities:

Disclosure

Investigators submitting applications for PHS research funding must disclose significant financial interests (SFIs), and those of their spouse and dependent children, to the University. Such SFIs are relevant when they occur within the following categories and reasonably appear to be related to the Investigator's institutional responsibilities:

- *Publicly traded entities* when the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.
- *Non-publicly traded entities* when the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g. stock, stock options, or other ownership interest).
- *Intellectual property rights and interests* (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
- *Reimbursed or sponsored travel* when related to their institutional responsibilities.

In completing their disclosures, Investigators may exclude the following types of financial interests:

- Salary, royalties, or other remuneration paid by DePaul to the Investigator as someone employed by or otherwise appointed by DePaul, 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 the Investigator does not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures, or teaching engagements, or service on advisory committees or review panels from a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;

- Travel reimbursed or sponsored by one of the agencies, institutions, or institutes listed immediately above.

Investigator disclosures of significant financial interests, as defined above, occur at the following times:

- When an application is submitted for PHS-funded research.
- Annually during the project period of a PHS-funded grant award.
- Within 30 days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new significant financial interest.

Training

Investigators must also complete training focusing on this university policy, the Investigator's responsibilities regarding disclosure of significant financial interest, and the provisions of Subpart F before engaging in research related to any PHS-funded grant and at least every four years, barring significant changes to this policy or the associated conflict of interest procedures.

University Responsibilities

Subpart F describes numerous responsibilities that DePaul University is required to fulfill as an applicant for and recipient of PHS research funding. DePaul's Designated University Official, working under the supervision of the Associate Vice President for Research, coordinates University compliance with these requirements.

Review, Management, and Monitoring of Financial Conflicts of Interest

Prior to Expenditure of PHS Funds

Prior to DePaul's expenditure of any funds under a PHS-funded research project, the University reviews all Investigator disclosures of SFIs. In doing so, it determines whether any of these interests relate to PHS-funded research and whether a financial conflict of interest (FCOI) exists. If a conflict exists, the University develops and implements a management plan that specifies the actions taken to manage the conflict.

As defined by Subpart F, an Investigator's SFI is related to PHS-funded research when the University reasonably determines that the SFI could be affected by the PHS-funded research, or involves an entity whose financial interest could be affected by the research.

An FCOI exists when the University reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

New Investigator or a New Disclosure by an Existing One

In situations where an Investigator who is new to participating in a PHS-funded research project or an existing Investigator discloses a new SFI to DePaul, the University reviews the disclosure within

60 days, making the determinations described above. If a conflict exists, the University implements a management plan that specifies the actions taken to manage the conflict. Depending upon the nature of the SFI, the University also determines whether any additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Institution's review.

SFI Not Disclosed in a Timely Manner or Not Previously Reviewed

Whenever the University identifies, during an ongoing PHS-funded research project, an SFI that was not disclosed in a timely manner by an Investigator or was not previously reviewed by the University as required in Subpart F, the University performs a review to determine whether the SFI is related to PHS-funded research and whether a conflict of interest exists, implementing any management plan needed within 60 days.

In addition, whenever an FCOI is not identified or managed in a timely manner, the University completes within 120 days a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research conducted during the period of noncompliance was biased in its design, conduct, or reporting. The University documents the retrospective review, including the key elements described in Subpart F. As needed, the University updates the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

If bias is found during the retrospective review, the University promptly notifies the PHS Awarding Component and submits a mitigation report describing the University's plan to eliminate or mitigate the effect of the bias.

Monitoring of FCOI Management Plans

Whenever the University implements a management plan pursuant to Subpart F, it monitors Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Reporting

The University provides the following FCOI Reports to the PHS Awarding Component, as required by Subpart F:

- An **initial report**, prior to the expenditure of any funds under a PHS-funded research project, regarding any Investigator's SFI found to be conflicting.
- A **subsequent disclosure report** for any SFI arising during an ongoing PHS-funded research project that the University identifies as conflicting.
- A **retrospective review report** in situations where an SFI is discovered during an ongoing PHS-funded project that was not disclosed in a timely manner by an Investigator or was not previously reviewed and managed by the University.
- A **mitigation report** if bias is found as the result of a retrospective review.
- An **annual report** that updates the status of a previously reported FCOI and describes any changes to the management plan.

These reports include the key elements prescribed in Subpart F.

Public Access

The University also facilitates public access and transparency by making this policy available to the public on a university web site and by responding within five business days to information requests from the public regarding any significant financial interest that meets all three of the following criteria:

- Disclosed to the University and still held by a DePaul Investigator.
- Determined by the University to be related to PHS-funded research.
- Determined by the University to be an FCOI.

Certification of Compliance

The University certifies, in each application for PHS funding, that it is in full compliance with Subpart F.

Subcontractors

In the event that PHS-funded research is carried out through a subrecipient, the University takes reasonable steps to ensure that any subrecipient Investigator complies with Subpart F.

Record Retention

The University maintains records relating to all Investigator disclosures of SFIs and the University's review of, and response to, those disclosures; and all actions under this policy, if applicable, for at least three years from the date the final expenditure report is submitted to PHS.

OTHER UNIVERSITY POLICIES

DePaul's *Conflict of Interest in Externally Sponsored Projects* policy applies to Investigators who are submitting proposals for or managing externally sponsored projects that are not funded by the Public Health Service.

DePaul's general *Conflict of Interest* policy applies to all DePaul employees, including DePaul Investigators.

DePaul's *Records Management* policy applies to the record retention component of the University responsibilities described above.

Procedures

The following procedures are designed to fulfill the key responsibilities described above:

- The Director of Grants Compliance and Award Management, who reports to the Associate Vice President for Research, serves as the Designated Institutional Official.
- Investigator disclosures are made via an on-line form provided by the Office of Research Services (ORS).
- Any disclosures of SFIs are reported to the Designated Institutional Official.
- The COI Committee, which shall contain adequate faculty representation, reviews disclosures of SFIs and develops management plans, in consultation with the Investigator, for those determined to be FCOIs.
- An Investigator dissatisfied with the COI Committee's decision may make an appeal in writing within 30 days to the Associate Vice President for Research.
- The Designated Institutional Official coordinates monitoring of FCOI management plans in communication and consultation with the COI Committee and others involved in the monitoring process.
- The reports required by Subpart F are submitted by the Designated Institutional Official to the PHS Awarding Component upon approval by the Associate Vice President for Research.
- This policy is made available to the public by ORS via its web site.
- Requests from the public regarding Investigator FCOIs are addressed by the Designated Institutional Official.
- The required training for Investigators is provided by ORS, which tracks completion of the training requirement.
- Certifications of compliance with Subpart F are provided by DePaul's Authorized Organizational Representatives (AORs) when submitting grant proposals to PHS entities.
- The requirement that subrecipient Investigators comply with Subpart F is addressed by ORS when issuing subawards.
- Records involving all actions under this policy are included in the award files, which are retained by ORS and by Restricted Accounting.

Possible sanctions for Investigator noncompliance with the policy include, but are not limited to, restricting access to project funds or terminating the Investigator's involvement with an externally sponsored project.

Divisional Collaborations

Faculty Committee on Research Policy

Office of the General Counsel

Restricted Accounting

Controllers Office

Contact Information

AVP for Research

(312) 362-5460

Director of Grants Compliance and Award Management

(312) 362-7595

Appendices

None.

History/Revisions

Origination Date: 08/17/2012

Last Amended Date: 08/11/2015

Next Review Date: N/A