

Policy on Financial Conflict of Interest in the Conduct of Public Sponsored Research

Policy Statement

The primary goal of the Financial Conflict of Interest (FCOI) regulations is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements and contracts is free from bias resulting from Investigator's financial conflicts of interest.

Institutions engaged in research funded by the PHS are required to develop an FCOI policy that is maintained and enforced and meets or exceeds the current Federal regulatory requirements. This policy should be made public, and applies to each Investigator, as defined by the regulation (see definition below), who is planning to participate in or is participating in PHS funded research.

Xemed LLC requires all Investigators, listed on Sponsored Research grant applications, to disclose a listing of significant financial interests (and those of their spouse and dependent children) that could be reasonably expected to bias the design, conduct, or reporting of the project. This is done by completing a Significant Financial Interest Disclosure Form before expenses can be charged to an award. This should be updated on a yearly basis or whenever the Investigator considers that a new significant financial interest has occurred. Investigators can include other personnel than just the senior research staff, PD/PI, and Key Personnel, see definition below.

Definitions

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or receives NIH research funding.

Investigator means 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 NIH, or proposed for such funding, which may include, for example, collaborators or consultants.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS including the NIH. PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development (e.g., a diagnostic test or drug). As used in this policy, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory

Significant Financial Interest (SFI) is a financial interest consisting of one or more of the interests listed below of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. With regard to any publicly traded entity, when the value of any remuneration (salary and any payment for services that are not otherwise identified as salary, for example consulting fees, honoraria, paid authorship) received from the entity in the twelve (12) months preceding disclosure of the interest aggregated with the value of any equity in the entity (for example, stock, stock options, or other ownership interests as determined through reference to public prices or other reasonable measure of fair market value) in the entity as of the date of the disclosure exceeds \$5,000.
2. With respect to any non-publicly traded entity, when the aggregated value of any remuneration received from the entity in the twelve (12) months preceding disclosure of the interest exceeds \$5,000, or any equity in the entity; or
3. Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests, in excess of \$5,000.
4. Any travel that is reimbursed (i.e., the Investigator is made whole for the financial outlay required) or sponsored (i.e., the costs are paid on behalf of the Investigator) other than by Xemed, a Federal state or local government agency, an institution or higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education, which is estimated to exceed \$5,000

SFI Exclusions The term Significant Financial Interest does not include the following types of financial interests Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;

1. Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights.
2. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization.
3. 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.
4. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an

Institution of higher education.

5. Income from service on advisory committees or review panels for a federal, state or local government agency, Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Financial Conflict of Interest (FCOI) is an **SFI** that could directly and significantly affect the design, conduct, or reporting of NIH-funded research, as deemed by the Institution. An FCOI needs to be managed and controlled by the Institution.

Disclosure Form refers to the Investigator's disclosure of Significant Financial Interests (SFI) to their Institution.

Manage FCOI means taking action to address an FCOI, which can include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

Report refers to the Institution's report of identified FCOIs to the NIH.

Senior/Key Personnel are Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under the regulation.

Small Business Innovative Research (SBIR) and **Small Business Technology Transfer (STTR)** programs and/or awards. The revised 2011 regulation does not apply to Phase I SBIR/STTR applications, but the revised 2011 regulation does apply to Phase II SBIR/STTR applications/awards.

Investigator Responsibility

All Investigators conducting Research for which a funding application has been made to an external PHS funding agency must:

1. Complete FCOI training:
 - a. Prior to beginning of PHS funded research
 - b. At least every 4 years thereafter
 - c. When Institution changes policy or in cases of non-compliance of the investigator
2. Complete Xemed's Significant Financial Interest Disclosure Form when requested.
3. Update Disclosure Form annually during the period of the PHS award, or as well as within 30 days of discovering or acquiring a new SFI.

Institutional (Xemed) Responsibilities

Prior to expenditure of any funds under a Sponsored Research award, Xemed's Designated Official must reasonably determine whether any Significant Financial Interest (SFI) disclosed by any Investigator is related to the Sponsored Research; and if so, whether it can reasonably be determined that the SFI constitutes a Financial Conflict of Interest (FCOI); and if a FCOI is determined to exist, how the FCOI will be managed:

1. **Relatedness Standard:** An Investigator's SFI is related to Sponsored Research when Xemed reasonably determines that the SFI could be affected by the PHS Sponsored Research; or is in an entity whose financial interest could be affected by the Sponsored Research. Xemed will be informed by the relevant Investigator in the determination of whether a SFI is related to the Sponsored Research.
2. **FCOI Standard:** An FCOI exists if Xemed reasonably determines that the SFI related to the Sponsored Research could directly and significantly affect the design, conduct or reporting of the Sponsored Research.

Management of Identified FCOIs

1. **Management Techniques:** For any identified FCOI, Xemed, through its Designated Officials, will take appropriate action to manage the conflict in order to reduce the potential for it to compromise the safety or validity of the Research. Research in which an Investigator is found to have an FCOI will not be permitted to proceed until the Investigator has agreed to implement an acceptable management plan.
2. **Disclosed Interests That are Not FCOIs:** Xemed reserves the right to impose any requirements it sees fit on any disclosed interest, even those that are not prohibited by the Xemed COI Policy, do not constitute SFIs and/or do not constitute an FCOI requiring management in accordance with this policy and/or applicable regulations.
3. **Compliance with Management Plans:** Investigators have an on-going obligation to adhere to an imposed management plan and failure to do so may be grounds for sanctions under this policy. Xemed will monitor Investigator compliance with an imposed management plan on an ongoing basis until the completion of the Sponsored Research project.

Reporting FCOIs to PHS

1. **Content of Report:** For all PHS awards, prior to expenditure of any funds under the award, Xemed is required to report to the PHS awarding agency the existence of an FCOI and submit an FCOI report.
2. **Timing of Report:** Xemed is responsible for submitting FCOI reports to PHS initially (prior to expenditure of funds), annually during the award period, and within 60 days of any subsequently identified FCOI.

Subawards

When proposed Xemed Research is to be funded by PHS and has a subaward component (collaborator, contractor, etc), Xemed will establish in writing in the subaward contract, whether this policy, or that of the subrecipient will apply to the subawardee's Investigators, as well as the time frames within which the subrecipient must provide any information necessary to ensure that Xemed is able to meet its reporting obligations to the PHS awarding agency.

Public Disclosure/Accessibility

For PHS-funded Research, Xemed will ensure public accessibility of information concerning the FCOIs currently held by Senior/Key Personnel subject to this policy. Unless and until Xemed determines otherwise, Xemed will, upon receipt of a complete written request for information, provide a written response within five (5) business days regarding any SFI disclosed and still held by the Senior/Key Personnel that has been determined to relate to the PHS-funded research and constitute an FCOI pursuant to this policy.

New SFI that Arise During an On-Going Sponsored Research Project

To the extent a new SFI is disclosed to Xemed in the course of an on-going Sponsored Research project (i.e., an Investigator who is new to participating in the Research discloses a SFI or an existing Investigator discloses a new SFI), or Xemed identifies a SFI that was not previously reviewed in a timely manner by Xemed in accordance with this policy, Xemed will, within 60 days from the date of the disclosure: (i)

determine if the SFI relates to the Investigator's Research; (ii) if it relates, determine if it qualifies as an FCOI; and (iii) if it is an FCOI, implement on at least an interim basis a management plan in accordance with this policy.

Retrospective Review, Identification of Bias and Mitigation Reporting of PHS-Funded Research

1. **Retrospective Review:** In the event of failure to meet PHS regulations, including failure by the Investigator to disclose timely a SFI that is determined to constitute an FCOI; Xemed's failure to review or manage such an FCOI; or Investigator failure to comply with an FCOI management plan, Xemed will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded Research project to determine any bias in the design, conduct or reporting of Research during the time period of the noncompliance. Xemed will document the retrospective review in accordance with its policies and procedures and applicable PHS regulations.
2. **Mitigation.** If bias is found during the retrospective review, Xemed will notify the PHS awarding agency promptly, if applicable, develop and implement a mitigation plan, and submit the PHS required mitigation report, which will include at least the elements documented in the retrospective review and a description of the impact of the bias on the Research project and Xemed's plan of action or actions taken to eliminate or mitigate the effect of the bias. Any FCOI report submitted to the PHS awarding agency with respect to such Research will be updated as necessary in light of the results of the retrospective review.
3. **Disclosure for PHS-Funded Drug/Device Research:** In any case in which the Department of Health and Human Services (HHS) determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by Xemed, the Investigator will be required to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

Training

Xemed will require Investigators to complete all required conflicts of interest training prior to engaging in Research, and at least every four years following the initial training. Additionally, Investigators will be required to receive training immediately in any of the following circumstances:

- Xemed revises its policy or procedures governing FCOI in PHS-funded Research in any manner that affects the requirements applicable to Investigators;
- An Investigator is new to Xemed;
- Xemed finds that an Investigator is not in compliance with this policy or an imposed management plan.

Record Retention

Xemed will retain documentation related to its SFI, FCOI review, and management process to the extent required by law, for at least three years.

Noncompliance and Sanctions

In the event an Investigator fails to comply with this policy or an FCOI management plan, Xemed may impose a wide variety of sanctions, including but not limited to restricting or conditioning the Investigator's ability to apply for grants through Xemed, as well as imposing one or more of the sanctions outlined in the Xemed COI Policy. Additionally, if the failure of an Investigator to comply with this policy or an FCOI management plan appears to have biased the design, conduct or reporting of the PHS Research, Xemed shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

Public Accessibility Process

Xemed has the obligation of making public this FCOI Policy on its website, or, if a website is not available, provide it upon request to the public within five (5) business days of receipt of the request. The policy can be requested in writing by email to fcoi-info@xemed.com.

Effective August 24, 2012, the PHS requires that funded institutions (including Xemed) provide public access to certain information regarding financial conflicts of interest held by senior/ key personnel on research projects funded by the Public Health Service. Xemed will make available the following information:

- Name of senior/key personnel with the financial conflict of interest;
- The individual's title and role in the research project;
- The name of the entity in which the financial interest is held;
- The nature of the financial interest;
- The approximate value of the financial interest (by ranges).

How to make a request: email fcoi-info@xemed.com with the details of your request. As required by the regulations, information will be provided within five (5) business days of receipt of the request by Xemed.