

Original: November 1995

Reviewed: May, 2012

August, 2012

July, 2016

Number: C1206

Financial Disclosure Policy for Sponsored Projects

Summary:

The Public Health Service (PHS) has published rules described in Title 42CFR Part 50, Subpart F, *2011 Revised Financial Conflict of Interest (FCOI) Regulation Promoting Objectivity in Research*, designed to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an investigator. Under these rules, the Institute must develop an FCOI Policy that will be maintained and enforced, and that meets or exceeds the regulatory requirements. The Policy must apply to each Investigator, as defined by the regulation, who is planning to participate in or is participating in Public Health Service (PHS) funded research, effective August 23, 2012. The Institute must be able to certify, in each application for funding, that the Institution:

- Has in effect an up-to-date, written and enforced administrative process to identify and manage FCOI.
- Shall promote and enforce Investigator compliance with the regulation.
- Shall manage FCOI and provide initial and ongoing FCOI reports.
- Agrees to make FCOI and Significant Financial Interest (SFI) information (including related Institutional reviews and determinations) available to HHS, promptly, upon request.
- Agrees to make Financial Disclosure Policy publicly accessible via the Institution's public website. If there is no presence on a publicly accessible website, the FCOI will be made available within 5 days of a request.
- Shall fully comply with the regulation's requirements.

The following policy implements these requirements. It is intended to supplement, not replace, the Institute's existing policy on conflicts of interest. Members of the scientific

staff, as well as other employees and the Institute's Board of Directors will continue to be subject to the Institute's existing conflicts of interest policy, which requires disclosure of personal financial interests and external commitments which may prove to be in conflict with the best interests of the Institute.

The Institute considers compliance with these rules fundamental to maintaining continued public trust in the integrity of research conducted at the Institute. Members of the scientific staff are encouraged to direct any questions concerning the rules to the Institute's administration.

Scope:

The following policy applies to those individuals identified and described in the definitions portion of the policy.

Policy:

1) Definitions

- a) **"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 PHS, or proposed for such funding, which may include collaborators or consultants.
- b) **"Research"** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health including behavioral and social-sciences research. The term encompasses basic and applied research and product development.
- c) **"Significant Financial Interest"** means: A financial interest consisting of one or more of the following interests 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:
 - i) With regard to any publicly traded entity, an SFI exists if 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. For the purpose of this definition, remuneration includes salary and any payment for services not otherwise identified as salary, (e.g. consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
 - ii) With regard to any non-publicly traded entity, a SFI exists if 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 option, or other ownership interest); or
 - iii) Intellectual property rights and interest (i.e., patents, copyrights), upon receipt of income related to such rights and interests.

- iv) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided ,however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, and Institution of higher education as defined at 20 U.S.C. 1001(a), and academic teaching hospital, medical center or a research institute that is affiliated with and Institution of higher education
- v) 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, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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 sponsored by a Federal, state, or local government agency, and Institutions of higher education as defined at 20 U.S.C. 1001(a), and academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, and Institutions of higher education as defined at 20 U.S.C. 1001(a), and academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- d) **“PHS Awarding Component”** means any granting agency which falls under the administrative umbrella of the Public Health Service (PHS) including NIH and NSF.
- e) **“Small Business Innovation Research (SBIR)”** means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For the purposes of this subpart, the term SBIR Program also includes the Small Business Tecghnology Transfer (STTR) Probram, which was established by Public Law 102-564.

2) Procedures

- a) **Training Requirements.**

- i) **Informing Investigators** - The Institute will inform each Investigator of the Institute's policy on financial conflict of interest, the Investigators' responsibilities regarding disclosure of significant financial interests, and of the underlying regulations.
 - ii) **Institution's Policy**-Each Investigator will receive a copy of the Institute's FCOI Policy, during orientation if a new hire, and certify receipt in writing.
 - iii) **Investigator's disclosure responsibilities**-All Investigators will be required (during orientation, for new hires), to attend training which will include a detailed description of Investigators disclosure responsibilities.
 - iv) **Federal Regulation** All Investigators will be required (during orientation, for new hires), to attend orientation which will include a description of the Federal regulation behind the FCOI requirements
 - (1) Each Investigator will be required to complete training regarding the FCOI Policy prior to conducting research related to any PHS-funded grant.
 - (2) Prior to conducting PHS-funded research activities an Investigator will be required to submit to HR a certificate of completion of the PHS FCOI Tutorial, or a certificate of completion issued 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
 - (3) Each Investigator will be required to complete refresher training at least every four (4) years
 - (4) Each Investigator will be required to attend additional training if:
 - (a) The Institute revises its FCOI Policy that affects requirements of Investigators
 - (b) An Investigator is new to the Institute
 - (c) An Investigator is not in compliance with the policy or a management plan.
- 3) Disclosure, Review and Reporting Requirements**
- a) **Disclosure**-Prior to preparing an application for funding from a PHS funding agency, the Investigator(s) (including any person responsible for the design, conduct or reporting of the funded research, subgrantee/contractor/collaborating investigators, but excluding applications for Phase I support under the SBIR/STTR Programs) must disclose any Significant Financial Interest as stated in Title 42CFR Part 50, Revised Subpart F, *Promoting Objectivity in Research*. The G&A Department will maintain disclosure forms, to be completed by each Investigator annually, which will ask the Investigator to disclose reportable Significant Financial Interests, or certify that he or she has no such interests. The Institute then must certify when submitting a grant application that it has received the Investigator's disclosure forms. During the term of any grant, Investigators must update the disclosure form annually, and within 30 days if they discover or acquire a new reportable Significant Financial Interests.
 - b) **Review**
 - i) The Institute's President, in consultation with the Institute's counsel, will act as the Institutional Official to solicit and review any disclosures reported by an Investigator to determine if such interest could constitute a Significant

Financial Interest or potential FCOI by directly and significantly affecting the design, conduct or reporting of the funded research. The President, with concurrence with the Board Chairperson, and as appropriate, after review by such committee as the Board of Directors may designate, shall implement measures to manage, reduce or eliminate the conflict of interest. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

- (1) public disclosure of Significant Financial Interests;
 - (2) for research projects involving humans subjects research, disclosure of financial conflicts of interest directly to participants; monitoring of research by independent reviewers
 - (3) modification of the research plan;
 - (4) disqualification from participation in all or a portion of the research funded by NIH or NSF;
 - (5) divestiture of Significant Financial Interests; or
 - (6) severance of relationships that create actual or potential conflicts of interest.
- ii) The Investigator will be asked to acknowledge in writing that he or she understands and will comply with any conditions imposed by the President for managing, reducing or eliminating a conflict of Interest. Should he or she decline or fail to agree to these conditions, the Institute will not accept the awarded grant.
- iii) If the President discloses a Significant Financial Interest when applying for funding, the Board Chairperson and such committee as the Board of Directors may designate will review the disclosure to determine if the financial interest could constitute a potential conflict of interest and, with concurrence of the Board of Directors, will implement measures to manage, reduce or eliminate any conflict of interest.
- iv) Prior to the expenditure of funds for any PHS-funded research, the Institute will submit an initial, FCOI report, for the Institute and its subrecipient, that includes all reporting elements required by 42 CFR Part 50 Subpart F. Thereafter, until the completion of the PHS-funded study, it will submit an annual FCOI report, (at the same time the Institute is required to submit a progress report, or request an extension), to provide the status of any FCOI and explain any changes to the management plan, if applicable.
- (1) Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, or for whatever reason, an SFI is discovered that was not reviewed by the Institute, the designated official of the Institute shall, within sixty(60) days: review the disclosure of the SFI, determine whether it is related to PHS-funded research;

determine whether a financial conflict of interest exists; and, if so implement, on at least an interim basis, a management plan that shall specify the actions that have been and will be taken to manage such FCOI. Depending on the nature of the significant financial interest, the Institute may determine that 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 Institute's review.

- (2) In addition, whenever a FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose an SFI that is determined by the Institute to constitute a FCOI; failure by the Institute to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, the Institute shall, within 120 days of the Institute's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or report of such research. The Institute must document this retrospective review and if appropriate update the previously submitted FCOI report specifying the actions to be taken to manage the FCOI going forward. If bias is found the Institute will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
- (3) If an Investigator fails to comply with the provisions of this policy, or with any conditions for managing, reducing or eliminating conflicts of interest mandated by the President, the President will discuss the violation with the Investigator and attempt to remedy it informally. If the President is unable to reach a resolution, the President shall impose appropriate sanctions up to and including suspension or termination of the Investigator.
- (4) Prior to the Institute's expenditure of any funds under a PHS-funded research project, the Institute shall ensure public accessibility of identified FCOIs, via a publicly accessible Web site or made available within 5 calendar days of a written request. The posted information will be updated at least annually and also within 60 days of a newly identified FCOI. This disclosure will meet the following criteria:
 - (a) The SFI was disclosed and is still held by the Investigator
 - (b) The Institute Determines that the SFI is related to the PHS-funded research and;
 - (c) The Institute determines that the SFI is a FCOI.
 - (d) The disclosure will include:
 - (i) The Investigator's name
 - (ii) The Investigator's title and role with respect to the research project.

- (iii) The name of the entity in which the SFI is held
- (iv) The nature of the SFI
- (v) The approximate dollar value of the SFI or a statement that the SFI is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair value.

4) Reporting Requirements

- a) Prior to the Institute's expenditure of grant funds from PHS, it will send to the PHS Awarding Component a FCOI report containing all reporting elements required by 42 CFR Part 50 Subpart F regarding any Investigator's or subrecipient's SFI found by the Institute to be a FCOI, and provide an assurance that the financial conflict of interest has been managed by the implementation of a management plan in accordance with 42 CFR Part 50 Subpart F. When conflicts of interest are identified during the term of the grant, the Institute will report them to the PHS awarding component that issued the award within sixty (60) days of identification. If the investigator with identified conflicts of interest has biased the research in question, the Institute will notify the PHS awarding component promptly of corrective action taken or to be taken.
- b) The Institute agrees to make conflict information available, upon request to PHS. If PHS determines that a PHS-funded project of clinical research to evaluate a drug, medical device or treatment was conducted by an investigator with a FCOI that was not managed or reported by the Institute as required by 42 CFR Part 50 Subpart F, the Institute will require the Investigator(s) to:
 - i) Disclose the conflict in each public presentation of the results of the research
 - ii) Request an addendum to previously published presentations

5) Subrecipient Requirements

- a) If PHS-funded research is carried out by the Institute through a subrecipient, it is the responsibility of the Institute to ensure that any subrecipient Institution complies with 42 CFR Part 50 Subpart F.
 - i) As of August 23, 2012, subrecipient agreements will include terms that establish that the financial conflict of interest policies of the subrecipient Institution will apply to the subrecipient's Investigators.
 - ii) If the subrecipient's investigators must comply with the subrecipient's FCOI policy, the subrecipient will certify that its policy complies with 42 CFR Part 50 Subpart F.

6) Maintenance of Records

- a) The Institute will maintain records of all financial disclosures and measures implemented to manage, reduce or eliminate conflicts of interest for at least three (3) years from the date of submission of the final grant expenditure report, or longer where applicable and from other dates specified in 45 CFR 74.53(b) and 92.42(b), where applicable.

7) Questions and Discussion

- a) Any Investigator may contact the Institutional Official mentioned above or the V.P. for Administration to discuss requirements or ramifications of this policy.