

INVESTIGATOR FINANCIAL DISCLOSURE POLICY

(Appendix 6.1)

Whenever an investigator has a significant financial interest in an enterprise which might reasonably appear to be affected by discoveries in the investigator's research, there is the potential for a real or perceived conflict of interest. Effective September 26, 2011, the Public Health Service (PHS) and the Office of the Secretary of the Department of Health and Human Services (HHS) published revised regulations on the *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50)* and *Responsible Prospective Contractors (45 CFR Part 94)*. These regulations (commonly known as the Financial Conflict of Interest (FCOI) regulations) establish new standards and clarify previously established standards to be followed by institutions that apply for or receive research funding from PHS Awarding Components, including the National Institutes of Health (NIH), for grants, cooperative agreements, and research contracts.

Because such disclosure is important to the integrity of research, the Institute's Board of Directors has decided to apply the principle of disclosure to all research conducted at the Institute.

Definitions

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research funded by PHS or the National Science Foundation (NSF).

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institute, which may include activities such as research, research consultation (consultation regarding Institutional research), teaching, and service on institutional committees.

Investigator means the principal investigator, co-principal investigator(s), and any other person at the Institute, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded or proposed to be funded by the PHS or NSF, which may include, for example, collaborators and consultants.

Significant Financial Interest means:

(a) 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, a Significant Financial Interest 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. Such remuneration includes salary, honoraria, paid authorship; equity interest includes any stock, stock option, or other ownership interest;
- (ii) With regard to any non-publicly traded entity, a Significant Financial Interest 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

Investigator's spouse or dependent children) holds any equity interest;

- (iii) Intellectual property rights and interests (e.g., patents, copyrights) not derived from the Institute, upon receipt of income related to such rights and interests.

(b) The occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed by 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, an institution of higher education as defined at 20 USC 1001 (a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

(c) A Significant Financial Interest does not include the Investigator's salary, royalties, or other remunerations paid by the Institute to the Investigator (if the Investigator is currently employed or otherwise appointed by the Institute), nor intellectual property rights assigned to the Institute and agreements to share in royalties related to such rights. Also excluded are: income from seminars, lectures or teaching engagements sponsored by and service on advisory or review panels for a federal, state or local government agency, an institution of higher education as defined in 20 USC 1001(a), an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education; and 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.

Investigator Responsibilities

To comply with federal regulations and to meet the objectives of this policy, the reporting responsibilities of an Investigator include:

(a) Initial Disclosure

Each Investigator who is planning to participate in federally funded research must disclose to the Institute's Vice President responsible for operations (hereinafter referred to as the "Vice President") the Investigator's Significant Financial Interests (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institute's proposal for such federal funding.

(b) Annual Disclosure

Each Investigator who is participating in federally funded research must submit an updated disclosure of Significant Financial Interests annually. Such disclosure must include any information that was not disclosed initially to the Institute pursuant to submission of a proposal and shall include updated information regarding previously disclosed Significant Financial Interests. The Investigator will forward the annual disclosures to the Vice President who will review all annual disclosures and confer with the Director as appropriate. Disclosures that in the opinion of the Vice President or the Director need further review will be referred to an *ad hoc* Conflict of Interest Committee. Any Investigator who desires to have his/her own disclosure reviewed by the Committee may so inform the Vice President, who will then refer it to the Committee. The Committee will review disclosures referred to it and initiate steps to manage, reduce, or eliminate potential conflicts as appropriate. The information disclosed will be kept confidential to the extent permitted by law.

(c) New Significant Financial Interests

Each Investigator who is participating in federally funded research must submit an updated disclosure

of Significant Financial Interests within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.

Institute Process for Managing and Reporting Conflicts of Interest

To comply with federal regulations and to meet the objectives of this policy, the Institute has adopted a process that specifies: the designation of a person(s) to receive and review the disclosures and resolve actual or potential problems revealed; methods to manage potential conflicts of interest/enforcement mechanisms; for PHS funded research only, a procedure for notifying PHS of the existence of a conflict of interest; arrangements for informing NSF or PHS of conflicts related to research funded by those agencies that are not resolved to the satisfaction of the Institute; and record retention procedures. Specific Institute procedures developed to meet these institutional responsibilities are detailed below:

(a) Designation of official(s) to receive and review the disclosures and resolve actual or potential problems revealed

The Institute has designated the Vice President as the authorized institutional official to receive the disclosures. The Vice President will review the disclosures and confer with the Director as appropriate. Disclosures that in the opinion of the Vice President or the Director need further review will be referred to an *ad hoc* Conflict of Interest Committee. Any Investigator who desires to have his/her own disclosure reviewed by the Committee may so inform the Vice President, who will then refer it to the Committee. The Committee will review the referred disclosures and, as necessary, initiate steps to manage, reduce, or eliminate any conflicts of interest when considered necessary by the Committee. For any award from NSF or PHS, the reviews and resolutions of conflicting situations must be completed prior to the expenditure of any funds on any award affected by the conflict. The information disclosed will be kept confidential to the extent permitted by law.

(b) Methods to manage potential conflicts

The *ad hoc* Conflict of Interest Committee is responsible for determining what mechanisms are appropriate for managing, reducing, or eliminating real or potential conflicts of interest. Examples of conditions or restrictions that might be imposed to manage, reduce, or eliminate conflicts of interest include:

- (i) Public disclosure of Financial Conflicts of Interest (e.g., when presenting or publishing the research);
- (ii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, which may result from the Financial Conflict of Interest;
- (iii) Modification of the research plan;
- (iv) Change of personnel or personnel responsibilities, or disqualification from participation in all or in the portion of funded research that could be affected by the Financial Conflict of Interest;
- (v) Reduction or elimination of the Significant Financial Interests; or
- (vi) Severance of relationships that create financial conflicts.

The NSF and the PHS require that the Institute impose sanctions for non-compliance related to NSF or PHS awards where necessary. The Institute may also impose sanctions for non-compliance with respect to any other research conducted at the Institute. Sanctions might include restrictions imposed on the individual with respect to submission of applications and may also include the disciplinary sanctions referenced in the Institute's Procedures for Responding to Allegations of Misconduct in Research.

(c) Conflict of interest management plan

Whenever, in the course of an ongoing PHS or NSF funded research project, an Investigator who is new to participating in the research project discloses a new Significant Financial Interest or an existing Investigator discloses a new Significant Financial Interest to the Institute, the Vice President shall, within sixty (60) days: review the disclosure of the Significant Financial Interest; determine whether it is related to PHS or NSF 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 Financial Conflict of Interest.

(d) Late disclosure of a Significant Financial Interest; retrospective review (PHS only)

If the Institute identifies a Significant Financial Interest that was not disclosed in a timely manner by an Investigator or was not previously reviewed by the Institute during an on-going PHS funded research project, the Vice President shall, within sixty (60) days: review the Significant Financial Interest; determine whether it is related to PHS funded research; determine whether a Financial Conflict of Interest exists, and if so:

- (i) 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 Financial Conflict of Interest going forward;
- (ii) In addition, whenever a Financial Conflict of Interest is not identified or managed in a timely manner including failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institute to constitute a Financial Conflict of Interest; failure by the Institute to review or manage such a Financial Conflict of Interest; or failure by the Investigator to comply with a Financial Conflict of Interest management plan, the Institute shall, within one hundred- twenty (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 reporting of such research. The Institute is required to document the retrospective review; and,
- (iii) Based on the results of the retrospective review, if appropriate, the Institute shall update any previously submitted FCOI report (as described below), specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the Institute is required to, and will, notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. Thereafter, the Institute will submit FCOI reports annually.

(e) Compliance

If the Institute implements a management plan, the Institute will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the NSF or PHS funded project.

(f) Accessibility of information relating to a Financial Conflict of Interest (PHS only) Prior to

the Institute's expenditure of any funds under a PHS funded research project, the Institute will provide to any requestor within five (5) business days of a request, information concerning any Significant Financial Interest disclosed to the Institute that meets the following three criteria:

- (i) The Significant Financial Interest was disclosed and is still held by the Investigator;
- (ii) The Institute determines that the Significant Financial Interest is related to the PHS funded research; and
- (iii) The Institute determines that the Significant Financial Interest is a Financial Conflict of Interest.

The information that the Institute will make available via a written response to any requestor within five (5) business days of a request shall include at minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the Significant Financial Interest is held; the nature of the Significant Financial Interest; and the approximate dollar value of the Significant Financial Interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of market value. The Institute will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty (60) days of the Institute's identification of a new Financial Conflict of Interest, which should be requested subsequently by the requestor. Information concerning the Significant Financial Interests of an Investigator subject to (f)(i) above shall remain available for responses to written requests for at least three years from the date that the information was most recently updated.

(g) Reporting requirements applicable to conflicts of interest related to PHS sponsored research (PHS only)

- (i) Prior to the Institute's expenditure of any funds under a PHS funded research project, the Institute shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's Significant Financial Interest found by the Institute to be an FCOI and ensure that the Institute has implemented a management plan in accordance with this Policy. If the Institute has identified a Financial Conflict of Interest and eliminates it prior to the expenditure of PHS awarded funds, the Institute will not submit an FCOI report to the PHS Awarding Component.
- (ii) For any Significant Financial Interest that the Institute identifies as conflicting subsequent to the Institute's initial FCOI report during an ongoing PHS-funded research project, the Institute shall provide to the PHS Awarding Component, within sixty (60) days, an FCOI report regarding the Financial Conflict of Interest and ensure that the Institute has implemented a management plan in accordance with this Policy. Where such FCOI report involves a Significant Financial Interest that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institute, the Institute will complete a retrospective review to determine whether any PHS funded research, or portion thereof, conducted prior to the identification and management of the Financial Conflict of Interest was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, the Institute will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
- (iii) Any FCOI report will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict and to assess the appropriateness of the Institute's management plan. Elements of the FCOI report shall include, but are not limited to the following: project number; PD/PI; name of the Investigator with the Financial Conflict of Interest; name of the entity with which the Investigator has a Financial Conflict of Interest; nature of the Financial Conflict of Interest; nature of the Significant Financial Interest; value of the Significant Financial Interest; and a description of the key elements of the

- Institute's management plan.
- (iv) For any Financial Conflict of Interest previously reported by the Institute with regard to an ongoing PHS funded research project, the Institute will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the Financial Conflict of Interest and any changes to the management plan for the duration of the PHS funded research project. The annual FCOI report will specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists. The Institute will provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

Remedies (PHS only)

- (a) If the failure of an Investigator to comply with the Institute's Financial Disclosure Policy or a Financial Conflict of Interest management plan appears to have biased the design, conduct, or reporting of the PHS funded research, the Institute will promptly notify the PHS Awarding Component of the failure and of the corrective action taken or to be taken.
- (b) The PHS Awarding Component and/or HHS may inquire at any time (before, during, or after award) into any Investigator disclosure of Financial Interests and the Institute's review of, and response to, such disclosure, regardless of whether or not the disclosure resulted in the Institute's determination of a Financial Conflict of Interest. The Institute is required to submit, or permit on-site review of, all records pertinent to compliance with this part. To the extent permitted by law, HHS will maintain the confidentiality of all records of Financial Interests. On the basis of records or other information that may be available, the PHS Awarding Component may decide that a particular Financial Conflict of Interest will bias the objectivity of the PHS funded research to such an extent that further corrective action is needed or that the Institute has not managed the Financial Conflict of Interest in accordance with this part. The PHS Awarding Component may determine that issuance of a Stop Work Order by the Contracting Office or other enforcement action is necessary until the matter is resolved.
- (c) In any case in which the 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 a Financial Conflict of Interest that was not managed or reported by the Institute as required by the PHS policy, the Institute will require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Record Retention

The Vice President shall maintain records of all financial disclosures and of all actions taken to resolve actual or potential conflicts of interest until at least 3 years after the later of the termination or completion date of the award to which they relate, or the resolution of any government action involving those records.

Subrecipient Requirements (PHS only)

If the Institute carries out the PHS funded research through a subrecipient (*e.g.*, subcontractors or consortium members), the Institute (as the awardee) must take reasonable steps to ensure that any subrecipient investigator complies with 42 CFR 50.604 by:

- (i) Incorporating, as part of a written agreement with the subrecipient, terms that establish whether the financial conflicts of interest policy of the Institute or that of the subrecipient will apply to the subrecipient's investigators. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with 42 CFR 50.604. If the subrecipient cannot provide such certification, the agreement shall state the subrecipient Investigators are subject to the financial conflicts of interest policy of the Institute for disclosing significant financial interests that are directly related to the subrecipient's work for the Institute. Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time periods for the subrecipient to report all identified conflicts of interest to the Institute. Such time period(s) shall be sufficient to enable the Institute to provide timely FCOI reports, as necessary, to the PHS as required by 42 CFR 50.604. Alternatively, if the subrecipient's Investigators must comply with the Institute's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the Institute. Such time period(s) shall be sufficient to enable the Institute to comply timely with its review, management, and reporting obligations under 42 CFR 50.604.
- (ii) Reporting to PHS Awarding Component regarding all Financial Conflicts of Interest of all subrecipient Investigators consistent with 42 CFR 50.604, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified Financial Conflict of Interest.

Anyone seeking clarification or assistance regarding this policy is encouraged to contact the Vice President.

Informational Links

PHS Policy: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

NSF Policy: http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp
