

## Financial Conflict of Interest in Research Policy

*In Accordance with the Requirements of the Public Health Service, including the National Institutes of Health, and the National Science Foundation*

### POLICY

HRiA is committed to promoting objectivity in research and compliance with National Science Foundation (NSF) and Public Health Services (PHS) regulations\* regarding the disclosure of Significant Financial Interests and the management of Financial Conflicts of Interest affecting covered research activities.

HRiA is implementing this policy and the corresponding procedures in order to provide a reasonable expectation that the design, conduct and reporting of research funded by the NSF or PHS, including the National Institutes of Health (NIH), will be free from bias resulting from Financial Conflicts of Interest as defined by the regulations. Compliance with these requirements shall be a condition for submitting proposals and accepting awards of Federal financial support from the NSF or PHS for all activities conducted under HRiA auspices. This policy and the associated procedures are intended to supplement existing HRiA policies on conflict of interest and conflict of commitment. This policy and these procedures apply to all individuals who meet the definition of Investigator as defined herein, including staff, interns, external collaborators and co-investigators from other organizations.

\* Investigator Financial Disclosure Policy -NSF -Federal Register, Vol 60, July 11, 1995, pp. 35820 to 35823. Objectivity in Research -DHHS -Federal Register, Vol. 76, August 25, 2011, pp. 53256 to 53293

### PROCEDURES

The following procedures may change from time to time to ensure efficiency in administration and effective compliance.

#### Definitions

**"Investigator"** is the project director or principal investigator, co-investigators, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of the research funded by NSF or PHS, or proposed for such funding, which may include staff, interns, external collaborators and co-investigators from other organizations.

**"Institutional responsibilities"** include an investigator's professional responsibilities on behalf of HRiA, including activities such as program service delivery, research, committee or board membership and services and other administrative duties.

**"Significant financial interest" (SFI):** The term is defined differently for PHS and NSF. Please review the following carefully to understand the differences and to ensure accurate reporting.

SFI for purposes of PHS (NIH) funding:

SFI 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 relate to the Investigator's Institutional Responsibilities:

1. 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 the disclosure, when aggregated, exceeds \$5,000.

Remuneration includes salary and other payments for services not otherwise identified as salary (e.g., consulting fees, paid authorships, or honoraria); equity interests includes any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

2. With regard to any non-publicly traded entity, an SFI exists if the aggregated value of any remuneration received from the entity, in the twelve months preceding the disclosure, 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);
3. Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of any income by the Investigator related to such rights and interests.

Included in the definition of SFI is the occurrence of any reimbursed or sponsored travel (i.e. "sponsored travel" is travel which is paid on behalf of the Investigator and not reimbursed directly to the Investigator so that the exact monetary value may not be readily available), related to the Investigator's institutional responsibilities.

The term SFI does not include the following:

1. For HRiA employees, salary, royalties, or other remuneration from HRiA, including intellectual property rights assigned to HRiA and agreements to share in royalties related to such rights;
2. 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;
3. Income from a federal, state or local government agency, an institution of higher education in the U.S. or its affiliated academic teaching hospital, medical center or research institute, when such income is payment for sponsored seminars, lectures, teaching engagements, or service on advisory committees or review panels, or travel reimbursement.

SFI for purposes of NSF funding:

SFI means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does not include:

1. salary, royalties or other remuneration from the applicant institution;
2. any ownership interests in the business, if the business is an applicant under a Phase I Small Business Innovation Research Program or Small Business Technology Transfer Program;
3. income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by public or non-profit entities;
4. an equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or
5. salary, royalties or other payments that, when aggregated for the Investigator and the Investigator's spouse and dependent children, are not expected to exceed \$10,000 during the twelve month period.

Disclosure is the submission of the HRIa Financial Conflict of Interest Disclosure form (FCOID) by each HRIa individual who meets the definition of Investigator. The Disclosure should include the details of the nature of any SFI for the applicable Federal agency (as defined by the agency), and which is held by the Investigator, his/her spouse and/or dependent children.

For NSF and PHS proposals or awards involving an external collaborator who meets the definition of Investigator and who has an SFI, Disclosure can take one of two forms:

1. If the collaboration is with an Investigator whose institution complies with NSF or PHS policies, an annual certification from the institution asserting that it complies with NSF and PHS policy will suffice.
2. If the collaboration is with an Investigator acting as an individual or through an organization that does not comply with NSF or PHS policies, the collaborator Investigator(s) must file a Disclosure. To obtain access to the Disclosure system, the non-HRIa Investigator must contact the Chief Operating Office (mfennel@hria.org.)

Financial Conflict of Interest is an SFI held by an Investigator that could directly and significantly affect the design, conduct, or reporting of his/her PHS or NSF funded research. The determination as to whether an SFI constitutes a Financial Conflict of Interest is made by the Chief Operating Officer. For purposes of PHS and NSF, any ownership interests (whether SFI or not) in a business will not constitute a Financial Conflict of Interest if the business is an applicant under a Phase I Small Business Innovation Research Program (SBIR) or Small Business Technology Transfer (STTR) Program.

Senior/Key Personnel the Project Director or Principal Investigator and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to PHS by HRIa.

#### Required Disclosures

Investigators are required to identify and disclose, or identify and re-verify, if previously disclosed, SFIs before an application is submitted to either NSF or PHS, and thereafter within 30 days of discovering or acquiring a new SFI, employing Disclosure forms made available for this purpose by the Office of Research and Sponsored Programs. Disclosures must also be updated at least annually in connection with HRIa's annual Financial Conflicts of Interest Disclosure process.

At the time a proposal is being prepared, the individual serving as Principal Investigator should alert any other individuals who may meet the definition of Investigator of the need to comply with these procedures. All individuals who are considered to be Investigators (including the principal investigator) are to determine and certify whether they have any SFIs and, if so, each must file Disclosure of the nature and magnitude of the financial interest, employing forms made available for this purpose by the Office of Research and Sponsored Programs. According to Federal requirements, all such Disclosures should be submitted to the Chief Operating Officer before HRIa forwards the proposal to the covered Federal funding agency. Proposals will only be processed if the appropriate Disclosures are on file.

#### Disclosure Review and Management of Financial Conflicts of Interest

HRIa will review Disclosures of SFIs in accordance with these procedures to determine whether an actual or potential Financial Conflict of Interest exists. HRIa's Chief Operating Officer will review and work with the Investigator(s) to develop a management plan for any such conflicts before awarded

funds are expended. Compliance with HRiA's governing policies and these procedures is an ongoing requirement that HRiA must fulfill in order to be eligible to receive funding from NSF and PHS.

The Chief Operating Officer is designated by HRiA as responsible for reviewing Disclosures of SFIs and determining whether a Financial Conflict of Interest exists for purposes of covered Federal funding. When a Financial Conflict of Interest is identified, the Chief Operating Officer is also responsible for determining what steps need to be taken to manage the conflict prior to the expenditure of covered funding.

Upon receiving a Disclosure, the Chief Operating Officer will: review the disclosure to determine if the disclosed SFI constitutes a Financial Conflict of Interest for purposes of the award. If any actual or potential Financial Conflict of Interest is identified, the Chief Operating Officer will work with the Investigator to determine the steps that should be taken to manage the conflict and will prepare a proposed written management plan. The proposed management plan will be forwarded to the President along with the Disclosure form.

The President will review the Disclosure in the context of the proposed activity along with the management plan proposed by the Investigator and Chief Operating Officer. Before permitting any expenditure of funds from the Federal sponsor, the President, in collaboration with the Chief Operating Officer, will approve the management plan describing the conditions and possible restrictions that HRiA believes are necessary to manage the actual or potential Financial Conflict of Interest. The following are examples of conditions or restrictions that may be included in a management plan:

- public disclosure of SFIs;
- monitoring of research by independent reviewers;
- modifications to the research plan;
- disqualification from participation in all or a portion of the activity funded by the Federal agency that would impact the SFI;
- divestiture of SFIs;
- severance of relationships that create potential or actual conflicts; or
- require placing of shares or other forms of equity ownership documents in a blind trust.

Copies of the approved management plan will be made available to the Investigator and the plan must be implemented before the expenditure of funds.

For PHS-funded activities, all SFI must be reviewed by the Chief Operating Officer and all potential Financial Conflicts of Interest completely addressed prior to expenditure of funds. Should an SFI arise during the term of the award, the Investigator must file a Disclosure within 30 days and the SFI must be reviewed by the Chief Operating Officer and all potential Financial Conflicts of Interest completely addressed within 60 days of the Disclosure. If an Investigator does not file his/her Disclosure in a timely manner, additional compliance action by the Chief Operating Officer and HRiA will be required pursuant to 42 CFR 50.605.

### Reporting

The Administration and Finance Office will make any required reports to PHS and NSF. In the case of PHS, the PHS will review the reported Financial Conflict of Interests to determine if additional information is needed. PHS may decide that further action is needed to ensure the objectivity of the

research or that the Financial Conflict of Interest has not been appropriately managed, reduced or eliminated. PHS may also require suspension of funding until the matter is resolved.

### Training

For PHS funded or proposing Investigators, HRiA requires Investigators to be familiar with this document and to receive training via the NIH tutorial or an acceptable equivalent:

1. prior to an Investigator's engagement in research related to any PHS funded project;
2. every four years; and
3. whenever an Investigator is found to be out of compliance with these procedures, their governing policy, or an applicable management plan.

The Principal Investigator will be responsible for identifying all investigators who should have undergone the required training prior to their engagement in the covered research.

NSF funded or proposing Investigators should familiarize themselves with this document relative to obligations required by NSF.

HRiA will maintain required records of all Disclosures and of all actions taken to manage actual or potential conflicts of interest for at least three (3) years from the date the final expenditure or project report is submitted to PHS or NSF or until the resolution of any legal or government action involving these records, whichever is later.

### Subrecipient Requirements

HRiA will include provisions in all covered subawards requiring subrecipients to comply with NSF and PHS rules related to the disclosure of SFIs and management of Financial Conflict of Interests consistent with Federal requirements for covered awards.

### Public Accessibility of Financial Conflicts of Interest

Upon written request to the Chief Operating Officer, HRiA is required to provide, within 5 business days, a written disclosure of Financial Conflicts of Interest held by Investigators proposing for funding or funded by PHS, including:

1. the Investigator's name;
2. the Investigator's title and role with respect to the research project;
3. the name of the entity in which the SFI is held;
4. the nature of the SFI;
5. the approximate dollar amount of the SFI or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.

### Principal Investigator Responsibilities

HRiA requires that the designated Principal Investigator for an activity that is proposed to be, or actually is, funded by a covered Federal sponsor is required to:

1. become familiar with these procedures and the governing policy for Financial Conflict of Interest requirements of federal sponsors
2. distribute copies or notify the Chief Operating Officer to distribute or give notice of this document to any individual who either meets or can reasonably be expected to meet the definition of Investigator and who will participate in a covered activity that is proposed to be, or is, Federally funded by NSF or PHS.

3. assure the Chief Operating Officer that the Principal Investigator and, to the best of his or her knowledge, all individuals who satisfy the definition of Investigator have:
  - I. (a) reviewed their responsibilities with respect to this document and/or the comparable documents at the Investigator's own institution, (b) determined whether they have any SFIs as defined in this document and/or the comparable documents at the Investigator's own institution, (c) submitted Disclosure to HRiA or the Investigator's own Institution, as required; and (d) completed all required Financial Conflicts of Interest training.
4. The Principal Investigator must also indicate whether he or she knows of any potential Financial Conflicts of Interest between any Investigator, including him/herself, arising from an SFI and the proposed work.
5. Notify the Chief Operating Officer of those external collaborators on NSF or PHS proposals that would fulfill the role of Investigator so that institutional certifications or Investigator Disclosures can be obtained.

#### Posting of Policy and Procedures

HRiA will post these procedures and the governing policy for financial conflicts of interest on the website. All current and future HRiA personnel receiving or proposing to receive funds from the covered federal sponsors are required to become familiar with these procedures and the governing policy.

#### Sanctions

Failure to comply in a timely manner with disclosure requirements for PHS-funded awards may result in delays in accessing funds or suspension of expenditures on PHS-funded activities.

Individuals who persistently or purposefully fail to adhere to these procedures and the governing policy may be subject to suspension of funds, removal from participation in the covered award and other disciplinary action as determined by the provost, subject to HRiA due process for disciplinary procedures.

#### Assistance

The Chief Operating Officer is available to provide advice and assistance to any individual on the interpretation of these requirements and the applicability to a specific situation.