FINANCIAL CONFLICT OF INTEREST
FOR NSF-, NIH-, AND PHS-SPONSORED PROJECTS

Purpose

The purpose of this Smithsonian Directive (SD) is to ensure that all individuals affiliated with the Smithsonian, currently participating in research activities funded by the National Institutes of Health (NIH), National Science Foundation (NSF), or Public Health Service (PHS includes NIH, the Centers for Disease Control and Prevention, and other agencies), are familiar and comply with the federal regulations on Objectivity in Research, and that the Smithsonian meets all requirements to ensure the Institution’s continued eligibility to receive grants and contracts from these agencies. Failure to comply with this SD can jeopardize continued or future funding from NIH, NSF, or PHS.

Background

The NIH, NSF, and PHS have issued regulations on Financial Conflict of Interest (FCOI) as related to research funded by these agencies.

The Smithsonian Institution (SI) recognizes that scholars and other staff engage in many relationships with outside entities, some of which might create a financial conflict of interest, or the appearance of a conflict of interest. These conflicts are increasingly common and sometimes unavoidable in a modern research setting. For example, an investigator, through federal grants, may develop a methodology which could be commercialized in the private sector.
Background (continued)  If the investigator has a financial interest in a small business in order to bring such a methodology to market, the relationship between the individual and the small business could be the source of potential conflicts of interest.

The Smithsonian Institution, therefore, recognizes its obligation to ensure that research and other scholarly activities are carried out under the highest standards of integrity and ethical conduct. This policy serves to protect the interests of the scholarly community of the Smithsonian by advancing an important goal: defense of the integrity and objectivity of the research carried out by our researchers.

This SD describes a disclosure process separate from the procedures in SD 103, Smithsonian Institution Standards of Conduct. Investigators who are required to make a disclosure under this directive may or may not also be required to disclose financial interests on SI Form 1085, under SD 103 procedures. Individuals may consult with their unit directors or the Office of Sponsored Projects (OSP) for more information.

Applicability  This directive applies to all Smithsonian employees and affiliated staff*, regardless of title, who are responsible for the design, conduct or reporting of research activities funded by NIH, NSF, or PHS through an award to the Smithsonian, or through a subaward from another institution that has been funded directly by NIH, NSF, or PHS.

Policy  The Smithsonian Institution shall adhere to the standards and procedures set forth in this directive in monitoring significant financial interests and managing disclosed financial conflicts of interest for investigators

* Affiliated staff means individuals other than employees who perform duties for the Smithsonian or who operate on Smithsonian property, including but not limited to contractors, volunteers, interns and Fellows, Friends of the National Zoo employees, visiting researchers and students, research associates and collaborators, and Smithsonian Associates (TSA) educators.
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Policy (continued) who propose or receive funding from the NIH, the NSF or the PHS, in order to comply with federal regulations.

Definitions

An Investigator is the project director (PD), principal investigator (PI) or co-principal investigator (co-PI), or other person, regardless of title, who is responsible for the design, conduct, or reporting of research funded by the NIH, NSF, or PHS, or in proposals for such funding. For the purposes of this policy, the financial interests of the investigator include the financial interests of his or her spouse and dependent children, according to NIH, NSF, and PHS requirements.

Institutional responsibilities are an investigator's professional responsibilities on behalf of the Smithsonian Institution, which may include activities such as research, research consultation, professional practice, Smithsonian committee memberships, and/or service on panels such as the Institutional Review Board of Animal Care and Use Committee.

A Significant Financial Interest (SFI) is defined at 42 Code of Federal Regulations (CFR) 50.603 as:

(1) 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 12 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. 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, an SFI exists if the value of any remuneration received from the entity in the 12 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 interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) 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; however, this disclosure requirement does not apply to travel that is reimbursed or sponsored by a government agency (federal, state, or local), an institution of higher education, or its affiliated entities, such as an academic teaching hospital, medical center, or research institute. (See SD 103, §11 regarding the approval process for reimbursed travel.)

(3) An SFI does not include the following:

(i) Salary, royalties, or other remuneration paid by the Institution, including intellectual property rights and agreements to share in royalties related to such rights;

(ii) 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;

(iii) Income from seminars, lectures, or teaching engagements sponsored by a government agency or institution of higher education; or
Definitions (continued)

(iv) Income from service on advisory committees or review panels for a government agency or institution of higher education.

A Financial Conflict of Interest (FCOI) is said to exist if a significant financial interest could directly and significantly affect the design, conduct, or reporting of NIH-, NSF-, or PHS-funded research.

Managing a financial conflict of interest 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.

Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to: public disclosure of FCOI (e.g., when presenting or publishing the research); disclosure of FCOI directly to human subject participants; appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI; modification of the research plan; change of personnel or personnel responsibilities; reduction or elimination of the financial interest (e.g., sale of an equity interest); and severance of relationships that create financial conflicts.

Any actual financial conflicts of interest will be managed by consultation with an ad hoc FCOI committee and the development of a management plan for the conflict. The ad hoc committee will consist of at least three persons, and may include a researcher from the investigator’s unit, a representative from the Office of General Counsel (OGC), a representative from OSP, or representatives of other areas as may be appropriate to ensure balanced representation of disciplines and interests. FCOI management plans will include a description of how the SFI is related to NIH-, NSF-, or PHS-funded research and will specify the actions that have been and will be taken to manage such FCOI.
Responsibilities

The Under Secretary for Science, the Under Secretary for History, Art and Culture, the Deputy Under Secretary for Collections and Interdisciplinary Support, and the Assistant Secretary for Education and Access are responsible for implementing FCOI policies and ensuring the availability of necessary FCOI training resources for Smithsonian staff. If a potential financial conflict is disclosed, the appropriate Under Secretary, Deputy, or Assistant Secretary will convene an ad hoc financial conflict of interest committee to review the matter and to develop a management plan for the conflict.

Unit Directors are responsible for ensuring that the appropriate individuals within their unit submit disclosures of significant financial interests and complete periodic training in FCOI, if they are investigators funded by NIH, NSF, or PHS. If a potential financial conflict is disclosed, the unit director or designee will assist the appropriate Under Secretary, Deputy, or Assistant Secretary in the convening of an ad hoc committee to review the matter and to develop a management plan for the conflict.

Investigators (PIs, co-PIs) who conduct basic research activities in history, art, and culture or the sciences, through NIH-, NSF-, and PHS-funded awards, are responsible for ensuring that they make disclosures at the following times:

a) when they submit a proposal for funding;

b) when they receive an award;

c) annually during the term of the award; and

d) within 30 days of discovering or acquiring a new significant financial interest

Investigators will complete training prior to engaging in research related to any NIH-, NSF-, or PHS-funded grant and at least every four years thereafter. Investigators who bring an NIH, NSF, or PHS grant with them to the Institution as new employees will complete
Responsibilities (continued)

training within 30 days upon being hired. Investigators will complete new training whenever this SD or related procedures are revised. If a conflict is found to exist, investigators are responsible for complying with the terms of an institutional FCOI management plan. Investigators will complete additional training whenever the investigator is found not to be in compliance with either this SD or a management plan created to manage a disclosed FCOI.

The Office of Sponsored Projects (OSP) will:

• provide training in financial conflict of interest to members of the SI community and will inform all investigators of their responsibility to complete training on this SD, their obligation to disclose SFIs, and of the content of NIH, NSF, and PHS regulations regarding financial conflict of interest.

• maintain records of the disclosure process for non-Smithsonian Astrophysical Observatory (SAO) investigators applying to, and all SI investigators receiving awards from, NIH, NSF, or PHS.

• ensure that the Director of OSP reviews disclosures from all Smithsonian investigators within 60 days and will determine whether any SFI is related to NIH-, NSF-, or PHS-funded research. In addition, in the event of a potential conflict of interest, OSP will confer with the appropriate Under Secretary, Deputy, or Assistant Secretary to convene an ad hoc committee to review the case and implement a management plan that shall specify the actions that have been and will be taken to manage such FCOI.

• prior to the expenditure of any funds under an NIH-, NSF-, or PHS-funded research project, provide to the appropriate funding agency an FCOI report regarding any investigator’s SFI found by the Institution to be a conflict of interest and ensure that the Smithsonian Institution has implemented a management plan in accordance with NIH, NSF, or PHS regulations. OSP will provide to the appropriate
Responsibilities (continued)

- funding agency, within 60 days of the disclosure, a revised FCOI report if any new SFIs are identified subsequent to the initial report and ensure that the Smithsonian Institution has implemented a management plan.

- maintain a publicly accessible website to report on the existence and management of any financial conflicts of interest, in accordance with 42 CFR Part 50 and 45 CFR Part 94. The information will be updated as described by NIH, NSF, and PHS regulations, at least annually, or within 60 days of identification of information that was not previously disclosed.

The Smithsonian Astrophysical Observatory (SAO) Administration will:

- inform all SAO investigators of their responsibility to complete training in financial conflict of interest and this SD, their obligation to disclose SFIs, and of the content of NIH, NSF, and PHS regulations regarding financial conflict of interest.

- maintain records of the disclosure process for SAO investigators proposing to NIH, NSF, or PHS.

- notify OSP of all NIH, NSF, and PHS awards received by SAO investigators. Should a conflict of interest be disclosed for an SAO investigator, SAO Administration will confer with the Under Secretary for Science and OSP to convene an ad hoc committee to review the case and implement a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI.

Enforcement and Sanctions

Smithsonian employees can be subject to the disciplinary process of the Institution if they fail to fully and truthfully disclose financial conflict of interest situations or fail to comply with any stipulated plan for managing the disclosed conflict.
References

- Public Health Service Policy Promoting Objectivity in Research:
  

- National Science Foundation Investigator Financial Disclosure Policy:

- Smithsonian Institution’s Guide to Sponsored Projects:
  http://prism.si.edu/osp/PIGuide/pi_guide.htm

- SD 103, Smithsonian Institution Standards of Conduct

- SD 312, Travel, and associated Travel Handbook

- SD 102, Disclosing, Protecting, and Commercializing Inventions, and

- SD 609, Digital Asset Access and Use

All SDs are available on the Prism Directives homepage

CANCELLATION: None.

INQUIRIES: Office of Sponsored Projects (OSP)

RETENTION: Indefinite. Subject to review for currency 24 months from date of issue