



## **FINANCIAL CONFLICT OF INTEREST FOR NSF- AND PHS-SPONSORED PROJECTS**

1. Purpose	1
2. Background	1
3. Applicability	2
4. Policy	2
5. Definitions	2
6. Responsibilities	5
7. Enforcement and Sanctions	7
8. References	7

### **1. 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 Science Foundation (NSF) or Public Health Service (PHS), which includes the National Institutes of Health (NIH), the Centers for Disease Control and Prevention, and other agencies, are familiar and comply with the federal regulations on Objectivity in Research. This SD also ensures that the Smithsonian meets all requirements for 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 NSF or PHS.

### **2. BACKGROUND**

The 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 FCOI, or the appearance of a conflict 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: the integrity and objectivity of the research carried out by SI staff.

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### 3. APPLICABILITY

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

### 4. POLICY

This directive sets forth the standards and procedures for monitoring significant financial interests and managing disclosed FCOI for investigators who propose or receive funding from the NSF or PHS, in order to comply with federal regulations. To effect the disclosures that may be required by this directive, [SD 103, \*Smithsonian Institution Standards of Conduct\*](#), Section 13(d), “Financial Disclosure Requirements,” applies to all SI staff or any “affiliated staff” as defined below if those individuals are a Principal Investigator (PI) or co-Principal Investigator (co-PI) on an award made to SI from NSF or PHS.

Other individuals, such as a post-doctoral Fellow or senior research staff, who are not a PI or co-PI on the NSF or PHS award, may be required to file a financial disclosure report in accordance with SD 103, Section 13(d), if a unit director, in consultation with the Office of Sponsored Projects (OSP), determines that he or she bears significant responsibility for the design, conduct or reporting of SI research funded by the NSF or PHS. Any individuals subject to this requirement will be so notified by the Office of General Counsel (OGC).

### 5. 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 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 NSF and PHS requirements.

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\* Affiliated persons means individuals other than employees who perform duties for the Smithsonian or who operate on SI 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 educators.

## 5. DEFINITIONS (continued)

**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 services on panels such as the Institutional Review Board or the 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:
  - (a) 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;
  - (b) 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
  - (c) 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 related to their institutional responsibilities unless the sponsor is (a) a government agency (federal, state or local), or (b) an institution of higher learning or its affiliated entities such as an academic teaching hospital, medical center or research institute. This includes both travel that is reimbursed through payment directly to the traveler and travel that is paid in-kind (e.g., when a sponsor books and pays for a plane ticket or hotel room on the traveler's behalf).
- (3) An SFI does not include the following:

## 5. DEFINITIONS (continued)

- (i) Salary, royalties, or other remuneration paid by the Smithsonian 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 individual assets that comprise the investment vehicles;
- (iii) Income from seminars, lectures, or teaching engagements sponsored by a government agency or institution of higher education, to the extent such income is paid directly to SI; or
- (iv) Income from service on advisory committees or review panels for a government agency or institution of higher education, to the extent such income is paid directly to SI.

These thresholds and definitions are applied specifically to investigators having an award from NSF or PHS, in the financial disclosure process using [SI Form 1085](#).

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 an 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.

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 FCOI will be managed by consultation with an Ethics Counselor in the OGC and the development of a management plan for the conflict. FCOI management plans will include a description of how the SFI is related to NSF- or PHS-funded research and will specify the actions that have been and will be taken to manage such FCOI.

## 6. RESPONSIBILITIES

**The Under Secretary for Museums and Research/Provost** is responsible for implementing FCOI policies. If a potential financial conflict is disclosed, the Under Secretary for Museums and Research/Provost, or designee, will review the matter with the unit director and OGC to develop a management plan for the conflict.

**Unit directors** are responsible for ensuring that Investigators within their unit, who are funded by NSF or PHS, comply with all financial disclosure and training requirements. Unit directors are also responsible for identifying and recommending to OSP and OGC any additional SI personnel who are not PIs or co-PIs but are responsible for the design, conduct or reporting of NSF- or PHS-supported research and should be required to file an annual financial disclosure report. If a potential financial conflict is disclosed, the unit director or designee will assist the Under Secretary for Museums and Research/Provost, or designee, and OGC in their review of the matter and with the development of a management plan for the conflict, as appropriate.

**Investigators** (PIs and co-PIs) who conduct basic research activities through 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, by submitting the Certification of Financial Interests to OSP or the Sponsored Programs and Procurement Department (SPPD) of the Smithsonian Astrophysical Observatory (SAO);
- b) when they receive an award, if there are any changes since the last annual disclosure, by filing a revised [SI Form 1085](#) with OGC prior to expending any award funds;
- c) annually during the term of the award, by filing the [SI Form 1085](#); and
- d) within 30 days of discovering or acquiring a new significant financial interest, by filing a revised [SI Form 1085](#).

Investigators will complete required FCOI training, provided through OSP, prior to engaging in research related to any NSF- or PHS-funded grant and at least every four (4) years thereafter. Investigators will complete new training whenever this SD or related procedures are revised in any manner that affects the requirements of investigators. Investigators who bring an NSF or PHS grant with them to the Institution as new employees will complete training within 30 days after entry on duty. Investigators found not to be in compliance with either this directive or a conflict management plan created to manage a disclosed FCOI must complete additional training.

If an FCOI is found to exist, investigators are responsible for complying with the terms of an institutional FCOI management plan.

## 6. RESPONSIBILITIES (continued)

Investigators are responsible for identifying to OSP and OGC any additional SI personnel supported on their NSF or PHS award who are responsible for the design, conduct or reporting of the research, and should be required to file an annual financial disclosure report.

The **Office of Sponsored Projects (OSP)** will:

- 1) notify OGC of any SFIs disclosed by PIs or co-PIs when proposals are submitted to NSF or PHS;
- 2) identify to OGC any PIs and co-PIs who should be required to file an annual financial disclosure statement;
- 3) provide training in FCOI to members of the SI community, prior to their engaging in research, and inform all investigators of their responsibility to complete training related to this SD, their obligation to disclose SFIs, and the content of NSF and PHS regulations regarding FCOI;
- 4) maintain records of FCOI training for all SI investigators applying to, and receiving awards from, NSF or PHS;
- 5) provide to the appropriate funding agency an FCOI report, compliant with 45 CFR 50.605, 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 NSF or PHS regulations. OSP will provide to the appropriate 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; and
- 6) maintain a publicly accessible website to report on the existence and management of any FCOI, in accordance with 42 CFR Part 50 and 45 CFR Part 94. The information will be updated as described by 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:

- 1) notify OGC of any SFIs disclosed by PIs or co-PIs when proposals are submitted to NSF or PHS;
- 2) identify to OGC any PIs and co-PIs who should be required to file an annual financial disclosure report; and

## 6. RESPONSIBILITIES (continued)

- 3) confer with the Under Secretary for Museums and Research/Provost and OGC 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, should a conflict of interest be disclosed for an SAO investigator.

The **Office of General Counsel (OGC)** will:

- 1) review within 60 days of submission to OGC all SI investigators' disclosures, which includes both annual disclosures and disclosures that are revised throughout the year to reflect newly acquired SFIs, and determine whether any SFI is related to NSF- or PHS-funded research.

In addition, in the event of a potential or actual conflict of interest, OGC will confer with the Under Secretary for Museums and Research/Provost to review the case. They will potentially implement a management plan for potential conflicts and will develop full management plans for actual conflicts 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 NSF- or PHS-funded research project.

## 7. ENFORCEMENT AND SANCTIONS

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

## 8. REFERENCES

- Public Health Service Policy Promoting Objectivity in Research:  
<http://grants.nih.gov/grants/policy/coi/> and  
<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>;
- National Science Foundation Investigator Financial Disclosure Policy:  
<http://www.nsf.gov/pub/stis1996/iin117/iin117.txt>;
- Smithsonian Institution's [\*Sponsored Projects Handbook\*](#);

## 8. REFERENCES (continued)

- [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\*](#).

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**CANCELLATION:** SD 608, July 3, 2012

**INQUIRIES:** Office of Sponsored Projects (OSP)

**RETENTION:** Indefinite. Subject to review for currency 36 months from date of issue.

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