



Smithsonian  
Institution

SMITHSONIAN DIRECTIVE 608,  
November 8, 2021

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

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### 1. BACKGROUND

The National Science Foundation (NSF) and Public Health Service (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.

### 2. 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 NSF or PHS, which includes the National Institutes of Health (NIH), the Centers for Disease Control and Prevention, and other agencies of the Department of Health and Human Services (DHHS), are familiar and comply with the federal regulations ([42 Code of Federal Regulations \[CFR\] 50.601 et seq.](#) for PHS grants, 45 CFR 94.1 et seq. for PHS contracts, and NSF [Proposal and Award Policies and Procedures Guide Chapter IX:A](#) for NSF grants) 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 the NSF or PHS.

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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 the NSF or PHS through an award to the Smithsonian, or through a subaward from another institution that has been funded directly by the 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 the NSF or PHS.

Other individuals, such as a postdoctoral 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 principal investigator, in consultation with the Office of Sponsored Projects (OSP) or Smithsonian Astrophysical Observatory (SAO) Sponsored Projects and Procurements Department (SAO-SPPD) for an SAO investigator, determines that he or she bears significant responsibility for the design, conduct, or reporting of SI research funded by the NSF or PHS. The PI is responsible for notifying the Research Compliance Officer (RCO) about any individuals subject to this requirement.

### 5. DEFINITIONS

An **Investigator** is the project director (PD), PI, or co-PI, or other person, regardless of title, who is responsible for the design, conduct, or reporting of research funded by the 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.

**Institutional responsibilities** are an investigator’s professional responsibilities on behalf of the Smithsonian Institution, which may include activities such as research, research consultation,

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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, Fellows, visiting researchers and students, research associates, and collaborators.

## 5. DEFINITIONS (continued)

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)** means:

(i) **for PHS awards**, as defined at 42 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:

(i) Salary, royalties, or other remuneration paid by the Smithsonian Institution, including

## 5. DEFINITIONS (continued)

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.
- (ii) **for NSF awards**, as defined in the [NSF Proposal and Award Policies and Procedures Guide](#):
- (1) Anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights);
  - (2) The term does not include:
    - a. salary, royalties or other remuneration from the proposing organization;
    - b. any ownership interests in the organization, if the organization is an applicant under the Small Business Innovation Research Program (SBIR) or Small Business Technology Transfer Program (STTR);
    - c. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
    - d. income from service on advisory committees or review panels for public or non-profit entities;
    - e. 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

## 5. DEFINITIONS (continued)

\$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 percent ownership interest in any single entity; or

- f. 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 prior 12-month period.

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

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 NSF- or PHS-funded research.

The **FCOI Review Team** is the institutional group tasked with reviewing potential FCOI cases, developing FCOI management plans, and conducting retrospective reviews and writing mitigation reports when needed. The FCOI Review Team consists of the unit director (or designee) of the unit of the subject investigator, the OSP or SAO-SPPD director, an OGC Ethics Counselor, the Research Compliance Officer (RCO), and designee of the appropriate Under Secretary.

**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. An FCOI Review Team will develop a **management plan** for the conflict that 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 the FCOI. The FCOI Review Team will develop the management plan so that it is implemented prior to expenditure of funds under a PHS- or NSF-funded research project (with respect to any FCOIs disclosed in the initial FCOI Report); and for any subsequent FCOI disclosures, within 60 days of such new disclosures. Management of an identified FCOI may also require a retrospective review and a mitigation report, as described below.

Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to, public disclosure of the FCOI (e.g., when presenting or publishing the research); disclosure of the 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.

## 5. DEFINITIONS (continued)

A **Retrospective review** is an investigation undertaken by the FCOI Review Team when an investigator is found to have not disclosed in a timely manner an SFI that is determined to constitute an FCOI or an SFI that is determined to constitute an FCOI and was not reviewed or managed in a timely manner or the failure of the investigator to comply with a management plan. The purpose of the retrospective review is to determine whether any NSF- or PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in its design, conduct, or reporting. Retrospective reviews document, at a minimum: the project number and title; principal investigator's names(s); name of investigator with an FCOI; name of the entity with which the investigator has an FCOI; the reason for the retrospective review; the detailed methodology used for the review; and findings and conclusions of the review. The FCOI Review Team completes and documents a retrospective review within 120 calendar days of the determination of noncompliance.

A **Mitigation report** follows a retrospective review if bias is found to have occurred. The FCOI Review Team will draft a mitigation report to include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the Institution's plan of action(s) taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; and an analysis of whether the research project is salvageable). OSP or SAO-SPPD, as appropriate, will promptly notify and submit a mitigation report to the NSF or PHS Awarding Component.

## 6. RESPONSIBILITIES

**The Under Secretary for Science and Research (USSR)** is responsible for implementing this FCOI policy. If a potential financial conflict is disclosed, the USSR or other Under Secretary, as appropriate to the investigator, designates a staff member to participate on the FCOI Review Team to review the matter and to develop a management plan for the conflict.

**Unit directors** are responsible for ensuring that investigators within their unit, who are funded by the NSF or PHS, comply with all financial disclosure and training requirements. If a potential financial conflict is disclosed, the unit director or designee will participate on the FCOI Review Team in their review of the matter and with their development of a management plan for the conflict, as appropriate. The unit director or designee oversees an investigator's compliance with a management plan. The unit director or designee participates with the FCOI Review Team in any needed retrospective review or writing of a mitigation report.

**Investigators** (e.g., PIs and co-PIs) who conduct basic research activities through NSF- and PHS-funded awards are responsible for ensuring they make disclosures at the following times:

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## 6. RESPONSIBILITIES (continued)

- a) when they submit a proposal for funding, by submitting the Certification of Financial Interests to the Sponsored Programs and Procurement Department (SPPD) of the Smithsonian Astrophysical Observatory (SAO) for SAO investigators; or to OSP for non-SAO investigators;
- 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 calendar 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 the RCO, 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 calendar 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.

Investigators are responsible for identifying to OSP or SAO-SPPD, as appropriate, and the RCO 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, therefore, be required to comply with this policy.

The **Office of Sponsored Projects (OSP)** and the **SAO Sponsored Projects and Procurements Department (SAO-SPPD)** will:

- 1) notify OGC of any SFIs disclosed by PIs or co-PIs when proposals are submitted to the NSF or PHS, and for providing backup material to assist in determining whether an investigator's SFI is related to NSF- or PHS-funded research;
- 2) identify to OGC any investigators who should be required to file an annual financial disclosure statement;

## 6. RESPONSIBILITIES (continued)

- 3) assist OGC in reviewing 1085 form annual disclosures to identify any potential conflicts of interest with ongoing grant/contract activities;
- 4) certify in each application for funding from the NSF or PHS that the Smithsonian has this policy in effect, and make any other application certifications required by NSF/PHS regulations, including those in 42 CFR 50.604(k);
- 5) notify the Research Compliance Officer of incoming NSF and PHS awards, prior to establishment of spending authority;
- 6) establish in any written subaward agreement of NSF or PHS funds whether the subrecipient will follow the FCOI policy of the Smithsonian or the FCOI policy of the subrecipient. This includes obtaining a certification from the subrecipient that its FCOI policy complies with the applicable agency policy. If applicable, the subaward agreement will require the subrecipient to report identified FCOIs for its investigators prior to the expenditure of funds, and within 30 calendar days of identification, to allow the Smithsonian to report identified FCOIs to the funding agency as required by the regulation. Alternatively, if the subrecipient has no PHS-compliant FCOI policy, the subaward agreement will require the subrecipient to provide investigator disclosures to the Smithsonian that enable Smithsonian to identify, manage, and report identified FCOIs to the NSF or PHS, prior to expenditure of funds and when otherwise required per the PHS and NSF regulations;
- 7) participate on FCOI Review Teams to review FCOI cases, and develop, implement, and monitor management plans that shall specify the actions that have been, and will be, taken to manage such FCOI, should a conflict of interest be determined for an investigator;
- 8) participate on FCOI Review Teams in conducting any needed retrospective reviews or the writing of a mitigation report;
- 9) provide to the appropriate funding agency all FCOI reports required under 42 CFR 50.605 for Smithsonian and subrecipient investigators, namely:
  - a. an initial FCOI report, if applicable, prior to the expenditure of any funds under a PHS- or NSF-funded research project and, for any FCOIs disclosed thereafter, an FCOI report within 60 calendar days of disclosure;
  - b. ongoing annual FCOI reports, which will be submitted at the same time as the annual progress report or at the time of extension;



## 6. RESPONSIBILITIES (continued)

- c. a revised FCOI report if any new SFIs are identified subsequent to the initial report within 60 calendar days of the disclosure;
  - d. a report of any retrospective reviews that reveal research bias, along with the mitigation report; and
  - e. a report of any instances of investigator noncompliance with this policy or with a management plan.
- 10) maintain all FCOI case records, other than 1085 disclosure forms, for at least three years from the date the final expenditures report is submitted to the PHS or NSF, or as specified in 45 CFR 75.361, where applicable.

The **Research Compliance Officer (RCO)** will:

- 1) provide training in FCOI to members of the SI community, prior to their engaging in research, and at least every four years thereafter and immediately when one of the circumstances in CFR 50.604(b) apply, 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;
- 2) maintain records of FCOI training for all SI investigators applying to, and receiving awards from, the NSF or PHS;
- 3) participate on FCOI Review Teams by contributing to the development of management plans, conducting any needed retrospective reviews, or the writing of mitigation reports; and
- 4) 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 calendar days of identification of information that was not previously disclosed. Information about FCOIs will remain available on the website for three years from the date it was most recently updated.

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

- 1) review, within 20 calendar days of submission to OGC, disclosures made by NSF- and PHS-funded investigators, which include both annual disclosures and disclosures that are revised throughout the year to reflect newly acquired SFIs, and alert OSP or SAO-SPPD and the RCO if any SFIs appear to constitute an FCOI to allow the Smithsonian to

## 6. RESPONSIBILITIES (continued)

report identified FCOIs to the funding agency within 60 days, as required by the regulation;

- 2) confer with the FCOI Review Team to review the case; in the event of a potential or actual conflict of interest, OGC will advise the FCOI Review Team in developing a management plan for potential and actual conflicts;
- 3) confer with the FCOI Review Team in support of their conduct of needed retrospective reviews or the writing of a mitigation report; and
- 4) maintain annual 1085 forms for at least three years from the date the final expenditures report is submitted to the PHS or NSF, or as specified in 45 CFR 75.361, where applicable.

## 7. ENFORCEMENT AND SANCTIONS

It is not anticipated that the Smithsonian will participate in clinical, drug, or device evaluation research. However, in any case in which the Department of Health and Human Services (DHHS) 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 Institution as required by 42 CFR Part 50, the Smithsonian shall 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.

SI employees can be subject to the disciplinary process of the Institution, up to and including removal, 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:  
[https://www.nsf.gov/pubs/policydocs/pappg20\\_1/index.jsp](https://www.nsf.gov/pubs/policydocs/pappg20_1/index.jsp) as set forth in the

## 8. REFERENCES (continued)

Smithsonian Institution's [Sponsored Projects Handbook](#);

- [SD 103, Smithsonian Institution Standards of Conduct](#);
- [SD 312, Travel](#), and associated [Travel Handbook](#); and
- [SD 102, Disclosing, Protecting, and Commercializing Inventions](#).

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**SUPERSEDES:** SD 608, December 20, 2016.  
**INQUIRIES:** Office of the Under Secretary for Science and Research (OUSSR)  
**RETENTION:** Indefinite. Subject to review for currency 36 months from date of issue.

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