

Guidance on Responsibilities Regarding Reporting and Disclosure Requirements

Reason for Guidance:

The purpose of this guidance is to reinforce Harvard's commitment to protecting federally-funded sponsored awards and to provide guidance on the expected obligations under Harvard and Federal policies. The guidance includes requirements for compliance with mandatory reporting of all sources of research or project-related support, financial interests, and relevant affiliations as well as steps to reduce risk to intellectual property (IP).

Recently, Federal sponsors have begun expressing serious concerns regarding threats to the integrity of U.S. research. The National Institutes of Health (NIH) has voiced their concerns¹ and announced that they are working with other government agencies and U.S. universities to mitigate these concerns, specifically:

- “Diversion of intellectual property (IP) in grant applications or produced by NIH-supported biomedical research to other entities, including other countries;
- Sharing of confidential information on grant applications by NIH peer reviewers with others, including foreign entities, or otherwise attempting to influence funding decisions; and
- Failure by some researchers working at NIH-funded institutions in the U.S. to disclose substantial resources from other organizations, including foreign governments, which threatens to distort decisions about the appropriate use of NIH funds.”²

NIH has also recently reminded the research community of its obligations under 42 CFR Part 50 Subpart F, Objectivity of Research, to disclose all forms of support and financial interest through the significant financial interest (SFI) disclosure process³ and under the NIH Grants Policy Statement to disclose this support in all applications and progress reports².

The National Science Foundation (NSF) has also expressed the same serious concerns with respect to NSF-supported basic and applied research. NSF expects that Principal Investigators (PIs) and senior personnel will list any activity that provides funding to their work and/or a commitment of time by the individual in the same manner as referenced above for NIH.

Applicability:

All Harvard researchers are responsible for maintaining the obligations listed below to ensure the integrity of research at Harvard as well as in the broader scientific community; it is important to note that it is the responsibility of the researcher/PI to comply with these obligations.

Faculty and Researcher Responsibilities:

Harvard faculty, researchers, PIs, and senior personnel supported by federal funding must do the following:

- Track and disclose all forms of support and financial interests via current and pending support in proposals to the sponsors and the Harvard financial conflict of interest disclosure system. Examples of what to disclose in proposal applications include, but are not limited to, foreign or

¹ NIH [Statement on Protecting the Integrity of U.S. Biomedical Research](#) dated August 23, 2018

² ["Dear Colleagues" letter from Francis Collins dated August 20, 2018](#)

³ NIH Guide Notice [NOT-OD-18-160](#), (Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests)

domestic grants, cooperative agreements, contracts and institutional awards. Additionally, include any planned collaborations, foreign and domestic, and the scope of the collaboration including the exchange of information, materials or data (see FAQ for more details).

- Update NIH other support documentation whenever there are changes. For NSF current and pending support, all sources of support (e.g., Federal, State, local or foreign government agencies, public or private foundations, industrial or other commercial organizations, or internal funds allocated toward specific projects) and commitments of time, even if not receiving salary support, must be included.
- In addition to their “Other Professional and External Activity Reports”; Disclose to Harvard all external financial interests⁴, affiliations, fiduciary roles, and non-Harvard sponsored travel that could be reasonably related to your institutional responsibilities through your school’s disclosure process. This includes any financial interests, relationships or affiliations with foreign entities, including foreign institutions of higher education or the government of another country.
- Biographical Sketches (Biosketches) must be current and thorough in compliance with sponsor requirements.
- Progress reports must indicate any change in support for all key personnel that occurred over the period covered by the report.
- Conflict of interest disclosures need to occur in accordance with the funder’s requirements, prior to application being submitted, annually thereafter, and whenever financial interests change. Approval for relationships with outside entities, including foreign entities and governments, must be requested in advance as described in the Harvard’s [Statement on Outside Activities of Holders of Academic Appointments and School specific requirements](#).
- Report inventions promptly as follows:
 - To the Office of Technology Development, the University’s technology transfer office, via the [Report of Innovation \(ROI\) form](#).
 - To federal research sponsors as part of progress reporting and in compliance with other federal invention reporting requirements (such as prompt reporting via iEdison).
- Use reasonable efforts to protect Harvard’s interest (and, in the case of federally-funded sponsored awards, the federal government’s interest) in intellectual property developed in the course of their Harvard research.
- Intellectual property developed at Harvard is subject to Harvard’s [Statement of Policy on Intellectual Property](#).
- Individuals serving on NIH, NSF or other scientific peer review panels should note and comply with all requirements to maintain the confidentiality of the information in research grant applications or other academic materials under review.

⁴ For additional information see: <https://vpr.harvard.edu/pages/financial-conflict-interest-policy>

Definitions:

Current and Pending Support:

A term generally used by all non-NIH federal sponsors and other types of funding entities to request the submission of information for key personnel's active and pending review or awarded research funding. This information is submitted at the time of proposal. The format varies by sponsor. NSF and other sponsors tend to call this "Current and Pending" Support. NIH tends to refer to it as "Other Support."

Other Support:

The term **other support** is specific to NIH and entails the submission of information regarding research funding that is either active (awarded) or pending review or award. The information needs to be submitted for all key personnel and needs to include all financial resources, whether Federal, non-Federal, commercial or organizational, foreign or domestic, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards.

Resources:

[Harvard University Office of the Vice Provost for Research](#)

[Office for Sponsored Programs](#)

[TH Chan School of Public Health Research Administration](#)

[Harvard Medical School Office of Research Administration](#)

[Faculty of Arts and Sciences Research Administration Services](#)

[Harvard University Financial Conflict of Interest School Contacts](#)

[NIH Grants Policy Statement](#)

[NSF Proposal & Award Policies & Procedures Guide \(PAPPG\)](#)

Related Policies:

[Harvard University Faculty of Medicine Policy on Conflicts of Interest and Commitment](#)

[Harvard University Policy on Individual Financial Conflicts of Interest for Persons Holding Faculty and Teaching Appointments](#)

[Statement of Policy on Intellectual Property](#)

[Statement on Outside Activities of Holders of Academic Appointments.](#)