

Guidance for Researchers in Addressing Faculty Disclosure & Intellectual Property Protection

(As of 7/15/2019)

Agencies continue to issue updates, modification or clarifications to existing requirements. The Office of the Vice Provost for Research is continuing to monitor the communications from the agencies and will update this site and the FAQs as appropriate.

GUIDANCE FOR RESEARCHERS IN ADDRESSING FD & IP PROTECTION

1. Introduction

Recently federal funding agencies and congressional committees have expressed concerns regarding certain activities that threaten the integrity of the U.S. research enterprise. These concerns have been widely referred to as “Foreign Influence on U.S. Research” or “Foreign Influence on U.S. Academia”. The issues raising concern for agencies and federal funders can be summarized as:

- a. *Integrity of Peer Review Process:*** Sharing of confidential information on grant applications by NIH peer reviewers with others, including foreign entities, or otherwise attempting to influence funding decisions; and
- b. *Failure to Fully Disclose Information:*** Failure by some researchers to fully disclose substantial resources from other organizations, including foreign governments, financial conflicts of interest; appointments at foreign institutions, etc. in their grant proposals or institutionally required disclosures.
- c. *Compliance with Regulatory Requirements:*** U.S. Export Control laws and regulations establish a set of requirements for transfer of technology and data to foreign countries and/or foreign nationals, including in the U.S. In addition, the Office of Foreign Assets Control (OFAC) restricts interactions with individuals or entities on its Sanctions Lists.
- d. *Loss of Intellectual Property (IP):*** A number of reported instances of unauthorized removal of data from research laboratories in the U.S. have resulted in the loss of intellectual property including, in some instances, publication of the misappropriated data before the U.S. scientists from whom it was taken were able to publish.

The following information has been compiled by the Office of the Vice Provost for Research to assist the faculty and administrators in addressing the concerns raised by the funding agencies and congressional committees. This information is drawn from current U.S. governmental regulations and Harvard University policies and guidelines.

2. Basic Principles

The following sets forth some guiding principles to help Harvard staff, faculty, and others conform to both federal expectations and Harvard University’s core values:

- a.** Harvard University holds as paramount the open exchange of ideas among students and scholars from across the globe as one of its core values and welcomes all such exchanges as

critical in advancing its mission as a global leader in the creation and dissemination of knowledge.

b. Harvard University's stewardship of research funding, both from federal government agencies and from private funders, is a core institutional responsibility, and Harvard has developed policies and adopted rules to ensure that its activities are conducted with integrity and with due regard for the health, safety, and privacy of everyone concerned.

c. Harvard University recognizes its important role in the advancement of legitimate national security needs and the protection of the intellectual property developed as a result of its research and scholarly activities.

The following sections outline the regulatory requirements, expectations of research sponsors, and Harvard's institutional policies and responsibilities, each of which informs best practices at Harvard.

A set of [Frequently Asked Questions for Harvard Researchers](#) (FAQs) further elaborates on these suggestions. The FAQs are organized in accordance with the four main issues described in the Introduction (Section 1) above.

Note: Regulatory requirements and sponsor expectations change frequently; therefore, we strongly recommend that this and the FAQ sites be visited frequently to ensure that you are aware of all relevant updates.

3. Integrity of Peer Review Process

Confidentiality of information obtained during peer review is critical to the integrity of the review process. The Office of Research Integrity ([ORI Introduction to RCR: Chapter 10. Peer Review](#)) explains:

"[I]nformation that is shared during peer review is shared confidentially, that is, with the understanding that it will not be shared with anyone else without permission. Confidentiality is generally required during grant reviews, manuscript reviews, and personnel reviews.

During grant and manuscript reviews, confidentiality helps protect ideas before they are funded or published. In personnel reviews, confidentiality is important to protect personal privacy."

[NIH's Peer Review: Grants and Cooperative Agreements](#) lists eight (8) core values of the peer review process: expert assessment, transparency, impartiality, fairness, confidentiality, security, integrity, and efficiency. The Confidentiality section articulates this as follows:

"In order to protect confidential information, portions of NIH review meetings (initial peer review and Council) are closed or partially closed to the public if grant applications (and contract proposals) are being reviewed or discussed. Only Federal employees with a need to know, reviewers, and support contractors are allowed to attend NIH review meetings.

In addition, all discussions, application materials (except those in the public domain such as publications), and information about conflicts of interest and assignments of individual reviewers to particular applications are strictly confidential. In fact, reviewers must sign a confidentiality certification indicating that they have read and understand the confidentiality rules for NIH peer review, and do so under penalty of perjury, before access to applications is granted. The NIH may take steps in response to a violation of the confidentiality agreement, in order to preserve the integrity of the NIH review process. Depending on the specific

circumstances, such steps may include but not be limited to: notifying or requesting information from a reviewer's institution; terminating a reviewer's service; Notifying the NIH Office of Management Assessment (OMA) with possible referral to the U.S. Department of Health and Human Services Office of Inspector General (OIG); pursuing a referral for government-wide suspension or debarment."

Harvard expects that its community members will respect and abide by the confidentiality of all peer review processes.

4. Transparency & Disclose of Information

The terms of Federal awards, as well as Harvard's internal policies and procedures, require the disclosure of such information. As stated in 1.b above, failure to fully disclose all relevant information either in a proposal or in accordance with Institutional requirements is one of the major issues identified by federal agencies (e.g., NIH) as a concern. All Harvard researchers are responsible for meeting the obligations listed below to ensure the integrity of research, both at Harvard and in the broader scientific community. It is important to note that it is the responsibility of the individual researcher/PI to comply with these requirements.

The following is a brief summary of the major requirements and information that should be included in such disclosures.

a. *Outside/Professional Activity Report:* Harvard University's "[Statement on Outside Activities of Holders of Academic Appointments](#)" establishes the requirement that faculty must request permission to engage in certain outside activities. It details what information must be included with a request, how it will be reviewed, and what criteria will govern approvals delegated to the Schools. Each School has developed a process by which faculty are required to submit annual disclosures of all their outside activities. Typically, these disclosures are made through academic/faculty deans' offices. Through their respective disclosure processes, most schools collect information on the following activities (paid and unpaid):

- i. Teaching and advising activities both within and outside of the school.
- ii. University service (e.g. committees, faculty mentoring, etc.).
- iii. Research and Scholarship, including a list of publications, presentations, lectures, colloquia, contracts, and grants.
- iv. Honors, awards, lectureships, or other significant recognition.
- v. Major accomplishments in the previous year.
- vi. Outside professional activities such as participation in professional associations, journal editorial boards, panels and committees, companies (e.g., boards of directors, scientific advisory committees, consulting, etc.), other academic institutions (e.g., appointment-paid and unpaid, visiting or review committee members, honorary lectureships, etc.)

Covered faculty are expected to provide complete information on all outside activities as required by the School-specific disclosure form, ensuring that all domestic and foreign

activities are included, and to update the information when substantial new activities are engaged in.

b. Financial Conflicts of Interest: "[Conflicts of Interest for Persons Holding Faculty](#)" establishes the requirements for annual disclosure of faculty's financial conflicts of interest. The implementation of the Policy is delegated to each School, and Harvard currently uses two electronic systems (one at Harvard Medical School - and the Harvard School of Dental Medicine, and another at all other Schools, except Harvard Law School, which uses a paper system).

FCOI disclosure requirements include information on:

- i. Payments from any non-Harvard entity (e.g., non-profit and for-profit institutions, companies, professional societies, government or quasi-governmental organizations, etc.).
- ii. Travel reimbursements that exceed a \$5,000 threshold from a single entity, including from all non-profits and foreign entities. The only exception is from Institutions of Higher Education (IHE) in the United States (Note: travel reimbursements from foreign IHE are not exempt and must be reported).
- iii. Ownership and/or payments for intellectual property ("IP"); equity in start-ups based on their IP.
- iv. Licensing agreements on their IP; industry collaborations; equity in companies, public or private; etc.

For the avoidance of doubt, the requirement to disclose includes financial interests received from a foreign institution of higher education or the government of another country. This requirement is distinct from other support and foreign components.

All Persons Holding Faculty and Teaching Appointments must follow their School's annual disclosure requirements and must update their disclosures when new conflicts are identified (e.g., a new consulting agreement, reaching the travel reimbursement threshold, etc.). The School's designated official will review the disclosure and contact you if any additional information or a management plan is required.

Other individuals who are not "Persons Holding Faculty and Teaching Appointments" but who are listed as Key Personnel in sponsored research funding applications may also be required (subject to funder policies) to disclose their financial conflict of interest. If required, they are expected to comply with the same disclosure requirements as above.

c. Other Support or Current and Pending Support: Current and Pending Support or Other Support are terms generally used by federal sponsors and some other 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. Depending on the funder, this section of the application may require information on sources of all financial resources, whether federal, non-federal, commercial or institutional, public or private foundations, industrial or other commercial organizations, foreign sources of funding, available in direct support of an individual's research endeavors (US training awards, prizes or gifts are not included) and commitments of time, even if not receiving salary support. This generally includes:

- i. Project Number

- ii. Contact
- iii. Principal Investigator
- iv. Source of Funding
- v. Title or Project or Subproject
- vi. Major goals of this project
- vii. Dates of approved/proposed project
- viii. Annual direct costs
- ix. Overlap with any existing project
- x. Location of the project
- xi. Effort (person months-cal./academic/summer)
- xii. Foreign resources (see [FAQs](#) for more details)
- xiii. Joint university and department of Veteran Affairs (VA) appointments
- xiv. Other

It is important to provide all the relevant information in the proposal and to update the information (e.g., NIH other support, NSF current and pending support) whenever there are changes.

NIH has recent provided further clarification to Other Support in Notice Number: NOT-OD-19-114 *Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components*.
{Hyperlink: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-114.html>} This Notice states that individuals must provide all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant. The NIH has also posted a set of FAQs that support NOT-OD-19-114 that are available here. {Hyperlink <https://grants.nih.gov/grants/faq-other-support-foreign-components.htm>}

NSF has provided draft language that is available for comment through July 29, 2019 that will affect current and pending support in the Proposal & Award Policies & Procedures Guide which is expected to be put into effect in January 2020.

d. Biosketches: Depending on the funder, Biosketches may be required to include significant information on an individual's activities, both domestic and foreign. These generally include educational background, positions and honors, appointments, contributions to science, research support and/or scholastic performance, publications, products (e.g., software,

patents, and copyrights), synergistic activities (e.g., co-chair of academic conference, membership of the National Academy of Sciences, peer reviewer, organizer of summer workshop, service, service on editorial board of academic journal, etc.), scientific collaborations with or without funding, etc. It is critical to follow the funders' guidelines and to include all relevant information. Generally, it is a good idea to include research collaborations or other activities that are not included in the Current and Pending Support, described above, in the Biosketch.

e. Research Performance Progress Report (RPPR): The RPPR is used by grantees to report on the progress of their project, identify significant changes, report on personnel and describe plans for the subsequent budget period or year. Typically, the RPPR requires the following information:

- i. Accomplishments
- ii. Products
- iii. Publications, conference papers, and presentations
- iv. Website(s) or other internet site(s)
- v. Technologies and/or techniques
- vi. Inventions, patent applications, and/or licenses
- vii. Participants and other collaborating organizations including the addition of a foreign component (As a reminder, new foreign components require prior NIH approval through the relevant Harvard Submitting Offices)
- viii. Actual or anticipated problems or delays and actions or plans to resolve them
- ix. Changes that have a significant impact on expenditures
- x. Significant changes in effort
- xi. Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
- xii. Names of individuals who have worked on the project

In order to facilitate the use of RPPR in the disclosure review process, a copy of the RPPR must be uploaded into GMAS.

Note: See special requirements for DOE grants below.

f. Collaboration Agreements: The term collaboration is used to define a broad range of agreements and is not just limited to those signed formally, as defined in the [Negotiating and Signing Authority for Agreements Related to Research](#) document. This applies to all research

collaboration agreements that are negotiated by the Dean's Office, Departments or faculty, or the Office of Technology Development. Such agreements may be structured as formal inter-institutional agreements, MOUs or letters of intent, or they may be informal ('hand-shake') arrangements to participate in joint research programs, with various levels of details on the nature of the collaboration, faculty involved, resource sharing, etc. As faculty discuss collaborations with their colleagues, it is essential that they consult with their research administrators to identify any potential constraints on the proposed work or possible impacts on their research portfolio. For example, collaborations with investigators at a foreign site anticipated to result in co-authorship qualifies as a "foreign component" that requires notification of NIH; or the new DOE reporting requirement (see below) that require inclusion of additional information on the collaborators.

g. U.S. Department of Energy (DOE) Requirements: On February 1, 2019, DOE issues a new policy mandating that "DOE federal and contractor personnel fully disclose and, as necessary, terminate affiliations with foreign government-supported talent recruitment programs." In addition, as reported in its recent notices, the DOE requires additional information in their required quarterly reports. The following is a summary of the DOE's new reporting requirements for senior or key personnel. These requirements (*italicized and underlined*), as listed below, are excerpted directly from the DOE terms:

"Include the following information on participants and other collaborating organizations during the reporting period:

i. What individuals have worked on the project?

Provide the following information for: (1) Project director(s)/Principal investigator(s) (PDs/PIs); and (2) each person who has worked at least 160 hours on the project during the reporting period, regardless of the source of compensation. Please note that such reporting does not constitute a formal institutional report of effort on the project, but rather is used by agency program staff to evaluate the progress of the project during a given reporting period.

ii. Provide the name and identify the role the person played in this project.

Indicate the total number of months (including partial months) (Calendar, Academic, Summer) that the individual worked on this project. Using the project roles identified below, select the most senior role in which the person worked on the project for any significant length of time. For example, if an undergraduate student graduated, entered graduate school, and continued to work on the project, show that person as a graduate student, preferably explaining the change in involvement.

Project Roles:

PD/PI

Co PD/PI

Faculty

Community College Faculty Technical School Faculty

K-12 Teacher

Postdoctoral (scholar, fellow or other postdoctoral position) Other Professional

Technician

iii. Identify the person's state, U.S. territory, and/or country of residence

State whether this person collaborated internationally.

If the participant was U.S.-based, state whether this person collaborated internationally with an individual located in a foreign country and specify whether the person traveled to the foreign country as part of the collaboration, and, if so, what the duration of stay was. The foreign country(ies) should be identified.

If the participant was not U.S.-based, state whether this person traveled to the U.S. or another country as part of a collaboration, and, if so, what the duration of stay was. The destination country should be identified.

Example:

Name: Mary Smith

Total Number of Months: 5.5

Project Role: Graduate Student

Researcher Identifier: 1234567

Contribution to Project: Ms. Smith has performed work in the area of combined error-control and constrained coding.

State, U.S. territory, and/or country of residence: Michigan, U.S.A.

Collaborated with individual in foreign country: Yes

Country(ies) of foreign collaborator: China

Travelled to foreign country: Yes

If traveled to foreign country(ies), duration of stay: 5 months

iv. What other organizations have been involved as partners?

Describe partner organizations- academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) - that have been involved with the project. Partner organizations may provide financial or in-kind support, supply facilities or equipment, collaborate in the research, exchange personnel, or otherwise contribute.

v. Have other collaborators or contacts been involved?

Some significant collaborators or contacts within the recipient's organization may not be covered by "What people have worked on the project?". Likewise, some significant collaborators or contacts outside the recipients' organization may not be covered under "What other organizations have been involved as partners?"

For example, describe any significant:

collaborations with others within the recipient's organization, especially interdepartmental or interdisciplinary collaborations;

collaborations or contact with others outside the organization; and

collaborations or contacts with others outside the United States or with an international organization."

5. Compliance with Regulatory Requirements

a. Export Controls:

Items, information, and technologies used for University research, including some readily available in the U.S., may be subject to U.S. export control regulations intended to prevent the proliferation of chemical or biological weapons, support national security policies, or protect U.S.- developed intellectual property. The entire research team will need to consider these regulations when transferring certain items, technology, or information to foreign nationals within the U.S. as well as outside the U.S.

b. Sanctions:

Additionally, U.S. government sanctions restrict travel to, financial transactions with, and the provision of services to, certain countries, individuals, and organizations, including certain foreign universities. It is important to understand and comply with country-specific sanctions when travelling abroad and to comply with financial sanctions on individuals and organizations when entering into research collaborations with foreign individuals and entities.

c. Why it is important:

Export controls apply to all activities, not just sponsored research activities. University researchers are individually subject to U.S. export control regulations and trade

sanctions. The consequences for violating these regulations and sanctions are substantial, including criminal and financial penalties.

d. How to Comply:

Make sure your research qualifies as fundamental research: Be alert to restrictions on the publication of your research results and on who can participate in your research. Provide your sponsored office with a complete description of the research you propose, including any non-disclosure agreements or other agreements that may outline restrictions on your research activities or that contemplate the possible acceptance or use of items or technology subject to U.S. export controls.

Consult your school's [Export Control Administrator or the Office of the Vice Provost for Research](#) before shipping or sharing technology, information or tangible research materials internationally. Research equipment, as well as the tangible results of research, such as prototypes, materials, and biological samples may require a license to ship or hand-carry outside the U.S. Consult your School's Export Control Administrator prior to shipping or travelling with research items or technology (including research equipment) internationally.

When collaborating with foreign individuals and organizations, confirm that they are not subject to U.S. embargoes or sanctions. Contact your School's Export Control Administrator to screen foreign nationals and organizations. Additionally, contact your School's Export Control Administrator before travelling to, or conducting research in Cuba, Iran, North Korea, Syria, or the Crimea Region of the Ukraine.

6. Protection of Intellectual Property (IP)

Harvard University researchers generate new data and information that contribute to the advancement of knowledge and serve as the basis for new products and services that benefit the public. The data generated, and developments created by researchers are defined in this discussion as Intellectual Property. Nationally, there are well documented instances of researcher's data being compromised and published by others with significant negative impact on the owner of the research data, such as of loss of valuable time and money used to create the data and potentially patentable inventions.

Federal policy and legislation relating to intellectual property (including patents and copyrights), as well as funders' requirements, have resulted in Harvard University developing policies and procedures to protect the intellectual property generated by its researchers. Below is an overview of key requirements:

a. **"Statement of Policy in Regard to Intellectual Property" (IP Policy)**

Harvard University's IP Policy governs the ownership and disposition of intellectual property which includes, but is not limited to, inventions, copyrights (including computer software) and unpatented research property, such as biological or other tangible materials.

You should report inventions promptly (prior to publication) to the University's Office of Technology Development: <http://www.otd.harvard.edu>.

b. **The Participation Agreement ("PA") and Visitor Participation Agreement ("VPA") forms**

To facilitate compliance with the IP Policy and all other Harvard policies and agreements relevant to research, and so mitigate the reputational and financial risks associated with non-compliance, Harvard utilizes its **Participation Agreement ("PA")** and **Visitor Participation Agreement ("VPA")** forms. By signing the PA or VPA, the terms of which are non-negotiable, individuals agree that they will abide with the terms of all Harvard policies and

agreements that may apply to their work and, with respect to IP developed through their Harvard activities:

- i. agree to cooperate with the University's representatives to protect the IP; and
- ii. assign (or 'deed') to Harvard their rights in IP that Harvard is entitled to own.

Each person who conducts research at (or administered by) Harvard and/or who participates in any externally-supported studies or programs, including: faculty members, staff members; postdoctoral or other research fellows, and students are required to sign the PA. The PA should be signed before an individual begins any research or engages in any externally-supported activity at Harvard.

To access the Harvard University Participation Agreement for signature, please follow this link: [To access the Harvard University Participation Agreement for signature, please follow this link:](#)

Harvard's research policies cover all individuals who perform work under the University's auspices, including visitors. Thus, in addition to the PA, there is the VPA. Because visitors may be differently situated with respect to pre-existing obligations that may relate to their research, alternative forms of the [VPA](#), as described and made available for download at <https://vpr.harvard.edu/visitor-participation-agreements>, have been designed to accommodate their various situations, depending on the type of organization, if any, from which they are visiting Harvard. Except as described below, each visitor who conducts research at (or administered by) Harvard and/or who participates in any externally-supported studies or programs, must sign a VPA.

Exceptions: The following, do not, by themselves, trigger the PA/VPA signature requirement:

- i. Engagement as a consultant, for which all issues of research compliance and IP ownership should **be addressed in the consulting agreement**.
- ii. Use of, or receipt of services from, a Harvard core facility under the terms of its user or vendor agreement, as applicable, even by personnel of other organizations.
- iii. Collaborators who are not paid by Harvard research funds, or who do not visit Harvard as part of the research collaboration.
- iv. Visitors from the Dana Farber Cancer Institute or MIT (unless they are undergraduates) need not sign the VPA.

The VPA should be signed before an individual begins any research or engages in any externally-supported activity at Harvard. ***Foreign visitors should be asked to sign and return the VPA before leaving their home country, so that if a visitor is unable or unwilling to sign the VPA, the issue can be addressed before he or she travels to the U.S.***

Timing of signature for the PA and VPA forms is critical, since a delay can cause Harvard to lose its IP rights to any third party that might stake an earlier claim.

Detailed information on the PA and VPA forms can be found at: https://vpr.harvard.edu/files/ovpr-test/files/harvard_pa_and_vpa_guidance_9_4_18.pdf

c. Protection of IP while Travelling:

The loss of intellectual property (e.g. research data) is not an unusual occurrence, whether due to loss or theft of laptops or other devices or intentional attacks on such devices with malicious software to collect information. The procedures outlined in this following are designed to provide guidance on security measures and protocols that should be followed when traveling abroad. The measures and protocols are designed to minimize the ability for technology and paper documents to be compromised.

The following measures should be considered as best practices when traveling anywhere outside of the United States:

- i. Register your international trip and sign up for travel alerts at globalsupport.harvard.edu.

- ii. Contact your school's IT Security Officer to get a secure thumb drive if you'll be carrying, or collecting, sensitive data.
- iii. Make your devices "healthy" for travel. For Harvard devices, work with HUIT Support (ithelp@harvard.edu).
- iv. It is strongly recommended that you do not take any personal technology or devices with you. Contact your school's IT department to see if they provide loaner equipment with additional security measures enabled.
- v. Keep your phone with you. Computers and sensitive paper records should be stored in a hotel safe. Computers should be powered down to activate encryption, not just placed in sleep mode.
- vi. Use VPN and be wary of free Wi-Fi hotspots that do not require a password or are unsecured open-access. Expect connectivity outages and blocked services such as Google or Yahoo webmail in some countries. If you have a personal hotspot, use that for access to the internet *via* your computer or tablet.
- vii. Disable Bluetooth and Wi-Fi on your phone when you aren't using it.
- viii. Communicate with contacts using a secure messaging program but be judicious in your content. Some governments may break encryption for regulatory monitoring, e.g., "illegal" content.
- ix. When you return: Contact IT support and change your password if you notice your computer acting strangely.
- x. Never plug in a USB drive that is not yours or that someone gives you. Use the secure USB drives provided to you that you can use if you need to transfer files that way.
- xi. Never plug in a USB drive that was previously plugged into a device not provided to you by Harvard for this trip.
- xii. Do not load files or data that are not required during your trip on your devices. Consider using a password for protection of any sensitive or unpublished files you need during your travel.

Contact your School's IT Security Officer for additional information or any questions you may have.

d. Protecting Research Data

Protection of research data is important for a variety of reasons such as:

- i. Preventing the loss of data, especially unpublished data.
- ii. Protecting intellectual property of Harvard researchers (e.g., potentially copyrightable or patentable material)
- iii. Regulatory requirements for the protection of sensitive or personal data (e.g., from human subject research) obtained during your research.
- iv. Maintaining confidential or proprietary information obtained from others (e.g., those from collaborators under a Data Use Agreements-DUA).

Available Resources: Harvard University has developed extensive enterprise and research data protection and security policies that could help with the specific requirements of various categories of data. You should become familiar with these requirements. Below are links to the relevant policies and procedures. Your School's Data Security Officers are available to assist with your specific needs.

The Information Security Policy: Defines Data Classification for different data types and the and the suggested requirements for each data security level.

<https://policy.security.harvard.edu/>

Harvard Research Data Security Policy (HRDSP): Provides information on research data security requirement, including those for protection of human subject data.

<https://vpr.harvard.edu/pages/harvard-research-data-security-policy>

Research Data Management @ Harvard: is a joint effort by Office of Vice Provost for Research, the Harvard Library, Harvard University Information Technology, and School Data Management Offices to provide a central hub to coordinate all the research data management efforts across Harvard.

<https://researchdatamanagement.harvard.edu/>

General Research Data Security Rules

The following are some general rules that you should consider as you develop your data protection plan:

- i. Ensure that all data collection and storage devices are password protected with a strong password. A strong password requires a level of complexity.
- ii. Use encryption to protect all sensitive research information on portable devices.
- iii. Store the data on Harvard University's secure servers and limit access to data to members of the study team. Consider creating different folders for different projects and limiting access to each to those involved in the corresponding element of the research.
- iv. Develop a process for removing access to the data when a team member is no longer involved with the research or has left your research group.
- v. For human subject data: identifiers, data, and keys should be placed in separate, password-protected/encrypted files and each file should be stored in a different secure location.
- vi. If it is necessary to use portable devices for initial collection of identifiers:
 - a. the data files should be encrypted, and the identifiers moved to a secure system as soon as possible; and
 - b. the portable device(s) should be locked up in a secure location when it is not in use.
- vii. When transmitting data, use secure data transmission channels to protect against data interception.
- viii. If using file sharing sites (e.g. Dropbox, cloud service) consult your School's Data Security Officers to determine if the site meets data security requirements for the type of data involved.
- ix. Avoid transmitting sensitive, or unpublished, data as e-mail attachments and always use your Harvard email.
- x. Notify your School's Data Security Officer immediately if there has been, or you suspect there may have been, a breach of data security.

7. 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."

Collaborator: The general definition is "a person who works jointly on an activity or project; an associate".

- **NIH's Definition:**

"Collaborators always play an active role in the research, and the position is sometimes defined interchangeably with co-investigator. As a loose guideline, think of a collaborator as a scientist whose distinct expertise complements your own while a co-

investigator shares your area of expertise and therefore contributes in guiding the scientific direction of the overall project. One provides unique expertise, the other umbrella expertise”.

<https://www.niaid.nih.gov/grants-contracts/consultants-collaborators-subawards>

- **DoD/VA Handbook:**

“Seeking a Collaborator: The first, critical step in any collaborative research project is to find an interested colleague within the other Department, *someone with complimentary research interests whom you like and trust and who can devote the necessary time to the project.* This person needs to work with you through the planning and implementation stages and will champion the project at their agency to ensure proper “buy in” and approvals”.

Export Control: The U.S. Government controls exports or transfer of sensitive equipment, information, software and technology as a means to promote our national security interests and foreign policy objectives. Through complicated network of federal agencies (e.g. U.S. Departments of State, Treasury, and Commerce) and number of inter-related regulations the U.S. governs such exports, these are collectively referred to as “Export Controls.

Foreign Component: Foreign component in an NIH funded requires approval from NIH before the collaboration can start. This is defined as: *“the performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are:*

- *collaborations with investigators at a foreign site anticipated to result in co-authorship;*
- *use of facilities or instrumentation at a foreign site; or*
- *receipt of financial support or resources from a foreign entity.*

Foreign travel for consultation is not considered a foreign component”.

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.

Progress Report: Funding agencies required periodic reports to be submitted by the recipient and used by the funder to assess progress and, except for the final progress report of a project period, to determine whether to provide funding for the budget period subsequent to that covered by the report. Funding requirements should be consulted to identify the frequency of required progress reports.

<https://www.med.navy.mil/sites/nmcp/Dept/Shared%20Documents/CID/VA-DoD-Guidebook-2013.pdf>