



Dear HMS and HSDM Faculty of Medicine and Research Staff:

Harvard Medical School and Harvard School of Dental Medicine continue to encourage and celebrate research collaboration and open scientific dialogue across borders. This academic principle remains at the core of our mission and community values.

In recent months, there have been several high-profile regulatory and law enforcement actions directed at members of the academic and research community resulting from the failure of individuals to adequately disclose foreign support and foreign collaborations. As recipients of federal funds and as employees of Harvard University, faculty and research staff must remain vigilant and fully comply with sponsor and University reporting and disclosure requirements.

The Office of Research Administration (ORA), together with the Office for Academic and Research Integrity (ARI), are here to provide support and resources to our research community. We engage in ongoing collaboration with the Office of the Vice Provost for Research (OVPR) to ensure that our policies and practices are up to date and fully compliant.

We have developed a comprehensive plan to promptly communicate about these issues with our research community and to provide support as individual needs and questions arise. A dedicated website on this topic will go live in the coming weeks, supplementing the in-person administrator and faculty trainings and forums already underway.

If you have not already done so, please review the <u>Guidance for Researchers</u> in <u>Addressing Faculty Disclosure & Intellectual Property Protection</u>, available from OVPR. Representatives from ORA and ARI are available to speak at your departmental meetings, and we encourage you to schedule an in-person discussion.

Also, if you plan to ship any biological materials outside of the U.S., please be sure to review the Provost's new <u>Updated Shipping and Transporting Research Materials Manual</u>.

Lastly, please see below a list of important requirements and available resources.

Please do not hesitate to contact us or members of our teams to discuss your specific questions or concerns. We are proud to support our faculty and research staff and the transformative work carried out here every day.

Sincerely,

Gretchen Brodnicki
Dean for Faculty and Research Integrity

Rachel Cahoon Chief Research Administration Officer Harvard Medical School

IMPORTANT REQUIREMENTS AND AVAILABLE RESOURCES

Reporting of Activities in Foreign Countries and/or with Foreign Governments/Entities

All HMS and HSDM faculty and research staff are required to report all outside activities, paid or unpaid, relevant to an individual's institutional role, including appointments, affiliations and engagements with foreign academic, nonprofit and government-supported entities. This includes, but is not limited to:

- Participation in a foreign talents program;
- Holding an honorary academic appointment at another institution; and
- Being employed by, or serving as a consultant to, an outside institution, company or foreign government, including any relationship with an entity that allows or expects you to receive grant funding through that outside institution/company, even if you are not paid for working with that entity.

Any new relationship or sponsored travel must be reported promptly and, in the case of federally supported researchers, within 30 days of acquiring a new significant financial interest. Any new interest you may have must be reported through the <u>Outside Activities Reporting (OAR) system</u>.

Foreign Components

The performance of any significant scientific element or segment of a federally supported research project that occurs outside the U.S. must be disclosed to federal sponsors in a grant application, if known at the time of submission, or, for awarded grants, through **a prior approval request**. These collaborations, known as "foreign components," include the performance of any work by a researcher or recipient in a foreign location, regardless of whether U.S. grant funds are expended.

HMS and HSDM researchers must consult with the Office of Research Administration if a significant portion of their research project will be conducted outside of the U.S. This may include, but is not limited to:

- 1. Extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling and similar activities; or
- Any activity of a grant recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country; or
- 3. The involvement of human subjects or animals in a foreign country or the performance of an important portion of a project by collaborators in a foreign country, resulting in co-authorship and dual-institution attribution.

Other activities MAY be indicative of a foreign component. ORA can guide you through assessing your interaction with a foreign institution or site and how that relates to your federally funded project. ORA can also help you determine if the activity should be disclosed as a foreign component.

Other Support & Biosketch

Over the past year, several federal sponsors, including the NIH, NSF, DOD and DOE, have issued revised guidelines and memoranda regarding disclosure obligations of grant recipients, including requirements for Other Support pages. NIH guidelines clarify that grant applicants and recipients are expected to fully report all available resources (financial, in-kind and personnel) broadly supporting one's research endeavors, excluding prizes, gifts, training awards and consulting activities only. This explicitly includes the disclosure of any grants received through any institution outside Harvard.

This represents a change in practice, and ORA has issued <u>guidelines</u> and <u>templates</u> to assist faculty in complying with the NIH's modified instructions. Please note that for any NIH requests or transactions that require submission of new or updated Other Support, including, but not limited to, JIT and RPPRs, **ORA must review and authorize the Other Support pages prior to submission to NIH**.

Information about affiliations, appointments and honors should also be disclosed to the NIH through an investigator's Biosketch.

We anticipate that other federal sponsors will be posting their own disclosure requirements for Other Support, Current and Pending Support, Biosketches and other grant documents in the near future. ORA will update the community as more information becomes available.

Available Support & Resources

- For questions regarding when to seek prior approval for a foreign component or what to disclose in your Biosketches, grant applications or Other Support pages, please contact your awards officer in the <u>Office of Research Administration</u>. You may contact ORA directly at 617-432-1596 or at <u>researchadmin@hms.harvard.edu</u>.
- For questions regarding your Outside Activities Reporting obligations, please contact the <u>Outside Activities Program</u> in <u>the Office for Academic and Research Integrity</u> at 617-432-1343 or <u>outside activities@hms.harvard.edu</u>.
- Please direct all other questions to the <u>Research Compliance</u> team within the Office for Academic and Research Integrity at 617-432-1343 or ari@hms.harvard.edu.