

# Harvard University

## Quick Guide for Researchers:

# 12 Essentials Every Researcher Should Know

### Introduction

Researchers are responsible for all aspects of their research including compliance with what can sometimes seem like a byzantine network of laws, regulations, and Harvard University (“University”) policies. Sometimes their importance is obvious; sometimes it seems like a lot of rules and paperwork for their own sake.

This resource guide is provided to help demystify these requirements and lighten the load for researchers. It highlights the top 12 issues surrounding research administration and compliance and provides a brief explanation of each topic, clarifies the researcher’s key responsibilities, and identifies University resources for additional help and information. This guide is intended for all University researchers, and identifies which responsibilities are specific to the Principal Investigator.

### Key Terms

***Department/Local Administrator:*** Department/local level managing unit administrator supports research administration activities and may include grant managers, finance managers, sponsored research administrators, or faculty assistants.

***Principal Investigator (PI):*** The individual officially responsible for the conduct of a sponsored project. On research projects, the PI is usually a faculty member; on other types of awards, such as financial aid, the PI may have an administrative appointment. PI eligibility is a school-level determination.

***Sponsored Office:*** The University’s sponsored offices include the Office for Sponsored Programs (University- area schools), Sponsored Projects Administration (Harvard T.H. Chan School of Public Health), and Office of Research Administration (Harvard Medical School).

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## External Sponsored Funding: Proposal Development and Submission

### What is essential

University researchers request external funding from a variety of sponsors, including federal and non-federal sponsors, foreign entities, and non-profit and for-profit organizations, to support their research and other activities. All sponsored proposals<sup>1</sup> that seek external funding must be submitted to the sponsor by the appropriate sponsored office authorized to submit external sponsored proposals on behalf of the President and Fellows of Harvard College.<sup>2</sup>

To submit proposals for external funding, you must have Principal Investigator (PI) status pursuant to your school's PI Eligibility Policy. Additionally, every PI must have signed a [Harvard University Participation Agreement](#), which is designed to help implement the Intellectual Property Policy and other University research policies and to enable the University to fulfill its responsibilities relating to research. Additional documentation may be required at the time of submission (e.g., a current [Financial Interest Disclosure](#)).

### Why it's important

Sponsored projects must comply with all applicable regulations and legal requirements, University policies, and sponsor terms and conditions. If the proposal is funded, the award must be made to the President and Fellows of Harvard College, not the submitting PI, as the University is legally liable and responsible for ensuring compliance with the terms and conditions of the award. Proposal review by the sponsored offices is critical to determine whether the University and the PI can meet these requirements, as well as complete the proposed scope of work within the required project period consistent with the proposed funding requested. If a sponsored proposal is not submitted through one of the sponsored offices, there is a risk the University may not accept the award.

### How to comply

Proposal processes vary by sponsor and by schools. Therefore, it is essential for PIs to work with their department/local administrators and/or school-based sponsored offices ("local support") to ensure that proposals are appropriately developed and budgeted, then submitted through the University's Grants Management Application Suite (GMAS) for review and submission by the appropriate sponsored office prior to the sponsor's deadline. Review by the sponsored offices requires time; therefore, each office has [prescribed review deadlines](#) of which the PI must be aware. Additionally, other reviews may be needed prior to submission (e.g., [Provost Criteria Review](#), Office of Technology Development) for proposals that may pose additional management challenges and/or reputational risk.

Working with department/local administrators, the PI needs to devote sufficient time to not only develop the proposed work, but to develop/review all other aspects of the proposal (e.g., data management plans, budgets sufficient to complete the scope of work, current & pending support, curriculum vita, subcontract proposals). The PI must also review the full proposal in GMAS prior to approving.

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<sup>1</sup> [Gifts](#) that can also support PI research projects follow a different process based on each School's and the University's development process.

<sup>2</sup> In some circumstances, non-federal sponsors use their own submission portals where the PI must submit. In this case, the PI must still go through the sponsored office review and approval process to obtain authorization to submit the proposal.

## Helpful Resources

- [University Policy on Individual Financial Conflicts of Interest for Persons Holding Faculty and Teaching Appointments](#)
- Harvard Longwood Campus Research Administration (HMS, HSDM, SPH) - [Preparing a Proposal](#)
- Office for Sponsored Programs – [Preparing a Proposal](#)
- Faculty of Arts and Sciences Research Administration Services (FAS/SEAS) - [Getting Started](#)
- Harvard Graduate School of Education – [Proposal Submission](#)
- [Harvard Kennedy School – Proposal Submission](#)

## PI Eligibility Policies

- [Faculty of Arts and Sciences](#)
- [Harvard T.H. Chan School of Public Health](#)
- [Harvard Medical School](#)
- [Harvard Graduate School of Education](#)
- [Request Eligibility Policy from Harvard Divinity School Grant Manager](#)

## Sponsored Office Proposal Deadline Dates

- [Office of Research Administration \(ORA\) – HMS, HSDM](#)
- [Sponsored Projects Administration \(SPA\) - SPH](#)
- [Office for Sponsored Programs \(OSP\) – All Other Schools](#)

## Allowable Charges on Sponsored Awards

### What is essential

As a researcher accepting money from a sponsor, a Principal Investigator (PI) has a responsibility to the sponsor, taxpayers (if federally funded), University, and their colleagues to be a good steward of the funding. This includes understanding the PI's, research team members', and University's roles and responsibilities to ensure that expenses incurred on the project are in compliance.

### Why it's important

The scrutiny applied to federal spending is at a point never seen before. Several high-profile audits have resulted in false claims at peer institutions for unsupported, unreasonable, and unallowable expenses for costs such as travel, equipment purchases (near the end of award), administrative salaries, cell phones, and more<sup>3</sup>. Non-federal sponsors are also applying more stringent rules and performing an increasing number of audits. *Misuse of federal funds can be subject to [False Claims Act](#) allegations, which carry the risk of substantial financial penalties, felony convictions, and/or imprisonment.*

### How to comply

**Understand what can be charged:** Work with your department/local administrator to determine what can and cannot be charged directly to a sponsored award. For federal awards, the expense must be:

- **Allowable:** An allowable cost is eligible for reimbursement from the sponsor either as a direct or indirect expense<sup>4</sup> and is permissible according to the terms and conditions of the award and established University policies and practices.
- **Necessary and reasonable:** The item/expense is necessary and reasonable for the performance of the award (i.e., what a "prudent person" would deem appropriate).
- **Allocable:** A cost is allocable as a direct cost if the goods or services provided are assignable in accordance with the relative benefits received (i.e., incurred solely to advance the work under the sponsored agreement).
- **Consistent:** Costs must be consistently treated (i.e., treated in like circumstances either as direct or indirect cost in order to avoid possible double-charging federal awards).

**Monitor expenditures:** Review account status and charges on a routine, preferably monthly, basis. Work with your knowledgeable and trained department/local administrator to ensure that: expenses are charged and documented correctly; accurately align/assign personnel effort to research aims (i.e., time and effort reporting); plan/forecast ahead; and make timely adjustments if needed.

### Helpful Resources

- [Administrative and Clerical Salaries on Federal Awards Policy](#)
- [Summary of Policy for Capital for Equipment in School with Sponsored Research](#)
- [Responsibilities of Purchasers, Preparers and Approvers](#)
- [Sponsored Expenditure Guidelines](#)
- [Sponsored Travel Guidance and Policy](#)
- [Uniform Guidance Subpart E – Cost Principles](#)

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<sup>3</sup> Costs may not be allocated to meet deficiencies caused by overruns; to avoid restrictions imposed by federal statutes, regulations, or terms/conditions of a federal award; for other reasons of convenience; or because one project has more funds.

<sup>4</sup> An expense is a "direct cost" if that expense can be identified specifically with a particular sponsored project or other activity with a high degree of accuracy. "Indirect costs" (sometimes referred to as facilities and administration (F&A) costs, or overhead), are costs that benefit many activities (e.g., building operations and maintenance, IT expenses, security, administrative personnel such as grant managers). F&A costs are recovered through the federally negotiated rate.

## Agreement Signature Authority

### What is essential

The University's processes governing the review, negotiation, approval and execution of agreements between the University and external entities differ based on the type of agreement, the parties' relationship, whether there is funding involved, and where that funding originates. Based on these characteristics, researchers and department/local administrators must route agreements to the appropriate office(s) designated in the [Legal Guidance Workflow](#), which may require the involvement of your sponsored office (SO), Office of Technology Development (OTD), the Provost's Office (OVPR), Alumni and Donor Services (ADS), and/or your school/tub. Ultimately, the authorizing office will ensure that the agreement is properly executed by a delegated official and includes appropriate terms and requirements that protect both the University and the researcher.

### Why it's important

Agreements that are not signed by the correct University official are invalid and potentially fraudulent. This could result in the withholding of funds or requested data or materials, a breach of contract claim, and possible legal repercussions for the individuals involved and the University. Additionally, proper management of legal agreements requires adherence to various policies and procedures relating to accounting, budgeting, research oversight, and legal compliance. The University's designated office(s) and officials must review any incoming or outgoing agreements intended to obligate the University and ensure compliance with applicable local, state, and federal laws.

### How to comply

If the agreement involves funding, the designated office must determine whether the agreement is: (i) a gift, which requires ADS review and signature; (ii) an incoming or outgoing non-industry (e.g., non-profit, government, or educational institution) sponsored agreement or fellowship agreement, which require SO review and signature; (iii) an incoming or outgoing industry sponsored research agreement or intellectual property agreement, which require OTD review and signature; or (iv) a Contractor Agreement (Vendor or Consulting Agreement)<sup>5</sup>, which should be developed in consultation with your school/tub research administrators, and upon request, may be reviewed by SO or OTD, and will ultimately be signed by a delegated school/tub official.

Additionally, University investigators engage in a variety of unfunded collaborations that may require agreements. Unfunded research, collaboration, and visiting-scientist agreements with industry partners, as well as material transfer agreements, are reviewed and executed by OTD. Unfunded research, collaboration, and visiting-scientist agreements with non-industry partners, as well all data use agreements, are reviewed and executed by your SO. Similarly, confidentiality agreements are reviewed and executed by your SO if non-industry and OTD if industry but may also require the signature of the Principal Investigator, depending on the scope. Please consult the [Legal Guidance Workflow](#) for additional information on routing agreements.

### Helpful Resources

- [Legal Agreements Workflow, Negotiating Authority and Signing Authority](#)
- [Consulting or Related Service Agreements Policy](#)
- [Gifts vs. Sponsored Research Policy](#)

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<sup>5</sup> Defined in "Working with External Collaborators" guidance.

## Cost Sharing

### What is essential

Cost sharing is the portion of project costs not reimbursed by the sponsor and may be in the form of cash or in-kind contributions funded by the University or a third party. In a proposal, cost sharing may be offered in response to a requirement from the sponsor (i.e., “mandatory cost sharing”). **The University strongly discourages cost sharing, unless such a commitment is mandated by the sponsor.** All committed cost sharing must be tracked, may require reporting, and must be allowable by the sponsor (see “Allowable Charges on Sponsored Awards” guidance).

### Why it’s important

Whether mandated by the sponsor or proposed voluntarily, cost sharing offered in a proposal becomes a binding commitment once an award is made. Failure to fulfill the cost-sharing obligation at the proposed level or appropriately document cost sharing commitments from verifiable official University records could result in audit findings and require the return of funds to the sponsor. The Principal Investigator (PI), in coordination with the department/local administrator, is responsible for funding cost sharing commitments.

### How to comply

**In the proposal:** PIs are strongly discouraged from including any quantifiable commitments that are not included in the proposed budget to the sponsor. If cost sharing is included in a proposal, the PI, in coordination with the department/local administrator, is responsible for identifying the type(s) of committed cost sharing sources and ensuring the budgeted cost share expenditures are allowable, allocable, reasonable, and consistently accounted for in accordance with University and sponsor policies.

**During the project:** PIs should coordinate with their department/local administrator to monitor cost sharing expenses during the duration of the project to make sure the costs are allowable and that the cost sharing commitment is being fulfilled. If there are any increases or decreases in the cost sharing commitment, the PI and department/local administrator should coordinate with the sponsored office.

**After project expiration:** PIs and their department/local administrator should:

- provide cost share information and confirm the cost sharing commitment has been met;
- coordinate with OSP Research Finance to resolve any cost sharing discrepancies; and
- assume any financial loss if cost sharing commitments are not met and sponsor does not approve a reduction of cost sharing commitment.

### Helpful Resources

- [Sponsored Expenditure Guidelines](#)
- [Effort Reporting Policy](#)
- [Sponsored Financial Reporting and Close Out Policy](#)
- [Harvard University Cost Sharing Procedure Guide](#)
- School-Specific Cost Share Procedures:
  - [FAS Cost Sharing Procedures](#)
  - [HGSE Cost Sharing Addendum](#)
  - [HKS Cost Sharing Procedures](#)
  - [HMS Cost Sharing Procedure Guide](#)
  - [SEAS Cost Sharing Procedures](#)
- [Harvard University Cost Sharing Form \(HUCSF\)](#) (applicable to University area only)
- [Cost Sharing FAQs](#)

## Working with External Collaborators

### What is essential

External collaborators on a sponsored project generally fall into one of two categories: (i) a *Subrecipient* performing research, or (ii) a *Contractor* providing goods and services (including consulting services).

### Why it's important

Based on the Principal Investigator's (PI) categorization of the collaborator, specific federal, state, and sponsor requirements will govern the lifecycle of the collaboration. The relationship must be accurately depicted in both the budget and scope of work (SoW) included in the proposal, as well as the resulting agreement<sup>6</sup>; otherwise the University risks financial and legal harm.

### How to comply

#### PROPOSAL STAGE:

(1) Make a determination between *Subrecipient* versus *Contractor*:

**A *Subrecipient* designation is appropriate when the collaborator:**

- Is performing substantive, programmatic work, or an important or significant portion of the research plan;
- Has its performance measured in relation to whether objectives of the SoW were met;
- Has responsibility for programmatic decision-making and discretion over how work is carried out;
- Makes independent decisions regarding how to implement the requested activities;
- Expects to retain ownership rights in potentially patentable or copyrightable technology or products that it produces in the course of fulfilling its SoW;
- May create or co-author publications; and/or
- Will use funds to carry out a program for public benefit, as opposed to providing goods or services for the benefit of the University.

**A *Contractor* designation is appropriate when the collaborator:**

- Has no employment relationship with the University;
- Is providing specified services in support of the research program;
- Is an individual vendor of consulting services;
- Has not significantly participated in the design of the research itself;
- Is not directly responsible to the sponsor for the research results;
- Markets its services to a range of customers, including those in non-academic fields;
- Has little or no independent decision-making authority in the design and conduct of the work;
- Commits to deliverable goods or services, which if not satisfactorily completed will result in nonpayment or requirement to redo deliverables;
- Does not expect to have its employees credited as co-authors on papers that emerge from the research; and/or
- Does not expect to retain ownership rights in potentially patentable or copyrightable technology or products that it produces in the course of fulfilling the contract.

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<sup>6</sup> **Subaward Agreement** – An award provided by a pass-through entity (Harvard University) to a *Subrecipient* to carry out part of a sponsored award. Subawards can be in the form of a grant or contract and require a detailed SoW and budget that specifies salary, fringe, supplies, and other direct costs, as well as applicable Facilities & Administrative (“indirect”) costs. Sponsored offices review and negotiate all Subawards.

**Contractor Agreement (Vendor or Consulting Agreement)** – A contract provided by Harvard University to a *Contractor* to provide goods or services as part of a sponsored award. Federal regulations require that competitive bids are sought from multiple *Contractors* whenever possible, and when the cost exceeds \$10,000, but this is a best practice for all *Contractor* engagements. A detailed SoW specifying distinct deliverables and due dates may be requested. The budget should only include direct costs.



- (2) Develop a SoW reflective of your collaborator's specific contribution, a budget delineating the appropriate indirect costs for *Subrecipients*, and a specification of *Contractor* rates and/or fees.

#### **AWARD STAGE:**

Work with the appropriate sponsored office to ensure clarity in the resulting agreement will enable University researchers to perform the work, submit required reports and deliverables, and manage the *Subrecipient* or *Contractor*.

#### **ONGOING AWARD MANAGEMENT:**

For *Subrecipients* only, federal regulations and University policies require PIs, in collaboration with their schools/tubs, to monitor the programmatic and financial activities of both federal and non-federal *Subrecipients*. Additionally, PIs should ensure all collaborators, whether a *Subrecipient* or a *Contractor*, are delivering timely and as proposed; critically review any required reports; review and approve submitted invoices; and notify the sponsored office if there are any performance issues. It is expected that PIs maintain regular communication with all collaborators.

#### **Helpful Resources**

- For additional information on making the Subrecipient and Contractor determination, see the [Subrecipient vs. Contractor Guidance](#).
- For additional details on the process for Contractor Agreement review, see the [Legal Agreements Workflow](#) and [Independent Contractor Classification Policy](#).
- For additional information on Subrecipient monitoring, see [Subrecipient Monitoring Policy](#) and [Subrecipient Monitoring Toolkit](#).
- [Procurement Policy](#)

## PI-Required Non-Financial Reports

### What is essential

Principal Investigators (PIs) have overall responsibility for the programmatic objectives of any sponsored project. In addition, PIs are responsible for complying with sponsored award terms and meeting all deliverables, including the timely submission of non-financial reports to sponsors (e.g., technical/scientific, invention/patent reports).

### Why it's important

Sponsors can and do suspend funding in cases where progress or final technical reports are not submitted by the deadline. Additionally, when reports have not been submitted by the deadline, sponsors may delay your funding, that of anyone else at the University funded by same agency, and/or not review proposals submitted by the University to the same agency. It is therefore critical to submit all reports in the proper format per the reporting schedule specified in the sponsored award.

### How to comply

PIs, in coordination with their department/local administrator, should be aware of the reporting schedule associated with each award and ensure that complete and accurate reports are submitted in a timely manner. Typical PI-required reports include the following:

- **Technical/Scientific Progress and Final Reports:** Most sponsors have a required format and submission system (online or other). Responsibility for submitting required technical reports belongs to the PI.
- **Final Invention/Patent Reports:** Most sponsors require that inventions or discoveries that are or may be patentable be reported to the sponsor. If a PI believes s/he may have made an invention or discovery, the inventor should report it to the Office of Technology Development (OTD), using the [Report of Innovation Form](#). This form provides the information that OTD needs to evaluate the invention or discovery and determine whether patenting is appropriate. The appropriate sponsored office will coordinate with OTD and the PI to collect the information necessary to prepare and submit any required patent or invention reports.
- **Property/Equipment Inventory Reports:** PIs should provide any information to their department/local administrator to provide school/tub equipment managers the information required for award property closeout reports and annual government-owned property reports. PIs should request permission from the appropriate contact(s) before equipment is transferred, disposed, loaned, traded in, donated, sold, etc.

Other reports may be required by a specific award and, therefore, would be the responsibility of the PI and department/local administrator to complete. This may include a Foreign Travel Report, non-standard financial report, data management reporting, or other.

### Helpful Resources

**Related to non-financial reporting management:** [Scheduling and tracking non-financial reports \(FAS\)](#)

**Related to invention/patent reporting:** [Office of Technology Development](#)

**Related to property reporting:**

- [University Sponsored Equipment Roles and Responsibilities Matrix](#)
- [Government Owned Property Overview and Procedures](#)
- [Appendix A: Summary of Policy for Capital Equipment in Schools with Sponsored Research](#) of the [Financial Management of Property, Plant and Equipment Policy](#)

## Salary/Effort Certifications

### What is essential

Principal Investigators (PIs) have the important responsibility of ensuring that salaries charged to research projects accurately reflect how the project personnel have spent their time on the project; i.e., the amount of salary charged to a sponsored project must be a true reflection of the effort of work performed. **Effort is *not* based on a 40- or 35-hour week.** Total effort is defined as the percentage of time an individual devotes to fulfill his/her Harvard responsibilities.

### Why it's important

The University is required to comply with federal regulations on how research funds may be spent, which includes salary effort verification. Non-compliance with salary/effort reporting and certification requirements can impact the PI, the project, and the University, including jeopardizing the University's eligibility for federal funding. ***Claiming work was performed that was not actually performed can be subject to [False Claims Act](#) allegations, which carry the risk of substantial financial penalties, felony convictions, and/or imprisonment.***

### How to comply

PIs are responsible for certifying their own effort annually on a federally funded sponsored award.<sup>7</sup> In addition, PIs must certify quarterly any non-faculty charging salary/effort to a federally-funded project (or a non-federal project requiring effort certification). There are circumstances when it may be appropriate for the PI to delegate the quarterly effort responsibility to another individual associated with the project but would require school approval via the [Request for Delegation of Authority for Quarterly Project Effort Certifications](#). The delegate must have sufficient technical knowledge and/or is in a position that provides for suitable means of verification that the work was performed. In addition, the PI and delegate must:

- Have direct knowledge of how research staff spent their time and have suitable means to verify how staff spent their time;
- Understand their own as well as their research team members' levels of effort committed, charged, and reported on all applicable awards;
- Review, initiate corrections if necessary, and electronically certify their individual Annual Faculty Effort Certification and their Quarterly Project Effort Certification(s) by the deadline;
- Communicate significant effort changes to the department/local effort coordinators;
- Review salary charges on awards on a routine basis with department/local administrator, identify any effort-related changes, and coordinate the posting of corrections if needed; and
- Recertify and electronically sign if effort changes are made after a statement has been certified.

### Helpful Resources

- [Harvard University Effort Reporting Policy](#)
- [HMS/HSDM Faculty Effort on Sponsored Awards](#)
- [Harvard Chan School Sponsored Effort Management Policy](#)

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<sup>7</sup> Only in extenuating circumstances may a [proxy may be designated](#) to sign an annual PI/ Faculty certification.

## Laboratory Safety and Regulated Research Materials

### What is essential

Research may require the use of hazardous or regulated materials such as chemicals, drugs, infectious microorganisms, human embryonic stem cells, radioactive material, or live animals. Safe and responsible management of these materials by University researchers is essential for securing funding, maintaining a safe environment for personnel, avoiding regulatory penalties, and safeguarding research continuity. Principal Investigators (PIs) are responsible for ensuring that all research materials are managed in a safe and responsible manner. [University policy](#) dictates that PIs are accountable for the safety of the laboratory staff, students, researchers, and visitors working under their direction or supervision.

### Why it's important

The University has both legal and ethical obligations to ensure that all research with hazardous or regulated materials is conducted in accordance with all federal, state, local and institutional regulations and policies. Misuse or improper management of hazardous or regulated materials carries the risk of injury to personnel or the community, environmental and reputational damage, regulatory penalties, and may compromise funding. Many granting agencies will require that provisions for health and safety programs are in place to secure funding.

### How to comply

Prior to initiating research, consider whether any materials may be considered hazardous and seek support from Environmental Health & Safety (EH&S). EH&S can help researchers perform risk assessments, find ways to mitigate risks, and identify regulatory requirements. Use of hazardous materials will almost always require training and in some cases will also need to be registered with a local committee for review prior to initiating work. Regulated research materials may require permitting or licensing with regulatory bodies as well as local committee oversight and usually have very specific instructions for waste disposal. Common hazardous and regulated research materials are listed below with the departments on campus that can provide guidance.

Hazardous and regulated research materials	University contact for guidance
Biological material, radioactive material, lasers, chemicals, controlled substances	<a href="#">Harvard EH&amp;S</a>
Research animals (vertebrates)	Institutional Animal Care and Use Committee (IACUC): <a href="#">Longwood Medical Area</a> or <a href="#">University Area (Cambridge)</a>
Human embryonic stem cells	<a href="#">Embryonic Stem Cell Research Oversight (ESCRO) Committee</a>

### Helpful Resources

- [Harvard University Laboratory Safety Policy](#)
- [Committee on Microbiological Safety](#)
- [Radiation Safety Committee](#)

## Human Subjects

### What is essential

The University is guided by the ethical principles regarding research involving the use of humans (human subjects, bio-specimens, or related data). The minimum standard is set by the Department of Health and Human Services regulations at 45 CFR 46 (the “Common Rule”). The University has additional provisions beyond that standard, which help to establish the highest expectations for performance and oversight by investigators, Institutional Review Boards (IRBs), and the University.

### Why it’s important

Researchers as individuals, together with the University, have ethical and legal obligations to treat the use of human subjects, human material, and human data used in research responsibly.

### How to comply

Consult with your area IRB to determine if your research needs to be reviewed by the IRB. Special considerations for research with human subjects, human material, or human-related data include the following:

- Tissues, specimens, or data coming in may require a [Material Transfer Agreement](#) (MTA) or a [Data Use Agreement \(DUA\)](#).
- The use of fetal tissue in research, even if it is considered *Not Human Subjects Research*, may need IRB review.
- Research that involves the use of [biological](#), [chemical](#), or [radioactive](#) materials in humans may require the approval or signoff from the appropriate area in [Lab Safety](#) or may require an [MTA](#).
- Research performed in collaboration with another institution may require review/approval from the collaborating institution. Alternatively, participating institutions may execute an IRB Reliance Agreement whereby one institution relies on another for IRB review and oversight.
- Research in foreign countries may require government and/or local research ethics committee approval. (See helpful [resources](#) from the DHHS Office for Human Research Protections.)
- For research collaborations with members of the European Economic Area (EEA), the General Data Privacy Regulation (GDPR) may apply.
- Research involving genomic data and sharing should comply with the [Harvard Genomic Data Sharing Policy and Procedures](#)
- Use of stem cells requires the review and approval of the [Embryonic Stem Cell Research Oversight](#) (ESCRO) Committee.
- Research must comply with the [University’s Research Data Security Policy](#).
- Research involving protected health information, e.g., identifiable medical record information, requires compliance with [HIPAA](#).

### Helpful Resources

- The [Committee on the Use of Human Subjects in Research](#) (CUHS), University-Area (HUA), reviews projects from FAS, GSE, HKS, HBS, HLS, SEAS, GSD, HDS, and the Radcliffe Institute.
- The University’s Longwood Medical Area Schools’ IRB, supported by the [Office of Human Research Administration](#), provides IRB review and oversight of human research conducted by faculty, staff, and students at Harvard Medical and Dental Schools and Harvard T.H. Chan School of Public Health.
- The University IRBs share a common eIRB submission system, Electronic Submission, Tracking and Reporting ([ESTR](#)), which is a web-based system where all researchers submit their IRB applications.

## Data Management

### What is essential

#### Data Management and Transparency

Many sponsors require Data Management Plans (DMPs) and impose minimum requirements for data retention. Failure to provide a sufficient DMP in your proposal may jeopardize your likelihood of receiving funding.

Additionally, journals increasingly require data sharing in accordance with [FAIR \(findable, accessible, interoperable, reusable\) principles](#). Failing to share data may be grounds for retraction of the paper in which the results were published.

#### Confidential Data and Data Security

Human subjects research involves the collection or use of people's identifiable private information. Federal and state laws and the [University Research Data Security Policy](#) provide specific guidance for protecting this identifiable information. Federal regulations (e.g., [HIPAA](#), [FERPA](#), and [NIST SP 800-171](#)), as well as state laws, identify specific types of student, patient, and other sensitive information that require extra security to prevent accidental disclosure or misuse. Institutional Review Boards ([IRBs](#)), in collaboration with Information Security, determine the security required. It is the responsibility of the Principal Investigator (PI) to comply with these security measures and usage restrictions.

#### Data Access

Both externally-generated data being used and University-generated data shared with external collaborators must be exchanged, managed, and secured in accordance with a Data Use Agreement (DUA), or the ability to use the data may be revoked. DUAs are reviewed and negotiated by the authorized [office](#). The PI is responsible for coordinating review by the [School Information Security Officer](#) and the relevant IRB.

### Why it's important

Linking published research articles to the protocols, data, and analyses used to generate the published results enhances the public utility of the work. [FAIR principles](#) build on DMP- and DUA-based data management and security by emphasizing metadata curation. By defining the format and content of the data more clearly, a simple data dump can become a more useful, reproducible, and reusable resource. This transparency may also be the best defense if anyone ever questions your work.

DUAs make sure that the people who know the data best and are responsible for following the conditions of the research subjects' consent (and any applicable regulations) are the same people who establish how the data must be stored and used. In addition to the obvious ethical issues, violations of federal or state laws and/or the terms of the DUA can have serious legal and financial consequences for the researcher and the University.

### How to Comply / Helpful Resources

#### Data Management and Transparency

- [Harvard Libraries](#) can help with [DMPs](#).
- The Office of the Vice Provost for Research provides [general guidance on data retention](#).

- The University is collating and developing new resources related to [data sharing](#). Discipline-appropriate resources are [local](#), e.g., at [Harvard Medical School](#) or [the Institute for Quantitative Social Science](#).

### **Confidential Data and Data Security**

- For policies and resources related to student information (FERPA), protected health information (HIPAA), information about EU citizens ([GDPR](#)), or other state and federal regulations, see the [Harvard Information Security website](#) and consult with the appropriate sponsored office.
- For the relevant IRB, consult the appropriate school/tub:
  - University Area – [Committee on the Use of Human Subjects](#)
  - Longwood Medical Area – [Office of Human Research Administration \(OHRA\)](#) and HMS/HSPH [OHRA Quality Improvement Program \(QIP\)](#)

### **Data Access: DUAs**

- [University Area -- Office for Sponsored Programs](#)
- [Harvard T.H. Chan School of Public Health – Sponsored Programs Administration](#)
- [Harvard Medical School – Office of Research Administration](#)

## International Research

### What is essential

Engaging in international research may require compliance with overlapping and potentially conflicting laws and regulations regarding the conduct of the research, and the researchers involved in the project. Additionally, conducting research abroad may raise other issues related to siting a project, accessing supplies, employing personnel, budgeting for unanticipated costs, ensuring the health and safety of personnel, and other unique legal and financial considerations.

### Why it's important

The University is committed to ensuring the safety and security of researchers and the responsible conduct of research abroad. When developing a research plan, it's important to account for the local variances in regulations and policies, which may differ in the areas of standards for human subjects research, data security, taxation, employment, real estate, intellectual property ownership and licensing, and other matters which could potentially impact the project. Additionally, U.S. [export-control laws and regulations](#) may apply to research activities that take place outside the U.S. that involve the use or transfer of certain technology and items (e.g., products, goods, hardware, software, and materials). Failure to anticipate or comply with such requirements may cause significant delays to the start of your research or otherwise negatively impact your research activities, and/or the safety of your research team.

### How to comply

Due to the complexities in applicable laws and regulations, all researchers involved in the project should be cognizant of their individual responsibilities when conducting research abroad, and educate themselves on University's policies and requirements, as well as the policies and requirements of their foreign collaborator(s). You should always consult with your departmental/local administrator and sponsored office as early in the planning process as possible and be aware that based on the scope of research, there may be a need for formal Office of the Vice Provost for Research approval.

Consult the [International Project Planning Guide](#), [register](#) your trip abroad with [Global Support Services](#), and reference the [International Shipping Guidance](#), [International Travel Guidance](#), and [Safety and Security](#) travel advisories.

### Helpful Resources

- [International Project Planning Guide](#)
- [Global Support Services](#) (tools and guidance on international business operations)



## Export Controls and Trade Sanctions

### What is essential

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.**

Additionally, U.S. government sanctions restrict travel to, and financial transactions with, 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.

### Why it's important

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. The University is committed to complying with export control laws and regulations while also preserving and protecting the freedom of research and maintaining a teaching and research environment where foreign faculty, students, and scholars will not be singled out for restriction in accessing the University's educational and research facilities.

### How to comply

1. **Make sure your research qualifies as fundamental research<sup>8</sup>:** 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.
2. **Consult your school Export Control Administrator or Office of the Vice Provost 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.
3. **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.

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<sup>8</sup> Fundamental Research is defined as "basic and applied research in science and engineering, the results of which are ordinarily published and shared broadly within the scientific community." Such research is exempt from many aspects of export control laws and regulations.

## Helpful Resources

- [School Export Control Administrator](#)
- [University Export Control Resources](#)
  - [Harvard's Openness in Research policy](#)
  - [Harvard's Export Control Policy Statement](#)
  - [Guidance: Specially Designated Nationals Screening Process and Monitoring](#)
  - [International Travel Guidance](#)
  - [Information Security Office Advisory for Travelers](#)
  - [International Data Security Guidance](#)
  - [International Shipping Guidance](#)
  - [Guidance on Online Education](#)