HARVARD UNIVERSITY



International Projects Guidance: International Project Planning Considerations

Last Revised: 10/01/2017

Responsible Office: Office for Sponsored Programs

This resource provides faculty and administrators with clear, simple guideposts for international

projects, including the policies, guides and contacts at Harvard to learn more.

Due to the complexities associated with international projects, you should always consult with your local research administrator and/or one of the offices below regarding potential and proposed projects abroad – the earlier, the better.

<u>Harvard Global Support Services</u> is available to provide tools and guidance on international business operations.

It is recommended that you start planning at least 6 - 12 months in advance of your planned arrival abroad.

A. Office Contact Information

Office	Function	Contacts
Global Support Services (GSS)	Works with students, faculty, and staff to help on matters of safety and security, outbound visas, employment, finance, taxes, and other operational and administrative considerations abroad.	GSS contacts
Office of the Vice Provost for Research (OVPR)	OVPR has broad responsibility and oversight for the review, development, and implementation of policies related to the organization and execution of academic research. A critical mission of the Office is to develop best practices for education, training, and guidance to promote the responsible conduct of research and to ensure compliance in all areas of research administration across the Harvard universe.	OVPR contacts

Office	Function	Contacts
Office for Sponsored Programs (OSP) / HMS Office of Research Administration (ORA) / HSPH Research Administration	These offices have responsibility for sponsored programs across the entire lifecycle of the award, including pre-award, research finance, and sponsored financial reporting, billing and collection.	University area: <u>OSP contacts</u> Longwood area: <u>HMS & HSDM</u> <u>Contacts</u> , <u>HSPH</u> <u>Contacts</u>
Institutional Review Board (IRB)	The IRB reviews research projects involving human participants, working with investigators to ensure adequate protection and informed, un-coerced consent.	University area: <u>CUHS contacts</u> Longwood area: <u>Harvard</u> Longwood <u>Campus IRB</u>
The Institutional Animal Care and Use Committee (IACUC)	The IACUC works to ensure that animal research is held to the highest ethical standards and carried out in accordance with regulatory requirements.	University area: <u>RAS contacts</u> Longwood area: <u>IACUC contacts</u>
Office of Technology Development	Office of Technology Development fosters technology commercialization through venture creation and intellectual property licensing of patents.	OTD contacts
Research Data Security	Federal law and Harvard policy provide specific guidance for protecting research data.	<u>Harvard</u> <u>Research Data</u> <u>Security Policy</u> (HRDSP) <u>GSS: IT & Data</u> <u>Security</u>
		<u>Research</u> Computing

Office	Function	Contacts
Environmental Health & Safety (EH&S)	EH&S assists laboratory researchers to manage shipments and transportation of dangerous goods, including chemicals, radioactive materials, and biological materials, by ground, air, or sea, in order to comply with the U.S. Department of Transportation (DOT) regulations, International Airline Transportation Association (IATA) guidelines and/or Maritime law. Transporting certain materials may require import/export permits or other documentation from federal agencies including, US Border Protection and Customs, FDA, USDA/APHIS, Fish and Wildlife, and CDC.	<u>Shipping &</u> <u>Transporting</u> <u>Research</u> <u>Materials</u>
Financial Conflicts of Interest	FCOI compliance at Harvard focuses on transparency and the management of "circumstances that reasonable observers would believe creates an undue risk that an individual's judgment or actions regarding a primary interest of the University will be inappropriately influenced by a secondary financial interest."	<u>Financial</u> <u>Conflicts of</u> <u>Interest School</u> <u>Contacts (pdf)</u>
Export Control	School Export Control Officers facilitate compliance with international sanctions as well as applicable U.S. laws and regulations pertaining to exports of items, services and technology.	Export Control Administrators
International Office	This Office provides information and services for Harvard international students, scholars and their family members who plan to travel inside and outside the United States during their time at Harvard including assistance with immigration issues (work permits, travel), financial questions, social and cultural differences, and resources at Harvard and in the community.	International Office contacts

B. Planning, budget and building alliances with foreign collaborators

1. Have you gained an understanding of the region and country where the research will be conducted?

- a. Research your destination
 - i. Closest city and services (e.g., post office, hospital and supermarket)
 - ii. Closest international airport
 - iii. Location of safe and reliable ground transportation
 - iv. Access to electricity and/or a generator

- v. Access to water for drinking and bathing
- vi. Sanitation
- vii. Technology and supplies for project, office and daily personal needs
- viii. Technical troubleshooting support
- ix. Work space, storage space and housing
- b. Contact Harvard researchers with experience in the area.
- c. Go to <u>Travel Tools</u> and follow the "Before you leave" checklist, which covers key areas such as travel policies, visa requirements, health consultations and more.

2. Do you have an affiliate with experience in the region to help with planning and compliance?

a. **Find local experts** and people with experience in the region, e.g., NGOs, governmental entities, foundations, local universities, and hospitals. Exercise diligence in selection; careful background and reference checks should be performed. When work in licensed professions is required, proof of local professional licensure and institutional appointments of collaborators should be secured; also, the administrative and financial infrastructure supporting a collaborator should be examined.

These resources may help identify partners:

- NCURA Global Partners,
- <u>Global Health Trials</u>, and the
- <u>Health Research Web Map</u>.
- b. Clearly define the partner role, e.g., participate in the research design and implementation, ensuring compliance with local laws and/or project management. Determine if your partner should be included as a subrecipient or a contractor: <u>Subrecipient vs. Contractor Guidance</u>
- c. **Draft the proposal and/or project plan together** including timelines, ownership of the work product, allocation of costs and liabilities, roles and responsibilities (guidance at <u>Preparing a Proposal</u>). Ask about any foreign government approvals that may be required.

3. Have you considered the special features of working abroad when developing your budget?

- a. Calculate indirect costs both locally and at the international site.
 - i. Review sponsor restrictions and budget for the sponsor's indirect rate as it applies to international sites (e.g., NIH only pays 8% to foreign institutions).
 - Subrecipients may be only permitted to receive direct costs, so consider the possibility of including direct costs that would normally be covered as indirect. Note that payments to subrecipients and consultants are ordinarily made in U.S. dollars.
 - Be aware of re-budgeting restrictions once awarded (check sponsor guidelines ahead of time to understand the process of re-budgeting funds after award time).

 iv. Also note that Foreign Per Diem rates are established monthly by the <u>Office of</u> <u>Allowances</u> as maximum U.S. dollar rates for reimbursement of U.S. Government civilians traveling on official business in foreign areas.

b. Consider the following added costs:

- i. Visas and/or relocation costs (not always recoverable under federal awards).
- ii. International shipping costs and import duties (e.g., Nearly every country in Africa applies a Value Added Tax ("VAT") to goods and supplies imported into the country and to purchases made within the country). In countries where tax exemptions are available, an application for exemption may require months of negotiations, and if granted, caution must be exercised including the monitoring of local employees.
- iii. Translation costs, i.e., contracts and other key documents will need to be translated to English if they are in a foreign language.
- iv. IACUC, IRB and/or EH&S (e.g., lab safety and biosafety) costs.
- v. Medical fees for licensure (e.g., malpractice, medical, and repatriation; consult the University Insurance Department at 617-495-7971 to obtain professional malpractice coverage, if it is available).
- vi. Travel expenses, taking into account potential need for peak season travel.
 - 1. When traveling on federal funds, ensure Fly America Act compliance (lowest rate air fares on U.S. Flag carriers) Fly America Act Overview
 - 2. Purchase airline tickets using the <u>Harvard Travel Portal</u>
 - 3. Relevant travel policies and reimbursement
- c. Notify OSP/SPA **if advanced payment is required** for those international sites that are not in a position to pre-finance a project.
- d. Clearance from the U.S. Department of State may be required prior to commencement of an international project when the project uses federal funds. Once approved, any sub-award or subcontract issued to the foreign component will need to contain provision for the "flowdown" of all applicable federal sponsor obligations to the "foreign component" organization. Most notably, these include research misconduct, animal welfare, human subjects, financial conflict of interest, debarment and suspension, lobbying, and fiscal controls.

e. Guidance for developing a budget:

- i. OSP: <u>Developing a Budget</u>
- ii. FAS: <u>Budget Preparation</u>
- iii. GSS: <u>Budgeting</u>
- iv. HSCRB: Budget and Business Office

4. Are you aware of Harvard's policies as they apply to contracts? Applicable federal law? Do you need assistance from Harvard's General Counsel?

If the overseas research program involves a subaward/subcontract to a foreign organization, it is important that these agreements facilitate a full and complete understanding of sponsor obligations by the foreign organization and its key personnel, as well as the obligations imposed by US and foreign law. The use of a standard subaward/subcontract template, such as those developed by the Federal Demonstration Partnership (FDP), will typically not work effectively as a model for a foreign component or foreign site agreement.

Instead, agreements should include brief descriptions of each regulatory requirement in plain language accompanied by a website link to enable the research and administrative staff of the foreign organization or foreign site to obtain a fuller understanding of these requirements and to establish policies and processes to ensure and monitor compliance.

Also, Consult with your local research administrator regarding potential projects abroad - the earlier, the better agreements to be executed with foreign persons must normally be prepared and/or reviewed by local counsel in the foreign country to ensure compliance with local laws, including labor laws. Coordinate with the Office of General Counsel (OGC) on the selection of local counsel and anticipate for these costs.

In addition, consider following contracting details:

a. Will there be a publication?

Harvard rigorously adheres to its <u>Policy on Publications</u> and the University <u>Open Access</u> <u>Policies</u>.

b. Will new intellectual property come out of the project?

Contemplate any work product that might arise in the conduct of the project. Will the international collaborator require any rights to ownership, access, or distribution of intellectual property? See the <u>Statement of Policy in Regard to Intellectual Property (IP Policy)</u>

c. Will you use the Harvard Name to promote your project?

Harvard use-of-name policies fully apply outside the United States. Foreign collaborators are often keenly interested in promoting their association with Harvard, and this promotion may take many forms, including the request to use the Harvard name in the titles of local entities or facilities, or attempts to use Harvard's shields or other indicia to brand written work product, or even objects such as vehicles. Requests to use the "Harvard" name must be reviewed and approved by the Harvard Trademark Program well in advance of any use of name. Please consult: Policy on the Use of Harvard Names and Insignias for further details.

In general, clauses for the protection of the university's name and marks should be clear and unambiguous in agreements with foreign institutions. One approach is to require that any use of the university's marks and name be subject to prior written approval by a designated person. Another approach is to specify the circumstances in which the university's name and marks may be used by the other party to fulfill its obligations under the agreement, with other uses subject to prior written approval.

Periodic review of the foreign institution's website is recommended to ensure appropriate use of the U.S. institution's name and marks. If the collaboration terminates early, the U.S. institution will want to ensure that its name/marks are removed from the materials, website, etc. The contract should make clear the period of time (e.g. the term of the agreement) during which the U.S. institution's name and marks can be used by the foreign institution.

d. Are there contract provisions on "choice of law" and dispute resolution? It is strongly preferred that contracts specify which legal jurisdiction applies. Options for

choice of law, in order of preference, include governing the contract under:

i. A particular State's law, such as the law of the jurisdiction of the university (i.e., Massachusetts);

- ii. New York or Delaware law, which are generally recognized as commercially developed and neutral; or
- iii. Laws of a neutral international jurisdiction, such as the United Kingdom, assuming the other party is not located there.

Also, when contracting with a foreign institution for academic activities, determine whether the program or activity is in a country that is a signatory to the NY Convention (prepared by the United Nations and adopted in 1958, the Convention requires courts of contracting "States" to recognize an agreement to arbitrate). If it is, consider binding arbitration for resolution of any disputes arising out of the contract as an alternative to a foreign country's courts.

e. Is the foreign partnering institution owned by the foreign government?

If so, the foreign institution may be entitled to sovereign immunity from enforcement of or performance under the contract. Claims of immunity are generally difficult to overcome, but in some cases can be under the Foreign Sovereign Immunities Act (FSIA), where one of the exceptions apply, such as the "commercial activity" exception, where a sovereign acts as a private player in the market, or where there is express waiver of immunity. Application of one of Consult with your local research administrator regarding potential projects abroad - the earlier, the better these FSIA exceptions would provide the basis for obtaining jurisdiction over a foreign state (including their agents or instrumentalities) in U.S. courts.

Therefore, to provide contract breach protection, universities have a few options:

- i. Structure the payments so they are made in full before the actual work is performed; or, stagger them throughout the project. This way, the university's expenses are covered if the foreign institution gives notice of its intent to terminate. Also, if the foreign institution misses a payment, the U.S. University is alerted to possible breach and may notify its partner or stop work.
- ii. Draft an express waiver of immunity into the contract or MOU. It must be clear and unambiguous and intended for enforcement in the United States.
- iii. An express arbitration provision may confer jurisdiction in U.S. courts under certain circumstances.
- f. Only a few people at Harvard have signing authority. Are you being asked to sign a contract on behalf of Harvard University?

Harvard designates only a limited set of people who have authority to sign agreements on behalf of Harvard, whether with foreign governments, provincial officials, municipal or otherwise political officials, subcontractors, vendors or landlords. Faculty may be involved in negotiating agreements, but only in concert with their school officials, the Office for Sponsored Programs, or the Office of the General Counsel. In general, all agreements with governmental units, offices, or parastatals (i.e., having some political authority and serving the state indirectly) must be negotiated with advice from the OGC and be co-signed by the Vice Provost for International Affairs.

5. Does your project need Provostial Review?

Provostial Review is conducted by the Provost's Office at Harvard University and is designed to review projects that pose management challenges and/or reputational risks beyond those routinely covered by the IRB or other review committees. The Provostial Review process also

considers the question of whether the proposed research project is within the research and academic mission of the University, as opposed to advocacy or consultancy.

There are ten criteria that can trigger a Provostial Review. These criteria are described on the Office of the Vice Provost for Research (OVPR) website under "<u>Provost Criteria for Review.</u>" Researchers planning international projects should consider if their project meets any of the criteria, and seek appropriate review as needed.

6. Does your project trigger U.S. "anti-boycott" laws?

The U.S. government maintains a complex set of "anti-boycott" laws designed to prevent U.S. organizations from supporting or participating in boycotts of friendly countries. These laws are primarily directed at the Arab League's economic boycott of Israel.

The range of boycott-related activity prohibited by the Department of Commerce includes the (i) refusal to do business with or in Israel or with blacklisted companies; (ii) furnishing of information about business relationships with or in Israel or with blacklisted companies; (iii) furnishing of information about the race, religion, sex, or national origin of another person; and (iv) discrimination against other persons based on race, religion, sex, national origin, or nationality.

Contractual agreements that require the institution to do any of the above are prohibited, and the receipt of a request, whether verbal or written, to further a boycott may need to be reported to the Department of Commerce. The Department of Treasury also implements antiboycott laws through section 999 of the Internal Revenue Code, which requires U.S. taxpayers to report operations in boycotting countries. The list of countries requiring cooperation with an international boycott currently includes Iraq, Kuwait, Lebanon, Libya, Qatar, Saudi Arabia, Syria, the United Arab Emirates, and Yemen. (From "Conducting Research Overseas: Setting up Operations" by William F. Ferreira. Nov. 2008, NACUA Conference and <u>Federal Register / Vol. 81, No. 68 / Friday, April 8, 2016 / Notices</u>).

C. Travel and Safety

7. Passports and Visas

a) Does everyone traveling have a valid passport?

Ensure Harvard project staff that travel to the foreign location have current passports. Passports should be valid for 3 months beyond your date of return: U.S. Passports

b) Are there any visa or work permit requirements?

Confirm in-country visa and work permit requirements. Work conducted in a foreign jurisdiction for more than a few weeks should generally be done only under appropriate research, academic or business visas, rather than under a tourist visa or a visa that allows attendance at seminars or professional/educational meetings.

Harvard faculty, staff and students should enter and remain in foreign jurisdictions only with appropriate visas. A visa is always required for travel unless the country to be visited offers a "visa waiver" for short-term stays (e.g. U.S. citizens do not need a visa to visit Canada for fewer than 180 days, though they may need one if their purpose is to study or work); visa waiver eligibility depends on the traveler's country of citizenship. Research, studies,

conferences, or business meetings may necessitate a business visa (or a more specialized visa such as a student or research visa) rather than a tourist visa. Commercial services are widely available to secure, before departure from the United States, appropriate visas for these purposes. It is important to consider the visa laws and historical practices of a country in which a project or program is sited, and to do so well in advance of travel to that jurisdiction by Harvard faculty, students or staff, so that these issues can be anticipated and resolved in non-urgent circumstances.

Some visas can take as long as six months to process, so, visa requirements should be researched as early as possible.

- i. Obtain the appropriate travel documents, including visas: Visas
- ii. Non-U.S. citizens in the U.S. on a visa (i.e. F-1, J Student, J Scholar, H1-B, O-1, TN or E-3), should confirm re-entry requirements: <u>Scholar Visa Types</u>

8. Do you need additional medical insurance, medications or vaccinations?

Contact your medical insurance provider to confirm international coverage. For long trips, consider pre-ordering a supply of medications. Check for any recommended vaccinations: <u>Travel Tools</u>

Also, in case of an emergency, a management plan and strategies, including provision for medical care arrangements and evacuation, should be inquired into on a site-specific basis.

9. Do you have any undergraduate or graduate students traveling abroad?

Review requirements for undergraduate and graduate students: Forms & Checklists

10. Hiring Abroad

a) What are your options for hiring an individual or placing Harvard personal abroad? There are several options for hiring an individual or placing Harvard personnel abroad. Programs must comply with the immigration and employment law of the country where the individual is working and must also comply with Harvard payroll, employment, and financial policies.

International hiring is a common need for projects and anyone who will spend the majority of their time abroad cannot be hired on the Harvard payroll under the Provost's payroll policy. However, there are six options that can be used by programs to meet their hiring objectives. They include:

- i. Partnering with an established organization in the host country
- ii. Hiring via Harvard Global
- iii. Using an existing Harvard entity
- iv. Contracting with a professional employer organization (PEO)
- v. Remaining based in the United States for a majority of the time with frequent travel, and
- vi. Engaging as an independent contractor.

A more substantial alternative to the six options outlined previously is for the University and the cognizant school to establish an entity in a country where there are recurrent and ongoing projects and frequent requests for postings abroad for Harvard faculty and/or staff. This entity is controlled by Harvard and may act as the local employer. The OGC, the UCIPS, Page **9** of **19**

and the Office of the Provost have experience in advising on the establishment of overseas entities and, in addition to the cognizant Dean, should be consulted if a faculty member or administrator is considering this significant step. Harvard currently has registered entities in the following countries: Argentina, Bostwana, Brazil, Chile, China, India, Japan, Mexico, South Africa, Tanzania, Tunisia, Turkey, the United Kingdom, and the United Arab Emirates.

Under exceptional circumstances, the University may employ individuals directly and station them abroad, for a defined period of time. If a faculty member seeks to remain abroad for a long period (more than six out of 12 months), they should consult with the Office of the Provost, the OGC, GSS, and the cognizant school administration, including the school's Dean of Faculty, as it necessitates significant preparation to assure appropriate compliance with both U.S. and non-U.S. regulations, the safety and welfare of the person stationed abroad, and consistency of the placement with University and school priorities.

In considering alternatives for hiring an individual abroad, faculty and staff should consult with the cognizant school's human resources office and GSS. If the project is supported by sources of federal funding external to the University, the cognizant sponsored programs officer(s) (Office for Sponsored Programs, Harvard Longwood Campus Research Administration, and Office of Technology Development) must also be consulted.

b) What issues should be considered before you undertake international hiring?

When a faculty member or administrator seeks to hire an individual, they first should consider and resolve a variety of practical issues. These include:

- i. how requirements of U.S. and host-country taxation, employment, employee benefits, and immigration laws will be met over time;
- ii. how costs of compliance with these laws will be paid;
- iii. how Harvard's administrative systems will accommodate those requirements; and
- iv. whether they can be accommodated using Harvard's existing payroll and benefits systems.

The cognizant school and department should also consider:

- i. how such employees will be supervised;
- ii. whether there is adequate insurance to cover risks associated with these employees' overseas responsibilities; and
- iii. whether stationing an employee abroad will require Harvard to register to do business in the relevant country.

This last measure—registering to do business in another national jurisdiction—is a highly consequential step that requires review from the University Committee on International Projects and Sites (UCIPS) and close consultation with the OGC and GSS. The costs associated with a failure to comply with local laws, such as fines and penalties, will be borne by the Harvard school that employs the faculty or staff member. The overall assessment is whether the risk incurred by the faculty or staff, the school, and the University are justified in relation to the programmatic benefit gained by stationing the person(s) abroad.

c) Will you be hiring foreign citizens?

If the program involves the use of local nationals as employees, serious attention must be directed to the tax, retirement, social security, health and other benefits that must be extended to such workers. Labor law regulations and practices in some countries, for example, limit an employer's ability to terminate employees without implementing a

progressive discipline system or providing severance packages. The use of local counsel "in country" who is familiar with these requirements for various categories of employees can prove invaluable.

Also, the following local laws should always be understood: discrimination, minimum wages, workplace safety, labor hours, vacation, benefits, and mandatory withholdings. National health insurance and retirement benefits are typical withholdings abroad. If the project is a "contract" for "public works" that includes "construction or repair", **the Defense Base Act** may apply and require workers' compensation insurance. Tax counsel, therefore, in cooperation with local accountants, should be consulted in order to develop a strategy to minimize double taxation of U.S. expatriates, and to minimize the burdens of complex local withholding and other requirements applicable to foreign nationals on the institution's payroll.

Harvard Global Support Services offers a wide range of assistance:

- i. Overview: Employment
- ii. Hiring & Staffing Options

d) Will you be hiring foreign citizens for longer than 3 months?

If the project requires Harvard employing staff that are citizens of the foreign location for a period lasting longer than 3 months (extended employment), seek approval from the relevant School Dean of Faculty. Extended employment abroad is typically done through an employer abroad such as a partner institution, a temp agency, or a Professional Employer Organization (PEO). Harvard rarely employs directly (i.e., engaging the person as an individual consultant).

e) Will you be hiring any Harvard students, staff or faculty for work abroad that is longer than 6 months?

With respect to any HU student or employee abroad longer than 6 months, Harvard Global will pay that person's wages. Longer employment may also trigger requirements to pay local taxes.

11. Are there additional training requirements?

Site initiation visits or other "hands on" training should be conducted by experienced research study staff to ensure that all critical staff members at the foreign site are familiar with the terms of the agreement and the processes mandated by law and regulation. Staff members at the foreign site need to be trained to create and maintain the requisite documentation and source documents in accordance with a detailed schedule.

In the case of FDA-regulated research or research involving complex therapeutic interventions or healthy volunteers, it is also highly recommended that "on-site" monitoring be conducted.

Confirm any in-country training requirements for study personnel and any associated costs.

D. Banking and Payments Abroad

12. Do you need a license to spend funds in that country?

If you are traveling to a sanctioned country, **you may need a license to spend certain funds in that country**. The <u>International Air Transport Association</u> (IATA) website provides a list of currency rules.

13. What is the mechanism for payment abroad?

Confirm the host country's banking system and how U.S. funds are sent and managed incountry. The project administrator should ensure that the specifics of the payment process (i.e. check versus wire transfer) are included in the agreement and processed appropriately.

If Harvard must purchase supplies or services on behalf of a subrecipient, a local Harvard bank account may be established with a local bank; each school's financial administration is familiar with this process and can help in working with Cash Management on establishing an account and managing cash flow. GSS can also advise on alternative arrangements when local bank accounts are impractical. For information about requesting and managing a bank account abroad, see the Harvard Bank Accounts Policy.

14. Can you pay in cash?

Harvard faculty, staff and students should **not** pay local labor in cash, or pay cash for local procurement of supplies or equipment unless it is unavoidable and has been approved in advance by school level Finance and the Office of the Controller. Managing large sums of cash when abroad may present a personal security risk, and may violate sponsor, U.S. or local laws and regulations. (See FCPA details below). It is illegal, for example, to carry more than \$10,000 in cash or cash equivalents (e.g., traveler's checks) across U.S. borders without declaring the funds in a customs declaration. Other countries' limits may be lower.

In general, for purchases and payments that must be made by Harvard rather than by subcontractors, a long-term operating account may be established with a local bank, and each school's financial administration is familiar with this process and can help in establishing an account and a mechanism for a reliable flow of funds into the account.

15. Will you need to purchase equipment or supplies abroad?

Where the value exceeds \$5,000 per unit, including motor vehicles, you will need to comply with procurement regulations, including securing at least three competing bids from potential vendors. Exceptions may be made for specific, well documented reasons. Also, all tangible materials with a value of more than \$5,000 must be accounted for in an inventory, tagged and tracked. In no case should these purchases be made in the personal name of a Harvard faculty member, staff member or student, unless this is unavoidable and has been approved in advance by OSP/SPA. Research and departmental administration staff are well versed in these requirements, including inventory tagging and tracking, and faculty should work through them.

Other than in truly exceptional circumstances, motor vehicles should be registered in the name of a local collaborating institution, which would then assume responsibility for maintenance and local insurance requirements.

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16. What is your payment schedule for subrecipients or researchers abroad?

Clearly define the payment schedule – either cost reimbursement or fixed price. Milestones are the most frequently used mechanisms. Also, discuss the foreign entity's cash reserves; if they do not have a lot of cash on hand, a fixed price agreement with some up-front funds may be needed to start the project.

17. Are you aware of the Foreign Corrupt Practices Act, prohibiting the exchange of anything for the purpose of securing an improper business advantage?

Under no circumstances may Harvard faculty, staff and students offer bribes, "payoffs" or "kick-backs" in attempts to influence officials of foreign governments or institutions. Offering bribes, emoluments or remuneration in any form to an official of another government to influence them to do what they may not otherwise do is illegal under the laws of the United States and other nations. If approached by an official soliciting a bribe, Harvard faculty, staff and students should politely decline; if pressed and if, for example, personal safety is at issue, then they should exercise good judgment, immediately reporting to school and University officials the circumstances of the solicitation and any payment.

The Foreign Corrupt Practices Act (FCPA) is a U.S. federal law that prohibits the exchange of "anything of value" to a foreign official for the purpose of "securing any improper advantage" in obtaining, retaining or directing business (e.g. – decision to award a contract to Harvard). *Items of value* encompasses both monetary and non-monetary exchanges, such as travel and entertainment or training, scholarships or employment opportunities (e.g., employing the child of a foreign official to curry favor). There is no monetary threshold - any exchange of value constitutes a violation of the FCPA. The FCPA provides an exception for *facilitating payments*, such as expediting a visa application, much like one may pay to have a passport application expedited here in the United States. But for clarity, it is never allowable to provide payment to obtain a favorable decision, so caution should be exercised when contemplating a facilitating payment. See "Rules to Keep in Mind When Conducting University Business Overseas," listed under Advisories at <u>Publications & Advisories</u> and also <u>The Foreign Corrupt Practices Act (FCPA):</u> <u>Guidance for Faculty & Staff</u>.

E. Compliance and The Law

18. Do you need to lease real estate abroad?

Leasing real estate abroad requires prior approval. Harvard does not ordinarily purchase real estate abroad. Review and/or approval by the University Committee on International Projects and Sites (UCIPS), a vice president of the University (usually the VP for Campus Services), and in some instances the Corporation, is required for the University or any of its employees to commit to real estate leases or purchases. The approval process may be initiated through each school's financial administration and/or OSP.

Since lessors often refuse to lease property to an unregistered institution, the process of leasing or purchasing real estate abroad often triggers foreign registration requirements and suggests that Harvard is seeking to establish a permanent or semi-permanent presence in a foreign jurisdiction. Some developing countries assess a "real property transfer tax" that is triggered

every time real property changes hands. This tax sometimes applies to lease payments and to funds allocated for renovation, construction, and infrastructure improvement.

Contact GSS for assistance, and see: <u>Renting or Purchasing Space</u>

19. Do you need to "register" with the host country?

The principal way for an institution to begin research activity is to "register" with the host country. Registration, broadly defined, is the means by which the institution notifies the country of its presence, and the method by which the foreign government approves the presence and keeps track of the institution. See <u>Legal Registration</u> requirements.

Some international projects will require the execution of memoranda of understanding with divisions of the foreign government (e.g., Ministries of Health or Education) to establish the bases for the institution's "presence" and authorization to "do business" in country.

It may also be necessary to obtain tax exempt (or its equivalent) status under the laws of the jurisdictions in which the research program is located. Application and support for these types of special treatments usually requires interaction with governmental officials (e.g., Ministry of Finance or Taxation). When there are no tax exemptions made available to nonprofit institutions abroad, interest income on funds held overseas are frequently taxed.

20. Does your research involve human subjects?

If the research includes human subjects, ensure the IRB application has been fully approved, and for partner institutions as well. Human subjects review at international universities and governmental sign-offs are a long process. In general, Harvard does not allow Harvard projects to engage in direct clinical care of patients, as clinical care lies outside the core mission of the University. Any such arrangement would require specific approval from the Provost and the pertinent Dean of Faculty.

- a. Human Research regulations/laws abroad. The IRB applies the same ethical and regulatory standards to research conducted abroad as to domestic research and must also ensure that the protections in place are appropriate for the local research context in which the research will be conducted. It is also important to note that investigators must comply with the relevant laws protecting human subjects in the host country and any requirements for local ethical review. Investigators should consider partnering with local researchers in order to ensure understanding of local context and regulations. International regulations can also be found online by navigating to <u>International Comilation of Human Research Standards</u> or <u>International Research</u>. For Longwood area investigators, submit a <u>Service Request</u> to the <u>Quality Improvement Program</u> for IRB submission assistance, assistance connecting with a local researcher, and/or navigating local regulation(s).
- b. Ensure you and all investigators have a clear understanding of cultural and societal norms in the region, ensuring adequate recruitment measures and consent process.
- c. Consult with your local IRB representatives for more information and to determine next steps:
 - i. University area IRB: CUHS
 - ii. Longwood area IRB (HMS, HSDM, HSPH): OHRA

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21. Data Storage and Ownership

a) Does the collection of data include human subjects data?

- i. If the data involves human subjects, see the section on IRB approval, above, and bring it to the attention of the IRB at the time of application.
- ii. Work with OSP/SPA to ensure appropriate data use terms are inserted into the subaward or negotiated in a separate Data Use Agreement (DUA): Contact OSP.
- iii. If you are receiving data under a DUA, also consult with the IRB to determine the data security level.
- iv. Work with appropriate school IT security officer to ensure that the data is stored in accordance with any data security requirements: <u>Contact Information</u> <u>Security</u>.

b) Do you know what data security level your project belongs to and the according responsibilities?

- i. See the <u>Harvard Research Data Security Policy (HRDSP)</u> and supporting documentation.
- ii. Work with appropriate school IT security officer to ensure that the data is stored in accordance with any data security requirements: <u>Contact Information</u> <u>Security</u>.
- iii. When traveling abroad, data security risks may be elevated, depending upon the nature of the data and your destination. See "<u>Keeping Your Data Safe</u> <u>Abroad</u>."
- iv. Additional information and resources:
 - 1. <u>Security Requirements</u>
 - 2. Information Security FAQs

c) How can you protect the security of your devices and the data on your devices? The security of devices and in particular, the data on those devices, should be considered in any international project. The risks can take many different forms from surveillance and theft to malware and hacks. The degrees of privacy and security can vary greatly from one country to the next.

To protect your information and devices—especially if you'll be conducting research—it's important that you develop a data security plan that both serves your project's needs and adheres to the import and export controls and local laws of the host country. HUIT and GSS can support in developing an appropriate data security plan and further information can be found here: Protecting Your Data

You may find it helpful to review the joint HUIT and GSS International Data Security Guide for Travelers and the general HUIT Advisory Resources. Many of the tips and recommendations for travelers are applicable while conducting an international project. See Keeping Your Data Safe Abroad.

If secure network access is available, always connect to Harvard's network via VPN. And if a secure network is not available, consider using an "empty" machine to collect the data. Consider using an iron key (provided by HUIT) or an encrypted external hard drive to store documents. Access to a SharePoint site of cloud service may also be accessible. If your project involves working with human subject data, contact your School's Institutional Review Board (IRB) for approval. They may be able to connect you with a foreign IRB that

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can help you navigate the host country's privacy and data protection regulations. The foreign IRB may also need to approve your research.

And if you're working with sensitive or confidential information, refer to the Research Data Security & Management Guidance from the Office of the Vice Provost for Research. See <u>Research Data Management</u>.

Cyberattacks and cyber monitoring are becoming more prolific and sophisticated. Be aware of and comply with visa, customs, and security rules to minimize the chances that you or your devices will be easy targets or selected for scrutiny.

If you're taking a group of students, faculty, or staff overseas and you're concerned about IT security, GSS and HUIT and coordinate an IT security overview for your group, conducted by your local IT group or HUIT. Contact GSS as soon as possible and at least a month before your travel.

If you believe you're an especially high-risk traveler due to the nature of your work or your destination, contact GSS for a personalized IT security plan in consultation with your local IT group or HUIT.

22. Is your project subject to Export Controls? For example, are you shipping materials abroad, entering into collaborations with foreign businesses or citizens, or traveling internationally?

a) When do Export Controls Apply?

Generally. Export controls refer to federal laws and regulations governing the export of certain items, information and technologies to foreign entities and foreign nationals either abroad or in the U.S. **Export controls apply whether the research activity is federally funded or not.** Failure to comply can result in severe consequences for individual researchers, including fines and imprisonment and limitations on future research. Export controls not only apply to the physical exchange of certain types of technical information and software, but also to the transfer of such information to individuals from other countries, even while they are at Harvard, and an export license may be required.

Export controls may apply to a number of activities in the academic research space, including shipping materials or equipment abroad, entering into international research collaborations with foreign entities, providing educational services abroad or travelling internationally. See <u>Export Control Policies & Procedures</u> for more details.

Licenses. If the project requires the transfer controlled technologies or information (i.e. prototypes, software or research results), a "license" must first be obtained from the relevant federal government entity:

- Department of Commerce oversees the **Export Administration Regulations (EAR)**, which is concerned with "dual use" items; i.e., items designed for commercial (civilian) purposes that can have military applications, such as computers, lasers and pathogens
- Department of State oversees the **International Traffic in Arms Regulations (ITAR)**, which is concerned with items that are military in nature, including equipment, software, algorithms and technical data and services directly related to those items. *The ITAR regulations also apply to the import of ITAR items.*

• Department of Treasury oversees the **Office of Foreign Asset Control (OFAC)**, which administers and enforces economic and trade sanctions based on U.S. foreign policy and national security goals with respect to specified foreign countries and regimes as well as, terrorists, those engaged in proliferation of weapons of mass destruction, and other threats to U.S. national security, foreign policy or the economy.

Contacts and Resources. Before collaborating with a foreign national/entity, or presenting your research at an international conference, contact your School's Export Control Officer to ensure that the individuals/entities you are collaborating with, or presenting to, are not included on a sanctions list.

- Contact your school's Export Control Officer to provide further guidance and assistance. See Export Control Administrators.
- Information about these restrictions is also available at:
 - i. Export & Import Controls
 - ii. Export Control Policies & Procedures
 - iii. <u>Export Controls and Universities: Information and Case Studies</u> by the <u>Council on Government Relations (COGR)</u>
 - iv. Export Administration Regulations (EAR)
 - v. Understand the ITAR and Export Controls
 - vi. <u>Sanctions</u>

b) Are you shipping items, samples or other materials abroad?

Shipment of Items, Equipment, Samples or other Materials: Consult with your School's <u>Export Control Administrator</u> prior to shipping or carrying any samples or materials abroad: even some seemingly ordinary commercial items and technologies may be controlled.

- i. Examples of controlled items: global positioning systems (GPS), thermal imaging cameras, encrypted software, the Ebola virus, etc.
- ii. License requirements also depend upon the destination, end-user or end use of the item or technology.
- iii. To expedite the license determination review: describe the item and include the specific destination, end-user and end-use of the item.
- iv. Ask early and ask often. Export Control Officers typically screen items quickly, but if a license is required, it could take up to 90 days for the government to issue the license.

For lab supplies that are not found in country, Harvard has well-established relationships with vendors, and purchases can be done on behalf of the international site through HCOM. Shipments can be coordinated through commercial carriers like FedEx, DHL and UPS. Harvard Strategic Procurement also has an agreement with E. Sidney Stockwell, Co., Inc., a <u>customs broker</u> who can expedite deliveries into and out of the U.S. and most countries.

23. Will there be animal subjects research?

If the foreign collaborator will be performing animal subjects research, work with them to determine the process for ethics review. Consult with a local IACUC representative to determine next steps

- i. University area: <u>IACUC</u>
- ii. Longwood area (HMS, HSDM, HSPH): Office of the IACUC

24. Environmental Health & Safety

- a) Biosafety: Will the project involve biological agents, recombinant DNA, and chemicals that elicit a biological response? Contact EH&S for next steps, Biosafety
- b) Lab Safety: Will the research involve chemicals in a laboratory? Consult EH&S and Lab safety officers, <u>Lab Safety</u>
- c) Radiation Safety: Will the research involve work with radioactive materials? (e.g., lasers, x-rays, machine produced radiation, etc.).
 Contact EH&S to determine what requirements must be met before beginning research, Radiation Protection
- d) Will you be shipping any chemicals, radioactive materials, biological materials? The shipment of chemicals, radioactive materials, and biological materials by air, ground or sea must comply with Department of Transportation ("DOT") regulations, International Air Transport Association ("IATA") guidelines and/or maritime law. Transporting certain materials may require import/export permits or other documentation from federal agencies including, US Border Protection and Customs, FDA, USDA/APHIS, Fish and Wildlife, and CDC.
 - EH&S assists laboratory researchers with managing shipments and transportation of these dangerous goods. More resources can be found at <u>Shipping & Transporting Research Materials</u> or contact <u>Lab Safety</u> for more information. See also:
 - 1. Harvard EH&S: Shipping & Transporting Research Materials
 - 2. <u>CDC Import Permit Program</u>
 - 3. FDA Import Program
 - 4. Fish and Wildlife Imports/Exports
 - ii. For shipments that include animal, plant, insect, or cell specimens or other general inquiries, <u>contact GSS</u>.
 - iii. For importing and exporting goods, Harvard Strategic Procurement also has an agreement with E. Sidney Stockwell Co., Inc., a <u>customs broker</u> who can expedite deliveries into and out of the U.S. and most countries. The broker can also assist in obtaining a carnet (<u>Exports & Imports</u>).
 - iv. Training courses on shipping materials are offered on the <u>Harvard Training</u> <u>Portal</u> (email <u>Contact Support</u> with any questions).
 - 1. Shipping Non-regulated Materials and Dry Ice
 - 2. <u>Shipping Excepted Quantities: Flammables, Corrosives, and</u> <u>Common Fixatives</u>
 - 3. <u>Shipping Biological Materials and Dry Ice</u>

25. Have all Investigators disclosed and been vetted for Financial Conflicts of Interest (FCOI)?

Ensure that all those responsible for the design, conduct and reporting of the project, including international collaborators, submit a disclosure form and complete training in accordance with the conflict of interest procedures set by the PI's school: <u>Financial Conflicts of Interest Policy</u>.

Foreign collaborators on projects funded by NSF or one of the <u>agencies following Public Health</u> <u>Service (PHS) rules</u> must abide by the sponsor's FCOI policies. OSP/SPA will verify that the foreign institution has a PHS compliant FCOI policy or that they are willing to follow Harvard's policy.

26. ESCRO: Does this project (a) use human embryonic stem cells (hESCs) or their derivatives, (b) introduce human pluripotent stem cells (hPSCs) or derivatives into non-human animals at any stage with expected integration into the testes, ovaries, or nervous system of the animal or (c) involve storing or disposing of human embryos or gametes obtained for stem cell research?

If so, contact the Harvard ESCRO to determine what oversight requirements must be met before beginning research:

- i. ESCRO Policies
- ii. <u>Submission Procedures, Deadlines and Forms</u>

Consult the International Society for Stem Cell Research ("ISSCR") <u>Guidelines for Stem Cell</u> <u>Research and Clinical Translation</u>