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Harvard University Area

Harvard University Area IRB Monthly Newsletter

July 2025

International Research

In January we shared the International Compilation of Human Research Standards page, a resource maintained by the Office for Human Research Protections (OHRP) within the United States Department of Health and Human Services (DHHS). The Compilation is a

"listing of over 1,000 standards on human subjects protections in 131 countries and from many international organizations. These standards may include laws, regulations, and/or guidelines." OHRP also maintains a page of Ethical Codes and Research Standards that express the core ethical principles underpinning reviews of human research here in the United States and worldwide.

Research conducted outside the United States may create additional challenges for a researcher and the IRB. Cultural, economic, or political conditions of the host country may alter the risk for participants compared to the same research conducted within the U.S. Other countries and institutions within those countries may have Institutional Review Boards, Ethics Committees or other research oversight bodies which require review of the research before it can be conducted in that country. Conversely, some may have no mechanism for ethics review of social and behavioral research. In this month's newsletter, we share more guidance and resources on conducting human subjects research internationally.

Local Context

When conducting international research, it is important to understand the local context. This includes consideration of the following:

- Local expectations or customs affecting the research (i.e., cultural beliefs, norms, attitudes as they relate to the proposed research). For example, survey/interview questions may be innocuous in one culture, but offensive in another; secular vs. religious cultures; expectations regarding autonomy; home dynamics (e.g., impact of parent-child relationship of consent procedures), etc.
- Local age of majority (i.e., when someone is an adult who can provide consent independently)
- Local scientific and ethical review structure (i.e.,national, regional, local state law, institution-based model). Some international communities require researchers to receive permission from the local government or community leaders prior to beginning research activities, while in some countries (like Brazil, for example) review must be obtained from a local ethics board in addition to Harvard IRB review
- Socioeconomic factors that may impact study-related costs, compensation, and reimbursement, if any. Note that consideration should be made for minimizing

potential undue influence resulting from economic benefit (e.g., compensation should align with local wages/rates)
- Political factors such as the stability of local government, including considerations for the safety of participants, local study staff, and Harvard investigators (see more below)

IRB Review

The IRB relies on investigators to be knowledgeable about their research locations and the local expectations and responsibilities they will face. The IRB also trusts investigators to share that information with us to guide aspects of our review, like the mitigation of risks and informed consent. We want to be sure our determinations are appropriately contextualized by your knowledge of the local context so together we can ensure we are protecting participants in a manner that is well-informed and culturally appropriate. In its review of your application, the IRB will consider the following information:

- Description of where the research will be conducted (including geographic location and specific performance sites, where applicable)
- Information about the local research context, including the current economic, cultural, political, or religious conditions of the area that may affect the conduct of the research, and a description of the researcher's personal experience conducting research (or studying or residing) in the region
- The language(s) in which consent will be sought from participants and the research will be conducted, as well as whether the researcher is fluent in this language or whether an interpreter will be required. If an interpreter will be used, it should be clear what limitations or risks, if any, this might present for participants, as well as how these potential problems will be overcome or minimized
- A description of the informed consent process as appropriate for the culture
- Any benefits to the local community that will remain in the community once the research is complete
- If compensation is being offered, a description of its appropriateness for the setting

- Procedures for data security and storage in the local setting and for transfer of data and/or specimens to Harvard University
- A copy of local IRB or equivalent ethics committee approval, where applicable. Depending on the location, this may take the form of a letter of approval from an IRB or research ethics committee, local university department sponsoring the research, institutional oversight committee, or an indigenous council. If the research is federally funded, check with the IRB for other regulatory requirements

Exempt Human Research

When conducting Exempt human research internationally, investigators are still required to comply with all applicable local laws, legislation, regulations, and/or policies. Additionally, if local IRB/ethics review is required, it must be obtained before any human research activities are conducted in the field. This is to say, core aspects of the standards described above still apply in Exempt-level human research.

Human Subjects Research Training Guide for International Enumerators

Many investigators partner with staff from local organizations or employ local research assistants while conducting research internationally. The HUA IRB has developed a paper-based human subjects research training for use by such international enumerators and research staff when it is not feasible for them to take an online human subjects protection training such as CITI training. As specified in the guide, "The content and language level of the guide is specifically worded to help the investigator convey basic research principles and behavior that accords with those principles to enumerators and/or field workers." More information may be found on our Required Ethics Training Overview page.

Provostial Review

For those research studies that are conducted internationally and are determined to meet the criteria for Expedited or Convened IRB review, the Office of the Vice Provost for Research (OVPR) will additionally review the study. OVPR's Provost Criteria for Review page provides background information on Provostial review.

The Provostial Review process is designed to review projects that pose management challenges and/or reputational risks beyond those routinely covered by the IRB or other review committees. It 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.

The Provostial Review team relies on the IRB to address human subject protection risks (e.g., risks-benefits to the participants, adequacy of consent forms, protection of privacy, etc.) and focuses its review on other risks. In general, the Provostial Review team reviews the same documents submitted to the IRB (e.g., the protocol, informed consent forms, and local ethics review materials). Therefore, the protocol should be complete and detailed, with a full explanation of the researcher's planned study design to assist with, and accelerate, both the IRB and the Provostial Review process.

One area potentially assessed in Provostial Review is **risks to researchers**. When planning an international research project, please complete the following:

- Check the Global Support Services risk ratings page to determine if the region of interest is rated as high or elevated risk and follow directions accordingly (i.e., for some groups travel may be prohibited).
- Develop a plan to protect your safety while working internationally. These plans could include checking in with the local U.S. embassy, working with local universities or non-governmental organizations (NGOs) to help navigate the cultural norms, and/or arranging safe meeting places when conducting interviews with research participants.

Planning Ahead

If you are traveling to an international setting for your research, submit your IRB application well in advance of your planned travel date so you and the IRB have adequate time to complete your review. This is particularly crucial for projects that may involve more than minimal risk to participants and will require review by the Convened IRB, which meets once a month. Please see our Convened HUA IRB Meeting Dates &

Application Deadlines page for more information on when the Convened IRB meets. [**Note:** International research does not by definition need to be reviewed by the Convened IRB and most projects are reviewed on a rolling basis by members of the IRB staff instead; however, if your project may impose unique or high risks, or involve novel procedures, Convened IRB review may be required.]

Biological Material Import/Transport

Perhaps your international research involves the transport of biological materials. In that case, the Office of the Vice President for Research (OVPR) and Environmental Health & Safety (EHS) recently released a memo regarding such transport of materials. If you obtain biological materials from a vendor or other third party for genetic sequencing, for example, or if you are collecting materials from human subjects while in the field, please consider the following resources:

EHS provides a number of resources to assist our community with the responsible shipping, transportation, and receipt of research materials, some of which are linked below. As per institutional guidance and policies, we highly encourage all other avenues

for shipping be explored in place of hand-carrying. Where hand-carrying is the only feasible option for your research, please consult EHS Research Transport and your Research Compliance office well in advance of your transport plans so appropriate documentation and declarations can be made.

Resources for safe and compliant transport/importation of research materials:

1. Shipping and receiving guidance documents and websites:
    - Shipping & Transporting Research Materials (webpage)
    - Research Material Shipment and Transport Manual (PDF)
    - Regulated Biological Materials Permits (PDF)

2. Training for biological material import/transport(inbound):
    - Biological Import and Transport Permits (EHS): Course ID: EHS-0000066003

Overview
This training's purpose is to address the selection and completion of permits through USDA, CDC, and FWS, PI/researcher responsibilities as permit holders, and the roles and responsibilities of those working with materials covered by such permits. The goals are to allow applicants to preview the submission process and prepare them for receipt of the permitted materials as well as outline the responsibilities of all those involved in the process.

3. The following courses also include modules andreferences that provide transport/ import information:
    - Laboratory Biosafety (EHS): Course ID: EHS-LAB103 (initial)
    - Laboratory Biosafety Refresher (EHS): Course ID: EHS-LAB203 (annual refresher)

4. General biosafety resource:

    - Biosafety Manual links to the above resources and reiterates the importance of transport/import compliance.

Please send any questions to EHS ResearchTransport@harvard.edu

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Check out our website at:
https://cuhs.harvard.edu