GW OHR Guidance:

International Research

This guidance document will outline general best practices and requirements for conducting research outside of the United States. This document should be used by investigators and research team members who are planning a study that will take place outside of the United States. If you are planning an international clinical trial, please also refer to the International Council for Harmonization of Technical Requirements for Pharmaceuticals in Human Use (ICH) Guidelines.

When should I seek IRB approval?

Submit the IRB application and study documents via iRIS when the research design and plan are solidified in order to receive a timely IRB review.

You should submit **at least 4-6 weeks before** a planned start date!

Include travel plans and hard start dates in the IRB application so that IRB staff can work with researchers to meet applicable deadlines. This is a collaborative process, so reach out to the IRB staff if you have questions.

From whom do I need approval?

- All institutions with which research team members are affiliated
- Research site (often called a site permission letter)
- In-country governing bodies (i.e., Ministry of Health, local ethics committee, etc.), if any
- Other culturally appropriate governing bodies (village elders, tribal councils, etc.), if any

If partnering with a local organization or institution, it may be helpful to work with them to get appropriate permissions and to navigate the ethics committee abroad.

Which U.S. regulations apply to international research?

All U.S. regulations and GW polices apply to international research because the researchers are U.S.-based or affiliated.

How do I find what governing body needs to approve my research and which regulations apply?

Each year, the Office for Human Research Protection (OHRP) publishes local research regulations and regulatory bodies by country.

https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html

If a country is not listed on the document, local permission(s) from the research site or culturally appropriate governing bodies may still apply. If local regulations are vague or confusing, the research team may have to search government websites or work with the partnering organization to navigate these regulations.

The GW IRB relies on investigators to provide this information in the IRB application.

Do I need to submit the local approvals?

We *strongly recommend* obtaining GW IRB approval before obtaining local ethics committee approval to reduce the number of requests for revisions. The GW IRB will grant contingent approval until the local approval can be obtained.

In limited situations, a local governing body may require a researcher to be physically present to receive approval. If it is not possible to obtain local approval before GW IRB approval, inform the GW IRB at ohrirb@gwu.edu as soon as possible.

What do I need to consider when designing an ethical international research study?

- **Age of majority** in the country. Adult status may be determined by marital status or tribal rites of passage and may not be a specific age. Any individuals who are not at the age of majority must have parental permission to participate in research with limited exceptions.
- **Language considerations** and mitigating strategies, such as translators
- **Cultural differences and sensitivities**, such as gender differences, modesty standards, stigmatizing health issues, etc. If the research is about a culturally sensitive topic, protections should be built into the protocol to protect the subject from either stigma or reputation harm. If research is about a legally questionable topic, you must justify why the topic is of scientific importance and provide additional protections to ensure that subjects are not at risk of legal action.
- **If signed consent is culturally appropriate.** In some cultures, asking for a signature on a consent form may not be the norm and could be considered stigmatizing or an insult as the subject's word is not taken at face value or can be rooted in mistrust of research.
- **Safety of the area**. Participation in research should not expose participants to greater safety risks than they experience in everyday life, unless the benefits of the research outweigh the risks. Also, researchers should consider their own safety needs.
- **Group harms**. It is important to consider whether the research topic itself and subsequent publications may be culturally insensitive or offensive to the country or its people, or, place them in a bad light in their own community and the international community.
- **Vulnerable populations** and the regulations that protect them. Prisoners, children, and pregnant women are vulnerable populations and have specific criteria that must be met in order to enroll them in a study. Please see 45 CFR 46 Subpart B, C, and D for more information.
- **Research topic and timeframe** are reasonable and realistic.

Do I need translated documents?

If the subjects do not speak English, all documents subjects will see, hear or otherwise be exposed to will need to be translated into the local language (e.g., recruitment materials, questionnaires, etc.). All translated documents must be approved by the GW IRB before they are used with participants. For greater than minimal risk studies receiving full board review certificates of translation and back translations are required.

When enrolling non-English speaking participants, investigators should also have a plan to manage communications with participants during all phases of study participation (even beyond consenting and data collection). Given that participants may have questions or concerns at any time, researchers should be prepared to manage these communications.

Local Context Review

A part of the GW IRB institutional review process to protect human participants often involves a "local context review" for international research.

This is a review conducted by an independent individual (not involved with the research) who is familiar with the local culture and can provide expertise with identifying any context or culture specific risks to human participants that might otherwise go unrecognized. The local context review provides the GW IRB with important information regarding unique risks or concerns relative to the local culture.

It is the responsibility of the research team to provide the GW IRB with the local context reviewer's contact information in the IRB application.

How do I ensure a smooth IRB approval?

It is important to view the IRB review as a collaborative process. It should be expected that the IRB reviewers will have questions and feedback about human subjects' protections in your study. However, there are things you may do to facilitate the review process.

All relevant documents must be included with the initial IRB application (e.g., permissions, translated documents, etc.) or an explanation for why they are not yet included (waiting for final site permissions etc.). It is best practice to ensure all information is *consistent* across documents, all IRB application questions are *answered thoroughly*, and all documents are *clearly labeled*.

Communication with the IRB should be prompt and streamlined. If you are working on a project with multiple researchers, we recommend choosing one researcher to be the primary contact for the IRB to handle inquiries.

If you have a specific timeline with a travel date, and/or start date, inform the GW IRB both in the IRB application and by emailing ohrirb@gwu.edu at the time of your submission.

Other Resources

- GW Office of Risk Management: Provides important information about your health, safety, and security while you are traveling on behalf of the university https://risk.gwu.edu/
- GW International Travel Policy: Provides important details on GW travel policies and approvals needed before traveling abroad for faculty, staff, and students https://global.gwu.edu/
- GW Technology Commercialization Office: Provides information about the Technology Commercialization Office (TCO) and intellectual property procedures at GW https://commercialization.gwu.edu/frequently-asked-questions
- GW Export Control Policy: The Office of the Vice President for Research provides information about limitation considerations for the distribution and sharing of information, technology, and commodities internationally and domestically http://my.gwu.edu/files/policies/ExportControlFINAL.pdf

Questions?

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References

45 CFR 46 Subpart B, C, D