

**The George Washington University
Office of Human Research
Frequently Asked Questions (FAQs) for International Research**

When should I seek IRB approval?

In order to gain approval in a timely manner, the IRB review process should be started as soon as possible. Once the research design and plan are solidified, the research team should submit the application to the Office of Human Research (OHR). This submission should be at least 30 days before a planned start date. Whenever possible, please include travel plans or hard start dates in the IRB application materials so that the OHR can work with the researchers to meet applicable deadlines.

From whom do I need approval?

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

If the research team is partnering with a local organization or institution, it may be helpful for the research team to work with the local entity to get appropriate permissions and to navigate the ethical committees abroad.

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

Each year, the Office for Human Research Protection publishes a document that lists local research regulations and regulatory bodies by country. The document may be found here: <http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html>. If the country in question is not listed on the document, local permission(s) from the research site or culturally appropriate governing bodies still apply. Sometimes, local regulations may be vague or confusing, so the research team may have to search government websites or work with the partnering institution to navigate these regulations.

Do I need to submit the local approvals?

We strongly recommend seeking GW IRB approval before obtaining any local ethical committee approval to cut down on the number of requests for revisions. Generally, the GW IRB will grant contingent approval until the local approvals can be obtained. In limited situations, some local governing bodies require a researcher to physically be present in order to receive approval. If obtaining local approval before full IRB approval is not possible, contact the assigned IRB Analyst as soon as possible to create another solution.

Which US regulations apply to international research?

All US regulations and GW policies will apply to international research because the researchers are US-based or affiliated.

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

- Age of majority in 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 barriers and mitigating factors, such as translators
- Cultural differences/sensitivities, such as gender differences, modesty standards, stigmatizing health issues. 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.

- Whether or not requesting signed consent forms is culturally appropriate. In some cultures, asking for a signature on a consent form may be a form of insult as the subject's word is not taken at face value.
- The relative safety of area in which you are working. Participation in research should not expose participants to greater safety risk than they experience in everyday life, unless the benefits of the research outweigh the risks. Also, researchers should keep in mind their own safety needs.
- Group harms. It is important to consider whether the research topic itself and subsequent publications may be offensive to the country or its people or place them in a bad light in the international community.

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 (such as recruitment materials, questionnaires, etc.). All translated documents must be approved by GWU IRB before they are used with the subject population. In addition, studies receiving full board review (or are considered greater than minimal risk) must submit back translations as well.

How do I ensure a swift IRB approval?

In order to ensure a swift IRB approval, be sure to include all relevant documents in the initial application, including permissions and translated documents. It is important to include sufficient detail in IRB submissions and be sure to answer all questions thoroughly and in a timely manner to cut down on review time. If a hard travel date or start date is set, tell the IRB Analyst as soon as possible so that s/he can work with the research schedule. Similarly, if there is a problem or hold up in responding to the review requests, please tell the Analyst as soon as possible to brainstorm a creative solution. The sooner the IRB/OHR knows about a problem, the sooner we can attempt to work with researchers to come up with alternative solutions.

Other resources:

- GW SOS Program: http://www.gwu.edu/~riskmgnt/program/insurance/intl_sos_progbenefits.cfm
Provides travel assistance abroad, such as medical and security assistance.
- GW International Travel Policy: <http://international.gwu.edu/policies2.aspx>
Provides details on approvals needed before traveling aboard for faculty and students.
- GW Export Control Policy: <http://my.gwu.edu/files/policies/ExportControlFINAL.pdf>
Discusses limiting the distribution and sharing of information, technology, and commodities internationally and domestically.

More questions?

Contact the OHR at any time by:

Email: ohrirb@gwu.edu

Call: 202-994-2715

Stop in Ross Hall, Suite 613, Foggy Bottom Campus