



Application Instructions: International Research

General Guidance:

Please consult the sections below for any information that will be applicable for your research.

Local Laws: Research conducted outside of the United States will also be subject to the local laws and regulations of the country. These regulations vary and it is the investigator's responsibility to research and follow all applicable laws, policies, and procedures. Please review Office of Human Research Protections' (OHRP) [International Compilation of Human Research Standards](#) or [Harvard's Research Ethics Guidelines International Online Navigation Map](#).

Approvals: Most studies need some form of local (in reference to the international site of the study) approval in addition to WWU IRB approval.

1. **Is there a local, registered IRB at the research site? If yes, determine whether they require separate review.**

For applications determined exempt, the WWU IRB will not require documentation of the international IRB's approval, however, it is still important to look into and follow the procedures of any local IRB.

For non-exempt applications, attach the notification of approval or the deferral of review from the local IRB to your application.

If the research involves collaborating at multiple sites, and the Lead PI between all the sites is at an international institution, Western's IRB may be able to defer to the international IRB's review. The international IRB must have an active and valid Federal Wide Assurance (FWA) with the U.S. Office of Human Research Protections and registration with the local government or regulatory body.

2. **If there is no local, registered IRB, is there a local ethical review body?**

There may be a local semi-formal ethics board or committee that is not a registered IRB, but can still provide local review and approval. If this type of board or committee does not exist, you should look for another qualified group that can provide review (described below).

3. **Is there a qualified group (local community leaders, authority figures, etc.) that should provide review?**

In some cases, research projects must be approved by local experts or community leaders. This is often referred to as gatekeeper consent. Leadership approval must be obtained prior to contact with the subjects and the IRB will require documentation of this local approval to be submitted with your application. Depending on the community, it may be the leadership of a Native American tribe, a village chief in an international setting, or the president of an organization. In their protocol, researchers should describe what if any, knowledge or experience they possess regarding the language and culture of the country in question.

Age of Majority: The age of majority is when a person has attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

A majority of the states in the United States share the age of majority as 18 years old. Currently, the age of majority in Alabama and Nebraska is 19 years old, while Mississippi is 21 years old. These laws may change over time, so we recommend checking for your states in question.

Many other countries share the age of majority as 18 years old, such as the United Kingdom. Countries may have a different age of majority that can be younger (for example: Saudi Arabia, Iran, Indonesia, or Cuba) or older (for example: some Canadian provinces, Honduras, or Thailand).

We recommend starting with a google search for the country or state in question, using the term "age of majority". If you have trouble finding the answer, contact a Research Compliance Officer.

Local Context & Risk: There may be locally sensitive issues that may affect the risk of participation. If you are aware of the issues, you can take steps to prevent them. For example, in Thailand it is illegal to insult the monarchy, so a researcher considering a study on political issue in Thailand will want to consider this local context.

Consent: Some cultures have different norms around consent. For example, written consent may not be appropriate in some communities. There also may be privacy laws that interfere with normal informed consent assurances.

Training Personnel: Principal Investigators are responsible for ensuring that anyone working with human subjects or identifiable data is trained in the protection of human research subjects. For most personnel, the online CITI training is an easy option.

There are times where it may not be feasible or appropriate to use the online training. For example, investigators may hire local people to collect data who, depending on their level of education, language, and web access, need a different training program. In these cases, the investigator can create a training program for these individuals. The training program should contain similar elements to the CITI program. John's Hopkins provides several [Ethics Field Training Guides](#) in different languages.

If you are using a training program other than CITI, the outline of your training program must be submitted along with your application for review and approval. You do not need to submit individual documentation of trainings with your application. PIs are still responsible for tracking documentation of these trainings.

European Union Data: If your research involves obtaining personal data from the European Union, there are very strict international requirements on the protection of this data that go above our required protections. Please speak to a Research Compliance Officer before submitting your application, so that we can work together to ensure that the right protections are in place.

Export Controls: Any time you travel with high tech equipment, confidential information, laptop computers, web-enabled cell phones, other personal equipment containing encryption hardware or software, you will want to check whether export controls apply. The federal government regulates the transfer of sensitive information, equipment, technology, and software that are considered to be in the interest of national security, the economy, or foreign policy. These regulations are collectively referred to as "export controls." These regulations also restrict the release of certain information to foreign nationals. These are complex regulations, so we recommend contacting Janai Symons (Janai.symons@wwu.edu) who works with export control compliance issues.

Application Form Instructions

This is guidance for how to complete the original Human Subjects Application form when your research involves collection or analysis of secondary data.

Question 2.5 Research Location: List the country(ies) where the research will be conducted.

Question 4.2. Adults or Minors: If your country has a different age of majority, then your answer to question 4.2 will look similar to the example below. In the scenario below, the investigator is recruiting only adults (19+) from British Columbia and intending to both screen them over the phone and have a statement about the age requirement in the consent form.

4.2. Adults or Minors: Will you recruit subjects under 18 years old, over 18, or both?

- <18 → Read our guidelines on research with minors and complete the [Minors in Research Supplement](#)
- 18+ → Select a method (or methods) for ensuring that subjects are 18 years old or older:
- Population:** The nature of your population naturally excludes participants under 18 (Ex. senior citizens). This option is possible for WWU students for non-federally funded research as the IRB considers WWU students to be mature minors. If checked, please describe the nature of the population in question 4.2.
 - Screening:** Participants will be asked for their age during screening. If checked, explain this process in your answer to question 5.2.
 - Consent:** A statement is included in the consent form indicating that by signing the form the participant is confirming that they are at least 18 years old.
- Other age of consent → If the age of majority to participate in research for your population is different (which may be possible in some states and international research), please specify the age of majority in the box to the right. Then check one of the boxes above (<18 or 18+) as if you are answering for the age of majority for your research subjects. *For example, if your research is conducted on adults in Alabama, you would type "19" in the box to the right and then select the "18+" box and indicate your method for screening.*
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6.2. Consent Process: If your research requires a process of consent, that does not involve a typical consent form, you can describe that here. For example, if a study is being conducted in a culture where a written consent form is not appropriate the researcher can describe this local culture in their answer to 6.2.a and leave 6.2.c unchecked.

9.2. Incentives & Amount: If you are providing compensation, include the amount in local currency and list the average daily wage in the country or area, or provide a similar type of context for the IRB.

DO NOT SUBMIT THIS INSTRUCTION PAGE