IRB Guidance
Conducting International Research

University at Albany researchers often conduct research outside of the United States. When conducting international research, researchers must ensure that these activities not only meet the ethical and regulatory requirements and also respect the cultural norms and research regulations in the host country.

In reviewing research protocols, the IRB must have sufficient knowledge of the local research context in order to fulfill its responsibilities to comply with all applicable required standards. In particular, the IRB must be sensitive to community attitudes and be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations; applicable law; and standards of professional conduct and practice. All policies and procedures that are applied to research conducted domestically will be applied to research conducted in other countries, as appropriate.

Research Oversight

Researchers who would like to conduct international research must plan in advance to obtain review of the research in the host country, in addition to fulfilling University at Albany IRB review requirements.

Approval from the appropriate oversight body in the host country is required for approval by the UAlbany IRB.

1. Applications for international research submitted to the IRB should indicate which local IRB, Ethics Committee, or government entity will perform review in the host country. If the study is not yet approved in the host country, clearly indicate the status of the local ethics review. If the study has been approved, provide a copy of the approval letter or notice from the host country’s ethics review (with translation into English, as needed). Provide the name and contact information/website of the ethics review body.

2. In some countries, local regulations do not require review of the research or there is no local ethics committee to review the research in the host country. In these cases, researchers must provide a letter of local context from an individual in who has the relevant expertise or institutional authority to review the research.

The letter should contain the contact information of the writer (e.g., letterhead) and:

- cannot be written by any key personnel on the current application,
- must contain contact info of the writer,
- describe the qualifications of the letter writer to provide a letter of cultural context,
- the writer must be familiar with the culture, customs and norms of the setting and able to vouch for the appropriateness of the activities and/or consenting process as well as the ability of the research team to carry out all study activities.

The following persons would qualify:

- An expert in the field at another institution
- A dissertation committee member
Demonstration of sufficient knowledge of local research context:

In your IRB submission, it is important that you tell the IRB what you know about the country where the study is being conducted. The IRB relies on the information you provide to help assess whether the rights protections are in place for subjects. In addition to the usually required information submitted for review to the IRB, the following points should be addressed in your submission.

Your IRB protocol should describe relevant local context information, any anticipated cultural sensitivities of conducting your research and how you intent to overcome those barriers. This should include, but not limited to the following:

1. Cities, regions countries where research will be conducted
2. Scientific/ethical justification for conducting the research in an international setting
3. Economic status of the country/community
4. Current events or socio-political environment in the country that may impact research conduct or alter the risks or benefits to subjects
5. Societal and cultural beliefs in the country that may impact research conduct or alter the risks or benefits to subjects
6. The role of women and children in the society, including their autonomy and legal capacity to make decisions
7. Literacy rate of the potential subject population
8. Languages and dialects of the potential subject population
9. Involvement of organizations, community leaders, or experts in engaging the subject population or conducting the research
10. Description of the research team’s knowledge of or experience in the host country
11. Relevance of the research to the area’s health, economic, educational, or other needs
12. Distribution of risks and current and future benefits
13. Detail any proposed remuneration (payment, gifts, incentives, etc.) for subjects including:
   - Specific description of the remuneration (payment, gifts, incentives, etc.)
   - Value both in US and local currency
   - Local household income information (e.g. how much an average household earns in a month or a year in US and local currency)
   - When remuneration will be given during the study (the payment schedule)
   - To whom remuneration will be given
   - Whether the remuneration could pose undue influence on the subject’s decision to participate.

Consideration of Issues Associated with Informed Consent:

The informed consent documents must be in a language appropriate to the location of the research, and understandable to the proposed participants. Informed Consent Translations – documents used
with the subjects will need to be reviewed in English by UAlbany’s IRB and a translated version will need to be submitted to UAlbany’s IRB as well after initial IRB approval.

The translation may be done by a certified translator (certification will need to be provided along with the translated documents to the IRB) or a back translation can be done (one person translates the documents into the language and a different person translates the translation back into English).

*The IRB strongly recommends you clearly understand the host country’s requirements for reviewing and approving human subject research.* Some countries have clear ethical guidelines that must be met for conducting domestic and/or international research. Other countries will not have a formal process but might rely on other neighboring countries to assist with the review.

- The Office of Human Research Protections (OHRP) publishes the [International Compilation of Human Research Standards](https://www.oahrp.org/index.php/publications/compilation-human-research-standards), a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in over 100 countries and several international organizations. Researchers should check this document to determine the countries applicable laws, regulations and guidelines on Human Subjects Researcher.

- The Office of Human Research Protection (OHRP) has issued a [Listing of 27 Social-Behavioral Research Standards](https://www.oahrp.org/index.php/publications/27-social-behavioral-research-standards). This includes laws, guidelines, and regulations applicable to social-behavioral research around the world.

- **Know the data laws.** While not specifically under the IRB’s domain, you should know that there are some restrictions on bringing identifiable data into/out of some countries. The EU, for example, has laws surrounding what kind of identifiable information can be taken out of Europe and brought to the US (this applies to electronic data that will be housed on a US server as well). Data export laws may also affect your research in countries with which the US has embargoes or trade restrictions, such as Iran. Describe how you will keep your data secure at all stages: while you are collecting it in the host country, while you are traveling back to the US and once you arrive here.