International Research Guidance

International research is not to be taken lightly. The principles of Respect for Persons, Beneficence, and Justice apply, but implementation of these principles requires extensive cultural knowledge and sensitivity, knowledge of local laws and customs, and close cooperation with local contacts.

First things first…

Start early! Preparing for an international research study can take as much as 4-6 months. You may have a limited window of time to travel (e.g. summer break) or have bought tickets already. By not starting early enough, you risk not having approval in time for your travel.

Reaching out to contacts and developing your plan will take time. Getting local approvals can also be a lengthy process, so find out what is needed as early as possible and get that process started as well.

See the Checklist at the end of this document for recommended timelines.

What are your qualifications?

What knowledge and skills will help you successfully conduct an international research study? Do you have experience with the country? Have you previously conducted international research? What training or preparation have you done?

Will you be doing the research on your own, or will you be part of a team? What are your team members' qualifications?

If this is your first time conducting international research, find someone who is experienced to give you tips, cultural information, and/or help with study design. Ideally, this will be someone who has worked in the country in question.

Fly in, fly out? (aka Helicopter research)

International research typically involves a researcher arriving in a location, conducting the research with local residents, and leaving. The danger and perception is often that the research benefits the researcher (dissertation, publications, career advancement, etc.) and leaves the participants – who gave their time, input, feedback, information, and hospitality to you – with nothing.

How are you, as the researcher, ensuring this does not happen? What are you giving in return? And we don't mean simply throwing monetary compensation at them. How are you building relationships and connections before you arrive? How are you actively involving local residents in the plan and design of your research? How are you ensuring you focus on matters that are important to them, and not only matters that will advance your career? How will you continue that relationship once you leave? What will you share with them when your research is complete?

Know your participants…

Each country has different cultures and values, and it is crucial to understand the local context. Attitudes towards research, or towards signing a consent form, may be different. In some places, it may be inappropriate for a researcher to conduct private interviews with members of the opposite sex, or it is considered respectful to get approval from a tribal or community leader before approaching local residents for study participation. In places there may be civil unrest that would make your research riskier than it would be in the US, and additional protections are needed.

Do you know what the differences are? Are you familiar with the culture? Do you know about current events? Do you know what is polite, and what is not? Are you familiar with local laws? If not, find out – before you design your study! How will you factor local customs, manners, etc. into your research design? You may need to change your plan based on what you discover.

… and then tell us about them.

In your IRB submission, tell us what you know and have learned. We rely on the information you provide to help us assess whether the right protections are in place for subjects. We want to work with you to ensure that subjects are protected, while acknowledging and respecting that there are different cultural norms.

Example: In the US, participants typically sign an informed consent document. But if you're doing research in a place where there is strong cultural resistance to signing names, or where many subjects are illiterate, we can usually waive the signature requirement on the consent form.

Who else needs to review your research?

Some places have a local ethics committee that should review your research. Some countries have a national review board that has to review and approve any research in their country. Some countries review biomedical research but not social/behavioral. Some places have nothing at all.

Reach out to your local contacts and other experienced researchers, search the internet, etc., and find out whether any other approval is needed. You should also find out how long local review typically takes (two weeks? two months? more?) and adjust your timeline accordingly.

If local review is needed, start the process early and allow lots of time. In your application, tell us about the other review that is occurring. If you have approval from the host country/local committee, submit a copy with your IRB application. If you don't have it yet, tell us where you are in the process of obtaining it.

Some local reviews want UWM IRB approval in place before they will review/approve. Be sure to build in enough time for the local review *after* IRB approval, if this is the case.

If there is no one else to review your study, tell us so, but we will ask again anyway – just to double check.

What about language?

Will you conduct your research in the local language, or in English?

If the local language, are you fluent in that language? If not, will you be using an interpreter/translator? Who? Has this person been involved in research before? What is their training/background?

If in English, how well do your participants know English? Would they be able to read a written consent form? Do you need to simplify the language in the consent document, surveys, or interview questions?

A hybrid approach

In some locations, schooling occurs in a different language than what is spoken at home. This can mean that the local language is primarily oral, and participants may actually be more literate in English/French/etc. A hybrid approach can be used where oral interactions occur in the local language, but subjects receive all written materials in the literacy language.

The consent document

Our consent templates are written with domestic studies in mind. When you are using them to write a consent for international research, you'll have to do some tweaking. As you are writing, make sure that everything in the document will a) make sense and b) apply to your participants.

As with all research, avoid technical terms. Explain your study simply. Try using tables, pictures, and diagrams.

Contact information

IRB contact information: Our templates include the IRB contact information, in case participants have a complaint or questions about their rights. But for international participants, would they be able to use this information? Do most have access to call internationally, or send emails? Will they have any idea what, or where, UW-Milwaukee is? What about participants who don't speak English? In most cases we won't be able to speak to/understand them. If applicable, include a comment that IRB office staff are in the US and can't speak [x] language.

Alternate, local contact information: Make sure your consent document provides contact information that is actually useful. Add contact information for the local ethics committee or someone else (other than researcher) they can talk to about their rights/complaints.

Your contact information: Include both your local and US contact information. It does your participants no good to give them your US phone or email if you will have limited access to these yourself. But make sure participants also know how to reach you after you've left.

Translations

If you are using a translator, get the English version of your consent form approved by the IRB first before having the form translated. Otherwise, the IRB may request revisions and you'll have to have multiple

translations done. Best practice is to have the translated document back-translated into English again to verify accuracy.

If you're doing your own translations, consider writing it in the target language and translating into English, instead of the other way around. This lets you use the grammatical structures, idioms, etc. of the target language for a more natural flow. It doesn't matter as much if the language is awkward in the English version, which is only for IRB review anyway. And since you are doing your own translations, it's fairly easy for you to incorporate any requested changes by the IRB.

This approach should improve comprehension and avoid phrases that are difficult to translate into the target language. HOWEVER, you should be aware that it places the entire burden of writing the consent on you, because you can't rely as heavily on our templates. If you go this route, make sure you include the required elements of informed consent (as applicable) in the form.

If you do your own translations, have someone who knows both languages review your translation for accuracy whenever possible.

How will you keep your data secure?

Plan how you will keep the 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.

One frequently overlooked area of data security is the transit. Are you keeping the data with you on the plane? Will it be in checked luggage? How sensitive is the data? What is the cost or potential harm if your bag/computer/luggage is lost or stolen?

Authorities in some countries have the right to require a researcher to hand over all their data. Using anonymous data wherever possible helps minimize any risk to your participants if this were to occur.

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.

Resources:

The Belmont Report outlines and explains the basic ethical principles (Respect for Persons, Beneficence, and Justice) on which all human subject research should be based:
http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/

The *International Compilation of Human Subjects Research Protections* provides a list of what regulatory oversight exists in various countries. However, it focuses primarily on biomedical research and has

limited usefulness for social-behavioral researchers: http://www.hhs.gov/ohrp/international/compilation-human-research-standards/

CIA's *World Factbook* provides a wealth of country-specific information about history, economy, politics, geography, etc.: https://www.cia.gov/library/publications/resources/the-world-factbook/

Checklist:

4 to 6 months before you leave:

Choose location

_____ Investigate local cultural context, laws, etc.

_____ Establish local contacts

_____ Find out about any local review required

_____ Create your initial study design

3 to 4 months before you leave:

_____ Work with your local contacts to revise your preliminary study design based on their feedback

_____ Finalize study design

Start local approval process

2 to 3 months before you leave:

_____ Submit to IRB (allow 3 months if the study is more than minimal risk)

1 to 2 months before you leave:

_____ Receive local approval

_____ Receive IRB approval

_ Make final preparations

Conduct your research

After you return:

_____ Keep in touch with your local contacts

_____ Analyze the study data according to your protocol

_____ Share your results with your local contacts and research participants.

_____ Allow your local contacts / participants to give feedback for cultural sensitivity and to ensure they are represented in a way they find acceptable.

_____ Publish / Present / Dissertate