ASU IRB Guidance: International Human Subjects Research Considerations

Introduction

When ASU Researchers conduct research outside of the United States, their research procedures undergo additional scrutiny to confirm that the procedures are appropriate to the country and population where the research is conducted. This guidance document is intended as a starting point for common issues that arise and require consideration by the research team.

NOTE: This is not an exhaustive list; however, it provides general guidance on common issues arising in the international context. This guidance is structured like the IRB protocol application for ASU researchers to review the guidance document while completing the application.

Background and Objectives

A clear explanation of the research purpose should be included. There should be a justification for conducting the research in the country or with the population described. The research should be relevant to the local participant population, whether this is with respect to the area's health, economic, educational, or other needs.

This concept stems from Belmont Report which is comprised of three ethical principles. The principle related to Justice describes that an injustice occurs when a population is unduly burdened for the benefit of another group or population.

Inclusion and Exclusion Criteria

A clear description of the inclusion and exclusion criteria is critical in understanding the population being researched. Be specific regarding where the research is being conducted in the country (e.g., in a city, urban environment, or rural setting) and who will be recruited to give the ASU IRB a clear picture of potential participants. The population inclusion criteria should influence the study's recruiting, consenting, data collection, and data security procedures.

Recruitment Methods

The research team must clearly articulate:

- How the population in the country will be recruited and what local people or organizations will be involved?
- If the ASU researcher is working with a local organization, a community leader, a village elder, or local government to recruit for their study, that relationship should be clearly explained and how they will collaborate and/or assist with the research. These partnerships/collaborations should be documented as a supporting document included with the IRB submission.
- The submission should clearly explain the roles and responsibilities of the ASU researcher and the external collaborator(s). Any permission should be included with the IRB submission.

Study Procedures

Every IRB protocol is required to explain the specific study procedures (Survey, Interview, etc.) and how data will be collected (Audio recorded interview, notetaking, etc.) for a study. However, there are a few additional considerations when conducting international research:

Language:
The study should be clear regarding what languages the research procedures are conducted in. If the researcher is not fluent in the language, it should be explained how the interaction between the researcher and participants will be conducted.
A study may require a translator or translators who will assist the researcher interact with participants. Other studies will hire local research assistants who collect the data on behalf of the ASU investigator. In each case, the role of the ASU researcher and those assisting the project should be described.
The IRB has a Translation Certification process for translated study materials:
If it is known that translation will occur, the research team should explain in the IRB protocol that translated materials and translation certificate will be uploaded via modification after the initial IRB submission is approved.

Cultural Sensitivity:
As noted in the Inclusion section of the guidance, how the study will be conducted should be culturally sensitive and reflect cultural context. Research conducted in the same country, but in a different region, may require different procedures. For example, in a city, recruiting students from a local university may require a different approach from that of the recruitment of agricultural workers in a rural setting. In a city, recruiting students from a local university may differ little from recruitment in the United States with a highly educated and literate participant population with recruitment via email to a university email account. In a rural setting, circumstances may differ, and a different communication strategy may be appropriate. For example, introducing the study and yourself with permission of village elders in a community meeting may be a more sensitive approach than turning up on individual residents' doorsteps without invitation.

Possible Issues include:
• What are the attitudes to research and signing documents? Requesting a waiver of signed consent may be appropriate and the IRB will consider alternative consenting methods when culturally appropriate.
• Is it disrespectful to approach local residents before approaching the tribal or community leader?
• What are the local laws in the area?
• What are the local manners or customs? Are procedures designed to avoid offending local people?
• Is it appropriate for a researcher to conduct private interviews with a member of the opposite sex?

Local Research Assistants:
If the ASU Researcher is hiring local research assistants to engage in human subjects research, these local research assistants will need to document completion of IRB CITI training or a local equivalent human subject research protection training. If they are affiliated with a university or institution they will also need to check about ethics/IRB review there.

Compensation for Participation
Every study, whether international or domestic, should describe the compensation to be received by participants with specificity when applicable. For international studies:

- Compensation should be described in US dollars and the local currency
- Justification on the appropriateness of compensation being offered (e.g., based on wages in the

country where the study will occur.)
    - NOTE: If significant monetary compensation is offered, the study team should address whether compensation could pose an undue influence if the amount is more than the local wage per hour.
- Form of compensation offered should be of practical use in the country. If recruiting in country where a retailer does not operate, a gift card for that retailer is not appropriate. For example, offering Target gift cards to Canadian participants would not be appropriate given that Target's Canadian subsidiary declared bankruptcy and closed all locations in the country.
- Often researchers discuss compensation with local researchers or local community leaders. Consulting with experienced researchers in an area and local people to understand local people's needs should always be part of planning the study when possible.

Anticipated Risks

When conducting international research, there are two general types of risks:

(A) Current events or the socio-political environment in the country that may impact the research or alter the risks or benefits to subjects; and/or

(B) Societal, legal and/or cultural beliefs in the country that may impact the research or alter the risks or benefits to subjects.

For Type (A):

- It is recommended to consult the U.S. Department of State Travel Advisories for current travel advice on a country which may impact the conduct of research.
- Another valuable resource is the Centers of Disease Control and Prevention Travelers' Advice.
- Before travel, it also recommended to review ASU's International Travel Guidance.

For Type (B):

- The ASU researcher must be familiar with local culture and laws to conduct research in a way which minimizes risks and maximizes benefits to participants.
- Risks specific to the locality should be described and how they are mitigated.
- Procedures that may be sufficient in the United States to conduct research with a legally protected minority group in the U.S., may be insufficient in a different legal or cultural environment.

Privacy and Confidentiality

As an initial step we recommend reviewing ASU's Research Data Storage Selector to help identify appropriate storage options for the research data being collected. Consulting with Department/Unit IT professionals prior to travel is also highly recommended to evaluate what resources are available at ASU and what are the best solutions for a study's specific needs.

As noted in previous sections, the country and environment where the study will be conducted should be reflected in the study's data protection protocols. Additional consideration include:

- When collecting information from participants regarding a sensitive subject or subject that could give rise to civil or criminal penalties, a procedure to secure identifiable information or, in some cases, eliminate collection of identifiable information entirely, will need to be clearly explained in the IRB protocol to ensure the mitigation or elimination of risk to participants.

- Access to a reliable and secure Internet connection to access ASU secure servers is not always available. When a researcher is in the field and cannot securely backup to a secure ASU Server or Cloud storage solution, there should be a clear explanation regarding how study data will be securely stored locally.

Global Data Protection Regulation (GDPR) for EU, EEA, and UK

Many ASU researchers conduct research within the European Union (EU), European Economic Area (EU states + Iceland, Liechtenstein, and Norway - EAA) and the United Kingdom (UK). The General Data Protection Regulation (GDPR) is a privacy law which may apply to your research study. The GDPR has a more expansive definition of personal data, defining this to mean any information that can identify a person, directly or indirectly, such as a name, birthdate, address, id number, location data, IP (Internet Protocol) address, or a factor specific to the person's physical, physiological, genetic, mental, economic, cultural, or social identity.

The ASU Researcher must address GDPR requirements before research can proceed. Research subjects must be provided notice regarding:

- What personal information is to be collected and for what purposes
- Who will access the information and how long it will be retained
- Includes a description of subject's rights under GDPR and how to exercise them.
- Any potential uses of IT apps or tools to collect subjects' information for transfer to research teams in the U.S. or stores data outside of the EU/EEA/UK.

ASU has created a template for ASU researchers to provide notice to participants when GDPR applies or may apply. This GDPR consent form template can be edited to include study specific information and what data is being collected from participants. EU/EEA/UK Participants whose personal data is being collected must be presented with this GDPR consent form in addition to the study-specific consent form. See GDRP Consent Form Template: https://acrobat.adobe.com/link/review?uri=urn:aaid:scds:US:e8a6b643-e4f6-307b-af8d-566ba87182e9

For more information, the following resources below are available:

- Compilation of Guidance on the EU General Data Protection Regulation: https://www.hhs.gov/ohrp/international/gdpr/compilation-of-gdpr-guidances-tables/index.html
- UK Information Commissioner's Office UK GDPR Guidance and resources: https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/

Consent Procedures

Consent procedures and the language used in the consent should reflect the cultural context and study population. If recruitment is in a population with a low literacy rate, procedures should take this into account when considering how to obtain informed consent.

For example, verbal consent procedures may be appropriate when:

- The research team reads a script to a participant if a participant cannot read or write.
- The research team is engaged with a community (and its members) may be suspicious of providing written consent.

The regulations specifically recognize this in 45 CFR 46.117(c)(1)(iii):

- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained, this should be described.

Investigators' procedures thus should reflect that context and obtain verbal consent if appropriate.

Sites of Locations Where Research is Performed

In addition to ASU IRB approval, local approvals may be required from a local ethics board or committee. The International Compilation of Human Research Standards from the Office for Human Research Protections must be reviewed to determine whether this additional local approval is required to conduct the HSR research. See below for a complete version of the International Compilation of Human Research Standards and as well as region-specific information:

- Africa - PDF
- Asia and the Pacific - PDF
- Europe - PDF
- International Organizations - PDF
- Latin America and the Caribbean - PDF
- Middle East/North Africa - PDF
- North America - PDF

Export Control Review

Export control regulations are federal laws that restrict the export of information, goods, technology, and services to foreign nationals, within and outside of the United States, and foreign countries of concern.

- The regulations are broad and apply to all activities, not just research; and they do provide several exclusions or exemptions for activities that are fundamental in nature.
- In addition, there are some limitations on travel to embargoed countries, and any additional oversight for specific fields of research.

Traveling outside the United States for professional reasons may require a license. This can depend upon:

- the destination (whether it is an embargoed country).
- the equipment or information that you will travel with or share.

In general, if traveling to a country without sanctions to conduct fundamental research or present information that is or will be published or publicly available, you will not need a license. If traveling to a sanctioned country, you will likely need a license. For a complete and current list of sanctioned countries, visit the U.S. Department of the Treasury: Sanctions Programs and Country Information page.

For assistance in determining whether a project is subject to export controls, see the "Export Control Wizard" or contact the Export Control team.

References

1. Cornell IRB Considerations for International Research: https://researchservices.cornell.edu/resources/irb-considerations-international-research
2. Fordham University IRB Guidelines on International Research: https://www.fordham.edu/academics/research/institutional-review-board/guidelines-and-procedures/irb-guidelines-on-international-research/
3. Northwestern IRB Review of International Research: https://irb.northwestern.edu/resources-guidance/policies-guidance/irb-review-of-international-research.html
4. University Michigan IRB International Human Subjects Research Resources: https://research-compliance.umich.edu/human-subjects/human-research-protection-program-hrpp/resources-international-human-subject-research
5. Washington University in St. Louis Human Research Protection Office: https://hrpo.wustl.edu/international-research-2/international-guidance/