

IRB Guidelines on International Research

International human subjects research may be conducted electronically or in person. Regardless of the mode of research, it must be culturally competent and sensitive to the local context and laws, as well as the security and confidentiality of research data.

Obtaining IRB Approval

As with all human subjects research, international research projects must be approved by the IRB before beginning the project. In addition to the usual information submitted for IRB review, a protocol for international research should include the following information regarding relevant local context, any anticipated cultural sensitivities of conducting the research, and how the research team intends to accommodate those issues. *This additional information is required for any and all countries in which the research will take place. For research conducted electronically, the research is considered to take place in the country in which the research subject(s) reside.*

Cultural, Political, Social, and Economic Context

- Cities, regions, and countries where research will be conducted
- Scientific/ethical justification for conducting the research in an international setting
- Economic status of the country/community
- Current events or socio-political environment that may impact research conduct or alter the risks or benefits to subjects
- Societal and cultural beliefs that may impact research conduct or alter the risks or benefits to subjects
- The role of women and children in the society, including their autonomy and legal capacity to make decisions
- Literacy rate, languages, and dialects of the potential subject population
- Planned involvement of organizations, community leaders, or experts in engaging the subject population or conducting the research
- Description of the research team's knowledge of or experience in the host country
- Relevance of the research to the area's health, economic, educational, or other needs

Remuneration for Participation

Any proposed remuneration (payment, gifts, incentives, etc.) for subjects should be described, 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, especially in the light of the above items.

Approval from Local Authorities

- Approval letter from the local IRB/Ethics Committee where research will be conducted. *This is required for any and all countries in which the research will take place or (for on-line studies) in which the subjects may reside.*

- Researchers should explain local standards and requirements and should consult with local experts or community leaders.

Consent Form and Recruitment Materials

- The consent form should be submitted in both the local language of the host country and English.
- The application should indicate who translated the form and provide a letter certifying the translation is correct.
- Local contact information for participants to contact about research-related questions.
- Recruitment materials to be used in both the local language of the host country and in English.

Data Security

Given significant variations in the technology infrastructures of different countries (and specific communities within countries), cultural/political/social/religious climate, and laws regulating data use and transmission, data security and confidentiality are a **significant** concern, *especially under circumstances where the subjects' health and safety are impacted/at risk*. Know the data laws for the countries through which your data will be passing and where it will be collected. The EU, for example, has laws surrounding what kind of identifiable information can be taken out of Europe and brought to the US (this also applies to electronic data that will be housed on a US server). Data export laws may also affect your research in countries with which the US has embargoes or trade restrictions, such as Iran. If you find that upon arrival in the host country or once the online research has begun, some aspects of your research may need to be modified. Please notify the IRB immediately.

Online Research. Conducting surveys and other research via the Internet is convenient and inexpensive. However, it raises concerns regarding the security of the research data and ways to protect the confidentiality of the participants. The researcher must consider the issues listed below. The IRB expects that any application for conducting international research in an international forum must include clear explanations for how these issues are being addressed including contact information for persons/entities responsible for encryption and other data security. The researcher should expect the IRB to take special care to assure subject safety and security in these circumstances.

- It is not safe to assume that complete anonymity on the internet is possible.
- Depending on the location of the participant, their information may pass through hardware and systems operated and owned by a government entity - or subject to the influence of one. Digital networks contain choke points (national boundaries and long distances) which provide an easy opportunity for others to access your research data.
- Encrypting the data may reduce the risk but does not change the fact that evidence of communication exists. That an individual is communicating with a US-based server or system will also, typically, be clearly identifiable. In some situations, simply communicating will place the participant at risk.
- Even with encryption, there is still the potential for information - either questions or responses - to be recovered.
- The contents of "data in transit" could, potentially, be read, encrypted or not. Encryption is similar to a safe - and is a rating for how long a determined intruder can be delayed, rather than a guarantee of absolute confidentiality.

- The participant could be identified via the identification information that is a necessary part of their device; promising complete anonymity on an Internet survey has the potential to be profoundly misleading.
- Even if the encrypted contents of a survey response are unreadable, the nature and title of a survey may pose issues with local norms and laws and can likely be determined easily.
- Without encryption, data in transit is as insecure as a postcard. The to/from and the contents of a message are readily and easily visible to any technician with access to one of the many routing and networking devices linking an individual device to a destination/server.

In-person Research. 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.

- It is important to keep the above internet concerns in mind even when the researcher is physically in another country – common practices such as using cell phones to photograph or record subjects and saving files to the cloud may create significant issues in other countries.

Resources

- The Office of Human Research Protections (OHRP) publishes the [International Compilation of 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 Research.
- The Office of Human Research Protection (OHRP) has issued a [Listing of 27 Social-Behavioral Research Standards](#). This includes laws, guidelines, and regulations applicable to social-behavioral research around the world.