**IRB Review of International Research**

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**Special Considerations**

Special attention should be given to local customs and to local cultural and religious norms in developing research, drafting recruitment material as well as written consent documents and data collection instruments. The following information is guide for researchers who plan to collect data internationally. Please note that additional time will be required to prepare studies and research personnel to engage in research outside the U.S.

**Local Oversight**

Where appropriate, research projects must have been approved by the local equivalent of an IRB, sometimes called a Research Ethics Committee (REC) or local ministries, local governance (before they are presented to the University IRB).  Where there is no equivalent board or group, researchers are expected to consult with local experts or community leaders about the project and to secure their support for the conduct of the research. The IRB does require that there be good faith effort applied to secure local cooperation for the research and to document those efforts as part of the application.

**Researcher Qualifications**

At the time of initial review, the researcher must demonstrate that he/she and key research personnel possess the appropriate qualifications for conducting research in a specific country or region. The International Research Supplement document is used to provide information to evaluate the qualifications of the research personnel. It is the responsibility of the principal investigator and key research personnel to be familiar with local context, to consult with University faculty, international campus organizations or community individuals experienced in the local law, culture and social values of the community where the research will take place.

**Consent Process**

Consideration should be given to the most appropriate method of obtaining informed consent, including literacy levels, confidentiality concerns, and cultural norms. Different cultures have different authority structures for approval and consent. Researchers should be aware of and honor different cultural attitudes regarding consent. These attitudes may include differences with regard to autonomy and coercion (e.g., what we might consider to be coercive in the US may not be so in a different culture and vice versa).When it is appropriate the IRB will consider alternative consent formats if culturally appropriate. In some instances, it may be appropriate for the IRB to waive some or all requirements for written consent in favor of a verbal consent for cultural, religious or literacy reasons.  Research proposals for which this may be reasonable should include explanations of cultural norms or conditions requiring such as waiver in section 14 of the application. (E.g. societies where no written language is used, or societies where signatures represent the surrender of spirit or soul to the researcher).

Consent is best obtained using the language that is most familiar to the prospective subject and ideally the researcher or research team is fluent in the local language. If not, the researcher might seek collaborators or hire assistants who are fluent in the local language. A third option is to hire interpreters.

When hiring interpreters, the following elements should be considered:

* In a small population, the relationship between the interpreter and the subjects must be considered.
* The interpreter might exert influence or undue pressure that could lead to selection bias.
* The interpreter may not relay information in a clear and unbiased manner (e.g., he/she may leave out information they believe is unpleasant or culturally inappropriate).
* In addition to the initial consent process, fluent researchers or interpreters should be available to answer questions, address complaints, or relay instructions throughout the conduct of the study.
* Some languages are not written and sometimes people speak a language but may not be able to read or write it.
* There may not be any translations of important words.
* It may be culturally inappropriate to ask for a signature and may indicate a lack of trust.
* It may be appropriate to use alternative consent procedures, such as the use of a short form and witness, photos or videos, or other alternate forms of documentation

**Research with Children**
Children may have different statuses in foreign countries than in the US. Questions that may need to be considered are:

* What is the age of majority?
* What is the relationship between parents and their children in that country?
* What is an acceptable and effective parental permission process?
* What is an acceptable and effective child assent process and are there laws pertaining to orphans in that country?

**Levels of Review**
Through consultation with experts, the IRB must ensure that the risk assessment holds true at the foreign site. Thus, knowledge of local context is important even in research that may be exempt.

Note: even in exempt research, informed consent, parental permission, or child assent may still be ethically appropriate and/or required under local law. The researcher should include information in the research submission to address the local community ethical standards where the study will be conducted. This information should include details regarding local review (as applicable) and the researcher’s experience with the locality. This information will be considered when approving exempt research conducted at a performance site outside of the U.S.

To assist researchers who are conducting expedited or full board research in a foreign country, the IRB requires that the International Research Supplement Form is submitted and uploaded to iRIS as a study document. This allows the researcher to consider and detail relevant political, social, cultural, and economic norms or issues and gives the IRB a sense of how knowledgeable the researcher is about the region where the research will take place.

**International Data Security Laws**

General Data Protection Regulation (GDPR)

The European Union (EU) General Data Protection Regulation, known as the GDPR, is a comprehensive privacy regulation enacted by the EU Parliament. Although the GDPR primarily protects the personal data of persons physically located in the European Economic Area (EEA), it may protect the personal data of persons located in other countries, as well.

The GDPR applies to controllers (someone who determines the purposes and means of processing personal data—principal investigators are often controllers) and processors (someone who processes data on behalf of a controller) in three circumstances:

* When they are established in the EEA; or,
* When they are not established in the EEA but they:
	+ Offer goods or services to persons in the EEA; or,
	+ Monitor the behavior of persons in the EEA.

The GDPR defines personal data broadly as any information associated with an identified or identifiable natural person.

The GDPR may affect to your research if:

* Your research involves the personal data of persons physically present in the EEA;
* You want to re-use personal data you previously collected from persons in the EEA (e.g., for a previous research project) or you want to obtain existing personal data about persons in the EEA from other persons or units at BYU (e.g., admissions data) to use in your research;
* A person or entity physically present in the EEA is providing you with the personal data of research subjects located anywhere in the world;
* You intend to conduct data scraping involving the accounts or websites of persons or entities physically present in the EEA; or,
* You are collaborating with researchers or entities physically present in the EEA.

The notice and consent requirements can be complex if the research involves certain special categories of personal data identified in Article 9 of the GDPR.

* These special categories include data revealing racial or ethnic origin, political opinions, religious beliefs or philosophical beliefs, or trade union membership; genetic data; biometric data for the purpose of uniquely identifying a natural person; health data; and data concerning a person’s sex life or sexual orientation.

Data Protection Regulations in Other Countries

Researchers should be aware that in recent years international data security laws, similar to GDPR have been emerging to protect personal data. Countries such as Russia, China and various African nations have adopted stricter regulations within the last two years.

Information about how researchers will abide by national personal data protection should be articulated in detail in section 15.3 of the application.

Some regulations require additional measures for researchers to implement during the consent process and documentation. Researchers must be well informed about the regulations, plan more time to review research methods to accommodate extra considerations before application submission.

**Federal Guidelines for International Research**

In addition, the OHRP International Program works to ensure that human subjects outside of the United States who participate in research projects conducted or funded by HHS receive an equal level of protection as research participants inside the United States. To that end, the Institution’s human research activities, regardless of whether the research is subject to the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), will be guided by an assurance of specific principles governing the institution in carrying out its responsibilities for protecting the rights and welfare of humans in research conducted at or sponsored by the institution. This requirement of an assurance applies to non-U.S. Institutions such that whenever non-U.S. institutions are engaged in non-exempt HHS-supported or -conducted human research, the HHS human subject protection regulations, 45 CFR part 46, apply.

This means that when appropriate the non-U.S. institution must obtain an FWA which is the only type of assurance of compliance accepted and approved by OHRP. There is a single version of the FWA and the Terms of Assurance for U.S. and non-U.S. institutions. For additional information see: (<http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html>)

It should be noted that there when considering local cultural norms, equivalent protections are required (see OHRP guidance for equivalent protections: <http://www.hhs.gov/ohrp/international/equivalent-protections/index.html>). For example, with all due respect and sensitivity for local customs, minors who are treated as adults in their own country will be treated a minors for the purpose of protection in research.  However, the definition of who may provide ‘parental permission’ to participate may appropriately be adjusted based on cultural norms. It is possible, that grandparents or even tribal leaders may be the cultural head of household and may ethically serve as the designated guardian for a minor participating in research. That said, the cultural norms in question must be identified in the research protocol and the exception to policy anticipated.

OHRP also publishes [The International Compilation of Human Research Standards](http://www.hhs.gov/ohrp/international/), a listing of over 1,000 laws, regulations, and guidelines on human subject protections in over 100 countries and from several international organizations. This document should be consulted to determine country level guidelines on human subject research. Many of the listings embed hyperlinks to the source document.