Conducting International Research

Conducting research in international settings has become increasingly popular among students and faculty in the University of Rochester research community. Carefully planning this type of research, well in advance, is critical as regulatory and cultural differences can vary drastically from one international site to the next.

One of the principal hurdles study teams will face in conducting international research is navigating regulatory requirements. Per OHSP Policy 301 RSRB Scope and Authority, when faculty, staff or students engage in human subject research on behalf of the University, regardless of where the research is conducted, review and approval by the Research Subjects Review Board (RSRB) is required. Based on the institution's FederalWide Assurance, this further requires study teams comply with the Common Rule (45 CFR 46), regardless of study of sponsorship.

To meet U.S. federal requirements as well as the University's institutional requirements, study teams must:

- Include information pertaining to the setting in which the research will be conducted in their RSRB submission (e.g., description of the population, information pertaining to local languages, laws and cultural issues), as described in the OHSP Guideline for Conducting International Research.
- Obtain a local letter of support or local IRB/Ethics Committee approval, as appropriate.
- Obtain RSRB approval prior to implementation of the research;
- Obtain documentation of the local site's FederalWide Assurance, if federally funded
- Comply with Food & Drug Administration (FDA) regulations, if the research involves the use of an FDA-regulated product.

Study teams must ***also*** comply with the regulatory requirements of the setting in which the research will be conducted. This can range from detailed national/regional human subject research requirements much like the US (e.g., Europe, India, and Japan) to no clearly defined human subject protections. When there are no clearly defined protections, the ethical principles that guide human subject research (e.g., Nuremberg Code, Declaration of Helsinki, Belmont Report) still hold true. This includes obtaining ethics committee approvals (or letters of support by community leaders or other local experts in the absence of an ethics committee), allowing subjects to participate in the research voluntary and with informed consent, minimizing risks to subjects, appropriately selecting study subjects, etc. To further aid study teams in identifying applicable international regulations and guidelines, the Office for Human Research Protections within the Department of Health and Human Services publishes the International Compilation of Human Research Standards annually (though study teams are also encouraged to collaborate closely with local experts to ensure local requirements are adequately addressed).

Once the research has met both RSRB and local approval requirements, study teams must continue to comply with both sets of expectations during the implementation and close out phases of the research (meaning, OHSP Policy 901 Investigator Responsibilities [inclusive of U.S. federal regulations and state law] and the requirements of the setting in which the research is conducted). Generally, this includes:

- Obtaining informed consent;
- Complying with the study protocol;
- Ensuring subject questions and concerns are properly addressed;

- Submitting recruitment/consent/protocol revisions to ***both*** ethics committees for review and approval prior to implementation (per their requirements); and
- Submitting research events to ***both*** ethics committees (per their requirements).

Additional Considerations

Cultural Competence – Having a thorough understanding of a site's social habits, language, political and religious views, attitudes, values, and infrastructure is key to the success of the research. Demonstrating awareness of these cultural components should begin early in the planning phase, as the research is being designed, and continue throughout the life of the project. Failing to do so will negatively impact a study team's ability to foster a relationship with the community, communicate and enroll subjects, carry out study procedures and protect the rights, safety and welfare of subjects.

Communication Barriers – Consistent with the Belmont Report, communications with potential and enrolled study subjects should be informative (providing adequate information) and understood (providing information in a manner that is comprehendible to the study population). Subject communications should initially be thought through with input from individuals with local knowledge, during the planning phase of the research in the development of recruitment methods/materials, informed consent processes and any subject-completed measures. During this time, study teams must be mindful of a site's literacy rates and cultural practices, incorporating the use of illustrations, videos, demonstrations and/or community advisors, as appropriate. All written materials provided to study subjects must be translated to the site's native language by a fluent individual (translation software is not sufficient) and submitted to the RSRB for review and approval with a corresponding Translator Declaration. In some cases, for example when a professional translation service is *not* used, additional confirmatory translations may be required by the RSRB.

Once a study has been approved and the team is ready to initiate the research, verbal communications including day-to-day recruiting, enrollment and study activities should be facilitated via an interpreter. Utilizing interpreters not only allows study teams to communicate clearly with subjects but also likely improves the likelihood of enrollment, retention and subject compliance. Generally, interpreters should be fluent in the community's native language and unaffiliated with the research (i.e., not part of the research team), though it is also best practice to ensure the interpreter has a general understanding of the purpose and design of the research, privacy and confidentiality, and medical terminology (as appropriate).

Privacy & Confidentiality – Generally, the requirements pertaining to adequately protecting the privacy of subjects and maintaining the confidentiality of data still apply (as defined by 45 CFR 46.111 and OHSP Policy 404). A common misconception is that requirements set forth by the Health Insurance Portability and Accountability Act (HIPAA) do not apply to research that involves collecting protected health information (PHI), given that research is being conducted outside of the U.S. While this is true while outside the U.S., HIPAA applies (and therefore must be complied with) once study teams return with PHI to the U.S. Furthermore, it is not uncommon for other countries to have their own standards for protecting privacy and confidentiality and, similar to regulations governing the conduct of human subject research, these must also be complied with (see the aforementioned International Compilation of Human Research Standards for privacy and data collection standards).

Respecting Subjects & Community Engagement – Respecting study subjects requires more than the necessary steps of obtaining ethics committee approvals and informed consent; it includes valuing their opinions and

choices. Conducting international research often involves fostering community partnerships secondary to the purposes of the research and respecting that relationship throughout the life of the project (and potentially beyond the project) is vital. Similar to understanding a community's culture, a study team must understand what the community's expectations are concerning the research and then honor those expectations, or provide feedback to the community on exactly what they can deliver from the research. This could include sharing the results of the research or providing training, resources or equipment.

Timing – Needless to say, not all of the requirements and considerations described above can happen overnight. Planning plenty of time to develop your study protocol, research the necessary review requirements, collaborate with local experts, digest applicable cultural elements, and obtain ethics committee approvals (including the RSRB) is essential. The more forethought and effort that goes into planning international research, the more likely you will be able to conduct compliant research, collect quality data and meet your objectives.

Have questions? Contact your IRB Coordinator.

Note: The recent Common Rule and National Institutes of Health policy/regulatory revisions pertaining to the use of a single Institutional Review Board for multi-site research do not apply to research conducted internationally.

ADDITIONAL RESOURCES:

- OHSP Policy 301 RSRB Scope and Authority
- OHSP Policy 701 Informed Consent
- OHSP Guideline for Informed Consent
- OHSP Policy 901 Investigator Responsibilities
- OHSP Guideline for Conducting International Research
- OHSP Explains… Enrolling Non-English Speaking Subjects: Considerations & Best Practices
- HHS International Compilation of Human Research Standards
- University of Michigan's International Human Subject Research Resources

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