

## **Guidance on Research Conducted in International Settings**

The UC Merced IRB applies the same regulations and ethical standards to domestic and international research. International research requires special consideration to ensure equivalent protections as research conducted within the United States. The local research context, level of risk, and nature of the proposed research are all considerations in these protections. Investigators must comply with all local laws and requirements regarding the protection of human subjects and should consider partnering with local researchers.

### **Local Context**

The investigators are responsible for identifying and ensuring compliance with all applicable laws, regulations and guidelines for human subjects research in the country (ies) where their research will be conducted.

The investigator is responsible for providing the following information in the protocol application:

- Identify all city(ies), country(ies) where research will be conducted.
- Identify each collaborating site/agency/institution and describe its role.
- Provide a justification for conducting the research in an international setting.
- Identify the local permissions required for the conduct of the research. The investigator is responsible for identifying and ensuring compliance with all applicable laws, regulations and guidelines for human subjects research in each location where the research will be conducted.
- Outline the investigator's knowledge of the local community. The protocol should include (1) the appropriateness of research design in the context of research design in context of political climate, societal norms and comfort levels; (2) discussion of a planned or completed community consultation activities and parties involved (3) description of the parties involved in the planned or completed community consultation. Where local personnel are employed to collect, code and/or translate data, investigators must provide assurance that the personnel will be trained to hold data confidential.
- Discuss the status of women in the local community/country. If the status of women in the international location(s) is different than in the United States, the protocol should explain the measures incorporated in the research in respect to women's autonomy to consent.
- Discuss the status of children in the local community/country. If the status, definition or guardianship of children in international locations is different than in the United States, the application should explain how.
- Describe both the standard of care in the United States and the available standard of care/alternatives in the host of community/country. If applicable, discuss how the proposal is responsive to local health needs of the host community/country and

whether the research will address an important scientific question regarding the host of community/country.

### **Informed Consent**

When conducting research in an international setting, the informed consent discussion, as well as all consent documents, must be in the subjects' native tongue, and the language of the consent document should be appropriate to communicate clearly to the intended audience. Ideally, the research team will include people who are fluent in the research subjects' language(s) and familiar with local cultural norms. When a translator/interpreter is employed, research staff, not the translator/interpreter, should carry out the consent process with the assistance of a translator/interpreter. Family members cannot be asked to provide such translation because they may not be qualified to fully explain the study's risks and benefits to the potential subjects.

The protocol should describe the literacy level of the population, discuss how participants' comprehension of the consent process will be maximized, and explain how cultural appropriateness of the consent process and consent document (if applicable), study instruments, etc. has been determined. In addition, the researcher should submit for review both English and foreign language versions of the consent materials, along with his/her affirmation of the accuracy of the translation(s). The IRB understands that standard U.S. informed consent requirements are not always appropriate for other cultures, and it may waive some or all consent requirement when the conditions for such waivers are met.

### **Local Approval/Oversight and Requirements for FWA**

The investigator should identify each collaborating site/agency/institution and describe their role (e.g., performance site, data coordinating center, agency whose employees are conducting research procedures). The investigator should identify the appropriate local permissions required for the conduct of the research. If the UCM investigator will collaborate with persons who are affiliated with a local institution (university, hospital, clinic) or the local government, the application should identify each collaborator and his/her institutional affiliation, specify their role in the research, and outline their scientific qualifications. The application should identify the institution(s)/government(s) who will have access to the data, and specify the level of data which they will access (anonymous, coded, individual-level identified).

Foreign institutions or organizations that "engage" in federally funded research with human subjects must, in order to receive those funds: (1) hold a Federalwide Assurance (FWA) of compliance with United States DHHS Office for Human Research Protections (OHRP); and (2) conduct local IRB review of the research or enter into an IRB Authorization Agreement to rely on the IRB review of another institution. Federal regulations do not require foreign institutions which do not receive federal funds to have an FWA or to conduct local IRB review, but it is often the case that the foreign institutions themselves will require local IRB review regardless of the source of funding for the research.

**Additional Protocol Requirement**

Investigators conducting international research should include the [International Research Form](#) in the protocol application.