

International Research	
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1. PURPOSE

- 1.1. The IRB applies the same ethical and regulatory standards for human subjects research conducted outside of the United States as to domestic research. Human subjects research must conform to applicable local laws and norms of the host country and the community where the research will take place as well as UCSB policies and procedures including the informed consent process and participation of vulnerable populations. The IRB must ensure that protections of participants are based on the local research context, level of risk, and nature of the proposed research. Investigators must pay special attention to the local culture, tradition, language, and current political and social climate. Investigators must also comply with any relevant laws protecting human subjects in the host country and any requirements for a local IRB or ethical review.

2. POLICY and PROCEDURE

Research Activities Conducted by UCSB Investigators in an International Location

- 2.1. It is essential that the research team have sufficient knowledge of the local research context in order to design and carry out research that protects the rights and welfare of the subjects while adhering to local customs and norms.
- 2.2. The investigator is responsible for providing the IRB with the necessary information to evaluate the research in light of the local research context. The investigator should include the following details in the appropriate section of the HS application when pertinent:
- **Research location(s):** Identification of cities, rural areas, and countries where the research will be conducted.
 - **Collaborator(s) and what the collaboration entails:** A description of each collaborating site/agency/institution and define their role in the research.
 - **Local permissions and requirements:** A description of an appropriate local IRB or ethical review and how local permissions will be obtained.
 - **Language and literacy:** Investigators should describe their linguistic proficiency and measures taken to ensure subjects are informed about the research (i.e., informed consent) and the literacy level of the population and how the appropriateness of the consent process will adhere to the cultural standards of the international location.
 - **Community and culture:** The investigator should outline the research team's knowledge of the local community including the appropriateness of the research in context of the political and socio-economic climate, and societal norms. The investigator should discuss consultation with community leaders/experts regarding the consent process, documentation to ensure they are appropriate to the targeted community.
 - **Payment to participants:** The investigator should include a description of payment methods, such as cash or goods, and how the payment method is non coercive and would be equivalent that what would be commonly available in the local community.

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- **Status of women:** If the status of women in the international location(s) is different than the United States, the investigator should explain measures incorporated into the research to respect women's autonomy to consent.
 - **Status of children:** If the definition or guardianship of children in the community is different than the United States, the investigator should explain how they will conform to these standards.
 - **Traumatized communities:** Any risks and complications of conducting research with victims of violence or disasters should be discussed and a plan for minimizing any said risks should be included in the protocol application and consent process.
- 2.3. Investigators must also take into account when designing the research protocol that some questions or procedures that seem innocuous in the United States could be offensive and/or risky elsewhere. Consultation with community leaders, stakeholders, or colleagues can aid in providing important insights about the local community in a research context.
- 2.3.1. When reviewing the application, the IRB may consult with outside experts in order to sufficiently evaluate the proposed research to ensure the appropriateness of the study being proposed.
- 2.3.2. Similarly, if the IRB concludes there is not sufficient information in the protocol to evaluate its appropriateness, the IRB may require the investigator contact a local community leader, expert, or institution in the international location for guidance.
- 2.3.3. The IRB may require documentation of approval from a local IRB, local review body equivalent to the IRB, or if no such body exists, from a local community leader or expert who can attest to the host country standards for human subjects research.

Consent Process

- 2.4. In most instances, federal regulations require that researchers obtain documented (i.e., signed) consent from adult subjects. Investigators must describe the informed consent and include copies of the consent documents. The documents must be able to be translated into the subjects' native language. Investigators are expected to either have a member of the research team fluent in the research subjects' language(s) or contact a translator/interpreter to assist with translating the consent documents and any research questions.
- 2.4.1. When a translator/interpreter is used, the research team should be responsible for carrying out the consent process with the assistance of the translator/interpreter. Family members of the participant cannot be asked to provide such translations because they may not be fully qualified to explain the study's risks and benefits and this may place undue influence of participation on the potential subjects. Similarly, in some cases it may be inappropriate to have an interpreter from the locale where the research is being conducted to translate the consent to members of their community as this may be conceived as coercive or could breach the participant's confidentiality.

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- 2.4.2. The IRB protocol application should provide a detailed description of the informed consent process, including any pertinent social, political, or cultural issues.
- 2.4.3. If U.S. standards for informed consent requirements are not appropriate to the culture, the investigator should provide sufficient justification for the request of a waiver including why the research meets conditions for a waiver. The IRB may waive some or all of the consent requirements when conditions for such waivers are met.
- 2.4.4. In addition to the consent of the research participants, there may be other individuals or groups whose permission must be sought. In some non-U.S. communities, people other than the individual taking part in the research may be required to give permission before the potential subject may be asked to participate. However, another individual's or group's permission should not substitute for a subject's voluntary informed consent.
- 2.4.5. Investigators should also consider whether the consent should be oral or written. In some instances individuals may not be able to read the language and in other instances the language may not actually be a written language.
- 2.4.6. The investigator should also consider whether the age of majority to consent in the location where the research will take place differs from the United States and if parental permission and child assent reflects the local standards.

Training Requirements

- 2.5. The UCSB IRB understands that in some situations, members of the research team may not be fluent in English and/or will not have readily available internet access in order to complete the UCSB human subjects training requirements.
 - 2.5.1. In instances where completion of the UCSB training requirements is not feasible, the investigators should have alternative human subjects training available to these individuals.
 - 2.5.2. The training should include a discussion of 1) research ethics; 2) the voluntary nature of research participation and the consent process; and 3) standards for maintaining confidentiality of participant data.
 - 2.5.3. The IRB may ask the investigator to describe the alternative training in the protocol application.

Federalwide Assurance (FWA) Requirements and Local IRB Reviews

- 2.6. When foreign institutions are "engaged" in federally funded research with human subjects, those institutions must 1) hold a FederalWide Assurance (FWA) to comply with the United States Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP); and 2) conduct a local IRB review of the research or enter into an IRB Authorization Agreement to rely on another IRB's review of the research project. The IRB must also be registered with OHRP.
 - 2.6.1. Federal regulations do not require foreign institutions which do not receive federal funding to have an FWA or to conduct a local IRB review, however in

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many instances the foreign institution themselves will require a local IRB review regardless of the funding source.

- 2.6.2. At UCSB, regardless of the funding source, foreign institutions considered to be engaged in human subjects research are required to submit verification of a local IRB or ethical review and verification of human subjects training.
- 2.6.3. If the foreign institution does not have human subjects training, they may complete UCSB's training program, or register with Citiprogram and affiliate their training with UCSB to comply with 2.5.2 above.
- 2.7. These are common examples of when an institution is considered to be "engaged" in the human subjects research:
- Institutions whose employees or agents obtain the informed consent of human subjects for the research.
 - Institutions whose employees or agents obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research (even if the institution's employees or agents do not directly interact or intervene with the human subjects).
 - Institutions whose employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures (e.g., medical interventions or surveys), or by manipulating the subject's environment.
- 2.8. In order to determine where the research should be reviewed, investigators should consider the following questions:
- 1) Will the researchers have collaborators at the research site abroad?
 - 2) What is the role of the collaborators and are they engaged in the research?
 - 3) Will the collaborators be seeking their own approval (e.g., IRB approval or local ethical review)?
 - 4) Is the research federally funded, or are there specific requirements by the agency funding the research?
- 2.9. U.S export control laws and sanctions may apply to international research activities. Export controls are federal laws and regulations that govern the transfer of technology, goods, software, services, etc. from the United States to foreign persons or entities. Investigators are encouraged to contact exportcontrol@research.ucsb.edu if their research activities fall under U.S export control laws.

3. SCOPE

These policies and procedures apply to all human subjects research conducted by investigators affiliated with UCSB.

4. RESPONSIBILITY

The investigator is responsible for planning ahead to allow greater time to submit a protocol application for IRB review and obtaining any appropriate local ethical reviews.

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The IRB staff are responsible for reviewing protocols submitted following the procedures in HSC SOP 14 and 17 – *Initial Review* and *Continuing Review*.

The IRB members are responsible for reviewing protocols and requesting additional information as needed, to assess whether the conduct of the research is appropriate to the locale.

5. PROCESS OVERVIEW

- 5.1. Investigators conducting research in an international location must conform to the ethical and legal standards of that location for conducting their research. The IRB expects investigators to adhere to the key ethical principles as set forth in the Belmont Report – respect for persons, beneficence and justice.
- 5.2. The IRB may require that an investigator provide documentation that a review and approval by a local review body equivalent to the IRB was completed.
- 5.3. If no local review body is available and the research is not federally funded, the IRB may require the investigator to provide documentation of review by a local community expert or leader (e.g., NGO director, university professor) who is independent from the research project to avoid any biases or the IRB may apply the provisions identified in Section 5.2 above.
- 5.4. The IRB will assess the informed consent process and may waive some or all of the requirements if conditions for a waiver are appropriate to the research.

References:

45 CFR 46 Regulations
 UC Berkeley Guidelines and Policies
 UC Los Angeles FAQs
 Belmont Report – Ethical Principles and Guidelines for the Protection of Human Subjects Research
 Declaration of Helsinki
 International Compilation of Human Research Standards