

INTERNATIONAL RESEARCH

This guidance document is intended for researchers planning to conduct research in international settings. Also see CPHS web page “[Human Subjects Research in an International Setting](#).” Should you need additional assistance, please contact OPHS at 510-642-7461 or ophs@berkeley.edu.

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A. General Information

The Committee for the Protection of Human Subjects (CPHS) applies the same ethical and regulatory standards to research conducted abroad as to domestic research. However, the Committee must also ensure that the protections in place are appropriate for the setting in which the research will be conducted. These protections should be based on the local research context, level of risk, and nature of the proposed research. Investigators must pay special attention to local culture, tradition, and language, as well as the current political and social climate. It is also important to note that investigators must comply with the relevant laws protecting human subjects in the host country and any requirements for local IRB approval. Investigators should consider partnering with local researchers in order to ensure understanding of local context and regulations.

B. Knowledge of Research Context

The investigator is responsible for providing the Committee with the necessary information to evaluate the research in light of the local research context, by including the following details in the appropriate sections of his/her CPHS application when pertinent:

- **Research site(s):** Identify all cities, countries where research will be conducted.
- **Collaborator(s):** Identify each collaborating site/agency/institution and describe its role (e.g., performance site, local PIs, data coordinating center, agency whose employees are conducting research procedures, etc.).
- **Local rules and requirements:** Identify the appropriate 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 country where the research will be conducted.
- **Language:** Researchers should indicate in the protocol their linguistic proficiency and measures taken to ensure that subjects will be well informed about the research.
- **Literacy:** Describe the literacy level of the population, discuss how subjects' comprehension of the consent process will be maximized, and explain how the cultural appropriateness of the consent process and consent document, study instruments, etc. has been/will be determined.

- **Community and culture:** Outline the research team's knowledge of the local community, including: (1) the appropriateness of research design in the context of political climate, societal norms, and comfort levels; (2) discussion of any planned or completed community consultation activities regarding the consent process, consent documentation, study instruments, research design; and (3) description of the parties involved in the planned or completed community consultation. Where local personnel are employed to collect, code, and/or transcribe data, investigators must provide assurance that the personnel will be trained to hold data confidential.
- **Status of women:** 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 to respect women's autonomy to consent. *Note:* In no case will a competent adult woman be enrolled in research solely upon the permission of another person.
- **Status of children:** Discuss the status of children in the local community/country. If the status, definition, or guardianship of children in the international location is different than in the United States, the application should explain how.
- **Traumatized communities:** Discuss the risks and complications of conducting research with victims of violence and disasters and how these will be managed. See National Institute of Mental Health (NIMH) guidelines on [Ethical Issues to Consider in Developing, Evaluating, and Conducting Research Post-Disaster](#) for points to consider and additional sources of information.
- **Standard of care:** Describe both the standard of care in the USA and the available standard of care/alternatives in the host 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 community/country. Also, explain whether, if proven effective, the treatment or intervention under research will be available to some or all of the host country population.
- **Prevention of therapeutic misconception:** Although it is not a misconception to believe that study subjects will probably receive good clinical care, it is a misconception to believe the purpose of clinical trials is to administer treatment rather than to conduct research. If there is a likelihood that subjects will believe mistakenly that the purpose of the research is solely to provide treatment rather than to contribute to scientific knowledge, explain how this risk for misconception will be minimized.

C. Cross-Cultural Issues and Informed Consent

Standard Consent Requirements: In general, federal regulations require that researchers obtain documented (signed) consent from adult subjects. 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 CPHS application should provide a detailed description of the informed consent process, including discussion of any pertinent social, political, or cultural issues. 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 Committee understands that standard U.S. informed consent requirements are not always appropriate for other cultures, and it may waive some or

all consent requirements when the conditions for such waivers are met. The CPHS application should include requests and justification as to why the research meets conditions for any waiver. For more information about consent requirements and waivers of these requirements, see [CPHS Informed Consent Guidelines](#).

D. Requirements for FWA and Local IRB Review

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.

These are common examples of when an institution is considered to be engaged in human 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 human subjects).
- Institutions whose employees or agents intervene for research purposes with any human subjects of the research by performing *invasive or noninvasive procedures*, or by *manipulating the subject's environment*.

"Engagement" in human subjects research is defined in the OHRP October 2008 [Guidance on Engagement of Institutions in Human Subjects Research](#).

Information about how to obtain an FWA, frequently asked questions about Assurances, and a template IRB Authorization Agreement can be found on the OHRP website at: <http://www.hhs.gov/ohrp/assurances/index.html>

E. Other Useful Links:

CPHS web page "[Human Subjects Research in an International Setting](#)"

[CPHS International Research Checklist](#)

[The International Compilation of Human Research Standards](#) (A listing of the laws, regulations, and guidelines that govern human subjects research in many countries around the world)

[Listing of Social-Behavioral Research Standards](#)