



Guidance: Research Conducted in International/Transnational Settings

(last updated June 8, 2016)

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Overview

UCLA researchers often conduct studies outside the United States – this international, sometimes referred to as “transnational”, research requires special consideration by researchers and the IRB in order to ensure equivalent levels of participant protection are provided to research conducted within the United States.

This guidance outlines the researcher responsibilities and UCLA IRB considerations required to assure that adequate provisions for the protection of human participants are in place for research under UCLA’s jurisdiction that is conducted in other countries.

UCLA researchers and the UCLA IRB share responsibility for ensuring that:

- the same or equivalent protections are provided to human participants in research conducted in other countries;
- researcher and IRB knowledge of local laws and cultural context is sufficient to inform decisions about how the research is conducted;
- the consent process is appropriate to the population and procedures; and
- adequate provisions are outlined for data and safety monitoring.

The [UCLA OHRPP International Research Checklist](#) serves as a quick guide of critical areas of consideration for the UCLA researchers and IRB members conducting and reviewing international research.

Local Research Context

The investigator is responsible for identifying and ensuring compliance with all applicable laws, regulations, and guidelines for human participants research in the country (ies) where the research will be conducted. This may include but is not limited to visa requirements for UCLA/American researchers in foreign countries, governmental approval for non-citizens to conduct research.

The investigator is responsible for including the following information about local context in the webIRB application:

- Identify city (ies), country (ies) where research will be conducted.
- Provide a scientific and ethical justification for conducting the research in an international setting.
- Outline the investigator's knowledge of the local community. The IRB application should: (1) include discussion of planned or completed community consultation activities regarding the consent process, consent documentation, study instruments, (2) identify the participants in the planned or completed community consultation, and (3) describe the methods, discussions, and meetings.
- Discuss the status of women in the local community/country. The application should discuss the following issues related to the autonomy of women in the international location(s):
 - How will you ensure women's voluntary participation in the research?
 - If women's consent will be supplemented by a male (spouse, brother, father, etc.), explain why it is impossible to conduct the research without obtaining supplemental male permission for female participants.
 - Explain why failure to conduct the research could deny its potential benefits to women in the host country.
 - Outline the measures to be incorporated in the research protocol to respect women's autonomy to consent.
 - Provide written assurance that in **no** case will a competent adult woman be enrolled in research solely upon the permission of another person.
- Discuss the status of children in the local community/country. If the status or definition of children in the international location(s) is different than in the United States, the application should explain how.

Consent Process

The investigator is responsible for including the following information about the consent process(es) in the webIRB application:

- Describe the literacy level of the population, discuss how participants' comprehension of the consent process will be maximized, and explain how the cultural appropriateness of the consent process and consent document (if applicable), study instruments, etc. has been determined.
- The informed consent documents must be in a language understandable to the proposed participants. The investigator must assure that the documents will be translated by a qualified translator. The translator's credentials should be detailed in the application or written response to the IRB.

Local Approval / Oversight

The investigator is responsible for including the following information about the local approval(s) in the webIRB application:

- 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 UCLA 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).

Considerations When Research Involves Clinical Care

When research conducted outside the United States involves clinical care, the investigator is responsible for including the following information in the webIRB application:

- Describe how the research may address an important scientific question regarding the host community/country. If applicable, describe how the proposal is responsive to local health needs of the host community/country. Describe both the standard of care in the USA and the available standard of care/alternatives in the host community/country.
- Research may provide participants with beneficial care. In some developing countries, the type and level of clinical care provided to participants may not be available to those participants outside of the research context. The investigator should:
 - Explain how the investigator will minimize the likelihood participants will believe mistakenly that the purpose of the research is solely to provide treatment rather than also to contribute to scientific knowledge.

- Clarify whether there has been an effort to secure continued access for all participants to needed experimental interventions that have been proven effective at the conclusion of the project.
- Explain how the investigator will secure continued access (*for participants*) to needed experimental interventions that have been proven effective at the conclusion of the project. Alternately, explain why the investigator has not secured continued access (*for participants*) to needed experimental interventions that have been proven effective at the conclusion of the project.
- Explain whether, if proven effective, the procedures will be available to some or all of the host country population. Also explain either:
 - **why** the research procedures (if effective) will **NOT** be made available to the *host country's population*, OR,
 - **how** the research procedures (if effective) **will** be made available to the *host country's population*. Please include a description of any pre-re negotiations among sponsors, host country officials, and other appropriate parties aimed at making interventions available after the research.

When Foreign Institution or Site IS “Engaged” in Research

For research that is sponsored by a U.S. federal agency, where UCLA is the prime grantee of the award, the UCLA investigator is responsible for ensuring that all engaged international sites hold a Federalwide Assurance (FWA) and that the research is approved by an IRB or Ethics Committee.

Monitoring of Approved International Research

- The Investigator is responsible for providing to the UCLA IRB any reports of correspondence with the foreign institution or site and appropriate documentation of data and safety measures throughout the course of the study, including serious and unexpected adverse events and unanticipated problems to participants or others (e.g., a breach of participant confidentiality resulting in local ramifications).
- The Investigator is responsible for notifying the UCLA IRB promptly if a change in research activities alters the performance site’s engagement in the research (e.g., performance site “not engaged” begins consenting research participants).

UCLA IRB's Responsibilities

The UCLA IRB is responsible for evaluating the protocol according to the items discussed above. Click here for the [UCLA OHRPP International Research Checklist](#)

Regulations & References

DHHS Regulations

- Applicability of HHS Policy for Protection of Human Research Subjects: [45 CFR 46.101\(h\)](#)

UCLA OHRPP Guidance

- [International Research Checklist](#)

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

- [The Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#), April 18, 1979.

DHHS – Office for Human Research Protections (OHRP)

- International Issues page: <http://www.hhs.gov/ohrp/international/>
- [International Compilation of Human Subject Research Protections](#)
- [Equivalent protections guidance](#)
- [Terms of the Federalwide Assurance](#) (FWA)

National Bioethics Advisory Commission

- [Ethical and Policy Issues in International Research](#), 2001

World Medical Association

- [Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects.](#)

Council for International Organizations of Medical Sciences (CIOMS)

- [International ethical guidelines for biomedical research involving human subjects](#), 2002

Other

- Harvard School of Public Health, [Global Research Ethics Map](#)
- [European Union General Data Protection Regulation](#)

Change history:

6/8/2016: Removed outdated references, updated links, fixed minor typos.