

Transnational Research

SOP 102
Revised: December 18, 2015

Purpose and Scope

This document describes the procedures regarding human subjects research conducted outside of the United States.¹

This SOP applies to Investigators who plan to conduct research outside of the United States, and individuals and entities responsible for reviewing and approving such human subjects research, including regulatory offices.

Definition

Transnational Research: research conducted outside of the United States. It is also referred to as "International Research."

Specific Issues

When a Foreign Site IS "Engaged"² in the Research

If research is sponsored by a U.S. federal agency and UH is the primary grantee of the award, the UH investigator is responsible to address the following two questions in the IRB application:

1. Whether there is an IRB or ethics committee (EC) governing the research conducted at the foreign site; and
2. Whether the foreign site has a Federalwide Assurance with the U.S. Department of Health and Human Services or an authorization agreement with UH.

The questions are to ensure that the research is approved by an IRB or EC. See [SOP 120 Collaborative Research](#) for more information on research involving more than one institution.

Local Knowledge

The reviewing IRB and the investigator should possess adequate knowledge about applicable local laws on research involving human subjects.³

Exemption from IRB Review

¹ For UH general policies and guidance on transnational research, see [the Global Sponsored Activities Guide by the Office of Research Services](#).

² "Engaged" means that an institution is involved in a human subjects study to such a degree that the institution must have the study reviewed and approved by an IRB before the study's research activities may be initiated. For details on engagement, see [SOP 109, When Must a Non-UH Investigator Seek Review by the UH IRB?—the Issue of Engagement](#).

³ For local laws, see [International Compilation of Human Research Standards](#), U.S. Dep't of Health and Human Servs. (2014), <http://www.hhs.gov/ohrp/international/intlcompilation/2014intlcomp.pdf>.

1. Performing research in another country does not exclude the research from exemption.
2. But locale-specific factors may disqualify the research from exemption.
3. Even in exempt research, informed consent, parental permission, and child assent may be ethically appropriate or required under local law.

Informed Consent

1. The informed consent process must honor local customs.
 - (a) Some cultures may have a different authority structure for consent.
 - (b) The local consent structure may seem coercive and clash with the researcher's or the IRB's views on autonomy.
2. Consent by a legally authorized representative should not substitute a participant's informed consent unless the IRB has approved it.
3. Investigators should try to obtain consent using the language that the participants are most familiar with, taking into account that
 - (a) participants may not be able to read;
 - (b) there may be words that do not translate to English from the foreign language or vice versa; and
 - (c) if researchers are not fluent in the local language, translators should be used.
4. Investigators may have to consider alternate consent procedures, e.g.
 - (a) use of pictures, video, or computers; or
 - (b) alternate signatures, such as thumbprints.
5. Consent Documentation may be difficult because
 - (a) some languages or dialects are not written;
 - (b) participants may not be able to read;
 - (c) in some cultures, it may not be appropriate to ask for a signature;
 - (d) signing documents may lead to legal implications; and
 - (e) participants may be fearful about their rights when asked to sign documents.

Risk Assessment by the IRB

The IRB must ensure, through consultation with experts if necessary, that its risk assessment is accurate for the foreign site. Research methods with minimal risk in the United States may have greater than minimal risk if conducted at certain foreign sites. The IRB must consider the following:

1. Questions that might be inoffensive in the United States could be offensive at certain foreign sites;
2. Confidentiality may be difficult to maintain in those foreign sites;
3. Breach of confidentiality in the research locale can pose dangerous consequences; and
4. Depending on political and other factors, there may be dangers to the researcher.

Communication with the IRB and Faculty Advisors

The investigator is responsible for providing responses for the following in the IRB application:

1. How the UH IRB and the local EC, if applicable, will communicate with each other.
2. Who will handle continuing review, modification requests, complaints, unanticipated problems, and noncompliance; and how.
3. If a student researcher will be abroad, how much the student knows about the country and how the student will communicate with the faculty advisor.
4. What the local contact is in case the principal investigator or the faculty advisor cannot be reached.

Monitoring of Approved Transnational Research

1. The investigator is responsible for providing the HSP with any reports from the foreign sites about data and safety measures throughout the course of the study, including unanticipated problems.
2. The Investigator is responsible for promptly notifying the HSP if a change in research activities alters the foreign site's engagement in the research. e.g., a foreign site becomes engaged when the originally not-engaged site begins consenting research participants.

Transnational Research Involving Women

In the IRB application, the investigator is required to discuss the following issues related to the autonomy of women in the foreign sites in terms of participating in research:

1. How the investigator will ensure that women voluntarily participate in the research;
2. If women's consent will be supplemented by a male—spouse, brother, or father, why the supplement is necessary; and
3. Whether the investigator will provide a written assurance that a competent adult woman will not be enrolled in research solely on the permission of another person.

Transnational Research Involving Children

The investigator and the IRB is required to address the following issues when the research involves children:

1. When a child is considered as an adult in the foreign locale;
2. What the relationship is like between parents and their children in the foreign locale;
3. What parental permission processes are acceptable and effective;
4. Whether child assent is acceptable by local customs; and
5. Whether there are laws regarding guardianship of orphans or unsupervised children.

Transnational Research Involving Clinical Care

When transnational research involves clinical care, the investigator is responsible for including the following information in the IRB application:

1. How the research may address an important scientific question involving the host community or country.
 - (a) If applicable, the investigator should describe how the research responds to local health needs of the host community or country.
 - (b) The investigator should describe the standard of care in the United States and the available standard of care or alternatives in the host community or country.
2. Whether the 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 people outside of the research context. In that case, the investigator should
 - (a) explain how the investigator will minimize the likelihood that participants will mistake the purpose of the research as solely to provide treatment, rather than also to contribute to scientific knowledge;
 - (b) describe any efforts to secure continued access for all participants to needed experimental interventions proven effective at the conclusion of the project by explaining
 - (i) how the investigator will secure the continued access; or
 - (ii) why the investigator has not secured the continued access;
 - (c) explain whether procedures proven effective will be available to some or all of the host country population;

- (i) if no, explain why; or
 - (ii) if yes, explain how—including a description of any negotiations among sponsors, host country officials, and other appropriate parties.
3. Whether the research procedures are therapeutic.

Summary of Additional Information that an Investigator Should Submit Before Conducting Transnational Research

The investigator is responsible for identifying and ensuring compliance with all applicable laws and guidelines on human subjects research in the country where the research will be conducted. Those laws and guidelines may include visa requirements and governmental approval for non-citizens to conduct research at the foreign site.⁴

The investigator is required to include the following information in the IRB application:

1. **Local Research Context.**

- (a) **The Locale.** The city and the country where the research will be conducted.
- (b) **Justification.** A scientific and ethical justification for conducting the research in an international setting.
- (c) **The Investigator's Local Knowledge.**
 - (i) The investigator's knowledge of the local community.
 - (ii) Whether the researcher speaks the language of the country where the research will be conducted. If the researcher does not speak the local language, describe how the researcher will communicate with research participants.
 - (iii) Whether the researcher is familiar with the local customs and culture or whether a local collaborator will conduct the research.
- (d) **Consultation with the Local Community.** Any planned or completed community consultation regarding participants, the consent process, consent documentation, and study instruments.
- (e) **Local contact information** for persons who can answer
 - (i) research-related questions—including local emergency contact information—if applicable; and
 - (ii) questions about participants' rights—e.g., local IRB or EC.

2. **Consent.**

- (a) **Consent Process.** If consent will be obtained, how or from whom will consent be obtained along with the following information if applicable:
 - (i) Local customs or culture where the participant may not have autonomy to consent;
 - (ii) Measures to ensure voluntary participation if a person other than the participant will be consenting;
 - (iii) The literacy level of the population;
 - (iv) Measures to maximize the participants' comprehension of the consent process; and
 - (v) Processes to determine the cultural appropriateness of the consent process, consent document if applicable, and study instruments.
- (b) **Payment.** Whether the participants will be paid and, if so, the amount and how it relates to

⁴ See *supra* note 1.

- the local economy and the participants' income.
- (c) **Consent Documentation.** Whether written consent documentation will be obtained.
 - (i) If yes and applicable, a description on translation of the consent documentation. The informed consent documents must be in a language understandable to the proposed participants. If the participants do not understand English, the investigator must ensure that the documents will be translated by a qualified translator. The translator's credentials should be detailed in the application.
 - (ii) If no, a description of whether local customs or culture discourages written documentation and how consent will be recorded.
 3. **Privacy and Confidentiality.** Whether a local custom requires research data to be revealed to someone other than the participant.
 4. **Local Oversight.** Information about the local oversight:
 - (a) local permissions required to conduct the research;
 - (b) collaborating sites and their roles—e.g., a performance site, a data coordinating center, an agency whose employees will be conducting research;
 - (c) collaborators and their institutional affiliations, roles in the research, and scientific qualifications;
 - (d) the institutions or governments who will have access to the data, and the identifiable level of the data—e.g., anonymous, coded, or individually identifiable without coding.
 5. **Communication between the HSP and the Local EC.** If applicable, describe how the local EC and the HSP will communicate with each other about continuing review, modification requests, complaints, unanticipated problems, and noncompliance.

Materials

- GUIDE 631: Transnational Research Checklist

References

- The Organization's transnational research activities are consistent with the ethical principles set forth in its Human Research Protection Program and meet equivalent levels of participant protection as research conducted in the Organization's principal location while complying with local laws and taking into account cultural context (AAHRPP Standard I-3)