



Title:	Transnational Research		
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1 Transnational Research

The IRB will review all transnational research involving human participants to assure adequate provisions are in place to protect the rights and welfare of the participants.

Approval of research is permitted if “the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in 45 CFR 46.”

All policies and procedures that are applied to research conducted domestically should be applied to research conducted in other countries, as appropriate.

For transnational research, the UNC-Chapel Hill IRB seeks sufficient knowledge of the local research context by requesting approval for the project from local IRBs or ethics committees (which may or may not be OHRP-registered) and/or local letters of support. The source of this information will depend on the nature of the study, on the country and on the resources available to the investigator. Where there is a local IRB/IEC, the UNC-Chapel Hill IRB must receive and review the foreign institution or site’s IRB/IEC review and approval of each study prior to beginning the research at the foreign institution or site.

In some circumstances where research may be performed internationally and/or in settings where there are no IRBs, the UNC-Chapel Hill IRB may, prior to approval of the research, require additional verification and information from people outside the particular research project who are familiar with the customs, practices, or standards of care where the research will be taking place, such as local IRBs or ethics committees, other the UNC-Chapel Hill investigators with knowledge of the region, or a consultant who is an expert on the region. These individuals may either provide a written review of a particular research plan or attend an IRB meeting to provide the UNC-Chapel Hill IRB with recommendations based on his or her expertise.

For Federally funded research, approval of research for foreign institutions or sites “engaged” in research is only permitted if the foreign institution or site holds an Assurance with OHRP and local IRB review and approval is obtained.

Approval of research for foreign institutions or sites “not engaged” in research is only permitted if one or more of the following circumstances exist:

- When the foreign institution or site has an established IRB/IEC, the investigator must obtain approval to conduct the research at the "not engaged" site from the site’s IRB/IEC or provide documentation that the site’s IRB/IEC has determined that approval is not necessary for the investigator to conduct the proposed research at the site.

- When the foreign institution or site does not have an established IRB/IEC, a letter of cooperation must be obtained demonstrating that the appropriate institutional or oversight officials permit the research to be conducted at the performance site.
- IRB approval to conduct research at the foreign institution or site is contingent upon receiving documentation of the performance site's IRB/IEC determination, or letter of cooperation, as applicable.

1.1 IRB Responsibilities

In addition to standard IRB review, the IRB will consider the following in the review of transnational research:

1. The investigator and research staff are qualified to conduct research in that country including knowledge of relevant laws, regulations, guidance and customs.
2. The consent process and consent documents are appropriate for the languages of the subjects and communication with the subject population. Arrangements are considered to communicate with the subjects throughout the study (e.g., to answer questions).
3. The IRB considers how modifications to the research will be handled. The IRB and investigators should consider as many contingencies (e.g., survey questions) as possible when research is reviewed and approved.
4. The IRB considers how complaints, non-compliance, protocol/research plan deviations and unanticipated problems involving risks to participants or other are handled.
5. The IRB considers how post-approval monitoring will be conducted.
6. The IRB considers if the investigator has obtained the appropriate host country permissions to conduct research (e.g., institutional, governmental or ministerial, IRB, local or tribal). When appropriate, the IRB communicates and coordinates with the local institutions or ethics committees.
7. The IRB considers mechanisms for communicating with the investigators and research staff when they are conducting the research in other countries.

1.2 Investigator Responsibilities

1. It is the responsibility of the UNC-Chapel Hill investigator and the foreign institution or site to assure that the resources and facilities are appropriate for the nature of the research.
2. It is the responsibility of the UNC-Chapel Hill investigator and the foreign institution or site to confirm the qualifications of the investigators and research staff for conducting research in that country(ies).
3. Investigators obtain all appropriate host country permissions to conduct research (e.g., institutional, governmental or ministerial, IRB, local or tribal).
4. It is the responsibility of the UNC-Chapel Hill investigator and the foreign institution or site to ensure that the consent process and consent document are appropriate for the

languages of the subjects and communication with the subject population. Arrangements are considered to communicate with the subjects throughout the study (e.g., to answer questions).

5. It is the responsibility of the UNC-Chapel Hill investigator and the foreign institution or site to ensure that the following activities will occur.
 - a. Initial review, continuing review, and review of modification
 - b. Post-approval monitoring
 - c. Handling of complaints, non-compliance and unanticipated problems involving risk to subjects or others.
6. The IRB will not rely on a local ethics committee that does not have policies and procedures for the activities listed above.
7. Investigators will consider how complaints, non-compliance, protocol/research plan deviations and unanticipated problems involving risks to participants or other are communicated to the IRB.
8. It is the responsibility of the UNC-Chapel Hill investigator and the foreign institution or site to notify the IRB promptly if a change in research activities alters the performance site's engagement in the research (e.g., performance site "not engaged" begins to obtain consent of research participants, etc.).
9. Investigators cooperate with the IRB regarding how and when post-approval monitoring will be conducted.
10. Investigators consider mechanisms for communicating with the IRB when they are conducting the research in other countries.

1.3 Consent Documents

The informed consent documents must be in a language understandable to the proposed participants. Therefore, the IRB will review the document and a back translation of the exact content contained in the foreign language informed consent document which must be provided by the investigator, with the credentials of the translator detailed in the IRB application or Modification Request form. Verification of the back translation should be placed in the IRB file.

1.4 Monitoring of Approved Transnational Research

The IRB is responsible for the ongoing review of international research conducted under its jurisdiction through the continuing review process in accordance with all applicable federal regulations.

When the IRB and a local ethics committee will both be involved in the review of research, there is a plan for coordination and communication with the local IRB/IECs.

The IRB will require documentation of regular correspondence between the UNC-Chapel Hill investigator and the foreign institution or site and may require verification from sources other than the UNC-Chapel Hill investigator that there have been no substantial changes in the research since its last review.