SOP-G-010: TC IRB Standard Operation Procedures (SOP) on Transnational Research

Policy

The TC IRB requires all transnational research to meet ethical and regulatory standards equivalent to those applied domestically. This includes compliance with local regulations, obtaining necessary approvals, and ensuring informed consent is provided in an understandable language for participants.

Scope

This SOP applies to all research involving human subjects conducted internationally under the oversight of the TC IRB, including those studies in collaboration with foreign institutions and local IRBs/Ethics Committees (ECs). The SOP outlines the requirements for IRB review, approval, and monitoring to protect the rights and welfare of participants in international settings.

Definitions

- **Transnational Research**: Research conducted outside of the United States involving human subjects under the TC IRB's jurisdiction.
- **Foreign Institution**: A research institution or site located outside the U.S. where research activities take place.
- **IRB/EC**: Institutional Review Board or Ethics Committee responsible for ethical review and approval of research protocols within its jurisdiction.
- **FWA**: Federalwide Assurance, a commitment by an institution to comply with U.S. regulations for the protection of human research subjects.
- **Local Context**: The customs, practices, laws, regulations, and standards of care in the region where the research is conducted.
- **Back Translation**: Translating a document back into the original language to verify accuracy.

IRB Responsibilities

In addition to the IRB review considerations discussed elsewhere in this manual, the IRB will consider the following when reviewing transnational research:

1. The qualifications of the investigator and research staff to conduct research in that country including knowledge of relevant laws, regulations, guidance and customs;
2. Whether the consent process and consent documents are appropriate for the language(s) and local customs of the subjects and the subject population, and that arrangements are made to be able to communicate with subjects throughout the study (e.g., to ask and answer questions). For instance, some locales prohibit traditional consent processes and/or the use of consent forms, and if so, the IRB will need to approve alterations in the process or forms);
3. How modifications to the research will be handled;
4. How complaints, noncompliance, protocol deviations and unanticipated problems involving risks to subjects or others are handled;

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5. How post-approval monitoring will be managed;
6. Whether the investigator has obtained the appropriate host country approvals and permissions to conduct the proposed research (e.g., institutional, governmental or ministerial, IRB, local, or tribal);
7. When applicable, whether the investigator has provided an appropriate plan, and any necessary supporting documentation, to comply with the requirements of country law for investigational articles; and
8. Mechanisms for communicating with the investigators and research staff when they are conducting the research in other countries.

Investigator Responsibilities

The investigator conducting transnational research is responsible for:

1. Ensuring that the resources and facilities are appropriate for the nature of the research;
2. Verifying the qualifications of the investigators and research staff for conducting research in the country(ies);
3. Obtaining all appropriate host country approvals and permissions to conduct research (e.g., institutional, governmental or ministerial, IRB, local, or tribal);
4. Complying with the requirements of country law; including, when applicable, requirements for research involving investigational articles and requirements for data management and privacy such as EU General Data Protection Regulation and the Personal Information Protection Law (PIPL);
5. Ensuring that the consent process and consent document are appropriate for the language(s) of the subjects and the subject population, and that arrangements are made to be able to communicate with subjects throughout the study (e.g., to ask and answer questions);
6. Ensuring that the following activities will occur:
    a. Initial review, continuing review (when required), and review of modifications;
    b. Post-approval monitoring of the conduct of the research in accordance with the plan approved by the IRB; and
    c. Management and reporting of complaints, noncompliance, unanticipated problems involving risk to subjects or others, and other issues that arise in accordance with the research plan, the requirements of the IRB, and the requirements of the locale where the research takes place;
    d. Not relying upon an IRB or EC that does not have policies and procedures for the activities listed above;
    e. Notifying 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.); and
    f. Ensuring that there are mechanisms for communicating with the IRB when they are conducting the research in other countries.

Procedures

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For federally conducted or supported research, approval of research for foreign institutions or sites "engaged" in research is only permitted if the foreign institution or site holds an FWA 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/EC, 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/EC 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/EC determination, or letter of cooperation, as applicable.

The TC 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/EC, TC IRB must receive and review the foreign institution or site's IRB/EC review and approval of each study prior to beginning the research at the foreign institution or site. When appropriate, the IRB communicates and coordinates with the local institutions or ethics committees.

In settings where there are no IRBs/ECs, TC IRB may 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, including other IRBs or committees with experience reviewing research in the region, other TC investigators with knowledge of the region, or a consultant who is an expert on the region, prior to approval. These individuals may either provide a written review of the research protocol or attend an IRB meeting to provide the TC IRB with recommendations based on his or her expertise.

Consent Documents

The informed consent documents must be appropriate for and in a language understandable to the proposed subjects. The IRB will review the proposed document, and a back translation of the exact content contained in the foreign language informed consent document, with the credentials of the translator detailed in the IRB application/modification memo or the TC IRB Translation Verification Form. All documents, including verification of the back translation, are maintained in the IRB file.

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 are both involved in the review of research, there must be a plan for coordination and communication with the local IRB/ECs.

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The IRB requires documentation of regular correspondence between the TC investigator and the foreign institution or site and may require verification from sources other than the TC investigator that there have been no changes made to the research since its last review.

Documentation and Record-Keeping

All documents, including IRB approvals, local permissions, consent forms, and correspondence with foreign institutions, must be retained in accordance with TC's record-keeping policies. Verification of back translation and all communications regarding the transnational study will be kept in the IRB file.

Resources

- **TC IRB International Research (blog)**
- **TC IRB Researcher Guidance for EU General Data Protection Regulation (GDPR) Compliance**
- **TC IRB GDPR Consent Notice Template**
- **TC IRB Researcher Guidance for China's Personal Information Protection Law (PIPL) Compliance**
- **TC IRB PIPL Consent Notice Template**
- **Translation Guide**
- **Translation Verification Form**
- **Translator/Interpreter Confidentiality Agreement**
- **International Travel Checklist**

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