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1. Overview

The Drexel University Institutional Review Board (IRB) will review international research involving human participants to ensure adequate provisions are in place to protect the rights and welfare of the participants. These procedures describe the considerations and responsibilities for conducting international research projects.

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

2. Procedures

For international research, the Drexel University IRB seeks sufficient knowledge of the local research context and may request approval for the project from local IRBs or ethics committees (which may or may not be registered with the U.S. Office for Human Research Protections (OHRP)) 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/Independent Ethics Committee (IEC), the Drexel University 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 Drexel University 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 Drexel University 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 Drexel University IRB with recommendations based on the individual's expertise.

3. Consent Documents

The IRB will review the foreign language informed consent document, which must be in a language understandable to the proposed participants. Investigators must provide the credentials of the translator, and verification of translation uploaded via an additional document.

4. Monitoring of Approved International 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 may require documentation of regular correspondence between the Drexel University investigator and the foreign institution or site and may require verification from sources other than the Drexel University investigator that there have been no substantial changes in the research since its last review.

5. Responsibilities

5.1 Office for Research & Innovation and Human Research Protections Responsibilities

The Office of Research & Innovation and Human Research Protections Office are responsible for maintaining these procedures, applicable tools, training, and monitoring. The HRP Office is responsible for review and approval of international human subjects research. For inquiries regarding these procedures, please contact the Executive Director for Human Research Protections, as part of the Office for Research & Innovation (ORI).

5.2 IRB Responsibilities

In addition to standard IRB review, the IRB will consider the following in the review of international 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 (e.g., institutional, governmental or ministerial, IRB, local, or tribal) to conduct research, including any necessary approvals for investigational articles. 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.
8. The Drexel IRB will consider reliance on an international IRB when appropriate.

5.3 Principal Investigator Responsibilities

1. It is the responsibility of the Drexel University 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 Drexel University 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), including appropriate regulatory authority approval for research involving investigational articles.
4. It is the responsibility of the Drexel University 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. Investigators are expected to ensure appropriate processes to communicate with the subjects throughout the study are maintained (e.g., to answer questions).

5. When a international IRB or site has been identified, then it is the responsibility of the Drexel University investigator to collaborate with the foreign institution to ensure the regulatory criteria are maintained on an ongoing basis, separate from the Drexel IRB review, when applicable. These activities may include:
    a. Initial review, continuing review, and review of modifications;
    b. Post-approval monitoring; and
    c. Handling of complaints, non-compliance, and unanticipated problems involving risk to subjects or others.
6. Investigators will consider how complaints, non-compliance, protocol/research plan deviations, and unanticipated problems involving risks to participants or other are communicated to the reviewing IRB(s), e.g. Drexel University IRB and the international IRB/IEC as applicable.
7. It is the responsibility of the Drexel University investigator and the foreign institution or site to notify the reviewing IRB(s) 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.).
8. Investigators cooperate with the reviewing IRB(s) regarding how and when post-approval monitoring will be conducted.
9. Investigators consider mechanisms for communicating with the reviewing IRB(s) when they are conducting the research in other countries.
10. The PI is responsible for ensuring any research personnel traveling outside of the U.S. have registered their official travel with Drexel Global.

In addition, the Principal Investigator (and Faculty Mentor as applicable) is ultimately responsible for the conduct and oversight of the project. Please refer to ORI-002, Principal Investigator Eligibility and Responsibilities, for a listing of the PI and Department Responsibilities. The PI is responsible for following these procedures, ensuring appropriate submissions, approvals and oversight, and submitting the applicable documentation or exceptions to the HRPP/IRB.

6. Resources

- ORHP International Compilation of Human Research Standards
- Drexel Global - Travel Authorization

7. Revision

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