

 DIVISION OF RESEARCH & INNOVATION Research Integrity & Compliance		Institutional Review Board Standard Operating Procedures	
Title: International (Transnational) Research			
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PURPOSE

This Standard Operating Procedure (SOP) describes the standards and parameters for the conduct, review, and approval of international human subjects research. This SOP outlines the general responsibilities of the Researchers who conduct international research involving human subjects under the oversight of the Institutional Review Board (IRB) program.

SCOPE

This SOP delineates systematic process activities and functions for compliance with the US Department of Health and Human Service, Office for Human Research Protections (OHRP) and Common Rule requirements, and University of North Texas requirements for the management, coordination, and operation under the oversight of the Institutional Review Board program. It applies to all Researchers and research staff involved in conducting human subjects research, as well as all IRB Members and IRB staff reviewing research involving human subjects.

DEFINITIONS/ ABBREVIATIONS

1. Definitions

- 1.1 *International (Transnational) Research*: UNT Researchers engaged in human subjects research studies or activities including, but not limited to, recruiting subjects, consenting subjects and/or collecting research data at any location outside of the United States, with or without collaborators, and with or without funding.
- 1.2 *IRB Analyst*: Staff member of Research Integrity and Compliance that perform administrative activities, pre-reviews, reviews, and approvals for the Institutional Review Board program

- 1.3 *IRB Submission Portal*: A web-based system for preparing, submitting, and routing research studies for IRB approval. All information is stored in a cloud system and can be accessed securely from any location. Researchers receive electronic notifications whenever an action is required on their part to move the study through the review and approval process.
- 1.4 *Principal Investigator*: The individual who is actively leading and/or supervising the initiation, execution, and completion of a research project in compliance with applicable laws, regulations, and institutional policy governing the conduct of research. It is ultimately the PI's responsibility to ensure that all personnel actively working on the project and interacting with human subjects are following the guidelines of the approved protocol and are treating subjects in a manner befitting ethical use of human subjects. The PI should be the party responsible for submitting the research protocol, providing the RIC or the IRB with requested changes in order to garner approval, and for following the guidelines stipulated for annual review of the protocol and submission of any modification requests.
- 1.5 *Researcher*: An individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from participants, interacting with participants, collecting data and communicating with the IRB.

2. Abbreviations

- 2.1 SOP/SOPs: Standard Operating Procedure(s)
- 2.2 OHRP: Office for Human Research Protections
- 2.3 RIC: Research Integrity and Compliance
- 2.4 IRB: Institutional Review Board
- 2.5 PI: Principal Investigator

RESPONSIBILITIES

This SOP is applicable to all University of North Texas Researchers who are involved in preparing, submitting, and conducting human subjects research. This SOP is also applicable to all members of Research Integrity and Compliance and Institutional Review Board members who are involved in record keeping, reviewing, or approving research studies for the Institutional Review Board program.

PROCEDURE

1. General Oversight

- 1.1 International Research involving or conducted by UNT Researchers remains subject to the review and approval authority of the UNT IRB and the obligations undertaken by UNT in its Federal Wide Assurance on file with the federal Office of Human Research Protections (OHRP).
 - 1.1.1 This includes locations overseas/outside of the United States, even if those locations or countries do not have a standard human subjects review or process of their own.
 - 1.1.2 When international research is conducted, both the UNT IRB and the applicable foreign site's IRB/ethics committee, if applicable, must approve the research before the research is initiated.
- 1.2 The IRB will review all international (transnational) research involving human participants to assure adequate provisions are in place to protect the rights and welfare of the participants.
- 1.3 The Principal Investigator must make themselves familiar with the guidelines of the

country where research will occur. If possible, the UNT Principal Investigator should work with a local collaborator in the country where research will be conducted. Some countries require an ethics committee or the equivalency of a local ethics board to review and approve research which involves human subjects.

- 1.4 Research projects that take place outside the United States require compliance with UNT policies and procedures as well as the relevant laws of the host country. For this reason, additional review and documentation are required when conducting research outside of the United States.

2. IRB Submission and Review

2.1 Minimal risk (Exempt) studies

- 2.1.1 If it is determined that the regulations of the foreign country do not require an ethics review of a minimal risk study:

- 2.1.1.1 A ‘memo of cultural appropriateness’ should be obtained to ensure that the proposed project does not interfere with or will not be an affront to the local culture’s societal norms. The memo should be written by someone who is not associated with the research study or who has a personal relationship with the research team but has the knowledge or expertise on the local culture. The memo should include the following:

- 2.1.1.1.1 The date

- 2.1.1.1.2 The name and title of the author

- 2.1.1.1.3 The title of the research project

- 2.1.1.1.4 A brief description of the author’s expertise and experience

- 2.1.1.1.5 A brief description of the research project showing the author’s understanding of the protocol

- 2.1.1.1.6 A statement that the author attests the appropriateness of the research project and that it is not in conflict of local societal norms

- 2.1.1.1.7 A signature of the author

- 2.1.1.2 In addition to the memo, the protocol application should also include documentation that the country’s regulations does not require any official local ethics review. This could be a direct evidence to the local regulations or a letter from the proposed foreign research site, provided on a letterhead of the organization/institution which states that further ethics review is not required. The document should not be authored by someone who is associated with the research study or who has a personal relationship with the research team. This document should be authored by someone who has the knowledge, expertise, and authority to provide this information. The document should be signed, dated, and include the protocol’s information and a brief confirmation that the author understands the nature of the proposed research project.

- 2.1.2 If the proposed project is minimal risk, but the country does require ethics review:

- 2.1.2.1 A letter of approval from the local ethics committee is required. The letter of approval should include the following:

- 2.1.2.1.1 The title of the study

- 2.1.2.1.2 A statement describing that the proposed research project

was deemed to be minimal risk

2.1.2.1.3 Clearly stated approval to commence by the local ethics committee

2.1.2.1.4 The document should be signed and dated

2.1.2.1.5 The letter should be on the letterhead of the committee's signatory

2.2 Greater than minimal risk (Expedited and Full Board) studies

2.2.1 For greater than minimal risk (expedited and full board) studies, a letter of approval by an ethics committee is required from the foreign agency where the research is taking place. Not all countries have formal ethics review committees, so a review may need to be conducted by a Department of Ministries or alternative government entity. The letter of approval must include the following:

2.2.1.1 The title of the research project

2.2.1.2 Clear statement(s) that the project has been reviewed and is approved

2.2.1.3 A signature and date

2.2.1.4 Letter on the official letterhead of the signatory

2.3 Site Approval

2.3.1 Just as with research conducted in the United States, approval letters must be provided for any and all locations where research may take place. The site permission letters should include the title of the study, signature and date, and a statement confirming that the site is approved to be a research location.

2.4 Age of Consent

2.4.1 If the legal age of an adult differs in another country from state law (for example, 18 years of age), the IRB should accept the local age of majority when considering who may provide their own consent.

2.5 Non-English-Speaking Participants

2.5.1 Investigators should have a plan for managing communications with non-English speaking participants. All documentation that a participant may see (informed consent document, survey questions, etc.), should be submitted in English and the language of potential participants.

2.5.2 Certification should be provided from an appropriate individual that the translated version of the document is complete and does not contain information that is not presented within the context of the approved English version of the document. While the IRB does not require the use of professional translation services, the researcher must provide an explanation as to who provided the document translation and this person's qualification to serve as the translator for the language. The IRB will request documentation of who completed the translation and their qualifications (ie. Resume/CV).

2.5.3 The English and translated documents will both need to be approved as part of the IRB application.

2.6 Additional IRB Application Contents

2.6.1 Items to be included or questions to be answered as part of application relevant to international sites:

2.6.1.1 Is the research being conducted in a county or at a cultural site (e.g. Native American communities), where the cultural norms and backgrounds are very different to the UNT community surrounding communities?

- 2.6.1.2 The following information should be included:
 - 2.6.1.2.1 Name of site
 - 2.6.1.2.2 Name and title of authorized individual who is acting as signatory or approver for foreign ethics committee
 - 2.6.1.2.3 Name and information of international site collaborator (as applicable)
 - 2.6.1.2.4 Anticipated number of subjects
 - 2.6.1.2.5 FWA number of the international site if the project is federally funded
- 2.6.1.3 Provide descriptions of the international sites cultural norms and highlight differences from standard U.S. culture. Also include the age of participants (including rules on age limits for minors if it differs from U.S. norms).
- 2.6.1.4 Describe any aspects of the local culture that may increase the level of risk or increase potential harm for participants or researchers. Describe the steps you will take to minimize these risks.
- 2.6.1.5 Will all individuals be able to read or comprehend English? If not, provide details on how you will manage communication with participants.
- 2.6.1.6 If translated documents or a translator is to be used, provide proof of credentials for the translator.
- 2.6.1.7 Explain how rules of confidentiality and privacy differ from U.S. regulations, and how you will manage subject confidentiality.
- 2.6.1.8 If research is being conducted by a student investigator, explain the PI's involvement, what their role will be, and how they will manage and oversee the research if being conducted at an international site.

2.7 Processing Time

- 2.7.1 IRB approval times can vary for IRB application involving international (transnational) research. There is no set time frame for a project to be approved. It is up to the investigator(s) to ensure they have submitted their application early as some approvals can take months depending on the review level and the permissions and ethics review required from the international site.
- 2.7.2 **Travel plans and airline tickets for investigators traveling to the international site should not be done until permissions and approvals have been obtained.**

REFERENCES

1. US Department of Health and Human Service, Office for Human Research Protections (OHRP)
2. 45 CFR part 46
3. The International Compilation of Human Research Standards
4. The Council of International Organization of Medical Sciences (CIOMS) International Ethical Guidelines for the Biomedical Research Involving Human Subjects

APPENDICES

1. IRB SOPs