| | SOP: Review of International Studies | |
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| TEXAS A&M UNIVERSITY KINGSVILLE | Section III: IRB Protocols | |
| | Number | Date |
| | IRB III-013 | 9/13/2025 |

## 1. PURPOSE

1.1. This SOP outlines the requirements for international (transnational) research involving human participants when the research falls under the auspices of the Texas A&M University-Kingsville (TAMUK) IRB.

## 2. REVISION FROM PREVIOUS VERSIONS

2.1. None

## 3. SOP STATEMENT

3.1. Approval of international research by the TAMUK IRB is permitted following federal regulations “if the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in 45 CFR 46."

3.2. All policies and procedures applied to research conducted domestically should be applied to research conducted in other countries, as appropriate. The TAMUK IRB must receive and review the foreign institution or site’s IRB review by means of meeting minutes, approved protocol descriptions, etc., and approval letters of each project before the commencement of the research at the foreign institution or site.

3.3. For federally funded research, approval of research conducted at foreign institutions or sites that are “engaged” in research is only permitted if the foreign institution or site holds a Federalwide Assurance with OHRP and has obtained local IRB review and approval.

3.3.1. An "engaged" institution is one whose agents (faculty, students, or staff) recruit subjects, obtain consent from subjects, conduct research procedures, or receive or share private, identifiable information. This definition aligns the federal definition of human subjects research. The aforementioned activities require IRB review.

3.3.2. Institutions are not engaged if their employees:

3.3.2.1. Inform prospective subjects about the availability of research.

3.3.2.2. Provide prospective subjects with written information about the research, which may include a copy of the relevant informed consent document, and other IRB-approved materials but do not obtain subjects' consent or present themselves as official representatives of the investigator/s;

3.3.2.3. Provide prospective subjects with investigator’s contact information to allow them to get more information or enquire about enrollment; or

3.3.2.4. Obtain and appropriately document prospective subjects' permission for investigators to contact them.

3.3.2.5. Provide space for U.S. researchers to conduct their own research.

3.3.3. Approval of research for foreign institutions or sites "not engaged" in U.S. research is only permitted if one or more of the following circumstances exist:

3.3.3.1. When the foreign institution or site has an established IRB/IEC, the researcher 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 researcher to conduct the proposed research at the site.

3.3.3.2. 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.

3.3.3.3. 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.

3.3.3.4. It is the responsibility of the TAMUK researcher and the foreign institution or site to ensure that the resources and facilities are appropriate for the nature of the research.

3.3.3.5. It is the responsibility of the TAMUK researcher and the foreign institution or site to confirm the qualifications of the researchers and research staff for conducting research in that country(ies).

3.3.3.6. It is the responsibility of the TAMUK researcher and the foreign institution or site to ensure that the following activities will occur:

3.3.3.6.1. Initial review, continuing review, and review of amendments

3.3.3.6.2. Post-approval monitoring

3.3.3.6.3. Handling of complaints, non-compliance, and unanticipated problems involving risks to participants or others.

## 4. RESPONSIBILITIES

4.1. This SOP is applicable to all Texas A&M University-Kingsville researchers who are involved in preparing, submitting, and conducting human subjects' research internationally (transnationally).

4.2. This SOP is also applicable to all Institutional Review Board members who are involved in record keeping, reviewing, or approving research studies.

## 5. PROCEDURE

5.1. International (transnational) research involving or conducted by TAMUK researchers remains subject to the review and approval authority of the TAMUK IRB and the obligations undertaken by TAMUK in its Federal Wide Assurance on file with the federal Office of Human Research Protections (OHRP).

5.1.1. 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.

5.1.2. When international (transnational) research is conducted, both the TAMUK IRB and the applicable foreign site's IRB/ethics committee, if applicable, must approve the research before the research is initiated.

5.1.2.1. The TAMUK IRB will require an approval letter from foreign site's IRB/ethics committee prior to issuing final approval of the protocol.

5.1.2.2. The Principal Investigator (PI) is responsible for meeting all requirements from both institutions.

5.1.3. International research is also subject to TAMUK Policy 15.02.99.K1 Export Control Program Management. All international protocols must go through export control prior to final IRB approval.

5.2. The IRB will review all international (transnational) research involving human participants to ensure adequate provisions are in place to protect the rights and welfare of the participants.

5.3. The Principal Investigator must make themself familiar with the guidelines of the research country where research will occur. If possible, the TAMUK Principal Investigator should work with a local collaborator in the country where research will be conducted, the host country. Some countries require an ethics committee or the equivalent of a local ethics board to review and approve research involving human subjects.

5.4. Research projects that take place outside the United States require compliance with TAMUK 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.

5.5. International research IRB submissions must comply with TAMUK IRB policies and procedures with the following additional requirements:

5.5.1. Exempt studies

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

5.5.1.2. A memo 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 knowledge or expertise on the local culture. The memo should include the following:

5.5.1.2.1. The date

5.5.1.2.2. The name and title of the author

5.5.1.2.3. The title of the research project

5.5.1.2.4. A brief description of the author's expertise and experience

5.5.1.2.5. A brief description of the research project showing the author's understanding of the protocol

5.5.1.2.6. A statement affirming the appropriateness of the research project and that it is not in conflict of local societal norms

5.5.1.2.7. A signature of the author

5.5.1.3. In addition to the memo, the protocol application should include documentation confirming that the country's regulations do not require any official local ethics review. This may be direct evidence of the applicable local regulations or a letter from the proposed foreign research site, on official letterhead of the organization/institution which states that further ethics review is not required. This document should be authored by

someone independent of the study and research team, but 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.

5.5.2. If the proposed project qualifes as exempt in the US, but requires an ethics review in the foreign country:

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

5.5.2.1.1. The title of the study.

5.5.2.1.2. A statement describing that the proposed research project was deemed to be minimal risk.

5.5.2.1.3. Clearly stated approval to commence study by the local ethics committee.

5.5.2.1.4. The document should be signed and dated.

5.5.2.1.5. The letter should be on the official letterhead of the committee's signatory.

5.6. Expedited and Convened studies:

5.6.1. For expedited and convened studies, a letter of approval by an ethics committee is required from the foreign agency where the research is taking place is required. 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:

5.6.1.1. The title of the research project.

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

5.6.1.3. A signature and date.

5.6.1.4. Letter on the official letterhead of the signatory.

5.7. Site Approval:

5.7.1. 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.

5.8. Age of Consent:

5.8.1. If the legal adult age differs in another country from state law (for example,18 years of age), the IRB will accept the local age of majority when considering who is eligible to provide informed consent.

5.9. Non-English-Speaking Participants:

5.9.1. 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.

5.9.2. 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).

5.9.3. The English and translated documents will both need approval as part of the IRB application.

5.10. Additional IRB Application Contents:

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

5.10.1.1. Is the research being conducted in a country or at a domestic site not subject to US Federal Regulations, e.g. First Nations communities, where the cultural norms and backgrounds are very different to the TAMUK community and surrounding communities?

5.10.1.2. The following information should be included:

5.10.1.2.1. Name of site.

5.10.1.2.2. Name and title of authorized individual who is acting as signatory or authorized representative for the foreign ethics committee.

5.10.1.2.3. Name and information of international site collaborator (as applicable).

5.10.1.2.4. Anticipated number of subjects.

5.10.1.2.5. FWA number of the international site if the project is federally funded.

5.10.1.3. Description of the international sites cultural norms highlighted differences from standard U.S. culture. The age of participants should be included (including rules on age limits for minors if it differs from U.S. norms).

5.10.1.4. Description of any aspects of the local culture that may increase the level of risk or increase potential harm for participants or researchers. Description of the steps that will be taken to minimize these risks.

5.10.1.5. Confirmation that all participants read and understand English; if not, describe how communication will be managed.

5.10.1.6. If translated documents or a translator is to be used, proof of credentials for the translator.

5.10.1.7. Explanation of how rules of confidentiality and privacy differ from U.S. regulations and how subject confidentiality will be managed.

5.10.1.8. If research is being conducted by a student investigator, explanation of the Supervising PI's involvement, what their role will be, and how they will manage and oversee the research if being conducted at an international site.

5.11. Processing Time:

5.11.1. IRB approval times can vary for IRB applications 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(s).

## 6. REFERENCES

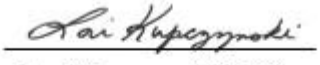
6.1. US Department of Health and Human Service, Office for Human Research Protections (OHRP)

6.2. 45 CFR part 46

6.3. The International Compilation of Human Research Standards

6.4. The Council of International Organization of Medical Sciences (CIOMS) International Ethical Guidelines for the Biomedical Research Involving Human Subjects

6.5. TAMUK Policy 15.02.99.K1 Export Control Program Management

Approved by: 

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