Human Research Protection Program
UNIVERSITY OF GEORGIA

Transnational Research

Number:	Date:	Author:	Approved By:	Page(s):
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1. PURPOSE

1.1. The University of Georgia Human Research Protection Program (HRPP) must ensure that human research conducted outside of the United States meets equivalent level of participant protection as research conducted inside the United States. The purpose of this ***policy*** is to describe the standards and considerations for conduct of international research.

2. DEFINITIONS

2.1. ***Transnational Research*****:** any human subject research activity that is conducted outside of the United States of America (USA) and its territories.

3. POLICY

3.1. The UGA HRPP has the responsibility to ensure that research performed in other countries meets equivalent levels of protections that would be required in the University's principal locations.

3.2. The research conducted in a foreign country is expected to comply with local laws, regulations, codes, and guidance and must take into account the cultural context in which the research will be conducted. This includes but is not limited to compliance with laws concerning privacy, genetic testing, and reporting child, elder, or spousal abuse.

3.3. The research conducted in a foreign country must be conducted in a manner that honors the ***autonomy*** and dignity of all persons as embodied in the Belmont Report.

3.3.1. Recruitment and consent must always be presented and obtained in the language that is understandable to the participants.

3.4. When research involves ***children*** or ***adults*** who have impaired decision making, see *Policy and Procedure: Research with Vulnerable Populations*.

3.5. When appropriate, the research must be approved by the local IRB (or equivalent Ethics Board), local or national official, or a community leader (gatekeeper) before UGA IRB can grant approval.

3.6. The ***researcher*** is responsible for having a study team member or a consultant who has the appropriate expertise and knowledge of the country.

3.6.1. Local collaborators who are ***engaged*** in research activities, must complete appropriate training in human subjects research**.** See *Policy and Procedure: Engagement Determination* and *Policy and Procedure: Investigator Training*.

3.7. The nature, value, and method of incentive/compensation should take into account the context of the local economy, cultural practices, living conditions, and opportunity of earnings. See Policy and Procedure: Participant Incentive and Compensation

3.8. If the research is sponsored by a U.S. federal agency, the regulations of that agency will apply. Providing equivalent protections in lieu of providing the required federal protections is unacceptable.

4. PROCEDURES: Researchers

4.1. The researcher is responsible for indicating that the research will be conducted outside of the USA.

4.2. When appropriate, the researcher is responsible for providing a letter of approval or review from the local IRB or Ethics Committee and/or a ***letter of support*** (***authorization***) from an appropriate local or national official.

4.3. The researcher is responsible for knowing, understanding, and applying all local laws and cultural context of the area and for providing the equivalent protections to human participants in research conducted in foreign countries. More information about international guidelines and equivalent human subjects protections may be found at http://www.hhs.gov/ohrp/international/index.html.

4.3.1. The study team must include someone or involve a consultant who has the appropriate expertise and knowledge of the country.

4.3.2. The researcher must identify all local collaborators and describe the role of each collaborator in the submission form.

4.3.2.1. The researcher must list individuals engaged in research activities as non-UGA collaborators in the Study Team Section of the submission and provide documentation of completion of human subjects training.

4.3.3. If the researcher does not speak the local language, he/she must provide a description in the submission form of how communication with the research subject will be managed.

4.3.4. If the research includes enrollment of children in other countries, the researcher must provide the IRB with sufficient information to verify the age at which participants in such jurisdictions have the ability to consent to participation in research, including any medical treatments or ***procedures*** if applicable.

4.4. The researcher is responsible for maintaining contact with the UGA IRB while abroad especially as this relates to ***modifications, continuing review,*** or handling of complaints, non-compliance, and reporting unanticipated problems involving risk to participants or others.

5. PROCEDURES: Institutional Review Board

5.1. The IRB Staff will make an initial determination whether the proposed research complies with local laws based on knowledge of the foreign country in which the research will be conducted.

5.2. The IRB Staff will assess the submission to ensure that equivalent protections are provided to research participants enrolled in research in international settings.

5.2.1. If necessary, the IRB Staff will assign a ***Subject Matter Reviewer*** or ***Consultant*** to assist with this determination.

5.3. For ***non-committee reviews***, IRB staff will offer the investigator the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence.

5.4. For committee reviews, IRB staff will offer the investigator the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence that describes missing information or required modifications.

5.5. IRB Staff will document information pertaining to determinations that the requirements of this policy have been met in the review history for non-committee reviews and in the meeting minutes by recording the motion to approve for research reviewed by committee.

6. MATERIALS

6.1. None

7. REFERENCES

7.1. Belmont Report, http://www.hhs.gov/ohrp/policy/belmont.html

7.2. International Compilation of Human Research Standards, http://www.hhs.gov/ohrp/international/index.html

7.3. Investigator Manual, Appendix A: Reporting Events and Information to the IRB

7.4. Policy and Procedure: Engagement Determination

7.5. Policy and Procedure: Investigator Training

7.6. Policy and Procedure: Non-Committee Review Preparation and Conduct

7.7. Policy and Procedure: Post-Review and Communication of Review Results

7.8. Policy and Procedure: Pre-Review of IRB Submissions

7.9. Policy and Procedure: Research with Vulnerable Populations

7.10. Policy and Procedure: Participant Incentive and Compensation

Revision History:
08/21/2015: REV0 New Document
07/12/2017: REV1
05/24/2021: REV2 minor revisions to title and to meet AAHRP Standards