1. PURPOSE

This procedure describes the standards and parameters for the review of international research.

2. PROCEDURE

Avera is committed to upholding the standards for ethical research and informed consent expectations for all international research. International research creates areas of concern for both the PI and the IRB. Cultural, economic, or political conditions of the host country may alter the risk for participants compared to the same research conducted domestically. Other countries and institutions within foreign countries may have IRB or Ethics Committees which require review of the research before research can be conducted in that country.

The Avera IRB shall require the PI to provide to the foreign IRB, the local applicable laws, regulations, customs, and practices for the country where the proposed study will occur, along with an outline of how the PI will follow those laws, regulations, customs, and practices. The Avera IRB will require the PI to provide to the IRB evidence of the qualifications of the researchers and the research staff for conducting international research.

All policies and procedures that are applied to research conducted domestically should be applied to international research, as appropriate, even if the governing laws of the other country are less stringent.

3. SPECIFIC PROCEDURES

3.1 Review of Research by the Foreign Ethic Committee

Approval by the foreign local IRB or Ethics committee where the research is taking place prior to Avera approval is optimal. If there is no equivalent board or group, PI must rely on local experts or community leaders to provide insight into local context.

It is important that all research with human subjects adequately protects the rights and welfare of the research participants, irrespective of whether the research is conducted domestically or internationally. In the international setting, special attention should be given to the involvement of local human subjects in the design and conduct of the research to ensure respect for differences in language, education, cultural and social history, and social mores, as well as compliance with local law. In addition, national policies such as the availability of national health insurance, philosophically different legal systems, and social policies distinguish international research from domestic research and must be considered carefully by the PI and the Avera IRB when contemplating conducting and reviewing such research.

3.3 Exempt and Expedited Review

International studies that are minimal risk, do not ask sensitive questions, and fall under the exempt or expedited categories may be reviewed by the Chair or other appropriate IRB member. A consultant familiar with local context may be sought out to provide guidance to the reviewer.

3.4 Institutional Review Board Considerations

In addition to obtaining Avera IRB approval, the PI must seek review of his/her research protocol by a foreign local IRB, Ethics Board or Independent Ethics Committee (IEC) whenever possible. The local IRB, Ethics Board, or IEC must be knowledgeable about and sensitive to local community composition,

mores, laws, and standards of conduct. In the event that no such local IRB, Ethics Board, or IEC exists or when such a local ethics board is unable or unwilling to review the research, the PI must take steps either to identify a review board within the general region or to identify a local institution that can serve in a comparable capacity (e.g., a tribal council, school board, town committee, or hospital board). A copy of the local IRB or IEC approval must be submitted to the Avera IRB. The IRB should have contact information of this organization and work with this committee via e-mail for regular updates. This committee should also be listed in the protocol and the informed consent, if applicable, as an area reference for human subjects to communicate problems and complaints.

If Avera IRB approval is required before the foreign IRB approval can be obtained, the Avera IRB may either:

- Require an expert consultant to address issues of local context; or
- Review the study and make a motion, "Approved, pending review and approval of the foreign IRB." The PI would then be required to submit to the Avera IRB a copy of all correspondence and all approval documents.

The protocol must provide evidence of sufficient local resources and facilities to support the proposed research in compliance with this policy and local law. The PI and the foreign site are responsible for ensuring that the resources and facilities are appropriate for the nature of the research, and are responsible for the ongoing monitoring of the research including the ability to submit the initial review, continuing reviews, amendments, all unanticipated events as well as regular communication with the Avera IRB.

In order to approve a protocol being carried out at a foreign site and to make an informed judgment about the level of risk to potential research participants, the IRB must demonstrate that it has sufficient information about the local research context and local law by its review of written material, or through discussions with either IRB members knowledgeable about the local context or appropriate expert consultants. The level of knowledge about the local context and local law required for approval is based on the degree of risk to potential research participants. Higher risk studies require more thorough considerations of local context and inclusion of strategies to mitigate harm than do minimal risk studies.

Before approval, the IRB will review and determine that equivalent levels of protections are afforded to international or local immigrant research participants that would otherwise be required in the United States. The application and informed consent must include a description of procedures for all participants to be able to contact an appropriate source for handling of complaints, reporting of non-compliance, as well as avenues to report unanticipated problems and risk to participant and others.

3.5 Informed Consent

The informed consent process, as well as the document should be in the human subjects' native language. See SOP 700 Informed Consent.

4. RESPONSIBILITY

Chair, IRB Manager or designee, or IRB members are responsible for the review of international research.

5. APPLICABLE REGULATIONS AND GUIDELINES

Office of Human Research Protections (OHRP) – International Issues

6. REFERENCED DOCUMENTS

None

REVISION HISTORY

Revision Number	Version Date	Approved By	Date Approved
2.0	7/14/2020	Avera Institutional Official	9/22/2020
• Minor administrative updates.			
1.0	August 2016	Director HSRP / August 2016	