INTERNATIONAL RESEARCH

SOP #:	**414**	**VERSION #:**	**1**	**EFFECTIVE DATE:**	**06/01/14**	**SUPERSEDES DOCUMENT:**	**/ /**
THIS POLICY PERTAINS TO:			**ALL RESEARCH CONDUCTED UNDER THE JURISDICTION OF THE IRB**				
RESPONSIBILITY FOR EXECUTING POLICY:			**IRB CHAIRPERSON, IRB VICE CHAIRPERSON, IRB COORDINATOR, IRB MEMBERS**				
LAST REVIEWED ON:		**/ /**		**RESULTS:**	**ORIGINAL**		
APPROVAL AUTHORITY:		**Associate Vice President for Research and Economic Development**					
APPROVED BY:						**DATE:**	**02/25/14**

1. POLICY

The University is committed to upholding the standards for ethical research and informed consent expectations for all research conducted outside the United States. Research conducted outside the U.S. creates areas of concern for both the investigator and the IRB. Cultural, economic, or political conditions of the host country may alter the risk for participants compared to the same research conducted within the U.S. 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 IRB shall require the investigator to provide to the 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 investigator will follow those laws, regulations, customs, and practices. The IRB will require the investigator to provide to the IRB evidence of the qualifications of the researchers and the research staff for conducting research in the country.

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

2. SPECIFIC POLICY

2.1 Review of the Research by the Foreign Ethics Committee

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

It is important that all research with living human beings adequately protects the rights and welfare of the research participants, irrespective of whether the research is conducted in the United States or at foreign sites. In the international setting, special attention should be given to the involvement of local participants 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 U.S. research and must be considered carefully by investigators and the UND IRB when contemplating conducting and reviewing such research

2.2 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 designee. A consultant familiar with local context may be sought out to provide guidance to the reviewer.

2.3 Institutional Review Board Considerations

In addition to obtaining IRB approval, the principal investigator must seek review of his/her human research protocol by a 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 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 as an area reference for participants to communicate problems and complaints.

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

1. Require an expert consultant to address issues of local context.
2. Review the study and make a motion, “Approved, pending review and approval of the foreign IRB.” The investigator will be required to submit to the UND IRB all correspondence and approval documents.

The protocol must provide evidence of sufficient local resources and facilities to support the proposed human subject protocol 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 UND 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.

2.4 Informed Consent

The informed consent process, as well as the document must be in the subjects’ native language. See SOP 701: Informed Consent for more information on the consent process.

3. RESPONSIBILITY

The IRB Chairperson, IRB Vice Chairperson, IRB Coordinator and/or IRB members are responsible for the review of international research.

4. APPLICABLE REGULATIONS AND GUIDELINES

Office of Human Research Protections (OHRP) – International Issues

5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
IRB Chairperson, IRB Vice Chairperson, IRB Coordinator, IRB Members	Determines if local context consultant is needed. Reviews IRB application and all associated documents.