Section 11 Special Research Topics 11.4 International Research	Effective Date: 10/9/2015 Revised:

Human subjects research conducted outside of the United States must conform to the same ethical and regulatory standards to which research conducted in the United States is held, and must conform to applicable local laws and norms of the host country. International human subjects research must be conducted in accordance with applicable NDSU policies for the conduct and review of human research, including those concerning informed consent and participation of vulnerable populations.

1.0 NDSU IRB Review

1.1. The protocol materials submitted to the NDSU IRB for approval must be written in English and must include the following:

1.1.1. The initial protocol application and associated documents (e.g., surveys, questionnaires, study information);

1.1.2. The proposed informed consent document(s) in English.

1.1.3. Once NDSU IRB approval has been granted, a copy of the relevant documents (e.g. recruitment and consent documents, questionnaires, etc.) translated into the appropriate language(s), must be provided to the IRB. Indicate to the IRB, who performed the translation services. Third party verification must be provided certifying the accuracy of the translation.

1.1.4. Appropriate review procedures will be followed as per HRPP Section 7 IRB Review Process.

2.0 IRB or Research Ethics Board Review

In addition to NDSU IRB review and approval, approval of a local IRB or **Research Ethics Board (REB)** may be required by the international site. Documentation of approval by the local IRB, Ethics Board or REB familiar with the local research context or local law must be submitted to the NDSU IRB upon receipt. If local review is not available, and/or not required, include a letter from the Principal Investigator stating that such review is not possible and explaining why.

3.0 Federally funded research

If an international institution or site is considered to be "**engaged**" in research supported by federal funding, the international institution must obtain and maintain compliance with a **FederalWide Assurance (FWA)** from the US Department of Health and Human Services (DHHS). The site also must receive approval for the research from an IRB familiar with the local context and registered with the Office of Human Research Protections of DHHS, or obtain DHHS approval as an equivalent host country entity.

4.0 Investigator Responsibilities

4.1. Local IRB Review

In addition to obtaining NDSU IRB approval, an NDSU Principal Investigator (PI) must seek review of his/her non-exempt human subjects research by a local IRB, Ethics board, or REB whenever possible. The local IRB, Ethics Board, or REB 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 REB exists, or when such a local ethics board is unable or unwilling to review the research, the PI should 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). Research that is particularly complex or presents significant risk to participants may require consultation with NDSU legal counsel to ensure that the rights of participants are appropriately protected, and that the research is conducted in conformance with local law. A copy of the local IRB or REB approval or other approvals must be submitted to the NDSU IRB.

4.2. Informed Consent

The PI and other IRB-approved study personnel must obtain the voluntary informed consent of the prospective participant, or in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative or surrogate in accordance with HRPP Section 9 – Requirements for Informed Consent, and applicable local law.

4.2.1. Additional Considerations for the informed consent process:

4.2.1.1. Consent must be sensitive to local cultural norms including but not limited to: age of consent, disclosure and reporting requirement of illegal activities, and applicable privacy laws.

4.2.1.2. The informed consent discussion and all consent documents must be presented in the language understood by participants.

4.2.1.3. For non-exempt research, if participants are likely to be unable to provide written consent, the investigator must provide justification for a waiver of written consent and propose an acceptable alternative method for obtaining oral consent that is appropriate for both the participants and their culture.

4.2.1.4. Consideration of how complaints will be reported and to whom.

4.3. Unanticipated Problems and Serious Adverse Events

Investigators must promptly report all unanticipated problems and/or serious adverse events to the NDSU IRB and local IRB/REB if applicable. See SOP 7.7 Unanticipated Problems and Serious Adverse Events for more information.

4.4. Export Controls/Embargoed Countries

Export controls are Federal statutes and regulations that govern the transfer of certain goods, technologies, services, data, and money to persons and entities outside the U.S. – as well as to foreign nationals located inside the U.S. In general, these regulations prevent the flow of certain items and information that would compromise U.S. national security and economic interests.

In certain circumstances, NDSU may be required to obtain prior authorization or licensing from the U.S. Government before allowing foreign nationals to participate in research (both on campus and outside of the U.S.); collaborating with a foreign institution; shipping research equipment out of the U.S.; or sharing research results or data with any non-US persons. Additionally, the NDSU research enterprise may be impacted by various trade embargoes, sanctions, international travel prohibitions, and restrictions on the exportation of information and research items to certain entities and persons (including non-US persons located in the U.S.). All of these regulations carry a range of potential penalties for individuals who violate them, including imprisonment and fines of up to $1 million per violation. NDSU is committed to acting in accordance with all applicable U.S. Government export regulations, and it requires ALL faculty, staff, students, researchers, and other University personnel to be aware of, and comply with, U.S. export control laws and regulations, and NDSU's policy and procedures thereto.

Investigators conducting international research should contact NDSU's Export Control Officer before engaging in international projects and activities. More information regarding export control compliance can be found at http://www.ndsu.edu/research/integrity_compliance/export_controls/.

4.5. HIPAA Applicability

HIPAA regulations do not apply to health information obtained and held at international sites; however, researchers must comply with all applicable local privacy laws. If identifiable health information collected at an international site is stored within an NDSU HIPAA-covered component, it becomes subject to HIPAA regulation.

4.6. Change in Research Activity

Changes in approved research require prior IRB review and approval, except where necessary to eliminate apparent immediate hazard to participants. Changes requiring prospective review and approval include, but are not limited to, changes in: investigator(s) or research team members, participant populations, inclusion or exclusion criteria, recruitment processes, informed consent processes, research interventions, compensation procedures, survey/interview questions, and/or confidentiality procedures.

5.0 IRB Responsibilities

5.1. IRB Review of Research

The IRB will conduct a review of the proposed research using the appropriate review process outlined in Section 7 – IRB Review Process. Where applicable, the IRB will confirm that the PI has a plan to obtain and submit documentation of local IRB/REB approval and current host institution FWA approval prior to initiating any research at the international site. The IRB will address procedures for participants to report concerns and complaints on a case-by-case basis.

5.2. Knowledge of Local Research Context

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 NDSU 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 of 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 or exempt research studies.

5.3. Informed Consent Process

The NDSU IRB will review the consent process, paying special consideration to maintaining sensitivity to local cultural norms and applicable law, including issues such as the following: disclosure of scientific and/or medical facts to individuals who may be unfamiliar with and distrustful of the concepts to be studied; differences in cultural and societal norms; differences in the role of women in society; differences in the role of family and community in the consent process; multiple local languages; and literacy level.

6.0 Special Situations and Exceptions

As an educational institution, the mission of the University includes the creation, preservation, and dissemination of knowledge. As such, there may be instances where compliance with local law would be contrary to research in furtherance of the University's mission. An exception to the requirement to comply with all local laws may be approved by the full convened IRB on a case by case basis. Review of such projects include consultation with the Institutional Official and the Assistant Attorney General assigned to the institution.

REFERENCES:

Office for Human Research Protection (OHRP), International,
http://www.hhs.gov/ohrp/international/index.html

International Compilation of Human Research Protections 2015 Edition, Compiled by: Office for Human Research Protections, DHHS
http://www.hhs.gov/ohrp/international/index.html

RELATED HRPP SECTIONS AND STANDARD OPERATING PROCEDURES:

Section 7 – IRB Review Process
Section 9 – Requirements for Informed Consent

DEFINITIONS:

FederalWide Assurance (FWA): A formal written, binding agreement required under 45 CFR §46.103 in which an institution assures DHHS that it will comply with applicable U.S. federal regulations governing research with human participants as well as the terms of the assurance.

Engagement in Research: An individual is considered engaged in human research when he/she for the purposes of the non-exempt research project, obtains: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. An institution is considered engaged when its employees or agents conduct the above activities, or when the institution receives a direct federal award to conduct human subject research, even when all activities involving human subjects are carried out by a subcontractor.

Research Ethics Board (REB): A specially constituted review body whose responsibility is to ensure the protection of the rights, welfare and safety of research participants. An REB shares the same general composition and operations as an Institutional Review Board.

Local Research Context: Knowledge of the non-U.S. institution(s), local cultural norms, community environment, and applicable law in which human research will be conducted.