Section 12: International Research

12.1 General Researcher Considerations
It is a relatively common occurrence that University researchers will perform human subjects research outside the borders of the United States. When performing human subjects research in foreign countries, expectations of the University are that the research activities are consistent with the ethical principles set forth in the University Human Research Protection Plan (HRPP) and provide levels of subject protections equivalent to those provided when performing human subjects research at the University. It is also expected that researchers will comply with applicable national and local laws and take into account the cultural context of the country in which the research is taking place. For additional information review Guidance on International Research.

When performing human subjects research in other countries, University researchers are expected to comply with U.S. regulations and guidelines and any applicable regulations of the country in which the research is performed. In addition, for biomedical research there are international guidelines that may be applicable and with which the University researchers should be familiar; e.g., The Declaration of Helsinki, the International Conference of Harmonization – Good Clinical Practice (E6) Guidelines and the International Ethical Guidelines for Biomedical Research Involving Human Subjects published by the Council for International Organizations for Medical Sciences.

Special Note: If you are or will be conducting research outside of the United States, please be aware that DU currently has an international travel policy that involves approval for student/faculty/staff travel to areas of high risk. Please refer to the official DU Travel Policy to Restricted Regions for more details, and to see whether your travel requires review.
Research in international settings may pose special or unusual risks to participants, and PI's should articulate the cultural, political, economic and/or legal context of the research and how this may create or affect ethical considerations of a research project or research design. For example, the use of Randomized Control Trials in developing-world settings has generated considerable debate over appropriate uses of these methods in various contexts, particularly in areas of extreme poverty.

12.2 Specific Principal Investigator Considerations
Federal regulations for oversight of international research require that when conducting international research the researcher:

1. Will provide the same or equivalent protections to human subjects in research conducted in other countries.
   a. The protections need not be the same as provided in the U.S. but should be equal in function or effect.
   b. Subject autonomy and dignity should be respected.
   c. Protections should encompass the ethical principles of respect for person, beneficence, and justice.

2. Is aware of local laws, regulations, political and socio-economic factors, and cultural context in all locations where the research is conducted.
   a. Researchers must have sufficient knowledge of the local context to enable carrying out of the research in ways that protect the rights and welfare of subjects.
   b. Knowledge of the local context may influence all aspects of the research design.

3. Will comply with local laws and adhere to cultural norms.

4. Will demonstrate whether the university or researcher has permission to conduct research in the country by local ethics committee review and approval or by certification (approval) by the local government when there is no local ethics committee.

Post-approval monitoring of international research will follow the same procedures used for monitoring of locally conducted research as described in Section 3.18. Due to budget constraints, monitoring will usually consist of a face-to-face meeting with the investigator to discuss the conduct of the research.

12.3 General Reviewer Considerations
There are also requirements and expectations for reviewing proposed international research. Generally:

1. IRBs or Ethics Committees (ECs) must ensure that equivalent protections are provided to research subjects enrolled in research in another country, and;

2. IRBs and ECs will make determinations and decisions based on laws and knowledge of the country in which the research will be conducted, such as:
   a. If there are laws or guidance related to human research subject protections.
   b. If there are other laws that will need to be factored into the research.
   c. If the local or government has their own required approvals.
Reviewers should review the U.S. Department of Health & Human Services 
International Compilation of Human Subjects Protections for more information on 
making these determinations.

12.4 Specific Principal Investigator and Reviewer Considerations

More specifically, IRB reviewers and the IRB will require certain information in order to 
fulfill the requirements and this information should be addressed in the submitted 
protocol. For example, the information provided should include but not be limited to:

1. Whether the researcher speaks the language of the country in which participants 
will be enrolled and the research will be conducted. If the researcher does not 
speak the local language, describe how communication with the research 
subjects will be accomplished.

2. Whether the researcher is familiar with the local customs and culture or whether 
a local collaborator will be used and the involvement of the local collaborator will 
have in the conduct of the research.

3. Whether the subjects will be paid and, if paid, the amount and how it relates to 
the local economy and subject income.

4. If consent will be obtained, how or from whom will consent be obtained along 
with the following information, if applicable:
   a. Describe local customs/culture in which the subject might not have the 
      autonomy to provide consent and a family member or other person will be 
      providing consent to participate.
   b. How the researcher will assure that there is no coercion for participation if 
      a person other than the subject will be providing consent.

5. If written documentation of consent will be obtained, and:
   a. If so, a description of how or from whom the consent will be translated.
   b. If not, a description of how consent will be documented or if there are 
      cultural/other prohibitions regarding use of consent forms.

6. Describe how the privacy for the subjects and confidentiality of their research 
data will be assured and if there is a local custom that research data be revealed 
to someone other than the subject.

7. Describe how the communications with the University IRB/local EC will be 
achieved for requesting amendments or reporting unanticipated problems.

8. For student researchers, a description how the academic advisor/faculty sponsor 
will oversee conduct of the research.

12.5 Exemptions

1. A great deal of research in the social and behavioral sciences may pose no more 
than minimal risk to subjects and may qualify for exemption. However, 
conducting research in another country does not necessarily exclude the 
research from IRB review.

2. There may be other factors, specific to the locale that would disqualify the 
research from exemption such as recruiting vulnerable populations (i.e. 
undocumented individuals or marginalized identity groups (refugees)).

3. Even in exempt research, informed consent, parental permission, and child 
assent may be ethically appropriate and/or required under local law.

4. Evaluating whether an international project would qualify under exempt status will
be dependent of whether the research qualifies under one of the exemption categories.

12.6 Risk Assessment
The IRB must assure, perhaps through consultation with experts, that the risk assessment is accurate for the foreign site. Research methods that have minimal risk in the U.S. might have greater than minimal risk when conducted at certain foreign sites.

The following must be given consideration:
1. Questions that might be innocuous in the U.S. could be offensive at certain foreign sites.
2. Assuring and maintaining confidentiality may be difficult in other countries.
3. Breach of confidentiality in the research locale could have dangerous consequences.
4. Depending on political and other factors, there may be dangers to the researcher.

12.7 Informed Consent
1. The informed consent process must honor local custom.
   a. Some cultures may have a different authority structure for consent.
   b. The local consent structure may seem coercive and clash with the researcher's, reviewer's, or IRB/EC's views on autonomy.
2. Surrogate consent/permission should not substitute for a subject's informed consent unless the IRB/EC has approved an alteration or waiver to the consent process. A standard practice is to provide a research information sheet with all the related consent information if a waiver of documentation is approved by the IRB.
3. The consent process/form should, unless waived by the IRB/EC, contain all required elements of informed consent. The consent process should also make clear the conditions under which research may have direct benefits to a participant or to be clear that there are no real or implied benefits as a result of participation in the research.
4. Consent is best obtained using the language that is most familiar to the subjects taking into account:
   a. Some languages/dialects are not written.
   b. Subjects may be unable to read.
   c. There may be words in the foreign language that do not translate to/from English.
   d. If researchers are not fluent in the local language, interpreters/translators who are fluent should be used.
5. Documentation of consent may be difficult because:
   a. Subjects may be illiterate.
   b. In some cultures, it may be inappropriate to ask for a signature.
   c. There may be legal implications when signing documents.
   d. Subjects may be suspicious, distrustful, or fearful they are giving up their rights when asked to sign documents.
6. Alternate consent procedures may have to be considered such as:
   a. Use of pictures, video, or computers.
   b. Alternate forms of documentation such as thumbprints.

12.8 International Research Involving Children
The following should be considered when the research involves children:
   1. In the locale of the research, when a child is considered an adult.
   2. The relationship between parents and their children in the specific country.
   3. Acceptable and effective parental permission processes.
   4. If child assent is acceptable/permitible by local custom.
   5. If there are laws pertaining to orphans.

12.9 Communication with IRB/Ethics Committee and Faculty Sponsor
With the research occurring outside of the country there should be consideration on how
the communication between the researcher and the University will take place. The
protocol should describe the following:
   1. How communication will occur with the University IRB and the local EC.
   2. How ongoing review, amendments, or reporting of unanticipated problems or
      complaints will be handled and by whom.
   3. If it is a student researcher abroad, the student's knowledge of the country and
      how the student will communicate with their faculty advisor.
   4. List local contact in case Principal Investigator or faculty sponsor cannot be
      reached.