APPENDIX G

INTERNATIONAL RESEARCH

Complete this form if the proposed research will be conducted outside of the United States. Complete a separate form for each country to which the PI or members of the research team will travel to conduct research described in the IRB application.

SECTION A: LOCATION OF RESEARCH

A.1
In what country, regions, cities or localities will the research be conducted?
Click here to enter text.

A.2
Describe the economic status of the country/community.
Click here to enter text.

A.3
Describe the current events or socio-political environment in the country and how that may impact research conduct or alter risks or benefits to the subjects.
Click here to enter text.

A.4
How does research in this setting relate to the overall research project and what factors were considered in selecting the national or local level in this country?
Click here to enter text.

SECTION B: INTERNATIONAL RESEARCH CONDUCTED BY/OR INCLUDING STUDENT AND LOCAL INVESTIGATORS

B.1
Provide scientific/ethical justification for conducting the research in an international setting.
Click here to enter text.
B.2

Who is conducting this international research?

☐ Faculty or Staff Investigator
☐ Student Investigator

If student investigator, describe how the Faculty Sponsor will ensure that adequate oversight of the project occurs.

Click here to enter text.

B.3

What specific risks could potentially occur for the investigator in the host country while conducting this research? What safeguards have been put in place to reduce potential risks?

Click here to enter text.

B.4

If individuals from the host country will be involved in recruiting and will assist in conducting the research, what specific risks could occur to them for their participation in this research? What safeguards have been put in place to reduce potential risks for these individuals?

Click here to enter text.

SECTION C: COMMUNICATING WITH RESEARCH SUBJECTS

C.1

What is the primary language(s)/dialect(s) of the targeted population for this research?

Click here to enter text.

C.2

Is the researcher fluent in the primary language/dialect?

☐ Yes

If yes, complete Appendix K: Certificate of Translation and attach the form to your IRB application in IRBNet and PROCEED TO SECTION D.

☐ No

If no, explain how the researcher will communicate with the subject population and COMPLETE THE SECTION C ITEMS BELOW.

Click here to enter text.
C.3
If the researcher is not fluent in the primary language/dialect, what steps will be taken to minimize how an interpretation may affect the subjects’ comprehension and increase the risks of the research?
Click here to enter text.

C.4
If a translator will be used, identify how the translator will be involved in the research: (select all that apply)

☐ Used as an interpreter during meetings with community leaders, etc.
☐ Translate consent documents (written consents, verbal consents, etc.) from English to the language/dialect of the participating subjects.
☐ Translate study documents (interview questions, focus group questions, survey documents, etc.) from English to the language/dialect of the targeted population(s)
☐ Translate recruitment documents from English to the language/dialect of the targeted population(s) (scripts, recruitment flyers, etc.)
☐ Used as an interpreter during the consent process and during any study intervention/interaction with subjects (interviews, focus groups, etc.)

If a translator/interpreter will be used, complete Appendix K: Certificate of Translation and attach the form to your IRB application in IRBNet.

NOTE: All translated documents must be submitted to the DU IRB from review and approval PRIOR to use with human subjects. The translated documents must be provided in English and in the language/dialect of the targeted population.

C.5
Explain the process for utilizing an interpreter to ensure communication with the subject population is properly conducted during the recruitment, consent and/or study interventions stages and the subject’s ongoing understanding of the proposed research and their ability to withdraw from the study.
Click here to enter text.

C.6
Based on the literacy rate of the potential subject population in the proposed location, what accommodations/measures will be implemented to ensure the potential subjects understand the proposed research procedures and that their participation is voluntary?
Click here to enter text.
SECTION D: INFORMED CONSENT PROCESS

Researchers are expected to adhere to the federal requirements for consent, whether the research is conducted in the US or internationally. The DU IRB may approve modifications to consent requirements if the procedures provide equivalent protection to research subjects and are approved by the local oversight body.

Any information presented to subjects during the course of the study must be submitted to the DU IRB for review and approval; the local review body (i.e., IRB/Ethics Committee) may also require review and approval of this information. This includes, but is not limited to recruitment materials, consent documents, educational or instructional materials, hand-outs, presentations, scripts, interview questions, etc.

D.1
If a request is submitted for a waiver of written consent for research in which written consent is typically required or a complete waiver of informed consent is requested, **provide justification for the request and describe how consent will be administered and documented in this international setting.** Examples may include low literacy levels within the population, the cultural significance of providing signatures, or providing a copy of the consent that may questioned by others, etc.

Click here to enter text.

D.2
**What steps or procedures will be implemented to confirm the subject’s comprehension on what they are being asked to do?** If using an interpreter, how will comprehension be confirmed?

Click here to enter text.

D.3
**If minors will be enrolled in research, provide the legal age of majority and describe an appropriate assent process for the local context.**

Click here to enter text.

D.4
**Consider the potential role of family and community during the consent process or issues related to autonomy (e.g., consent from community leaders or supplemental consent from male family members). Describe how the research team will address additional consent processes, if they need to occur.**

Click here to enter text.
D.5
If women and/or children will be recruited for this research project, are there any potential restrictions regarding their autonomy and legal capacity to make decisions about their willingness to consent or participate in any research interventions? Please explain any potential situations where this might occur.
Click here to enter text.

D.6
Will the proposed research intersect with any cultural sensitivities or societal norms? If so, describe how this will be addressed in the consent process and forms and other study documents.
Click here to enter text.

D.7
The researcher must provide subjects with locally-based and US-based contact information. Researchers should select contact information (i.e., email and/or phone) that will ensure subjects have access to individuals who can answer research-related questions in their native language/dialect, even after the researcher(s) has left the host country.

- Provide the locally-based information: Click here to enter text.
- Provide the US-based contact information: Click here to enter text.

D.8
Detail any proposed remuneration (payment, gifts, incentives, etc.) for subjects.
Click here to enter text.

SECTION E: LOCATION SPECIFIC AND CULTURAL CONSIDERATIONS

E.1
Describe the researcher’s qualifications to conduct research at the host site. Include any past experience, relevant training and/or coursework that explains his/her ability to conduct this research in accordance with local laws, culture and customs, while remaining in compliance with U.S. regulations governing the ethical conduct of research.
Click here to enter text.
E.2
What procedures are to be in place in the event the research yields information that would be reported to authorities in similar research in the US? (e.g., child abuse, imminent violence, etc.)

Click here to enter text.

E.3
Describe how the researcher will obtain culturally appropriate access to this community. Please provide information on the involvement of any organizations, community leaders, or experts in engaging the subject population or conducting the research. Please provide the appropriate contact names and their relationship to the community. If appropriate, please provide a letter of support from the aforementioned individual(s)/organization(s)/etc. in your IRBNet package.

Click here to enter text.

E.4
Describe the ways in which cultural norms and/or local laws differ between the host site and the United States. Consider the differences in consent procedures, age of majority, autonomy of individuals, group consent, and/or parental consent. Guidance on this topic is found at: www.hhs.gov/ohrp/international

Click here to enter text.

SECTION F: ADDITIONAL AND ONGOING RESEARCH OVERSIGHT

F.1
In most instances, an ethics committee or other regulatory entity in the host country must review and approve proposed research projects. If required, has a research permit been obtained? Please provide the contact information for the committee or entity reviewing this project.

Click here to enter text.

References:
2019 Edition of International Compilation of Human Research Standards – a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in over 100 countries and several international organizations.
Listing of 27 Social-Behavioral Research Standards – a reference to laws, guidelines, and regulations applicable to social-behavioral research around the world.

F.2
Describe how research data will be protected or what measures will be taken to ensure confidentiality of the data at all stages: while you are collecting in the host country, while you are traveling back to the US, and once you arrive back at DU.

Click here to enter text.
Institutional Review Board (IRB)

For research conducted in Europe, reference *Compilation of European General Data Protection Regulations (GDPR) Guidances*

**F.3**

Customs officials in any country, including the U.S., may inspect your belongings, including electronic content of computers, phones, tablets, and storage devices. They may take possession of these items for various periods of time – even permanently. It is a best practice to only take items with you that are absolutely needed for your trip.

Some countries also have import regulations that specifically prohibit travelers from bringing into those countries encrypted laptops or other mobile devices. Violations of those countries’ prohibitions could result in confiscation of your device by customs authorities and/or fines or other penalties.

Please select any of the following items that you will take when you travel:

- [ ] Devices, systems or software that are NOT standard, off-the-shelf products generally available to the public
- [ ] Devices, systems or software that are specifically designed or modified for military or space applications
- [ ] Data or information received under an obligation of confidentiality
- [ ] Data or analyses that result from a project that has restrictions on the dissemination of the research results
- [ ] Classified information
- [ ] Export controlled information

Contact the DU Export Control Office if you selected any of the items listed above.

**F.4**

Are there any foreseeable issues that will impede the researcher’s ability to communicate with the IRB if the project requires changes or if there are reportable events?

- [ ] Yes
- [ ] No

If yes, provide an explanation below and address how the researcher will address and/or mitigate this/these barrier(s).

Click here to enter text.
SECTION G: TRAINING

G.1
Have all research team members, including the Principal Investigator, completed the “International Research” module in the Collaborative Institutional Training Initiative (CITI) Program?

☐ Yes
☐ No

If no, please go to: citiprogram.org to complete the required training on international research.

SECTION H: TRAVEL APPROVAL

H.1
Has the investigator registered their international travel in DU Passport and obtained authorization from Enterprise Risk Management?

☐ Yes
☐ No

If “YES”, attach a copy of the authorization email issued by Enterprise Risk Management to your IRBNet package.

If “NO”, register your international travels through DU Passport on the Enterprise Risk Management webpage. Once approved, attach a copy of the authorization email confirming approval from Enterprise Risk Management.