October 2, 2023

Columbia University Institutional Review Board

Guidance for International Research: Information and documents to be provided for IRB review

When research is conducted outside of the United States (U.S.), investigators must comply with both the U.S. regulations for the protection of human subjects in research and local policies and regulations governing the international research sites.

In order for the IRB to satisfy regulatory IRB review criteria, i.e., determine the risk level and appropriateness of the study with respect to local laws or regulations, and the cultural, social and political context, the IRB requires information about these 'local context' factors, with documentation of such by an appropriate authority.

1) **IRB knowledge of local context**
   Investigators may inform the IRB of local context as follows:

   - Provide the local IRB/Ethics committee (hereafter, "local IRB") approval if required for the site and if available at the time of submission of the protocol to the IRB.

     Some countries specifically require local IRB review or approval from a government agency and have their own policies on human subjects research. Consult the OHRP International Compilation of Human Research Protections that is maintained by the Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services.

     Consultation with the local IRB during the initial planning stages of the research is highly recommended.

     The CU IRB can approve the research before local IRB review, but research activities should not begin until all required approvals are obtained and submitted, and are acknowledged by the CU IRB. This stipulation will be included in the CU IRB determination letter.

     A letter of approval from the local IRB should be on the official letterhead of the signatory and provide, at a minimum, the title of the study displayed in the Rascal application and a statement that the planned research was reviewed and approved. If the original letter is in a language other than English, a translated version is required, with a certification of translation. Please refer to the Enrollment of Non-English speaking Subjects in Research policy for information on appropriate certifications.
   - The following options may supplement the letter of approval from the local IRB, if local IRB review is required, or may serve as the sole justification for conduct of the study in the proposed international location if local IRB review is not required.
     - Provide written input from an individual with expert knowledge of the local context. This "local expert" must be experienced and knowledgeable about the local laws, regulations and customs in the country/region in which the study is

conducted and in the field of research. The local expert should generally be someone who is unaffiliated with the research.
- Provide context of cultural, social and political norms and differences from U.S. culture with respect to research autonomy, consent, recruitment, etc. Include an explanation of the cultural sensitivities that will need to be considered and addressed to conduct this study, i.e., consider relevant historical and current events, attaching additional documentation if necessary.

2) Investigator knowledge/experience of study locale

The IRB submission should provide information about the knowledge and experience of the investigator(s) who are conducting research activities in the proposed locale by addressing the items below, as relevant:

- Describe the knowledge and/or experience the investigator(s) possess(es) regarding the language and culture.
  - Does the investigator have knowledge of local community attitudes to address cultural norms while remaining in compliance with U.S. and foreign regulations for research?
  - Does the investigator speak/read/write the language of the potential subjects?
- Provide a statement addressing the appropriateness of the research methods and the adequacy of the procedures to protect the privacy of subjects and confidentiality of the data, especially if the information to be collected is sensitive in nature. Safeguards for protection of data in transit, e.g., from the research site to CU, should be included. Collection and storage of Sensitive Data must comply with CU Information Technology Data Security policies.
- Provide a plan to manage communications with participants during all phases of study participation, beyond the consent process and data collection. The plan should be consistent with requirements and recommendations in the IRB Enrollment of Non-English-speaking Subjects in Research policy.
- Describe how the safety of participants will be safeguarded, particularly if the topic of the research is culturally sensitive.
- Identify any local/unaffiliated individuals, if any, who will participate in conducting the research, and describe their roles and IRB coverage.

3) Sanctioned Countries/other CU review (if applicable to research):

The list of sanctioned countries and/or other restrictions under U.S. law are available at: Economic Sanctions and Restricted Parties | Columbia | Research

HRPO staff will inform the CU Office of Research Compliance & Training (ORCT) if research is proposed to be performed in a sanctioned country. ORCT staff may provide clearance for research to proceed or may refer the project to the International Research Committee (IRC) for review; such review is conducted independently of the IRB review but the IRC may provide recommendations that affect study conduct. ORCT or IRC recommendations or requirements that impact the study conduct will be communicated to the investigator and need to be submitted to and reviewed by the IRB before implementation.

Review by the IRC will also be initiated if the project meets criteria specified in the Risk Management Procedures available at: https://research.columbia.edu/international-research

Additional considerations:

- A site permission letter, from an authorized individual or authority confirming that the research project/activities can be performed in the proposed location, may be required.
- If documents that will be used with research subjects (e.g., recruitment materials, consent documents, etc.) at the international site were approved by the local IRB in the local language, English versions are required.
- If non-English speaking subjects will be enrolled, English language materials approved by the CU IRB and/or local IRB should be translated, and the translated documents submitted to the CU IRB via a modification.
- If the laws and regulations of the foreign country permit research participants to receive monetary compensation for their participation, the IRB application should describe the planned amount of compensation in both U.S. and foreign currency. To prevent undue influence from inappropriately high levels of compensation, information regarding the average daily wage in the country must also be provided.
- Investigators may also be asked to obtain permission from community leaders, especially if the local culture requires community leaders' approval.
- Studies enrolling research subjects located in the European Economic Area (EEA) will need to consider the EU General Data Protection Regulation (GDPR). Please consult the Compilation of the EU General Data Protection Regulation available on the OHRP website, and the GDPR Guidelines for Human Subjects Research Studies available on the CU HRPO/IRB website.