Oversight of International Collaborators

The WU IRB recognizes that the conduct of international research may involve collaborations with individuals in country. In general, the WU IRB will not assume IRB oversight for these individuals. However, if certain criteria are met, the WU IRB will not require that these individuals obtain a separate IRB approval for their research activities. While separate IRB oversight will not be required, there is an expectation that these individuals will conduct the research in compliance with all regulatory requirements and ethical principles.

The following criteria must be met:

1. The country in which the research will be conducted does not have a requirement for IRB review. See OHRP International Compilation of Human Research Standards for information about IRB review requirements.

2. The study falls under one or more exempt categories outlined in the federal regulations or is non-exempt and falls under one or more expedited review categories listed on the Office for Human Research Protections (OHRP) website.

3. If the study is funded by the US federal government, the human subjects research activity must fall under one or more of the exempt categories.

4. The PI has experience conducting research in the country where the research takes place or experience with the participant population.
    a. With the exception of PhD students, students are not allowed to serve as the PI, for the purpose of this guidance.
    b. If the PI is a PhD student, the experience of the faculty sponsor may be taken into consideration.
    c. It is not necessary for the faculty sponsor to be in the country with the PhD student; however if the Faculty Sponsor will not be in the country with the student, there must be a plan in place to ensure the student receives the appropriate support and guidance on their research project. This plan is developed between the faculty sponsor and the student.

5. The PI must have a physical presence in the country while the international collaborator conducts the research unless:
    a. The international collaborator's involvement is limited to the analysis of identifiable, private information; or
    b. The study occurs all on-line with no physical interaction with participants.

The following exceptions apply:

a. There may be circumstances where the start of the research needs to occur before the PI arrives in country. The plan for oversight, described in Section 6, should include a sequence of events for the research and describe what research activities will occur before the PI arrives in country and how oversight will be maintained. NOTE: Consent and data collection cannot commence until the PI is in country. The international collaborators must be trained on any research activity that will occur before the arrival of the PI.
b. If the PI leaves the country prior to the completion of the research, the details of this arrangement should be described in the oversight plan described in Section 6. This description should include the circumstances under which the PI will leave the country and how oversight of the international collaborators will be maintained.
c. Allowing another WU study team member to serve as a substitute for a PI's presence in country will be decided on a case by case basis and should be proposed in the IRB application. This individual should serve in a leadership role for the study, such as a Co-PI or MPI, and have the appropriate experience, as described in section 3 of this document.

6. The PI agrees to assume responsibility for the international collaborator's involvement in the research study.

7. The PI has a plan for oversight which includes the following components:
   a. A description of the collaborators and their role in the research.
   b. Training that covers the:
      i. ethical conduct of human subject research;
      ii. purpose of the study, how it will be conducted and the international collaborator(s) specific responsibilities; and
      iii. recruitment and consent process.
   c. Monitoring to ensure the research conducted by the international collaborators is consistent with IRB approval, including an evaluation of consent processes and consent documentation for individuals that have been enrolled in the study.
   d. A timeline and sequence of events for the research project that includes what research, if any, will be initiated prior to the PI being in country and any research that will continue after the PI leaves the country.
   e. Managing oversight of the international collaborators if the research will commence prior to the PI being in country. The plan must describe what research will occur prior to the PI's arrival.
   f. Managing oversight of the international collaborators if the PI does not remain in country for the duration of the research. The plan must describe under what circumstances the PI will leave the country while research is still being conducted and how oversight will be maintained.

g. A plan for communication between the PI and international collaborator(s) to ensure the study is conducted in accordance with IRB approval.
h. How protected health information or other data between in country and WU investigators will be transmitted securely.
i. Documentation that the international collaborators have been trained.

8. The Dean or Department Head attests that the PI and faculty sponsor, as applicable, possess the necessary experience and the oversight plan is appropriate.

9. The study will not be performed in a restricted country as designated by the U.S. Department of the Treasury or other U.S. agency. Studies proposed to be performed in a country that has been identified as a country of concern by a federal funding agency or poses other safety or security concerns will be addressed on a case by cases basis.
10. PI and their Dean or Department head sign the Assurance - IRB oversight of international collaborators 04.03.2022.docx and upload it to the assurance document attachment section of the study.

If the above criteria are not met, IRB approval for the international collaborators involvement in the study is required. The WU IRB will not serve in this role. For more information, please contact your HRPO international research partners.