

International Human Subjects Research Checklist for Students

Visit the [IRB website](#) for additional information. Use the Human Subjects Research drop down menu to find specific subtopics.

Following are the steps you should take to ensure that your human subjects research project is successfully approved by the Institutional Review Board (IRB) *before* traveling abroad:

- This year it is especially important that you keep up-to-date on COVID-19 restrictions that could affect your travel and your destination(s). We recommend that you include multiple scenarios in your project planning. For example, in Plan A, you travel abroad and conduct in-person interviews; Plan B reflects a shift to virtual or phone interviews if additional restrictions are enacted during your stay.
- Establish contact with someone who knows the local research context of your destination. Ideally, this will be someone in the country with whom you will be working. If that is not possible, it could be someone here who has expert knowledge of the research setting and culture. Communicate with your contact to find out if approvals to conduct research are required in the country and/or specific location (e.g. schools, hospitals) where you will be working.
- Personal data collected in, or transferred from, the European Union is subject to the General Data Protection Regulation (GDPR). The United Kingdom has its own version of the law, the UK-GDPR. The WFU HRPP will help you comply. EU-GDPR Portal: https://ec.europa.eu/commission/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules_en
- A WFU faculty member must be the Principal Investigator (PI) for your eIRB application. Ideally, someone who is an experienced and qualified human subjects researcher with some knowledge of the country, culture, and type of research will be willing to serve in this capacity. The PI must have the necessary certification (CITI) and an eIRB account (see below).
- Complete the required human subjects protection training (<http://www.citiprogram.org>). This is an online, self-paced tutorial which takes between 4 and 6 hours to complete. Register with WFU as your affiliation, choose the *Human Subjects Research Basic Course* that applies to your type of research activities (Social-behavioral, Educational or Biomedical) and complete the required modules and the International Research-SBR module as an elective. You must score 80% to pass.
- WFU uses an electronic application process called eIRB; you will need an account to access the system. Once you successfully complete CITI, click [here](#) to access the eIRB account request form (Google Drive). Complete the form and submit. Allow 1 business day for the account request to process.
- Log in to [eIRB](#) to access the application.

- The eIRB system will communicate with you and the PI via your WFU Gmail accounts—check it often. The PI must submit the application; you as the Student Co-PI cannot perform this step. Once submitted, the system will prompt you to “agree to participate”; the application cannot be approved until you do so.
- Once submitted, the application comes to the administrator for review. They will return the application to you with “concerns” that you will address and then return the application to them. If all concerns were adequately addressed, they will send it to a Board reviewer* for review. The Board reviewer may have additional “concerns” which you will address and then return the application.

This part is like tennis—when the application is in your court, the IRB cannot interact with it and when you return it to the IRB court; you cannot make any revisions until it is sent back to you. This is also where progress can be brought to a screeching halt, often because concerns were not adequately addressed. Do your best to address every concern with strict attention to detail. Be consistent throughout the application and proofread carefully. If you don’t understand a concern, contact the administrator. Every time your application is returned it goes to the end of the queue. Board reviewers do their utmost to perform their reviews in a timely manner; however, they are faculty volunteers who have a full-time day job.

After the initial submission, the Student Co-PI can address concerns and re-submit the application; however, the Faculty PI must remain involved in advising and assisting the SCPI regarding application as needed to craft a research project with sound methods and a scope of work that does not exceed the capabilities of the student researcher.

Once all concerns are adequately addressed, all study team members will receive an electronic notification that the research is approved. If your study uses an informed consent document, access the approved watermarked version from the study workspace > Attachments tab. Links to other approved documents (recruiting materials, measures, optional supporting documents) are in this tab as well.

*Research that is determined to be “greater than minimal risk” for the subjects must be reviewed by the full board at the IRB’s regular monthly meeting; it is not feasible for undergraduate international research.

- Be advised that, by regulation, any changes to your research must be reviewed and approved via the amendment process. Because it is unlikely that you will be able to navigate the amendment process while abroad, your project **must** be conducted **as approved**. If you find it is not possible to do so, your independent study will have to proceed without the human subjects research component. Performing human subjects research without IRB approval is not an option.
- Take copies of your IRB approval letter, approved measures and watermarked informed consent document (if applicable) with you if access to printers is questionable.
- Have a wonderfully enriching research experience while abroad! Remember to request study closure and complete the final report when your research study is completed.