Human Subjects Research eIRB Checklist—for Students

eIRB is Wake Forest University's web-based IRB application submission, review, and approval system.

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 help ensure that your eIRB application is successfully approved in a timely manner:

☐ 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 population 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 an elective module that pertains to your application or research interests. You must score 80% to pass.

☐ Once you successfully complete CITI, click here to access the eIRB account request form (Google Drive). Complete the form and submit. You will receive an email from our office when your account is active. 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 via your WFU Gmail account—check it often and ensure that the messages are not being sent to spam. The PI must submit the application; Student Co-PIs cannot perform this step. Once submitted, the system will prompt the study team members to "agree to participate"; the application cannot progress until they do so.

☐ Once submitted, the application comes to the administrator who reviews the application. they will return the application to you with "concerns" which 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, 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.

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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" must be reviewed by the full board at the IRB's regular monthly meeting; it is not feasible for student projects.

☐ Be advised that, by regulation, any changes to your approved research must be reviewed and approved via the amendment process.

☐ Remember to request study closure and complete the final report when your research study is completed.