IRB Application Process for Graduate Student PIs

Faculty sponsors of graduate students, see Graduate Student Faculty Sponsor Instructions for more information.

Step 1: Complete CITI training. More here:

https://research.cofc.edu/administration/documents/policies-documents/irb-training.php

Step 2: Complete any attachments that are needed for the application. This includes:

- Consent form: use one of the templates available here, under the Templates heading: <u>https://research.cofc.edu/administration/research-protections-and-compliance/human-participants-irb.php</u>
- Recruitment document: Document with script text, email text, etc. No template available for this since it is specific to your project and recruitment method.
- Document with survey/interview questions
- (optional) Obtain Site permission Letter, if recruiting from a specific location (i.e., a school, business. CofC department)

Step 3: Start the eForm application here: <u>https://www.axiommentor.com/login/shibLogin.cfm?i=cofc</u>

- Go to My Protocols tab and select "Create New Protocol" button (the gray box on the screen)
- Provide your faculty sponsor's name when prompted.
 - Faculty sponsor must be determined prior to initiating the application.
 - Faculty sponsor must have current CITI training.
- Fill in the basic protocol information—title, personnel, dates, review category, consent waivers (if needed, see below). Then Press save at the bottom.
- If you are obtaining consent orally, select "Yes" to "Waiver of Documentation of Consent."
- If you need to waive parts or all of the consent, then request Yes to "Waiver of Consent" and select waiver type (full or partial).

Step 4: Upload Attachments

You are now on the protocol main page and can now upload those attachments to the application.

- Select the gray "Upload Docs" button at the top of the page, just above your protocol title.
- Select your file for upload and choose the appropriate file type from the drop-down menu. Do this for each individual document upload.
- Press "Save" after each upload.

Step 5: Complete the Full Application

- Press on "Application Forms," located twice on the protocol main page and has a green arrow next to it. This will take you to the main text part of the application.
- Press on each heading to expand to see the questions. Press the gray "Edit Answer" button to answer your first questions. Details about required information are provided below, but in general, be as detailed as possible. Once you have filled in the text box press "Save Answers" at the bottom. This will automatically take you to the next question.
- Note: you can start and stop at any time, just be sure to save any work you've done first.

Application Sections:

- Methods and Procedures: be sure to be detailed in this section. For example, include information about the survey platform (Qualtrics is preferred), recording and transcription methods, and/or any logic involved with experiments.
- Expected time commitment: Just include the time to participate in the research. Time spent on travel or normal class participation should not be included here.
- Benefits to the participant: do not include any money or extra credit given for participation, this goes under a different section.
- Compensation: if offering extra credit, be sure to include alternative assignments for students to earn extra credit if they choose not to participate in research. *Note: can now use gift cards and no longer required to collect SSNs. See Gift Card <u>policy</u> and <u>procedures</u>.*
- Recruitment: Be detailed. For example, if using a listserv email, name the listserv.
 - If using an outside organization to recruit, you will need to select "Yes" to that question and upload a site permission letter from that organization.
- Privacy and Confidentiality:
 - Select yes to anonymous only if participants are truly anonymous, even to you (e.g., anonymous online survey).
 - Select yes to identifiable in the database if identifiers will be included and provide a justification and privacy protection measures. Otherwise, select no and explain how identifying information will be removed from the dataset and by whom. Also provide details about the disposition of any research recordings.
- Consent Information: Check the appropriate box(es) and upload the requested document(s).
 - May be appropriate to select more than one option, especially if using mixed data collection methods.
 - If requesting a full waiver of consent or a waiver of signed consent (for oral consent), an additional application section will appear.

Step 5: Submit the Application

- Once all the information is filled in and required documents have been uploaded, press "View Protocol Page" on the upper right of the screen to navigate back to the protocol main page. From there you can press the "Submit to the Faculty Sponsor" button.
- After reviewing the application contents, the faculty sponsor will then submit the application to the IRB for review.

Step 6: Revisions and Approval

- If revisions are required, they will be communicated via email through the eForm system. Be sure to review the required changes with your faculty sponsor before the revisions are submitted to the IRB. You can submit revisions without action by the faculty sponsor.
- The approval letter will be sent via email. Interaction with participants cannot begin until the approval is obtained.
- Faculty sponsor will be responsible for any follow-up reporting.