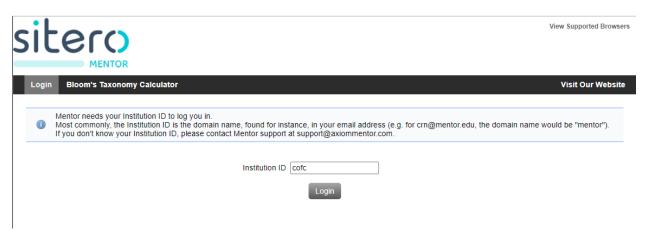
IRB eForm Application Instructions Faculty Sponsor of Undergraduate Student Researchers

LOGIN AND VIEW YOUR PROTOCOLS

Login to Sitero Mentor using your CofC ID and password:

https://www.axiommentor.com/login/shibLogin.cfm?i=cofc

Institution ID: CofC



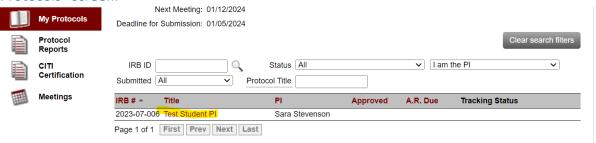
Once you are logged in, press the "IRB" tab in the top left corner.



Select the "My Protocols" option from the left navigation menu.



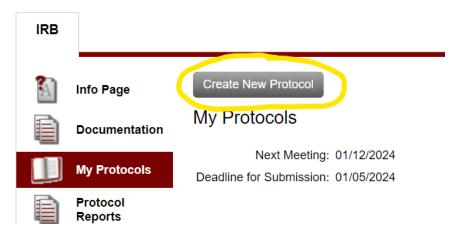
You can open any of your existing applications by pressing on the protocol title from the "My Protocols" screen.



START A NEW IRB APPLICATION

**Must be initiated by the undergraduate student's faculty sponsor. The faculty sponsor will serve as the PI of Record.

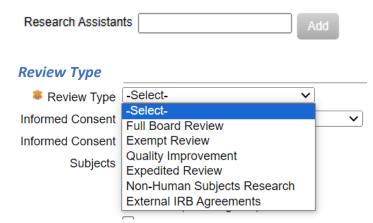
To start a new protocol, the faculty sponsor must press "Create New Protocol" from the "My Protocols" tab. Undergraduate students may not initiate IRB applications. If you would like to work with the undergraduate student on the application questions, please email complaince@cofc.edu for a Word version copy of the questions.



This will pull up a window for you to put in the basic protocol information—title, personnel, dates, review category, consent waivers (if needed, see below).

Adding the Student Investigator to the Application

Type the first letters of the student's last name where it says, "Research Assistants." Select their name from the popup list, then click "Add." Repeat to add multiple students.



Select the review type from the options provided. If expedited or exempt, then select the review category from the options provided.

	- Notice Type (
	Based On Please choose the option that you think best fits your project:
Review Type Exempt Review Based On Please choose the option that you think best fits your project:	$\ \square$ (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met
	(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows
(1) Educational Research	(3) Prospective collection of biological specimens for research purposes by noninvasive means
(2) Tests, Surveys, Interviews	(4) Collection of data through noninvasive procedures
(3) Benign Behavioral Interventions - Adults	(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes
(4) Secondary Research Uses of Data or Specimens	
(6) Taste and food quality evaluation and consumer acceptance studies	$\ \square$ (6) Collection of data from voice, video, digital, or image recordings made for research purposes
$\ \square$ (8) Secondary research for which broad consent is required	(7) Research on Individual or group characteristics or behavior

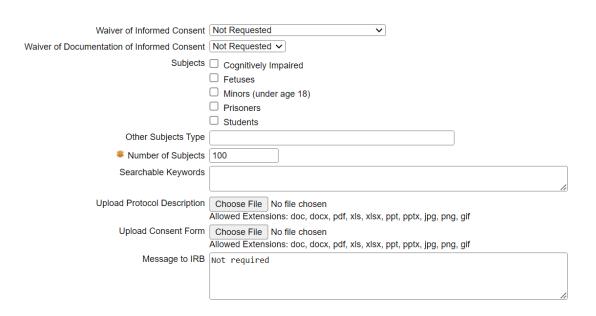
You can view more information about each category by hovering over the text with the review category:

(1) Educational Research	
(2) Tests, Surveys, I	(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public
(3) Benign Behavior	behavior (including visual or auditory recording) if at least one of the following criteria is met:
(4) Secondary Rese	(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the
(6) Taste and food q	subjects;
(8) Secondary resea	(ii) Any disclosure of the human subjects' responses outside the research would not reasonably
	place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial
	standing ,employability, educational advancement, or reputation; or
t Not Requested	(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the
t Not Requested 🗸	subjects, and an IRB conducts a limited IRB review to make the determination required by Sec.
[₿] Cognitively Impaired	111(a)(7).

Waivers of Consent

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).



Note that you do not have to upload the Protocol description at all, and do not need to upload the consent form from this menu.

The press Save.

When you click on the "Save" button below, your protocol record will be created. You can then upload additional files, and edit this form as needed. When your protocol is ready, click the "Submit Protocol for Review" button that will appear at the top of the view protocol page. That will formally submit your protocol to the IRB and notify the IRB coordinator that a new protocol has been received.



You have now started your IRB application and may proceed with completing the eForm and uploading the required attachments. Once you press save you will automatically be taken to the "Protocol Home Page," which can be accessed anytime by pressing on the protocol's title from the "My Protocols" tab.



EDITING AND SUBMITTING YOUR IRB APPLICATION

If you are not already viewing the "Protocol Home Page," press on the protocol's title from the "My Protocols"

Edit the Basic Information

If you need to edit the Basic information (such as the level of review or the personnel), simply press on the "Edit" button located above the protocol title to open the window to make those changes.



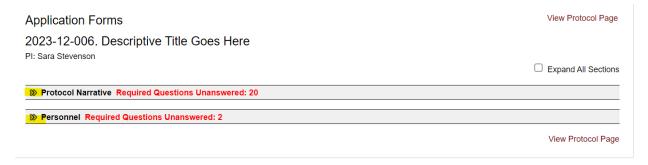
Descriptive Title Goes Here

Complete the "Application Forms"

From the "Protocol Home Page," 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 "Answer" button to begin the Application Forms text.

* In Rationale, Objectives and Significance
Provide a brief statement describing the importance of the proposed research.

Answer Required

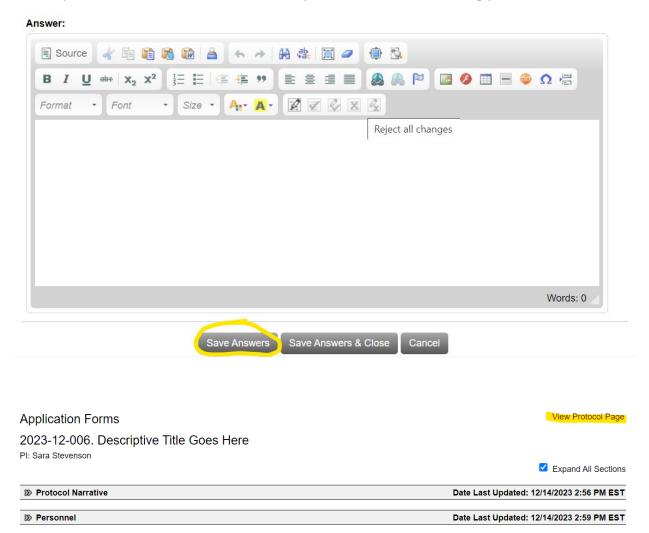
Answer

* Describe the benefits of the proposed research to science and/or society.

Answer Required

Answer

Provide your response in the text box and press "Save Answers" to continue to the next question. Press "Save Answers and Close" if you would like to return to all the Application Forms questions. Press Cancel to exit the response menu without saving your work.



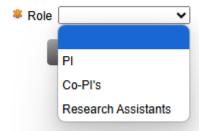
Add Student Researcher(s) from the Application Forms

Press the Arrows next to Personnel. Then press the "Add Personnel" button:



Then select "Research Assistants" from the drop-down menu for the Role:

Add Personnel to Protocol



Then type in the student's last name in the "Last Name Lookup" and select their name when it appears. Then press save.

Add Personnel to Protocol



Once you have filled in all the required information, press "View Protocol Page" to return to the Protocol Home Page.

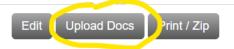
Note: The students' CITI Program training data will be associated with their CofC email account and will be listed with their information in the Personnel Section of the Application Forms.

Approval of the IRB application cannot be provided until all personnel listed have completed the CITI training.

Upload Attachments

The Application Forms section will prompt you to provide most required uploads. However, if there are additional items that need to be included, they can be uploaded from the Protocol Home Page.

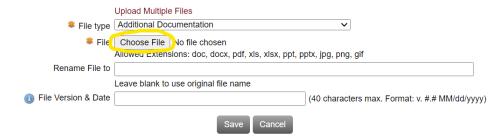
Select the gray "Upload Docs" button at the top of the page, just above your protocol title.



Descriptive Title Goes Here

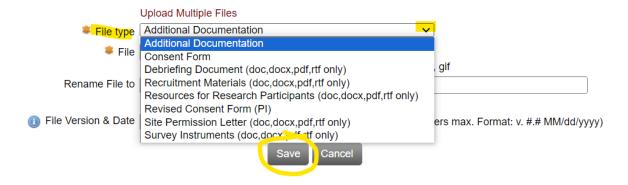
You can upload the attachments individually by selecting "Choose File" and choosing the file from your documents to upload.

Upload Documents



Then select the File Type from the drop-down menu

Upload Documents



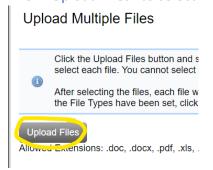
And Press "Save" to continue.

Or you can upload all files at once by selecting the text "Upload Multiple Files"

Upload Documents

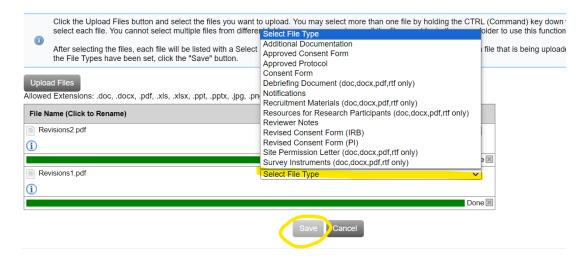


Then "Upload Files" to select from your documents.



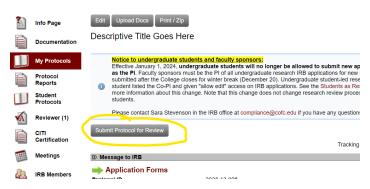
Once the files are selected, choose the File Type from the drop-down menu and press save to continue working on the protocol.

Upload Multiple Files



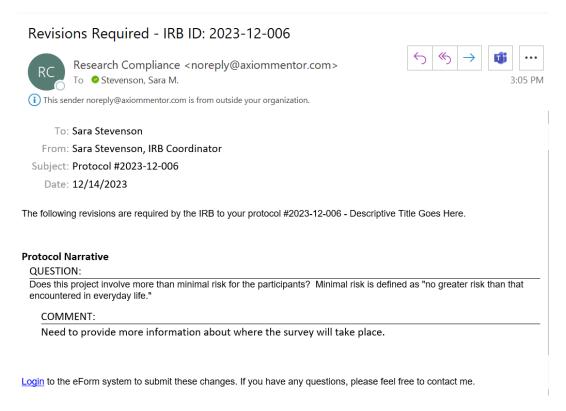
SUBMIT THE APPLICATION FOR REVIEW

From the Protocol Home Page, press the "Submit for Review" button. Note that this action will not be available unless all required questions in the Application Forms are completed.

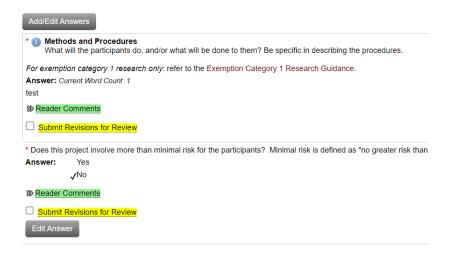


SUBMITTING REVISIONS

If revisions are required, they will be communicated via email through the eForm system.



Once you have reviewed the "Revision Required" email, open your protocol and the Application Forms to begin making changes. Sections that have comments that require revisions will be highlighted in Green Press "Edit Answer" to make changes to sections where revisions are needed. Check the box next to "Submit Revisions for Review" once revisions to each section are made.



If new/revised uploads are required, follow the steps above for uploading documents.

Once changes have been made to the Application Forms, press "View Protocol Page" to return the Protocol Home Page. From there, check the box where it states, "Submit Revisions for Review"

☐ Submit Revisions for Review

Application Forms

APPROVAL

The approval letter will be sent via email, and the IRB Chair and your department chair will be cc'd on the notification. Interaction with participants cannot begin until the approval is obtained.

As PI, you are responsible for any follow-up reporting.