

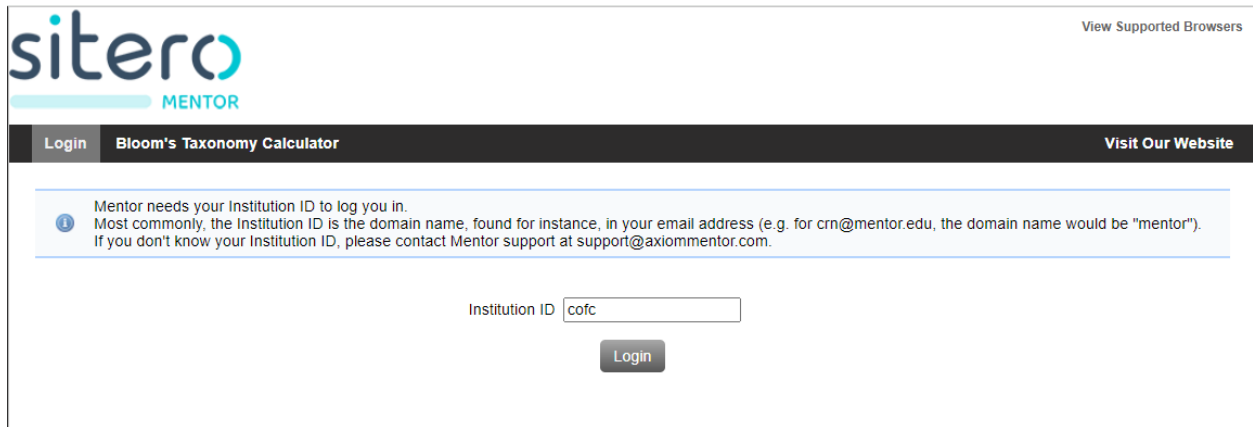
IRB eForm Application Instructions Faculty and Staff PIs

[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



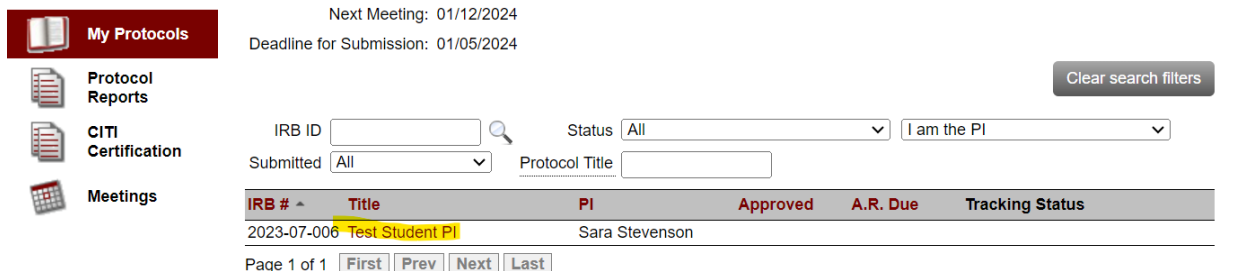
Once you are logged in, press the “IRB” tab in the top left corner.



Then select the “My Protocols” option from the left navigation menu.



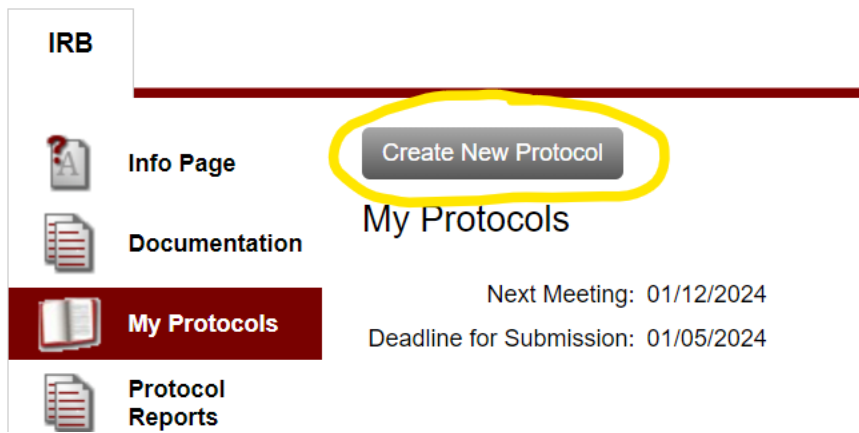
You can open any of your existing applications by pressing on the protocol title from the “My Protocols” screen.



IRB #	Title	PI	Approved	A.R. Due	Tracking Status
2023-07-006	Test Student PI	Sara Stevenson			

START A NEW IRB APPLICATION

To start a new protocol, select “Create New Protocol” from the “My Protocols” tab.



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). Then Press save at the bottom.

Create IRB Protocol

Next Meeting 01/12/2024
Deadline for Submission 01/05/2024

PI

Co-PI's (Type first letters of last name and select from popup list, then click "Add")

External PIs

Research Assistants (Type first letters of last name and select from popup list, then click "Add")

Protocol Title

Proposed Start Date

End Date

Funding Source

Grant Number

Review Type

Review Type

Informed Consent

Informed Consent

Subjects

- Select-
- Full Board Review
- Exempt Review
- Quality Improvement
- Expedited Review
- Non-Human Subjects Research
- External IRB Agreements

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

Review Type

Based On Please choose the option that you think best fits your project:

- (1) Educational Research
- (2) Tests, Surveys, Interviews
- (3) Benign Behavioral Interventions - Adults
- (4) Secondary Research Uses of Data or Specimens
- (6) Taste and food quality evaluation and consumer acceptance studies
- (8) Secondary research for which broad consent is required

Review Type

Based On Please choose the option that you think best fits your project:

- (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
- (3) Prospective collection of biological specimens for research purposes by noninvasive means
- (4) Collection of data through noninvasive procedures
- (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes
- (6) Collection of data from voice, video, digital, or image recordings made for research purposes
- (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:

<input type="checkbox"/> (1) Educational Research	
<input type="checkbox"/> (2) Tests, Surveys, Interviews	(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
<input type="checkbox"/> (3) Benign Behavioral Interventions - Adults	(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 subjects;
<input type="checkbox"/> (4) Secondary Research Uses of Data or Specimens	(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
<input type="checkbox"/> (6) Taste and food quality evaluation and consumer acceptance studies	(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 subjects, and an IRB conducts a limited IRB review to make the determination required by Sec. ___ .111(a)(7).
<input type="checkbox"/> (8) Secondary research for which broad consent is required	

Not Requested

Not Requested

Cognitively Impaired

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).

Waiver of Informed Consent

Waiver of Documentation of Informed Consent

Subjects

- Cognitively Impaired
- Fetuses
- Minors (under age 18)
- Prisoners
- Students

Other Subjects Type

Number of Subjects

Searchable Keywords

Upload Protocol Description No file chosen
Allowed Extensions: doc, docx, pdf, xls, xlsx, ppt, pptx, jpg, png, gif

Upload Consent Form No file chosen
Allowed Extensions: doc, docx, pdf, xls, xlsx, ppt, pptx, jpg, png, gif

Message to IRB

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.



Requested

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.

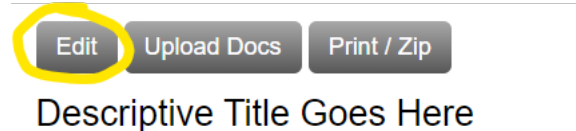
The screenshot shows the IRB application interface. On the left is a navigation menu with tabs: Info Page, Documentation, My Protocols (highlighted), Protocol Reports, Student Protocols, Reviewer (1), CITI Certification, Meetings, and IRB Members. At the top right, there are buttons for Edit, Upload Docs, and Print / Zip, and a link for Messages (0) | Back. The main content area has a header "Descriptive Title Goes Here". Below this is a notice box with a yellow background and a blue information icon, containing text about undergraduate students and faculty sponsors. Below the notice is a "Submit Protocol for Review" button. At the bottom, there is a "Message to IRB" section and an "Application Forms" section with a table showing Protocol ID (2023-12-006) and Panel (No Panel Assigned). A "Tracking Status: No Status Recorded" message is also visible.

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.



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.

A screenshot of the protocol application page. At the top, there is a grey bar with a double arrow icon and the text "Message to IRB". Below this, there are two green arrows pointing right, each followed by the text "Application Forms". The first "Application Forms" link is circled in yellow. Below the links, there is a list of protocol details:

Protocol ID	2023-12-006
Panel	No Panel Assigned
PI	Sara Stevenson (Click here to view PI Docs)
PI Type	General Faculty
External PIs	List non-CofC Personnel here
Review Type	Exempt Review
Approval Status	Exempt Review Requested Withdraw Protocol from Review
Based On	(2) Tests, Surveys, Interviews
Submitted By	Sara Stevenson
Proposed Start Date	12/21/2023
Consent Waived	Not Requested
Waiver of Documentation of Informed Consent	Not Requested
Number of Subjects	100

Below the details, there is another green arrow pointing right, followed by the text "Application Forms", which is also circled in yellow. Below this, there is an "Upload Docs" button and a list of documents:

Survey Instruments	12/14/2023	Revisions1.pdf
Additional Documentation	12/14/2023	Revisions2.pdf
Consent Form	12/14/2023	Revisions2.pdf

At the bottom, there are three tabs: "Amendments", "Additional Documents", and "Protocol Questions".

Press on each heading to expand to see the questions.

» Protocol Narrative Required Questions Unanswered: 20

» Personnel Required Questions Unanswered: 2

Press the gray "Answer" button to begin the Application Forms text.

* **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.

Answer:

The image shows a rich text editor interface. At the top, there is a toolbar with various icons for text formatting (bold, italic, underline), alignment, and other functions. Below the toolbar is a large text area for entering the answer. In the bottom right corner of the text area, it says "Words: 0".

Save Answers Save Answers & Close Cancel

For more details about the application questions, see the [Sample IRB eForm questions](#)

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

Application Forms

[View Protocol Page](#)

2023-12-006. Descriptive Title Goes Here

PI: Sara Stevenson

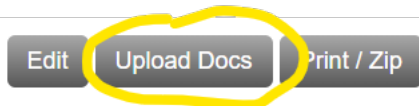
Expand All Sections

⌵ Protocol Narrative	Date Last Updated: 12/14/2023 2:56 PM EST
⌵ Personnel	Date Last Updated: 12/14/2023 2:59 PM EST

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

Upload Multiple Files

File type:

File: No file chosen

Allowed Extensions: doc, docx, pdf, xls, xlsx, ppt, pptx, jpg, png, gif

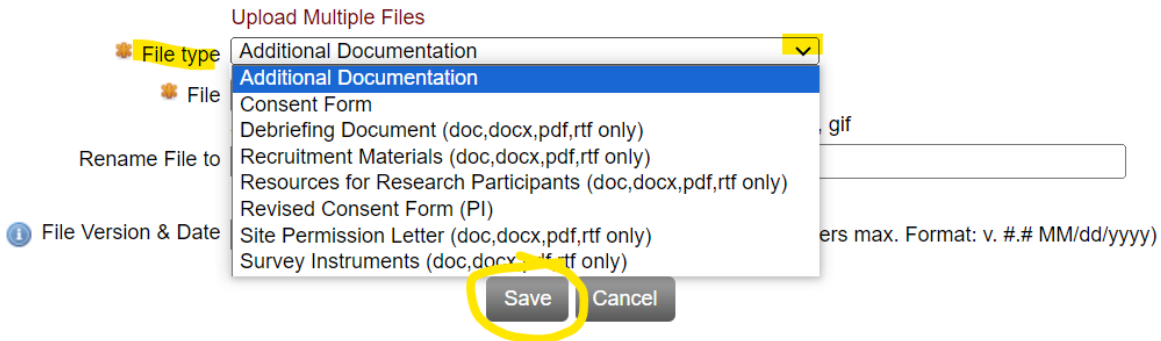
Rename File to:

Leave blank to use original file name

File Version & Date: (40 characters max. Format: v. #. # MM/dd/yyyy)

Then select the File Type from the drop-down menu

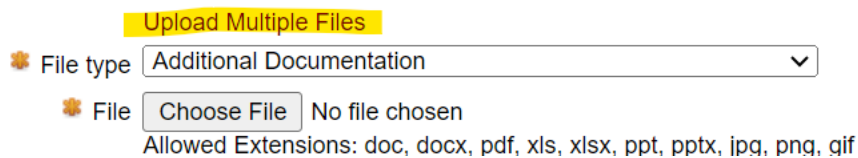
Upload Documents



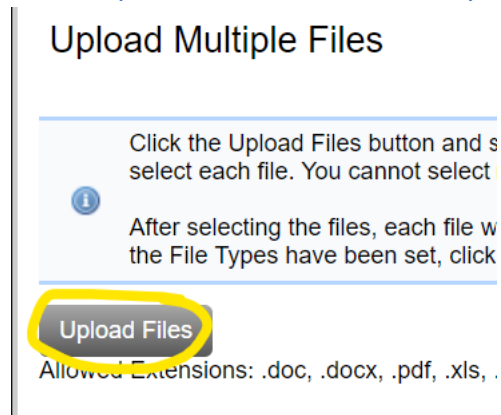
And Press “Save” to continue.

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

Click the Upload Files button and select the files you want to upload. You may select more than one file by holding the CTRL (Command) key down and select each file. You cannot select multiple files from different folders. If you are using a file explorer, you must select the folder to use this function.

After selecting the files, each file will be listed with a Select File Type button. After the Select File Types have been set, click the "Save" button.

Upload Files
Allowed Extensions: .doc, .docx, .pdf, .xls, .xlsx, .ppt, .pptx, .jpg, .png

File Name (Click to Rename)	Select File Type
Revisions2.pdf	Additional Documentation
	Approved Consent Form
	Approved Protocol
	Consent Form
	Debriefing Document (doc,docx,pdf,rtf only)
	Notifications
	Recruitment Materials (doc,docx,pdf,rtf only)
	Resources for Research Participants (doc,docx,pdf,rtf only)
	Reviewer Notes
	Revised Consent Form (IRB)
	Revised Consent Form (PI)
	Site Permission Letter (doc,docx,pdf,rtf only)
	Survey Instruments (doc,docx,pdf,rtf only)
	Select File Type

Save Cancel

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.

Info Page Edit Upload Docs Print / Zip

Documentation Descriptive Title Goes Here

My Protocols

- Protocol Reports
- Student Protocols
- Reviewer (1)
- CITI Certification
- Meetings
- IRB Members

Notice to undergraduate students and faculty sponsors:
Effective January 1, 2024, undergraduate students will no longer be allowed to submit new applications as the PI. Faculty sponsors must be the PI of all undergraduate research IRB applications for new submissions after the College closes for winter break (December 20). Undergraduate student-led research student listed the Co-PI and given "allow edit" access on IRB applications. See the Students as Reviewers page for more information about this change. Note that this change does not change research review process for students.

Please contact Sara Stevenson in the IRB office at compliance@cofc.edu if you have any question.

Submit Protocol for Review

Message to IRB Tracking

Application Forms

SUBMITTING REVISIONS

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

Revisions Required - IRB ID: 2023-12-006



Research Compliance <noreply@axiommentor.com>

To Stevenson, Sara M.



3:05 PM

This sender noreply@axiommentor.com is from outside your organization.

To: Sara Stevenson

From: Sara Stevenson, IRB Coordinator

Subject: Protocol #2023-12-006

Date: 12/14/2023

The following revisions are required by the IRB to your protocol #2023-12-006 - Descriptive Title Goes Here.

Protocol Narrative

QUESTION:

Does this project involve more than minimal risk for the participants? Minimal risk is defined as "no greater risk than that encountered in everyday life."

COMMENT:

Need to provide more information about where the survey will take place.

[Login](#) to the eForm system to submit these changes. If you have any questions, please feel free to contact me.

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.

Add/Edit Answers

* **Methods and Procedures**
What will the participants do, and/or what will be done to them? Be specific in describing the procedures.

For exemption category 1 research only: refer to the Exemption Category 1 Research Guidance.

Answer: Current Word Count: 1
test

» [Reader Comments](#)

[Submit Revisions for Review](#)

* Does this project involve more than minimal risk for the participants? Minimal risk is defined as "no greater risk than

Answer: Yes
 No

» [Reader Comments](#)

[Submit Revisions for Review](#)

Edit Answer

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. If needed, see instructions for submitting a modification.