



# IRB Instructions for Axiom Mentor

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Comprehensive Guide for Investigators, Faculty Sponsors, IRB Members  
and IRB Staff

# INDEX

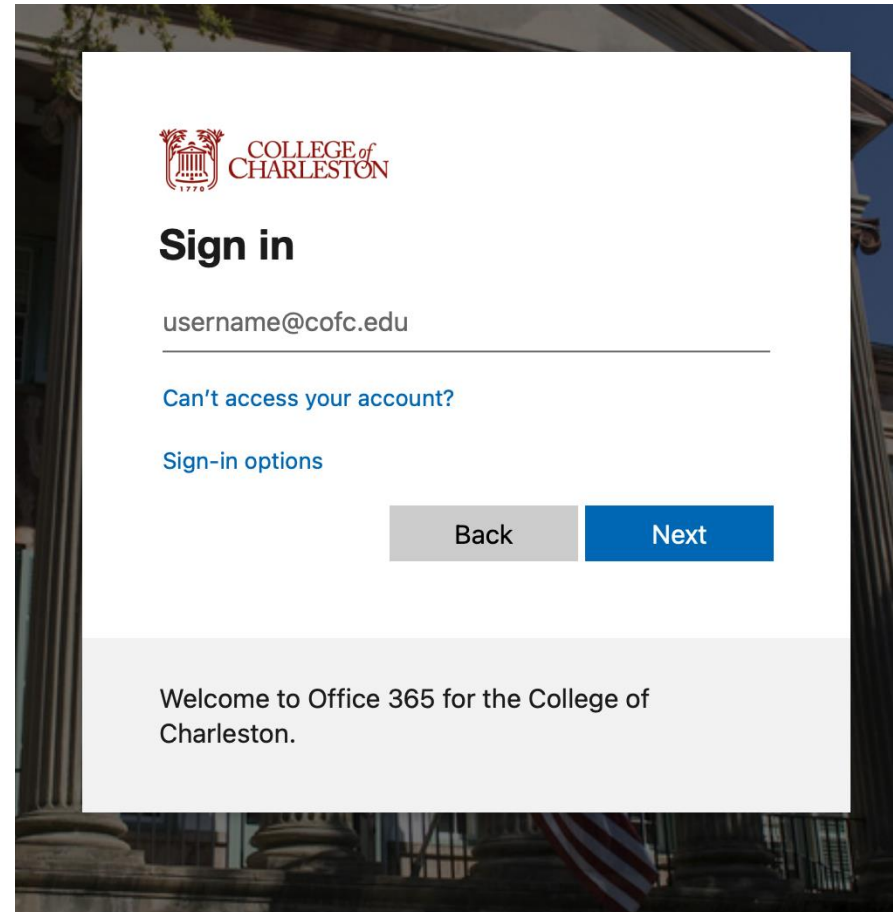
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# Basic Information: Login and Site Orientation

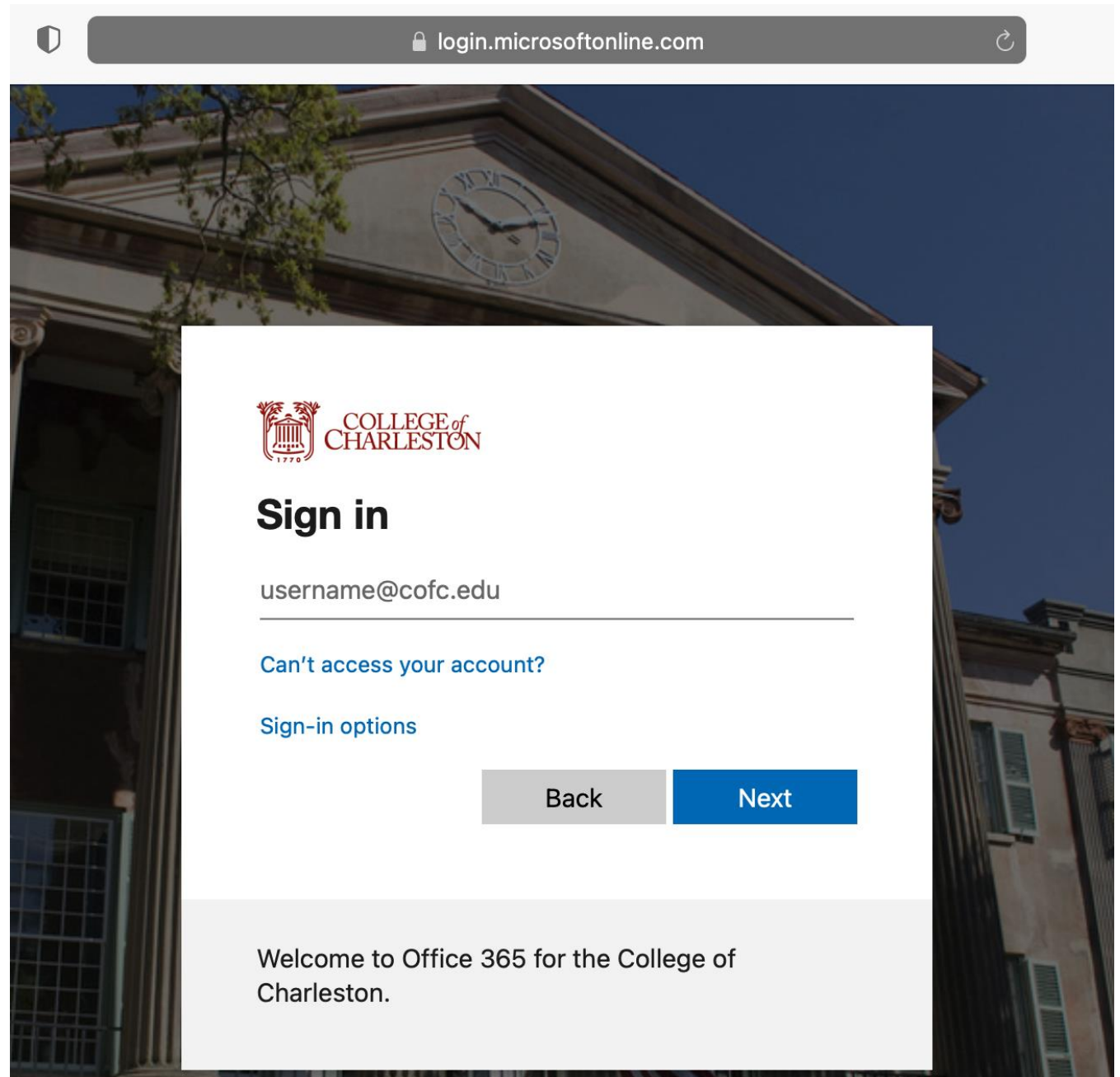


Login:

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


The image shows a login page for the College of Charleston. At the top left is the college's logo, which includes a crest with a building and the year 1770, followed by the text "COLLEGE of CHARLESTON". Below the logo is the heading "Sign in". Underneath is a text input field containing the placeholder "username@cofc.edu". To the right of the input field is a blue link that says "Can't access your account?". Below that is another blue link that says "Sign-in options". At the bottom of the form area are two buttons: a grey "Back" button and a blue "Next" button. At the very bottom of the page, there is a light grey footer area with the text "Welcome to Office 365 for the College of Charleston." The entire login form is overlaid on a background image of a classical building with columns and an American flag.

Use your regular CofC email address and password to login; you will only need to do this step occasionally, will save your login for future uses.



The screenshot shows a web browser window with the address bar displaying "login.microsoftonline.com". The background of the page is a photograph of a classical building with a clock tower. Overlaid on this is a white login form for the College of Charleston. The form includes the college's logo and name, a "Sign in" heading, a text input field containing "username@cofc.edu", and links for "Can't access your account?" and "Sign-in options". At the bottom of the form are "Back" and "Next" buttons. A footer message reads: "Welcome to Office 365 for the College of Charleston."

login.microsoftonline.com

 COLLEGE of CHARLESTON

**Sign in**

username@cofc.edu

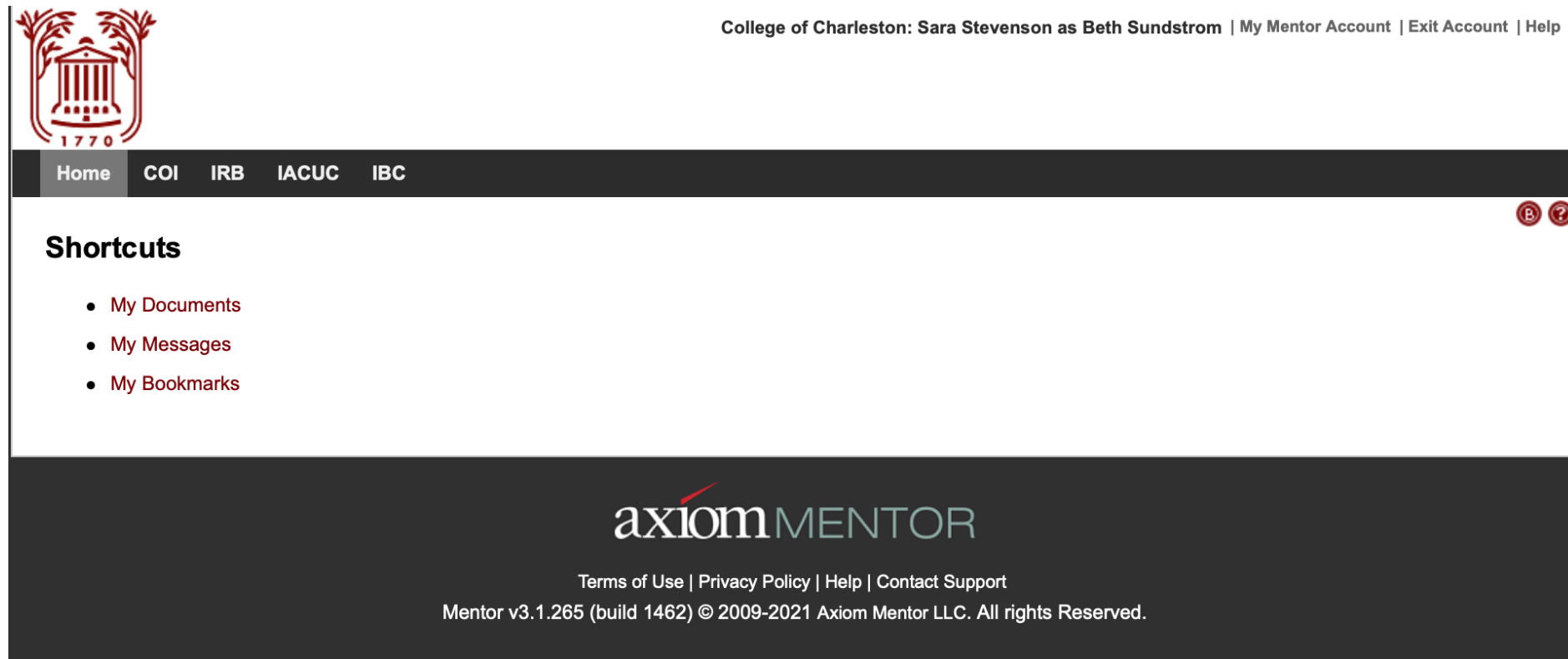
[Can't access your account?](#)

[Sign-in options](#)

Back Next

Welcome to Office 365 for the College of Charleston.

# Once logged in, will take you to the home page, which looks like this:

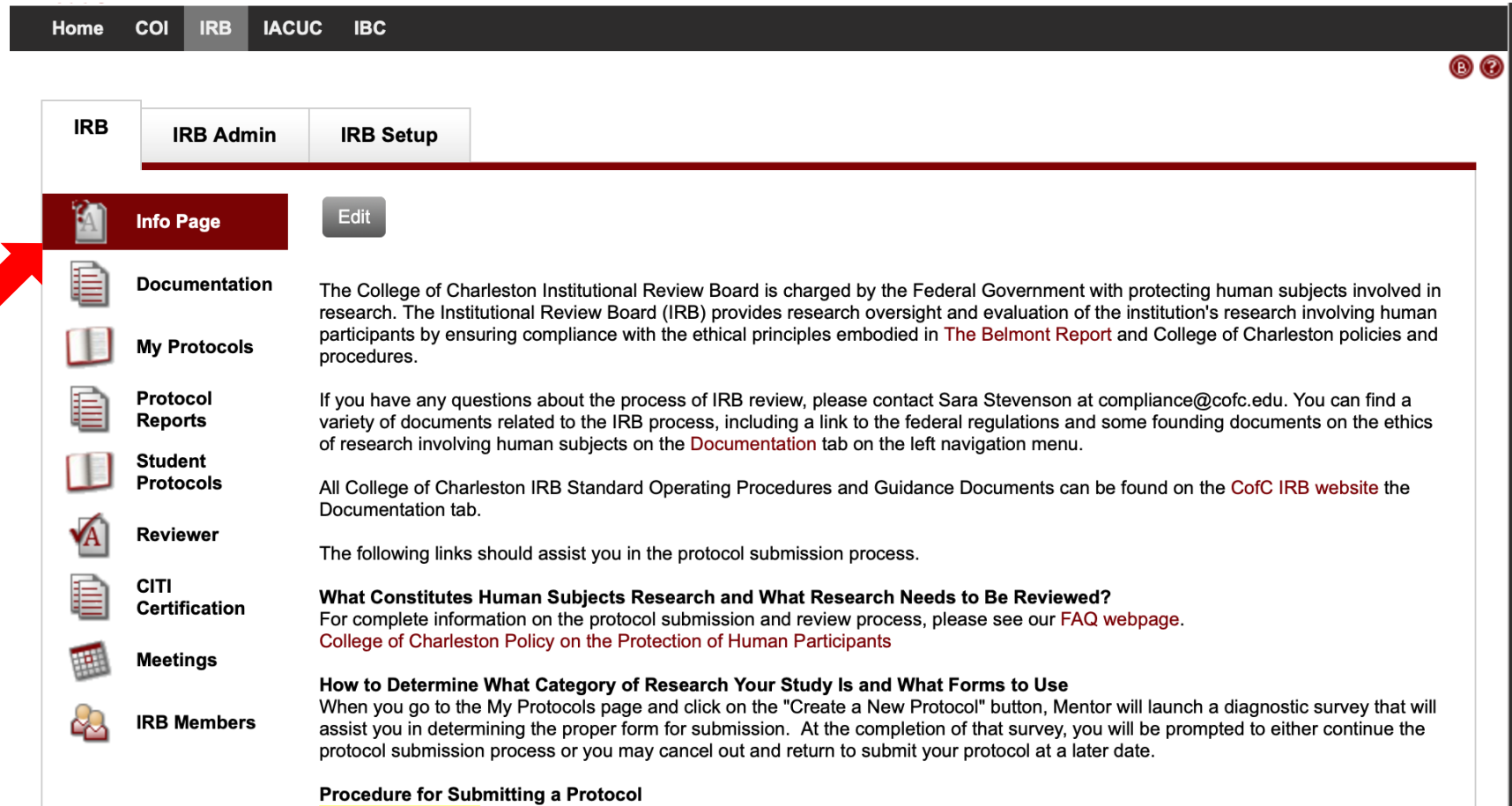


# IRB Main Page/Info Page

Select the IRB tab in the top navigation bar to access the IRB page

The IRB home page is also the Info Page, which includes many helpful links and form templates

Left Navigation bar contains all the needed links for IRB submission and review



The screenshot shows the IRB Main Page/Info Page. At the top, there is a navigation bar with tabs: Home, COI, IRB, IACUC, and IBC. The IRB tab is selected. Below this, there is a sub-navigation bar with tabs: IRB, IRB Admin, and IRB Setup. The IRB tab is selected. On the left side, there is a left navigation bar with links: Info Page, Documentation, My Protocols, Protocol Reports, Student Protocols, Reviewer, CITI Certification, Meetings, and IRB Members. The Info Page link is selected. The main content area displays the IRB Info Page, which includes a welcome message, contact information for Sara Stevenson, a list of links for protocol submission, and sections for human subjects research and protocol submission procedures.

Home COI **IRB** IACUC IBC

IRB IRB Admin IRB Setup

**Info Page** Edit

**Documentation**

The College of Charleston Institutional Review Board is charged by the Federal Government with protecting human subjects involved in research. The Institutional Review Board (IRB) provides research oversight and evaluation of the institution's research involving human participants by ensuring compliance with the ethical principles embodied in **The Belmont Report** and College of Charleston policies and procedures.

**My Protocols**

If you have any questions about the process of IRB review, please contact Sara Stevenson at [compliance@cofc.edu](mailto:compliance@cofc.edu). You can find a variety of documents related to the IRB process, including a link to the federal regulations and some founding documents on the ethics of research involving human subjects on the **Documentation** tab on the left navigation menu.

**Protocol Reports**

All College of Charleston IRB Standard Operating Procedures and Guidance Documents can be found on the **CofC IRB website** the Documentation tab.

**Student Protocols**

The following links should assist you in the protocol submission process.

**Reviewer**

**What Constitutes Human Subjects Research and What Research Needs to Be Reviewed?**  
For complete information on the protocol submission and review process, please see our **FAQ webpage**.  
**College of Charleston Policy on the Protection of Human Participants**

**CITI Certification**

**Meetings**

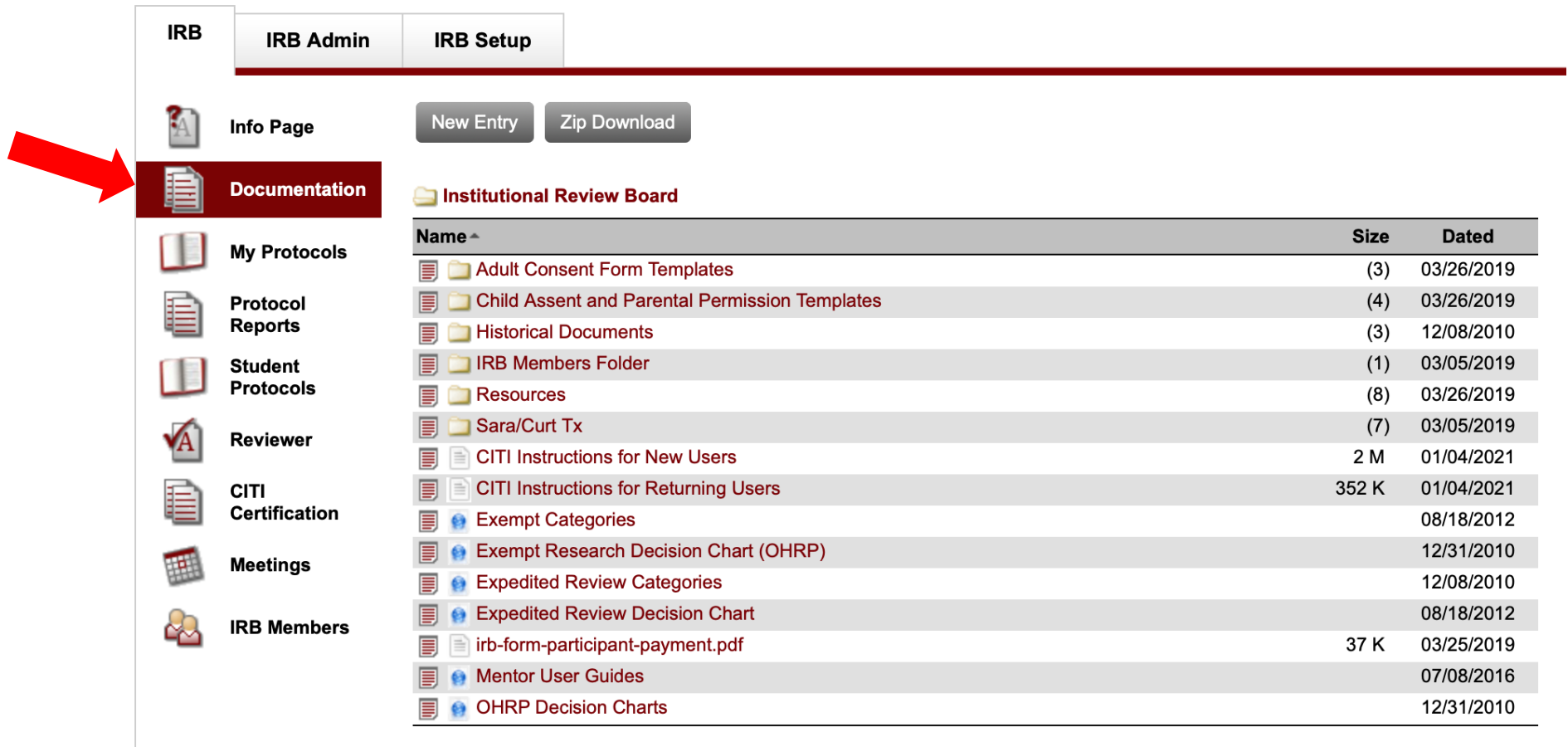
**IRB Members**

**How to Determine What Category of Research Your Study Is and What Forms to Use**  
When you go to the My Protocols page and click on the "Create a New Protocol" button, Mentor will launch a diagnostic survey that will assist you in determining the proper form for submission. At the completion of that survey, you will be prompted to either continue the protocol submission process or you may cancel out and return to submit your protocol at a later date.

**Procedure for Submitting a Protocol**

# Documentation Page

Use the left navigation bar to access the Documentation page, which includes all the IRB-related documents and forms



The screenshot shows the IRB system interface. At the top, there are tabs for 'IRB', 'IRB Admin', and 'IRB Setup'. Below these, the 'Documentation' page is selected, indicated by a red arrow from the left navigation bar. The left navigation bar contains links for 'Info Page', 'Documentation', 'My Protocols', 'Protocol Reports', 'Student Protocols', 'Reviewer', 'CITI Certification', 'Meetings', and 'IRB Members'. The main content area displays a list of documents under the heading 'Institutional Review Board'. The list includes folders like 'Adult Consent Form Templates', 'Child Assent and Parental Permission Templates', 'Historical Documents', 'IRB Members Folder', 'Resources', and 'Sara/Curt Tx', as well as individual documents like 'CITI Instructions for New Users', 'CITI Instructions for Returning Users', 'Exempt Categories', 'Exempt Research Decision Chart (OHRP)', 'Expedited Review Categories', 'Expedited Review Decision Chart', 'irb-form-participant-payment.pdf', 'Mentor User Guides', and 'OHRP Decision Charts'. Each entry shows its size and date.

Name ^	Size	Dated
Adult Consent Form Templates	(3)	03/26/2019
Child Assent and Parental Permission Templates	(4)	03/26/2019
Historical Documents	(3)	12/08/2010
IRB Members Folder	(1)	03/05/2019
Resources	(8)	03/26/2019
Sara/Curt Tx	(7)	03/05/2019
CITI Instructions for New Users	2 M	01/04/2021
CITI Instructions for Returning Users	352 K	01/04/2021
Exempt Categories		08/18/2012
Exempt Research Decision Chart (OHRP)		12/31/2010
Expedited Review Categories		12/08/2010
Expedited Review Decision Chart		08/18/2012
irb-form-participant-payment.pdf	37 K	03/25/2019
Mentor User Guides		07/08/2016
OHRP Decision Charts		12/31/2010



# My Protocols

Select My Protocols to  
create a new protocol  
application or view/edit  
existing protocols



Approval dates,  
reporting dates, and  
current application  
status can be found at  
this link

[Home](#) [COI](#) [IRB](#) [IACUC](#) [IBC](#)

IRB

IRB Admin

IRB Setup

Info Page

Documentation

**My Protocols**

Protocol Reports

Student Protocols

Reviewer

CITI Certification

Meetings

IRB Members

Create New Protocol

## My Protocols

» PI Documentation No Certificate

Next Meeting:

Deadline for Submission:

IRB ID

Status

I am the PI or Research Assistan

Submitted

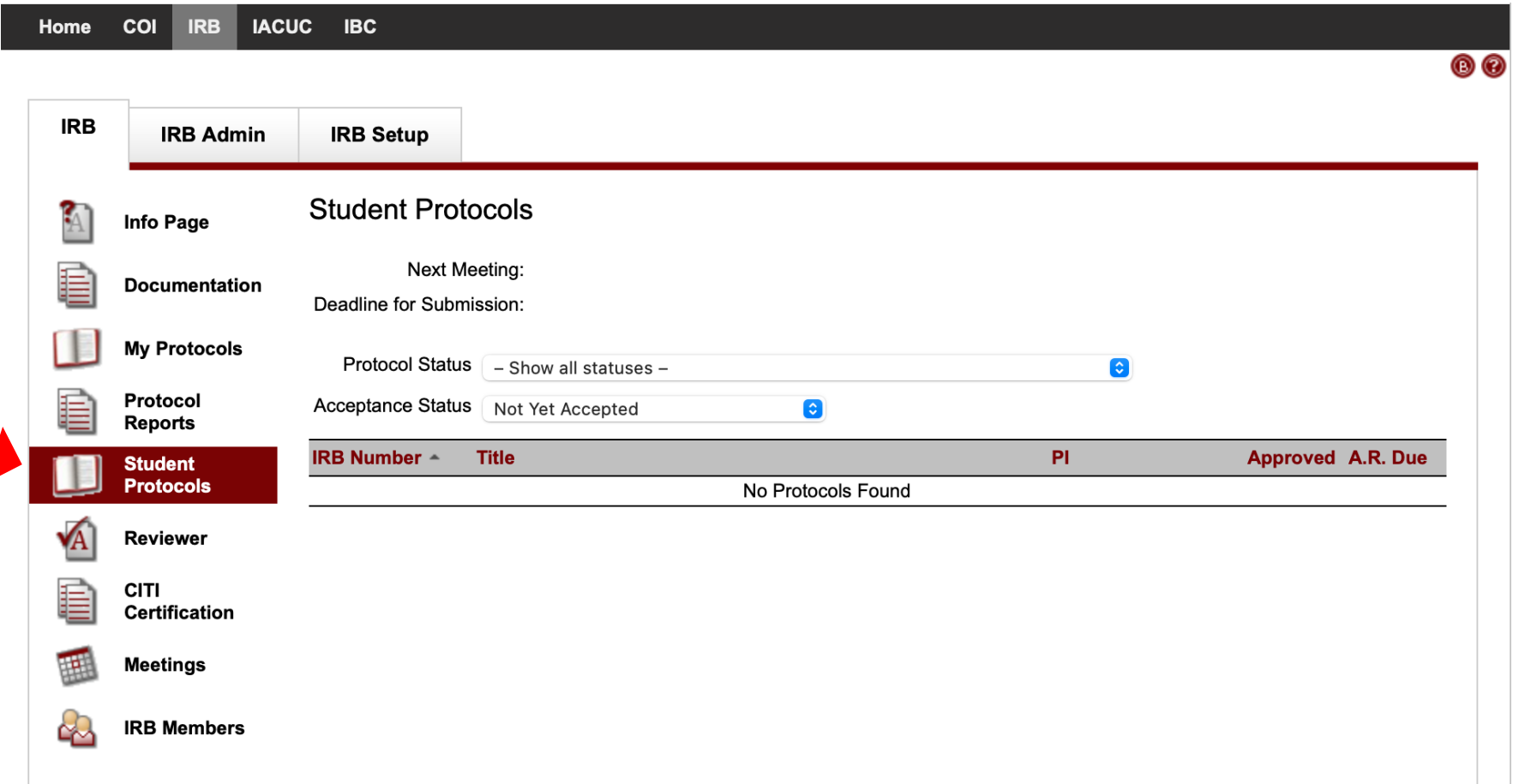
IRB #	Title	PI	Approved	A.R. Due	Tracking Status
13	Understanding knowledge, attitudes,...	Beth Sundstrom			With IRB Staff

Page 1 of 1 [First](#) [Prev](#) [Next](#) [Last](#)

# Student Protocols-Faculty Sponsor

Faculty sponsors of student investigators can view, edit, and submit their student applications using Student Protocols tab.

Only faculty sponsors can submit to the IRB and will receive a notification from the system when an application requires an action.



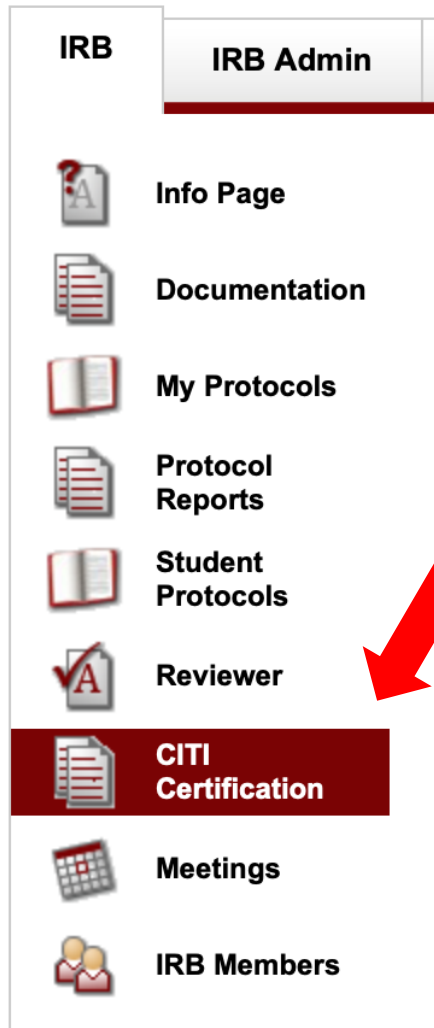
The screenshot displays the IRB Admin interface. The top navigation bar includes links for Home, COI, IRB, IACUC, and IBC. The IRB section is active, showing sub-tabs for IRB Admin and IRB Setup. The left sidebar contains a list of menu items: Info Page, Documentation, My Protocols, Protocol Reports, Student Protocols (highlighted with a red arrow), Reviewer, CITI Certification, Meetings, and IRB Members. The main content area is titled 'Student Protocols' and includes fields for 'Next Meeting:', 'Deadline for Submission:', 'Protocol Status' (set to '- Show all statuses -'), and 'Acceptance Status' (set to 'Not Yet Accepted'). Below these fields is a table with columns: IRB Number, Title, PI, Approved, and A.R. Due. The table currently displays 'No Protocols Found'.

IRB Number	Title	PI	Approved	A.R. Due
No Protocols Found				

# IMPORTANT NOTE REGARDING STUDENT RESEARCH

- If you are a student submitting an application, it must first be submitted to your faculty sponsor for initial review and approval.
- Only the faculty sponsor can submit to the IRB on behalf of the student
- Faculty sponsors must follow the steps outlined Faculty Sponsor Instructions, below.

# Required Training for all Researchers and Faculty Sponsors



- CITI Program certification is required of all individuals listed on the IRB protocol, including faculty sponsors. Training must have been completed in the past 5 years.
- See [CofC webpage](#) for more instructions and links
- Your CITI Certificates are listed under the CITI Certification tab in the left-hand navigation menu
- CITI information is automatically uploaded each night, so please wait 24 hours after you complete the training at CITI Program for it to appear in Axiom Mentor
- Contact [compliance@cofc.edu](mailto:compliance@cofc.edu) if you have any issues with your CITI Certifications

# IRB Application Instructions for Researchers



# Create/Edit Protocol

Press this to start a new protocol application

Select My Protocols from the left navigation menu

To edit a protocol, press on the Title

Home

COI

IRB

IACUC

IBC

Admin

IRB

IRB Admin

IRB Setup

Info Page

Documentation

**My Protocols**

Protocol Reports

Student Protocols

Reviewer

CITI Certification

Meetings

IRB Members

Create New Protocol

My Protocols

Next Meeting:

Deadline for Submission:

IRB ID

Status

All

I am the PI or Research Assistan

Submitted

All

IRB #	Title	PI	Approved	A.R. Due	Tracking Status
1	Title goes here	Sara Stevenson	Approval Expired	04/04/19	02/21/20
2	Title 2	Sara Stevenson			
3	title here	Sara Stevenson			
4	Descriptive Title	Sara Stevenson			
8	Experiences with Online Learning an...	Sara Stevenson	04/18/20		Approved
10	Understanding Communication about C...	Sara Stevenson	01/06/21		Approved
12	The Development and Evaluation of a...	Sara Stevenson	12/10/20		Approved
15	The Development and Evaluation of a...	Maggie McCabe			Waiting for Faculty Sponsor Approval

Page 1 of 1

First

Prev

Next

Last

# Create/Edit Protocol

- Instructions/Insights:
  - To create or edit a protocol, first select “My Protocols” from the left navigation menu
  - Select the Create New Protocol button to start a new protocol application
  - To edit an existing application, press on the protocol title

# Creating a new protocol: Basic Information

Create IRB Protocol

Next Meeting

Deadline for Submission

\* PI Sara Stevenson

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   Acceptable Formats

End Date   Acceptable Formats

Funding Source

Grant Number

\* Review Type

- Instructions/Insights:
  - Once you press “Create a New Protocol” button, this screen will appear with the basic information about the protocol.
  - When you add Co-PIs, you can also select which level of access they have-view or edit



# Select Review Type

\* 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

- Full Board Review
- Exempt Review
- Quality Improvement
- Expedited Review
- Reliance Agreement with External IRB
- Non-Human Subjects Research

## • Instructions/Insights:

- To choose Review Type, choose the appropriate option listed in the drop-down menu.
  - The categories, along with the definitions, will then appear below.
- Select the check box(es) that most accurately fits your project. This can be changed later if needed.

\* 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

# New protocol continued: vulnerable populations, informed consent options

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 Consent Form  no file selected  
Allowed Extensions: doc, docx, pdf, rtf, xls, xlsx, ppt, pptx, jpg, png, gif

Message to IRB

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.

Save

Cancel

# New protocol continued: Vulnerable populations, informed consent options

- Instructions/Insights:

- You will also need to provide information about the consent and subjects.
- A Waiver of Informed Consent means that you will not be providing any informed consent to the subjects
- A Waiver of DOCUMENTATION of consent is often called "oral consent" because the consent information will still be provided to them, but the research participants, or subjects, will not sign a consent document.
- You will also need to select if your subjects include any of the following: cognitively impaired, fetuses, minors, prisoners, or students. Other subject types can also be provided, for example, veterans.
- Finally, you will upload the consent form(s) from this page. This can also be done later under uploads, which will be discussed later.

# Protocol Page:

will see this page whenever you select the protocol from the “My Protocols” menu

Edit the Basic Information here



Messages (0) | [Back](#)

## Test Exempt Waiver of Documentation of Consent Survey Research



**IF you are a new investigator (only)** please contact Sara Stevenson in the IRB office at [stevensonsm1@cofc.edu](mailto:stevensonsm1@cofc.edu) for guidance before you go too far into the protocol submission process.

**Required questions not answered**

[Submit Protocol for Review](#)

Tracking Status: No Status Recorded

Complete the rest of the application here



**Application Forms**

- Instructions/Insights:
  - Once the basic information is provided and submitted, this will appear.
  - To change the basic information, select Edit. To Upload documents, select Upload Docs.
  - Application Forms will take you the remaining protocol sections

Protocol ID	17
PI	Sara Stevenson (Click here to view PI Docs)
PI Type	General Faculty
Review Type	Exempt Review
Approval Status	Exempt Review Requested
Based On	(2) Tests, Surveys, Interviews
Submitted By	Sara Stevenson
Proposed Start Date	01/13/2021
End Date	01/13/2022
Consent Waived	Not Requested
Waiver of Documentation of Informed Consent	Requested
Number of Subjects	50

**Application Forms**

# Upload Documents

## Upload Documents

**Upload Multiple Files**

\* File type

\* File  consent\_mccabe.pdf

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

Rename File to

Leave blank to use original file name

☐ Visible to IRB Only

## Upload Documents

## Upload Documents

**Upload Multiple Files**

\* File type

\* File

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

Rename File to

- Instructions/Insights:
  - Select the Upload Documents button from the top of the protocol page.
  - You can then upload individual or bulk documents.
  - To upload an individual document, select the File Type from the drop down menu, then choose file, then save.
  - Or, select “Upload Multiple Files”

# Upload Multiple Files

- Instructions:
  - By pressing "Upload Multiple Files" it will take you to this screen.
  - You can then upload all the protocol documents and then select the file type.
  - Then select save.

## 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 shift key down while you select each file. You cannot select multiple files from different folders on your computer so all files must be in the same folder to use this function.

After selecting the files, each file will be listed with a Select File Type drop down menu. You must select a File Type for each file being uploaded. Once all the File Types have been set, click the "Save" button.

### Upload Files

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

File Name (Click to Rename)	Set Type
coopletter_mccabe.pdf	Site Permission Letter (doc,docx,pdf,rtf only)
recuit_mccabe.pdf	Recruitment Materials (doc,docx,pdf,rtf only)
survey_mccabe.pdf	Survey Instruments (doc,docx,pdf,rtf only)













Save

Cancel

# View/Edit/Compare Attachments

## ➔ Application Forms

Upload Docs

 <b>Approved Consent Form</b>	 01/06/2021  <b>consent form</b> (Approved Consent Form)
 <b>Recruitment Materials</b>	 View Document  <b>mccabe.pdf</b> (Recruitment Materials)
 <b>Survey Instruments</b>	 Compare to Prior Version  <b>mccabe.pdf</b> (Survey Instruments)
 <b>Site Permission Letter</b>	 Convert to Word  <b>r_mccabe.pdf</b> (Site Permission Letter)

- Instructions/Insights:
  - Once uploaded, all the documents are listed at the bottom of the Protocol Page.
  - Further options are available by selecting the paper icon to the left

# Accessing Application Forms

## Test Exempt Waiver of Documentation of Consent Survey Research



**IF you are a new investigator (only)** please contact Sara Stevenson in the IRB office at [stevensonsm1@cofc.edu](mailto:stevensonsm1@cofc.edu) for guidance before you go too far into the protocol submission process.

**Required questions not answered**

Submit Protocol for Review

Tracking Status: No Status Recorded

Select Application Forms in either location to complete the rest of the IRB application



➔ **Application Forms**

Protocol ID	17
PI	Sara Stevenson (Click here to view PI Docs)
PI Type	General Faculty
Review Type	Exempt Review
Approval Status	Exempt Review Requested
Based On	(2) Tests, Surveys, Interviews
Submitted By	Sara Stevenson
Proposed Start Date	01/13/2021
End Date	01/13/2022
Consent Waived	Not Requested
Waiver of Documentation of Informed Consent	Requested
Number of Subjects	50



➔ **Application Forms**

Upload Docs

Approved Consent Form	01/06/2021	consent form (Approved Consent Form)
Recruitment Materials	01/06/2021	recruit_mccabe.pdf (Recruitment Materials)
Survey Instruments	01/06/2021	survey_mccabe.pdf (Survey Instruments)
Site Permission Letter	01/06/2021	coopletter_mccabe.pdf (Site Permission Letter)



Application Sections can be expanded by pressing on the two arrows. Additional application may appear depending on the answers provided in the basic information section. Sections with unanswered questions will be marked in red.

CITI Program Certification can be found under Personnel tab. This data is uploaded directly from CITI each night. Please contact [compliance@cofc.edu](mailto:compliance@cofc.edu) if your CITI certification does not appear here. Additional personnel can also be added to the protocol here

## Application Forms

[View Protocol Page](#)

### Test Exempt Waiver of Documentation of Consent Survey Research

PI: Sara Stevenson

☐ Expand All Sections

» Protocol Outline **Required Questions Unanswered: 16**

» Waiver of Documentation of Informed Consent **Required Questions Unanswered: 1**

» Personnel

- Instructions/Insights:
  - Once you Select Application Sections, this screen will appear.
  - Press on the two areas to expand the application questions.
  - You can see how many questions are unanswered in each section, in red.

# Personnel Application Section

CITI Program Certification can be found under Personnel tab. This data is uploaded directly from CITI each night. Please contact [compliance@cofc.edu](mailto:compliance@cofc.edu) if your CITI certification does not appear here. Additional personnel can also be added to the protocol here

## Personnel

Add Personnel

Edit Section Data

### PI

Sara Stevenson (01/05/2021)

### PI Documents

- IRB Human Subjects Training Certification

#### Curriculum/Group/Stage

Basic/Refresher Course - Human Subjects Research / Research with Vulnerable Participants / 1 12/12/2021

Basic/Refresher Course - Human Subjects Research / Research in Schools / 1 12/11/2021

Basic/Refresher Course - Human Subjects Research / Research with Children (outside school) / 1 12/11/2021

Social Behavioral and Education (SBE) Researchers/RCR / Social Behavioral and Education (SBE) Researchers/RCR / 1 12/05/2021

# Personnel Application Section

- Instructions/Insights:

- The Personnel section also includes the CITI Training certificates for each of the personnel listed on the protocol.
  - This information is refreshed overnight. Please wait 24 hours after completing the CITI training for the certificates to be listed in this section.
- CITI Training must have been completed under the College of Charleston affiliation in order to be sent to this section of the application.
  - If completed under another affiliation, contact [compliance@cofc.edu](mailto:compliance@cofc.edu).

# Complete the Application sections; once complete select View Protocol Page

Application Forms

[View Protocol Page](#)

Test Exempt Waiver of Documentation of Consent Survey Research

PI: Sara Stevenson

☒ Expand All Sections

 Protocol Outline

Date Last Updated: 01/06/2021 2:11 PM EST

 You have answered all questions in this Survey.



## \* Rationale, Objectives and Significance

Provide a brief statement:

**Answer:** Suggested Word Count Limit: 750, Current Word Count: 4

brief statement goes here

[Reader Comments](#)


 

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

**Answer:** Suggested Word Count Limit: 750, Current Word Count: 4

these are the benefits

[Reader Comments](#)



## \* Methods and Procedures


What will the participants do, and/or what will be done to them?

Include a description of the research participant population(s).

**Answer:** Suggested Word Count Limit: 750, Current Word Count: 13

methods and procedures should be outlined here, including a description of the population

[Reader Comments](#)



\* 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."

**Answer:** Yes

☒ No

- Instructions/Insights:
  - Select Edit Answer to start application sections.
  - You can go back and edit each section at any time or can complete it at once.

# And “Submit Protocol for Review” once complete

EditUpload DocsPrint / Zip

Messages (0) | Back

Test Exempt Waiver of Documentation of Consent Survey Research

**IF you are a new investigator (only)** please contact Sara Stevenson in the IRB office at [stevensonsm1@cofc.edu](mailto:stevensonsm1@cofc.edu) for guidance before you go too far into the protocol submission process.

Submit Protocol for Review

Tracking Status: No Status Recorded


This action will formally submit your Protocol to the IRB.  
Continue?

CancelOK

- Instructions/Insights:
  - Go through all the application sections.
  - Once all the sections are complete, select “Submit Protocol for Review”

# Should see the status change in Axiom Mentor and received email confirmation of submission

Tracking Status: Submitted to the IRB

 Protocol Submitted

- Instructions/Insights:
  - Once submitted, you will receive an email confirmation of the submission to the IRB

## PI Confirmation of Submission - IRB ID: 17



**Research Compliance** <noreply@axiommentor.com>

To: Stevenson, Sara M.

# If revisions are requested: you will be notified via email after the review

*College of Charleston IRB*

*Protocol Revisions Required*

To: Sara Stevenson

From: Sara Stevenson, IRB Coordinator

Subject: Protocol #10

Date: 01/06/2021

The following revisions are requested by the IRB to your protocol 10 - Understanding Communication about Childhood Vaccinations.

Test test test

If you have any questions, please feel free to contact me.

Sara Stevenson  
Research Compliance Coordinator  
[stevensonsm1@cofc.edu](mailto:stevensonsm1@cofc.edu)


- Instructions/Insights:
  - After submission and review, it is possible/likely that revisions will be requested.
  - If so, you will receive an email outlining the requested changes.
  - Go to the My Protocols page to open and edit the protocol as requested.


# Revisions Required of PI


IRB


IRB Admin


IRB Setup


 Info Page


 Documentation


 My Protocols


 Protocol Reports

 Student Protocols

 Reviewer

 CITI Certification

 Meetings

 IRB Members

Create New Protocol

My Protocols

Next Meeting:

Deadline for Submission:

IRB ID

Status

I am the PI or Research Assistan

Submitted

IRB # ^	Title	PI	Approved	A.R. Due	Tracking Status
1	Title goes here	Sara Stevenson	Approval Expired	04/04/19	02/21/20
2	Title 2	Sara Stevenson			
3	title here	Sara Stevenson			
4	Descriptive Title	Sara Stevenson			
8	Experiences with Online Learning an...	Sara Stevenson	04/18/20		Approved
10	Understanding Communication about C...	Sara Stevenson	Revisions Required		Pending PI Revisions
12	The Development and Evaluation of a...	Sara Stevenson	12/10/20		Approved
15	The Development and Evaluation of a...	Maggie McCabe			Waiting for Faculty Sponsor Approval

Page 1 of 1

- Instructions/Insights:
  - It will be easy to see, as it will be highlighted and the status will say “Revisions Required”



# Email to PI

*College of Charleston IRB*

*Protocol Revisions Required*

To: Sara Stevenson

From: Sara Stevenson, IRB Coordinator

Subject: Protocol #10

Date: 01/06/2021

The following revisions are requested by the IRB to your protocol 10 - Understanding Communication about Childhood Vaccinations.

Test test test

If you have any questions, please feel free to contact me.

Sara Stevenson  
Research Compliance Coordinator  
[stevensm1@cofc.edu](mailto:stevensm1@cofc.edu)


- Instructions/Insights:
  - They will receive an email that looks like this


# Revisions Required of PI


IRB


IRB Admin


IRB Setup


 Info Page


 Documentation


 My Protocols


 Protocol Reports

 Student Protocols

 Reviewer

 CITI Certification

 Meetings

 IRB Members

Create New Protocol

My Protocols

Next Meeting:

Deadline for Submission:

IRB ID

Status

I am the PI or Research Assistan

Submitted

IRB #	Title	PI	Approved	A.R. Due	Tracking Status
1	Title goes here	Sara Stevenson	Approval Expired	04/04/19	02/21/20
2	Title 2	Sara Stevenson			
3	title here	Sara Stevenson			
4	Descriptive Title	Sara Stevenson			
8	Experiences with Online Learning an...	Sara Stevenson	04/18/20		Approved
10	Understanding Communication about C...	Sara Stevenson	Revisions Required		Pending PI Revisions
12	The Development and Evaluation of a...	Sara Stevenson	12/10/20		Approved
15	The Development and Evaluation of a...	Maggie McCabe			Waiting for Faculty Sponsor Approval

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Last

- Instructions/Insights:
  - And their protocol will be highlight and the status “Revisions Required”

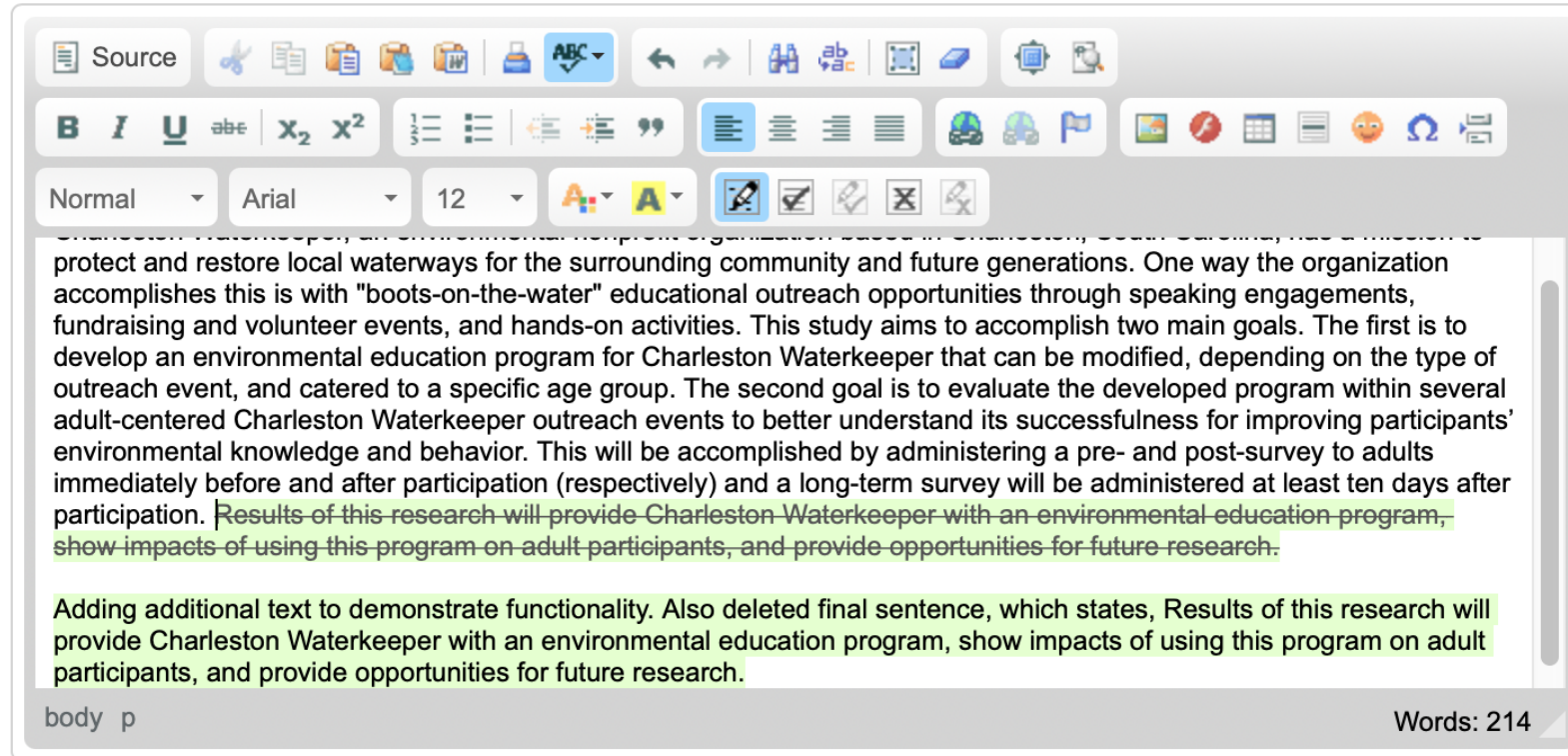
# Changes to the protocol

## \* Rationale, Objectives and Significance

Provide a brief statement:

Suggested Word Count Limit: 750

Answer:



The screenshot shows a text editor interface. At the top is a rich text toolbar with various icons for text formatting (bold, italic, underline, text color, background color, font size, font family), alignment, bulleted and numbered lists, indentation, link, unlink, and other functions. Below the toolbar is a text area containing a paragraph of text. The text is as follows:

Charleston Waterkeeper, an environmental nonprofit organization based in Charleston, South Carolina, has a mission to protect and restore local waterways for the surrounding community and future generations. One way the organization accomplishes this is with "boots-on-the-water" educational outreach opportunities through speaking engagements, fundraising and volunteer events, and hands-on activities. This study aims to accomplish two main goals. The first is to develop an environmental education program for Charleston Waterkeeper that can be modified, depending on the type of outreach event, and catered to a specific age group. The second goal is to evaluate the developed program within several adult-centered Charleston Waterkeeper outreach events to better understand its successfulness for improving participants' environmental knowledge and behavior. This will be accomplished by administering a pre- and post-survey to adults immediately before and after participation (respectively) and a long-term survey will be administered at least ten days after participation. Results of this research will provide Charleston Waterkeeper with an environmental education program, show impacts of using this program on adult participants, and provide opportunities for future research.

Adding additional text to demonstrate functionality. Also deleted final sentence, which states, Results of this research will provide Charleston Waterkeeper with an environmental education program, show impacts of using this program on adult participants, and provide opportunities for future research.

body p

Words: 214

- Instructions/Insights:
  - Any changes to the application will be tracked

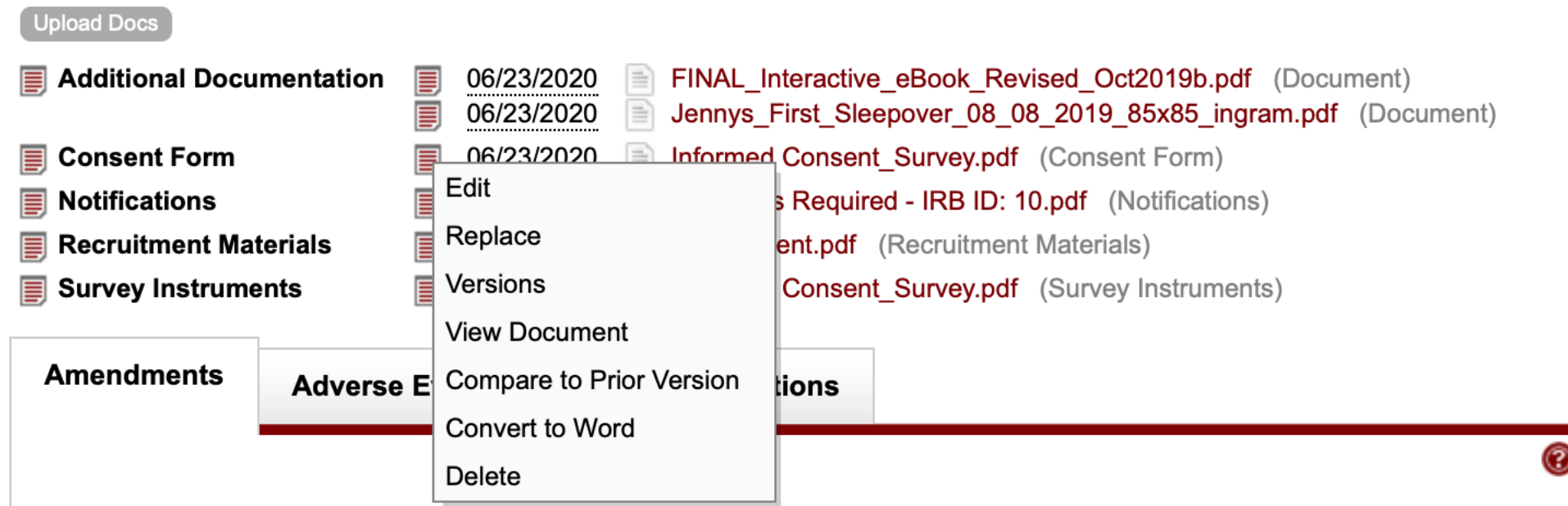
Save Answers

Cancel

# Changing/editing uploads:

Replace or edit any attachment by clicking on paper icon to left and choose from menu option

Version histories are saved, and different versions can be compared by reviewers



- Instructions/Insights:
  - You can also replace and edit attachments, and compare versions

# Select “Submit Revisions to Review”

## The Development and Evaluation of an Environmental Education Program within a Nonprofit Organization



***IF you are a new investigator (only)*** please contact Sara Stevenson in the IRB office at [stevensonsm1@cofc.edu](mailto:stevensonsm1@cofc.edu) for guidance before you go too far into the protocol submission process.

☐ Submit Revisions for Review

Tracking Status: Pending PI Revisions



Protocol Review Assignment

# Open protocol, make requested changes, and submit

## Application Forms

[View Protocol Page](#)

### Understanding Communication about Childhood Vaccinations

PI: Sara Stevenson

☐ [Submit Revisions for Review](#)

☐ Expand All Sections

Protocol Outline

Date Last Updated: 06/23/2020 4:12 PM EDT

Are you ready to submit your revisions to the IRB?

Cancel

OK

- Instructions/Insights:
  - Once you address all the requested revisions, you will then select “Submit revisions for review”

# Once approved, you will be notified via email

## Expedited Review Approved by Chair - IRB ID: 10



Research Compliance <noreply@axiommentor.co...>

Today at 12:58 PM

To: Stevenson, Sara M.

College of Charleston IRB

Approval Notification

To: Sara Stevenson

From: Sara Stevenson, IRB Coordinator

Subject: Protocol #10

Date: 01/06/2021

The protocol **Understanding Communication about Childhood Vaccinations** has been approved by the IRB Chair under the rules for expedited review on **01/06/2021**.

Annual Review and Final Report are not required for minimal risk research which is not federally funded and has been approved following Expedited Review, unless otherwise specified by the IRB. If changes in the protocol, whether major or minor, are required, a Protocol Modification must be submitted and approved by the IRB before the changes may be implemented.

If the project will continue beyond No Expiration Date, a request for continuation or continuation with modification must be submitted and approved by the IRB. Protocol continuation includes the data analysis phase after data collection is complete.

If any adverse events or unanticipated problems involving risks or injury to the participants or other persons occur at any time during the study, such events or problems must be immediately reported to the IRB through the Research Compliance Coordinator and to the cognizant administrator (department chair, dean, or unit director).

If you have any questions, feel free to contact me.

Sara Stevenson  
Research Compliance Coordinator  
[stevensonsm1@cofc.edu](mailto:stevensonsm1@cofc.edu)

- Instructions/Insights:
  - Finally, once approved, you will receive an email with the approval letter.
  - The approval letter will also contain an updated consent form PDF, which will include the IRB approval stamp.

# IRB Application Instructions for Faculty Sponsors





*IMPORTANT NOTE: FACULTY SPONSOR ACTION  
IS REQUIRED IN ORDER FOR THE STUDENT TO  
SUBMIT AN APPLICATION TO THE IRB*

# When to Submit to the IRB

<http://research.cofc.edu/administration/documents/policies-documents/irb-guidance-students-as-researchers.php>

**INDIVIDUAL RESEARCH PROJECTS** require IRB review and approval. This includes:

- undergraduate bachelor's essays,
- capstone or senior research projects, graduate thesis research, and
- independent studies

**RESEARCH PRACTICA OR COURSE-BASED RESEARCH:** IRB review and approval is **not required** *unless* study subjects include persons who are not enrolled in the course and/or departmental research participant pool and involve:

- Minors or other special or vulnerable populations whose ability to give informed consent may be compromised,
- a topic of a sensitive nature, the examination or reporting of such may place the participant at more than minimal risk, or
- any type of activity that places the participant at more than minimal risk.

# Protocols for Research Methods Class ONLY

(does not require IRB review)

- You may use the Axiom Mentor system for class projects by following the directions below to review student applications.
- The final step, submitting to the IRB, is not required unless the research meets the criteria.
- Any student protocols not submitted to the IRB will be deleted from the system at the end of each term.

# Student Protocols-Faculty Sponsor

IRB



Info Page



Documentation



My Protocols



Protocol Reports



Student Protocols



Reviewer



CITI Certification



Meetings

## Student Protocols

Next Meeting:

Deadline for Submission:

Protocol Status



Acceptance Status



IRB Number	Title	PI	Status	Approved	A.R. Due
15	The Development and Evaluation of a...	Maggie McCabe	Exempt Review Requested		

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Last

- Instructions/Insights:
  - If you are a faculty sponsor, you will find the student protocols in the Left Navigation menu.
  - Then press on the title to review and submit.

# Student Protocol Page

- Info Page
- Documentation
- My Protocols
- Protocol Reports
- Student Protocols**
- Reviewer
- CITI Certification
- Meetings

[Edit](#) [Upload Docs](#) [Faculty Sponsor Action](#) [Print / Zip](#)

[Messages \(0\)](#) | [Back](#)

## The Development and Evaluation of an Environmental Education Program within a Nonprofit Organization

**IF you are a new investigator (only)** please contact Sara Stevenson in the IRB office at [stevensonsm1@cofc.edu](mailto:stevensonsm1@cofc.edu) for guidance before you go too far into the protocol submission process.

Protocol not yet submitted to Faculty Sponsor.

Tracking Status: Waiting for Faculty Sponsor Approval

### Application Forms

Protocol ID	15
PI	Maggie McCabe (Click here to view PI Docs)
PI Type	Student
Faculty Sponsor	Tracey Hunter-Doniger (Click here to view PI Docs) 12/09/2020
Faculty Sponsor Acceptance Status	Not Yet Accepted
Co-PI's	Sara Stevenson (Click here to view PI Docs) 12/09/2020 (Can Edit)
Review Type	Exempt Review
Approval Status	Exempt Review Requested
Based On	(2) Tests, Surveys, Interviews
Submitted By	Sara Stevenson
Proposed Start Date	01/01/2020
End Date	12/31/2020
Consent Waived	Not Requested
Waiver of Documentation of Informed Consent	Not Requested
Number of Subjects	300

### Application Forms

[Upload Docs](#)

Recruitment Materials	12/10/2020	<a href="#">recuit_mccabe.pdf</a> (Recruitment Materials)
Survey Instruments	12/10/2020	<a href="#">survey_mccabe.pdf</a> (Survey Instruments)
Site Permission Letter	12/10/2020	<a href="#">coopletter_mccabe.pdf</a> (Site Permission Letter)
Additional Documentation	12/10/2020	<a href="#">facultysponsor_mccabe.pdf</a> (Document)
Consent Form	12/10/2020	<a href="#">consent_mccabe.pdf</a> (Consent Form)
Notifications	12/10/2020	<a href="#">Inform Faculty Sponsor of Student Protocol - IRB I...</a> (Notifications)

- Instructions/Insights:
  - You can view the protocol by selection Application Forms and the Uploads by clicking on the upload name

View all sections of application by selecting Application Forms and by opening and reviewing the Uploads

# You can request revisions on any response or edit it directly yourself. Version changes are tracked.

**\* Rationale, Objectives and Significance**

Provide a brief statement:

**Answer:** *Suggested Word Count Limit: 750, Current Word Count: 174*

Charleston Waterkeeper, an environmental nonprofit organization based in Charleston, South Carolina, has a mission to protect and restore local waterways for the surrounding community and future generations. One way the organization accomplishes this is with "boots-on-the-water" educational outreach opportunities through speaking engagements, fundraising and volunteer events, and hands-on activities. This study aims to accomplish two main goals. The first is to develop an environmental education program for Charleston Waterkeeper that can be modified, depending on the type of outreach event, and catered to a specific age group. The second goal is to evaluate the developed program within several adult-centered Charleston Waterkeeper outreach events to better understand its successfulness for improving participants' environmental knowledge and behavior. This will be accomplished by administering a pre- and post-survey to adults immediately before and after participation (respectively) and a long-term survey will be administered at least ten days after participation. Results of this research will provide Charleston Waterkeeper with an environmental education program, show impacts of using this program on adult participants, and provide opportunities for future research.

**Reader Comments**

☐ Request Revisions

Edit Answer

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

**Answer:** *Suggested Word Count Limit: 750, Current Word Count: 90*

This research will provide Charleston Waterkeeper with an environmental education program that the organization can modify, depending on the type of outreach event, and cater to a specific age group. It will also provide insight into the effectiveness of the developed program for improving adult participants' environmental knowledge and behavior. With information obtained from this research, Charleston Waterkeeper will be able to better serve its target population (individuals and communities living in the Tri-County region) by enhancing the implementation of these events and improving the content relayed to adult participants.

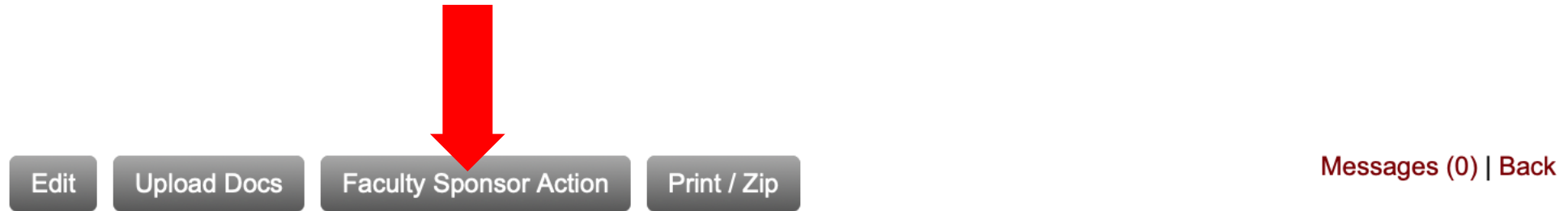
**Reader Comments**

☐ Request Revisions

Edit Answer

- Instructions/Insights:
  - Select the Request Revisions section to open a box to describe requested revisions.
  - Or edit them directly by selecting "Edit Answer"

Once the review of the student application is complete, select the Faculty Sponsor Admin button



The Development and Evaluation of an Environmental Education Program within a Nonprofit Organization

And select the appropriate response from the dropdown box.

### Faculty Sponsor Action

Acceptance Status

✓ Not Yet Accepted

Faculty Sponsor Revisions Required

Accepted

Rejected

- Instructions/Insights:
  - Choose the appropriate option from the drop down menu



THE STUDENT APPLICATION IS ONLY  
SUBMITTED TO THE IRB ONCE YOU HAVE  
ACCEPTED AND PRESS “UPDATE STATUS”

### Faculty Sponsor Action

Acceptance Status

Update Status

Cancel

Tracking Status: Submitted to the IRB

- Instructions/Insights:
  - If it is complete and ready to be submitted to the IRB, select “Accepted” then “Update Status,” which will then submit it to the IRB

If unsure if IRB review is required, you can submit the application to IRB for staff review

- After review of the protocol, IRB staff can change the review type if necessary
- ORGA staff can change the review to “non-human subjects research,” if no further review is required

# Non-HSR Determination Notification sent

*College of Charleston IRB*

*IRB Review Not Required*

To: Jamileh Soueidan

From: Sara Stevenson, IRB Coordinator

Subject: Protocol #6

Date: 01/25/2021

The protocol **6. Title Goes Here** has been reviewed by the IRB coordinator and found not to require further IRB review or oversight.

Please note that changes to your protocol may affect its this determination. Please contact me directly to discuss any changes you may contemplate.

Thanks,


- Instructions/Insights:
  - If deemed Non-HSR, a notification will be sent to PI and faculty advisor


# Status Updated in Student Protocols


IRB


IRB Admin


IRB Setup


 Info Page


 Documentation


 My Protocols


 Protocol Reports

 Student Protocols

 Reviewer

 CITI Certification

 Meetings

 IRB Members

## Student Protocols

Next Meeting:  
Deadline for Submission:

Protocol Status – Show all statuses –

Acceptance Status Not Yet Accepted

IRB Number	Title	PI	Status	Approved	A.R. Due
6	Title Goes Here	Jamileh Soueidan	Non-Human Subjects Research Verified		
7	Vulnerable Populations	Jamileh Soueidan	New - Full Board Review		

Page 1 of 1 First Prev Next Last

- Instructions/Insights:
  - If no IRB review is required, the status in the Student Protocols section will state, “Non-human subjects research verified”

# Researcher Amendment Submission Instructions



# Amendments/Modifications

Amendments

Adverse Events

Protocol Deviations

Create New Amendment

Create New Amendment

Cancel

## Create New Amendment



This form will create a new Amendment. You will be prompted after the Amendment record is created to provide additional information and/or file uploads.

Protocol Title The Development and Evaluation of a...

Amendment Type ☐ Personnel Changes  
☐ Minor Changes to Study Procedures  
☐ Significant Changes to Study Procedures


Select Application Forms you wish to revise

☐ Protocol Outline

Create Amendment

Cancel

- Instructions/Insights:
  - Open the Protocol from the My Protocols page.
  - Then select Amendments at the bottom of the protocol page and select "Create New Amendment"
  - Check the applicable boxes and create the amendment.
  - If you need to edit the application, check the box


Status		Type	Status Date
 2	01/07/2021	New - Not Yet Submitted Personnel Changes, Minor Changes to Study Procedures	


Submit

Edit Application Forms  
Amendment Summary



Print Messages (0)

 Protocol Outline	Date Last Updated: 01/07/2021 10:04 AM EST
--	--

 You have answered all questions in this Survey.

**\* Rationale, Objectives and Significance**

Provide a brief statement:

**Answer:** *Suggested Word Count Limit: 750, Current Word Count: 185*


Charleston Waterkeeper, an environmental nonprofit organization based in Charleston, South Carolina, has a mission to protect and restore local waterways for the surrounding community and future generations. One way the organization accomplishes this is with "boots-on-the-water" educational outreach opportunities through speaking engagements, fundraising and volunteer events, and hands-on activities. This study aims to accomplish two main goals. The first is to develop an environmental education program for Charleston Waterkeeper that can be modified, depending on the type of outreach event, and catered to a specific age group. The second goal is to evaluate the developed program within several adult-centered Charleston Waterkeeper outreach events to better understand its successfulness for improving participants' environmental knowledge and behavior. This will be accomplished by administering a pre- and post-survey to adults immediately before and after participation (respectively) and a long-term survey will be administered at least ten days after participation. Results of this research will provide Charleston Waterkeeper with an environmental education program, show impacts of using this program on adult participants, and provide opportunities for future research.

Testing editing the protocol through the amendment function. Just a test.

Versions 01/07/2021 10:04 AM EST Reader Comments

Edit Answer

- Instructions/Insights:
  - Select Edit Application Forms to edit the existing application, if necessary.
  - Changes will be tracked.

Status		Type	Status Date
 2	01/07/2021	New - Not Yet Submitted Personnel Changes, Minor Changes to Study Procedures	

Submit

Edit Application Forms

Print Messages (0)

Amendment Summary



Amendment Summary

1. Summary	Type: Short answer	Required
<p>* Please provide a summary of the changes and a rationale for each change:</p>		
<p>Answer</p>		

- Instructions/Insights:
  - Click on Amendment Summary to submit a summary of changes to the IRB.
  - Select Answer to open the text box.




## Amendments

## Adverse Events

## Protocol Deviations

Create New Amendment

	Status	Type	Status Date
 2 01/07/2021	New - Not Yet Submitted	Personnel Changes, Minor Changes to Study Procedures	

Submit

Edit Application Forms

Print Messages (0)

Amendment Summary 

 Consent Form - Final Version

 Consent Form - Track Changes

 New Site Approvals

 New/Revised Recruitment Materials

 Revised Survey/Questionnaire/Interview

- Instructions/Insights:
  - Then select "Submit" and confirm

Create New Amendment

You are about to submit this amendment.  
Would you like to proceed?

Submit

Edit App

Amendment Summary 

 Consent Form - Final Version

Cancel

OK

# IRB Member/Administrator Amendment Review Instructions



# Email notification

*College of Charleston IRB*

*Reviewer Assigned Notification*

To: Sara Stevenson

From: Sara Stevenson, IRB Coordinator

Subject: Protocol #16

Date: 01/13/2021

You have been assigned to review protocol #16. **Effect of body size on thirst and urine concentration in humans.**

You will find this protocol listed on the Reviewer page under the IRB tab in Mentor. Alternatively, you can click on this link to access the protocol directly:

[https://www.axiommentor.com/login/authkey.cfm?  
i=cofc&key=7q4xtD9wtHz5TFLqyw5QjPGA85zA0JhCqTQNXtjCtCxIVdTkEmaqxdP98XXgNJU3](https://www.axiommentor.com/login/authkey.cfm?i=cofc&key=7q4xtD9wtHz5TFLqyw5QjPGA85zA0JhCqTQNXtjCtCxIVdTkEmaqxdP98XXgNJU3)

When the protocol loads, scroll to the bottom to find the Amendments tab.

Your review is due on 01/20/2021


If you have any questions, feel free to contact me.


# Reviewer View


IRB


IRB Admin


IRB Setup


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## Review Protocols

Review Status

Pending

P.I.

Search

Review type

All

IRB ID

Search

IRB Number	Title	PI	Status	Review Role / Review Type	Date Assigned
12	The Development and Evaluation of a...	Sara Stevenson	Exemption Verified	• Primary Reviewer (P) Amendment	01/07/2021

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- Instructions/Insights:
  - Return to the Reviewer tab in the left navigation menu.
  - Press on the protocol title to view full protocol

# Press the Icon to view the full amendment, or the Application Forms and Amendment Summary Links

Amendments

Adverse Events

Protocol Deviations

	Status	Type	Status Date
<div><div></div>2</div> 01/07/2021	New - Submitted: 01/07/2021	Personnel Changes, Minor Changes to Study Procedures	

Edit Application Forms

Amendment Summary ✓

Print

Messages (0)

Reviewers

Primary Reviewer Eileen Callahan / Pending / 01/14/2021 5:00 PM EST

Review

# View changes to protocol sections, highlighted in green


Application Forms: Amendment

[View Protocol Page](#)

## The Development and Evaluation of an Environmental Education Program within a Nonprofit Organization

PI: Sara Stevenson

☐ Expand All Sections

 Protocol Outline	Date Last Updated: 01/07/2021 10:04 AM EST
<div><div><b>Rationale, Objectives and Significance</b></div><div>Provide a brief statement:</div><div><b>Answer:</b> <i>Suggested Word Count Limit: 750, Current Word Count: 185</i></div><div>Charleston Waterkeeper, an environmental nonprofit organization based in Charleston, South Carolina, has a mission to protect and restore local waterways for the surrounding community and future generations. One way the organization accomplishes this is with "boots-on-the-water" educational outreach opportunities through speaking engagements, fundraising and volunteer events, and hands-on activities. This study aims to accomplish two main goals. The first is to develop an environmental education program for Charleston Waterkeeper that can be modified, depending on the type of outreach event, and catered to a specific age group. The second goal is to evaluate the developed program within several adult-centered Charleston Waterkeeper outreach events to better understand its successfulness for improving participants' environmental knowledge and behavior. This will be accomplished by administering a pre- and post-survey to adults immediately before and after participation (respectively) and a long-term survey will be administered at least ten days after participation. Results of this research will provide Charleston Waterkeeper with an environmental education program, show impacts of using this program on adult participants, and provide opportunities for future research.</div></div>	
<div>Testing editing the protocol through the amendment function. Just a test.</div>	
<div><div>Versions</div><div>01/07/2021 10:04 AM EST</div><div>Reader Comments</div></div>	

- Instructions/Insights:
    - Press Edit Application Summary to view application sections

# Amendment Summary

## 12. The Development and Evaluation of an Environmental Education Program within a Nonprofit Organization

### Amendment Summary

1. Summary	Type: Short answer	Required
Please provide a summary of the changes and a rationale for each change:		
<b>Answer:</b> test amendment sample		
<a href="#">Reader Comments</a>		

- Instructions/Insights:
  - View the amendment summary by pressing on the link on the protocol page


# Press Review

**Amendments**

**Adverse Events**

**Protocol Deviations**



	Status	Type	Status Date
 2 01/07/2021	New - Submitted: 01/07/2021	Personnel Changes, Minor Changes to Study Procedures	

[Edit Application Forms](#)

[Print](#) [Messages \(0\)](#)

[Amendment Summary](#) ✓

## Reviewers

Primary Reviewer Eileen Callahan / Pending / 01/14/2021 5:00 PM EST

[Review](#)





# The Development and Evaluation of an Environmental Education Program within a Nonprofit Organization



## Amendment Review Assignment

Reviewer Eileen Callahan (Primary Reviewer)

Review Status: Completed

Due Date 01/14/2021 5:00 PM EST

Reviewer General Comments:

- Instructions/Insights:
  - Change review status once complete, include comments with review:
    - Approve, approve with stipulations, etc.

### Amendments

### Adverse Events

### Protocol Deviations

		Status	Type	Status Date
	2 01/07/2021	New - Submitted: 01/07/2021	Personnel Changes, Minor Changes to Study Procedures	

[Edit Application Forms](#)

[Print](#) [Messages \(0\)](#)

[Amendment Summary](#) ✓

### Reviewers

Primary Reviewer Eileen Callahan / **Completed** / 01/14/2021 5:00 PM EST



01/07/2021



[Primary Reviewer Review Notes.pdf](#)