IRB eForm Questions

Last updated: 12/18/2023

Instructions for this document:

- Each Application eForm section is underlined and bolded.
- Application questions are bolded.
- Addition guidance for the application question in italics.
- Application navigation instructions in blue.

“Create IRB Protocol”- Basic Protocol Information (required for all applications)

Appears whenever you press “Create New Protocol” button at the top of the page while under the “My Protocols” tab.

PI: *automatically populates with your name*
Co-PI's: *Add Internal Collaborators by typing first letters of last name and select from popup list, then click "Add"*
External PIs: *Provide name, email, and institution*
Research Assistants: *Add student research assistants by typing first letters of last name and select from popup list, then click "Add"*
Protocol Title*: Make sure this is descriptive of your project*
Proposed Start Date:
End Date:
Funding Source:
Grant Number:
Review Type (Drop Down menu)
-Full Board Review
-Exempt Review: 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
-Expedited Review: 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
-Non-Human Subjects Research. *Note that application sections will be different and shorter if you select this option. This will only ask four questions to confirm this is non-HSR. The full application form questions will appear if deemed necessary based on your response to these questions.*

Waiver of Informed Consent: Drop down menu.
Not Requested

Yes- Request Waiver. *Select this option if you are waiving consent for any reason, including if you are only using pre-existing data and will not be recontacting research participants.*

Yes- Request Modification for deception. *Select this option only if your research involves deception.*

Waiver of Documentation of Informed Consent

Not Requested

Requested. *This is appropriate if you are obtaining consent orally. For example, oral consent collected for Zoom interview procedures.*

Subjects: Check boxes, check all that apply. Can leave all unselected if not applicable.

Cognitively Impaired

Fetuses

Minors (under age 18)

Prisoners

Students

Other Subjects Type: *Fill in the blank if working with a special or potentially vulnerable population.*

Number of Subjects:

Searchable Keywords

Upload Protocol Description*: If the IRB application is related to external funding, upload the description of the research as submitted for the grant application.*

Upload Consent Form: *You may upload this document now, or later when promoted in the Application Forms*

Message to IRB: *No response required here unless there's extra information you want IRB staff to know (e.g., of a pressing deadline).*

Press "Save" at the bottom of this screen to continue.

You will now be on the **Protocol Home Page**.

Additional upload can be provided from here by selecting the "Upload Docs" button at the top of the page, above your protocol's title. You can also upload these documents when prompted in the Application Forms.

Application Forms

Access these questions by pressing the "Application Forms" text in red, next to the green arrows, located above and below the basic protocol information.

Protocol Narrative (required for all applications)

Press the arrows next to this section header to see all the questions.

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

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

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.

Provide the survey instrument type(s) you will be using for data collection and upload a PDF or Word version of each survey instrument selected.

Muti-select Options:

- Survey questionnaire. Upload a copy of the document and provide the survey platform in the explanation prompt.
- Interview questions/prongs. Upload a copy of the document and provide the interview location(s) in the explanation prompt.
- Focus Group questions/prongs. Upload a copy of the document and provide the focus group location(s) in the explanation prompt.
- Other (this includes pre- and post- testing, biometric data collection, etc.), describe in Methods and Procedures section.
- None, pre-existing data only.

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."
Options:

- Yes- *Explanation prompt*: **Describe the risks and the precautions that will be taken to minimize those risks:**
- No

If you have conducted prior research that bears on the risk-benefit ratio of this study, please provide a brief summary of the methods and results. If not, please enter 'NA'.

How will interviewers or data collectors be trained? *All investigators should have taken CITI training at a minimum. You can also provide other relevant training, courses taken or experiences here in addition to the CITI training.*

Participant Information:
Provide a description of the research participant population(s).

Does the research population include any of the following? Check all that apply.
Options (check all that apply): Additional application sections will appear if you select any of the first four options listed here.

1.Students
2.Minors (under age 18)
3.Employees
4.Other populations needing special protections, such as: Native Americans, undocumented immigrants, prisoners, cognitively impaired, fetuses, veterans, non-native English speakers, unhoused, etc.
5.None of the above

What is the expected time commitment for the participants?

Describe benefits which are likely to accrue to the participant. If none, please enter 'none'.

Preferred Number of Participants:
Minimum Number of Participants:
Maximum Number of Participants:

Will participants receive payment, extra credit points, or other form of compensation for participation?
Options:

- Yes- If you provide a monetary (cash, gift, or certificate) incentive for research participants, you must submit each participant's name to the College of Charleston Controller's office. You may download the Participant Compensation form here. For student participants, notification must also be sent to College of Charleston's Financial Aid office. Any amount a student receives from any source of $10 or more is added to the student's annual income record for financial aid accounting.
  - *Explanation prompt:* **State the amount, form, and conditions for payment/compensation.**
- No

Will you be recruiting participants? *Be as detailed as possible. If using social media, name the social media platforms and the specific groups you will be targeting. Also, provide if those platforms and groups are private or publicly accessible.*
Options:

- 1.Yes. *Explanation prompt:* **Describe in detail how the human participants will be recruited AND upload a copy of the recruitment document to the application.**
- 2.No, pre-existing data only. *Explanation prompt:* **Explain how dataset will be obtained.**

Are you recruiting participants through (or using the resources of) an institution, organization, or business other than the College of Charleston?
You will need to upload a copy of the site permission letter if you select yes.
Options:

- Yes- *Explanation prompt:* **Provide both the name and address for each institution involved.**
- No

Privacy and Confidentiality:
Will the participants be identifiable at any time during the research process, including research documents or recordings?
Options:

- Yes- *Explanation prompt:* **describe the procedures to assure confidentiality.**
- No- *Explanation prompt:* **describe the procedures to assure anonymity.**

Will the participants be identifiable in the final research record or database? *See the Data Security SOP for best practices.*
Options:

- Yes- *Explanation prompt:* **describe the procedures you will use to assure confidentiality unless participants have given permission to use their identities. If your research involves audio/video recordings, provide information about how recorded materials will be securely shared, stored, transcribed and deleted.**
- No- *Explanation prompt:* **provide information about when, how, and by whom the data will be de-identified (anonymized) including when audio/video recordings will be deleted.**

Consent Information:
Does the research involve deception?
Options:

1.Yes Deception application section will appear if you select yes to this question.
2.No

How will you obtain informed consent?

Note: You must use the informed consent templates from the IRB webpage. Will be prompted to upload a copy of the informed consent document. Use the hyperlinks to access the appropriate template.
Options:

1. Pre-existing de-identified data only. No informed consent or waiver required.
2. Anonymous survey consent. Use the Anonymous Survey Consent Template. No waiver required.
3. Signed consent. Consent form includes signature lines. No waiver requested. Use the templates on the IRB webpage.
4. Consent form will be presented orally or in written form without signature lines. Oral/verbal consent requested. Requires a waiver of signed consent. Use the templates on the IRB webpage. ***Waiver of signed consent*** *application section will appear if you select this option.*
5.
6. Waiver of some elements of informed consent requested. ***Waiver of consent*** *application section will appear if you select this option.*
7. Full waiver of informed consent requested. ***Waiver of consent*** *application section will appear if you select this option.*

End of Protocol Narrative section of the Application Forms.

Additional Application Form sections will appear based on your response in the Protocol Narrative.

Personnel (required for all applications)

- Continue to Personnel Section, required by all PIs. Press on the arrows next to the Personnel Text to answer these questions.
- Can also add additional personnel here by selecting "Add Personnel" button at the top right of this section.

Provide the PI's primary department, program, or major:
Provide the PI's position.
Options:

1. Roster Faculty
2. Instructor
3. Visiting Faculty
4. Adjunct Faculty
5. Librarian
6. Staff
7. Graduate Student
8. Undergraduate Student

End of Personnel Section. If no other sections are in the in the application forms, press the red text "View Protocol Page" located at the top or bottom right side of this webpage to return the Protocol Home Page.

If all questions in the eForm are answered, you press the "Submit Protocol for Review" button, located below the protocol title.

Additional Application Form Sections- Required when Applicable to your Research

The following sections will only appear if prompted by your previous responses. You will not be prompted to answer any of these sections unless it applies to your research.

Waiver of Informed Consent

This section will appear if you have requested a full or partial waiver of consent in the Application Forms or the Basic Protocol Information.

What is the specific modification you are requesting?

Options:

- Full Waiver of Informed Consent
- Modification of Specific Elements of Informed Consent. *Answer the prompt,* **Specify all details of requested waiver or modification(s) of informed consent.**

Explain why this study cannot practicably be carried out without the waiver/modification of informed consent.

Explain how this waiver/modification will not adversely affect the rights or welfare of the subjects.

Waiver of Signed Consent

This section will appear if you have requested a waiver of signed consent in the Application Forms or the Basic Protocol Information.

A waiver of signed consent is requested. A consent script or form shall be read and/or given to the participants. You must use one of the informed consent templates from the CofC IRB webpage with the signature lines removed.

Please select the appropriate category.

Options:

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern
- The research presents no more than minimal risk of harm to research participants and involves no procedures for which written consent is normally required outside of the research context.
- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
- If none of the above categories apply, then you are not eligible for a Waiver of Signed Consent

Modification of Informed Consent for Deception

This section will appear if you have indicated that deception is involved in the Application Forms.

Why is deception needed?

What information is being withheld or how are the participants being deceived or misled?

Describe the debriefing plan.

Student Participants

This section will appear if you have indicated you will be working with students in the Application Forms or the Basic Protocol Information.

The IRB strongly discourages faculty from using students currently enrolled in their courses as research participants in their own research project unless there are sound reasons. A problem with student participation in research conducted by the students' instructor is the possibility that their agreement to participate will not be freely given; that they will feel subtly coerced, even if that is not your intention. Students may volunteer to participate out of a belief that doing so will place them in good favor with the instructor (i.e., that participating will result in receiving better grades, recommendations, or the like), or that failure to participate will negatively affect their relationship with the faculty generally (i.e., by seeming "uncooperative"). For this reason, the IRB pays special attention to the potential for coercion or undue influence and researchers should consider ways to reduce or eliminate the possibility of exploitation/coercion.

Will the student participants be recruited from one or more classes?
Options:

- Yes- *Explanation prompt:* **What are the procedures to minimize perceived coercion?**
- No

Does the research involve pre-existing data?
Options:

- Yes- Class assignments from one or more of the research investigators. Data must be de-identified and used after the course grades are posted. *Explanation prompt:* **Describe what student will be used.**
- Yes- Other pre-existing data. *Explanation prompt:* **Describe what student will be used.**
- No

How will the students be recruited?
Options:

- No recruitment, pre-existing data only.
- Participants will be recruited from one or more of the research investigators' classes.
- Other recruitment.

Minors

This section will appear if you have indicated you will be working with minors in the Application Forms or the Basic Protocol Information.

Will parental permission and child assent documents be submitted with the application?
Options:

- Yes, all parental permission and child assent (if 7 years or older) documents that will be provided to the participants will be attached.
- No, waiver of parental permission is requested. Explanation prompt: **Explain why a waiver of parental permission is necessary.**

Vulnerable-Other

Does this project involve prisoners, fetuses, in vitro fertilization, veterans of wars after WWII, or persons with reduced ability to give consent (e.g., institutionalized elderly, mentally incapacitated persons)?
Options:

- Yes- Explanation prompt: **Describe special protections required and how they are addressed in the protocol.**
- No

Which protected population do your participants belong to?
Options:

1. Cognitively impaired
2. Fetuses or neonates
3. Native Americans and Alaska Natives
4. Prisoners
5. Undocumented immigrants
6. Veterans
7. Other, explain why they are situationally or otherwise vulnerable.

Explanation prompt for all options: **Describe the protected population and explain the special protections required.**

If no Application Form sections are showing "Required Questions Unanswered" in red text, then the application is completed. Press the red text "View Protocol Page" located at the top or bottom right side of this webpage to return the Protocol Home Page.

From the Protocol Home Page, press the "Submit Protocol for Review" button, located below the protocol title.