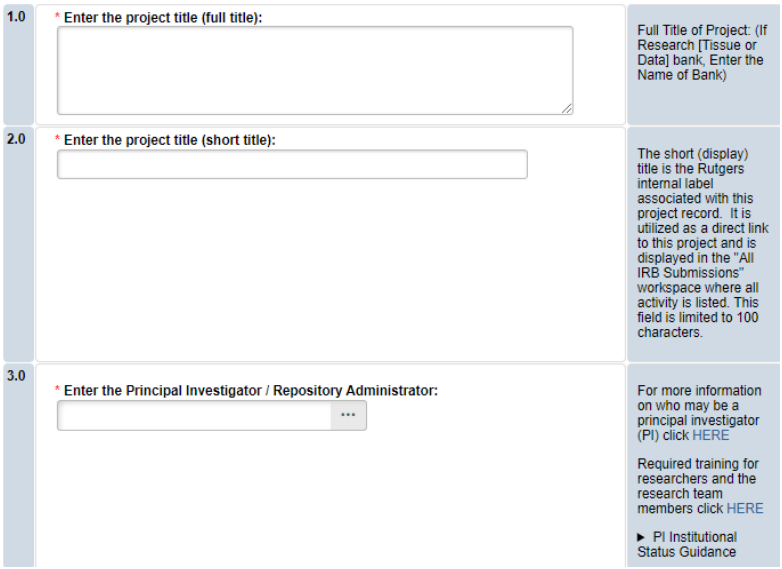
eIRB+ Application Guide

for Commercial IRB Submissions

Please remember that not all sections below will apply to your application/research study. Some sections might NOT appear. The sections that appear as you complete your eIRB+ application are contingent upon your responses in previous sections. If you encounter difficulty in completing a section that does not appear below but DOES appear in your application, kindly contact the IRB office at irboffice@research.rutgers.edu for assistance.

Section 1.0 General Project Information

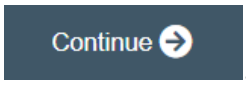


- **ENTER** the study's Full Title (Q 1.0) and Short Title (Q 2.0).

*Note, the Short Title entered will display in the eIRB+ dashboard.

- **ENTER** the Principal Investigator (Q 3.0) of the study.
  - **VISIT** our page to see who can and cannot serve as Principal Investigator (PI).
  - **RU graduate** students serving as the PI must **ADD** a faculty advisor as a Co-Investigator

- **ADD** a study coordinator in Q 4.0, the person entered here will receive all correspondence and notifications regarding this study along with the Principal Investigator.
- **ADD** any Rutgers-affiliated study team members in Q 5.0 Co-Investigators to Q 6.0 Other Study Staff.
  - **IRB Tip**: Ensure all members completed Rutgers CITI requirements

Once all information is provided, click 

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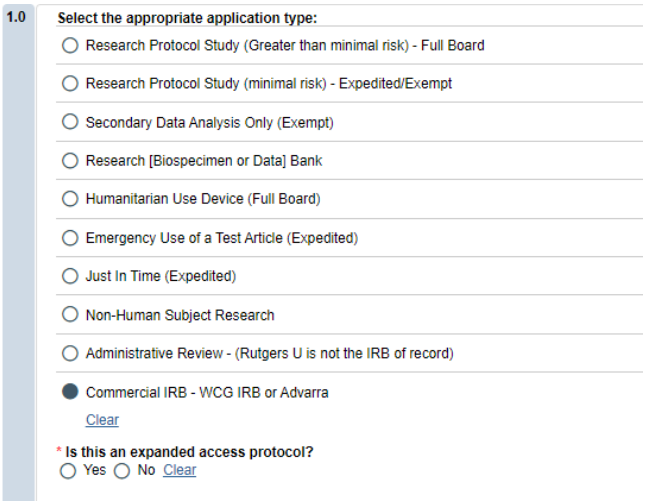
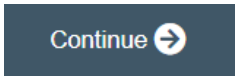
Section 1.1 Submission Type



- **SELECT 'Commercial IRB – WCG IRB or Advarra'**
  - This means a Commercial IRB is providing regulatory and ethical review for the academic institution and Rutgers University is relying on a Commercial IRB to serve as the IRB of Record.
  - **CONTACT** the Reliance Team at irbrelianceteam@research.rutgers.edu for assistance if you are unsure this is the correct application type.

Once all information is provided, click 

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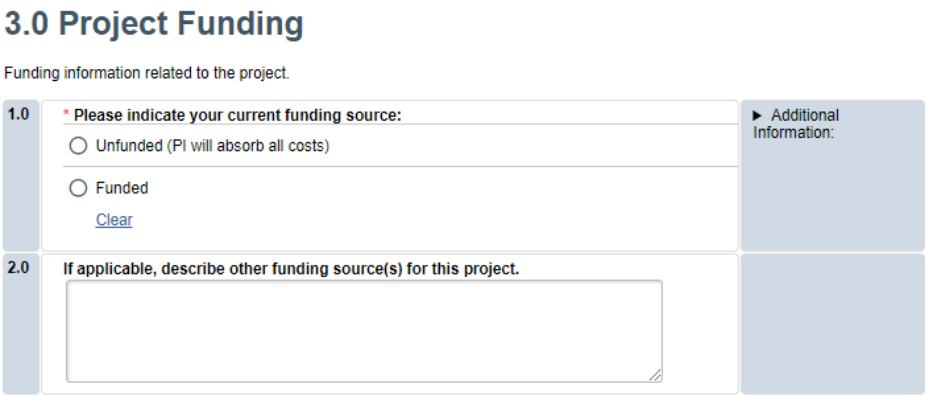
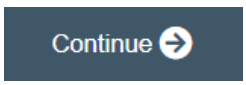
Section 3.0 Project Funding



- **SELECT** whether the study is **funded** or **unfunded** in Q 1.0.
  - Select **unfunded** only if the PI of the study will absorb all costs.
  - If funded externally or by department, select **funded** and fill out the following section 3.1 Funding Sponsor Information.

Once all information is provided, click 

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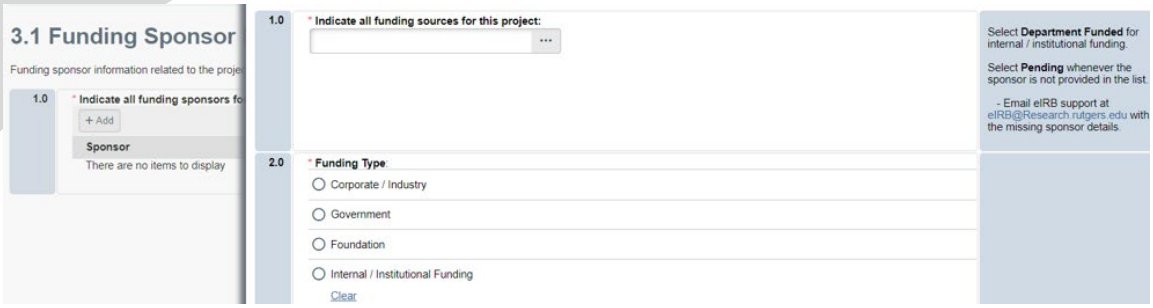
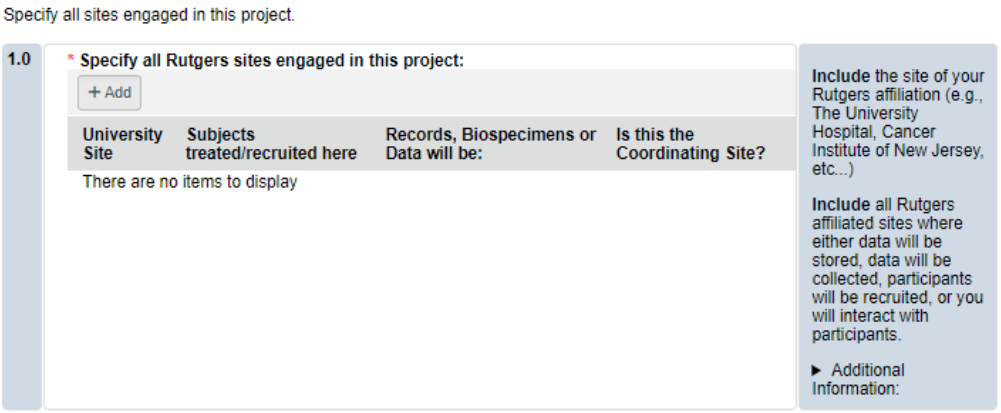
Section 3.1 Funding Sponsor Information



- **ADD** funding source by selecting the + Add
- **TYPE** the name of funding source or type 'Department Funded' for internal/institutional funding.
- **SELECT** funding type and select OK to save.
- **DELETE** a sponsor you've listed by accident by hovering over the sponsor entry and selecting the 'X' that appears on the right side of the highlighted row.

Once all information is provided, click Continue .

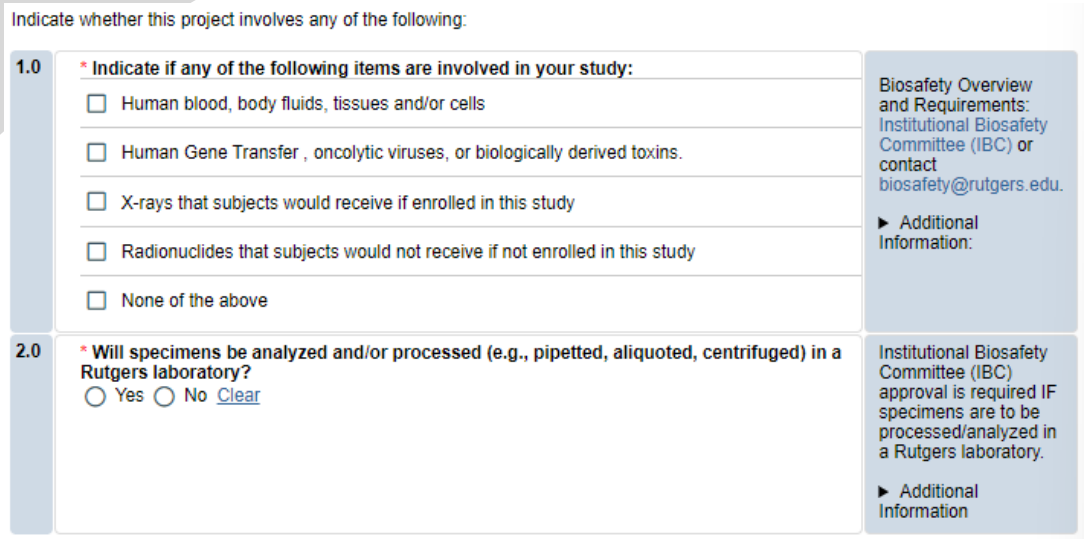
Section 4.0 Rutgers Affiliated Sites



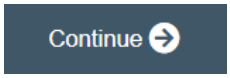
- **ADD** all Rutgers sites engaged in your study by selecting the + Add . This will populate an additional box where you will need to answer additional questions.
- **ADD** multiple Rutgers study sites by clicking OK and Add Another
- **DELETE** a site you've listed by accident by hovering over the site entry and selecting the 'X' that appears on the right side of the highlighted row.

Once all information is provided, click Continue .

Section 5.0 Biosafety & Radiation Safety



- **SELECT** all that apply in Q 1.0, if applicable.
- **UPLOAD** Institutional Biosafety Committee (IBC) approval in section 10.0 (section will appear at the end of the application) if specimens are to be processed/analyzed in a Rutgers laboratory.

Once all information is provided, click 

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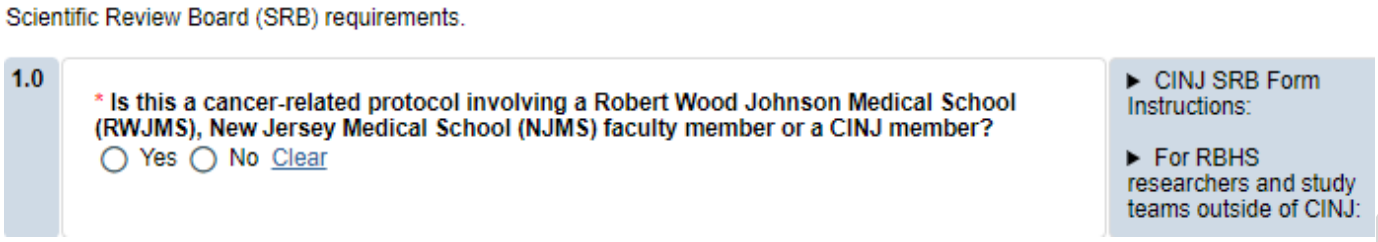
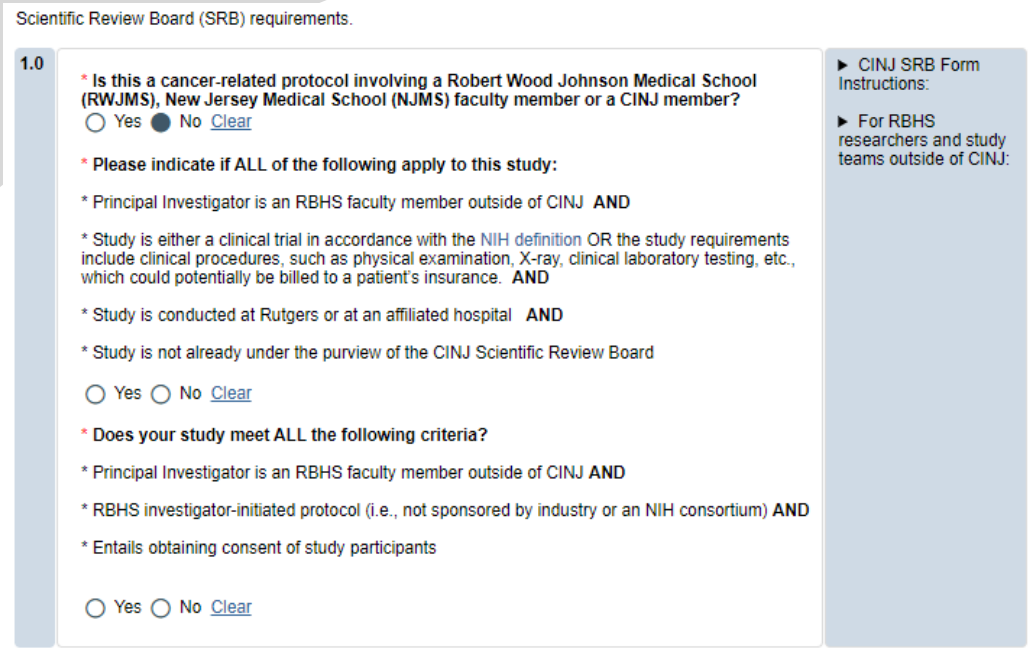
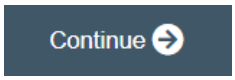
Section 5.1 Scientific Review Board (SRB)

For Scientific Review Board information and requirements visit RBHS Scientific Review Board - CINJ Studies and RBHS Scientific Review Board - Non-Oncology Studies.



- **SELECT** 'Yes' if this study is a cancer related protocol involving RWJMS or NJMS or CINJ member, otherwise select 'No'.
- If you meet all the criteria below, **SELECT** 'No' in Q 1.0 and answer 'Yes' to the questions that appear after. If you meet the criteria below you will need to visit Scientific Review Board and obtain SRB approval.
    - Principal Investigator is an RBHS faculty member outside of CINJ
    - This is an RBHS investigator initial protocol (i.e., not industry sponsored or NIH consortium)
    - Study entails obtaining consent of study participants.



Once all information is provided, click 

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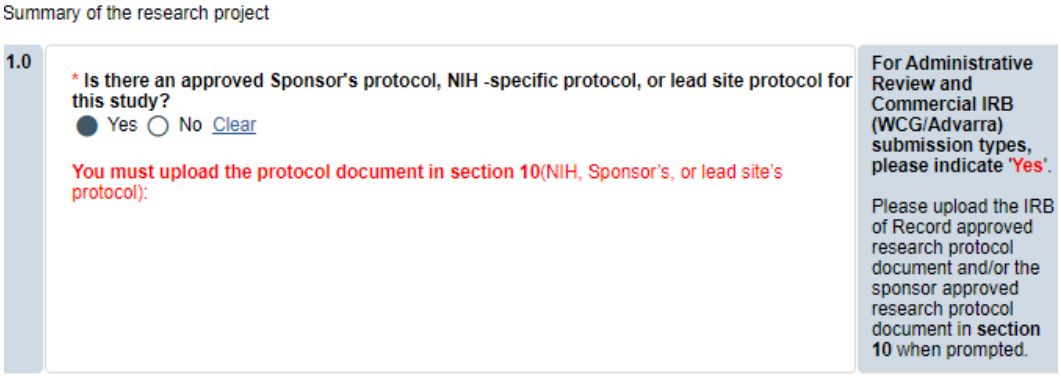
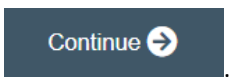
Section 6.0 Research Summary



- **COMMERCIAL IRB** submissions have an approved Sponsors protocol and/or NIH-specific protocol therefore Q 1.0 must indicate **YES.**
- **SUMMARIZE** your project in Q 3.0 using lay language or language understood by a person unfamiliar with your area of research.
- **SELECT** all that apply under Q 5.0 and enter the number corresponding to the selection. For example, select subjects and records if you are enrolling 100 subjects and are also reviewing 50 student records.

Once all information is provided, click 

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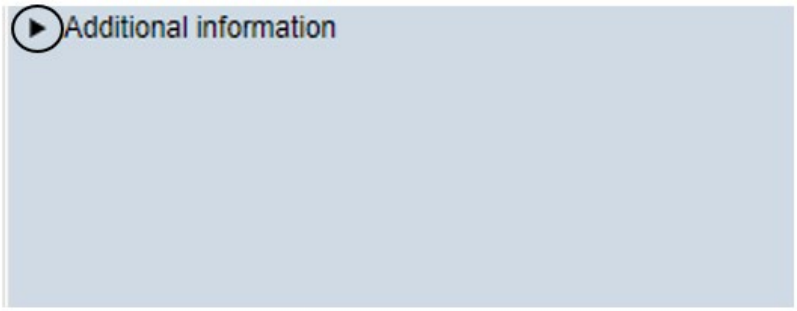
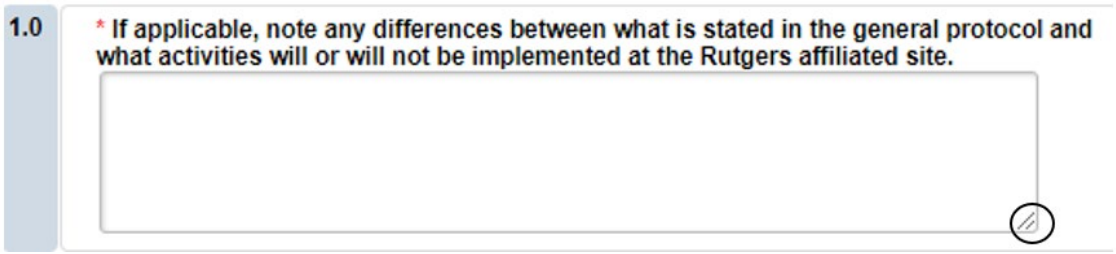
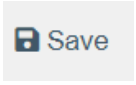
Section 6.01 Local Context Summary

- This section will ask you specific questions about your research as it pertains to the involvement of Rutgers Investigators and Rutgers Sites. Please answer the questions and provide details in the text boxes provided.
- **IRB TIP #1:** Click the arrow icon on the right-side panel of the page to **access additional guidance and examples** related to each protocol section.

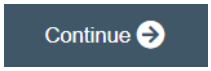


- **IRB TIP #2:** Expand each text box by dragging the corner of the text box where the three diagonal lines are.



- **IRB TIP #3:** 

your work regularly to prevent any loss of progress by selecting the **SAVE** icon at the bottom of the screen.

Once all information is provided, click 

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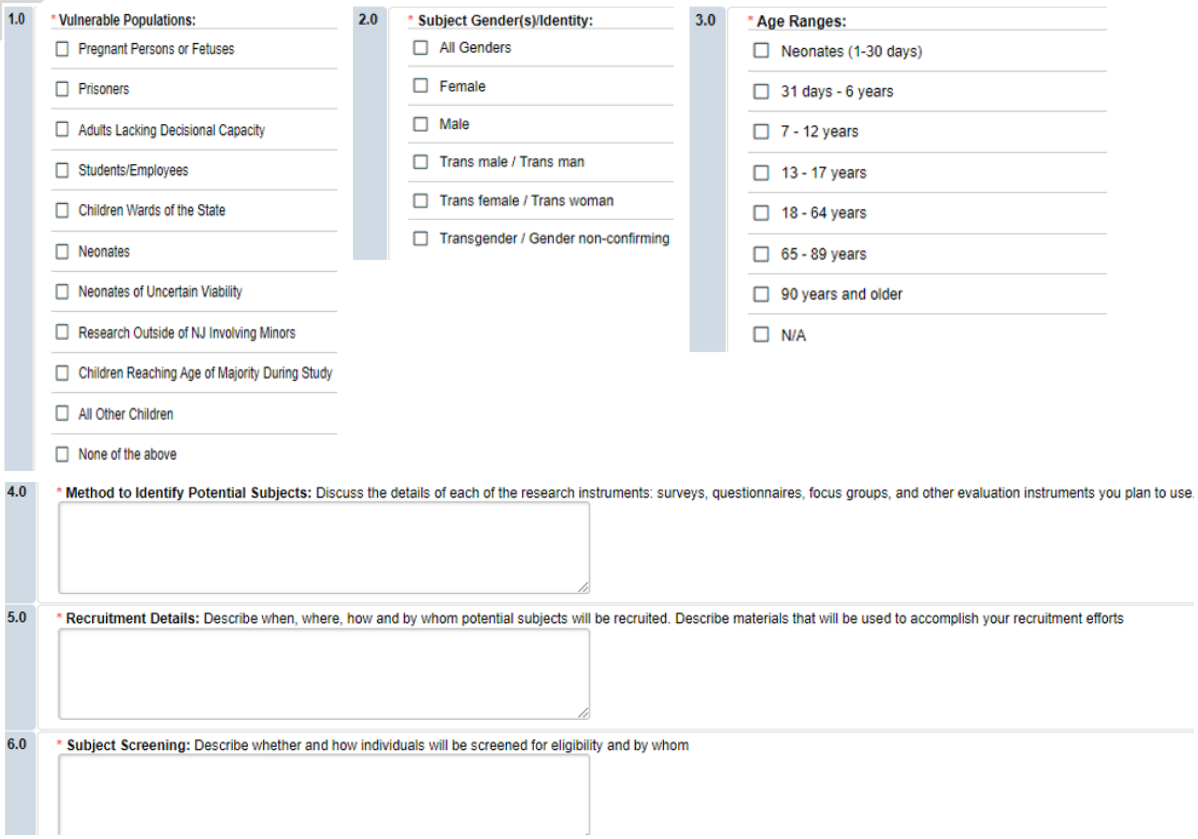
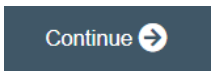
Section 6.06 Interaction or Intervention with Subjects

- **SELECT** all that apply in Q 1.0 - 3.0 that describes your subject population.
- Q 4.0 - 10.0 will ask you specific questions about your research. Please answer the questions and provide details in the text boxes provided.



Section 6.07 and 6.08 Interaction or Intervention with Subjects (Continued)

- These sections will ask you to enter details regarding different items such as privacy protections, risk of harms, direct benefits to subjects, consent process, data analysis/security. Please answer the questions and provide details in the text boxes provided.

Once all information is provided, click 

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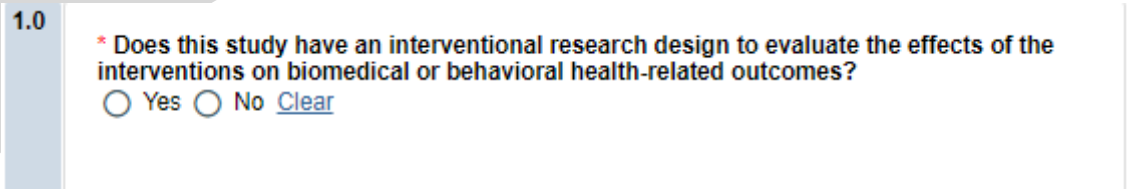
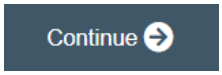
Section 6.1 Clinical Trial Information



Your research may require registration with ClinicalTrials.gov. More information about ClinicalTrials.gov Registration Requirements here.

- **SELECT** 'Yes' if your study meets ClinicalTrial.gov submission requirements. Selecting 'Yes' will trigger additional eIRB+ sections: 6.2 Clinical Trial Information – Section 2 and Section 6.3 Clinical Trials Registration Information.

Once all information is provided, click 

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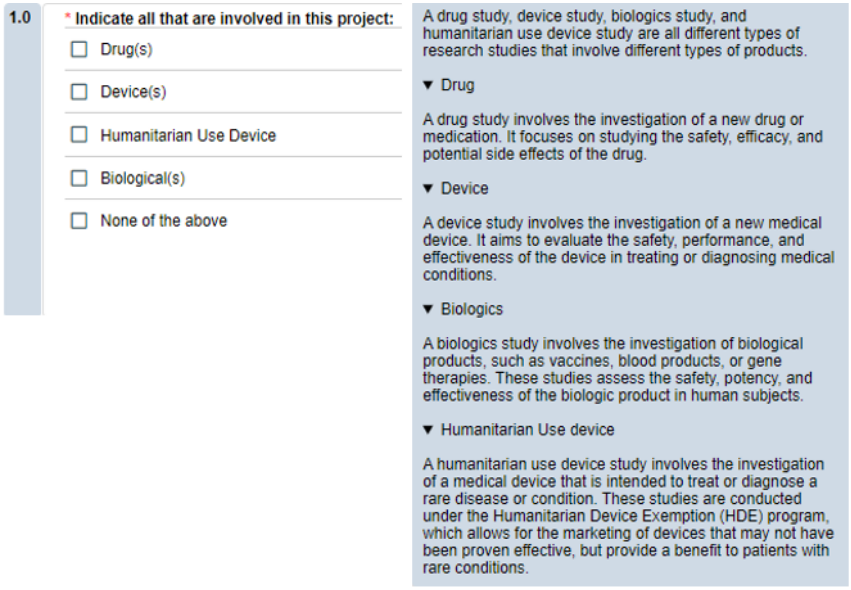
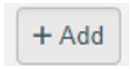
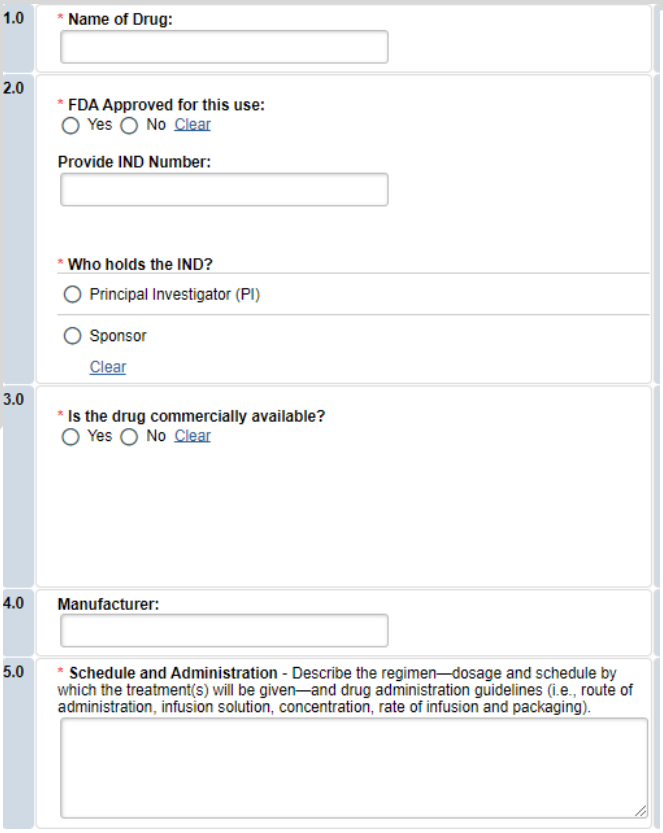
Section 7.0 Drugs/Devices/Biologics



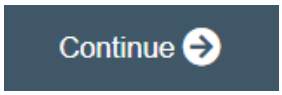
This section will ask you if your study involves any drugs, devices, or biologics. **Indicate all that are involved in your project**.

- When you click 

, a pop up requesting more information will appear.



For each Drug, Device or Biologic added, an additional field will appear for more details. You will be prompted to upload FDA documentation where applicable. Adding a drug, device or biologic triggers Section 7.1 Storage, Securing, and Dispensing.

Once all information is provided, click 

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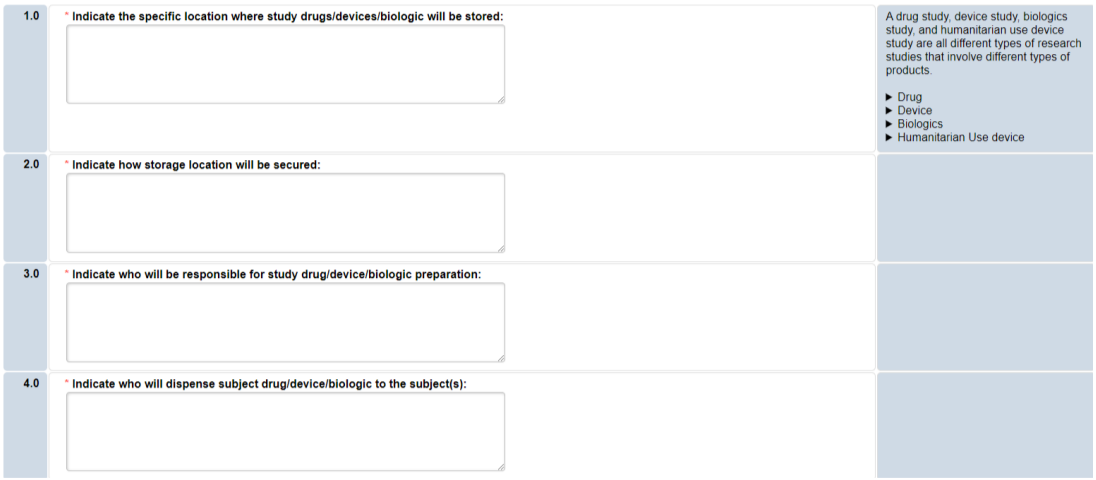
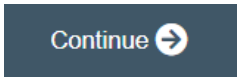
Section 7.1 Storage, Security, and Dispensing



Once all information is provided, click 

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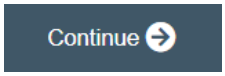
Section 8.0 Informed Consent

- **SELECT** if subjects will be providing consent (includes verbal consent, and electronic signatures).
    - Selecting 'No' will take you to section **8.2 Waivers.**
    - Selecting 'Yes, some but not all' OR 'Yes, all' will take you to section **8.1-Informed Consent Process.**
- **USE** our interactive tool if unsure what consent form template to use
- **VISIT** our website for the most up-to-date consent form templates.

Once all information is provided, click 

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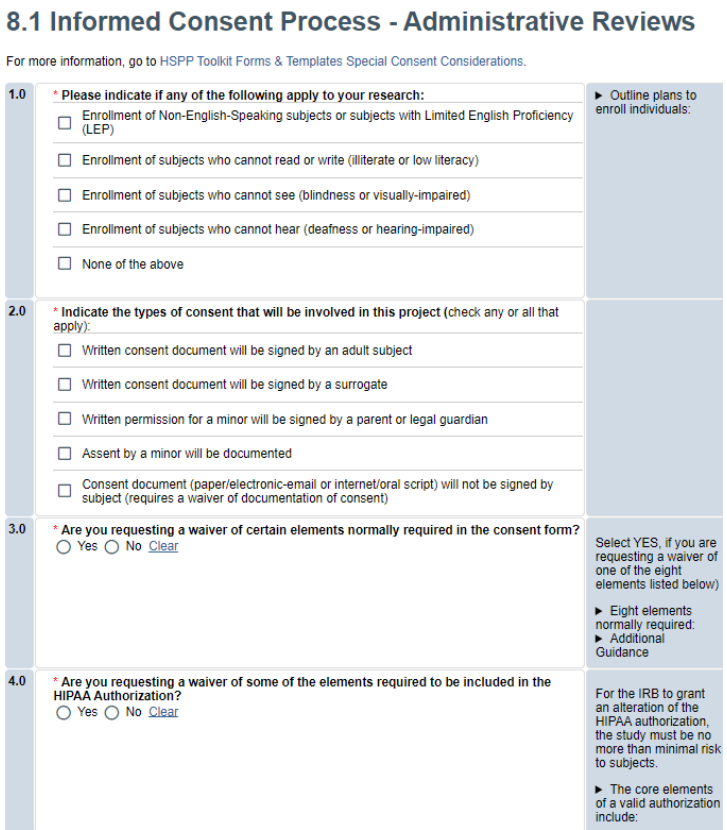
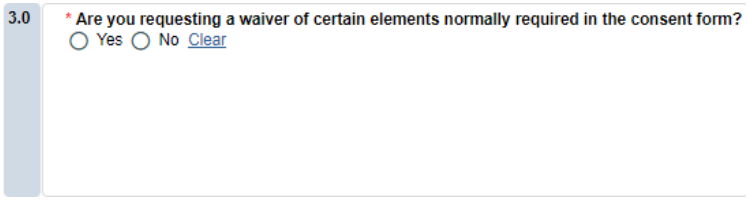
Section 8.1 Informed Consent Process- Administrative Review



- **SELECT** all the types of consent that will be involved in this project in Q 2.0.
- If you select *'Consent document will NOT be signed by a subject'* you will be required to fill out section **8.5 Waiver of Documentation of Informed Consent** on the next screen.
- **SELECT** 'Yes' in Q 2.0 **ONLY** if you are requesting a waiver of one of the eight elements below. You will be required to fill out the section **8.6 Waiver of Elements of Consent** on the next screen.



▼ Eight elements normally required:

Elements normally required include:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

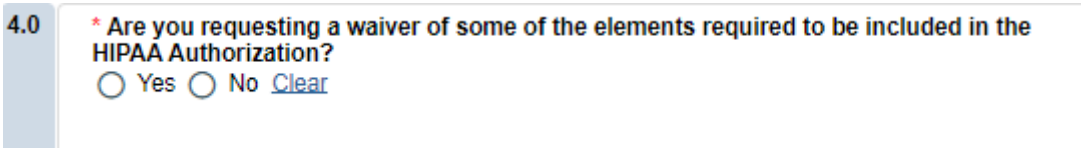
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

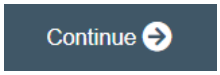
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

- **SELECT** 'Yes' in Q 4.0 **ONLY** if you are requesting a waiver of some of the elements required to be included in the HIPAA Authorization. You will be required to fill out section **8.9 HIPAA Waiver.**



Once all information is provided, click 

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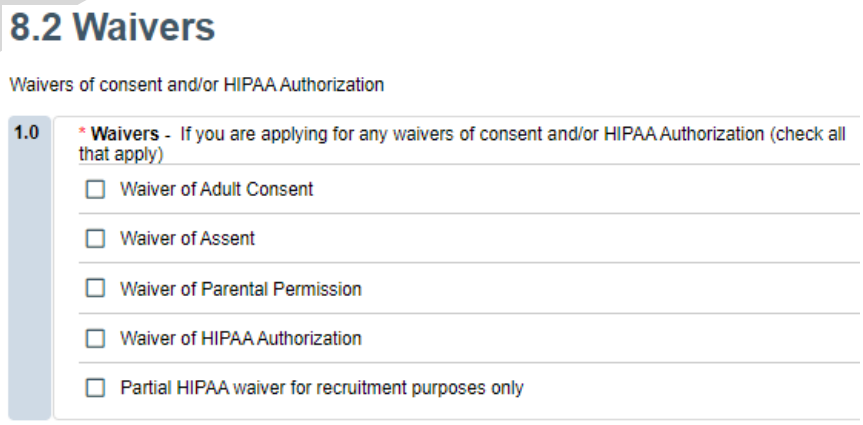
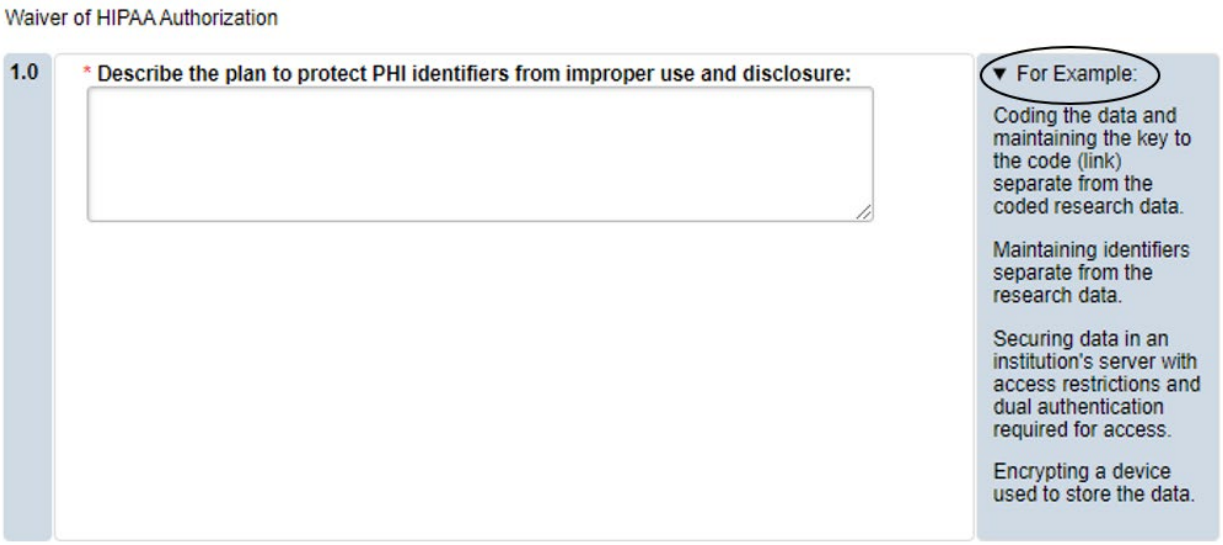
8.2 Waivers

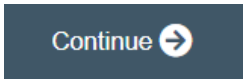


- **APPLY** for any waivers by selecting them under Q 1.0. Additional sections regarding the waivers will appear on the next page depending on your selection. For example, section **8.9 HIPAA Waiver** will populate if you select Waiver of HIPAA Authorization.

8.9 HIPAA Waiver

- **REMEMBER** to use the right-side panel for additional information and examples if you are unsure how to answer a question regarding any waivers.



Once all information is provided, click 

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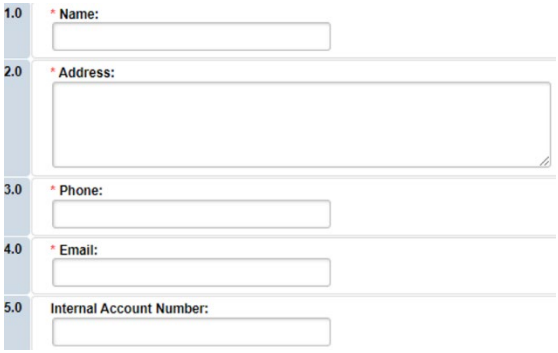
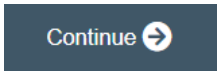
Section 9.0 Invoice/Billing Information



- Provide contact information of who will receive the one-time service fee.

Once all information is provided, click 

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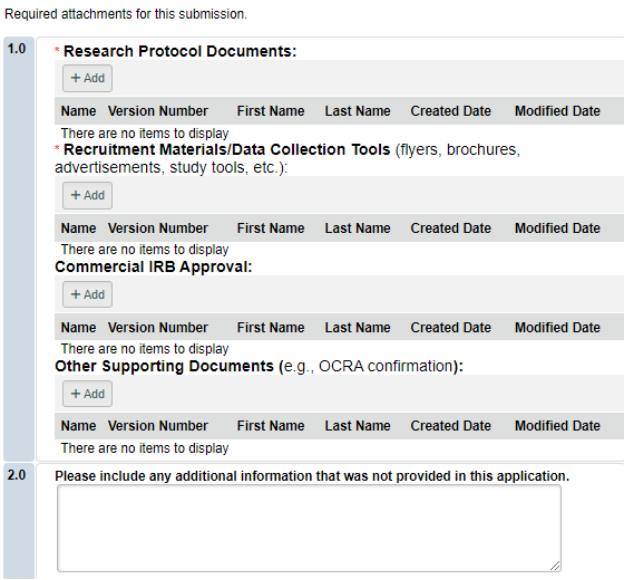
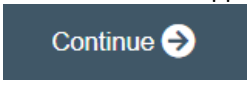
Section 10.0 Attachments



- **UPLOAD** consent forms, Sponsor Protocol, Local Context Supplement, Commercial IRB Approval and any data collection tools (surveys, interview guides).
- **REVIEW** the above documents to ensure that they have version dates and numbers.
- **UPLOAD** the Commercial IRB approval upon receipt and any site documentation for the Rutgers study performance sites (these were listed in section 4.0).
- **VISIT** our website for site approval forms: [Other Documents>Performance Site Approval Forms]
- **SELECT** 

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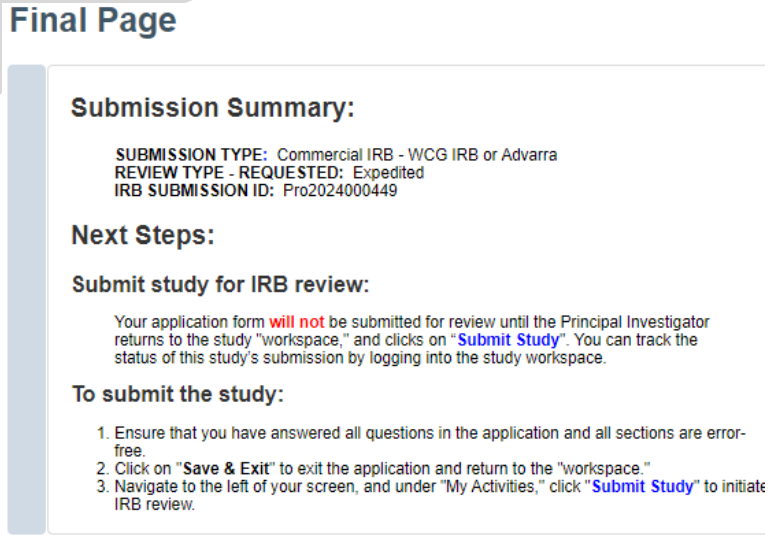
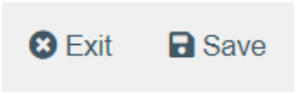
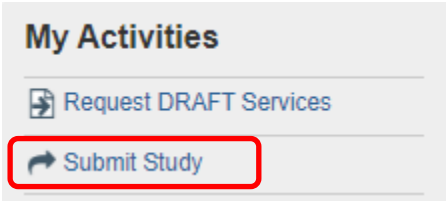




- **REMEMBER** to select which will take you to the study main page. Selecting this will **NOT** submit your application to the IRB. You must navigate to MY ACTIVITIES and select Submit Study if you are ready to submit to the IRB.



Related Links and Interactive Tools

I do not know if my research is considered human subject research or if I need to submit to the IRB?

Who can serve as the Principal Investigator on a research study?

What are the CITI requirements for the study personnel on my application?

What are the Commercial IRB Submission requirements?

What is the order of submission between Rutgers IRB and WCG IRB?

What is the order of submission between Rutgers IRB and Advarra IRB?

Are my research sites engaged in research?

I will be using a site for recruitment only, where can I find the performance site approval form?

Who can I contact regarding Institutional Biosafety Committee (IBC) approval?

Who can I contact for questions about Scientific Review Board and obtaining SRB approval?

Where can I find the most recent consent form templates?

If you have any other questions, please contact the IRB Reliance Team at irbrelianceteam@research.rutgers.edu.