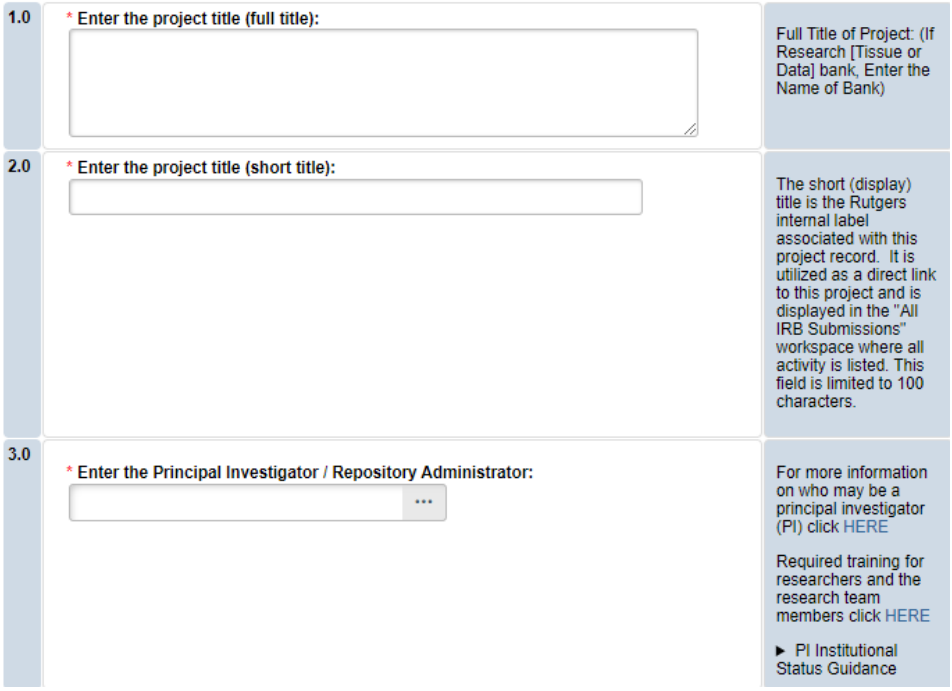
EIRB+ Application Guide

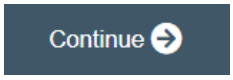
for Secondary use of Data

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). The Short Title entered will display in the eIRB+ dashboard.
- **ENTER** the Principal Investigator (Q 3.0) by clicking the 3 dots (right side) or by typing the person's name in the open field.
    - **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 (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 and 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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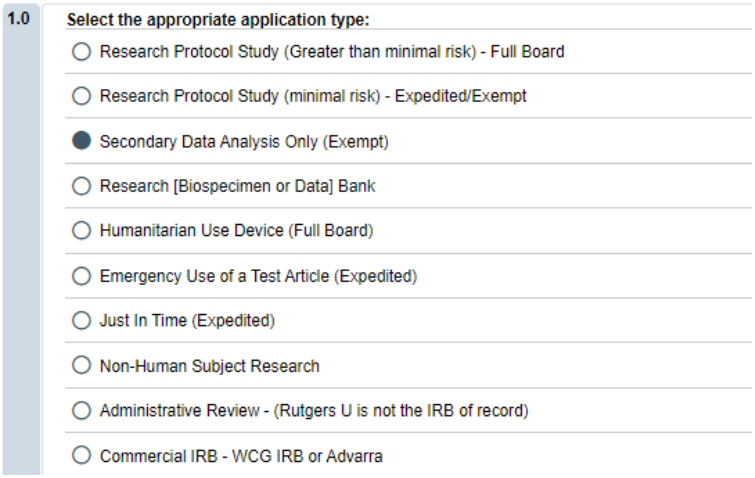
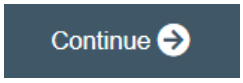
Section 1.1 - Submission Type



- **SELECT Secondary Data Analysis Only (Exempt)**
    - This application is only for secondary research with data only and NOT for those who wish to conduct secondary research with biospecimens.

Once all information is provided, click 

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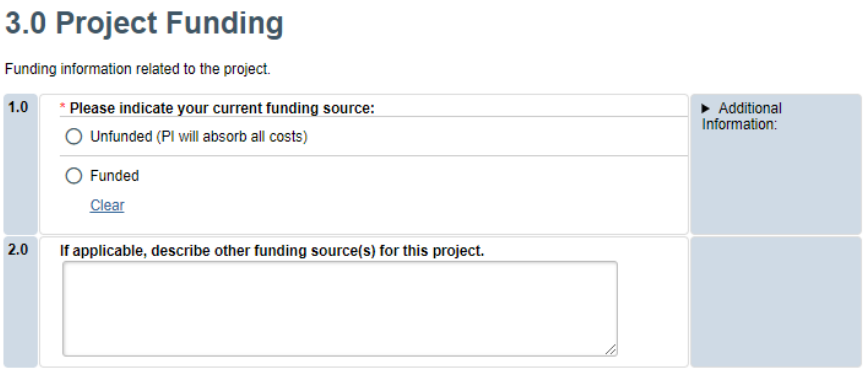
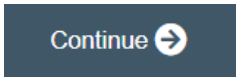
Section 3.0 Project Funding



- **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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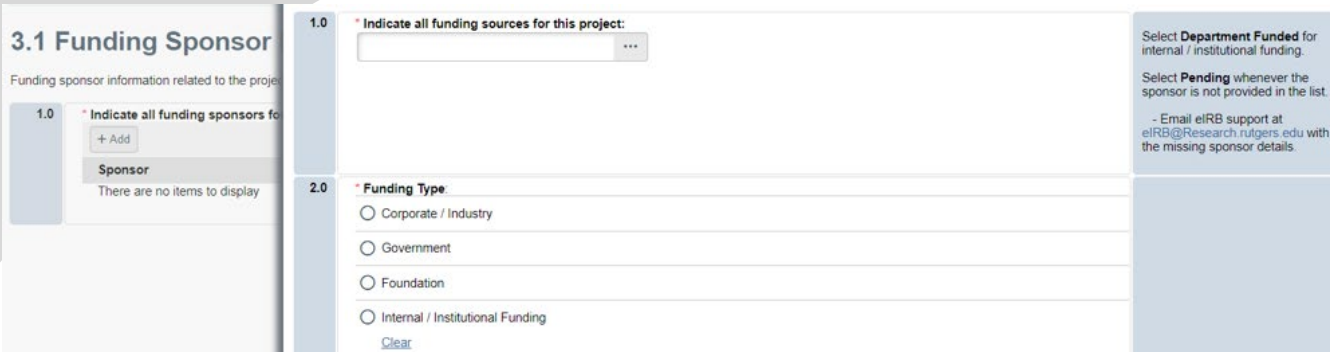
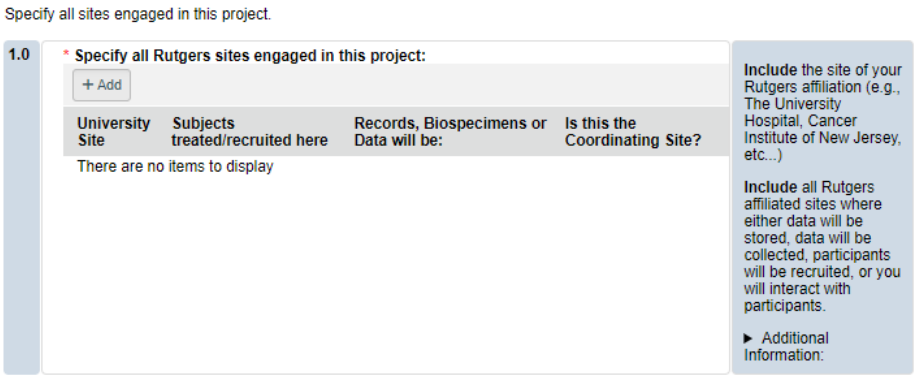
Section 3.1 Funding Sponsor Information



- **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 .

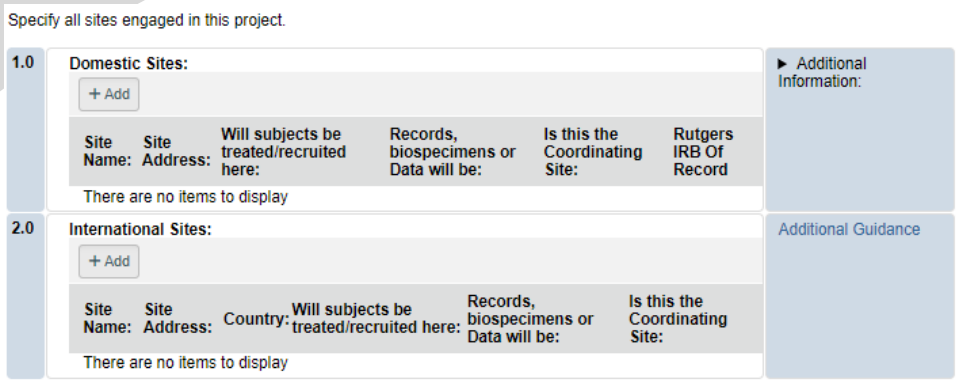
Section 4.0 – Rutgers Affiliated Sites

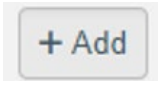


- **ADD** all Rutgers sites engaged in your study by selecting the + Add . This will populate an additional box where you will need to answer additional questions.
- **ADD** multiple Rutgers study sites by clicking OK and Add Another
- **DELETE** a site you've listed by accident by hovering over the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

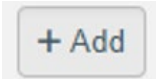
Once all information is provided, click Continue .

Section 4.1 Non-Rutgers Project Sites

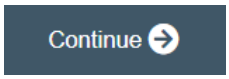


- **ADD** all domestic sites (within the USA) in Q 1.0 by clicking 

and answer the questions that populate after.
    - **USE** our interactive tool if unsure if a domestic (non-Rutgers) site is engaged in research.
    - **CONTACT** the IRB Reliance Team (irbrelianceteam@research.rutgers.edu) if you answer **YES** to "Are you requesting Rutgers to serve as the IRB of record for this site (NON-Rutgers site)?"

- **ADD** an international site in Q2.0 by selecting 

and fill out the additional questions on the following page.
    - **VISIT** our guidance page on International Research if needed.

Once all information is provided, click 

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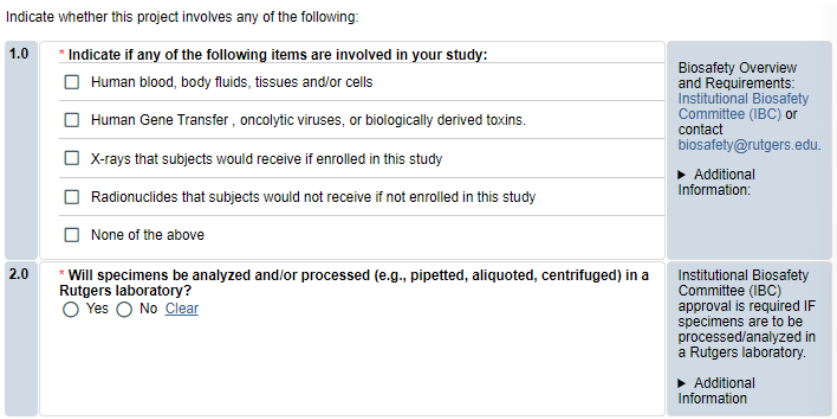
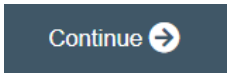
Section 5.0 Biosafety & Radiation Safety



- **SELECT** all that apply in Q1.0, 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 (Q2.0) or Radiation Safety (REHS) approval if applicable.

Once all information is provided, click 

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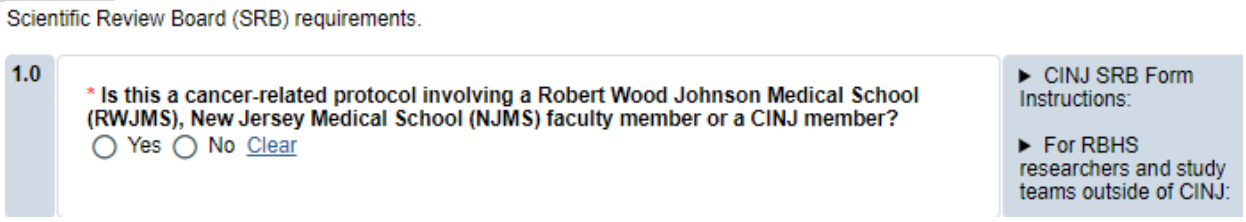
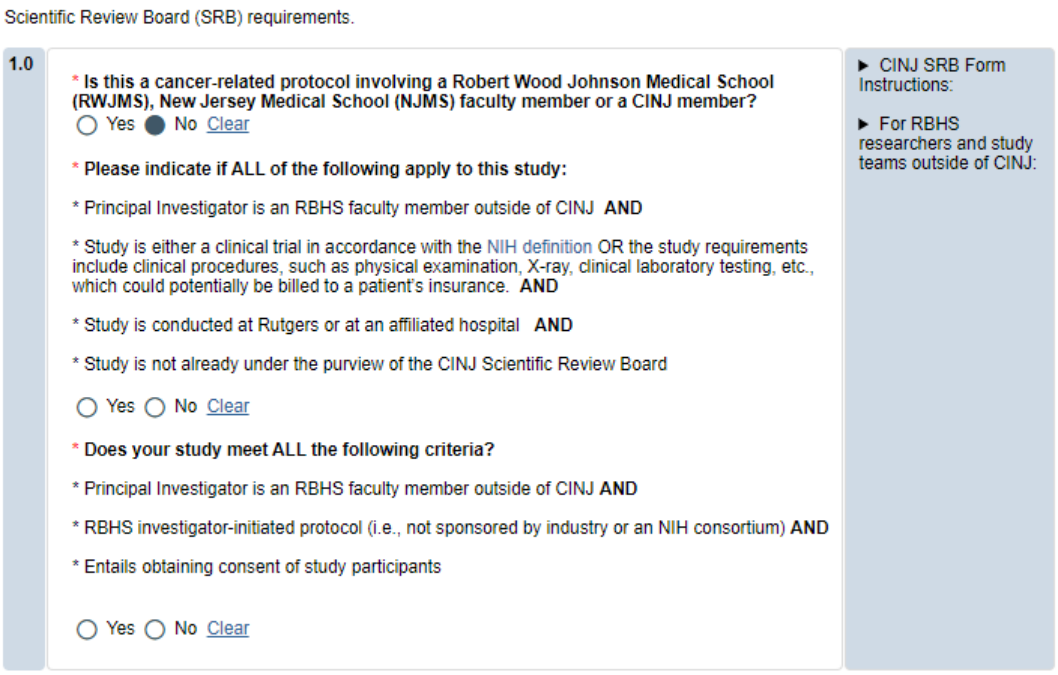
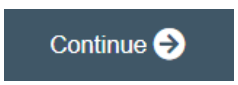
Section 5.1 Scientific Review Board (SRB)

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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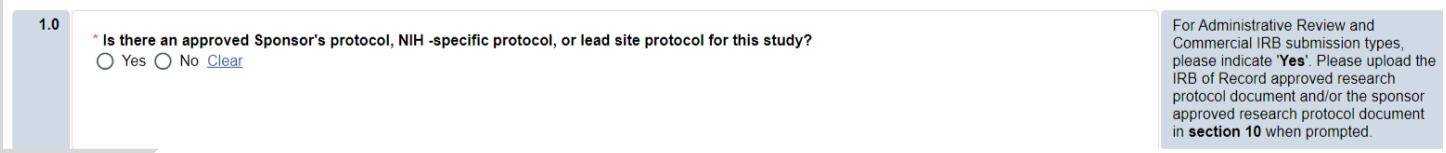
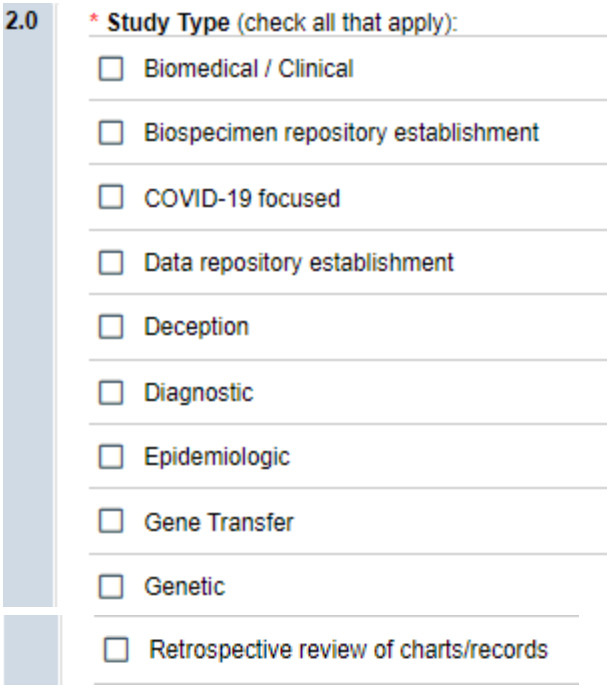
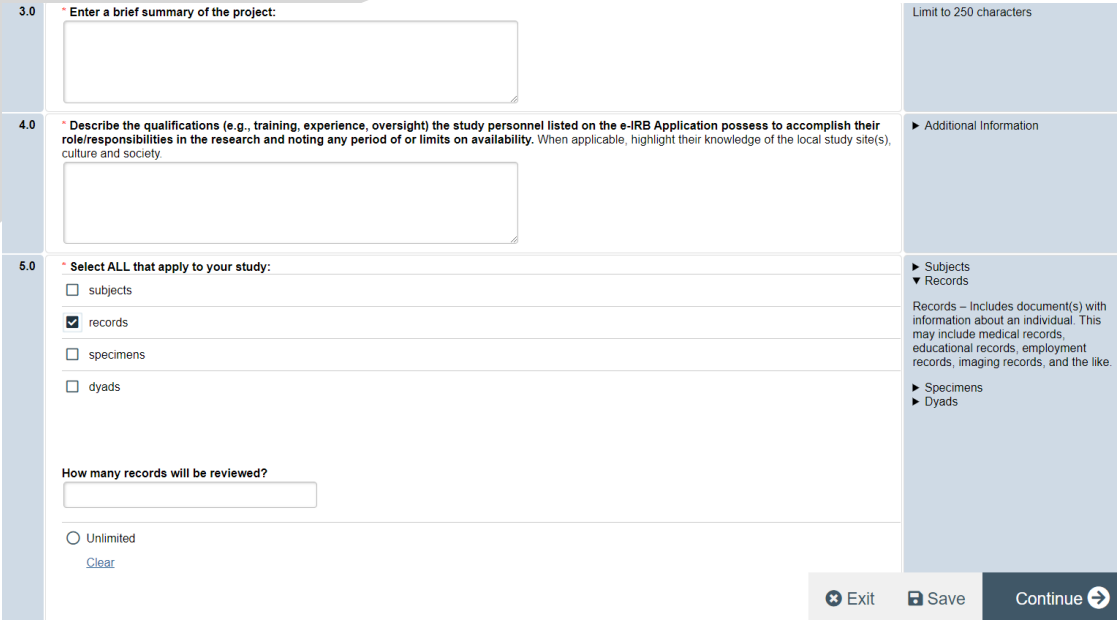
Section 6.0 - Research Summary



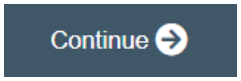
- If 'Yes' is **SELECTED** for Q 1.0, an alert will appear instructing you to upload the protocol document in section 10.0. eIRB+ Section 6.01 Local Context Summary will populate.
- If 'No' is **SELECTED** for Q 1.0, a standalone protocol document will not be requested because all protocol questions are included as part of the eIRB+ application.



- **SELECT** "Retrospective review of charts/records" for Q 2.0.



- **SELECT** <u>only</u> 'records' for Q 5.0. When 'records' is selected, an additional required field will appear to fill in the corresponding number of records for your research.

Once all information is provided, click 

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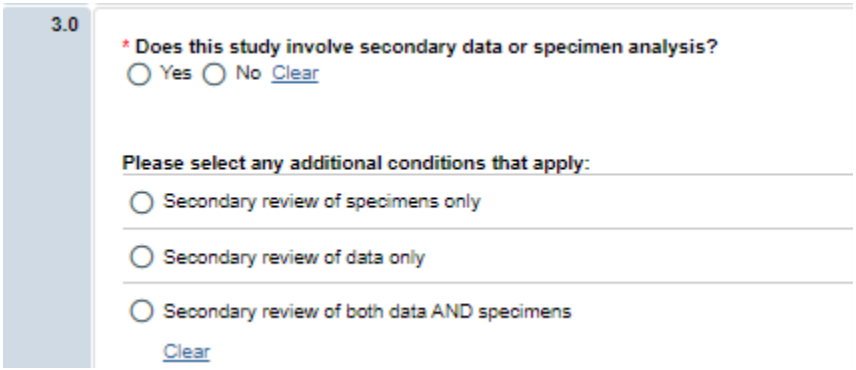
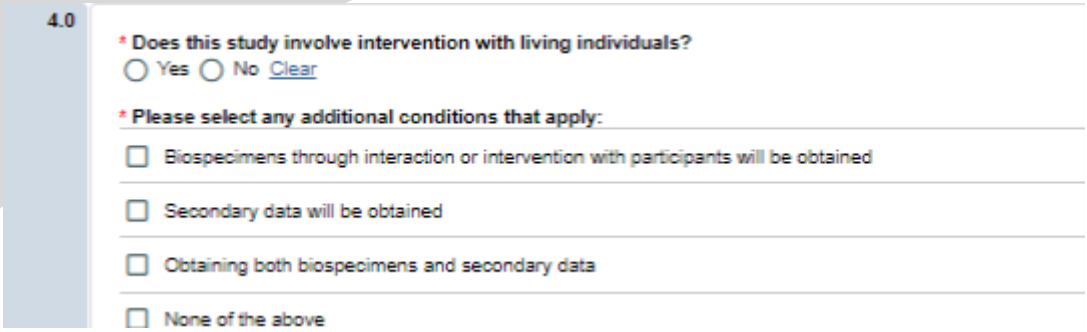
Section 6.01 Local Context Summary - Secondary Data Analysis

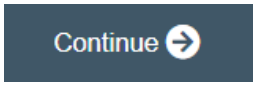
Note: This section will only appear if you answered “Yes” in response to question 1.0 in section 6.0.



- **SELECT** ‘Yes’ to Q 3.0 and then select “Secondary review of data only”



- **SELECT** 'No' to Q 4.0 and then select "None of the above"

Once all information is provided, click 

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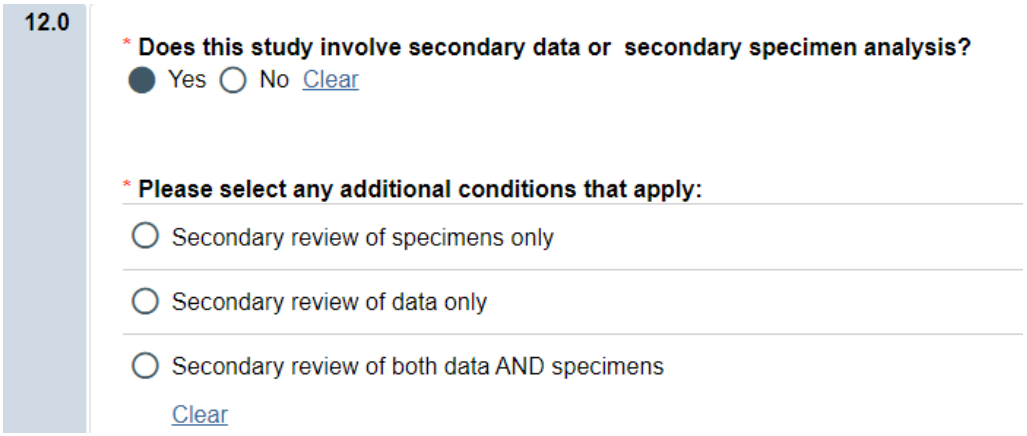
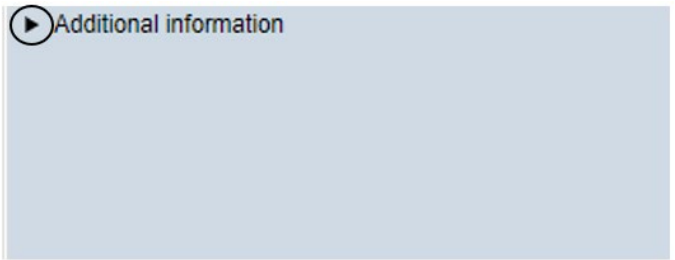
Section 6.02 Protocol Questions - Secondary Data Analysis

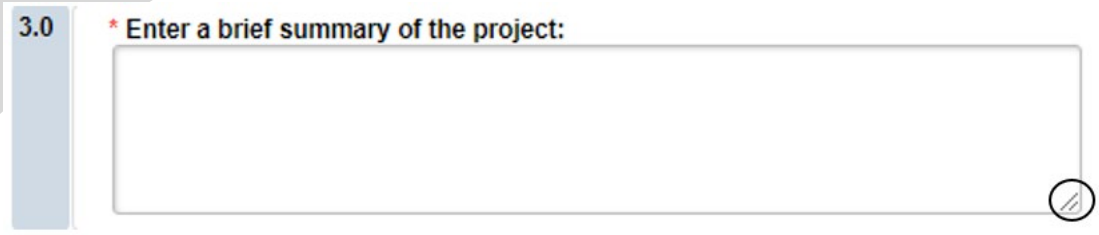
- Note: This section will only appear if you answered "No" in response to question 1.0 in section 6.0.
- This section will ask you specific questions about your research. Please answer the questions and provide details in the text boxes provided.
- Please note: **SELECT** 'Yes' to Q 12.0 and then select "Secondary review of data only".

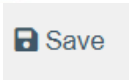


- **IRB TIP #1:** Click the arrow icon on the right-side panel of the page to **access additional guidance and examples** related to each protocol section.

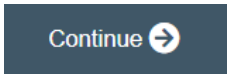


- **IRB TIP #2:** Expand each text box by dragging the corner of the text box where the three diagonal lines are.



- **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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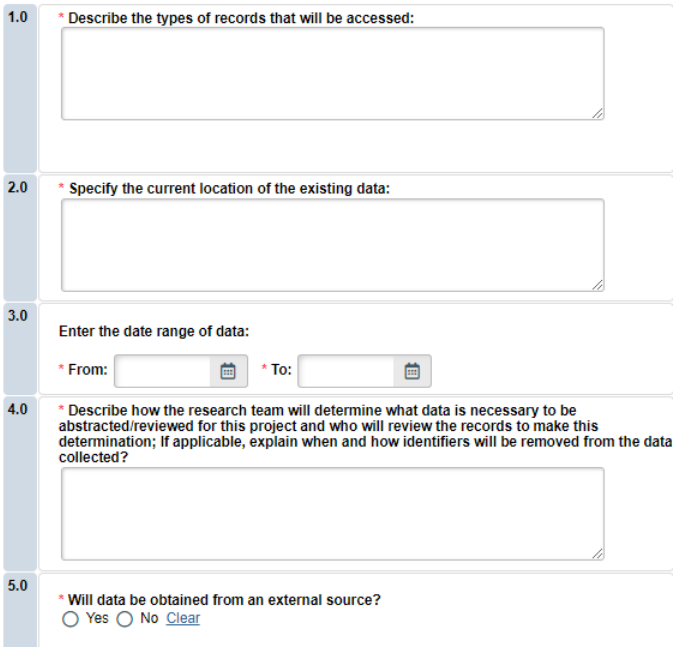
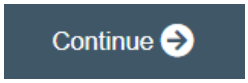
Section 6.04 Secondary Review of Data



- If 'Yes' is SELECTED for Q 5.0, additional required fields will appear.
- If 'Data is publicly available…' is selected, a field will appear requiring the URL for the data source.

Once all information is provided, click 

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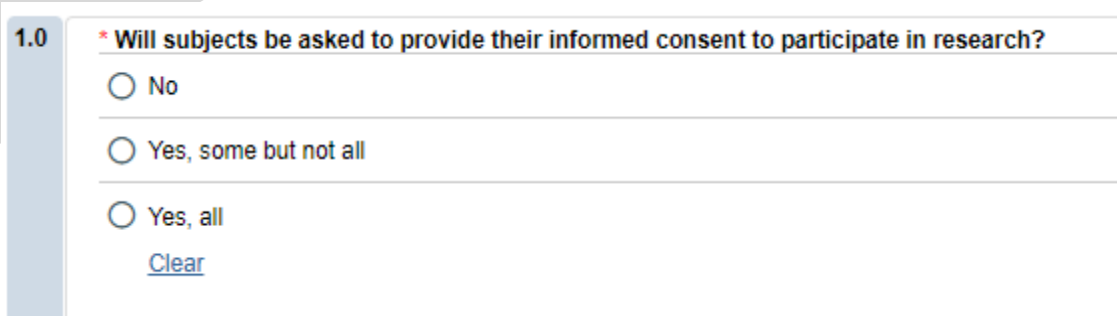
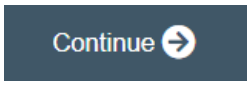
Section 8.0 Consent, HIPAA and Waivers



- **SELECT** "No" because this is a secondary use of data.

Once all information is provided, click 

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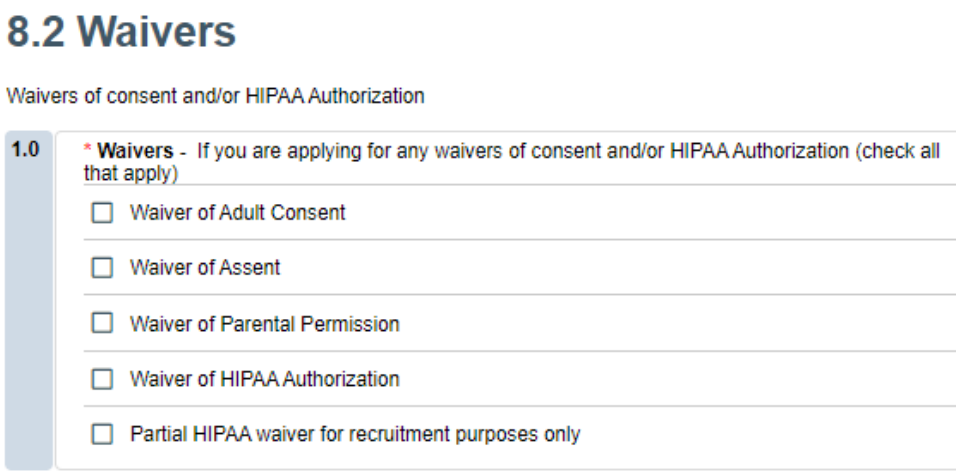
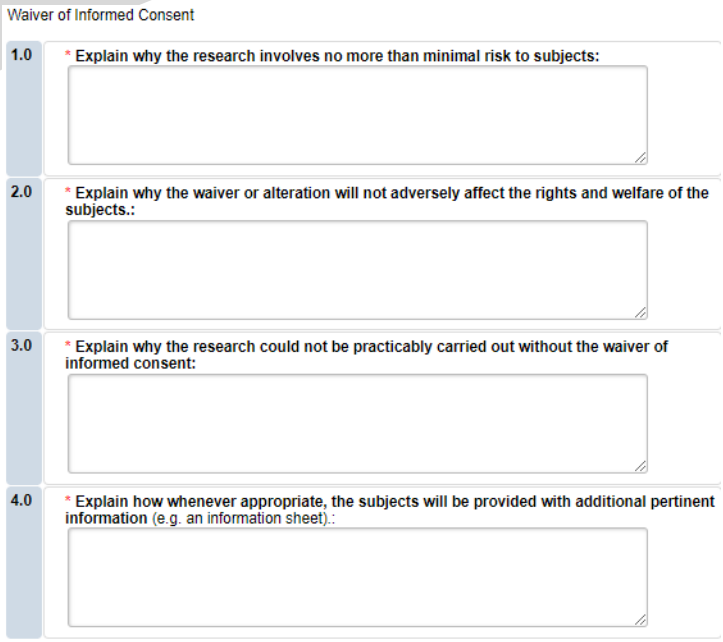
Section 8.2 - Waivers

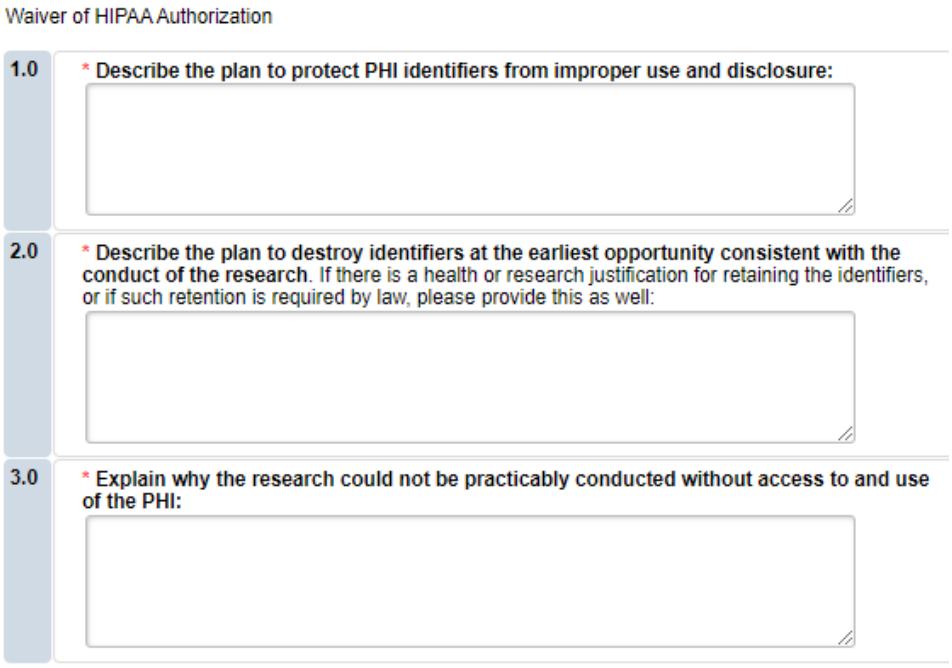


8.2 Waivers note: Your request for consent waivers will be contingent upon the age range of your data set.

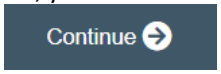
- **SELECTING** 'Waiver of Adult Consent' triggers section 8.8 to appear in the application after clicking Continue.



- **SELECTING** 'Waiver of Parental Permission' triggers section 8.3 to appear in the application after clicking Continue.
- **SELECTING** 'Waiver of Assent' triggers section 8.4 to appear in the application after clicking Continue.
- **SELECTING** 'Waiver of HIPAA Authorization' triggers section 8.9 to appear in the application after clicking Continue.



- For a secondary analysis submission, you would not select 'Partial HIPAA waiver for recruitment purposes only.'

Once all information is provided, click 

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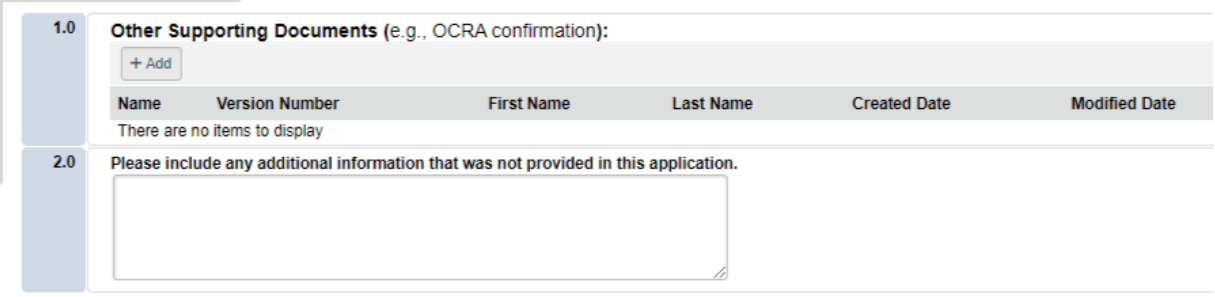
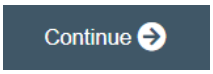
Section 10.0 Attachments



- **UPLOAD** consent forms, recruitment materials and any data collection tools (surveys, interview guides, screening forms).
  - **REVIEW** the above documents to ensure that they have version dates and numbers.
- **UPLOAD** site approvals for any domestic or international sites (these were listed in section 5.1).
  - **VISIT** our website for site approval forms: Other Documents>Performance Site Approval Forms
- **SELECT** 

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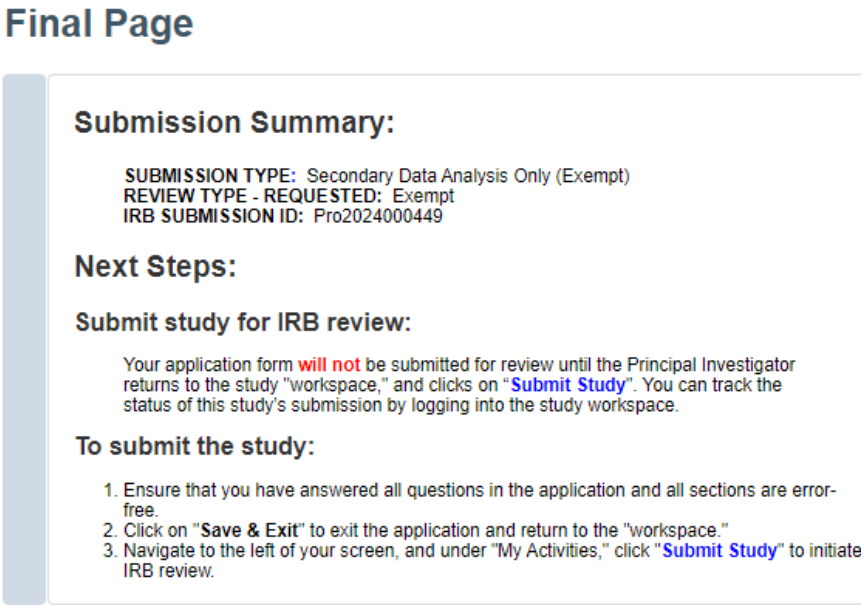
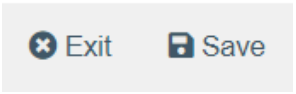
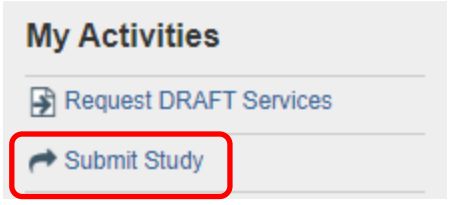


- **REMEMBER** to select 

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 application type should I choose?

Are my research sites engaged in research? Use the Engagement in research tool.

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

Where can I read more information about international research and sites?

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

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

What consent template should I use? Use IRB Review Type and Template Recommendation Tool.

Where can I find the most recent consent form templates?

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

If you have any other questions, please contact the IRB inbox at irboffice@research.rutgers.edu.