eIRB+ Application Guide
for Administrative Review 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 **Continue**.
Section 1.1 Submission Type

- SELECT ‘Administrative Review’
  - ‘Administrative Review’ is selected when Rutgers University is relying on an External IRB to serve as the IRB of Record (e.g., Reviewing IRB or External Institution is providing regulatory and ethical review for the academic institution as well as Rutgers University).
  - CONTACT the Reliance Team at irbrelianceteam@research.rutgers.edu for assistance if you are unsure if this is the correct application type.

Once all information is provided, click .

1.2 Administrative Review

- SELECT ‘Other’ and enter the name of the External IRB in Q 1.0.
- Please SELECT ‘Yes’ if you plan to facilitate a reliance agreement via the Smart IRB Portal or HURON IRB Exchange service. Enter the assigned SMART ID Number or Study ID Number.
- ENTER the expiration date provided by the External IRB if referenced on the IRB approval.

Once all information is provided, click .
Section 3.0 Project Funding

3.0 Project Funding
Funding information related to the project.

1.0 Please indicate your current funding source:
- Unfunded (PI will absorb all costs)
- Funded

2.0 If applicable, describe other funding source(s) for this project.

- 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 Continue.

Section 3.1 Funding Sponsor Information

- **ADD** funding source by selecting the
- **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] button. This will populate an additional box where you will need to answer additional questions.
- **ADD** multiple Rutgers study sites by clicking [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 [OK and Add Another].

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 [Continue].
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.

Scientific Review Board (SRB) requirements.

- 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 Continue.
Section 6.0 Research Summary

- **IRB of RECORD OR REVIEWING IRB** submissions have an approved protocol and/or lead site’s 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 **Continue**.

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.

![Image of text box](image1)

• **IRB TIP #3:** Save 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 **Continue**.

**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 Continue .

Section 6.1 Clinical Trial Information

1. Does this study have an interventional research design to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes?
   - Yes  
   - No  
   - Clear

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 Continue .
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 **Add**, 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.

<table>
<thead>
<tr>
<th>Section</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>* Indicate all that are involved in this project:</td>
</tr>
<tr>
<td></td>
<td>- Drug(s)</td>
</tr>
<tr>
<td></td>
<td>- Device(s)</td>
</tr>
<tr>
<td></td>
<td>- Humanitarian Use Device</td>
</tr>
<tr>
<td></td>
<td>- Biological(s)</td>
</tr>
<tr>
<td></td>
<td>- None of the above</td>
</tr>
<tr>
<td>2.0</td>
<td>* Name of Drug:</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3.0</td>
<td>* FDA Approved for this use:</td>
</tr>
<tr>
<td></td>
<td>- Yes</td>
</tr>
<tr>
<td></td>
<td>- No</td>
</tr>
<tr>
<td></td>
<td>- Other</td>
</tr>
<tr>
<td></td>
<td>Provide IND Number:</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>4.0</td>
<td>* Who holds the IND?</td>
</tr>
<tr>
<td></td>
<td>- Principal Investigator (PI)</td>
</tr>
<tr>
<td></td>
<td>- Sponsor</td>
</tr>
<tr>
<td></td>
<td>- Other</td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td>5.0</td>
<td>* Is the drug commercially available?</td>
</tr>
<tr>
<td></td>
<td>- Yes</td>
</tr>
<tr>
<td></td>
<td>- No</td>
</tr>
<tr>
<td></td>
<td>- Other</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>6.0</td>
<td>* Schedule and Administration - Describe the regimen—dose and schedule by which the treatments will be given—and drug administration guidelines (i.e., route of administration, infusion solution, concentration, rate of infusion and packaging):</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Once all information is provided, click **Continue**.
Section 7.1 Storage, Security, and Dispensing

1.0 * Indicate the specific location where study drug/devices/biologic will be stored:

2.0 * Indicate how storage location will be secured:

3.0 * Indicate who will be responsible for study drug/device/biologic preparation:

4.0 * Indicate who will dispense subject drug/device/biologic to the subject(s):

Once all information is provided, click continue.

Section 8.0 Informed Consent

1.0 * Will subjects be asked to provide their informed consent to participate in research?

- No
- Yes, some but not all
- Yes, all

A subject provides informed consent by doing any of the following:
- Physically documenting, eSign/enter their name into a consent form
- Verbal agreement to participate in the research
- Review the consent statement prior to participation and complete the research activity (survey, focus group, etc.).

Select options based on the target population and identify who will provide consent for participants in the research study.

- 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 continue.
Section 8.1 Informed Consent Process- Administrative Review

### 8.1 Informed Consent Process - Administrative Reviews

For more information, go to HSFP Toolkit Forms & Templates Special Consent Considerations.

<table>
<thead>
<tr>
<th>1.0</th>
<th>* Please indicate if any of the following apply to your research:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Enrollment of Non-English-Speaking subjects or subjects with Limited English Proficiency (LEP)</td>
</tr>
<tr>
<td></td>
<td>- Enrollment of subjects who cannot read or write (illiterate or low literacy)</td>
</tr>
<tr>
<td></td>
<td>- Enrollment of subjects who cannot see (blindness or visually-impaired)</td>
</tr>
<tr>
<td></td>
<td>- Enrollment of subjects who cannot hear (deafness or hearing-impaired)</td>
</tr>
<tr>
<td></td>
<td>- None of the above</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.0</th>
<th>* Indicate the types of consent that will be involved in this project (check any or all that apply):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Written consent document will be signed by an adult subject</td>
</tr>
<tr>
<td></td>
<td>- Written consent document will be signed by a surrogate</td>
</tr>
<tr>
<td></td>
<td>- Written permission for a minor will be signed by a parent or legal guardian</td>
</tr>
<tr>
<td></td>
<td>- Assent by a minor will be documented</td>
</tr>
<tr>
<td></td>
<td>- Consent document (paper/electronic-email or interactive media) will not be signed by subject (requires a waiver of documentation of consent)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3.0</th>
<th>* Are you requesting a waiver of certain elements normally required in the consent form?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Yes</td>
</tr>
<tr>
<td></td>
<td>- No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.0</th>
<th>* Are you requesting a waiver of some of the elements required to be included in the HIPAA Authorization?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Yes</td>
</tr>
<tr>
<td></td>
<td>- No</td>
</tr>
</tbody>
</table>

- **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.
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 .

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 **Continue**.

Section 9.0 Invoice/Billing Information

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

Once all information is provided, click **Continue**.
### Section 10.0 Attachments

**Required attachments for this submission:**

1. **Research Protocol Documents:**

2. **Other Supporting Documents** (e.g., OCRA confirmation):
   - [SELECT](#)

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- **SELECT** (if applicable).
• **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

Administrative Review Overview

Administrative Review Submission Guidance

Administrative Review Flowchart

Administrative Review IRB Fees

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