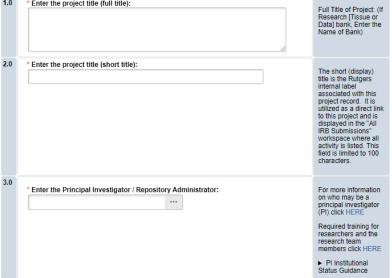
# **eIRB+ Application Guide**

# 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 <a href="mailto:irboffice@research.rutgers.edu">irboffice@research.rutgers.edu</a> for assistance.

# Section 1.0 General Project Information \*Enter the project title (full title):



• 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.
  - o VISIT our page to see who can and cannot serve as Principal Investigator (PI).
  - o 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.
  - o IRB Tip: Ensure all members completed Rutgers CITI requirements





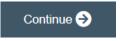
## **Section 1.1 Submission Type**

Select the appropriate application type:
Research Protocol Study (Greater than minimal risk) - Full Board
O Research Protocol Study (minimal risk) - Expedited/Exempt
O Secondary Data Analysis Only (Exempt)
Research [Biospecimen or Data] Bank
O Humanitarian Use Device (Full Board)
Emergency Use of a Test Article (Expedited)
O Just In Time (Expedited)
O Non-Human Subject Research
Administrative Review - (Rutgers U is not the IRB of record)
Commercial IRB - WCG IRB or Advarra
Clear
* Is this an expanded access protocol?  Yes No Clear

#### 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.
- o **CONTACT** the Reliance Team at <u>irbrelianceteam@research.rutgers.edu</u> for assistance if you are unsure this is the correct application type.

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

Clear

Clear

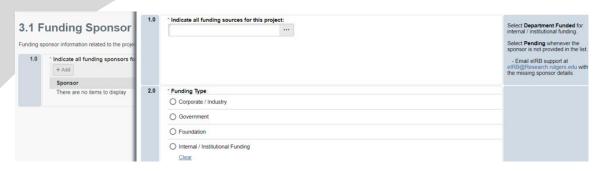
If applicable, describe other funding source(s) for this project.

- 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.
  - o If funded externally or by department, select **funded** and fill out the following section 3.1 Funding Sponsor Information.





## **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.
- **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



## **Section 4.0 Rutgers Affiliated Sites**

Specify all sites engaged in this project. Specify all Rutgers sites engaged in this project: Include the site of your Rutgers affiliation (e.g., + Add The University Hospital, Cancer Records, Biospecimens or Is this the Institute of New Jersey, treated/recruited here Coordinating Site? Data will be: There are no items to display Include all Rutgers affiliated sites where either data will be stored, data will be collected, participants will be recruited, or you will interact with participants. Additional Information

- ADD all Rutgers sites engaged in your study by selecting the hadden and 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.





## Section 5.0 Biosafety & Radiation Safety

Indica	ate whether this project involves any of the following:	
1.0	* Indicate if any of the following items are involved in your study:	Discrete Consider
	☐ Human blood, body fluids, tissues and/or cells	Biosafety Overview and Requirements: Institutional Biosafety
	☐ Human Gene Transfer , oncolytic viruses, or biologically derived toxins.	Committee (IBC) or contact
	☐ X-rays that subjects would receive if enrolled in this study	biosafety@rutgers.edu.  • Additional
	☐ Radionuclides that subjects would not receive if not enrolled in this study	Information:
	☐ None of the above	
2.0	* Will specimens be analyzed and/or processed (e.g., pipetted, aliquoted, centrifuged) in a Rutgers laboratory?  Yes No Clear	Institutional Biosafety Committee (IBC) approval is required IF specimens are to be processed/analyzed in a Rutgers laboratory.
		► Additional Information

- **SELECT** all that apply in Q 1.0, if applicable.
- **UPLOAD** <u>Institutional Biosafety Committee (IBC)</u> 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



## Section 5.1 Scientific Review Board (SRB)

For Scientific Review Board information and requirements visit <u>RBHS Scientific Review Board - CINJ Studies</u> and <u>RBHS Scientific Review Board - Non-Oncology Studies</u>.

Scientific Review Board (SRB) requirements.

1.0

\* Is this a cancer-related protocol involving a Robert Wood Johnson Medical School (RWJMS), New Jersey Medical School (NJMS) faculty member or a CINJ member?

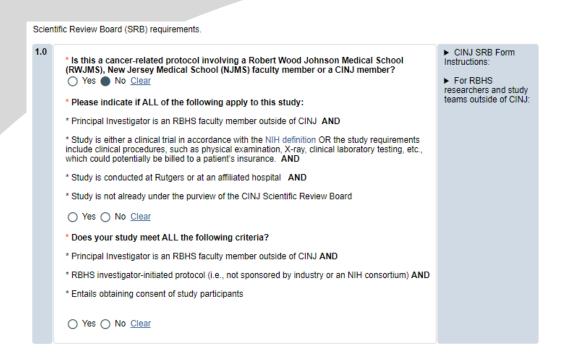
○ Yes ○ No Clear

CINJ SRB Form Instructions:

► For RBHS researchers and study teams outside of CINJ:

- **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 <u>Scientific Review Board</u> and obtain SRB approval.
  - o 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



## **Section 6.0 Research Summary**

Summary of the research project



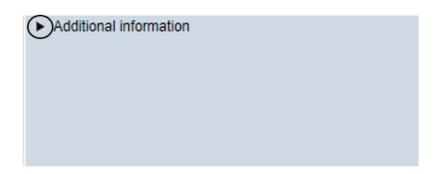
- **COMMERCIAL IRB** submissions have an approved Sponsors protocol and/or NIH-specific protocol therefore Q 1.0 must indicate **YES**.
- **SUMMARIZE** your project in Q 3.0 using lay language or language understood by a person unfamiliar with your area of research.
- **SELECT** all that apply under 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.



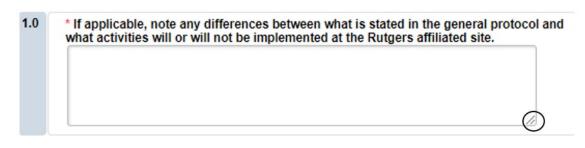


## **Section 6.01 Local Context Summary**

- 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

■ Save





## 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.

1.0	* Vulnerable Populations:	2.0	* Subject Gender(s)/Identity:	3.0	* Age Ranges:	
	☐ Pregnant Persons or Fetuses		☐ All Genders		☐ Neonates (1-30 days)	
	Prisoners		☐ Female		31 days - 6 years	
	Adults Lacking Decisional Capacity		☐ Male		7 - 12 years	
	☐ Students/Employees		☐ Trans male / Trans man		☐ 13 - 17 years	
	☐ Children Wards of the State		☐ Trans female / Trans woman		☐ 18 - 64 years	
	☐ Neonates		☐ Transgender / Gender non-confirming		☐ 65 - 89 years	
	☐ Neonates of Uncertain Viability				90 years and older	
	Research Outside of NJ Involving Minors				□ N/A	
	☐ Children Reaching Age of Majority During Study					
	All Other Children					
	☐ None of the above					
4.0	* Method to Identify Potential Subjects: Discr	uss the o	details of each of the research instruments: surv	eys, que	estionnaires, focus groups, and other evaluation instruments you	ı plan to use
5.0	* Recruitment Details: Describe when, where,	how and	d by whom potential subjects will be recruited. D	escribe	materials that will be used to accomplish your recruitment effort	s
6.0	* Subject Screening: Describe whether and ho	w indivi	duals will be screened for eligibility and by whon	n		

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

1.0	* Privacy Protections During Recruitment: Explain the measures implemented to safeguard privacy in the process of identifying and recruiting potential participants in the research
2.0	* Consent Process - Describe consent process:
	A A

• 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.





#### Section 6.1 Clinical Trial Information

\* 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

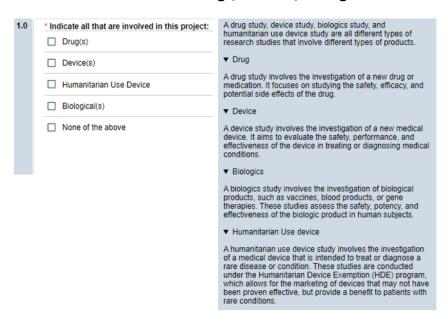
Your research may require registration with ClinicalTrials.gov. More information about <u>ClinicalTrials.gov Registration Requirements</u> here.

• **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



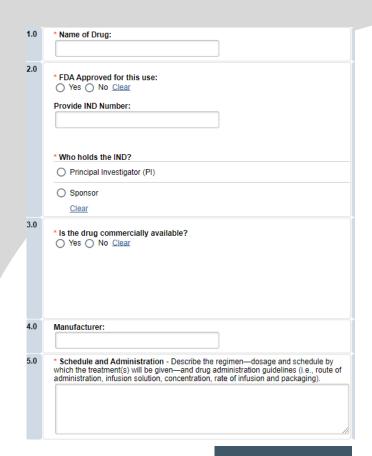
## Section 7.0 Drugs/Devices/Biologics



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.

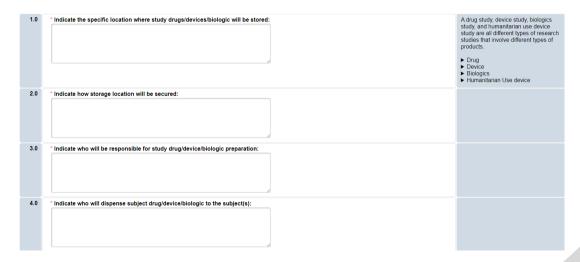




For each Drug, Device or Biologic added, an additional field will appear for more details. You will be prompted to upload FDA documentation where applicable. Adding a drug, device or biologic triggers Section 7.1 Storage, Securing, and Dispensing.

Once all information is provided, click





Once all information is provided, click



Continue →



#### **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 <u>interactive tool</u> 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



#### Section 8.1 Informed Consent Process- Administrative Review

#### 8.1 Informed Consent Process - Administrative Reviews

For more information, go to HSPP Toolkit Forms & Templates Special Consent Considerations. ► Outline plans to enroll individuals: \* Please indicate if any of the following apply to your research: Enrollment of Non-English-Speaking subjects or subjects with Limited English Proficiency (LEP) ☐ Enrollment of subjects who cannot read or write (illiterate or low literacy) ☐ Enrollment of subjects who cannot see (blindness or visually-impaired) ☐ Enrollment of subjects who cannot hear (deafness or hearing-impaired) ■ None of the above 2.0 \* Indicate the types of consent that will be involved in this project (check any or all that ☐ Written consent document will be signed by an adult subject ☐ Written consent document will be signed by a surrogate ☐ Written permission for a minor will be signed by a parent or legal guardian Assent by a minor will be documented ☐ Consent document (paper/electronic-email or internet/oral script) will not be signed by subject (requires a waiver of documentation of consent) 3.0 \*Are you requesting a waiver of certain elements normally required in the consent form? Select YES, if you are requesting a waiver of one of the eight elements listed below) ► Eight elements normally required: ► Additional Guidance \* Are you requesting a waiver of some of the elements required to be included in the HIPAA Authorization? For the IRB to grant an alteration of the HIPAA authorization, the study must be no more than minimal ris to subjects. ► The core elements of a valid authorization



- **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.

3.0	* Are you requesting a waiver of certain elements normally required in the consent form?  Yes  No Clear

Eight elements normally required:

Elements normally required include:

- 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;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

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

4.0	* Are you requesting a waiver of some of the elements required to be included in the HIPAA Authorization?
	○ Yes ○ No <u>Clear</u>

Once all information is provided, click

Continue ⋺



#### 8.2 Waivers

## 8.2 Waivers

Waivers of consent and/or HIPAA Authorization

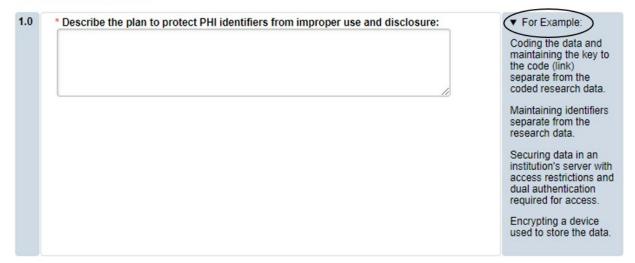
1.0	<ul> <li>Waivers - If you are applying for any waivers of consent and/or HIPAA Authorization (check all that apply)</li> </ul>
	☐ Waiver of Adult Consent
	☐ Waiver of Assent
	☐ Waiver of Parental Permission
	☐ Waiver of HIPAA Authorization
	☐ Partial HIPAA waiver for recruitment purposes only

• 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.

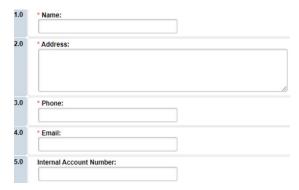
Waiver of HIPAA Authorization







## **Section 9.0 Invoice/Billing Information**

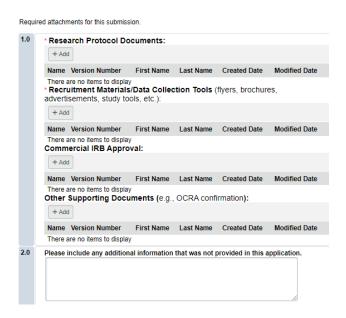


• Provide contact information of who will receive the one-time service fee.

Once all information is provided, click



## **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

Continue (>)



# **Final Page**

#### **Submission Summary:**

SUBMISSION TYPE: Commercial IRB - WCG IRB or Advarra REVIEW TYPE - REQUESTED: Expedited IRB SUBMISSION ID: Pro2024000449

## **Next Steps:**

#### Submit study for IRB review:

Your application form will not be submitted for review until the Principal Investigator returns to the study "workspace," and clicks on "Submit Study". You can track the status of this study's submission by logging into the study workspace.

#### To submit the study:

- 1. Ensure that you have answered all questions in the application and all sections are error-
- free.

  2. Click on "Save & Exit" to exit the application and return to the "workspace."

  3. Navigate to the left of your screen, and under "My Activities," click "Submit Study" to initiate IRB review.



**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 <a href="mailto:irbrelianceteam@research.rutgers.edu">irbrelianceteam@research.rutgers.edu</a>.

