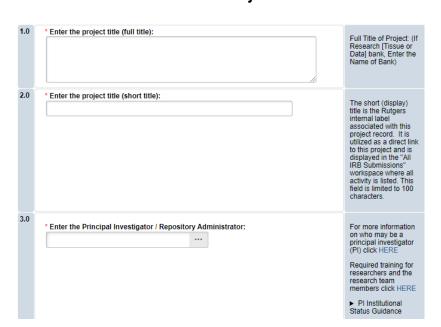
eIRB+ Application Guide

for Greater Than Minimal Risk Research Studies

Please remember that not all sections below will apply to your application/research study. Therefore, some sections might NOT appear. The sections that appear as you complete your 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.
 - o IRB Tip: Ensure all members completed Rutgers CITI requirements

Continue ⋺

Section 1.1 Submission Type

1.0	Select the appropriate application type:
	Research Protocol Study (Greater than minimal risk) - Full Board
	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 a Single IRB (sIRB) human subjects study involving multi-center (external sites) research with Rutgers as the reviewing IRB? Yes O No Clear
	* Is this an expanded access protocol? Yes No Clear

- SELECT Research Protocol Study (Greater than minimal risk) Full Board
 - This means you consider the study greater than minimal risk and the study is not relying on an external IRB as the IRB of record.
 - o **VISIT** the <u>IRB Recommendation Tool</u> if you are unsure if this is the correct application type for your research study.

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

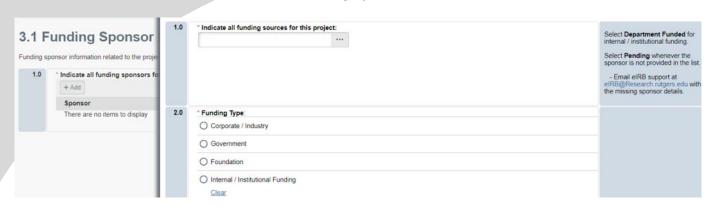
2.0 If applicable, describe other funding source(s) for this project.

- **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.





Section 3.1 Funding Sponsor Information



- 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

Section 4.0 – Rutgers Affiliated Sites



- ADD all Rutgers sites engaged in your study by selecting the need to answer additional questions. + Add . This will populate an additional box where you will
- 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.





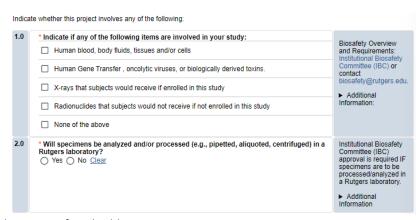
Section 4.1 Non-Rutgers Project Sites



- ADD all domestic sites (within the USA) in Q 1.0 by clicking and answer the questions that populate after.
 - USE our <u>interactive tool</u> if unsure if a domestic (non-Rutgers) site is engaged in research.
 - o **CONTACT** the IRB Reliance Team (<u>irbrelianceteam@research.rutgers.edu</u>) 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 <u>International Research</u> if needed.

Once all information is provided, click

Section 5.0 Biosafety & Radiation Safety



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





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</u> 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.
 - 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.

Scientific Review Board (SRB) requirements.

1.0 CINJ SRB Form * Is this a cancer-related protocol involving a Robert Wood Johnson Medical School Instructions: (RWJMS), New Jersey Medical School (NJMS) faculty member or a CINJ member? Yes No Clear For RBHS researchers and study teams outside of CINJ: * Please indicate if ALL of the following apply to this study: * Principal Investigator is an RBHS faculty member outside of CINJ AND * Study is either a clinical trial in accordance with the NIH definition OR the study requirements include clinical procedures, such as physical examination, X-ray, clinical laboratory testing, etc., which could potentially be billed to a patient's insurance. AND * Study is conducted at Rutgers or at an affiliated hospital AND * Study is not already under the purview of the CINJ Scientific Review Board * Does your study meet ALL the following criteria? * Principal Investigator is an RBHS faculty member outside of CINJ AND * RBHS investigator-initiated protocol (i.e., not sponsored by industry or an NIH consortium) AND * Entails obtaining consent of study participants



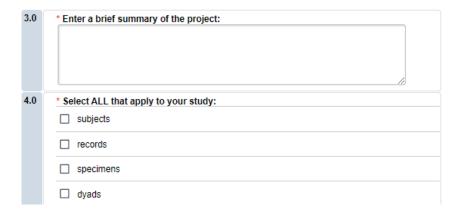


Section 6.0 - Research Summary



For Administrative Review and Commercial IRB submission types, please indicate 'Yes'. Please upload the IRB of Record approved research protocol document and/or the sponsor approved research protocol document in section 10 when prompted.

- 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.



- **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.

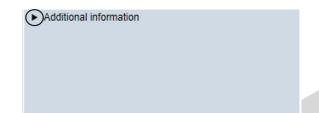
If you select records, specimens or dyads, additional required fields will appear for you to fill in the corresponding number for your research. Additional eIRB+ sections will also populate depending on your selections (e.g., Section 6.03 Biospecimens, 6.04 Secondary Review of Data).

Once all information is provided, click



Section 6.02 Protocol Questions

- This section will ask you specific questions about your research. 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.



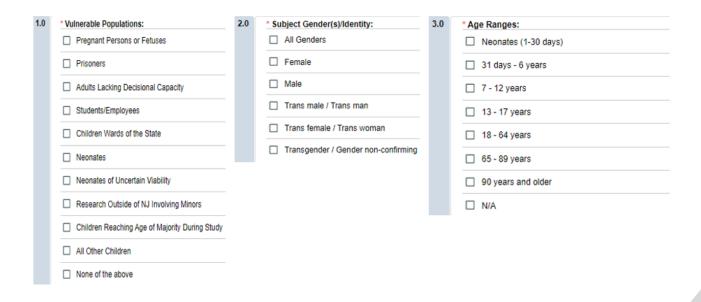


• IRB TIP #2: Expand each text box by dragging the corner of the text box where the three diagonal lines are.



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.



4.0	* Method to Identify Potential Subjects: Discuss the details of each of the research instruments: surveys, questionnaires, focus groups, and other evaluation instruments you plan to use.
5.0	* Recruitment Details: Describe when, where, how and by whom potential subjects will be recruited. Describe materials that will be used to accomplish your recruitment efforts
6.0	* Subject Screening: Describe whether and how individuals will be screened for eligibility and by whom

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 res	earch
2.0	* Consent Process - Describe consent process:	

• 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



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

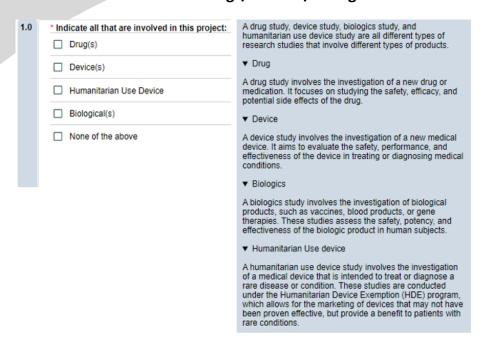
Your research may require registration with ClinicalTrials.gov. More information about <u>ClinicalTrials.gov Registration</u> <u>Requirements here.</u>

• **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.



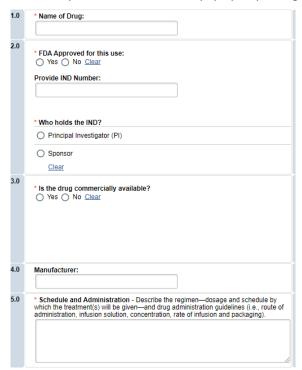


Section 7.0 Drugs/Devices/Biologics



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.





Section 7.1 Storage, Security, and Dispensing

1.0	* Indicate the specific location where study drugs/devices/biologic will be stored:	A drug study, device study, biologics study, and humanitarian use device study are all different types of research studies that involve different types of products. Drug Device Biologics Humanitarian Use device
2.0	* Indicate how storage location will be secured:	
2.0	Indicate now stringe 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



Section 8.0 Informed Consent



- SELECT if subjects will be providing consent (includes verbal consent, and electronic signatures).
 - O 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.
- The following question will appear if you select 'Yes, some but not all' or 'Yes, all'.

You must upload all relevant Adult Consent, Assent, Parent/Guardian Permission, Surrogate Forms into section 10.

* Is this a greater than minimal risk study?

O Yes O No Clear

- **SELECT** 'NO' to question 'Is this a greater than minimal risk study.'
- USE our <u>interactive tool</u> if unsure what consent form template to use
- VISIT our website for the most <u>up-to-date consent form templates.</u>





Section 8.1 Informed Consent Process

- This section will ask you specific questions about the consent process such as location of consent and consent form duration. Please answer the questions and provide details in the text boxes provided for Q 1.0 Q 7.0.
- READ the right-side panel of the page to access additional guidance and examples related to each section.

2.0	* Location of Consent Process and Protecting Privacy:	Indicate where the consent process will take place and outline provisions made to protect subjects' privacy during consent discussions (this includes adult consent, assent, parent/guardian permission/and surrogate consent).
3.0	* Ongoing Consent:	If the duration of subjects' participation in the research is lengthy, outline any plans to re-contact them to determine whether they have any questions or concerns about continued participation in the research (this includes adult consent, assent, parent/guardian permission/and surrogate consent).

Once all information is provided, click



Section 8.1 Informed Consent Process (Continued)

8.0	* Indicate the types of consent that will be involved in this project (check any or all that apply):
	☐ 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)

- **SELECT** all the types of consent that will be involved in this project in Q 8.0.
 - o 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 9.0 **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.



9.0	*Are you requesting a waiver of certain elements normally required in the consent form? No Clear	Select YES, if you are requesting a waiver of one of the eight elements listed below)
		➤ Eight elements normally required: ➤ Additional Guidance

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:

- 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
- 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 10.0 **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.**

10	.0	*Are you requesting a waiver of some of the elements required to be included in the HIPAA Authorization? Yes No Clear

Once all information is provided, click

8.2 Waivers

Continue (>)

Waivers of consent and/or HIPAA Authorization

* Waivers - If you are applying for any waivers of consent and/or HIPAA Authorization (check all that apply)

Waiver of Adult Consent

Waiver of Assent

Waiver of Parental Permission

Waiver of HIPAA Authorization

Partial HIPAA waiver for recruitment purposes only

8.2 Waivers

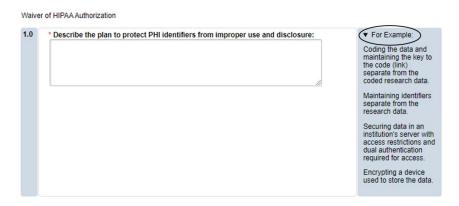
• APPLY for any waivers by selecting them under Q 1.0. Additional sections regarding the waivers will appear on the next page depending on your selection. For example, section **8.9 HIPAA Waiver** will populate if you select Waiver of HIPAA Authorization.





8.9 HIPAA Waiver

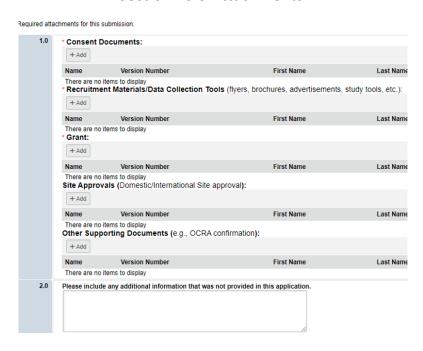
• **REMEMBER** to use the right-side panel for additional information and examples if you are unsure how to answer a question regarding any waivers.



Once all information is provided, click



Section 10.0 Attachments

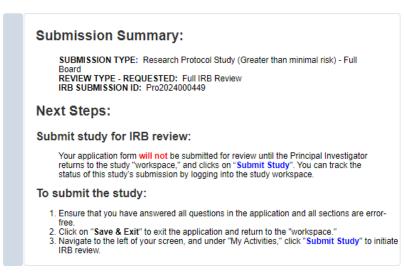


- UPLOAD consent forms, recruitment materials and any data collection tools (surveys, interview guides, screening forms).
 - REVIEW the above documents to ensure that they have version dates and numbers.
- UPLOAD site approvals for any domestic or international sites (these were listed in section 5.1).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





Final Page



• **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.

