

# 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](mailto:irboffice@research.rutgers.edu) for assistance.


### Section 1.0 General Project Information

1.0	* Enter the project title (full title): <input type="text"/>	Full Title of Project: (If Research [Tissue or Data] bank, Enter the Name of Bank)
2.0	* Enter the project title (short title): <input type="text"/>	The short (display) title is the Rutgers internal label associated with this project record. It is utilized as a direct link to this project and is displayed in the "All IRB Submissions" workspace where all activity is listed. This field is limited to 100 characters.
3.0	* Enter the Principal Investigator / Repository Administrator: <input type="text"/>	For more information on who may be a principal investigator (PI) click <a href="#">HERE</a>  Required training for researchers and the research team members click <a href="#">HERE</a>  ▶ PI Institutional Status Guidance

- **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](#)

Continue 

Once all information is provided, click  .

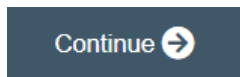
## Section 1.1 Submission Type

1.0 Select the appropriate application type:

- Research Protocol Study (Greater than minimal risk) - Full Board
- Research Protocol Study (minimal risk) - Expedited/Exempt
- Secondary Data Analysis Only (Exempt)
- Research [Biospecimen or Data] Bank
- Humanitarian Use Device (Full Board)
- Emergency Use of a Test Article (Expedited)
- Just In Time (Expedited)
- Non-Human Subject Research
- Administrative Review - (Rutgers U is not the IRB of record)
- Commercial IRB - WCG IRB or Advarra

[Clear](#)

- **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](mailto: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

It is common for investigators from two or more institutions to partner to conduct human subjects research or be involved in multi-site research studies. To conserve resources and enhance and streamline the Institutional Review Board (IRB) review process when such collaborations occur, regulations allow institutions to "enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort" (45 CFR 46.114).

1.0 \* Please indicate the IRB of Record:

- WCG
- Advarra
- Other

[Clear](#)

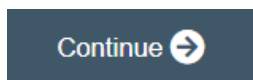
\* Is the SMART IRB Online Reliance System being utilized to establish the reliance agreement?  
 Yes  No [Clear](#)

\* Is the Huron IRB Exchange (IREx) online platform being utilized to establish a reliance agreement?  
 Yes  No [Clear](#)

2.0 Provide the expiration date issued by the IRB of Record which is located on the IRB Approval Letter:

[Click here for more information on reliance agreements.](#)  
▶ SMART IRB  
▶ Huron IRB Exchange

- **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	<p><b>* Please indicate your current funding source:</b></p> <p><input type="radio"/> Unfunded (PI will absorb all costs)</p> <p><input type="radio"/> Funded</p> <p><a href="#">Clear</a></p>	▶ Additional Information:
2.0	<p>If applicable, describe other funding source(s) for this project.</p> <div style="border: 1px solid #ccc; height: 40px;"></div>	

- **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.

Continue →

Once all information is provided, click

## Section 3.1 Funding Sponsor Information

<h3>3.1 Funding Sponsor</h3> <p>Funding sponsor information related to the project.</p> <p>1.0 * Indicate all funding sponsors for this project:</p> <p><a href="#">+ Add</a></p> <p>Sponsor</p> <p>There are no items to display</p>	<p>1.0 * Indicate all funding sources for this project:</p> <div style="border: 1px solid #ccc; height: 20px;"></div>	<p>Select <b>Department Funded</b> for internal / institutional funding.</p> <p>Select <b>Pending</b> whenever the sponsor is not provided in the list.</p> <p>- Email eIRB support at <a href="mailto:eIRB@Research.rutgers.edu">eIRB@Research.rutgers.edu</a> with the missing sponsor details.</p>
	<p>2.0 * Funding Type:</p> <p><input type="radio"/> Corporate / Industry</p> <p><input type="radio"/> Government</p> <p><input type="radio"/> Foundation</p> <p><input type="radio"/> Internal / Institutional Funding</p> <p><a href="#">Clear</a></p>	

- **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.

Continue →

Once all information is provided, click

## Section 4.0 Rutgers Affiliated Sites

Specify all sites engaged in this project.

1.0 \* Specify all Rutgers sites engaged in this project:

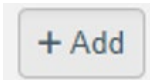

[+ Add](#)

University Site	Subjects treated/recruited here	Records, Biospecimens or Data will be:	Is this the Coordinating Site?
There are no items to display			

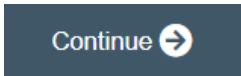
**Include** the site of your Rutgers affiliation (e.g., The University Hospital, Cancer Institute of New Jersey, etc...)

**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 . This will populate an additional box where you will need to answer additional questions.
- **ADD** multiple Rutgers study sites by clicking 
- **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



## Section 5.0 Biosafety & Radiation Safety

Indicate whether this project involves any of the following:

1.0 \* Indicate if any of the following items are involved in your study:

Human blood, body fluids, tissues and/or cells

Human Gene Transfer, oncolytic viruses, or biologically derived toxins.

X-rays that subjects would receive if enrolled in this study

Radionuclides that subjects would not receive if not enrolled in this study

None of the above

**Biosafety Overview and Requirements:** Institutional Biosafety Committee (IBC) or contact [biosafety@rutgers.edu](mailto:biosafety@rutgers.edu).

▶ Additional Information:

2.0 \* Will specimens be analyzed and/or processed (e.g., pipetted, aliquoted, centrifuged) in a Rutgers laboratory?

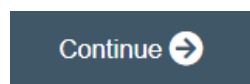
Yes  No [Clear](#)

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** [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



## 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.

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 [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.

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](#)

\* 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

Yes  No [Clear](#)

\* 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

Yes  No [Clear](#)

► CINJ SRB Form Instructions:

► For RBHS researchers and study teams outside of CINJ:

Continue 

Once all information is provided, click



## Section 6.0 Research Summary

Summary of the research project

1.0

\* Is there an approved Sponsor's protocol, NIH -specific protocol, or lead site protocol for this study?


Yes  No [Clear](#)

You must upload the protocol document in section 10(NIH, Sponsor's, or lead site's protocol):

For Administrative Review and Commercial IRB (WCG/Advarra) 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.


- **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.

Continue 

Once all information is provided, click

### Section 6.01 Local Context Summary

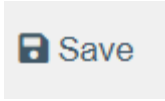
- This section will ask you specific questions about your research as it pertains to the involvement of Rutgers Investigators and Rutgers Sites. Please answer the questions and provide details in the text boxes provided.
- **IRB TIP #1:** Click the arrow icon on the right-side panel of the page to **access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

 Additional information

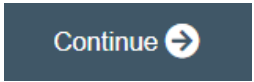


- **IRB TIP #2:** Expand each text box by dragging the corner of the text box where the three diagonal lines are.

**1.0** \* If applicable, note any differences between what is stated in the general protocol and what activities will or will not be implemented at the Rutgers affiliated site.



- **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 .

### 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.

<p><b>1.0</b> * <b>Vulnerable Populations:</b></p> <p><input type="checkbox"/> Pregnant Persons or Fetuses</p> <p><input type="checkbox"/> Prisoners</p> <p><input type="checkbox"/> Adults Lacking Decisional Capacity</p> <p><input type="checkbox"/> Students/Employees</p> <p><input type="checkbox"/> Children Wards of the State</p> <p><input type="checkbox"/> Neonates</p> <p><input type="checkbox"/> Neonates of Uncertain Viability</p> <p><input type="checkbox"/> Research Outside of NJ Involving Minors</p> <p><input type="checkbox"/> Children Reaching Age of Majority During Study</p> <p><input type="checkbox"/> All Other Children</p> <p><input type="checkbox"/> None of the above</p>	<p><b>2.0</b> * <b>Subject Gender(s)/Identity:</b></p> <p><input type="checkbox"/> All Genders</p> <p><input type="checkbox"/> Female</p> <p><input type="checkbox"/> Male</p> <p><input type="checkbox"/> Trans male / Trans man</p> <p><input type="checkbox"/> Trans female / Trans woman</p> <p><input type="checkbox"/> Transgender / Gender non-confirming</p>	<p><b>3.0</b> * <b>Age Ranges:</b></p> <p><input type="checkbox"/> Neonates (1-30 days)</p> <p><input type="checkbox"/> 31 days - 6 years</p> <p><input type="checkbox"/> 7 - 12 years</p> <p><input type="checkbox"/> 13 - 17 years</p> <p><input type="checkbox"/> 18 - 64 years</p> <p><input type="checkbox"/> 65 - 89 years</p> <p><input type="checkbox"/> 90 years and older</p> <p><input type="checkbox"/> N/A</p>
<p><b>4.0</b> * <b>Method to Identify Potential Subjects:</b> Discuss the details of each of the research instruments: surveys, questionnaires, focus groups, and other evaluation instruments you plan to use.</p> <div style="border: 1px solid gray; height: 40px; width: 100%;"></div>		
<p><b>5.0</b> * <b>Recruitment Details:</b> Describe when, where, how and by whom potential subjects will be recruited. Describe materials that will be used to accomplish your recruitment efforts</p> <div style="border: 1px solid gray; height: 40px; width: 100%;"></div>		
<p><b>6.0</b> * <b>Subject Screening:</b> Describe whether and how individuals will be screened for eligibility and by whom</p> <div style="border: 1px solid gray; height: 40px; width: 100%;"></div>		

## 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:

- 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.

Continue →

Once all information is provided, click

## Section 6.1 Clinical Trial Information

1.0 \* 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 ClinicalTrials.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.

Continue →

Once all information is provided, click



## Section 7.0 Drugs/Devices/Biologics

1.0 \* Indicate all that are involved in this project:

Drug(s)

Device(s)

Humanitarian Use Device

Biological(s)

None of the above

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

A drug study involves the investigation of a new drug or medication. It focuses on studying the safety, efficacy, and potential side effects of the drug.

▼ Device

A device study involves the investigation of a new medical device. It aims to evaluate the safety, performance, and effectiveness of the device in treating or diagnosing medical conditions.

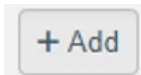
▼ Biologics

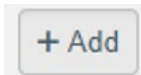
A biologics study involves the investigation of biological products, such as vaccines, blood products, or gene therapies. These studies assess the safety, potency, and effectiveness of the biologic product in human subjects.

▼ Humanitarian Use device

A humanitarian use device study involves the investigation of a medical device that is intended to treat or diagnose a rare disease or condition. These studies are conducted under the Humanitarian Device Exemption (HDE) program, which allows for the marketing of devices that may not have been proven effective, but provide a benefit to patients with rare conditions.

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.

1.0 \* Name of Drug:

2.0 \* FDA Approved for this use:  
 Yes  No [Clear](#)

Provide IND Number:

\* Who holds the IND?

Principal Investigator (PI)

Sponsor

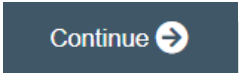
[Clear](#)

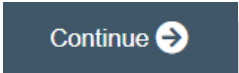
3.0 \* Is the drug commercially available?  
 Yes  No [Clear](#)

4.0 Manufacturer:

5.0 \* Schedule and Administration - Describe the regimen—dosage and schedule by which the treatment(s) will be given—and drug administration guidelines (i.e., route of administration, infusion solution, concentration, rate of infusion and packaging).

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 .



## Section 7.1 Storage, Security, and Dispensing

1.0	<p>* Indicate the specific location where study drugs/devices/biologic will be stored:</p> <input type="text"/>	<p>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.</p> <ul style="list-style-type: none"><li>▶ Drug</li><li>▶ Device</li><li>▶ Biologics</li><li>▶ Humanitarian Use device</li></ul>
2.0	<p>* Indicate how storage location will be secured:</p> <input type="text"/>	
3.0	<p>* Indicate who will be responsible for study drug/device/biologic preparation:</p> <input type="text"/>	
4.0	<p>* Indicate who will dispense subject drug/device/biologic to the subject(s):</p> <input type="text"/>	

Continue →

Once all information is provided, click

## Section 8.0 Informed Consent

1.0	<p>* Will subjects be asked to provide their informed consent to participate in research?</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Yes, some but not all</p> <p><input type="radio"/> Yes, all</p> <p><a href="#">Clear</a></p>	<p>A subject provides informed consent by doing any of the following:</p> <ul style="list-style-type: none"><li>• Physically document/sign, eSign/enter their name into a consent form</li><li>• Verbally agree to participate in the research</li><li>• Review the consent statement prior to participation and complete the research activity (survey, focus group, etc.).</li></ul> <p>Select options based on the target population and identify who will provide consent for participants in the research study.</p>
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- **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](#).

Continue →

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](#).

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

- **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:

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**.

4.0 \* Are you requesting a waiver of some of the elements required to be included in the HIPAA Authorization?  
 Yes  No [Clear](#)

Continue →

Once all information is provided, click

## 8.2 Waivers

### 8.2 Waivers

Waivers of consent and/or HIPAA Authorization

1.0 \* **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

- **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

<b>1.0</b>	<b>* Describe the plan to protect PHI identifiers from improper use and disclosure:</b> <input type="text"/>	<b>▼ For Example:</b> Coding the data and maintaining the key to the code (link) separate from the coded research data.  Maintaining identifiers separate from the research data.  Securing data in an institution's server with access restrictions and dual authentication required for access.  Encrypting a device used to store the data.
------------	-----------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Continue →

Once all information is provided, click

## Section 9.0 Invoice/Billing Information

<b>1.0</b>	<b>* Name:</b> <input type="text"/>
<b>2.0</b>	<b>* Address:</b> <input type="text"/>
<b>3.0</b>	<b>* Phone:</b> <input type="text"/>
<b>4.0</b>	<b>* Email:</b> <input type="text"/>
<b>5.0</b>	<b>Internal Account Number:</b> <input type="text"/>

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

Continue →

Once all information is provided, click

## Section 10.0 Attachments

Required attachments for this submission.

**1.0** \* **Research Protocol Documents:**

Name	Version Number	First Name	Last Name	Created Date	Modified Date
There are no items to display					

\* **Recruitment Materials/Data Collection Tools** (flyers, brochures, advertisements, study tools, etc.):

Name	Version Number	First Name	Last Name	Created Date	Modified Date
There are no items to display					

\* **Please upload IRB Approval and/or Institutional Authorization Agreement (IAA):**


Name	Version Number	First Name	Last Name	Created Date	Modified Date
There are no items to display					

**Other Supporting Documents** (e.g., OCRA confirmation):

Name	Version Number	First Name	Last Name	Created Date	Modified Date
There are no items to display					

**2.0** Please include any additional information that was not provided in this application.

- **UPLOAD** Consent forms, Approved Research Protocol, Local Context Supplement (HRP-508), Recruitment Materials/Data Collection Tools, IRB Approval and/or Institutional Authorization Agreement (Reliance Agreement) and Other Supporting Documents (if applicable).

Continue 

- **SELECT**



# Final Page

## Submission Summary:

SUBMISSION TYPE: Administrative Review - (Rutgers U is not the IRB of record)  
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.

 Exit  Save

- **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.

### My Activities

 Request DRAFT Services

 [Submit Study](#)



## 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](mailto:irbrelianceteam@research.rutgers.edu).



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