

eIRB+ Application Guide

for Humanitarian Use Device Submissions

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

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 HERE Required training for researchers and the research team members click HERE ▶ PI Institutional Status Guidance

- **ENTER** the study's Full Title (Q 1.0) and Short Title (Q 2.0). The Short Title entered will display in the eIRB+ dashboard.
- **ENTER** the Principal Investigator (Q 3.0) by clicking the 3 dots (right side) or by typing the person's name in the open field.
 - **VISIT** our page to see who can and cannot serve as [Principal Investigator \(PI\)](#).
 - **RU graduate** students serving as the PI must **ADD** a faculty advisor as a Co-Investigator.
- **ADD** a study coordinator (Q 4.0). The person entered here will receive all correspondence and notifications regarding this study along with the Principal Investigator.
- **ADD** any Rutgers-affiliated study team members in Q 5.0 Co-Investigators and Q 6.0 Other Study Staff.
 - **IRB Tip:** Ensure all members completed [Rutgers CITI requirements](#)

Once all information is provided, click

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
- 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](#)

* Is this a Single IRB (sIRB) human subjects study involving multi-center (external sites) research with Rutgers as the reviewing IRB?
 Yes No [Clear](#)

* Is this an expanded access protocol?
 Yes No [Clear](#)

- **SELECT Humanitarian Use Device (Full Board)**
 - **VISIT** the [IRB Recommendation Tool](#) if you are unsure if this is the correct application type for your research study.

Continue 

Once all information is provided, click

Section 3.0 Project Funding

3.0 Project Funding

Funding information related to the project.

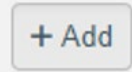

1.0	<p>* Please indicate your current funding source:</p> <ul style="list-style-type: none"><input type="radio"/> Unfunded (PI will absorb all costs)<input type="radio"/> Funded <p>Clear</p>	▶ Additional Information:
2.0	<p>If applicable, describe other funding source(s) for this project.</p> <div style="border: 1px solid #ccc; height: 40px;"></div>	

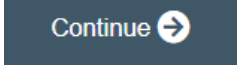
- **SELECT** whether the study is **funded** or **unfunded** in Q 1.0.
 - Select **unfunded** only if the PI of the study will absorb all costs.
 - If funded externally or by department, select **funded** and fill out the following section 3.1 Funding Sponsor Information.

Continue 

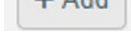

Once all information is provided, click

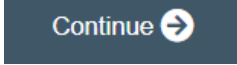
Section 3.1 Funding Sponsor Information

- **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  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  . 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 4.1 Non-Rutgers Project Sites

Specify all sites engaged in this project.

1.0	Domestic Sites:					▶ Additional Information:										
	<input type="button" value="+ Add"/> <table border="1"> <thead> <tr> <th>Site Name:</th> <th>Site Address:</th> <th>Will subjects be treated/recruited here:</th> <th>Records, biospecimens or Data will be:</th> <th>Is this the Coordinating Site:</th> <th>Rutgers IRB Of Record</th> </tr> </thead> <tbody> <tr> <td colspan="6">There are no items to display</td> </tr> </tbody> </table>						Site Name:	Site Address:	Will subjects be treated/recruited here:	Records, biospecimens or Data will be:	Is this the Coordinating Site:	Rutgers IRB Of Record	There are no items to display			
Site Name:	Site Address:	Will subjects be treated/recruited here:	Records, biospecimens or Data will be:	Is this the Coordinating Site:	Rutgers IRB Of Record											
There are no items to display																
2.0	International Sites:					Additional Guidance										
	<input type="button" value="+ Add"/> <table border="1"> <thead> <tr> <th>Site Name:</th> <th>Site Address:</th> <th>Country:</th> <th>Will subjects be treated/recruited here:</th> <th>Records, biospecimens or Data will be:</th> <th>Is this the Coordinating Site:</th> </tr> </thead> <tbody> <tr> <td colspan="6">There are no items to display</td> </tr> </tbody> </table>						Site Name:	Site Address:	Country:	Will subjects be treated/recruited here:	Records, biospecimens or Data will be:	Is this the Coordinating Site:	There are no items to display			
Site Name:	Site Address:	Country:	Will subjects be treated/recruited here:	Records, biospecimens or Data will be:	Is this the Coordinating Site:											
There are no items to display																

- **ADD** all domestic sites (within the USA) in Q 1.0 by clicking and answer the questions that populate after.
 - **USE** our [interactive tool](#) if unsure if a domestic (non-Rutgers) site is engaged in research.
 - **CONTACT** the IRB Reliance Team (irbrelianceteam@research.rutgers.edu) if you answer **YES** to “Are you requesting Rutgers to serve as the IRB of record for this site (NON-Rutgers site)?”
- **ADD** an international site in Q2.0 by selecting and fill out the additional questions on the following page.
 - **VISIT** our guidance page on [International Research](#) if needed.

Once all information is provided, click

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:		Biosafety Overview and Requirements: Institutional Biosafety Committee (IBC) or contact biosafety@rutgers.edu . ▶ Additional Information:
	<input type="checkbox"/>	Human blood, body fluids, tissues and/or cells	
	<input type="checkbox"/>	Human Gene Transfer, oncolytic viruses, or biologically derived toxins.	
	<input type="checkbox"/>	X-rays that subjects would receive if enrolled in this study	
	<input type="checkbox"/>	Radionuclides that subjects would not receive if not enrolled in this study	
	<input type="checkbox"/>	None of the above	
2.0	* Will specimens be analyzed and/or processed (e.g., pipetted, aliquoted, centrifuged) in a Rutgers laboratory? <input type="radio"/> Yes <input type="radio"/> 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 Q1.0, if applicable.
- **UPLOAD** [Institutional Biosafety Committee \(IBC\)](#) approval in section 10.0 (section will appear at the end of the application) if specimens are to be processed/analyzed in a Rutgers laboratory (Q2.0) or Radiation Safety (REHS) approval if applicable.

Once all information is provided, click



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



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Section 6.0 - Research Summary

1.0

* Is there an approved Sponsor's protocol, NIH -specific protocol, or lead site protocol for this study?
 Yes No [Clear](#)

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.

3.0	* Enter a brief summary of the project: <input type="text"/>
4.0	* Select ALL that apply to your study: <input type="checkbox"/> subjects <input type="checkbox"/> records <input type="checkbox"/> specimens <input type="checkbox"/> dyads

- **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.

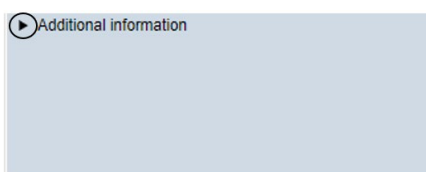
If you select records, specimens or dyads, additional required fields will appear for you to fill in the corresponding number for your research. Additional eIRB+ sections will also populate depending on your selections (e.g., Section 6.03 Biospecimens, 6.04 Secondary Review of Data).

Continue →

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.

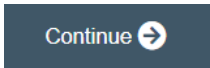


- **IRB TIP #2:** Expand each text box by dragging the corner of the text box where the three diagonal lines are.

3.0 * Enter a brief summary of the project:



- **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>1.0 * Vulnerable Populations:</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>2.0 * Subject Gender(s)/Identity:</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>3.0 * Age Ranges:</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>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.</p> <div style="border: 1px solid gray; height: 40px; width: 100%; margin-left: 20px;"></div>		
<p>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</p> <div style="border: 1px solid gray; height: 40px; width: 100%; margin-left: 20px;"></div>		
<p>6.0 * Subject Screening: Describe whether and how individuals will be screened for eligibility and by whom</p> <div style="border: 1px solid gray; height: 40px; width: 100%; margin-left: 20px;"></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 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

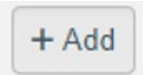
A biologics study involves the investigation of biological products, such as vaccines, blood products, or gene therapies. These studies assess the safety, potency, and effectiveness of the biologic product in human subjects.

▼ 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.**

+ Add

- When you click , a pop up requesting more information will appear.



HUD Device

Use this form to complete the information about the device(s), included in this protocol. You may add multiple devices by clicking the 'OK Add Another' button

1.0	* Device Name: <input type="text"/>	
2.0	* Describe the device and how you intend to use it: <input type="text"/>	
3.0	* Describe what kind of training is required to use this device: <input type="text"/>	
4.0	* Will the clinicians receive a certificate for training? <input type="radio"/> Yes - before the device is ever used <input type="radio"/> Yes - after proctored/monitored cases <input type="radio"/> No Clear	If YES, Upload a copy of the certificate for all clinicians who will use the device in section 10

* Required

OK

OK and Add Another

Cancel

Section 7.1 Storage, Security, and Dispensing

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

Continue →

Once all information is provided, click



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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>Clear</p>	<p>A subject provides informed consent by doing any of the following:</p> <ul style="list-style-type: none">• Physically document/sign, eSign/enter their name into a consent form• Verbally agree to participate in the research• Review the consent statement prior to participation and complete the research activity (survey, focus group, etc.). <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**.
- 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?

Yes No [Clear](#)

- **SELECT** 'NO' to question 'Is this a greater than minimal risk study.'
- **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

- 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	<p>* Location of Consent Process and Protecting Privacy:</p> <div style="border: 1px solid #ccc; height: 40px;"></div>	<p>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).</p>
3.0	<p>* Ongoing Consent:</p> <div style="border: 1px solid #ccc; height: 40px;"></div>	<p>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).</p>



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.
 - 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?

Yes 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:

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;
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 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](#)

Continue →

Once all information is provided, click

8.2 Waivers

8.2 Waivers

Waivers of consent and/or HIPAA Authorization

1.0	<p>* Waivers - If you are applying for any waivers of consent and/or HIPAA Authorization (check all that apply)</p> <p><input type="checkbox"/> Waiver of Adult Consent</p> <p><input type="checkbox"/> Waiver of Assent</p> <p><input type="checkbox"/> Waiver of Parental Permission</p> <p><input type="checkbox"/> Waiver of HIPAA Authorization</p> <p><input type="checkbox"/> Partial HIPAA waiver for recruitment purposes only</p>
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- **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

1.0	<p>* Describe the plan to protect PHI identifiers from improper use and disclosure:</p> <div style="border: 1px solid gray; height: 60px; width: 100%;"></div>	<p>▼ For Example:</p> <p>Coding the data and maintaining the key to the code (link) separate from the coded research data.</p> <p>Maintaining identifiers separate from the research data.</p> <p>Securing data in an institution's server with access restrictions and dual authentication required for access.</p> <p>Encrypting a device used to store the data.</p>
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Once all information is provided, click

Continue →



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Section 10.0 - Attachments

1.0 * Consent 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					

* Institutional Biosafety Committee Approvals:

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

* Scientific Review Board approval:

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

* HUD manufacturer's product labeling, clinical brochure, and/or other pertinent manufacturer informational materials

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

* HUD Training Manual:

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

- **SELECT**

Final Page

Submission Summary:

SUBMISSION TYPE: Humanitarian Use Device (Full Board)
REVIEW TYPE - REQUESTED: Full IRB Review
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  Exit 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

[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.

