

# eIRB+ Application Guide

## for Establishment of Data or Biospecimen Repository


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). The Short Title entered will display in the eIRB+ dashboard.
- **ENTER** the Principal Investigator (Q 3.0) of the study 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 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 Q6.0 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](#)

- **SELECT Research [Biospecimen or Data] Bank**

- This application is only for the **establishment** of a biospecimen or data bank/repository and NOT for those who wish to conduct research using data or biospecimens from a bank/repository.

Once all information is provided, click

Continue →

## Section 3.0 Project Funding

### 3.0 Project Funding

Funding information related to the project.

1.0	* Please indicate your current funding source: <input type="radio"/> Unfunded (PI will absorb all costs) <input type="radio"/> Funded <a href="#">Clear</a>	▶ Additional Information:
2.0	If applicable, describe other funding source(s) for this project. <input type="text"/>	

- **SELECT** whether the study is **funded** or **unfunded** in Q 1.0.

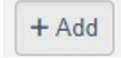
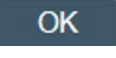
- Select **unfunded** only if the PI of the study will absorb all costs.
- If funded externally or by department, select **funded** and fill out the following section 3.1 Funding Sponsor Information.

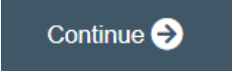
Once all information is provided, click

Continue →

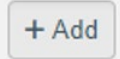
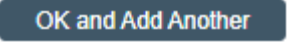


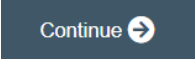
## Section 3.1 Funding Sponsor Information

- **ADD** funding source by selecting the 
- **TYPE** the name of funding source or type 'Department Funded' for internal/institutional funding.
- **SELECT** funding type and select  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](mailto: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 Q 2.0 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 <a href="mailto:biosafety@rutgers.edu">biosafety@rutgers.edu</a> .  ▶ 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 <a href="#">Clear</a>		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



RUTGERS UNIVERSITY  
Office for Research

## Section 6.0 Research [Biospecimen or Data] Bank Summary

Summary of the research bank.

1.0 \* Study Type (check all that apply):

Biomedical / Clinical

Biospecimen repository establishment

COVID-19 focused

Data repository establishment

- **SELECT** all study types that apply; make sure to select repository establishment (for data and/or specimens).

2.0 \* Enter a brief summary of the project:

3.0 \* Describe the qualifications (e.g., training, experience, oversight) the study personnel listed on the e-IRB Application possess to accomplish their role/responsibilities in the research and noting any period of or limits on availability. When applicable, highlight their knowledge of the local study site(s), culture and society.

4.0 \* Select ALL that apply to your study:

subjects

records

specimens

dyads

- **SUMMARIZE** your project in Q 2.0 using lay language or language understood by a person unfamiliar with your area of research.
- **SELECT** all that apply under Q 4.0 and enter the number corresponding to the selection. For example, select specimens if you are storing 300 specimens.

Continue →

Once all information is provided, click

## Section 8.0 Informed Consent

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

No

Yes, some but not all

Yes, all

[Clear](#)

A subject provides informed consent by doing any of the following:

- 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.).

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

- **SELECT** if subjects will be providing consent (includes verbal consent, and electronic signatures).
  - Selecting 'No' will take you to section 8.2 Waivers.
  - Selecting 'Yes, some but not all' OR 'Yes, all' will take you to section 8.1-Informed Consent Process.
- 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** 'Yes' to question 'Is this a greater than minimal risk study.'
- Make sure you include the question "What will happen if I am injured during this study" in the consent form that you upload in section 10.0 (section will appear at the end of the eIRB+ application). Instructions and standard language will be provided in the consent form template.
- **USE** our [interactive tool](#) if unsure what consent form template to use
- **VISIT** our website for the most [up-to-date consent form templates](#).

Once all information is provided, click

Continue →

## Section 8.1 Informed Consent Process

- 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).

- **SAVE** your work regularly to prevent any loss of progress while typing and answering each question by selecting the **SAVE** icon at the bottom of the screen

Save

Continue →



## 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.

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 9.0 **ONLY** if you are requesting a waiver of one of the eight elements below. You must fill out the section **8.6 Waiver of Elements of Consent** on the next screen.

10.0 \* Are you requesting a waiver of some of the elements required to be included in the HIPAA Authorization?

Yes  No [Clear](#)

- **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**.

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

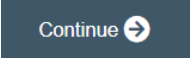
- **REMEMBER** to use the right-side panel for additional information and examples if you are unsure how to answer a question regarding any waivers.

Waiver of HIPAA Authorization

1.0 \* Describe the plan to protect PHI identifiers from improper use and disclosure:

▼ For Example:

- 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.

Once all information is provided, click  .

## Section 10.0 Attachments

Required attachments for this submission.

**1.0**

**\* Consent Documents:**

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

**\* Standard Operating Procedures (SOPs):**

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					

**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** the Standard Operating Procedures (SOP) for this repository.
- **VISIT** our website for the most updated template ([HRP-503d Data/Tissue Repository SOP](#))
- **UPLOAD** consent forms, recruitment materials and any data collection tools (surveys, interview guides).
  - **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 information and site approval forms: [Other Documents>Performance Site Approval Forms](#)

Continue 

- **SELECT**



## Final Page

### Submission Summary:

SUBMISSION TYPE: Research [Biospecimen or Data] Bank  
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

[Where can I find information and IRB guidance on repositories? See Registries & Repositories.](#)

[Where can I find the most updated Repository SOP \(HRP-503d\)?](#)

[What consent template should I use? Use IRB Review Type and Template Recommendation Tool.](#)

[Where can I find the most recent consent form templates?](#)

[Who can serve as the Principal Investigator on a research study?](#)

[What are the CITI requirements for the study personnel on my application?](#)

[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?](#)

[Who can I contact regarding Institutional Biosafety Committee \(IBC\) approval?](#)

[Who can I contact for questions about Scientific Review Board and obtaining SRB approval?](#)

If you have any other questions, please contact the IRB inbox at [irboffice@research.rutgers.edu](mailto:irboffice@research.rutgers.edu).

