

EIRB+ Application Guide

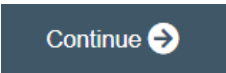
for Secondary use of Data

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 for assistance.

Section 1.0 – General Project Information

1.0	<p>* Enter the project title (full title):</p> <input type="text"/>	Full Title of Project: (If Research [Tissue or Data] bank, Enter the Name of Bank)
2.0	<p>* Enter the project title (short title):</p> <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	<p>* Enter the Principal Investigator / Repository Administrator:</p> <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  .

Section 1.1 - Submission Type

1.0	Select the appropriate application type:
	<input type="radio"/> Research Protocol Study (Greater than minimal risk) - Full Board
	<input type="radio"/> Research Protocol Study (minimal risk) - Expedited/Exempt
	<input checked="" type="radio"/> Secondary Data Analysis Only (Exempt)
	<input type="radio"/> Research [Biospecimen or Data] Bank
	<input type="radio"/> Humanitarian Use Device (Full Board)
	<input type="radio"/> Emergency Use of a Test Article (Expedited)
	<input type="radio"/> Just In Time (Expedited)
	<input type="radio"/> Non-Human Subject Research
	<input type="radio"/> Administrative Review - (Rutgers U is not the IRB of record)
	<input type="radio"/> Commercial IRB - WCG IRB or Advarra

- **SELECT Secondary Data Analysis Only (Exempt)**
 - This application is only for secondary research with data only and NOT for those who wish to conduct secondary research with biospecimens.

Continue →

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: <input type="radio"/> Unfunded (PI will absorb all costs) <input type="radio"/> Funded Clear	▶ Additional Information:
2.0	If applicable, describe other funding source(s) for this project. <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

3.1 Funding Sponsor
Funding sponsor information related to the project.

1.0 * Indicate all funding sources for this project:

+ Add

Sponsor
There are no items to display

2.0 * Funding Type:

Corporate / Industry

Government

Foundation

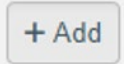

Internal / Institutional Funding

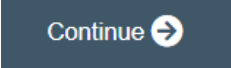
Clear

Select **Department Funded** for internal / institutional funding.

Select **Pending** whenever the sponsor is not provided in the list.

- Email eIRB support at eIRB@Research.rutgers.edu with the missing sponsor details.

- **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

Specify all sites engaged in this project.

1.0 * Specify all Rutgers sites engaged in this project:

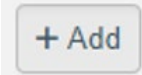

+ Add

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:

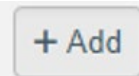
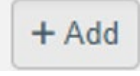
- **ADD** all Rutgers sites engaged in your study by selecting the . This will populate an additional box where you will need to answer additional questions.
- **ADD** multiple Rutgers study sites by clicking 
- **DELETE** a site you've listed by accident by hovering over the site entry and selecting the 'X' that appears on the right side of the highlighted row.

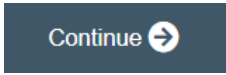
Once all information is provided, click .

Section 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.

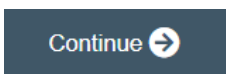
Once all information is provided, click .

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?		Institutional Biosafety Committee (IBC) approval is required IF specimens are to be processed/analyzed in a Rutgers laboratory. ▶ Additional Information
	<input type="radio"/> Yes <input type="radio"/> No Clear		

- **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



RUTGERS UNIVERSITY
Office for Research

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.

2.0

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

- Biomedical / Clinical
- Biospecimen repository establishment
- COVID-19 focused
- Data repository establishment
- Deception
- Diagnostic
- Epidemiologic
- Gene Transfer
- Genetic
- Retrospective review of charts/records

- **SELECT** "Retrospective review of charts/records" for Q 2.0.



3.0 * Enter a brief summary of the project:

Limit to 250 characters

4.0 * 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.

▶ Additional Information

5.0 * Select ALL that apply to your study:

subjects

records

specimens

dyads

▶ Subjects

▼ Records

Records – Includes document(s) with information about an individual. This may include medical records, educational records, employment records, imaging records, and the like.

▶ Specimens

▶ Dyads

How many records will be reviewed?

Unlimited

[Clear](#)

✦ Exit 📁 Save Continue ➔

- **SELECT only** 'records' for Q 5.0. When 'records' is selected, an additional required field will appear to fill in the corresponding number of records for your research.

Continue ➔

Once all information is provided, click

Section 6.01 Local Context Summary - Secondary Data Analysis

Note: This section will only appear if you answered “Yes” in response to question 1.0 in section 6.0.

3.0

* Does this study involve secondary data or specimen analysis?

Yes No [Clear](#)

Please select any additional conditions that apply:

Secondary review of specimens only

Secondary review of data only

Secondary review of both data AND specimens

[Clear](#)

- **SELECT 'Yes'** to Q 3.0 and then select “Secondary review of data only”



4.0

* Does this study involve intervention with living individuals?
 Yes No [Clear](#)

* Please select any additional conditions that apply:

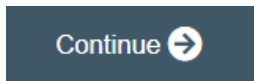
Biospecimens through interaction or intervention with participants will be obtained

Secondary data will be obtained

Obtaining both biospecimens and secondary data

None of the above

- **SELECT 'No'** to Q 4.0 and then select "None of the above"



Once all information is provided, click

Section 6.02 Protocol Questions - Secondary Data Analysis

- Note: This section will only appear if you answered "No" in response to question 1.0 in section 6.0.
- This section will ask you specific questions about your research. Please answer the questions and provide details in the text boxes provided.
- Please note: **SELECT 'Yes'** to Q 12.0 and then select "Secondary review of data only".

12.0

* Does this study involve secondary data or secondary specimen analysis?
 Yes No [Clear](#)

* Please select any additional conditions that apply:

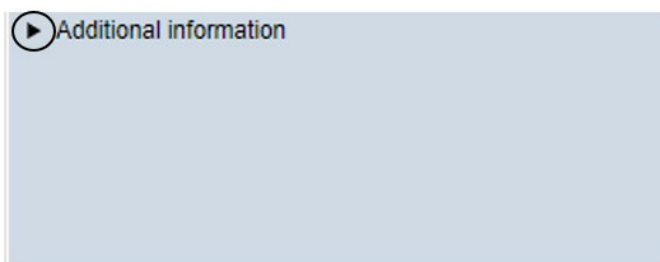
Secondary review of specimens only

Secondary review of data only

Secondary review of both data AND specimens

[Clear](#)

- **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:

 Save

- **IRB TIP #3:** Save your work regularly to prevent any loss of progress by selecting the **SAVE** icon at the bottom of the screen.

Continue 



Once all information is provided, click

Section 6.04 Secondary Review of Data

1.0 * Describe the types of records that will be accessed:

2.0 * Specify the current location of the existing data:


3.0 Enter the date range of data:

* From:  * To: 

4.0 * Describe how the research team will determine what data is necessary to be abstracted/reviewed for this project and who will review the records to make this determination; If applicable, explain when and how identifiers will be removed from the data collected?

5.0 * Will data be obtained from an external source?
 Yes No [Clear](#)

- If 'Yes' is SELECTED for Q 5.0, additional required fields will appear.
- If 'Data is publicly available...' is selected, a field will appear requiring the URL for the data source.

Continue 

Once all information is provided, click



Section 8.0 Consent, HIPAA and Waivers

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

No

Yes, some but not all

Yes, all

[Clear](#)

- **SELECT** "No" because this is a secondary use of data.

Continue →

Once all information is provided, click

Section 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

8.2 Waivers note: Your request for consent waivers will be contingent upon the age range of your data set.

- **SELECTING** 'Waiver of Adult Consent' triggers section 8.8 to appear in the application after clicking Continue.



Waiver of Informed Consent

1.0	* Explain why the research involves no more than minimal risk to subjects: <input type="text"/>
2.0	* Explain why the waiver or alteration will not adversely affect the rights and welfare of the subjects.: <input type="text"/>
3.0	* Explain why the research could not be practicably carried out without the waiver of informed consent: <input type="text"/>
4.0	* Explain how whenever appropriate, the subjects will be provided with additional pertinent information (e.g. an information sheet).: <input type="text"/>

- **SELECTING** 'Waiver of Parental Permission' triggers section 8.3 to appear in the application after clicking Continue.
- **SELECTING** 'Waiver of Assent' triggers section 8.4 to appear in the application after clicking Continue.
- **SELECTING** 'Waiver of HIPAA Authorization' triggers section 8.9 to appear in the application after clicking Continue.

Waiver of HIPAA Authorization

1.0	* Describe the plan to protect PHI identifiers from improper use and disclosure: <input type="text"/>
2.0	* Describe the plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research. If there is a health or research justification for retaining the identifiers, or if such retention is required by law, please provide this as well: <input type="text"/>
3.0	* Explain why the research could not be practicably conducted without access to and use of the PHI: <input type="text"/>

- For a secondary analysis submission, you would not select 'Partial HIPAA waiver for recruitment purposes only.'

Continue →

Once all information is provided, click



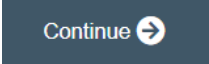
Section 10.0 Attachments

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

+ Add

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: Secondary Data Analysis Only (Exempt)
REVIEW TYPE - REQUESTED: Exempt
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

[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.

