

eIRB+ Application Guide

for Determinations of Non-Human Subjects Research

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	* 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) 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 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](#)

▼ Non-Human Subject Research (Including Quality Assurance/Quality Improvement)

Select this when you are requesting a formal determination of non-human subjects research (NHSR) for your project. What qualifies for NHSR determination:

- Project is not a systematic investigation designed to contribute to generalizable knowledge.
- Project does not involve interaction or intervention with a living individual about whom the project team collects information or biospecimens.
- Project does not involve the collection, access, or use of private identifiable information.

• To access the Rutgers HRPP Tools to help with your application selection, please visit:
<https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/interactive-irb-tools>

- For Non-Human Subject Research or Quality Assurance/Quality, **SELECT 'Non-Human Subject Research.'**

Continue →

Once all information is provided, click

Section 2.0 Non-Human Subjects Research

- **SELECTING 'No'** to all three conditions of Q 1.0 will populate eIRB+ application sections 2.1, 2.2, 2.3, 2.5.
- If submitting a case report (study of three or less cases) **SELECT 'No'** to the first condition of Q 1.0 and **'Yes'** to the second condition. This will populate eIRB+ application section 2.5.
- **SELECTING 'No'** to the first two conditions of Q 1.0 and **'Yes'** to the third condition Quality Assurance/Quality Improvement (QA/QI) will populate the QA/QI sections of the eIRB+ application. Please instead refer to our separate QA/QI Quick Guide for further guidance.

2.0 Non-Human Subjects Research

The Non-Human Research Self-Certification tool can be helpful for determining if a project is Human Research requiring IRB Review.

1.0

* Does the activity involve any of the following?

- In the United States: The use of a drug in one or more persons other than use of an approved drug in the course of medical practice.
- In the United States: The use of a device in one or more persons that evaluates the safety or effectiveness of that device
- Data regarding subjects or control subjects submitted to or held for inspection by FDA
- Data regarding the use of a device or biospecimens (identified or unidentified) submitted to or held for inspection by FDA

Yes No [Clear](#)

* Are you submitting a determination request for a single patient case study or case-series involving three or less individuals?

Yes No [Clear](#)

* Are you submitting a determination request for a Quality Improvement / Quality Assurance Project?

Yes No [Clear](#)

NOTE: Indicating Yes means that your study **does not** meet the requirements for Non-Human Subjects review.

► Additional information:

Continue →

Once all information is provided, click



Section 2.1 – Non-Human Subjects Determination

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

- **SELECTING** 'Yes' indicates that this study involves research or may be classified as research. However, it does not imply that it meets the definition of human subjects research.

2.1 Non-Human Subjects Determination

The Non-Human Research Self-Certification tool can be helpful for determining if a project is Human Research requiring IRB Review.

1.0	<p>* Does the proposed activity constitute research according to the federal definition of research at 45 CFR 46_102 d?</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No Clear</p>	<p>Definition: Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.</p> <p>▼ Additional Information:</p> <p>Quality Improvement activities that do include a research component should select NO.</p> <p>Click here for: Reference Guide: Quality Assurance of Research.</p>
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Continue →

Once all information is provided, click

Section 2.3 – Non-Human Subjects Determination – Living Individuals

- **RESPOND** to Q 1.0 as it pertains to your study.
- Responding 'Yes' to Q 2.0 (using newborn dried spots) will stop the submission, as it will not meet NHSR requirements.

2.2 Non-Human Subjects Determination - Living Individuals

The Non-Human Research Self-Certification tool can be helpful for determining if a project is Human Research requiring IRB Review.

1.0	<p>* Does the research involve obtaining information about living individuals and not just from them?</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No Clear</p>	<p>Definition: Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.</p> <p>► Additional Information:</p>
2.0	<p>* Does the research involve using newborn dried spots?</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No Clear</p>	

Continue →

Once all information is provided, click



Section 2.3 – Non-Human Subjects Determination – Deceased Individuals

- **RESPOND** to Q 1.0 as it pertains to your study.
- Responding 'Yes' to Q 1.0 will trigger a sub-question. If you **SELECT** 'No' to the sub-question, your NHSR submission will stop, as it will not meet NHSR requirements.

2.3 Non-Human Subjects Determination - Deceased Individuals

The Non-Human Research Self-Certification tool can be helpful for determining if a project is Human Research requiring IRB Review.

1.0	<p>* Does the activity involve obtaining protected health information (PHI) about deceased individuals? <input checked="" type="radio"/> Yes <input type="radio"/> No Clear</p> <p>* Please attest that the following is true:</p> <ul style="list-style-type: none">- The use or disclosure requested is solely for research on the protected health information of deceased individuals- The requested protected health information is necessary for the research purposes- The requested information constitutes the minimum necessary data to accomplish the goals of the research- Upon request, the investigator can provide documentation of the death of the individuals <p><input checked="" type="radio"/> Yes <input type="radio"/> No Clear</p>
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Continue →

Once all information is provided, click

Section 2.5 Non-Human Subjects Research Study Summary

2.5 Non-Human Subjects Research Study Summary

Summary of the project.

1.0	<p>* Enter a brief summary of the project:</p> <input type="text"/>	Describe the specific objectives, including background information and rationale for the proposed project.
2.0	<p>* Describe the subject population/type of data or biospecimens to be studied.</p> <input type="text"/>	Identify who your subjects will be and indicate the type of data or biospecimens you will collect. Describe the methods in which the data or biospecimens will be collected, stored, and how confidentiality will be maintained.
3.0	<p>Provide the name and address of the source/provider of the data or biospecimens:</p> <p>* Name: <input type="text"/></p> <p>* Address: <input type="text"/></p>	

[Exit](#) [Save](#) [Continue →](#)

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 sponsors for this project: + Add Sponsor There are no items to display	1.0 * Indicate all funding sources for this project: <input type="text" value=""/> 2.0 * Funding Type: <input type="radio"/> Corporate / Industry <input type="radio"/> Government <input type="radio"/> Foundation <input type="radio"/> 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.
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- **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 10.0 – Attachments

10.0 Attachments

Required attachments for this submission.

1.0	* Grant: + Add <table border="1"><thead><tr><th>Name</th><th>Version Number</th><th>First Name</th><th>Last Name</th><th>Created Date</th><th>Modified Date</th></tr></thead><tbody><tr><td colspan="6">There are no items to display</td></tr></tbody></table> Other Supporting Documents (e.g., OCRA confirmation): + Add <table border="1"><thead><tr><th>Name</th><th>Version Number</th><th>First Name</th><th>Last Name</th><th>Created Date</th><th>Modified Date</th></tr></thead><tbody><tr><td colspan="6">There are no items to display</td></tr></tbody></table>	Name	Version Number	First Name	Last Name	Created Date	Modified Date	There are no items to display						Name	Version Number	First Name	Last Name	Created Date	Modified Date	There are no items to display						▶ Additional Information:
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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. <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>																									

[✕ Exit](#) [💾 Save](#) [Continue →](#)

- **UPLOAD** any other supporting documents: Site agreements, surveys, data collection tools, certifications, etc.

[Continue →](#)

- **SELECT**

Final Page

Submission Summary:

SUBMISSION TYPE: Non-Human Subject Research
REVIEW TYPE - REQUESTED: Non-Human Determination
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.

