

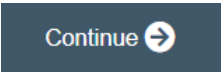
eIRB+ Application Guide

for Emergency Use of an Investigational Device, Drug, or Biologic

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  .

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

▼ Emergency Use of a Test Article (Expedited)

ONLY USE WHEN: The use of a test article (e.g., investigation drug/biologic or device) on a human subject is necessary in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval for the use.

This submission may be used prior to use of the test article to report the emergency use to the IRB; or within five days of the use of the test article to report the use to the IRB.

The life of the patient is the priority.

For continued use, beyond the emergency situation, the clinician **MUST** submit a Research Protocol Study application requesting expanded access (compassionate use).

For more information, visit: [HRPP Guidance Topics](#)

SELECT Emergency Use of a Test Article (Expedited)

- VISIT the [IRB Recommendation Tool](#) if you are unsure if this is the correct application type for your research study.

Once all information is provided, click

Continue →

Section 1.3 Emergency Use

Emergency Use is defined as the use of a test article (e.g. investigation drug/biologic or device) on a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval for the use. The clinician is still required to obtain informed consent under these circumstances.

1.0

* The patient is confronted with a life-threatening situation and no alternative approved treatment/therapy is available that provides an equal or greater likelihood of saving the patient's life [21 CFR 50.23(a) (1-4)].
 Yes No [Clear](#)

A "No" response indicates that the submission **does not** qualify for review as "Emergency Use".

► Additional Information:

'Yes' must be **SELECTED** for the Emergency Use submission to continue. You will be prompted to **SELECT** Drug or Device.

Once all information is provided, click

Continue →



Section 1.3.1 Emergency Use – Drugs/Biologic

OR Section 1.3.3 Emergency Use - Device

A follow-up report is required within 5 days of the treatment date.

1.0 * Enter the date for treatment:

2.0 * Describe the clinical condition of the patient requiring emergency permission:

3.0 * Describe the emergency treatment:

4.0 * Explain why the clinician believes that the drug or treatment is necessary:

5.0 * Indicate alternatives to using this emergency treatment:

6.0 * Upload the information about the drug/biologic (i.e., package insert):

Name	Version Number	First Name	Last Name
There are no items to display			

7.0 * Upload written permission from the manufacturer for the use of the test article u

Name	Version Number	First Name	Last Name
There are no items to display			

8.0 * Was or will consent be obtained:
 Yes No [Clear](#)

A follow-up report is required within 5 days of the treatment date.

1.0 * Date device was or will be used:

2.0 * Describe the clinical condition of the patient requiring emergency permission:

3.0 * Describe emergency treatment:

4.0 * Explain why the clinician believes that the device or treatment is necessary:

5.0 * Indicate alternatives to using this emergency treatment:

6.0 * Upload written permission from the manufacturer for the use of the test article under their IDE:

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

7.0 * Was or will consent be obtained?
 Yes No [Clear](#)

The final question in section 1.3.1 or 1.3.3 asks if the patient will be consented. Depending on your response, eIRB+ application section 1.3.2 or 1.3.4 will populate.


Once all required sections are completed, click [Continue](#) .

Section 1.3.2 Emergency Use – No Consent Form (drug/biologic)

1.0	<p>* The patient was or is confronted with a life-threatening situation and no alternative approved treatment/therapy was or is available that provides an equal or greater likelihood of saving the patient's life [21CFR 50.23 (a)(1-4):</p> <p><input type="radio"/> Yes <input type="radio"/> No Clear</p>												
2.0	<p>* Informed consent cannot be obtained from the patient (because patient cannot communicate or is unable to provide effective consent):</p> <p><input type="radio"/> Yes <input type="radio"/> No Clear</p>												
3.0	<p>* There was or is insufficient time to obtain consent from the subject's legally authorized representative (court appointed guardian for research):</p> <p><input type="radio"/> Yes <input type="radio"/> No Clear</p>												
4.0	<p>* Upload the Independent Physician Certification for Emergency Use of a Test Article Without Informed Consent:</p> <p><input type="button" value="+ Add"/></p> <table><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								
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Section 1.3.4 Emergency Use – No Consent Form (device)

1.0	<p>* The device is intended to treat or diagnose a serious or immediately life-threatening disease or condition:</p> <p><input type="radio"/> Yes <input type="radio"/> No Clear</p>												
2.0	<p>* There is no comparable or satisfactory alternative device or other therapy available to treat or diagnose that stage of the disease or condition in the intended patient population:</p> <p><input type="radio"/> Yes <input type="radio"/> No Clear</p>												
3.0	<p>* Informed consent cannot be obtained from the patient (because patient cannot communicate or is unable to provide effective consent):</p> <p><input type="radio"/> Yes <input type="radio"/> No Clear</p>												
4.0	<p>* There is insufficient time to obtain consent from the subject's legally authorized representative (court appointed guardian for research):</p> <p><input type="radio"/> Yes <input type="radio"/> No Clear</p>												
5.0	<p>* Upload the Independent Physician Certification for Emergency Use of a Test Article Without Informed Consent:</p> <p><input type="button" value="+ Add"/></p> <table><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													

Continue 

Once all information is provided, click



Section 10.0 - Attachments

Attach any other required or relevant files. Your attachments from 1.3.2 or 1.3.3 will appear automatically.

10.0 Attachments

Required attachments for this submission.

1.0 **Emergency Use:** Written permission from the manufacturer for use of the test article.

+ Add

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

Emergency Use: Upload the information about the drug/biologic:

+ Add

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

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** all required forms and documents.
 - **REVIEW** the above documents to ensure that they have version dates and numbers.

- **SELECT** 

Final Page

Submission Summary:

SUBMISSION TYPE: Emergency Use of a Test Article (Expedited)
REVIEW TYPE - REQUESTED: Expedited
IRB SUBMISSION ID: Pro2024000449



Next Steps:

Submit study for IRB review:


Your application form **will not** be submitted for review until the Principal Investigator returns to the study "workspace," and clicks on **"Submit Study"**. You can track the status of this study's submission by logging into the study workspace.

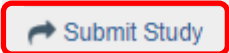
To submit the study:

1. Ensure that you have answered all questions in the application and all sections are error-free.
2. Click on **"Save & Exit"** to exit the application and return to the "workspace."
3. Navigate to the left of your screen, and under "My Activities," click **"Submit Study"** to initiate IRB review.

- **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





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.

