Section 1.0 General Project Information

- **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

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., investigational 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 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.

‘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

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):

   + Add

   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 drug:

   + Add

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

8.0  * Was or will consent be obtained:
   ○ Yes  ○ No  □ Clear

Section 1.3.3 Emergency Use - Device

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 device:

   + Add

   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 * 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 (e)(1-4):
   ○ Yes ○ No Clear

2.0 * Informed consent cannot be obtained from the patient (because patient cannot communicate or is unable to provide effective consent):
   ○ Yes ○ No Clear

3.0 * There was or is insufficient time to obtain consent from the subject’s legally authorized representative (court appointed guardian for research):
   ○ Yes ○ No Clear

4.0 * Upload the Independent Physician Certification for Emergency Use of a Test Article Without Informed Consent:
   + Add

Name  Version Number  First Name  Last Name  Created Date  Modified Date

There are no items to display

Section 1.3.4 Emergency Use – No Consent Form (device)

1.0 * The device is intended to treat or diagnose a serious or immediately life-threatening disease or condition:
   ○ Yes ○ No Clear

2.0 * 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:
   ○ Yes ○ No Clear

3.0 * Informed consent cannot be obtained from the patient (because patient cannot communicate or is unable to provide effective consent):
   ○ Yes ○ No Clear

4.0 * There is insufficient time to obtain consent from the subject’s legally authorized representative (court appointed guardian for research):
   ○ Yes ○ No Clear

5.0 * Upload the Independent Physician Certification for Emergency Use of a Test Article Without Informed Consent:
   + Add

Name  Version Number  First Name  Last Name  Created Date  Modified Date

There are no items to display

Once all information is provided, click **Continue**.
Section 10.0 - Attachments

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

1.0 Attachments

Required attachments for this submission.

- 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** 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.

**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 approved.
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** 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.