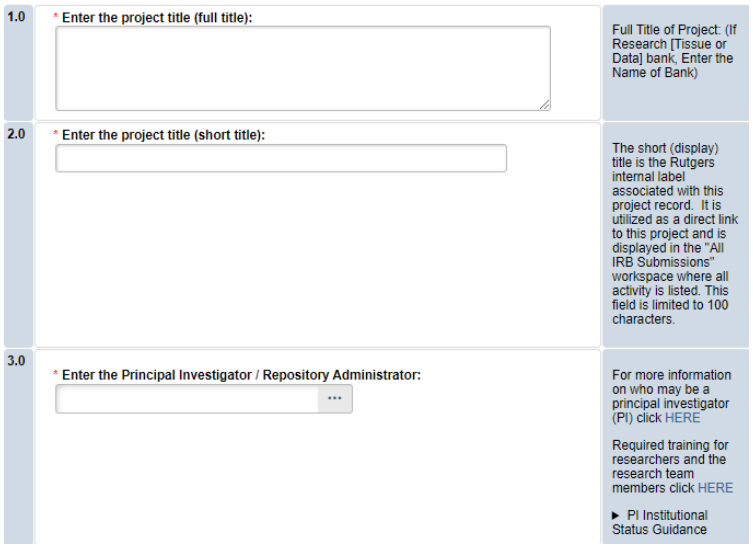
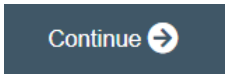
eIRB+ Application Guide

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

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 

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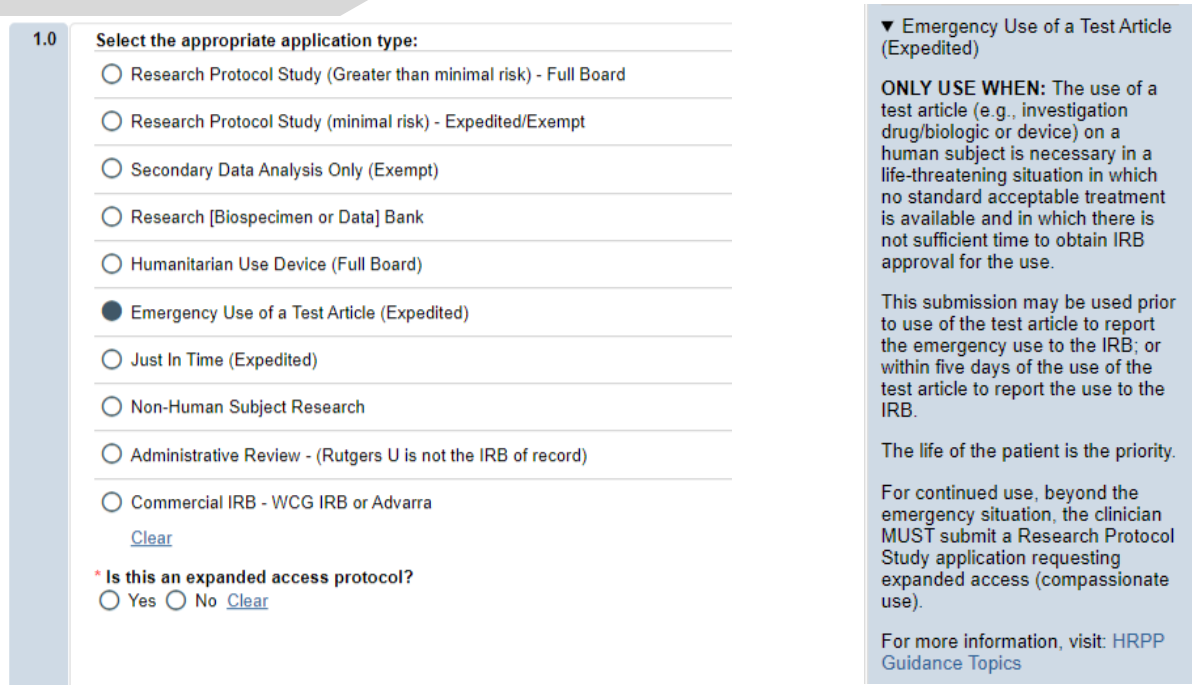
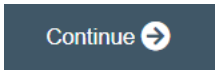
RUTGERS UNIVERSITY
Office for Research

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 

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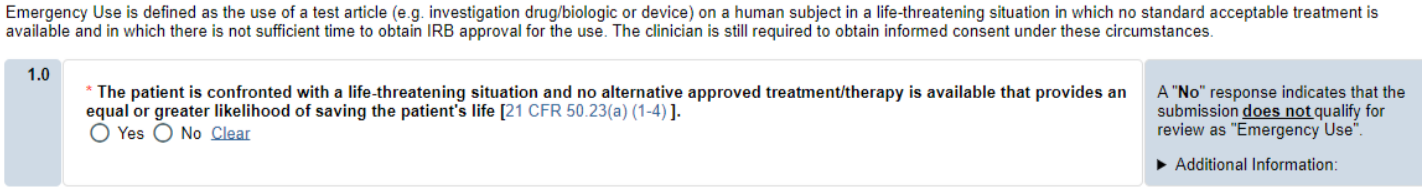
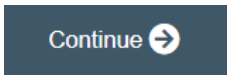
Section 1.3 Emergency Use



'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 

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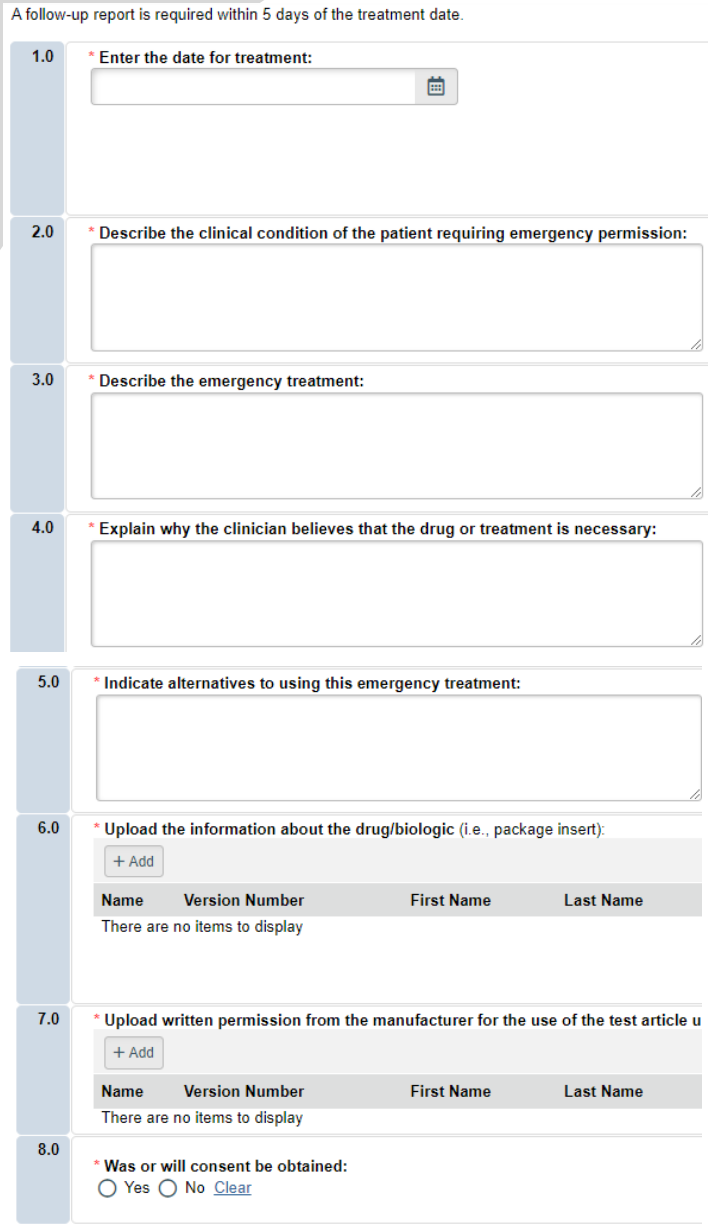
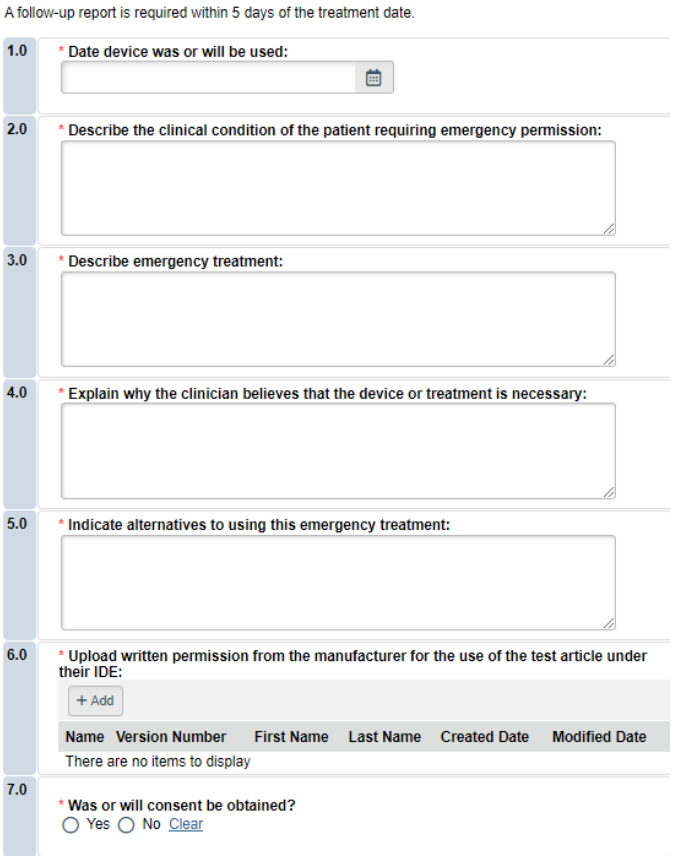
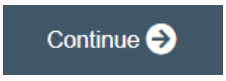
Section 1.3.1 Emergency Use – Drugs/Biologic OR Section 1.3.3 Emergency Use - Device





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 

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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 (a)(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)

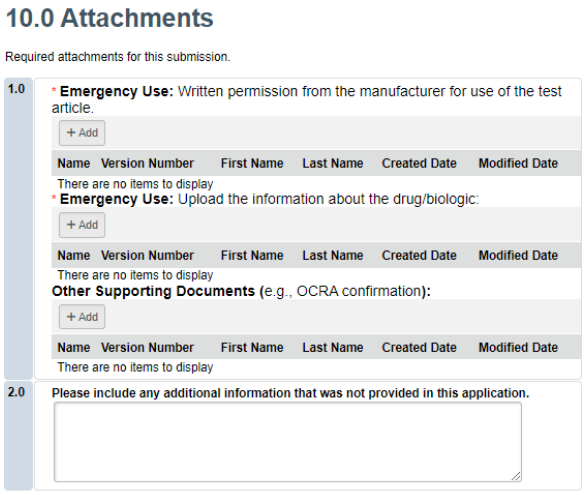
1.0	* The device is intended to treat or diagnose a serious or immediately life-threatening disease or condition: ◯ Yes ◯ No Clear
2.0	* There is no comparable or satisfactory alternative device or other therapy available to treat or diagnose that stage of the disease or condition in the intended patient 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

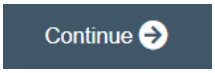
Name	Version Number	First Name	Last Name	Created Date	Modified Date
There are no items to display					

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.



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

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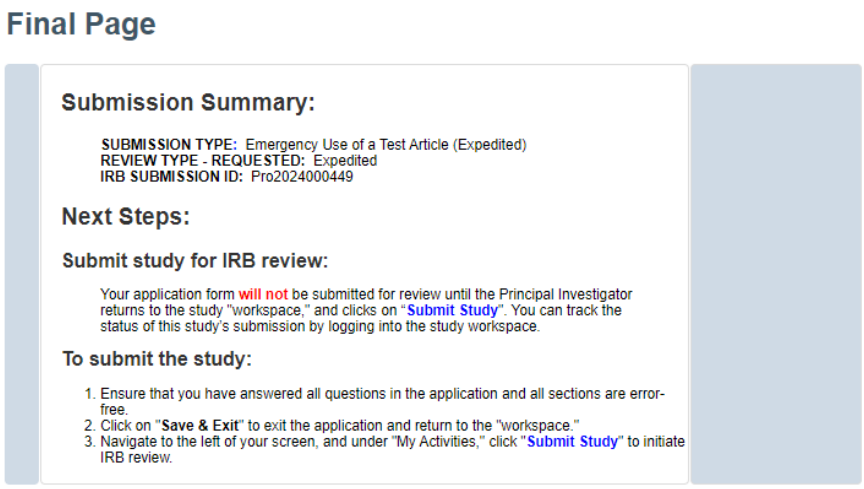
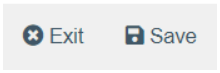
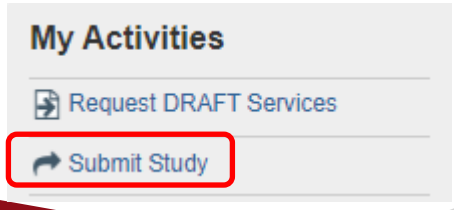


- **REMEMBER** to select 

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.



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.