

QUICK GUIDE

EMERGENCY USE OF A TEST ARTICLE

I. GENERAL INSTRUCTIONS

- A. **Principal Investigator:** For purposes of this guide and the Emergency Use of a Test Article (EUTA) protocol, Principal Investigator (PI) refers to the Treating Physician.
- B. **This Quick Guide applies to:** Creation of a new Emergency Use of a Test Article (EUTA) Protocol
- C. **Navigation:**
 - a. In order to move through the smart form, you must complete all sections within the General Information Page, starting with the Study Identification section. Once you have completed all sections, press “**Next**” to continue with the EUTA Questionnaire Page.
- D. **Website Guidance:** Federal regulations allow for the emergency use of test articles (unapproved investigational drugs, biologics or devices) (EUTA) to treat patients. Prospective IRB review and approval of the EUTA is not required, provided that such emergency use is reported to the IRB within 5 working days after treatment. The LSUHSC-NO (LSUNO) HRPP does, however, request prior notification of emergency use, if time permits. Additional information is available on the [IRB website](#).
- E. **Attachment:** Protocols and consent/assent/information sheet documents should initially be provided as Word documents; all other documents should be in PDF format. For emergency use of a drug, biologic or device, the investigator/treating physician is required to obtain the written informed consent of the participant or the participant’s legally authorized representative. The IRB has developed an *Emergency Use Consent Template* for this purpose.
- A. **New Protocol Overview:** Reference this quick guide found on our [Kuali Quickguide webpage](#) for an overview and additional guidance related to each section.

II. GENERAL INFORMATION PAGE

- A. **Study Identification:**
 - a. **Title:** Enter the title of your study.
 - b. **Principal Investigator:** Identify the Principal Investigator (PI) by:
 - i. Begin typing the name of the PI and users that are listed in kuali will automatically begin to populate.
 - ii. Click on the populated box listing the correct information of the PI.
 - c. **Department:** Primary appointment of PI
 - i. Begin typing the name of the department and candidates will automatically appear from the list of departments stored in Kuali.
 - ii. Click the department’s name and it will be entered in the field.
 - d. **School:** Select the School from the drop-down list that corresponds to the primary appointment of the PI.

- e. Press “Next”
- B. Level of Review:**
 - a. Select the “Protocol Type” from the drop down menu: **Emergency Use of a Test Article**
 - b. Press “Next”
- C. Performance Site(s):**
 - a. Follow instructions to select the facility where the EUTA will be carried out.
 - b. If the facility is not listed in the drop-down menu, select “Other” and provide the name of the facility.

Once all required information has been entered on the General Information Page, press “Next” to begin the EUTA specific questionnaire.

III. REVIEW TYPE QUESTIONNAIRE PAGE

- A. Questionnaire: Emergency Use of a Test Article**
 - a. Preliminary Question: Indicate if the protocol is being submitted for the first time before or after the treatment (emergency use).
 - i. If before treatment, only Part I - *Before Treatment* - of the form will appear; complete Part I
 - ii. If after, both Part I and Part II - *After Treatment* will appear; complete Part I and Part II
 - b. Answer all applicable questions or provide all requested information.
 - c. The protocol adapts using built-in logic (smart-form).
 - i. Depending on your response, you will be required to provide additional information.
 - ii. Depending on your response, you will be required to attach either a redacted copy of the signed consent form or the signed copy of the [Independent Physician Certification](#) letter.

IV. SUPPORTING DOCUMENTS

- A. Relevant Documents**

Load all relevant documents not previously attached in the EUTA protocol. Relevant documents include the following (either b or c is a required document):

 - a. A copy of the institution’s (facility’s) approval document for use of the device, if applicable;
 - b. Any statements or documents from the sponsor/manufacturer supporting the emergency use of the test article in the identified patient; OR
 - c. Any statements or documents from the FDA approving the proposed emergency use of the drug or device in this patient).
- B. Instructions**
 - a. Click the “+Add Line” button to the right to upload a Supporting Document.
 - b. In the dialogue box, Drag and Drop a file or Click “+ Choose” and browse for a file:

- i. If browsing, locate the file and click open to attach. Note: all commonly used file types should be compatible except for “.msg” (Outlook messages).
- c. Enter a Name that will help you identify the document
- d. Select an Attachment Type from the drop-down list.
- e. Repeat Steps a-d as many times as necessary to add all necessary documents.

V. PI CERTIFICATION

The protocol may only be submitted by the PI.

- a. If you are the PI, you will be asked to provide your statement of assurance. If you do not agree with the statement, you can permanently terminate the submission by clicking the “abandon” button.
- b. *Reference the New Protocol Overview Quick Guide for Detailed Guidance.*

VI. SUBMISSION INSTRUCTIONS

A. When the EUTA application is ready for submission

- a. Click “**Submit**” for it to be sent to the HRPP office.
- b. If required fields have no entry, error messages will appear
 - i. Complete all required fields and click “**Submit**” again.
- c. Submission’s status will change from “In Progress” to “Submitted for Review”

VII. CHECKING STATUS OF A EUTA PROTOCOL

Click on “Manage Protocols” to view the submission type and status of your EUTA protocol

Once your EUTA Protocol is Approved, the status will be:

A. EUTA Status Post Approval:

- a. **Submission Type:** Initial
- b. **Review Type:** Expedited
- c. **Status:** Approved
- d. **Continuing Review Date:** N/A

B. Submission Type Definitions:

- a. **New:** an initial (new) protocol submission.
- b. **Initial:** “New” submission that is approved by the IRB
- c. **Amendment:** Used to provide information after use of the Test Article, if the EUTA Protocol was created before use of the Test Article.
- d. **Close Request:** Not Applicable - Once all information regarding the EUTA is received by the IRB Office, the protocol will be closed administratively.

C. Status Type Definitions:

- a. **In Progress:** This is the first version of the Protocol and it has not yet been submitted for review.
- b. **Submitted for Review:** This submission has been submitted to the compliance office for review for the first time.

- c. **Revisions in Progress:** This is the new version of a protocol created when the Revisions Requested action is taken. This version is sent to the researcher so they can make their changes.
- d. **Approved:** This version of the protocol has been approved by the compliance office.
- e. **Disapproved:** This protocol was disapproved by the compliance office.
- f. **{Submission Type: Amendment} In Progress:** An Amendment is being worked on in this version and has not yet been submitted for review.
- g. **{Submission Type: Close Request} In Progress:** A request to close the protocol is being worked on and has not yet been submitted for review.
- h. **Closed:** This protocol has been closed and is no longer active.
- i. **Abandoned:** This submission was abandoned by the researcher.

VIII. EUTA POST APPROVAL REQUIREMENTS

A. EUTA SUBMITTED BEFORE USE OF TEST ARTICLE:

- a. Within 5 business days after use of the test article, you must "amend" this protocol, change your response to "AFTER Use", complete [Part II - After Treatment](#), and re-submit the application for review and approval.
- b. After the test article has been used and approved "After Use," no additional actions in KR are needed.

B. EUTA SUBMITTED AFTER USE OF TEST ARTICLE: N/A.

- a. After EUTA is approved, no additional actions in KR are needed. If the test article is used in the future, a new protocol will need to be submitted in KR.