

Emergency Use Report Form

ETSU/VA IRB Notification

Please refer to ETSU IRB Policy 20 Emergency Use for detailed information and procedures surrounding emergency use. Complete and email this form to IRB@etsu.edu before the emergency use, when possible. The fully complete form MUST be submitted to the IRB within 5 working days after initiation of the emergency use.

Please fill out the following information:

Name of Treating Physician:

Department or Division:

Phone number:

Email:

Alternate Contact Person:

Contact Information:

Institutions Responsible for Review:

Was the emergency use subject to legacy MSHA (an affiliate of Ballad Health) oversight?

Yes

No

Was the treatment conducted at VA facilities, or using VA patients, time, or equipment?

Yes

No

IF YES, SUBMIT THIS FORM TO VA R&D OFFICE

If yes to above, is this a VHA Operation Activity?

Yes

No

If yes to above, is the activity you are involved in directed by a VHA Program Office?

Yes

No

A. Test Article Information

Name of Test Article:

Name of Manufacturer:

Who holds the IND or IDE? Sponsor/Manufacturer Treating Physician

For drug or biologic, include eIND#: (attach FDA IND documentation)

For device, include IDE#: (attach FDA or Sponsor IDE documentation)

If no IDE# exists, the treating physician must submit a report on use of the device to CDRH.

Will the sponsor/manufacturer provide the test article at cost or no charge?

B. Confirm Emergency Use is Appropriate (all must be checked for emergency use criteria to be met)

This emergency use of the test article was not a systematic investigation designed to develop or contribute to generalizable knowledge.

Patient has a life-threatening (drugs and devices) or severely debilitating disease or condition (drugs only).

Explain the nature of the life-threatening or severely debilitating situation and why use of the test article was necessary:

No generally acceptable alternative is available for treating the patient.

A. Describe available alternative methods:

B. Explain why alternatives are not acceptable:

C. Explain proposed treatment (and attach relevant IB, protocols, and materials provided by the manufacturer):

Patient's condition requires immediate treatment such that there was not sufficient time to obtain convened IRB approval.

Explain why there was not sufficient time to obtain IRB approval of the Emergency Use of the Test Article:

Depending on if the test article is drug/biologic or device, the treating physician has made the additional determinations as specified in IRB Policy 20.

For drugs/biologics, determine that the probable risk to the patient from the investigational test article is not greater than the probable risk from the disease or condition.

For devices, assess the potential for benefit from the use of the unapproved device, and have substantial reason to believe benefits will exist.

C. Patient Protection Measures Taken

Complete as many as possible before treating the patient with test article.

1. Concurrence of IRB Chair, or designee, via email.
 - Email: After completing Parts A & B of this form, email to IRB Chair and IRB Office as directed in Policy 20.
 - Follow-up by Phone: After emailing the partially completed form to the IRB, call the IRB Chair and OPHRS Director (listed in Policy 20) to discuss emergency use criteria.
 - Confirmation Email: The IRB Chair, or designee, sends confirmation email to treating physician and IRB Office documenting concurrence.

All attempts to reach IRB Chair or staff should be documented by the treating physical and maintained with this form as part of the Emergency Use records.

2. Devices only: Concurrence by an independent physician that emergency use criteria are satisfied.

Written informed consent of the patient or their LAR (attach documentation of informed consent).

No written consent obtained (attach documentation).

Before treatment, determine and **document** (via email) that criteria for waiving emergency informed consent are met, in opinion of:

Treating physician, AND

Independent/uninvolved physician

If no time for independent physician opinion before treatment, treating physician should document criteria are met and obtain documentation from second physician within 5 days of treatment per IRB Policy 20.

Signature

Please ensure all corresponding documentation is attached to this signed form. Submit documentation to IRB@etsu.edu on **high priority**.

Signature of Treating Physician

Date