

Please refer to the PPMH IRB Policy “Emergency Use of Drugs, Biologics, and Devices” for more detailed information about emergency uses. Sections A & B of this form should be emailed to the IRB representative (per IRB policy) and discussed **before the use, whenever possible**. The fully completed form **must** be submitted to the IRB Coordinator within **5 working days after initiation** of the emergency use.

Physician Information

**Treating Physician’s
Name:**

Department:

Email / Telephone:

**Preferred Method of
Contact:**

Date of Submission:

Confirm that Emergency Use is Appropriate (all boxes must be checked)

Patient has a **life-threatening** or **serious disease or condition** (see IRB policy listed above for the definitions of these terms, which differ for drugs/biologics vs. devices)

Describe the patient’s condition (noting why it is life-threatening/serious):

Explain why available alternatives are not acceptable (e.g., *standard therapies have been exhausted; patient does not qualify for research study; research study is not approved at PPMH*):

No generally acceptable alternative for treating the patient is available

Explain the proposed therapy (*also attach any available materials, protocols, investigator’s brochures provided from the manufacturer*):

Patient's condition **requires immediate treatment**, such that there is not sufficient time to obtain IRB review and approval at a convened meeting.

Explain timing considerations:

Depending on whether the test article is a drug/biologic or device, the treating physician has made the **additional determinations** specified in the IRB Policy listed above.

For Drugs/Biologics, determine that the **probable risk** to the persons from the investigational test article is not greater than the probable risk from the disease or condition. See IRB Policy listed above for the additional determinations to be made by the FDA.

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

→ **(1) Email:** After completing parts A & B above, **email this form** to the IRB Chair or designee as directed in the IRB policy.

→ **(2) Follow-up by Phone:** Next, **call the designee at the number listed on the IRB policy** and request the IRB Chair or designee to discuss the emergency use criteria. If you are unable to reach any of the IRB representatives listed in the IRB policy before you must use the investigational test article, you may continue with the emergency use process.

→ **(3)** IRB Chair or designee sends **confirmation email** to treating physician and IRB Administrator/Coordinator.

While seeking IRB concurrence, you may simultaneously work through the other steps in the process, per IRB Policy.

→ Contact the **manufacturer** of the investigational agent about their willingness to make the test article available to your patient.

→ Refer to the IRB Policy for information about the necessary approvals from the **sponsor** and/or **FDA** for the emergency use.

Test Article Information

Name of Test Article

Name of Manufacturer

Who holds the IND (for drugs/biologics) or IDE (for devices)?

Treating Physician

Manufacturer/Sponsor

For Drug or Biologics, include emergency IND# (from FDA):

For Device, include applicable IDE# (usually from sponsor):

**Patient Protection Measures
(Complete as many as possible *before* using the investigational article)**

Written informed consent from patient or their legally authorized representative. See [Emergency Use Consent Form Template](#)

Concurrence of the IRB Chair or designee, confirmed by email.

DEVICES ONLY:
Independent assessment from uninvolved physician that [emergency use criteria](#) are satisfied.

OR

Written informed consent NOT obtained → **Before** using the test article, **determine** and, if possible, **document** (in writing/email) that criteria for **waiving emergency use consent** (see below) are met, in the opinion of:

Physician treating the patient with the test article; **and**

Physician not participating in the emergency use (independent/uninvolved physician)

→ If **no time** to get an independent determination from a second physician, the treating physician should **determine** that the criteria for waiving emergency use consent are met and proceed with the emergency use. Treating physician should have his/her determination **evaluated in writing** by an independent/uninvolved physician **within 5 working days** after the use.

Follow-up Report

This completed form must be submitted to the IRB Coordinator within **5 working days after the initiation** of the investigational article. See IRB Policy for information about follow-up reporting to the **FDA** and/or **sponsor**.

Date of Emergency Use

Date this follow-up report submitted to IRB

Provide patient outcome information as of the date when this report is submitted to the IRB.		Patient's current condition:	
No adverse events have occurred	OR	Adverse events have occurred and the PPMH IRB's <u>Adverse Event Reporting Form</u> is attached .	
Attached copy of the signed emergency use consent form	OR	Written informed consent could not be obtained → See waiver criteria: Submit written documentation from the treating physician and a second independent/uninvolved physician that the emergency situation fulfills the following criteria: 1) The patient was confronted by a life-threatening situation that necessitated the use of the test article; 2) Informed consent could not be obtained because of an inability to communicate with or obtain legally effective consent from the patient; 3) There was insufficient time to obtain consent from the patient's legally authorized representative; and (4) No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the patient's life.	
Attached email confirmation of IRB concurrence (Chair or designee)	OR	It was not possible to obtain prior IRB concurrence; please explain :	
For Drugs/Biologics, obtained emergency IND from FDA.	OR	For Devices, obtained prior authorization from IDE sponsor. If sponsor authorization not obtained, explain :	
No additional uses of the investigational agent are anticipated.	OR	Additional uses of the investigational agent are anticipated. Explain whether there is a research study available that could be opened at Phoebe Putney Memorial Hospital:	

DEVICES only: attached second opinion of an uninvolved physician that the patient meets the criteria for emergency use (part B above)	OR	DEVICES only: Second opinion that patient met criteria for emergency use was not obtained prior to the emergency use; please explain why it was not possible to obtain a second opinion:
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Physician Signature

Physician's Name: _____ Date: _____

Electronic Signature:

Please save a copy of the form for your records and submit the final form electronically by clicking the "Submit Form" to the left or at top of page.

IRB Review of Follow-Up Emergency Use Report (Completed by IRB Office Only)

IRB Chair Signature: _____ Date Noted: _____

All requirements for Emergency Use are satisfied; no further action is required. Retain documentation for your files.

Subject to the additional requirements detailed in IRB correspondence dated:

Additional requirements met on:

Physician (or member of appropriate Department/Division) must request an IRB consultation about the need for a new IRB application.