

**Emergency Use Report**

This form is to be used for the reporting of an Emergency Use of an Unapproved or Investigational Drug, Device, or Biologic or an Emergency Use of a Humanitarian Use Device (HUD)[[1]](#footnote-1). Detailed information regarding emergency uses is available in the *Human Research Protection Program (HRPP) and Institutional Review Board (IRB) Handbook*.

Physicians should report intended emergency uses to the IRB Office in advance of the use whenever possible in order to obtain concurrence of the IRB Chair or their designee that the proposed use and, if applicable, exemption from the requirement for informed consent is consistent with the regulations.

In all instances (including when a preliminary report has been submitted), emergency uses and emergency consent exemptions must be reported to the IRB within 5 working days after the use of the test article.

**NOTE:** Any subsequent use of the investigational product at this institution is subject to prospective convened IRB review. If you anticipate that there may be a need for further use of this product at this institution, please submit an IRB application for review as soon as possible.

1. **REPORTING PHYSICIAN INFORMATION**

|  |  |
| --- | --- |
| **Name:**  | **Date:**  |
| Title:  |
| **Email:**  |
| **Phone Number:**  | **Fax Number:**  |
| Mailing Address:  |

**Alternative Contact**

[ ]  NA – Reporting Physician will serve as the prime contact for the purposes of this report

|  |
| --- |
| **Name:**  |
| Title:  |
| **Email:**  |
| **Phone Number:**  | **Fax Number:**  |
| Mailing Address:  |

1. **PATIENT INFORMATION**

|  |  |
| --- | --- |
| Initials:  | Age:  |
| **Diagnosis:**  |
| Anticipated or Actual Date of Emergency Use/Intervention:  |

1. **ELIGIBILITY FOR EMERGENCY USE**

The emergency use of an investigational article, unapproved device, or Humanitarian Use Device is permitted under FDA regulations if a patient is 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.

**Life‐threatening**, for the purposes of section 56.102(d), includes the scope of both life‐threatening and severely debilitating, as defined below.

***Life‐threatening*** *means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life‐threatening do not require the condition to be immediately life‐threatening or to immediately result in death. Rather, the subjects must be in a life‐threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.*

***Severely debilitating*** *means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.*

Describe the patient’s medical condition, why it is life-threatening, and why the use of the investigational product is required:

Describe any standard treatments for the patient’s condition and why these treatments are considered inappropriate or unavailable to this patient:

1. **PRODUCT INFORMATION**

[ ]  **Investigational Drug or Biologic**

Name of Investigational Drug:

IND#:

Sponsor Name:

Sponsor Address:

Sponsor Contact Person and Phone Number:

[ ]  **Investigational Device**

Name of Investigational Device:

IDE#:

Sponsor Name:

Sponsor Address:

Sponsor Contact Person and Phone Number:

[ ]  **Humanitarian Use Device**

Name of Humanitarian Use Device:

HDE#:

Manufacturer Name:

Manufacturer Address:

Manufacturer Contact Person and Phone Number:

[ ]  **Other**, describe as above:

1. **INFORMED CONSENT**

An exception under FDA regulations at 21 CFR 50.23 permits the emergency use of an investigational drug, device, or biologic without informed consent when the investigator and an independent physician who is not otherwise participating in the clinical investigation certify in writing that all four of the following specific conditions apply.

* + 1. The subject is confronted by a life-threatening situation necessitating the use of the test article.
		2. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject.
		3. Time is not sufficient to obtain consent form the subject’s legally authorized representative.
		4. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject’s life.

If time is not sufficient to obtain the independent physician determination before use of the test article, the actions of the investigator must be reviewed and evaluated in writing by an independent physician within 5 working days. The IRB must be notified within 5 working days when an emergency waiver is used.

[ ]  **Informed Consent Has Been/Will Be Obtained Before the Emergency Use Occurs** – include a copy of the intended/executed consent form with your submission. If sending an executed copy, please black out the patient’s name and any other identifiers.

[ ]  **Informed Consent Has NOT Been/Will NOT Be Obtained Before the Emergency Use Occurs.** The following criteria must be satisfied for an emergency consent exception. Certify that each of the following are true by providing an explanation for each.

1. The subject is confronted by a life-threatening situation necessitating the use of the test article. Explain:
2. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject. Explain:
3. Time is not sufficient to obtain consent form the subject’s legally authorized representative. Explain:
4. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject’s life. Explain:
5. **Supporting Documentation**

In addition to completing this form, please attach:

1. If an exception from the requirement for informed consent is used, include independent physician documentation. The independent physician documentation should address the criteria in Section V above.
2. A copy of the consent form if one has been or will be used to document the informed consent of the patient. Redact any identifiers prior to submission.
3. Documentation of any other applicable institutional approvals such as Radiation Safety, Biosafety, Pharmacy, etc.
4. **SIGNATURE**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physician Signature Date

**HRPP/IRB Use Only**

1. **Determinations**

[ ]  Yes [ ]  No - The emergency use appears consistent with the regulatory criteria.

[ ]  Yes [ ]  No - Consent was obtained and documented with an appropriate consent form.

[ ]  Yes [ ]  No - Informed consent was not obtained.

If Yes (no consent):

[ ]  Yes [ ]  No – The criteria for an emergency consent exception appear satisfied.

☐ Yes [ ]  No - Independent physician certification was obtained.

[ ]  Acknowledge Emergency Use.

[ ]  Use may not be consistent with regulations, refer to convened IRB.

[ ]  Additional information is needed:

|  |  |
| --- | --- |
| **Reviewer Signature:** | **Date:** |

1. If an HUD is already IRB-approved for use at a facility, the HUD may be used off-label to prevent serious harm or death to a patient unless the IRB has specifically restricted its use. The IRB should be contacted in advance whenever possible to determine any approval requirements. If a HUD is not approved for use in a facility, and a physician in an emergency situation determines that IRB approval for the use of the HUD at the facility cannot be obtained in time to prevent serious harm or death to a patient, the HUD may be used and reported using this Emergency Use mechanism. [↑](#footnote-ref-1)