 Institutional Review Board

Emergency Use of a Humanitarian Use Device (HUD)

**When to use this Form**

This form should be used to notify the Institutional Review Board of the emergency use of an HUD on a patient 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 for the HUD prior to use [21 CFR 814.124]; or
* The HUD is approved by the IRB, but the emergency use is outside of the approved indications.

**Investigator Responsibilities**

### **When an HUD is used without approval**

**If 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, a HUD may be used without prior IRB approval.**

**The physician should be sure to follow any requirements of the HDE holder with regards to the emergency use and follow up.**

1. **When an HUD is used- off label**

**The** [FDA FAQs](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110203.pdf) **regarding HDE regulations note that:**

* **Physicians should be cognizant that FDA has made a determination of safety and probable benefit for use of the HUD only within its approved indication(s).**
* **If a physician wants to use a HUD outside its approved indication(s), FDA recommends that the physician obtain informed consent from the patient.**
* **The FDA also recommends that the physician ensure reasonable patient protection measures are followed, such as devising schedules to monitor the patient, taking into consideration the patient's specific needs and the limited information available about the risks and benefits of the device.**

**The physician should be sure to follow any requirements of the HDE holder with regards to the emergency use and follow up.**

1. **IRB Submission Requirements**

This form should be submitted no later than 5 working days after the emergency use.

**The Physician must also report to the IRB if the device may have caused or contributed to death or serious injury and for certain malfunctions.**

**If the HUD has not been previously approved**

Complete this form and fax it to 414-465-4493 or email to IRB@Ascension.org.

**If the HUD is approved but this is an off-label emergency use**

Complete this form and upload it into Mentor, under the approved HUD protocol under the Deviation tab.

*If you have any questions on how or when to use this form, contact IRB staff at th414-465-3134 or 414-465-3059.*

 **INFORMATION ABOUT THE EMERGENCY USE**

### **Type of Emergency Use**

|  |
| --- |
| [ ]  The HUD was used according to the approved labeling, but Ascension Wisconsin IRB approval was not obtained prior to use |
| [ ]  This HUD is approved, but was used off-label, for a use outside of the approved indication, in an emergency situation  |

### **Emergency Use Status**

|  |
| --- |
| [ ]  The emergency use has already occurred and I am reporting this for the first time to the IRB. |
| [ ]  This is a follow-up report to the IRB for an emergency use that was prospectively reported to the IRB on insert date here.  |

### **Emergency Use Requirements**

|  |  |
| --- | --- |
| 1. The patient was/is in a life-threatening or severely debilitating situation
 | [ ]  Yes [ ]  No  |
| 1. There was/is no alternative method of approved or generally recognized therapy available that provides an equal or greater likelihood of saving the participant’s life.
 | [ ]  Yes [ ]  No  |
| There was/is not sufficient time to obtain IRB approval prior to the use of the investigational test article.  | [ ]  Yes [ ]  No  |

1. **Test Article & Use Information**

|  |  |
| --- | --- |
| * + - 1. Name of test article
 | Click here to enter text. |
| * + - 1. HDE#
 | Click here to enter text. |
| * + - 1. Conditions requiring use of the test article
 | Click here to enter text. |
| * + - 1. Patient protection measures
 | Click here to enter text. |
| * + - 1. Ascension Wisconsin site where treatment occurred
 | Click here to enter text. |

1. **Follow-up information after the use of the test article:**

|  |  |
| --- | --- |
| * + - 1. Date the HUD was used
 | Click here to enter a date. |
| * + - 1. Description of the patient’s status
 | Click here to enter text. |
| * + - 1. Was written consent obtained from the patient or the patient’s legally authorized representative?
 | [ ]  Yes[ ]  No, explain why written informed consent could not be obtained from the patient or the patient’s legally authorized representative. Click here to enter text. |

**INVESTIGATOR’S ASSURANCE**

I certify that the information provided in this form is accurate and I agree to report to IRB any unexpected side effects at any time they occur.

If the HUD is not already approved, and the HUD may need to be used again at Ascension Wisconsin, a formal IRB application will be submitted for IRB review and approval before the next use.

Click here to enter text.

Print Name

Signature of the Physician Date

Hospital/Department: Click here to enter text.

Email: Click here to enter text.

Phone/Pager: Click here to enter text.

**Concurrence by the IRB Chair or Designated Member of the IRB**

The IRB Chair or Designee must complete the following:

|  |
| --- |
| I verify that all of the following statements are true:[ ]  The participant was confronted by a life-threatening or severely debilitating situation.[ ]  No standard acceptable treatment was/is available.[ ]  There was/is not sufficient time to obtain IRB approval in advance of the use of the HUD.If consent was not obtained:[ ]  Time was sufficient to obtain consent from the participant’s legal representative. |

Click here to enter text.

Print Name

Signature the IRB Chair or Designee Date