

Emergency Use of a Humanitarian Use Device (HUD) in a Single Patient

Introduction

A Humanitarian Use Device (HUD) is defined as a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year (Orphan Diseases). An HUD is marketed under an HDE and is exempt from the requirement of establishing a reasonable assurance of effectiveness.

Although the use of a HUD within its approved labeling does not constitute research, the FDA requires IRB approval be obtained before a HUD can be used in a facility.

Emergency Use in a Single Patient

If a physician in an emergency situation determines that IRB / FDA approval for the use of an HUD cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be used within the scope of its labeling or off-label without prior IRB approval. Emergency use situations are those in which:

1. The patient has a life-threatening condition that needs **immediate** treatment;
2. No generally acceptable alternative treatment for the condition exists that provides an equal or greater likelihood of saving the subject's life;
AND
3. **Because of the immediate need to use the device**, there is insufficient time to contact the FDA or the IRB.

Physician responsibilities prior to emergency HUD use:

1. Determine if the proposed use meets the regulatory definition for emergency use (see above), AND

Complete as many of the following patient protection measures as possible:

2. Obtain authorization of the HDE holder to use the HUD in the emergency situation
3. Obtain an independent assessment by an uninvolved physician (i.e., not the referring physician)
4. Obtain informed consent of the patient or his/her legally authorized representative OR, if informed consent cannot be obtained because of an inability to communicate with or obtain legally effective consent from the patient or legally authorized representative, written certification of an uninvolved physician that the conditions warrant emergency use and informed consent cannot be obtained for the aforementioned reasons.
5. Obtain applicable institutional clearances for HUD use (e.g., EHRS approval)

Physician responsibilities following emergency HUD use

1. Within 5 days after the emergency use of the HUD, provide notification to the IRB of the emergency use via an Initial Submission in HSERA. Include the following (**Please do not send PHI to the IRB**):

- Initials of the patient involved and a description of their clinical case;
 - The date of the use;
 - A description of the patient(s)' condition and the circumstances necessitating use of the device, and an assessment of why alternative therapies or diagnostics are unsatisfactory;
 - Outline a schedule for monitoring the patient, taking into account the specific needs of the patient and the limited information available about the risks and benefits of the device.
 - Copies of all patient protection measures taken, including:
 - The authorization from the HDE holder to use the HUD in the emergency situation
 - Independent assessment by an uninvolved physician (i.e., not the referring physician)
 - **Redacted** or **unsigned** informed consent document used
 - Obtain informed consent of the patient or his/her legally authorized representative OR, if informed consent could not be obtained, the written certification of an uninvolved physician that the conditions warrant emergency use and informed consent cannot be obtained for the aforementioned reasons.
2. Submit a follow-up report on the patient's condition and information regarding the patient protection measures to the HDE holder, who would then submit this information as a HDE report to the FDA.
 3. Report to the HDE holder/FDA and to the IRB whenever a HUD may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (21 CFR 814.126(a)).