HUMANITARIAN USE DEVICE (HUD): RESPONSIBILITIES & CHECKLISTS

As defined in 21 CFR 814.3(n), a Humanitarian Use Device (HUD) is a "medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year." HUDs cannot be sold for profit except in narrow circumstances and they can only be used in a facility after an IRB has approved their use in that facility, except in emergencies where the physician determines that approval cannot be obtained in time to prevent serious harm or death to the patient (see Emergency Use Situations). 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. The responsibilities of physicians, IRBs and HDE holders are listed below. Responsibilities in Emergency and Compassionate Use Situations follow.

Physician Responsibilities

- Obtain IRB approval and institutional clearances ***prior*** to first use of the HUD and maintain IRB approval (continuing review) as long as the HUD continues to be used in the institution **(see exceptions in emergency situations)**
- Ensure that patients receive the labeling information prepared by the HDE holder or, when safety and effectiveness data is being collected for a PMA, informed consent is obtained (21 CFR 50)
- Ensure that the device is used only by designated individuals in designated facilities approved for HUD use (i.e., individuals and facilities listed in the IRB approved protocol for HUD use); [See Partners Human Research QI Program Device Accountability]
- Ensure that the HUD is used within the scope of its labeling (i.e., indication listed in the Directions for Use) [See Partners Human Research QI Program Subject Eligibility checklist]
- 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))

IRB Responsibilities

- Conduct initial (full board) as well as continuing review (full board or expedited) of the HUD
- Ensure that health care providers are qualified through training and expertise to use the device as required in the HDE Approval Order
- Ensure that patients receive the labeling information prepared by the HDE holder or, when safety and effectiveness data is being collected for a PMA, informed consent is obtained (21 CFR 50)
- Ensure that physicians submit reports to the HDE holder 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))

HDE Holder Responsibilities

- Ensure that the HUD is used only in facilities with IRB approval
- Maintain records of the names and addresses of the facilities to which the HUD is shipped; correspondence with reviewing IRBs; and any other information required by a reviewing IRB or FDA (21 CFR 814.126(b)(2))
- Submit a report to FDA and to the IRB of record 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))
- Provide the FDA with updated information on a periodic basis demonstrating that the HUD designation is still valid, based on the most current and authoritative information available (21 CFR 814.126(b)) and provide FDA with information on the number of devices shipped or sold since initial marketing approval, the clinical experience with the device and a summary of any changes made to the device (see 21 CFR 814.126(b)(1))
- Register HDE clinical trial information on CT.gov

Emergency Use Situations

If a physician in an emergency situation determines that IRB 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:

- The patient has a life-threatening condition that needs immediate treatment;
- No generally acceptable alternative treatment for the condition exists; and
- Because of the immediate need to use the device, there is no time to use existing FDA approval procedures for the use.

Whenever possible, physicians should follow certain patient protection measures (i.e., concurrence of the IRB chairperson, informed consent, independent assessment by an uninvolved physician). Physicians must obtain authorization of the HDE holder and, whenever possible, complete and submit the Emergency Use Form to the Partners Human Research Office for concurrence of the IRB chairperson. When time is limited, the physician may contact an IRB chairperson by phone to discuss the emergency situation. Within five (5) days of the emergency use, the physician must report the emergency use in writing to the IRB chairperson.

HUD EMERGENCY USE CHECKLIST
Physician responsibilities *prior* to emergency HUD use
☐ 1. Determine if the proposed use meets the regulatory definition for emergency use (see above).
Complete as many of the following patient protection measures as possible:
☐ 2. Obtain an independent assessment by an uninvolved physician (i.e., not the referring physician)
☐ 3. Obtain authorization of the HDE holder to use the HUD in the emergency situation.
☐ 4. Obtain concurrence of the IRB chairperson for the emergency use. Complete PHRC Emergency Use Form and/or contact the Partners Human Research Office, 617-424-4100.
☐ 5. 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 form 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.
☐ 6. Obtain applicable institutional clearances for HUD use; for example, electrical safety clearance from Biomedical Engineering or clearance from the Director of the Operating Room
Physician responsibilities *following* emergency HUD use
☐ 7. Within 5 days after the emergency use of the HUD, provide written notification to the IRB chairperson of the emergency use, which shall include identification of the patient involved, the date of the use, and the reason for the use (21 CFR 814.124).
☐ 8. 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.
☐ 9. Devise 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.
☐ 10. 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)).
HDE Holder responsibilities
▪ Authorize access of HUD to the physician *prior* to the emergency.
▪ Report emergency use to FDA, as required by 21 CFR 814.126(b)(1)(iii).

Compassionate Use Situations

If a physician in a non-emergent situation (see emergency use situations) determines that there is no alternative device for the patient's condition, the HUD may be used off-label in a compassionate use situation. Because both FDA and IRB approval are required before a HUD can be used within its approved labeling, similar procedures must be followed before a HUD is used off-label.

HUD COMPASSIONATE USE CHECKLIST
Physician responsibilities *prior* to compassionate HUD use
☐ 1. Determine that there is no alternative device for the patient's condition.
☐ 2. Obtain an independent assessment by an uninvolved physician (i.e., not the referring physician)
☐ 3. Provide the information below to the HDE holder and obtain authorization of the HDE holder for the compassionate use of the HUD: ▪ A description of the patient's condition; ▪ The circumstances necessitating use of the device; ▪ A discussion of why alternative therapies or diagnostics are unsatisfactory; and ▪ Information to address the patient protection measures (i.e., concurrence of the IRB chairperson, informed consent, independent assessment as described below).
☐ 4. Obtain documentation of FDA approval for compassionate use of the HUD (see HDE holder responsibilities).
☐ 5. Obtain concurrence of the IRB chairperson for the compassionate use and institutional clearances for the device *prior* to compassionate use.
☐ 6. 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 form 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.
Physician responsibilities *following* compassionate HUD use
☐ 7. 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.
☐ 8. Devise 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.
☐ 9. 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))
HDE Holder responsibilities
▪ Obtain FDA approval for compassionate use of the HUD. ▪ Report compassionate use to FDA, as required by 21 CFR 814.126(b)(1)(iii).

References:

Federal Food, Drug, and Cosmetic Act, Section 510(m)(2)
21 CFR 814 - Premarket Approval of Medical Devices
21 CFR 50 - Protection of Human Subjects
21 CFR 56 - Institutional Review Boards
U.S. Food and Drug Administration Guidance for Industry and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answers