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.” 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 clinicians, IRBs and the Institution are listed below.

Clinician Responsibilities

- Obtain IRB approval and institutional clearances prior to first use of the HUD
- Maintain IRB approval (continuing review) as long as the HUD continues to be used in the institution
- Obtain and document informed consent in a manner approved by the IRB
- Ensure and document that patients receive the labeling information prepared by the HDE holder
- Ensure that the device is used only by designated clinicians approved for the specific HUD (i.e., individuals listed in the IRB approved protocol and approved by the institution for HUD use)
- Ensure that the HUD is used within the scope of its labeling (i.e., indication listed in the Directions for Use)
- 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))

Institutional Responsibilities

- Access: Ensure that the device is used only by designated individuals approved and credentialed for HUD use (i.e., individuals listed in the IRB approved protocol for HUD use and approved by the institution)
- Credentialing: Ensure that health care providers are qualified through training and expertise to use the device as required in the HDE Approval Order
- Accountability: Ensure Device Accountability is maintained for each HUD use and is reported as required

IRB Responsibilities

- Conduct initial (full board) as well as continuing review (full board or expedited) of the HUD
- Ensure that the Clinician has a plan with documentation that patients receive the labeling information prepared by the HDE holder
- When safety and effectiveness data is being collected for a PMA, ensure that appropriate approved informed consent is obtained (21 CFR 50)