The HDE holder is responsible for ensuring that a HUD approved under [21 CFR 814, Medical Devices] is administered only in facilities having an Institutional Review Board (IRB) constituted and acting pursuant to [the Food and Drug Administration], including continuing review of use of the device. In addition, a HUD may be administered only if such use has been approved by the IRB located at the facility or by a similarly constituted IRB that has agreed to oversee such use and to which the local IRB has deferred in a letter to the HDE holder, signed by the IRB chair or an authorized designee. If, however, a physician in an emergency situation determines that approval from an IRB cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered without prior approval by the IRB located at the facility or by a similarly constituted IRB that has agreed to oversee such use. In such an emergency situation, the physician shall, within 5 days after the use of the device, provide written notification to the chairman of the IRB of such use. Such written notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use. 21 CFR 814.124

A HUD (humanitarian use device) means 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. 21 CFR 814.3(n)

A HDE means a premarket approval application submitted pursuant to [21 CFR 814, Medical Devices] seeking a humanitarian device exemption from the effectiveness requirements of sections 514 and 515 of the Federal Food, Drug and Cosmetic Act, (“Act”) as authorized by section 520(m)(2) of the Act. 21 CFR 814.3(m)

FDA approval of an HDE authorizes an applicant to market a HUD, subject to certain profit and use restrictions set forth in section 520(m) of the Act. 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 certain emergencies. If the HUD is used according to its approved labeling and indication(s) to treat or diagnose patients, IRB review and approval must be obtained according to 21 CFR 814.124.

When HUD use is proposed by an individual to whom the Michigan State University HRPP policies and procedures apply as defined by HRPP Manual Section 4-1, Applicability, an HUD application shall be submitted to the MSU Institutional Review Board.
Board (IRB). An IRB member will make a determination of whether MSU IRB review and approval is required after evaluating the HUD application.

MSU IRB review and approval is required, unless an Institutional Authorization Agreement is executed, when a HUD is being used in a clinical investigation (i.e. collection of safety or effectiveness data). Prior to the approval of an HDE application for a device, any studies conducted using the device must be under the IDE regulations (21 CFR Part 812) and are subject to MSU IRB review under 21 CFR 50 and 56. After approval of an HDE, if safety and effectiveness data is collected in a clinical investigation, either for the HDE-approved indication(s) or for a different indication, 21 CFR Part 56 and Part 50 of the Act are applicable and MSU IRB review is required.

When a HUD is used according to its approved labeling and indication(s) to treat or diagnose patients and is not used in a clinical investigation, MSU IRB review and approval is required if the device is being administered in an MSU facility. An MSU facility is a facility that is part of MSU as a legal entity. However, MSU IRB review and approval is not required if the HUD is being administered in a non-MSU facility. If the HUD is being administered in a non-MSU facility, the individual proposing its use is responsible for obtaining IRB approval in accordance with 21 CFR 814.

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 must report the emergency use within five days; provide written notification of the use to the IRB chairperson including identification of the patient involved, the date of the use, and the reason for the use. See section 520(m)(4) of the Act; 21 CFR 814.124.