

Policy and Guidance: Humanitarian Device Exemption (HDE)/ Humanitarian Use Devices (HUD)

(February 26, 2021)

[Brief Overview](#)

[Clinician Responsibilities](#)

[BruinIRB Application Requirements](#)

- [BruinIRB protocol requirements](#)

[References and Regulations](#)

Brief Overview

A [Humanitarian Device Exemption \(HDE\)](#) is a type of Premarket Application described under the Safe Medical Devices Act (SMDA) of 1990 and allows the FDA to grant an exemption from the effectiveness requirements of the Premarket Approval (PMA) regulations. Devices approved as an HDE are referred to as a Humanitarian Use Devices (HUD). The provisions for obtaining an HDE are:

- The device is designed to treat or diagnose a disease or condition that affects fewer than 8,000 individuals per year in the U.S.
- The device is not available otherwise, and there is no comparable device available to treat or diagnose the disease or condition; and
- The device will not expose patients to unreasonable or significant risk, and the benefits to health from the use outweigh the risks.

Treatment under an HDE is not considered research, but the FDA requires IRB review prior to use.

Clinician Responsibilities

- Complete and submit a HUD application in BruinIRB
- Obtain and document clinical informed consent as required by the institution at which the HUD will be used.

NOTE: Use of a HUD within its approved labeling for clinical diagnosis or treatment does not constitute research; therefore, research informed consent, HIPAA authorization for research, and California Experimental Bill of Rights are not required.

- Provide patient information packets (when available) to patients prior to their receiving the HUD. If no packet is available, the patient should be provided with the following information:
 - An explanation that the HUD is designed to diagnose or treat the disease or condition described in the HDE labeling
 - A statement that no other comparable device is available to treat the disease or condition
 - A description of the use of the HUD

- All known risks or discomforts
- Information reflecting the HUD status of the device including that the effectiveness of the device for this use has not been demonstrated.
- Report all serious adverse events and deaths should be reported in accordance with [21 CFR 803](#) to the IRB and FDA.
- Comply with the continuing review or annual assurance requirements until the submission is closed in BruinIRB.

Bruin IRB Application Requirements

All HUD applications must be submitted through [BruinIRB](#) for review and approval **prior** to administering any treatment.

The BruinIRB application requires the following documents:

- HDE approval order from the FDA
- HDE number issued by the FDA
- Product labeling
- Patient information packet
- Any other applicable documents

BruinIRB protocol requirements:

The BruinIRB application system requires a protocol upload for all HUD applications. The protocol should contain the following information:

- Description of the use of the device including the screening and HUD procedures
- Follow-up visits, tests, or procedures
- A summary of safety and benefits
- Is there an intention of doing research?
- Is the device being used as off-label or on-label use?

See OHRPP [HUD protocol template](#).

References and Regulations

- [FDA Guidance for Humanitarian Device Exemptions](#)
- FDA Regulation Premarket Approval of Medical Devices (includes HUDs): [21 CFR 814](#)
- FDA Medical Device Reporting [21 CFR 803](#)
- UCLA OHRPP [Guidance and Procedures: Use of Devices in Clinical Research and Treatment](#)