



Office of the
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Humanitarian Use Device

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What is a Humanitarian Use Device (HUD)?

A device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the US per year.

Humanitarian Device Exemption (HDE)

Indicates that the device is approved for marketing, but the approval is based on evidence of safety and probable benefit (rather than the “higher” standard of reasonable assurance of effectiveness).

- Must have sufficient info for the FDA to determine device does not pose an unreasonable risk and that probable benefit outweighs risk
- Applicant must demonstrate that no comparable devices are available and that they could not otherwise bring the device to market
- The labeling for an HUD must state that the device is an humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated.

What does it mean to “use” a HUD?

A HUD can be used in two general ways:

- **Medical Practice:** A HUD can be used according to its approved labeling and indications to treat or diagnose patients. It can also be used “off label” as part of medical practice
- **Clinical Investigation:** A HUD can be used in a clinical investigation in accordance with its approved indications or for a different indication.

When the HUD is used in Medical Practice

- The IRB does not need to review a protocol because it is not research
- The IRB is not required to monitor the number of HUD uses per year (responsibility of HDE holder)
- The IRB is not required to audit the medical records of patients who received the HUD

When the HUD is used in Medical Practice

- The IRB does not function as HUD Data Monitoring committee
- The IRB does not apply 45 CFR 46 (DHHS)
- The IRB does not need to approve an informed consent

What is the IRB required to do?

Use approval criteria at 21 CFR 56.111

- Consideration of the patients need for the HUD
- Likelihood that the device is appropriate for the patient's condition

The IRB should:

- Review the risks to patients that are found in the product labeling
- Ensure that risks are minimized
- Evaluate whether the risks are reasonable in relation to the proposed use of the device.

FDA recommends reviewing the following materials during initial review of the HUD:

- Copy of the HDE approval order
- Description of the device
- Product labeling
- Patient information packet
- Summary of how physician proposes to use the device, including
 - A description of any screening procedures, HUD procedure, and any patient follow-up visits, tests, or procedures.

IRB approval for use of HUD

- In general
- For groups of HUD patients that meet certain criteria
- Under a HUD treatment protocol
- On a case by case HUD basis

The IRB may put limitations on HUD use

- One or more measures of disease progression
- Prior use and failure of alternate treatment modalities
- Reporting requirements to the IRB or IRB Chair
- Appropriate follow-up precautions and evaluations
- Any other criteria it determines appropriate

IRB withdrawal of approval

- IRBs must be act in accordance with the agency's regulations to withdraw approval for
 - Failure to follow IRB or FDA requirements
 - Unexpected serious harm or death
- Questions to ask at continuing review
 - Reporting serious adverse events or deaths
 - Following IRB conditions of approval or limitations

Medical Device Reporting (MDR)

- Applies to all FDA approved devices
- Serious adverse events and deaths must be reported to the FDA and the IRB using the Medical Device Reporting system at 21 CFR 803
- HDE holders and IRBs should ensure that physicians know about this requirement

FDA Concerns

- Off label use of a HUD
 - IRB should ensure that physicians are made aware of any restrictions or limitations of off-label use at time of initial review
 - FDA recommends informed consent and reasonable patient protections measures
 - Summary report to IRB and HDE holder following the use

FDA Concerns

- Research for HDE approved indication
 - No Investigational Device Exemption (IDE) required
 - IRB review and informed consent recommended
- Research outside approved indication
 - Requires an IDE
 - IRB review and informed consent required

Thank you