Humanitarian Use Device (HUD)

Miles T. McFann
IRB Administration
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Learning Objectives

• Define Humanitarian Use Device

• Describe FDA’s Approval

• Describe the IRB responsibilities
Humanitarian Use Device (HUD)

- A device intended to benefit patients in the treatment or diagnosis of a disease or condition affecting fewer than 4,000 individuals in the US per year.
Humanitarian Use Device (HUD)

- Office of Orphan Products Development designates a device as a Humanitarian Use Device (HUD)
  - Verifies that the device is designed to treat or diagnose a disease or condition following the parameters in the definition
  - Reviews a description of the device
  - Reviews a description of the rare disease or condition
Humanitarian Device Exemption (HDE)

- A premarket approval application submitted to FDA seeking a Humanitarian Device Exemption from the effectiveness requirements of sections 514 and 515 of the Food, Drug, Cosmetic Act.
Humanitarian Device Exemption Application to FDA

FDA approval of HDE application

- HUD does not pose unreasonable risk of injury to patients
- That the probable benefit outweighs risk of injury from its use
Humanitarian Device Exemption Application to FDA

FDA approval of HDE application

- The device is a Humanitarian Use Device

- The device, to treat or diagnose a specific disease or condition, is authorized by federal law

- The effectiveness of this device for this use has not been demonstrated
IRB review of HUDs

• At initial review
  • Consideration of the patient’s need for the HUD
  • Likelihood that device is appropriate for the patient’s condition or disease state

• At continual renewal
  • Convened meeting, or
  • Expedited review is acceptable because it is an approved device
FDA Concerns

Off label use of an HUD

- IRB should ensure that physicians are made aware of any restrictions or limitations of off-label use at the time of initial review.
- FDA recommends informed consent and reasonable patient protections measures
  - Monitoring and considering the specific needs of the patient and limited information about risks and effectiveness of the HUD
- Summary report to IRB and HDE-holder following the use
References

- Regulation
  - 21 CFR 814 Subpart H
  - 21 CFR 56 Institutional Review Boards
  - 21 CFR 803 Medical Device Reporting

- Guidance
  - List of all HUDs
  - Frequently asked questions and answers
Questions?

Thank you!