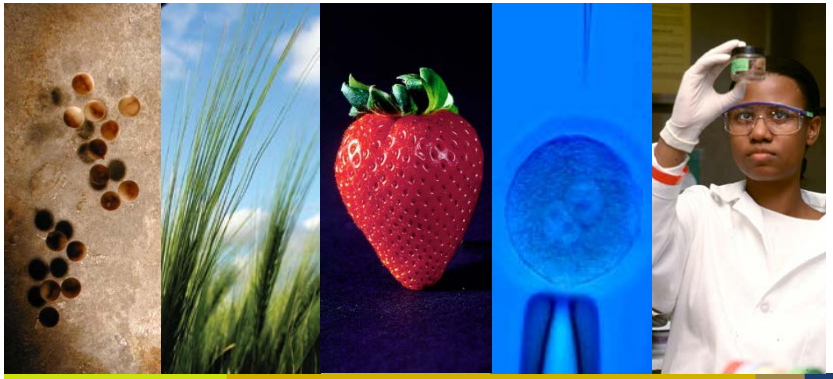

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Humanitarian Use Device (HUD)

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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!

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