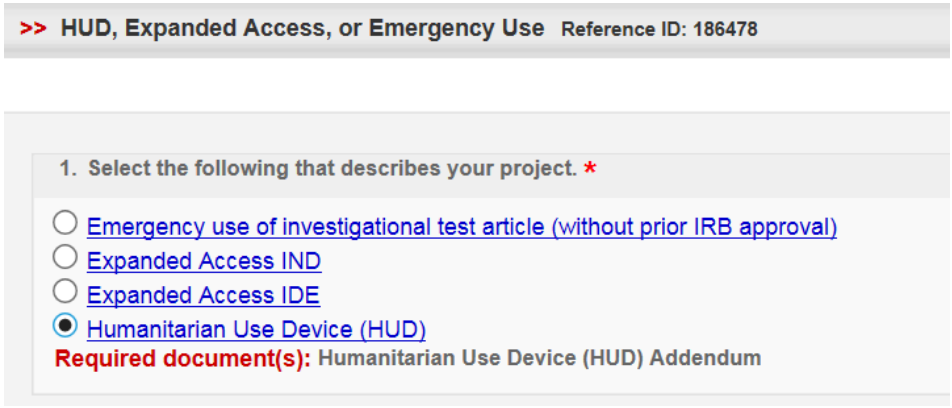
## How to complete a Humanitarian Use Device (HUD) Application

A Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

The following instructions apply to applications for the use of a HUD, limited to the indications approved by the FDA in the Humanitarian Device Exemption. Collection of safety and effectiveness data must be limited to the HDE-approved indication.

1. Create a "New Study"
2. The "Project Title" should reflect request for use of HUD.
3. Screening questions: Answer "No" to #1.
    - Answer "Yes" to #1.A.
4. NHSR Activities:
    - Select "Humanitarian Use Device (HUD)"




5. Required Attachments:
    - Complete the Humanitarian Use Device Addendum, found here, and upload to the attachments section of the online application.
    - FDA Approval Order
    - Summary of Safety and Probable Benefit
    - Product Labeling
    - Consumer Information (HUD information packet to be provided to patients)
    - Hospital-approved procedure consent form that will be used to consent patients.
    - Any other pertinent information
6. Cover memo: Please use the cover memo to identify your submission as a "Request for use of Humanitarian Use Device".

References:

21 CFR 814 Subpart H—Humanitarian Use Devices (April 1, 2013)

FDA-Medical Devices--Humanitarian Device Exemption

Listing of CDRH Humanitarian Device Exemptions

Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators and Food and Drug Administration Staff—Humanitarian Device Exemption (HDE) Regulation: Questions and Answers (July 8, 2010

Premarket Assessment of Pediatric Medical Devices—Guidance for Industry and Food and Drug Administration (March 24, 2014)

Annotated HUD Addendum (sample application)—LINK TO DOCUMENT

For more information, please call the IRB office at 919-966-3113.

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