

**Humanitarian Use Device Continuing Review Checklist**

**(Non-Research Use)**

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| **Responsible Physician Name:** | **Protocol Number:** |
| **Protocol Title:** | |
| **Name of HUD:** | |
| **Reviewer:** | **Date:** |

Per FDA Guidance, a Humanitarian Use Device (HUD) is a *“medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.”* A Humanitarian Device Exemption (HDE) is a “premarket approval application” submitted to FDA. HDE approval is based upon, among other criteria, a determination by FDA that the HUD will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use while taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The initial review of a HUD must be by the convened IRB, however, subsequent reviews, including continuing reviews, may be conducted using expedited procedures. As always, the designated reviewer may refer the review to the convened board.

References to Assist in Your Review: [Humanitarian Device Exemption (HDE) Regulation: Questions & Answers](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM389275.pdf); [Frequently Asked Questions About Medical Devices](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf).

This checklist should only be used when the use of the HUD **does not** include a clinical investigation to evaluate the safety or effectiveness of the device. Clinical investigations of an HUD should be evaluated using the standard continuing review checklist.

1. Do you have any interests, financial or otherwise, related to this submission that could present a conflict of interest?

Yes. Please do not conduct this review, contact the IRB office so the submission may be reassigned.

No

2. Have the local uses of the HUD been in accordance with the indications approved by the IRB and any required conditions (e.g., prospective consent)?

Yes

No. Explain:

3. Has the responsible physician fulfilled their Medical Device Reporting responsibilities to the IRB, manufacturer, and FDA?

Yes

No. Explain:

4. Based upon the information provided, do the provisions to minimize risks and monitor patient safety remain acceptable?

Yes

No. Explain:

5. Based upon the information provided, does the risk associated with the HUD remain justified by the potential benefit to the patient?

Yes

No. Explain:

6. Based upon the information provided, does the proposed plan by the investigator to provide patients with information about the HUD prior to or after use remain acceptable?

Yes

No. Explain:

7. Based upon the information provided, do the patient materials (e.g., patient information packet, consent) remain acceptable?

Yes

No. Explain:

**Determinations:**

Approve as submitted

Partial Approval (e.g., there are restrictions on the approval (e.g., age restriction))

Conditions required for approval (e.g., prescriptive changes are needed to finalize approval/acknowledgement), conditions described below

Defer for the reason(s) described below (e.g., additional information or non-prescriptive changes are needed)

Refer to convened IRB for review

Comments: