

**Humanitarian Use Device Application 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.

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 proposed use of the HUD **does not** include a clinical investigation to evaluate the safety or effectiveness of the device. Research uses of an HUD should be evaluated using the standard initial 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. Are the providers who will use the HUD appropriately trained and qualified to do so?

Yes

No. Explain:

3. Are there appropriate precautions in place to minimize the chances of device use by unauthorized providers?

Yes

No. Explain:

4. Is the proposed patient population appropriate per the HUD labeling?

Yes

No. Explain:

5. Is the proposed use of the HUD in accordance with its approved labeling?

Yes

No

a. If No, does the information provided support a determination that the proposed off label use is appropriate?

Yes

No. Explain:

6. Are the provisions to minimize risks and monitor patient safety sufficient?

Yes

No. Explain:

7. Is the risk associated with the HUD justified by the potential benefit to the patient?

Yes

No. Explain:

8. Is the proposed plan by the investigator to provide patients with information about the HUD prior to or after use acceptable?

Yes

No. Explain:

9. Are the patient materials (e.g., patient information packet, consent) acceptable?

Yes

No. Explain:

**Recommendations:**

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)

Disapprove (Note: only the convened IRB can issue a disapproval)

Comments: