CENTER FOR HEALTH SCIENCES	**WORKSHEET:** Criteria for Approval of Humanitarian Use Device		
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Study #:	**Reviewer:**	**Date:**

The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating an application to use a HUD.

1 Humanitarian Use Device: (All must be **"Yes"**)	
☐ **Yes** ☐ **No**	Has the FDA issued an approved Humanitarian Device Exemption (HUD) for this device?
☐ **Yes** ☐ **No**	The HUD is not being used in the context of a clinical research study to evaluate its safety and effectiveness. **(If "No," complete WORKSHEET: Criteria for Approval and Additional Considerations)**
2 General Considerations (All must be **"Yes"**)	
☐ **Yes** ☐ **No**	The convened IRB (or Designated Reviewer) has adequate expertise to review this HUD application. **(If "No", obtain consultation.)**
☐ **Yes** ☐ **No**	None of the physicians or staff are Restricted. **(If "No," the research cannot be approved.)**
☐ **Yes** ☐ **No**	Materials are complete. **(If "No," the HUD application cannot be approved.)**
3 Criteria For Approval Of HUD: (All must be **"Yes"**) Applies to all reviews: initial, continuing, modifications, convened, and expedited)	
☐ **Yes** ☐ **No**	Risks to patients are minimized by using procedures, which do not unnecessarily expose patients to risk.
☐ **Yes** ☐ **No**	Risks to patients are reasonable in relation to the proposed use of the device.
☐ **Yes** ☐ **No**	The probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.
☐ **Yes** ☐ **No**	There are adequate provisions to protect the privacy of patients.
☐ **Yes** ☐ **No**	There are adequate provisions to maintain the confidentiality of patient data.
☐ **Yes** ☐ **No**	The proposed use of the HUD is within the scope of the indication approved in the HDE.
☐ **Yes** ☐ **No**	Patients will be informed of the potential risks and benefits of the HUD and any procedures associated with its use by one of the following: ☐ **PATIENT LABELING PROVIDED BY THE MANUFACTURER** ☐ **IRB-APPROVED CONSENT DOCUMENT (COMPLETE SECTIONS 6 AND 7)**
4 Additional Considerations	
☐ **Yes** ☐ **No**	**For Initial Review:** The use of the HUD is approved under at least one of the following criteria: ☐ As submitted without any further restrictions ☐ On a case-by-case basis ☐ Other:
☐ **Yes** ☐ **No**	**For Initial Review:** Should continuing review be done via expedited review?
☐ **Yes** ☐ **No**	**For Initial and Continuing Review:** Should review take place more often than annually? (Implement when risks are high.) If so, specify period of review:
☐ **Yes** ☐ **No**	**For Continuing Review and Modifications:** Is verification needed from sources other than the physician that no material changes have occurred since prior IRB review? (Implement when there are questions about the veracity of the information provided.)
☐ **Yes** ☐ **No**	**For Continuing Review and Modifications:** Is there information that needs to be provided to current patients because it may affect their willingness to receive/use the HUD?