

	<b>WORKSHEET: Criteria for Approval for HUD</b>			<b>IRB #</b>
	<b>NUMBER</b>	<b>DATE</b>	<b>PAGE</b>	<b>Review Type:</b>
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The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating an application to use a Humanitarian Use Device (HUD) at initial or continuing review. This worksheet is to be used. It does not have to be completed or retained.

**1 Humanitarian Use Device: (All must be “Yes”)**

<input type="checkbox"/> Yes <input type="checkbox"/> No	Has the FDA issued an approved Humanitarian Device Exemption (HDE) for this device?
<input type="checkbox"/> Yes <input type="checkbox"/> No	The HUD is <u>not</u> being used in the context of a clinical research study to evaluate its safety and effectiveness. (If “No,” complete <b>WORKSHEET: Criteria for Approval and Additional Considerations (HRP-311)</b> )

**2 General Considerations (All must be “Yes”)**

<input type="checkbox"/> Yes <input type="checkbox"/> No	The convened IRB (or <u>Designated Reviewer</u> ) has adequate expertise to review this HUD application. (If “No,” obtain <b>consultation.</b> )
<input type="checkbox"/> Yes <input type="checkbox"/> No	The following materials have been submitted: <ul style="list-style-type: none"> <li>• FDA Approval Letter</li> <li>• Description of the device</li> <li>• Product labeling</li> <li>• Patient Information Packet/Patient Brochure</li> <li>• A proposed consent procedure using an ICF or patient brochure</li> <li>• A summary of how the physician proposes to use the device, including a description of any screening procedures, and any patient follow-up visits, tests or procedures.</li> </ul>

**3 Criteria for Approval Of HUD: (All must be “Yes”) Applies to all reviews: initial, continuing and modifications – convened or expedited.**

<input type="checkbox"/> Yes <input type="checkbox"/> No	Risks to patients are minimized by using procedures, which do not unnecessarily expose patients to risk.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Risks to patients are reasonable in relation to the proposed use of the device.
<input type="checkbox"/> Yes <input type="checkbox"/> No	There are adequate provisions to protect the privacy of patients.
<input type="checkbox"/> Yes <input type="checkbox"/> No	There are adequate provisions to maintain the confidentiality of patient data.
<input type="checkbox"/> Yes <input type="checkbox"/> No	The proposed use of the HUD is within the scope of the indication approved in the HDE, or proposed use is off-label for clinical care purposes only.
<input type="checkbox"/> Yes <input type="checkbox"/> No	The institution has approved the use of the HUD as a clinical service.
<input type="checkbox"/> Yes <input type="checkbox"/> No	The study personnel has the appropriate qualifications to use the device through training and expertise.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Patients or their legally authorized representative will be informed of the potential risks and benefits of the HUD and any procedures associated with its use by one of the following: <input type="checkbox"/> PATIENT LABELING PROVIDED BY THE MANUFACTURER <input type="checkbox"/> IRB-APPROVED CONSENT DOCUMENT (COMPLETE SECTIONS 6 AND 7)

**4 Additional Considerations**

<input type="checkbox"/> Yes <input type="checkbox"/> No	<b>For Initial Review:</b> Should there be any limitations on the use of the HUD? (e.g., limitations based on one or more measures of disease progression, prior to use and failure of any alternative treatment modalities, reporting requirements to the IRB or IRB chair, or appropriate follow-up precautions and evaluations.)
<input type="checkbox"/> Yes <input type="checkbox"/> No	<b>For Initial Review:</b> Should continuing review be done via Full Board review? If so, provide rationale for convened review:
<input type="checkbox"/> Yes <input type="checkbox"/> No	<b>For Initial and Continuing Review:</b> Should review take place more often than annually? If so, specify period of review and document in the minutes:
<input type="checkbox"/> Yes <input type="checkbox"/> No	<b>For Continuing Review and Modifications:</b> Is there information that needs to be provided to current patients because it may affect their willingness to receive/use the HUD?

**5 Consent Process (All must be “Yes” in order to recommend approval)**

<input type="checkbox"/> Yes <input type="checkbox"/> No	The HUD labeling states that the device is a humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Patients will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Patients or their legally authorized representatives will be given sufficient opportunity to consider whether or not to receive/use the HUD.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Information regarding the HUD will be communicated in language understandable to the patient.

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<b>6 Informed Consent Documentation</b> (Complete this section if the IRB has determined that consent document must be used)	
<input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b>	The written consent document is accurate and complete
<input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b>	The written consent document embodies at a minimum, the elements in <b>Section 7: ELEMENTS OF CONSENT DISCLOSURE (HUD)</b>
<input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b>	The physician will give either the patient or the patient's legally authorized representative adequate opportunity to read the consent document.
<input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b>	The patient or the patient's legally authorized representative will sign and date the consent document.
<input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b>	The person obtaining consent will sign and date the consent document.
<input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b>	A copy of the consent document will be given to the patient (if consent document will be signed and dated, the signed consent document will be given to the patient).
<input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b>	When a patient or patient's legally authorized representative is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the patient or the patient's legally authorized representative, and that consent was freely given.

<b>7 Elements of Consent Disclosure (HUD)</b>	
<input type="checkbox"/>	An explanation that the HUD is designed to diagnose or treat the disease or condition described in the HDE labeling and that no comparable device is available to treat the disease or condition
<input type="checkbox"/>	A disclosure that the effectiveness of the HUD for the specific indication has not been demonstrated.
<input type="checkbox"/>	A description of any ancillary procedures associated with use of the HUD.
<input type="checkbox"/>	A description of the use of the HUD.
<input type="checkbox"/>	A description of all known risks or discomforts to the patient.
<input type="checkbox"/>	A description of the mechanism of action of the HUD in relation to the disease or condition.