WORKSHEET: Criteria for Approval and Additional Considerations for HUD		
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The purpose of this worksheet is to provide support for the convened IRB when evaluating an application to use a Humanitarian Use Device (HUD). This worksheet is to be used. It does not have to be completed or retained.

1	Humanitarian Use Device: (Check if "Yes." All must be checked)
☐	The FDA has issued an approved Humanitarian Device Exemption (HUD) for this device.
☐	The HUD is not being used to evaluate its safety and effectiveness. (If the HUD is being used to evaluate its safety and effectiveness complete WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314))
2	General Considerations (Check if "Yes." All must be checked)
☐	The convened IRB (or Designated Reviewer) has adequate expertise to review this HUD application. (If "No", obtain consultation.)
☐	Materials are complete. (If "No," the HUD application cannot be approved.)
3	Criteria for Approval Of HUD: (Check if "Yes." All must be checked) Applies to all reviews: initial, continuing, and modifications.
☐	Risks to patients are minimized by using procedures, which do not unnecessarily expose patients to risk.
☐	Risks to patients are reasonable in relation to the proposed use of the device.
☐	There are adequate provisions to protect the privacy of patients.
☐	There are adequate provisions to maintain the confidentiality of patient data.
☐	The proposed use of the HUD is within the scope of the indication approved in the HDE.
☐	The institution has approved the use of the HUD as a clinical service.
4	Additional Considerations (Check all that apply).
☐	For Initial Review: 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.)
☐	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?
5	Consent Process (Check if "Yes." All must be checked)
☐	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.
☐	Patients or their legally authorized representatives will be informed of the patient labeling provided by the manufacturer.
☐	Patients or their legally authorized representatives will be given sufficient opportunity to consider whether or not to receive/use the HUD.
☐	Information regarding the HUD will be communicated in language understandable to the patient.