

UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-323 WORKSHEET: Criteria for Approval and Additional Considerations HUD		
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The purpose of this worksheet is to provide support for the convened IRB or designated reviewer when evaluating an application to use a Humanitarian Use Device (HUD). This worksheet, or equivalent, is to be used. It does not have to be completed or retained.

1 Humanitarian Use Device (HUD): (Check if "Yes." All must be checked)

The Food and Drug Administration (FDA) has issued an approved Humanitarian Device Exemption (HDE) 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 **OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations, or equivalent.**)

2 General Considerations (Check if "Yes". All must be checked)

The convened IRB (or designated reviewer¹) has adequate expertise to review this HUD application. (If "No," obtain consultation.)

Materials are complete.² (If "No," the HUD application cannot be approved.)

The proposed use of the HUD is: (Check if "Yes." At least one must be checked)

Within the scope of the indication authorized in the HDE.

Outside the scope of the indication authorized in the HDE.

3 Criteria for Approval of HUD: (Check if "Yes." All must be checked) Applies to all reviews: initial, continuing, and amendments.

Risks to patients are minimized by using procedures that do not unnecessarily expose patients to risk.

Risks to patients are reasonable in relation to the proposed use of the device.

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 Amendments: 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 an HUD 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 representative (LAR) will be informed of the patient labeling provided by the manufacturer.

Patients or their LAR will be given sufficient opportunity, as allowed by their condition, to consider whether or not to receive/use the HUD.

Information regarding the HUD will be communicated in language understandable to the patient.

If the HUD is being used outside the scope of the indication authorized in the HDE, there will be a consent process which will disclose that the proposed use is outside of the indications for which the FDA has approved the use of the HUD.³ (N/A, if used within the scope of the indication authorized in the HDE)

¹ A designated reviewer may be used for the review of amendments and continuing review when criteria at *OIA-313 WORKSHEET: Eligibility for Review Using the Expedited Procedure*, or equivalent, have been met.

² See *OIA-301 WORKSHEET: Review Materials*, or equivalent, for a list of materials to be included.

³ If not contained in manufacturer/sponsor information to be provided to patients or manufacturer/sponsor will not update their provided information for patients, may be provided as a separate information sheet.