Institutional Review Board

Checklist: Criteria for Approval for HUD

NUMBER	HRP-323

Once completed, return this checklist to the IRB manager.

IRB Number	
Protocol Name	
Investigator	

The purpose of this checklist is to provide support for the convened IRB when evaluating an application to use a Humanitarian Use Device (HUD). (LAR= "subjects legally authorized representative")

1 Humanitarian Use Device (Check if "Yes". All must be checked)	
☐	The 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 Checklist: Criterial for Approval (HRP-314)]**.
2 Criteria for Approval of HUD: (Check if "Yes". All must be checked) Applies to all reviews: initial, continuing, and modifications	
☐	Risks to subjects are minimized by using procedures, which do not unnecessarily expose subjects to risk.
☐	Risks to subjects are reasonable in relation to the proposed use of the device.
☐	There are adequate provisions to protect the privacy of the subjects.
☐	There are adequate provisions to maintain the confidentiality of subject 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.
3 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 appropriate follow-up precautions and evaluations.)
☐	**For Continuing Review and Modifications:** Is there information that needs to be provided to current subjects because it may affect their willingness to receive/use the HUD?
4 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.
☐	Subjects or their LAR will be informed of the patient labeling provided by the manufacturer.
☐	Subjects or their LAR will be given sufficient opportunity to consider whether or not to receive/use the HUD.

The HUD is: (Please check one, and sign/date)

- ☐ APPROVED
- ☐ Approved with Conditions, Minor Clarifications and/or Modifications back to the IRB Office
- ☐ Approved with Conditions, Major Clarifications and/or Modifications back to the Full (Convened) IRB Meeting
- ☐ Do Not Recommend approval at this time. List Reasons. (Convened board must agree by a vote if study is not approved.)

Comments Section:

_____ _____

(Reviewer) (Date)