HRP-323 | 1/1/2024

WORKSHEET: Criteria for Approval for HUD[i]

The purpose of this worksheet is to provide support for the convened IRB when evaluating an initial application to use a Humanitarian Use Device (HUD), and for Designated Reviewers when evaluating a continuing review submission. (LAR = "subject's Legally Authorized Representative"). This worksheet 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 (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 HRP-314 - WORKSHEET - Criteria for Approval)**

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 LAR will be informed of the patient labeling provided by the manufacturer.

☐ Patients or their LAR will be given sufficient opportunity to consider whether or not to receive/use the HUD; or when HUD is used in emergent situations, patients or their LAR will be given information about the HUD after its use/receipt.

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

[i] This document satisfies AAHRPP elements II.2.E, II.2.F