Humanitarian Use Device (HUD) Checklist

Device:

Full Board Review  Initial Review

Expedited Review  Continuing Review

Amendment

Reviewer:       COMIRB #:

Principal Clinician:       Submission ID:

Do you have a conflict of interest with this submission? Yes  No

For additional guidance and background on reviewing HUD protocols, see FDA Guidance at: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110194.htm#8>

For Continuing Reviews and Amendments, skip to the last page and use Initial Review checklist for reference as needed.

- Initial Review -

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| **SUMMARY OF FINDINGS AND RECOMMENDATIONS** | | | |
|  | **YES** | **NO** | **Comment or N/A** |
| 1. Has a Humanitarian Device Exemption (HDE) number been issued by the FDA?      1. Is the HUD used in accordance with the FDA-approved indications?    1. If not, do the application and protocol adequately describe the off-label use?    2. Does the off-label use increase the risks of the device?   *Note: Off label use of the HUD may require a separate protocol for clinical investigation and may require an IDE, particularly if the off-label use increases the risk of the device.*   1. Is the protocol collecting safety and/or effectiveness data on the HUD?   *Note: The collection of safety and/or efficacy data related to use of a HUD must be reviewed as a clinical investigation. Additional checklist(s) are required. COMIRB recommends that a separate protocol be submitted for collection of safety and efficacy data.* |  | **Stop** |  |

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| --- | --- | --- | --- |
| 1. **Clinical Sites**   University Hospital: Is portal clearance attached?  CHCO: Is portal clearance attached?  Denver Health: Is SPARO letter attached?  VA: Is Purple Clearance Letter attached? |  |  |  |
| 1. **Patient Advisory Form** (consent form) 2. Does the Patient Advisory Form adequately inform patients of the following? 3. The name of the device 4. The effectiveness of the device has not been demonstrated 5. Significant procedures 6. Device and/or surgical risks 7. Off-label use of the device (if applicable) 8. For children, is parental permission sought? 9. For adults unable to consent, is permission from a LAR sought? 10. Are any additional consent protections needed? 11. If so, explain: |  |  | N/A  N/A  N/A |
| 1. **Approval Criteria**    1. Risks to patients are minimized by following standard clinical practices, and are reasonable in relation to the anticipated benefits from the device.    2. Patient eligibility is determined by clinical need for the device.    3. Patient privacy and confidentiality are adequately protected by standard HIPAA requirements for Treatment, Payment, and/or Operations.    4. Consent will be obtained with a Patient Advisory Form. |  |  |  |
| 1. **Continuing Review Cycle** 2. Annual review is appropriate due to clinical nature of the protocol.    1. If a shorter review cycle is necessary, explain why:    2. What is the appropriate review period?       months 3. Continuing review may be conducted by expedited review, as recommended in FDA guidance.    1. If no, why not? (e.g., off-label use of HUD) |  |  |  |

**- Amendments and Continuing Review -**

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| --- | --- | --- | --- |
| **SUMMARY OF FINDINGS AND RECOMMENDATIONS** | | | |
|  | **YES** | **NO** | **Comment or N/A** |
| 1. Is there new information that requires changes to the protocol and/or patient advisory form?  * If yes, have the appropriate documents been updated? |  |  |  |
| 1. Have any unforeseen problems involving risks to patients or compliance with the terms of this approval occurred?  * If yes, has the IRB been properly informed? |  |  |  |
| 1. Does the Patient Advisory Form continue to be satisfactory? |  |  |  |
| 1. Do previous patients need to be notified about any new information?  * If yes, have appropriate notifications been provided for review, and are they adequate? |  |  |  |
| 1. Does the protocol continue to satisfy the approval criteria? 2. Risks to patients are minimized by following standard clinical practices, and are reasonable in relation to the anticipated benefits from the device. 3. Patient eligibility is determined by clinical need 4. Patient privacy and confidentiality are adequately protected by standard HIPAA requirements for Treatment, Payment, and/or Operations. 5. Consent will be obtained with a Patient Advisory Form. |  |  |  |

**Additional Comments:**

**Reviewer Date**