# IRB Administration Office
# Humanitarian Use Device Reviewer Checklist

| PI's Name | IRB# | Committee Assigned: |
|---|---|---|
| | | |

| IRB Reviewers Assigned | Primary: | Secondary: |
|---|---|---|
| | | |

| Humanitarian Use Device Form Review<br>(HUD form must be attached for the Protocol Information Attachments section) | |
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| **Section A**<br>**Physician Information** | The Physician's contact information has been provided and is complete.<br>☐ **Yes** ☐ **No** |
| **Section B**<br>**Submission Details** | Submission details are complete.<br>☐ **Yes** ☐ **No** |
| **Section C**<br>**Sponsor Information** | Sponsor Information has been provided and is complete.<br>☐ **Yes** ☐ **No** |
| **Section D**<br>**Site/Location of Device Use** | Site Information is selected.<br>☐ **Yes** ☐ **No**<br><br>Check eProtocol attachments section for any applicable site approval letter(s). |

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| **Section E**<br>**Device Information** | • Is the device's name provided? ☐ **Yes** ☐ **No**<br>• Is the HUD designation provided? ☐ **Yes** ☐ **No**<br>• Are the indications/conditions for use of HUD clearly described? ☐ **Yes** ☐ **No**<br>• Is the use of the HUD for treatment purposes only? ☐ **Yes** ☐ **No**<br>○ If the use of the device will be a part of a clinical investigation, the full requirements for IRB review and informed consent apply (21 CFR 50 and 56) as well as other applicable regulations, therefore an HUD submission is not appropriate.<br>• Is there a clear description of the device? ☐ **Yes** ☐ **No**<br>• Is there a complete accountability plan for receiving, storing, dispensing, and final disposition and accountability of the device? ☐ **Yes** ☐ **No**<br>• Is the physician qualified to use this device? ☐ **Yes** ☐ **No**<br>▪ **(please also see attachments section for physician's CV/Resume)**<br>• Are contraindications, warnings, and precautions for use of the device thoroughly described? ☐ **Yes** ☐ **No**<br>• Are the risks of using this device described? ☐ **Yes** ☐ **No**<br>▪ Confirm that risks are also indicated in the HUD consent form.<br>• Are the benefits of using the device described? ☐ **Yes** ☐ **No**<br>▪ Confirm that benefits are also indicated in the HUD consent form.<br>• If there are any alternatives to using device, are the alternatives described? ☐ **Yes** ☐ **No**<br>▪ Confirm if alternatives are listed in the HUD consent form. |
| **Section F**<br>**Patient Information** | • Is the clinical consent process described? ☐ **Yes** ☐ **No**<br>▪ Must also indicate for eProtocol Consent-Information section.<br>• Are there educational materials provided that will be given to participants? ☐ **Yes** ☐ **No**<br>▪ See eProtocol Attachments section to confirm.<br>• If the device will be used in an emergency situation, is a plan provided regarding how patients will be consented**?** ☐ **Yes** ☐ **No** |

| **Section G:**<br>**eProtocol Submission** | |
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| Personnel Information | Does the eProtocol Personnel Information match what is indicated for the Humanitarian Use Device Form Section A?<br>For example: The PI/Physician is the same listed for the HUD form.<br>The department for the PI/Physician is the same for the HUD form.<br><br>☐ **Yes** ☐ **No** |
| Protocol Checklist | Is Humanitarian Use Device is selected?<br>☐ **Yes** ☐ **No** |
| Protocol Information-Consent Information | Is information provided regarding the clinical consent process?<br>☐ **Yes** ☐ **No**<br><br>Is the Humanitarian Use Device Consent Form attached?<br>☐ **Yes** ☐ **No**<br><br>Is the HUD Consent form complete as per the IRB's Humanitarian Use Device Consent Form Template?<br>☐ **Yes** ☐ **No**<br><br>**Are the risks of using the device included for the HUD consent?** ☐ **Yes** ☐ **No**<br><br>**Are the benefits of using the device included for the HUD consent?** ☐ **Yes** ☐ **No**<br><br>**Are the alternatives for using the device addressed for the HUD consent?** ☐ **Yes** ☐ **No** |
| Protocol Information-Data Safety and Monitoring | Are the responses appropriate? ☐ **Yes** ☐ **No**<br><br>Note this is not considered a research study. "No" should be selected for "Is this a treatment study?" and "Is this an intervention study?" |
| Protocol Information Drugs and Devices | Is "Treatment" indicated with justification of Humanitarian Use Device?<br>☐ **Yes** ☐ **No** |
| Protocol information Attachments section | Have the following documents been attached? ☐ **Yes** ☐ **No**<br><br>☐ Physician's CV/Resume<br>☐ Humanitarian Use Device (HUD) Form<br>☐ A copy of the HDE approval letter from the FDA<br>☐ The patient information packet for the HUD<br>☐ Other relevant materials (e.g., training certificates) as identified in the Application Form<br>☐ Department/Facility Approval letter(s) attached |

Note the following sections for eProtocol are not required as this is not a research study submission.

- Background, Rationale, Data Analysis, and Procedures and Recruitment section
- Recruitment Process, Participant Compensation, and Costs
- HIPAA section

| IRB Reviewer's Recommendation |
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| **Comments/Recommendations:**<br><br>**IRB reviewer please make comments/recommendations on the eProtocol reviewer checklist and submit comments via eProtocol** |

| ☐ Approval | ☐ Specific Minor Revisions Required | ☐ Table | ☐ Disapprove |
|---|---|---|---|
| **Recommended Approval Period:**<br>☐ 12 months ☐ 6 months<br>☐ Other: | | | |
| **Reviewer's Signature:**<br>To complete the digital signature open form in Adobe or using software that allows for digital signature. | | | |
| **Printed name:** | | **Date:** | |