**Instructions:**

* IRB approval is required for all uses of a humanitarian use device (HUD). FDA guidance on HUD submission and review requirements can be found at: <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110203.pdf>
* This Protocol (HRP-XXX-HUD) is required for IRB review the use of a HUD is according to its approved labeling and indication(s) to treat or diagnose patients.
* When a HUD is being used in a clinical investigation – i.e. to study its safety or effectiveness –HRP-590 or HRP-508 (with Sponsor Protocol) must be completed and submitted instead of this template.
* **If you are reporting an emergency use of a HUD, please submit a report in qualtrics according to instructions in the Investigator Manual (HRP-103).**
* IRB staff will assign required ancillary reviews will be tagged according to HRP-309 Ancillary Review Matrix
* When making modifications to this document after its approval, use the Track Changes feature in Microsoft Word and update the version date on page 1.
* ***Other Documents:***

http://www.clipartbest.com/cliparts/acq/eAx/acqeAxyRi.pngOther documents will be required as part of the IRB submission. Below are examples.

1) Device Information Materials (Upload to Devices page in ETHOS)

1. Device labeling
2. Instructions for use
3. Summary of safety and probable benefit

2) Patient Information Materials(Upload to Supporting Documents page)

3) FDA HUD Designation Request Materials (Upload to Devices page in ETHOS)

* 1. FDA HDE approval letter

|  |  |
| --- | --- |
| **Protocol Title** | This should align with the ETHOS submission title. |
| **Principal Investigator who will Administer  Device** | Name: |
| Department: |
| Telephone Number: |
| Email Address: |
| **Device Name:** |  |
| **HDE Number** |  |
| **Manufacturer** |  |
| **Version Number/Date:** | Include the current version number and date of this protocol. |

**REVISION HISTORY**

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| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
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NOTE: Leave this section blank for the initial submission. The revision history should be documented for modifications to approved studies.

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# Background and HUD Procedures

# If you reference a separate document in a response on this form, specify the section or page number of that document (e.g. FDA HDE Approval)

# *Provide a description of the device, indications for its use, and a summary of how you propose to use the device.*

Response: *Click here to enter text.*

* 1. *Confirm whether the proposed use of the HUD is within the scope of the indication approved in the HDE.*

Response: *Click here to enter text.*

* 1. *Indicate any screening procedures for identifying patients who are eligible to receive the HUD.*

Response: *Click here to enter text.*

* 1. *Indicate any patient follow-up visits, tests, or procedures related to use or administration of the HUD.*

Response: *Click here to enter text.*

# Resources and Other Approvals

# See [HRP-309 Ancillary Review Matrix](https://drive.google.com/open?id=0B7644h9N2vLcMTl0ZE9yQkhLd3c) for additional information regarding required compliance reviews.

# *Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the clinician(s) who will use or administer the HUD.*

Response: *Click here to enter text.*

* 1. *Indicate the institution that has approved the use of the HUD as a clinical service.*

Response: *Click here to enter text.*

* 1. *Indicate any other approvals obtained for use of the HUD at the institution named in 3.2 (e.g. committee review).*

Response: *Click here to enter text.*

# Privacy

* 1. *Describe how you will protect the privacy interests of patients who receive or use the HUD.*

NOTE: Privacy refers to an individual’s right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how information collected about individuals will be protected by the clinician from release. Confidentiality applies to the information and should be addressed in Section 5.0.

Response: *Click here to enter text.*

# Confidentiality

# *Describe the provisions to protect the confidentiality of data.*

Response: *Click here to enter text.*

NOTE: Records regarding administration of the HUD must be maintained per manufacturer and FDA. Confidentiality of these records must be described above.

# Risks and Benefits

* 1. *List the reasonably foreseeable risks to patients who receive or use the HUD. Include a description of the probability, magnitude, duration, and reversibility of the risks.*

Response: *Click here to enter text.*

* 1. *Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor patients for safety.*

Response: *Click here to enter text.*

* 1. *Describe the potential benefits that patients may experience by receiving or using the HUD. Include the probability, magnitude, and duration of the potential benefits.*

Response: *Click here to enter text.*

# Consent Process

NOTE: The UMN IRB must ensure that the process used to obtain patient or legally authorized representative consent meets the criteria for approval (HRP-323). Therefore the consent process must be described here and materials used to consent patients must be submitted to the IRB.

* 1. *Indicate what documentation will be used to inform patients or their legally authorized representative of required information about the HUD, including: a description of the device, that it is designed to treat the disease or condition described in the labeling, that there is no comparable device available, any procedures associated with its use, risks and potential benefits of use, and information that makes clear that although the device is authorized by Federal Law, its effectiveness for the specific use being proposed has not been demonstrated.*

Response: *Click here to enter text.*

* 1. *Describe how you will ensure that patients are provided with a sufficient opportunity to consider whether or not to receive or use the HUD.*

Response: *Click here to enter text.*

* 1. *Indicate how you will ensure that information regarding the HUD will be communicated in language understandable to the patient.*

Response: *Click here to enter text.*

* 1. Confirm that the patient or LAR will be informed of the patient labeling provided by the manufacturer.

Response: *Click here to enter text.*

# Process to Document Consent

* 1. *Indicate how you will be documenting consent of the patient to receive or use the HUD.*NOTE: This may be done via clinical consent, via recordkeeping of the clinician obtaining consent, or some combination of these.

Response: *Click here to enter text.*