**Humanitarian Use Device Application (HRP-503-HUD)**

***This template corresponds with IRB Toolkit Worksheet HRP-323: Criteria for Approval for HUD***

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| **Version** | **Date** | **Revisions** |
| R00 | 9/2017 | Original issue |
| R01 | 12/18/20 | Annual review, add track change feature |
| R01 | 6/16/22 | Annual review, no changes |
| R02 | 12/8/23 | Annual review, update logo and address, minor wording changes and minor edits. |

**DEVICE NAME, MANUFACTURER:**

Response:

**CLINICIAN(S) WHO WILL ADMINISTER DEVICE:**

Response:

**VERSION DATE:**

Response:

Table of Contents

[1.0 Template and Submission Instructions 2](#_Toc152937614)

[2.0 Background and HUD Procedures 3](#_Toc152937615)

[3.0 Resources and Other Approvals 3](#_Toc152937616)

[4.0 Privacy 3](#_Toc152937617)

[5.0 Confidentiality 3](#_Toc152937618)

[6.0 Risks and Benefits 4](#_Toc152937619)

[7.0 Consent Process 4](#_Toc152937620)

[8.0 Process to Document Consent 5](#_Toc152937621)

# Template and Submission Instructions

***Applicability***

1. IRB approval is required for use of a humanitarian use device (HUD) at institutions that fall under purview of the UB IRB. FDA guidance on HUD submission and review requirements can be found at:

[Humanitarian Device Exemption (HDE) Program | FDA](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-device-exemption-hde-program)

1. This Protocol (HRP-503-HUD) is required for IRB review of the use of a HUD 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 – the HRP-503 or HRP-508 (with Sponsor Protocol) must be completed instead of this document.
2. HUD Submissions that have been previously approved by the UB IRB may remain on the HRP-503 or HRP-508, but conversion to this form is recommended.
3. A HUD may not be used or administered without prior IRB approval of this and other documents **unless in an emergency situation** to prevent serious harm or death of a patient when alternative therapies have failed or do not exist. If you are reporting an emergency use of a HUD, please instead create a Report of New Information (RNI) in Click according to instructions in the investigator manual (HRP-103)

***Formatting:***

1. If you reference a separate document in a response on this form, specify the section or page number of that document.
2. 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. Mark change using the Track Changes feature.

***Other Documents:***

Other documents will be required as part of the IRB submission. Below are examples. Not all of the documents below are required; however, at least one in each category must be submitted.

1. Device Information Materials (Upload to Devices page)
   1. Device labeling
   2. Instructions for use
   3. Summary of safety and probable benefits
2. Patient Information Materials (Upload to Supporting Documents page)
   1. Manufacturer information
   2. Clinical consent
   3. HRP-502 adapted consent document template
3. FDA HDE approval letter
   1. FDA HDE approval letter

# Background and HUD Procedures

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

Response:

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

Response:

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

Response:

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

Response:

# Resources and Other Approvals

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

Response:

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

Response:

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

Response:

# 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:

# Confidentiality

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

* 1. Where and how will all records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers from other information, as applicable. Include physical and electronic files.

Response:

* 1. How long will the records be stored?

Response:

* 1. Who will have access to the records?

Response:

# 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:

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

Response:

* 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:

# Consent Process

NOTE: Although the UB IRB does not require the use of an adapted HRP-502 template consent document for HUD use, the 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:

* 1. Describe where the consent process will take place. Include steps to maximize patients’ privacy.

Response:

* 1. Describe how you will ensure that subjects are provided with a sufficient period of time to consider whether or not to receive or use the HUD.

Response:

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

Response:

# 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, an adapted HRP-502 Template Consent Document, via recordkeeping of the clinician obtaining consent, or some combination of these.

Response: