**HRP-593 Protocol Template for**

**Humanitarian Use Device**

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| *Per FDA regulation 21 CFR 814.124(a), an HUD may be administered only if such use has been approved by the IRB, and submitted to the IRB annually thereafter. This application is to be submitted as a supplement to the manufacturer’s materials.* |

**Humanitarian Use Device Name:**

*Provide the full protocol title as listed in IRES IRB*

Click or tap here to enter text.

**Principal Responsible Physician:**

*Name:*Click or tap here to enter text.

*Department:*Click or tap here to enter text.

*Telephone:*Click or tap here to enter text.

*E-mail Address:*Click or tap here to enter text.

**Version Date:**

*Provide the date of this submission:*Click or tap to enter a date.

1. **YNHH Information**

Please note that if this protocol includes Yale-New Haven Hospital patients, including patients at the Hospital Research Unit, the Principal Physician and any other listed clinicians who are physicians or mid-level practitioners (includes PAs, APRNs, psychologists and speech pathologists) who may have direct patient contact with patients on YNHH premises must have medical staff appointment and appropriate clinical privileges at YNHH. If you are uncertain whether the study personnel meet the criteria, please telephone the Physician Services Department at 203-688-2615. By signing this protocol as a Principal Physician, you attest that you and any co-investigator who may have patient contact has a medical staff appointment and appropriate clinical privileges at YNHH.

Once obtained, the PI is to submit IRB approval to the relevant YNHH Vice President or Service Line director for YNHH review and approval. If the HUD is approved for use at YNHH, an individual shall be designated in the relevant department to control the inventory, dispensation and chain of custody of the device(s). This individual must be notified of any use by the PI, prior to use for a planned procedure and as soon as possible thereafter in the event of an emergency use. Your request must be reviewed and approved in writing by the appropriate YNHH committee before patients/subjects may be scheduled to receive the investigational device or investigational procedure.

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| **If you need help…** |
| Yale University Human Research Protection Program<https://your.yale.edu/research-support/human-research> 25 Science Park 3rd floor150 Munson StreetNew Haven CT, 06520Phone: 203-785-4688Email: hrpp@yale.edu  |  |
| **Instructions for using this protocol template:**1. Use this template for studies involving the use of a Humanitarian Use Device (HUD)
2. Add this completed protocol template to your study in IRES IRB in the “Basic Information” section.
3. This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB.
4. There may be sections in this template that do not apply. If so, provide the response “Not Applicable”.
5. **DO NOT TYPE IN THE GRAY BOXES.** All guidance language appears in *gray boxes* and must be deleted from the final version of the protocol prior to submission.
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# Description of the Humanitarian Use Device

## Device Manufacturer Information

*Provide the name, address, contact information for the HUD manufacturer.*

##  Click or tap here to enter text.

## Generic and Trade Name of the HUD

*Provide the generic and trade name of the HUD.*

Click or tap here to enter text.

## FDA Humanitarian Device Exemption (HDE) number

*Provide the HDE number and the date of the HUD designation.*

Click or tap here to enter text.

## Description of the HUD

*Describe the device that qualifies as an HUD, the condition/disease that indicates the need for an HUD, and the indication approved by the FDA for use of the device. Include information on previous use.*

*Describe the contraindications, warnings, precautions for the use of the device.*

*List the alternative FDA-approved practices and procedures, if any.*

 Click or tap here to enter text.

# Use Request

*Describe the eligibility criteria, usual treatment history for a patient who would qualify for use of an HUD, the reason use of the HUD is worth the risk to the patient at this time, and the procedures and methods that the patient(s) will undergo.*

 Click or tap here to enter text.

# Consent Process

*Describe the process of clinical consent for the procedure: personnel obtaining consent, assessment of the patient’s capacity to consent, conditions under which consent will be obtained, any steps to minimize undue influence and any steps to enhance the patient’s independent decision-making, such as a waiting period. If non-English-speaking patients are to receive the device, describe provisions in place to assure comprehension. If the patient is a minor, describe how parental or guardian permission will be obtained*

 Click or tap here to enter text.

# Unanticipated Problems Involving Risk to Patients or Others

***NOTE****: The following unanticipated problems must be reported to the HIC promptly (at least within 5 days of becoming known to the physician):*

*a. Problems or events that are unexpected (in terms of nature, severity, or frequency) given the HUD procedures and the characteristics of the patient population;*

*b. Problems or events that suggest that the HUD places the patient at greater risk or harm (including physical, psychological, economic, or social harm) than was previously known or recognized; and*

*c. Problems or events that are related or possibly related to the patient’s receipt of the HUD.*

*(Describe who will be responsible for monitoring patient safety and reporting unanticipated problems.)*

 Click or tap here to enter text.

# Risks and Discomforts

*Describe the potential risks and discomforts to patients and methods of minimizing these risks.*

 Click or tap here to enter text.

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# Financial Information

*Describe what the patient will be told about the cost of the device and procedure and how insurance/Medicare will handle billing for this device and procedure.*

 Click or tap here to enter text.

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# Benefits

*Describe the potential benefits to patients.*

 Click or tap here to enter text.

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# Device Storage Plan

*Describe how the device will be handled, dispensed, and stored to ensure that it is used only for appropriate patients.*

 Click or tap here to enter text.

**Upload the following supporting materials with this submission in IRES IRB**:

* The HUD manufacturer’s product labeling, clinical brochure, and/or other pertinent manufacturer informational materials\*
* The FDA letter documenting the HDE number\*
* The patient information booklet from the sponsor\*
* The package insert, supporting literature provided by the sponsor, summary of safety information and probable benefit brochure

***\* These documents are required for review.***