



**Yale University School of Medicine
Human Investigation Committee
Yale New Haven Hospital**

HUMANITARIAN USE DEVICE APPLICATION

Initial Request: _____ **Renewal Request:** _____

Per FDA regulation 21 CFR 814.124(a), the HUD Application must be completed before initiating use of an HUD, and annually thereafter. This application is to be submitted as a supplement to the manufacturer's materials delineated in Section IX.

If this is a renewal request, complete the Contact Information below and Sections I and X only.

Contact Information:

Principal Responsible Physician: _____

Department: _____

Campus Address: _____

Email Address: _____

Telephone Number: _____

I. Device Information

Humanitarian Use Device Name: _____

Manufacturer: _____

FDA Humanitarian Device Exemption (HDE) Identifier Number: _____

II. Background: *(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.)*

III. 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.)*

IV. Consent (*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*)

V. Unanticipated Problems Involving Risk to Patients or Others:

NOTE.: The following unanticipated problems must be reported to the HIC within 48 hours 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.)

VI. Financial Considerations: Will the patient incur any financial obligation as a result of receiving this device?

VII. Personnel: (*All personnel who will be administering the HUD must be listed below, with their affiliation [Yale New Haven Hospital, Yale University], attestation regarding Conflict of Interest, and signature.*)

	Name	Signature	Affiliation	COI?
Principal Physician				Y__N__
Physician				Y__N__
Physician				Y__N__
Physician				Y__N__
Physician				Y__N__

Conflict of Interest: If you, your spouse, domestic partner or any dependent children have any stock or patent position with the device company, have participated in the product design or development of this device, have received compensation from this company or serve as a director or consultant to this company, you must complete an HIC protocol-related conflict of interest form. This form can be found at <http://info.med.yale.edu/hic/forms/index.html>.

VIII. Attestation

I certify that the information provided in this request is complete and accurate. I agree to:

- perform the procedure as outlined herein and approved by the IRB;
- use the device only as described on the FDA approved label
- provide the patient with appropriate information to make an informed decision about the use of the device
- report unanticipated problems involving risk to patients to the IRB according to IRB procedures
- notify the patient of any new findings regarding the device

I certify that the HUD is not being used as part of a research project or clinical investigation designed to collect data to support an FDA pre-marketing approval application.

Signature

Date

IX. Enclosures: *(The following materials must be submitted with the application)*

___ **Sponsor's Clinical brochure, protocol, or other pertinent informational materials**

___ **Patient information booklet—from the Sponsor**

___ **Other relevant documents (e.g., package insert)**

X. Annual Renewal

A. How many times has the device been used in the past year?

**B. Describe any unanticipated problems occurring in the past year.
Were these problems reported to the HIC? *(Give date of report.)***

**C. Has there been any change in the FDA approval status of the device?
Yes ___ No ___ *(If yes, describe)***

D. Are there any changes to personnel?

Yes ___ No ___

(If yes, new personnel must complete the information below)

	Name	Signature	Affiliation	COI?
Principal Physician				Y__ N__
Physician				Y__ N__
Physician				Y__ N__
Physician				Y__ N__
Physician				Y__ N__

E. Principal Physician Attestation

I certify that the information provided in this request is complete and accurate. I agree to:

- perform the procedure as outlined herein and approved by the IRB;
- use the device only as described on the FDA approved label
- provide the patient with appropriate information to make an informed decision about the use of the device
- report unanticipated problems involving risk to patients to the IRB according to IRB procedures

I certify that the HUD is not being used as part of a research project or clinical investigation designed to collect data to support an FDA pre-marketing approval application.

Signature

Date

For HIC Use Only

Date Approved

Human Investigation Committee Signature