Humanitarian Use Device (HUD) Application Form

When to use this form

In accordance with FDA regulations 21 CFR 814.124, IRBs are required to approve the use of a Humanitarian Use Device (HUD), except in emergency situations, in order for an institution to deliver the device to patients. In addition to the initial approval by the convened IRB Committee, IRBs must perform continuing review of a HUD application at least yearly.

Note: If this HUD is to be used in the context of a clinical investigation OUTSIDE its approved indication, a full IRB application is required, as well as a research-specific HIPAA authorization.

Instructions

Use this form when requesting approval to use a HUD at Children's Wisconsin (Children's) in the eBridge submission system. The document checklist below is provided to help physicians ensure the completeness of a HUD submission for IRB review. Please check relevant items and upload all designated materials in eBridge Section 52.

Document Checklist

- ☐ eBridge PRO submission
- ☐ Signed HUD Application Form
- ☐ HUD Product Labeling, Clinical Brochure, and/or other pertinent informational materials provided by the device sponsor
- ☐ FDA HDE Approval Letter
- ☐ Patient Information Booklet provided by the device sponsor
- ☐ HUD Consent/Permission Form using Children's Wisconsin template (research consent template should NOT be used for a HUD)
  - Required per the Children's HRPP policy
  - Contact the HRPP Office at 414-337-7133 with questions.

Humanitarian Device Name (include HDE Number)

Primary Physician Contact*

Affiliation

☐ Children's Medical Staff, Privileges Only

☐ Medical College of Wisconsin Faculty on Staff at Children's

Individual Responsible for IRB Paperwork (Name, Contact Phone and Email)

***Note**: The primary physician contact is responsible for corresponding with the IRB regarding the HUD.

Device Sponsor Information

Company Name	Contact Name

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Contact Address	Contact Phone

Other Physicians Authorized to Use this Device (insert additional lines if needed)				
Full Name/Degree	Dept./Division	Contact Phone	Contact Email	Affiliation
				☐ MCW ☐ Staff Privileges Only
				☐ MCW ☐ Staff Privileges Only
				☐ MCW ☐ Staff Privileges Only
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1. **Humanitarian Use Device Information**

   a. Describe the nature and purpose of the HUD

   b. Describe the intended use of the HUD

   c. Clinical indication for the HUD

   d. Will the HUD be used according to the approved clinical indications only?
   ☐ No ☐ Yes

   If no, please explain:

   e. Will safety or effectiveness data be collected?
   (i.e., is this a clinical investigation of the HUD?)
   ☐ No ☐ Yes

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f. Approximate cost

g. Does the HDE Application specify use in pediatric populations?
☐ No ☐ Yes

2. **Patient Population(s)**

a. Check all categories of patients that will be included:

☐ Inpatients	☐ Outpatients	☐ Adults with Decisional Impairments
☐ Men	☐ Women	☐ Pregnant Women
☐ Children Under Age 18	☐ Comatose	☐ Terminally Ill
☐ Other, explain:		

3. **Cost to Patients**

a. What financial obligations will the patient incur as a result of receiving this device?

b. Medicare approval is required prior to use of the device. Have you already obtained approval?
☐ o ☐ es, Medicare approval was granted

4. **Patient Recruitment**
Note: Patients should be told that the device is a HUD and that the effectiveness of the device has not been demonstrated.

a. Describe how this device will be explained to the patient. If the patient is a child, describe the process for obtaining and documenting assent (if applicable).

5. **Risks**

a. What are the potential risks/discomforts associated with the procedure?

b. If data is available, estimate, (1) the probability that a given harm will occur; (2) its severity; (3) its potential reversibility. ☐ Data is not available

c. What procedures will be used to prevent/minimize any potential risks/discomforts?

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6. **Benefits**

   a. Describe the probable benefits of the procedure for patients.

   b. Explain how the potential benefits of the use of the device outweigh the potential risks and how these risks are justified.

7. **Alternatives**

   a. There is always the alternative to choose not to receive a HUD. What therapeutic alternatives are available to patients?

8. **Conflict of Interest**

   a. Do any of the physicians listed on this form requesting authorization to use this device have any stock or patent position with the device company?

   ☐ No ☐ Yes, explain:

   b. Did any of the physicians listed on this form requesting authorization to use this device participate in the product design or development for this device, or as company director or consultant?

   ☐ No ☐ Yes, explain:

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Physician's Assurance Statement

I agree to comply with all Children's Wisconsin (Children's) policies and procedures, as well as with all applicable Federal, state, and local laws regarding treatment involving a Humanitarian Use Device, including, but not limited to:

- FDA regulations 21 CFR Part 812, Subpart H: Humanitarian Use Devices http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=814&showFR=1&subpartNode=21:8.0.1.1.11.7;
- Children's HRPP Policy posted in the IRBNet Document Library;
- Performing the procedure as outlined to and approved by the IRB of record;
- Medicare Part A & B Notification prior to billing (if applicable);
- Providing the patient with appropriate information to make an informed decision about the use of Humanitarian Device, using the IRB-approved consent document (if applicable);
- Promptly (within 5 working days) report to the IRB of record any new information involving risks to patients, including any unanticipated adverse events and all unanticipated problems involving risks to patients in accordance with Children's HRPP policy.

Check all that apply. Each physician listed on this form must sign. Copy signature box as needed.

☐ I hold the necessary clinical privileges to perform this procedure at Children's Wisconsin locations.

Select One:

☐ The HDE holder requires additional training prior to health care provider use of the device. The training requirements have been satisfied and documentation is attached.

☐ The HDE holder does not require additional training. I have read and understood the Instructions for Use.

Printed Name of Physician

Signature of Physician | Date

☐ I hold the necessary clinical privileges to perform this procedure at Children's Wisconsin locations.

Select One:

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Printed Name of Physician	
Signature of Physician	Date

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