Community Healthcare System Central IRB
Non Investigational Humanitarian Use Device (HUD) Application
(Form Date 4/2019)

Date Submitted: Click here to enter text.	**IRB use only** **IRB Number:** **Date Received:**
All uses of Humanitarian Use Devices require CHS CIRB review and approval. Use this form to apply for initial review by the CHS CIRB requesting the use of a HUD according to its approved labeling and indication(s) to treat or diagnose patients. (Investigational use of a HUD requires the submission of a complete Submission of a New Protocol form to the CHS CIRB)	

Project Site(s)	Community Hospital ☐	
	St. Catherine's Hospital ☐	
	St. Mary Medical Center ☐	
You must ensure these person(s)/facilities are kept adequately informed about the device and their duties and functions as they relate to this device and to the protection of human participants.		
Project Title	Click here to enter text.	
Requesting Physician	Click here to enter text.	
Address	Click here to enter text.	
Phone	Click here to enter text.	Email Click here to enter text.
Department	Click here to enter text.	
Primary Contact	Click here to enter text.	Title Click here to enter text.
Phone	Click here to enter text.	Email Click here to enter text.
Device Name	Click here to enter text.	
HDE #	Click here to enter text.	
Manufacturer Name	Click here to enter text.	
Manufacturer Address	Click here to enter text.	
Manufacturer Contact	Click here to enter text.	Phone Click here to enter text.

A. DEVICE USE

1. Will the HUD be used for its HDE- approved indication(s):

☐ **Yes** Will safety or effectiveness data be collected for the purpose of supporting a premarket approval (PMA) application for the HDE-approved indication:

☐ **No** The proposed HUD use is not a clinical investigation. Proceed to Section B.

☐ **Yes** The proposed HUD use is a clinical investigation. **DO NOT COMPLETE THIS FORM.** The Submission of a New Protocol Form must be completed for this submission.

☐ **No** The proposed HUD use is a clinical investigation, subject to 21 CFR § 50, 56, 812. **DO NOT COMPLETE THIS FORM.** The Submission of a New Protocol Form must be completed for this submission.

B. DEVICE DESCRIPTION/INDICATIONS

1. Provide a brief summary of the FDA-approved product indications for use of the device:
Click here to enter text.

2. Provide a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures for which it will be used. If appropriate, describe any alternative devices that were considered but not chosen, and why:
Click here to enter text.

3. List specific eligibility criteria for the use of the device:
Click here to enter text.

4. List specific exclusion criteria for the use of the device:
Click here to enter text.

5. Will the device be used for any indication(s) not listed in the FDA-approved label?
☐ Yes ☐ No
If **yes**, list the additional indications and justification for allowing use of the device in this way;
Click here to enter text.

C. RISKS AND BENEFITS

Briefly describe the potential risks and benefits to the patient associated with the use of this device.
Click here to enter text.

D. PARTICIPANT FINANCIAL OBLIGATIONS

What financial obligations will the patient incur as a result of receiving this device?
Click here to enter text.

NOTE: FDA Regulations limit the charge to patients for the device to the cost of research, development, fabrication, and distribution.

E. TARGET POPULATION

☐ Adults Age Range Click here to enter text.
☐ Children Age Range Click here to enter text.
☐ Vulnerable Population Specify Click here to enter text.

F. DEVICE USERS/PERSONNEL

List all individuals who will be **directly** involved with the insertion/ application/administration of this device. All listed must be adequately trained and/or supervised. This does not include technologists/technicians, radiological technologists, phlebotomist, or patient care services staff who do not have a research specific role.

Physician/Investigators	
Name Click here to enter text.	Name Click here to enter text.
Name Click here to enter text.	Name Click here to enter text.
Name Click here to enter text.	Name Click here to enter text.
Name Click here to enter text.	Name Click here to enter text.
Other Team Members	
Name	Job Title/Role
Name Click here to enter text.	
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Name Click here to enter text.	
Name Click here to enter text.	

G. SUPPORTING DOCUMENTS – SUBMIT WITH APPLICATION

1. Copy of FDA HDE Approval Letter(s)
2. Device Description
3. Product Labeling
4. Instructions for Use
5. Any information intended for patient information, education; consent, product information, etc.
6. Any other pertinent manufacturer informational materials

H. REQUIRED EDUCATION AND DOCUMENTATION – MUST BE ON FILE IN CLINICAL RESEARCH DEPARTMENT

Each physician/investigator and involved personnel must have the following documents on file in the department's research office:

1. Documentation of any additional training or proctoring required by the manufacturer
2. Current Curriculum Vitae
3. Current Privilege/credentials
4. A signed Physician/Investigator/Clinical Research Staff Acknowledgement form for the a Humanitarian Use Device Education Module
5. Certificate of Completion from Course #21760, Humanitarian Use Device (HUD) found in HealthStream

Each investigator is required to disclose financial interests when those interests are related to the test article.

Investigator: Includes the PI, all Co-Is and clinical staff involved in the of the test article, as well as spouses and dependent children of the PI, Co-Is and research staff

Related to the test article: A financial interest is related to the test article when financial interest is in the sponsor, product or service being tested or competitor of the sponsor, product or service being tested in this research study.

NOTE: Refer to the policy "Conflict of Interest in Research", IRB 2, for additional information and definitions.

I. Physician/Investigator Agreement

This form must be signed by the Physician/Investigator. Your signature certifies that the information provided is accurate, current and complete. He/she assures that procedures performed under this project will be conducted in strict accordance with federal regulations and Community Healthcare System policies and procedures that govern research involving human subjects. He/she agrees to submit any change to the project (e.g. change in physician/investigator, research methodology, subject recruitment procedures, etc.) to the CHS CIRB in the form of an amendment for IRB approval prior to implementation.

_____ _____

Physician/investigator Name (Print) Date

_____

Physician/Investigator Signature