TITLE: Humanitarian Use Device (HUD) Humanitarian Device Exemption (HDE)		POLICY/PROCEDURE NUMBER: IRB 17	
Author:	Jana L. Lacera, RN, MSA, CDM	Applicable To:	CHS CIRB
Supersedes:		Issued By:	CHS CIRB
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	CFNI		Community Hospital		St. Catherine Hospital		St. Mary Medical Center
X	Munster, Indiana	X	Munster, Indiana	X	East Chicago, Indiana	X	Hobart, Indiana

POLICY/PROCEDURE STATEMENT/PURPOSE:

The Humanitarian Device Exemption provides for marketing approval of a Humanitarian Use Device. (21 CFR 814.124(a)) The use of a HUD *does not* constitute research or an investigation. This is the only situation where federal regulations require the CHS CIRB to approve and monitor an activity that is clearly not research. If the HUD is being used in a research project, then the CHS CIRB must comply with all the FDA regulations pertaining to the review of research.

The physician/investigator is responsible for seeking CHS CIRB review and approval before the HUD is administered to or implanted into a patient.

CHS CIRB approval will extend to all physician/investigators, designated by the applying physician/investigator (Principal Investigator of record), in the department where the request for IRB review originated, example, physicians governed by the Department of Cardiovascular Services. The applying physician/ investigator will be responsible for ensuring that all designated physician/investigators possess the credentials necessary to use the device, are knowledgeable regarding the use of the device and abide by the conditions of the approval letter issued by the CHS CIRB.

DEFINITIONS:

Humanitarian Use Device (HUD): "A device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 8,000 individuals in the United States per year, rather than to generate data to support a finding of effectiveness." (21 CFR 814.102(a)).

Humanitarian Device Exemption (HDE): An application that is similar to a premarket approval (PMA) application, but exempt from the effectiveness requirements of a PMA. HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. An approved HDE authorizes marketing of a HUD.

Independent Physician Reviewer: A licensed physician who is a member of or consultant to the CHS CIRB and who is not otherwise participating in the clinical investigation or care of the patient

For the purposes of this policy and to ensure a prompt response, an Independent Physician Reviewer could be:

- Chair of the CHS CIRB
- Physician member of the CHS CIRB
- Medical Department Chair
- A licensed physician with expertise in the clinical area associated with the test article.

NOTE: The Physician may ask to be excused from participation in the review process if there is a perceived conflict of interest.

Non-Emergent Use of a HUD: The use of a legally marketed humanitarian use device to treat or diagnose patients within HDE-approved indication(s) (on-label)

NOTE: Prior CHS CIRB approval is needed before non-emergent compassionate/humanitarian or "off label" use occurs.

Premarket Approval (PMA): The routine process for approval of a device or drug by the FDA.

PROCEDURE FOR INITIAL REQUEST (On label use)

Applying Physician/Investigator Responsibilities

1. Complete and submit the *Humanitarian Use Device Application Form*
2. Complete and submit the *CHS CIRB Fees Form* to the sponsor.
3. Submit the documentation required on the *Non-Investigational Humanitarian Use Device (HUD) Application* including;
    - The list of physician/investigators that will be authorized to use the HUD under his/her direction
    - The physician/investigators must present evidence of having obtained or are in the process of obtaining the necessary privileges to perform all of the procedures necessary to administer or implant the device from the Medical Staff Credential's Office.
    - A statement that the HUD is not being used as a part of a research project or clinical investigation designed to collect data to support an FDA premarket application.
4. Each physician/investigator and involved personnel must complete a Humanitarian Use Device Education Module containing:
    - Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff – Humanitarian Device Exemption (HDE) Regulation issued July 8, 2010
    - IRB Policy 17: Humanitarian Use Device (HUD), Humanitarian Device Exemption (HDE)
    - Humanitarian Use Device (HUD) FAQs
    - IRB Policy 16: Emergency or Compassionate/Humanitarian Use of a Test Article
    - Application/Report for the Emergency/Compassionate Use of a Test Article
    - Humanitarian Use Device (HUD) FAQs for Physician/Investigators
    - Humanitarian Use Device (HUD) FAQs for Clinical Staff
    - Documentation of any additional training or proctoring required by the sponsor.
    - Physician/investigator/Clinical Staff Acknowledgment
    - Certificate of Completion from HealthStream Course #21760; Humanitarian Use Device (HUD)
5. Submit copies of the document(s) from the sponsor that includes:
    - Generic and trade name of the device
    - A copy of the HDE order from FDA
    - Instructions for Use
    - Product Labeling
    - Information that will be provided to the patient during the consent process, (i.e., consent form, labeling information)
6. A physician/investigator using a consent form or labeling information in another language will need to submit the translated version and the credentials of the translator(s), if appropriate.
7. The physician/investigator or one of the co-physician/investigators is required to attend and present the protocol to the CHS CIRB when scheduled.
8. Required documentation post CHS CIRB approval: To be submitted within 5 working days of use of the Test article:
    - Any information reasonably suggesting that the HUD may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.
    - All Medical Device Reports (MDRs)

- Any additional information or reporting stipulated by the CHS CIRB upon approval.

NOTE: The CHS CIRB is not required to review and approve each individual use of a HUD, nor is it required to audit medical records of patients who receive a HUD when used according to its HDE-approved indication(s).

Department Responsibilities

1. New requests received by the department will be entered into the database and assigned a new protocol number.
2. An initial review of the *Non-Investigational Humanitarian Use Device (HUD) Application* will be completed *by* the administrative staff. Physician/Investigators will be contacted to provide clarification and/or additional documentation if necessary.
3. The request may be forwarded to an independent reviewer after it has cleared the preliminary review process for further review if necessary. The independent reviewer will possess the necessary expertise to competently assess the merit of the request. Additional reviewers may be assigned at the discretion of the CHS CIRB Chair. The reviewer(s) will receive all of the documents submitted for review. The reviewer(s) will complete their task within 1 week and return the documents to the Department with their recommendation regarding the approval of the request.
4. The CHS CIRB Chair or the IRB Director may elect to table the request if the formal review process is not completed by the date of the CHS CIRB meeting or may proceed with the presentation of the protocol before a convened meeting.
5. Notify the Physician/Investigator in writing of the CHS CIRB determination following the convened meeting.

CHS CIRB Responsibilities

1. Review and approve the use of the HUD prior to use.
2. Is not required to review each individual use of an HUD, but may stipulate, as a condition of the approval, that it will require a summary following each use of the HUD.
3. Shall conduct both initial and continuing review.
   - The interval of continuing review shall be at an interval appropriate to the degree of risk, but no less than annually.
   - The CHS CIRB may elect to use an expedited review process for continuing review (21 CFR § 56.110).
   - The CHS CIRB will conduct a substantive review, considering any risk and benefit information available and any Medical Device Reports (MDRs)
4. Determine whether the patient must sign an informed consent and/or receive the patient labeling information stating the unproven status of the device.
5. Determine if there is any additional information the board will require as stipulations of the approval.

PROCEDURE FOR EMERGENT USE (OFF LABEL) of a HUD

Reference CHS CIRB Policy: Emergency or Compassionate/Humanitarian Use of a Test Article IRB 12 Application/Report for the Emergency or Compassionate/Humanitarian Use of a Test Article

PROCEDURE FOR NON-EMERGENT/COMPASSIONATE USE (OFF LABEL) of a HUD

Reference CHS CIRB Policy: Emergency or Compassionate/Humanitarian Use of a Test Article IRB 12 Application/Report for the Emergency or Compassionate/Humanitarian Use of a Test Article

NOTE: In the instance of a request for a planned non-emergent/compassionate, off-label use, the use of the HUD must have received prior CHS CIRB review and approval.

REFERENCE:
21 CFR 814.124(a)
21 CFR 56.107(a)

CROSS REFERENCE:
CHS CIRB Policy: Emergency or Compassionate/Humanitarian Use of a Test Article IRB 16
Application/Report for the Emergency Use of a Test Article
Non-Investigational Humanitarian Use Device (HUD) Application
Request to Renew a Humanitarian Use Device (HUD)
Humanitarian Use Devices (HUD) FAQs

ACCEPTED BY:

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DATE REVISED: 12/28/2007, 5/2010, 7/2018, 4/2019

REVIEWED BY: CHS CIRB 8/9/05, 2/12/08, 6/8/2010, 6/11, 2013, 5/10/2016, 11/2017, 8/2018, 6/2019, 2/2022

REVIEWED BY: Clinical Research Committee 5/2019

REVIEWED BY:

Date	Initials
2/2008	JL
5/2010	JL
5/2013	JL
5/2016	JL
11/2017	JL
7/2018	JL
4/2019	JL
2/2022	JL