

Title: Humanitarian Device Exemption (HDE)	*Applicable to: Beaumont Health	Effective Date: 01/12/2018
Policy Owner: Administrative Director	Document Type: Policy	Last Periodic Review Date: 01/12/2018 Functional Area: IRB and Clinical Research, Research Institute

***For This Document, Beaumont Health Includes:**

- Beaumont Corporate Shared Services
- Beaumont Hospital, Dearborn
- Beaumont Hospital, Farmington Hills
- Beaumont Hospital, Grosse Pointe
- Beaumont Hospital, Royal Oak
- Beaumont Hospital, Taylor
- Beaumont Hospital, Trenton
- Beaumont Hospital, Troy
- Beaumont Hospital, Wayne
- Beaumont Medical Group
- Beaumont Pharmacy Solutions
- Post Acute Care

I. PURPOSE:

The purpose of this policy is to establish a procedure for reviewing and approving the use of a Humanitarian Use Device (HUD) at Beaumont Health.

II. SCOPE:

This policy applies to investigators, key personnel, Institutional Review Board (IRB) members, staff and any physician who may use an HUD at Beaumont.

III. BACKGROUND:

- A. An HUD is a device intended to benefit patients in the treatment and diagnosis of diseases or conditions affecting fewer than 4,000 individuals per year in the United States. Because of the limited population involved, the Food and Drug Administration (FDA) has determined it is not reasonable to complete a scientific clinical trial proving the effectiveness of the device. Therefore, an HUD undergoes only limited safety testing.
- B. A **Humanitarian Device Exemption (HDE)** is an approval from the FDA to market an HUD on a limited basis and for a specific indication(s). An HDE application is submitted to the FDA by a device manufacturer. The application is similar to a pre-market approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. In accordance with FDA regulations, the application must contain sufficient information for FDA to determine the device does not pose an unreasonable or significant risk of illness or injury, and the probable benefit to health outweighs the risk of injury or illness from its use,

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taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. In addition, the applicant must demonstrate there are no comparable devices available to treat or diagnose the disease or condition, and the device manufacturer could not otherwise bring the device to market.

- C. The use of an HUD is restricted to facilities having a constituted IRB. The use of an HUD at Beaumont Health must be reviewed by the Beaumont Health IRB.
- D. The Beaumont Health IRB must review and approve all projects involving the use of an HUD; external IRB's may not review and approve the use of an HUD at any Beaumont facility. The HUD must have been granted an HDE by the FDA. The use of an HUD is not typically considered research, and is not subject to the Department of Health and Human Services (HHS) regulations or International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines.
- E. **IRB Initial Review:** The initial IRB review of an HUD project will be conducted by the full board. The following documents must be submitted to the IRB:
 1. An iMedRIS application for a Humanitarian Use Device (HUD) including a summary of how the physician proposes to use the device, a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures. The device use, as described in the IRB application, must be consistent with the FDA HDE approval.
 2. The HUD description, product labeling, clinical brochure, and/or any information provided by the sponsor, including materials to be provided to the patient.
 3. A copy of the HDE approval order/letter from the FDA.
 4. An HUD informed consent document or similar document including information for the patients use in deciding whether to proceed with the treatment (see Patient Consent/Information below).
 5. Any other materials being given to the patient, if applicable.

The HUD may only be used by investigators listed on the IRB-approved HUD application. The Principal Investigator (PI) is responsible for the use of the HUD at Beaumont. After initial IRB approval is granted, the IRB is not required to approve individual uses of an HUD. Although the use of an HUD is not considered research, the HUD requires submission of a Progress Report for continuing review.

- F. **Medical Device Reporting** – The PI must submit reports to the IRB and manufacturer whenever an HUD may have caused or contributed to a death or serious injury. Serious injury means an injury or illness which (1) is life-threatening, (2) results in permanent impairment of a body function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or

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permanent damage to a body structure. The manufacturer will be required to further report to the FDA. PIs are required to submit **Quality and Safety Reports** for any incident or occurrence inconsistent with the routine operation of the hospital or the routine care of patients, including device occurrences, **following procedures outlined in [Safety Event Reporting - RL Solutions](#)**.

- G. **IRB Continuing Review** - The FDA allows HUD protocols to undergo expedited continuing review by the IRB. Please refer to IRB Policy [Continuing Review and Renewal of a Protocol](#), for continuing review submission guidance.
- H. **Patient Consent/Information** - The IRB requires the patient be provided with information needed to make an informed decision about their treatment. Although the regulations do not require written informed consent, the IRB prefers an informed consent document be provided to the patient. The consent template for HUD projects is available on the IRB website or on the Operating Procedures page in iMedRIS under Forms. Often an HUD is placed in an emergency situation and consent cannot be provided in advance of the procedure. If this is the case, an Information Sheet about the device should be provided to the patient post HUD use.

The patient must be made aware of all of the following:

1. The absence of clinical testing to determine the effectiveness of the device in treating their condition;
2. The potential risks and benefits related to the device;
3. Any other procedures they may undergo in association with the use of the device;
4. Any cost(s) associated with the use of the device.

Most HDE holders/manufacturers have developed materials which incorporate information to assist a patient in making an informed decision about the use of the device. This material must be reviewed and approved by the IRB before being provided to a patient. If these materials contain the information listed above (items 1 through 4), the IRB may allow this information sheet/educational material to be used in lieu of the HUD informed consent.

If a consent form is utilized, the original document must be retained by the PI for his/her files. A signed copy must be provided to the patient. HUD consent processes are not subject to Research Institute consent audit program requirements, when the HUD is not used in clinical research (see section below “When the Use of an HUD Becomes Clinical Research”).

- I. **When the Use of an HUD Becomes Clinical Research** - An HDE holder may collect safety and effectiveness data to support a PMA under the approved HDE without applying separately for an Investigational Device Exemption; however, the collection of this data is

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considered research. A complete IRB application must be submitted to the IRB and project approval must be granted by the IRB prior to any data collection. Please refer to [IRB Initial Review of Research Protocols](#) for additional guidance. When an investigator wants to study a significant risk (SR) HUD for a new indication, an IDE application must be submitted to the FDA; an IDE is not required for non-significant risk devices (NSR). Clinical investigations of both SR and NSR HUDs require IRB approval before initiation. For more information on device risk determination, refer to IRB policy *Determination of Significant Risk Device*.

- J. **Emergency Use of an HUD** - HUDs may be used in an **emergency** situation for circumstances outside of those defined in the HUD Application form (e.g., an unapproved indication, patient not meeting inclusion/exclusion, etc.) to save the life or protect the physical well-being of a patient; however, special requirements must be met, including the following three criteria.
1. The patient has a life threatening condition and needs immediate treatment,
 2. No generally acceptable alternative treatment for the conditional exists, and
 3. Because of the immediate need to use the device, there is no time to use existing FDA approval procedures for the use.

If the HUD is used in an emergency situation for an unapproved indication, the physician should ensure reasonable patient protection measures are followed, such as developing schedules to monitor the patient, taking into consideration the patient's specific needs and the limited information available about the risks and benefits of the device. When a physician needs to use the HUD in an emergency situation, she/he must submit written notification to the IRB chairperson outlining the need and include patient initials, date of use, and the reason for the use, within 5 days of HUD use. The physician should obtain an independent assessment from an uninvolved physician for concurrence of the HUD use. The physician should submit a follow-up report on the patient's condition to the HDE holder, the IRB, and the device manufacturer.

For a complete explanation of the requirements when using an HUD for single time emergency use, see IRB policy *Single Emergency Use of a Test Article*.

If the HDE holder requires a letter from the IRB for an emergency use of an HUD, the IRB will provide a letter acknowledging the review of the emergency use. The IRB will be review the request using the expedited process unless the IRB determines full board review is required.

- K. **Off Label Use of an HUD** - Physicians should be cognizant the FDA has made a determination of safety and probable benefit for use of the HUD only within its approved

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indication(s). A physician may use an HUD in extenuating circumstances in an **Off Label** indication when the physician deems the use is in the best interest of the patient, in accordance with good medical practice. Physicians have the responsibility to be well informed about the HUD, to base its use on firm scientific rationale and on sound medical evidence, and to notify the IRB prior to use. Notification must include (1) the name of the HUD to be used; (2) why the HUD is being utilized; (3) the patient protection measures established for the patient (i.e., consideration of the patient’s specific needs, the limited information available about the risks and benefits of the device and schedules devised to monitor the patient) and (4) what information is being provided to the patient.

The physician must inform the patient of all of the following:

1. The absence of clinical testing to determine the effectiveness of the device in treating their condition.
2. The potential risks and benefits related to the device.
3. Any other procedures they may undergo or follow up care required in association with the use of the device.
4. Any cost(s) associated with the use of the device.

The information above and a description of any written materials provided to the patient should be documented in the patient’s medical record. The physician should submit a follow-up report on the patient’s condition to the HDE holder and to the IRB. The IRB will be review the request using the expedited process unless the IRB determines full board review is required.

IV. APPLICABLE REGULATIONS AND GUIDELINES:

- 21 CFR 50 Protection of Human Participants
- 21 CFR 56 Institutional Review Boards
- 21 CFR 803 Medical Device Reporting
- 21 CFR 814 Premarket Approval of Medical Devices Subpart H-Humanitarian Use Devices
- 45 CFR 164 HIPAA
- FDA Device Advice- Humanitarian Use Device
- Draft Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answers
- FDA: Safe Medical Device Act of 1990
- SEC.906 [21 USC §396] Practice of Medicine
- Pediatric Medical Device Safety & Improvement Act 514, 515 and 520

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V. REFERENCES TO OTHER APPLICABLE POLICIES:

- IRB policy [*Continuing Review and Renewal of a Protocol*](#)
- IRB policy *Determination of Significant Risk Device*
- IRB policy [*IRB Initial Review of Research Protocols*](#)
- IRB policy *Single Emergency Use of a Test Article*
- Beaumont Health Policy [*Safety Event Reporting - RL Solutions*](#)

CORPORATE AUTHORITY:

Beaumont Health (“BH”) as the corporate parent to William Beaumont Hospital, Botsford General Hospital, and Oakwood Healthcare Inc., (“Subsidiary Hospitals”) establishes the standards for all policies related to the clinical, administrative and financial operations of the Subsidiary Hospitals. The Subsidiary Hospitals, which hold all health facility and agency licenses according to Michigan law, are the covered entities and the providers of health care services under the corporate direction of BH. The Subsidiary Hospitals’ workforces are collectively designated as BH workforce throughout BH policies.