

Humanitarian Use Device Procedure

I. Purpose

This Procedure outlines requirements for the use of Humanitarian Use Devices (“HUD”) at sites under the auspices of the Einstein Institutional Review Board (“IRB”).

II. Scope

This Procedure covers all use of HUDs at sites under the auspices of the Einstein IRB.

III. Definitions

Humanitarian Use Device: As defined by 21 CFR 814.3(n), a Humanitarian Use Device (HUD) is a “medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.” The HUD designation is granted by FDA Office of Orphan Products Development. The labeling for the HUD must state that the device is a Humanitarian Use Device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated.

Humanitarian Device Exemption (HDE): If the FDA Office of Device Evaluation makes the determination that the HUD does not pose unreasonable risk of injury to patients and that the probable benefit outweighs risk of injury from its use, it may grant a Humanitarian Device Exemption (HDE). A HDE authorizes an applicant to market a Humanitarian Use Device subject to certain restrictions.

IV. Procedure

This procedure only applies only to the use of a HUD for diagnosis and treatment. If systematic safety or efficacy data are collected, the use is for research purposes and a complete IRB application must be submitted (and an IDE may be required).

Though a HUD is an FDA-approved medical device, the FDA requires IRB approval before a HUD may be used at an institution, except for an emergency use situation. The IRB is required to perform its initial review at a convened meeting using the criteria for approval at 21 CFR 56.111. Subsequent continuing reviews - at least annually - may be performed using expedited procedures.

The IRB approval must verify that the use of the HUD, as proposed, is congruent with current labeling of the device and does not exceed the scope of the FDA approved indication.

The IRB may impose more stringent restrictions for use of the HUD as a means of additional protections, as deemed necessary.

The IRB may approve the device for either

- General use; or
- For groups of HUD patients that meet certain criteria; or
- For patients under a HUD protocol; or
- On a case-by-case basis.

The Einstein IRB generally requires that treating clinicians obtain informed consent for the use of a HUD.

The following should be submitted to the IRB, as applicable:

- Documentation of the HDE
- Sign-off by the Department Chair certifying that the providers are credentialed to use the device
- Consent form or manufacturer device brochure
- Product labeling
- Patient information packet

Adverse Event Reporting

Serious device-related adverse events and device-related deaths must be reported to the IRB within 5 business days. They must also be reported to the FDA and manufacturer within their specified timelines.

Off-Label Use and Emergency Use of an HUD

A HUD may be used off-label for clinical care when the HUD is the only option available for a patient(s) faced with a serious or life-threatening condition.

Non-emergency off-label use of a HUD must follow the “Treatment Use of Investigational Devices” Procedure.

Emergency uses of a HUD must follow the “Emergency Use of Investigational Drugs, Biologics, and Devices” Procedure.

V. Effective Date

Effective as of: July 1, 2020

VI. Procedure Management and Responsibilities

Einstein’s Office of Human Research Affairs is the Responsible Office under this Procedure. The Executive Dean is the Responsible Executive for this Procedure. The OHRA Director is the Responsible Officer for the management of this Procedure.