Human Research Protection Program Departmental Policy and Procedure

7.3 Humanitarian Use Device (HUD)

Responsible Office: Human Research Protection Program Department (HRPPD)

Effective Date: June 5, 2026

I. Policy Statement

a. A HUD is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or are manifested in less than 8,000 individuals in the United States per year. The U.S. Office of Orphan Products Development (OOPD) determines if a device meets specific requirements, including scientific rationale and population prevalence, for designation as an HUD.

b. UT Southwestern IRB recognizes humanitarian device exemption (HDE) approval by the FDA is based on safety and probable benefit of a designated Humanitarian Use Device (HUD). All uses of a HUD require IRB approval.

c. This policy applies to the following HUD uses that <u>are not</u> considered to be Clinical Investigations (research):

   i. When a HUD is used according to its approved labeling and indication(s) and does not involve collection of safety and effectiveness data.

   ii. When a HUD is used for an indication not approved under the existing HDE <u>and</u> the IRB has determined there is no intention or plan to collect safety or effectiveness data to support a PMA for that new indication.

   iii. Uses that do not meet the regulatory definition of a clinical investigation are not subject to 21 CFR Parts 50 & 56.

d. **Exception to this policy:** The following uses meet the regulatory definition of a clinical investigation and are subject to 21 CFR Parts 50 & 56. As such, this policy does not apply in the following situations. Instead, the following uses will be reviewed under 2.1. Initial Review Of Research:

i. When a HUD is used according to its approved labeling and indication(s) and involves the collection of safety and effectiveness data. As such, the device is legally marketed and an IDE is not required.

ii. When a HUD is used for an indication not approved under the existing HDE and the plan is to collect safety or effectiveness data to support a PMA. As such, requires prior submission to the FDA for an IDE.

II. Scope

a. This policy applies to the IRB and all research personnel involved with the use of a Humanitarian Use Device.

III. Procedures For Policy Implementation

a. Initial Submission to HRPPD

i. All requests for use of an HUD under an HDE must be initially reviewed and approved by the convened IRB unless used in an emergency as follows:

1. A physician in an emergency situation determines that IRB approval for the use of the HUD at the facility cannot be obtained in time to prevent serious harm or death to a patient

2. The physician must report the emergency use within five days; provide written notification of the use to the IRB chairperson including identification of the patient involved, the date of the use, and the reason for the use. See section 520(m)(4) of the Act; 21 CFR 814.124.

ii. The Health Care Provider must submit the request for use of an HUD in ETHOS. The submission must include:

1. A copy of the HDE approval order;

2. A description of the device;

3. The product labeling;

4. The patient information packet that may accompany the HUD;
5. A sample consent form for the use of the HUD if required by the IRB or sponsor; and
6. A summary of how the physician proposes to use the device, including:
    a. A description of any screening procedures,
    b. The HUD procedure, and
    c. Any patient follow-up visits, tests or procedures.

iii. Upon receipt of the application, HRPPD staff designated to pre-review HUD requests, screen the application including any informed consent process and documentation for completeness and accuracy and forwarded for review by the convened IRB (see 1.1. Receiving, Routing, And Administrative Review Of IRB Submissions)

b. IRB Initial Review – the Board members:

i. Receive access to a copy of the submitted materials in ETHOS. A list of approved HDEs may be found at "CDRH Humanitarian Device Exemption Summaries of Safety and Possible Benefit".

ii. Ensure that health care providers are qualified through training and expertise to use the device. For many HDEs, the HDE holder is required to provide training on the use of the device prior to the health care provider using the device. Such requirements would be specified in the HDE approval order, available at "CDRH Humanitarian Device Exemption Summaries of Safety and Possible Benefit" (select the HDE number).

iii. Where the plan is to use the device beyond the scope of the FDA HDE-approved indications, ensure the rationale for the off-label use is reasonable with regards to safety and probable benefit.

c. IRB Review Outcomes:

i. The IRB considers the following as applicable:

1. Additional information needed to determine HUD or HDE status;
2. Required revisions needed to qualify for approval;
3. How the HUD may be used (within approved labeling, outside approved labeling where there is no intention or plan to collect safety or effectiveness data to support a PMA for that new indication);
4. Where the use of the HUD may take place;
5. Who may use the HUD (Individuals, departments, hospitals, etc.);
6. Whether or not IRB approval is needed prior to use on each patient;
7. Determination that the activity does not qualify for approval with rationale for the determination and recommendations for submission of full review human research application where applicable;
8. Approved for implementation (general comments or suggestions may be included but not required for approval).

ii. The HRPPD records all determinations concerning the use of an HUD under an HDE as described in 8.1 IRB Minutes.

iii. The Health Care Provider requesting the use of the HUD under an HDE is notified as described in 8.2 Reporting Policy And Procedure.

d. Informed Consent:

i. Use of a consent form is not required by the federal regulations, however, it is permitted.

ii. When the HUD is used according to the approved labeling, the IRB may or may not require that consent be obtained. It is generally advisable to obtain consent for the use of a HUD, if the Health Care Provider would obtain consent for other similar clinical procedures, if the need for the HUD can be anticipated, and the clinical situation will permit obtaining

consent.

1. When a HUD is used for an indication not approved under the existing HDE, the Health Care Provider will obtain informed consent from the patient (21 CFR Part 803).

e. Modifications in ongoing HUD use

   i. All requests for alterations to the IRB approved use of an HUD under an HDE must be reviewed and approved by the IRB and may be reviewed by expedited procedure (except where necessary to eliminate apparent immediate hazards to the patient).

   ii. The PI must submit the proposed changes to the HRPPD by submitting a modification request in ETHOS.

   iii. The designated IRB reviewer (either expedited or convened IRB) will determine whether the change alters the determination that the device may be used under the HDE in place.

   iv. If the changes do not affect the HDE determination and are acceptable, the IRB reviewer documents the determination in the ETHOS record and notifies the local Health Care Provider that requested the use of the HUD is approved according to 8.2 Reporting Policy And Procedure.

   v. If the changes do affect the determination such that the study will no longer be eligible for use of an HUD under an HDE, the reviewer contacts the local Health Care Provider that requested the use of the HUD and develops a plan to either withdraw the change or submit the study as human research under the appropriate review process (expedited or full review).

f. Annual Continuing Review of the use of an HUD

   i. Continuing review of the use of an HUD under an HDE must be reviewed and approved at least annually by the IRB.

ii. Health care providers must to submit a Progress Report in ETHOS and any applicable attachments for continuing review.

iii. Continuing Review may be completed by expedited procedure. [FDA recommends the use of an expedited procedure because a HUD is a legally marketed device and no safety and effectiveness information is being collected systematically, as is required for a research protocol.]

iv. At Continuing Review, the Chair or the Chair's designated member(s) will consider the risk and benefit information available and any Medical Device Reporting (MDR) reports

g. Review of HDE Medical Device Reports

i. 21 CFR 814.126(a) requires HDE medical device reports (MDRs) that are submitted to FDA in compliance with the requirements of part 803 of this chapter also be submitted to the IRB of record.

ii. The IRB Director will review all MDRs submitted directly to the IRB from manufacturers.

1. MDRs requiring immediate action are forwarded to the IRB Chair or IRB Director for consideration of suspension or termination.

2. MDRs not requiring immediate action

a. Filing MDR reports does not necessarily mean that the product caused or contributed to the event. Many reports are incomplete and do not provide enough information to rule in or out a relationship between the event and the device.

b. The IRB designated reviewer will send a letter advising the PI that the IRB has received the MDRs and that further evaluation by the local Health Care Provider that requested the use of the HUD is required.

i. If the events are determined to require immediate local action

the Health Care Provider will submit a modification.

ii. If the events do not require immediate local action the Health Care Provider will submit a list and summary of all MDRs, adverse events and unanticipated problems with the next continuing review.

h. The Health Care Provider requesting the use of the HUD under an HDE is notified of any IRB determinations for initial review, continuing review or modifications of use as described in 8.2 Reporting Policy And Procedure.

IV. Definitions

See glossary of human research terms

V. References

a. 21 CFR 50: Protection Of Human Subjects

b. 45 CFR 46: Protection Of Human Subjects

c. 45 CFR 164: Security And Privacy (HIPAA Privacy Rule)

d. 21 CFR 56: Institutional Review Boards

VI. Revision and Review History

a. Revision Date: June 2026; Author: HRPP; Description: Reference to eIRB updated to ETHOS

b. Revision Date: June 2021; Author: HRPP; Description: Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.

c. Revision Date: August 2017; Author: HRPP; Description: New Policy Development

d. Revision Date: March 2012; Author: IRB Office; Description: IRB Written Procedures