

	Institutional Review Board	
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Responsibility: OIRB		Page 1 of 5

Humanitarian Use Device (HUD)  
Policy and Procedure

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I. Policy

- A. UTHSCSA 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.
  - 1. HUD uses that are not a Clinical Investigation (research)
    - a) When a HUD is used according to its approved labeling and indication(s) and does not involve collection of safety and effectiveness data.
    - b) When a HUD is used for an indication not approved under the existing HDE and the IRB has determined there is no intention or plan to collect safety or effectiveness data to support a PMA for that new indication.
    - c) Uses that do not meet the regulatory definition of a clinical investigation are not subject to 21 CFR Parts 50 & 56).
  - 2. HUD uses that are a Clinical Investigation (research) –
    - a) 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.
    - b) 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.
    - c) Uses that meet the regulatory definition of a clinical investigation are subject to 21 CFR Parts 50 & 56) and are not approved under this policy, See [Initial Review of Research Policy and Procedure](#)
- B. 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 chair person 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.

- C. Use of a consent form is not required by the federal regulations, however, it is permitted.
- D. 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. Continuing review of the use of an HUD under an HDE must be reviewed and approved at least annually by the IRB and may be reviewed by expedited procedure.
- F. 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.

## II. Procedure

### A. Submission

- 1. The Health Care Provider submits:
  - a) Humanitarian Use Device - Report of Emergency Use (HUD used without IRB approval), or
  - b) Request for use of an HUD under an HDE with a copy of package insert or FDA approved label. 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.
- 2. Upon receipt of the application, OIRB 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 [Receiving, Routing, and Administrative Review of Submissions](#))

B. IRB Initial Review – the Board members:

1. Receive access to a copy of the HDE approval order; a description of the device; the product labeling; the patient information packet that may accompany the HUD; a sample consent form for the use of the HUD if required by the IRB; and a summary of how the physician proposes to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures. A list of approved HDEs may be found at "CDRH Humanitarian Device Exemption Summaries of Safety and Possible Benefit".
2. 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).
3. 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. Review Outcome(s)

1. The IRB considers the following as applicable:
  - a) Additional information needed to determine HUD or HDE status;
  - b) Required revisions needed to qualify for approval;
  - c) 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);
  - d) Where the use of the HUD may take place;
  - e) Who may use the HUD (Individuals, departments, hospitals, etc);
  - f) Whether or not IRB approval is needed prior to use on each patient;
  - g) 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;
  - h) Approved for implementation (general comments or suggestions may be included but not required for approval).
2. Appeals - If the Health Care Provider has concerns regarding the IRB decision/recommendations for changes in the use of the HUD, he/she may submit the concerns to the IRB including a justification for changing the IRB decision. The Health Care Provider may send the request to the reviewer and/or the IRB Director or Chair for final resolution.
3. The OIRB records all determinations concerning the use of an HUD under an HDE.
4. The Health Care Provider requesting the use of the HUD under an HDE is notified as described in the [Reporting Policy and Procedure](#)

D. Changes in ongoing HUD use

1. Any changes to the activities described in the initial request to use the HUD must be reviewed by the IRB designated reviewer prior to implementing (except where necessary to eliminate apparent immediate hazards to the patient).
  2. The PI must submit the proposed changes to the OIRB either by Amendment Form, memo or email.
  3. The designated IRB reviewer will determine whether the change alters the determination that the device may be used under the HDE in place.
  4. If the changes do not affect the HDE determination and are acceptable, the reviewer documents the determination in the IRB record and notifies the local Health Care Provider that requested the use of the HUD.
  5. 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).
- E. Continuing Review of the use of an HUD
1. 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.
    - a) The IRB designated reviewer will review all MDRs submitted directly to the IRB from manufacturers.
    - b) MDRs requiring immediate action are forwarded to the IRB Chair or IRB Director for consideration of suspension or termination.
    - c) MDRs not requiring immediate action
      - (1) 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).
      - (2) 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.
        - (a) If the events are determined to require immediate local action the Health Care Provider will submit an amendment.
        - (b) 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.
  2. The IRB requires Investigators to submit an HDE Progress Report and any applicable attachments for continuing review.
  3. 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.] (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110194.htm#9> )

4. 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. (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110194.htm#9>).
5. The Health Care Provider requesting the use of the HUD under an HDE is notified as described in the [Reporting Policy and Procedure](#).

### III. References

- A. Definitions (see [Glossary](#))
- B. Regulatory (see [Policy on Policies Policy and Procedure](#))