

IRB Policy 35: Humanitarian Use Devices

Creation Date: May 16, 2007, revised November 19, 2009, revised January 27, 2011, revised April 2, 2012, revised October 15, 2015

I. Definitions

a. Humanitarian Use Device (HUD): A Humanitarian Use Device is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals per year in the United States.

b. Humanitarian Device Exemption (HDE): A Humanitarian Device Exemption (HDE) is an application that is similar to a premarket approval application (PMA), but exempt from the effectiveness requirements of a PMA.

II. Summary Policy

It is the policy of the ETSU/VA IRB to review the use of all Humanitarian Use Devices under the purview of the ETSU/VA IRB.

III. IRB Review of HUD Use

The initial review of a HUD is to be completed by the full, convened IRB Committee. The full Committee may make the determination at initial review that continuing reviews meet expedited criteria.

For an initial HUD submission, the following documents must be submitted to the ETSU/VA IRB by the submission deadline for the subsequent convened IRB meeting.

1. XForm 200 (Humanitarian Use Device (HUD) Initial Submission
As attachments
2. a copy of the FDA HDE approval letter and any other pertinent correspondence
3. a copy of the manufacturer-provided patient information.
4. a copy of the HUD manufacturer's product labeling, clinical brochure, and/or other pertinent manufacturer informational materials (i.e., Summary of Safety and Probable Benefit and Product Information Summary)
5. an original Unaffiliated Investigator Agreement, as applicable

[Note: If the HUD is the subject of a clinical investigation (one in which safety and effectiveness data is being collected to support a PMA), xForm 200 may not be used. Instead, a complete new protocol submission xform with informed consent (and all applicable attachments per policy) is required.

Before HUD approval is issued, the PI must complete with passing scores (overall score of 80% or above), the following three Collaborative Institutional Training Initiative (CITI) modules:

1. History and Ethical Principles
2. Basic IRB Regulations and Review Process
3. FDA Regulated Research

The ETSU/VA IRB may approve the use of the device in general, use of the device for groups of patients meeting a certain criteria, or use of the device under a treatment protocol. The use of the device should not exceed the scope of the FDA approved indication. If the IRB wishes, the IRB may specify limitations on the use of the device based upon one of more measures of disease progression, prior use and failure of any alternative treatment modalities, reporting requirements to the IRB or IRB Chair, appropriate follow-up precautions and evaluations, or any other criteria it determines to be appropriate.

For use of the HUD outside of its approved indication of use in an emergency situation, refer to the procedures in IRB Policy 20, Emergency Use of a Test Article.

For compassionate use of the HUD outside of its approved indication, **prior to use**, the PI must provide both the HDE holder and the ETSU/VA IRB with the following information:

- a description of the patient's condition and
- the circumstances necessitating use of the device,
- a discussion of why alternative therapies or diagnostics are unsatisfactory
- information to address the patient protection measures
- a schedule for monitoring the patient, taking into consideration the specific needs of the patient and the limited information available regarding the risks and benefits of the device for this unapproved use.

The request for compassionate use must be reviewed and approved by the ETSU/VA IRB Chair prior to the proposed use. The ETSU/VA IRB Chair will obtain FDA guidance and/or approval as necessary.

IV. Informed Consent

The regulations do not require informed consent because an HDE provides for marketing approval, and so use of the HUD does not constitute research or an investigation which would normally require informed consent. Although consent is not required by the FDA regulations, consent may be required by State law or institutional policy. The manufacturer-provided patient information must be provided to each patient and prospectively reviewed with the patient to allow the patient to make an informed decision. The patient file must document this

provision of information as well. The IRB may impose the requirement for written informed consent or more stringent restrictions for use of the HUD as deemed necessary.

If the HUD is the subject of a clinical investigation (one in which safety and effectiveness data is being collected to support a PMA), IRB approval and informed consent are required.

When the use of a HUD is for diagnosis or treatment, and not for research or data collection, HIPAA regulations for research do not apply. However, HIPAA regulations for hospital medical records per the Institutional Policies are applicable.

V. Approval Period

The IRB may approve the use of the device for a period not to exceed one year. The IRB may choose to approve the device for a specific number of patients and require a summary report before approving the use in additional patients.

VI. Reporting

The PI must promptly report any FDA action(s) regarding the HUD to the IRB. Amendments, Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs) and continuing reviews are required to be reported according to IRB Policies and Procedures. In addition, these occurrences are to be reported to the FDA and/or manufacturer per 21 CFR 803.30. IRB submissions of amendments, UPIRTSOs and continuing review will be reviewed at the level for which criteria is met. XForm 207 is submitted to request continuing review or closure.

Sources

Humanitarian Device Exemption (HAD) Regulation: Questions and Answers: Final Guidance for Industry, FDA, July 12, 2001

Humanitarian Use Device Regulations, www.fda.gov/orphan, humuse.htm

FDA 21 CFR 814, 803.30