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| Policy Name: Humanitarian Use Device Policy and Procedures | | | |
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I. POLICY

A. Introduction

A humanitarian use device is defined by the FDA as a device intended to benefit patients in the treatment and diagnosis of disease or conditions that affect or is manifested in fewer than 4,000 individuals in the US per year.

B. Regulations

Designation of a device as a HUD is determined by the Office of Orphan Products Development. Use of an HUD within its approved labeling does not constitute research.

II. PROCEDURES

- A. Informed consent is not required when treating or diagnosing a patient under an HDE, but prospective informed consent should be obtained when feasible. Patient labeling information may also provide information about the potential risks and benefits of the HUD and informs patients about the humanitarian use of device and that effectiveness for the labeled indication has not been demonstrated in previous clinical trials.
- B. After the Humanitarian Device Exemption (HDE) has granted FDA approval, IRB approval must also be approved prior to its use.
- C. Investigators must submit a HERRA application to the IRB. This application must also contain a copy of the HDE application submitted to the FDA, documentation of FDA approval, any consent document that may be used, and the patient labeling information.
- D. Initial IRB approval must be performed at a convened meeting of the Board. The IRB may approve use of the HUD without restrictions or may require review on a case-by- case basis. Applications to the IRB should describe the approximate number of the patients the investigator anticipates will be treated or diagnosed with the device.

- E. Unless the IRB determines full boards review is necessary, continuing review and approval of the use of the device (not to exceed one year) may be conducted using expedited review procedures.
- F. All unanticipated problems and adverse events involving the use of a HUD should be submitted to the IRB in accordance with policies and procedures involving the use of investigational devices under an IDE application.

G. Off-Label Use of Humanitarian Use Device

Prior FDA approval for an emergency use of a HUD is recommended. If this is not feasible, FDA recommends that the procedures in the Expanded Access of Unapproved Devices be used as guidance. **(Note: IRB may not approve a waiver of informed consent for planned emergency research that is subject to VA Regulations)**

H. Future Research Designed to Obtain Marketing Approval

If the holder of HDE develops a research protocol designed to collect safety and effectiveness data to support marketing of the device, the investigational study must receive prior IRB review and approval. While an Investigational Device Exemption (IDE) is not required if the device is used within the FDA approved HUD labeling, IDE regulations must be followed and consent must be obtained from prospective participants in accordance with the IRB approved application. **(Note: IRB may not approve a waiver of informed consent for planned emergency research that is subject to VA Regulations)**