This document describes the responsibilities of clinicians and the USA Institutional Review Board (IRB) and processes related to use and review of Humanitarian Use Devices (HUD) including clinical, emergency, compassionate and investigational use.

This Standard Operating Procedures (SOP) applies to the following situations involving HUDs:

- Clinical use of a HUD as a legally marketed device, or
- Emergency or compassionate use of a HUD based on a healthcare provider request that meets IRB criteria, or
- Investigational use for research purposes either consistent with approved labeling or off-label

This SOP applies to IRB administrative staff, IRB members, and healthcare providers.

Collection of safety and effectiveness data pertaining to a Humanitarian Use Device (HUD). Note: Clinical investigations are not the focus of this document, however,

when required by the IRB. The IRB generally requires that treating physicians obtain informed consent.

1.2 Confirm initial IRB approval for clinical use of the HUD at the institution.

1.3 Obtain and document clinical informed consent as required by the University of South Alabama Health Systems. (When the use of a HUD is for clinical diagnosis or treatment, i.e. not associated with human subject research activity, research informed consent and HIPAA regulations for research do not apply).

1.4 Provide patient information packets (when available) to patients prior to their receiving the HUD. If no packet is available, the patient should be provided with the following information:

- An explanation that the HUD is designed to diagnose or treat the disease or condition described in the HDE labeling and that no comparable device is available to treat the disease or condition.
- A description of any ancillary procedures associated with the use of the HUD.
- A description of the use of the HUD.
- All known risks or discomforts.
- Information reflecting the HUD status of the device including a statement indicating that the effectiveness of the device for this use has not been demonstrated.

1.5 Federal regulations require that an annual review be submitted to the IRB. The annual review can b8buviewofew ca within1 (n)]TJtx(nua)4ps(io)8 (n)0 (w)6 (it)6 (h(h)6 (ems)16

IRB Reviewer Checklist: Criteria for Approval and Considerations for HUD (IRBNet Forms and Templates)

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

Humanitarian Use Devices, A brief guide for clinicians, investigators, and IRB members, Dale E. Hammerschmidt, M.D., University of Minnesota, October, 2001

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