

**I. Policy**

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) to review and approve the use of all Humanitarian Use Devices.

**II. Authority**

A. Chapter 381.86, Florida Statutes, Institutional Review Board

**III. Supportive Data**

A. FDA 21 CFR 814, 803.30

B. U.S. Food and Drug Administration Device Exemptions Regulation: Questions and Answers; Final Guidance for Industry, July 12, 2001.

C. U.S. Food and Drug Administration Device Regulations, June 26, 1996.

**IV. Definitions**

A. Food and Drug Administration (FDA): The FDA is the federal oversight agency responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

B. Humanitarian Use Device (HUD): A device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year.

C. Humanitarian Use Device Exemption (HDE): A Federal Drug Administration (FDA) approval for a physician to use a HUD in clinical treatment or as the subject of a clinical investigation.

**V. Procedures****A. IRB Review of HUD Use**

1. In order for a HUD to be used in treatment, diagnosis, or research, the DOH IRB and the FDA must approve it and a Humanitarian Device Exemption (HDE) issued.

a. The IRB approval must verify that the use of the HUD, as proposed, is congruent with current labeling of the device and does not exceed the scope of the FDA approved indication.



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John O. Agwunobi, M.D., M.B.A., M.P.H.  
Secretary, Department of Health

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Date