Rush University Medical Center
Policies and Procedures

Policy Number:	RA-IRB-212
Category Name:	Research
Title:	Use and Review of a Humanitarian Use Device
Type:	Policy and Procedure
Revised:	4/2014 (replaces 6/2009)
Applies To:	Rush Investigators/Study Staff, Rush IRB Members and IRB Administrative Staff
Policy	**To encourage the discovery and use of devices intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect or are manifested in fewer than 4,000 individuals in the United States per year, yet remain consistent with the protection of the public health and safety and with ethical standards. Rush clinicians may use a Humanitarian Use Device (HUD) provided they follow state and federal regulations and Rush policies.**
Definitions:	A **Humanitarian Device Exemption (HDE)** is an approved application from the FDA that is similar to a premarket approval (PMA) application, but exempt from the effectiveness requirements of sections 514 and 515 of the act. FDA approval of the HDE authorizes a sponsor to market their Humanitarian Use Device (HUD) device. A **Humanitarian Use Device (HUD)** is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. The device sponsor must complete a Humanitarian Device Exemption (HDE) application to the FDA containing sufficient information to determine that the device does not present an unreasonable risk of illness or injury and the probable benefit from its use justifies the potential risk. There is no requirement to provide neither evidence of effectiveness nor the results of clinical investigations. Once the device obtains HDE approval, an investigator may request use of the device at an institution that has a local IRB.

Procedure: The sponsor of the device must apply to the FDA for Humanitarian Use Designation and then approval for the HDE.

A request for IRB review of an HUD is by an investigator is the only situation where federal regulations require IRB review of an activity that is not research.

The investigator must apply for IRB approval prior to the use of the device.

The investigator needs to document, or upload a letter or document from the sponsor that includes the following:

1. The generic and trade name of the device.
2. The FDA HDE number (a six digit number preceded by the letter H).
3. The date of HUD designation.
4. Indications for use of the device.
5. A description of the device.
6. Contraindications, warnings and precautions for use of the device.
7. Adverse effects of the device on the health of the patient.
8. Alternative practices and procedures.
9. Marketing history.
10. Summary of studies using the device.
11. A statement from the Rush investigator that the device is not being used in research that will be used for premarket approval application.

An informed treatment consent should be included that clearly states that the device has not been approved by the FDA as an effective treatment for this disease.

The IRB must conduct both initial and continuing review of the HUD at least annually.

The IRB does not have to review each use of the HUD, but may specify circumstances of approval (for example, the number of patients allowed to receive the HUD or circumstances of use).

Reference 21 CFR 814 Subpart H

Last Reviewed: 5/13/2014