

**Sent:** Wednesday, August 13, 2008 11:59 AM  
**To:** UKORI-IRB-L@lsv.uky.edu  
**Subject:** Humanitarian Use Device (HUD)

Announcement/Reminder from the [Office of Research Integrity](#)

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. To obtain approval for an HUD, a humanitarian device exemption (HDE) application is submitted to FDA (see FDA guidance links below). When an HUD is used in clinical practice, the federal regulations [21 CFR 814.124\(a\)](#) require IRB review and approval before a HUD is used. The HUD may only be used in facilities that have established a local institutional review board (IRB) to supervise clinical testing of devices and after an IRB has approved the use of the device to treat or diagnose the specific disease.

The healthcare provider is responsible for obtaining IRB approval before he or she uses a HUD to treat or diagnose patients.

[Medical IRB Full Review forms](#) are available to download on the Office of Research Integrity website. Form P [Use of Investigational New Device Form](#) should be included in the IRB application. Contact the [Office of Research Integrity](#) at 257-9428 with questions.

FDA Device Advice – [Humanitarian Device Exemption](#)  
FDA Guidance for Industry and FDA – [Humanitarian Device Exemption \(HDE\) Regulation Questions and Answers](#)

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