Humanitarian Use Device (HUD): Clinical Care Under IRB Review

A HUD is a device intended to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the US per year. Unlike other devices that must demonstrate both safety and effectiveness, a HUD may gain FDA approval when sufficient data exists to show that probable benefits to health outweigh potential risks. However, unlike other marketed devices, clinical use of HUDs carry unique restrictions and requirements, one of which is prospective IRB review and oversight. While this process is familiar to research investigators, clinicians may be unaware of FDA requirements or even not be familiar with the IRB. The following reminders and resources are provided to help health care providers recognize a HUD and follow established UK standard operating procedures (SOP) that are in place to allow routine and emergent use of a HUD for clinical care.

Reminders:
- The healthcare provider must obtain IRB approval before use of the HUD.
- To ensure accountability and traceability and prevent use outside of designated sponsor or IRB restrictions or limitations, the provider should clearly label and store the HUD including appropriate contact information.
- Depending on the planned use, the IRB may approve a range of consent documents from a simple modified operating permit with an IRB stamp to a standard informed consent form. Patients should be consented using the IRB approved form and process. The FDA HDE website provides patient information packets for use in preparing or supplementing the informed consent document.
- HUD regulatory requirements vary depending on whether the situation involves clinical use of a HUD according to approved labeling, emergency or compassionate use, or investigational use. Physicians should be cognizant that FDA has made a determination of safety and probable benefit for use of the HUD only within its approved indication(s). If a HUD is used outside its approved indication(s) in an emergency or compassionate situation, the UK IRB applies the same procedures that govern emergency use of an unapproved device. The UK IRB HUD SOP outlines the various use requirements.
- Serious adverse events and deaths that a HUD device has or may have caused or contributed to must be reported to the Humanitarian Device Exemption (HDE) holder/FDA and the UK IRB (Medical Device Reporting 21 CFR 803).

Resources:
- UK IRB HUD SOP
- UK IRB Summary Humanitarian Use Devices
- FDA 2010 Humanitarian Device Exemption (HDE) Regulation: Questions and Answers
- FDA Presentation IRB and HUD by Fabienne Santel, MD

Hitting a Milestone
For the first time ORI logged in more than 1000 new protocol submissions in 2011. UK research investigators are hard at work!!

In addition the IRB performed more than 13,000 reviews and maintained oversight of approximately 3000 active human research protocols.

VAMC IRB CONTACTS

Effective December 31, 2011, research studies that include VA patients, VA resources and/or VA funding must be reviewed and approved by the Veterans Affairs Medical Center (VAMC) IRB. For information on IRB review at the VA, contact IRB Coordinator Michele Jackson at 233-4511, extension 4282 or Michele.jackson2@va.gov. Resources are available at the following link—www.lexington.va.gov/healthprofessionals/research/index.asp

If you plan to conduct research at the VAMC but UK resources (faculty, staff, funding, etc.) will be utilized you should contact Beverly Raisor at UK ORI at 257-9819 or beverly. raisor@uky.edu for assistance on how to proceed.
More Secure Survey Software
Representatives from the UK Center for Clinical and Translational Science (CCTS) presented information on REDCap at a recent IRB In-Service program. REDCap (Research Electronic Data Capture) is a secure, web-based application designed exclusively to support data capture for research studies. UK faculty, staff, and students are able to use REDCap at no cost. Data is maintained on a secure web server located behind a firewall housed within UK’s network. Data is encrypted when transmitted to the REDCap server. Data may also be exported as de-identified and usage rights may be limited as appropriate.

Details and features are outlined on the CCTS REDCap website at http://ccts.uky.edu/BIC/InformaticsTools.aspx

UK Biomedical Informatics provides various types of support and training for REDCap users. Learn more about REDCap via web videos available at www.project-redcap.org/

Time to Renew?
If you last obtained Human Subject Protection training in 2009 you have or will soon approach the three year renewal time. If you recertify using the CITI web based training, the home page provides a link in the event that you forgot your login information. If you choose, you can also merge multiple accounts, update your profile or obtain technical assistance at the CITI Knowledge base support center.

Contact Belinda Smith (Belinda.smith@uky.edu or Selena Smith (sssmith@uky.edu) with questions regarding CITI or other HSP renewal options.

Upcoming Events—2012

Office of Research Integrity: IRB Lessons & Sessions

Could Your Research Qualify for Exempt Review?
ADA SUE SELWITZ, M.A.
Director, Office of Research Integrity Adjunct Associate Professor, Behavioral Sciences
Director, Regulatory Support and Research Ethics, CCTS

WEDNESDAY, FEBRUARY 8, 2012, 12:00 PM TO 1:30 PM
RM. 158 TAYLOR EDUCATION BUILDING AUDITORIUM
RSVP to Belinda Smith at 323-2446 or belinda.smith@uky.edu

NOTE: Food WILL NOT be provided for this seminar however it is allowed in the auditorium if you choose to bring your lunch. Beverages will be provided.

SAVE THE DATE for the 2012 Human Research Protection Regional Conference which will be held Friday, October 5, 2012 at the Northern Kentucky Convention Center.