UK IRB Confidentiality and Data Security Guidelines for Electronic Data

Ensuring basic protection provisions for electronic research data is a challenge for investigators given rapidly advancing technology, the variety of storage and transmission devices, and diverse university systems.

A working group made up of IRB members, ORI staff, and research investigators has developed a guidance document including an investigator checklist for electronic data protections in research.

Campus research faculty, students, and others interested in this topic are invited to the education session below where leaders from ORI and UK Information Technology will provide practical advice for implementation. An equivalent presentation was conducted at the UK Medical Center campus in June.

The guidance document and checklist are available online at http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#Electronic.

Office of Research Integrity
IRB Sessions and Lessons
Topical human subject research seminars

New Institutional Review Board (IRB) Guidance: Confidentiality & Data Security Guidelines for Electronic Data

Wednesday, August 31, 2011
Noon—1:00 PM
Room 102 Mining & Minerals Building

speakers:
♦ Helene Lake-Bullock Ph.D., J.D.,
  Research Compliance Officer, Office of Research Integrity
♦ Michael Carr, UK Information Technology (IT),
  Chief Information Security Officer

RSVP to ORI at 859-257-0582 or samo222@uky.edu

Questions or comments? E-mail us at belinda.smith@uky.edu. To remove your name from our mailing list, please click here.
J:\ORI Listserv announcements\2011
13 Annual Human Subject Protection Regional Conference
Thursday, September 15, 2011
9:00 am – 4:30 pm
Northern Kentucky Convention Center

Don’t miss the opportunity to hear national level speakers present on current issues and topics of interest to all members of the research community, including:

- THE U.S. STD INOCULATION STUDIES IN GUATEMALA: DID THE U.S. HAVE TO APOLOGIZE?
- INTERNET RESEARCH
- U.S. HEALTHCARE REFORM AND HUMAN SUBJECT PROTECTION: OPPORTUNITIES AND CHALLENGE
- WHAT’S THE POINT OF THE COMMON RULE?
- ENGAGING AND RETAINING COMMUNITY AND MINORITY POPULATIONS IN CLINICAL RESEARCH: STRATEGIES AND OPPORTUNITIES
- THE MIS-MEASURE OF IRBS

BROCHURES/REGISTRATION information available at http://www.research.uky.edu/ori/upcoming_events.htm
Registration fee includes conference materials, CME and CEU credit, box lunch and refreshments.
★ Attendance at the regional conference satisfies the U.K. human subject protection continuing education requirement.

Updated investigational drug and device IRB forms

With input from several clinical investigators and medical IRB members, the ORI has updated their Form P (investigational device) and Form O (investigational drug), combining content from previous form O and O-1. Based on recent guidance from the Food and Drug Administration (FDA), the forms were redesigned to better capture categories of drug and device studies including those subject to, and those exempt from, investigational new drug (IND) and investigational device exemption (IDE) requirements. The forms allow the IRB to assess the risk/benefit ratio, confirm that the drug has appropriate regulatory approvals and ensure that procedures for receiving, storing, dispensing, and accountability meet regulatory requirements and are appropriate for human subject protections.

Completion of the forms would be applicable for the following types of studies:
- Drugs – Any protocol involving any use of a drug in a human other than the use of an approved drug in the course of medical practice.
- Devices – Any protocol evaluating the safety or effectiveness of a device in subjects, controls, or their specimens or protocol involving a Humanitarian Use Device (HUD).