

IRB Review

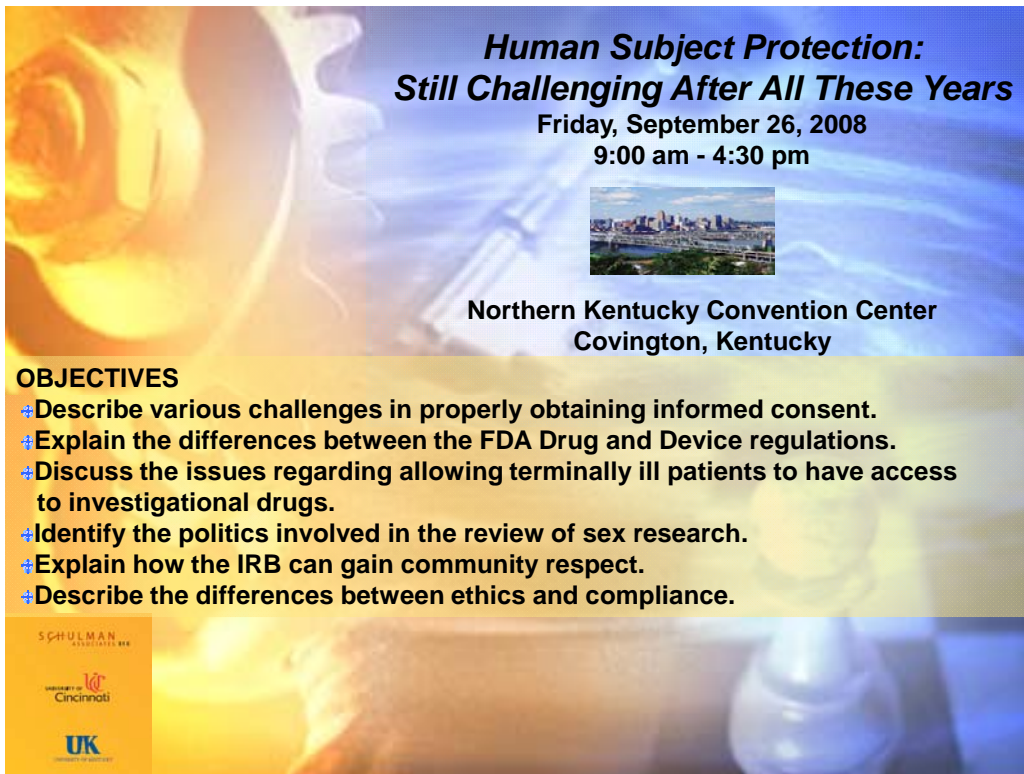
A compilation of 'need to know' updates for UK IRB Members
investigators & others involved in human subject research

Volume #2 July 28, 2008

UK UNIVERSITY OF KENTUCKY
Office of Research Integrity

UK Regional Human Research Protection Conference

This year's regional conference truly offers a topic of interest to all involved in human subject research and in addition, attendance will satisfy the UK mandatory human research protection [continuing education requirement](#). **Register early and save!** A limited number of reduced cost registrations are available. Brochures and registrations specific for UK researchers and staff as well as UK IRB members are located on the ORI Upcoming Events Website at www.research.uky.edu/ori/upcoming_events.htm or call 323-2446 to request a hardcopy brochure.



**Human Subject Protection:
Still Challenging After All These Years**
Friday, September 26, 2008
9:00 am - 4:30 pm

Northern Kentucky Convention Center
Covington, Kentucky

OBJECTIVES

- ✦ Describe various challenges in properly obtaining informed consent.
- ✦ Explain the differences between the FDA Drug and Device regulations.
- ✦ Discuss the issues regarding allowing terminally ill patients to have access to investigational drugs.
- ✦ Identify the politics involved in the review of sex research.
- ✦ Explain how the IRB can gain community respect.
- ✦ Describe the differences between ethics and compliance.

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UK

Unanticipated Problem/Adverse Events (UP/AE) involving prisoners

If an UP/AE involves a prisoner, regulations require that the IRB prisoner representative evaluate how an UP/AE may affect the prisoner subject's safety and welfare and determines the appropriateness for continued participation in the research.

To aid in this process, additions have been made to the [UK Internal Prompt Reporting Form](#). Specifically, investigators are asked to indicate if the prisoner was a patient at the UK hospital/medical center when the UP/AE occurred. If the prisoner was treated at a facility other than UK, the investigator is asked to describe his/her involvement in the prisoner's care during the event.



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