IRB Meeting
Schedule Update

PLEASE NOTE, the Nonmedical IRB meeting scheduled on Friday, November 13, 2009 has been rescheduled for Friday, November 20, 2009.

The rescheduled meeting will take place in room 104 Gillis Building.

Thank you for your patience with this adjustment. The schedule change will allow some IRB board members and staff to attend a national training conference on advancing ethical research.

A complete updated schedule of meeting dates and submission deadlines is available at http://www.research.uky.edu/ori/human/NonMedIRB_MtgDates.pdf. For additional information, please contact the Office of Research Integrity at 859-257-1639.

REVISED IRB FORM W for RESEARCH INVOLVING CHILDREN

An updated IRB Form W is available in the applicable online IRB application linked through the ORI forms page at www.research.uky.edu/ori/human/HumanResearchForms.htm

The updated form provides more checkbox options to describe how parental permission will be obtained and how assent will be solicited and/or justification for waiving assent for all, none, or a sub-group of children.

If you missed either of the seminars presented by Bruce Gordon, MD, FAAP on Children as Research Subjects and would like to view a taped telecast, please contact Belinda Smith at 323-2446 for instructions on accessing the video.

Documentation of IRB Registration

The Office of Human Research Protection (OHRP) and Food and Drug Administration (FDA) have issued a joint requirement for Institutional Review Boards (IRB) to register in the OHRP Electronic Submission System.

The registration provides the regulatory agencies with an accurate and current listing of IRBs involved with review of FDA regulated studies and allows more up-to-date communication exchange.

If your sponsor requests documentation of the UK IRB’s compliance with this requirement, contact the Office of Research Integrity at 257-9428 with your protocol number and your request will be forwarded to the appropriate administrator who will provide you with a signed letter of compliance.
Responsible Conduct in Research Training available via CITI

The National Science Foundation (NSF) is implementing training in Responsible Conduct of Research as an integral part of preparation and development of current and future scientists. RCR training is also a requirement for various other funding opportunities.

The UK curriculum on the Collaborative IRB Training Initiative (CITI) web-based program offers RCR training. If you need to complete RCR training and are new to CITI, you may create your own registration and affiliate with the University of Kentucky. If you have used CITI in the past, simply log on and update your learner group to add a course. Once registered and logged in, choose the applicable RCR based on your field of research. The following options are available on the UK curriculum:

- Biomedical RCR
- Social and Behavioral RCR
- Physical Science RCR
- Humanities RCR
- Administrators RCR
- Engineers RCR

Once complete, you may print a certificate of completion as documentation for your funding agency.

Is your research conduct HIPAA compliant?

If your college or department is covered by the Health Insurance Portability and Accountability Act (HIPAA) then your human subject research falls under the HIPAA Privacy Regulation and therefore should be conducted in compliance with HIPAA requirements. The UK IRB acts as the privacy board for human subject research.

There are several options available for investigators to propose in the IRB submission to assure HIPAA compliance. Depending on the nature of the research and how you plan to use or disclose the Protected Health Information (PHI) will affect which options are most applicable to your protocol.

Even if you are not part of a college or department covered by HIPAA, you may need to employ one of the options in order to access PHI from the HIPAA covered entity. It is important that you understand that you could face criminal and/or civil liabilities for non-compliance.

HIPAA HELP

- ORI HIPAA in Human Research Website
- ORI Research Privacy Specialist Joe Brown, (859)-257-9428
- UK Healthcare Privacy Officer, Brett Short, (859) 323-9817