Nonmedical IRB Meeting
Schedule Update

PLEASE NOTE, the Nonmedical IRB meeting scheduled on Friday, June 25, 2010 has been rescheduled for Friday, June 18, 2010.

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

Thank you for your patience with this adjustment. The new deadline for nonmedical IRB submissions for inclusion in this meeting is now June 4th.

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.

Informed Consent Process Quick Quiz

True or False
Research participants should never have to be re-consented if the initial consent process was thorough.

Answer
False. While this might be the case for some studies, informed consent requires that research participants be informed of significant new findings. This is particularly true if the information might affect his/her willingness to continue participation. The need to re-consent may also be participant driven (i.e. due to fluctuations in consent capacity).

Changes in research procedures, the informed consent process, and/or the consent/assent document cannot be initiated by the investigator without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participant.

To request changes to your current IRB approved protocol, submit two copies of the completed Modification Request Form, and materials relating to your modification request to ORI. If the modification involves new information or findings, describe to the IRB how you propose to inform current and future participants regarding the new information. The IRB must review and approve your plan as well as any modified consent documents. Typically when an informed consent document is modified, an investigator will re-consent all active research participants.

The following are examples which may require consent document modifications and/or re-consent of active participants:

♦ protocol modifications or altered research procedures;
♦ unanticipated problems involving risks to participants;
♦ any new information affects the risk /benefit ratio;
♦ a minor subject reaches adulthood (18 years old);
♦ new alternative treatments become readily available;
♦ subjects were consented by individuals not approved as study personnel; or
♦ any other changes as required by the IRB or sponsoring agency.
NIH Requirements for Instruction in Responsible Conduct in Research


In order to assist faculty with this requirement, the Office of Research Integrity (ORI) is offering a presentation on NIH Requirements for RCR instruction for initial submission and progress reports.

ORI Director Ada Sue Selwitz will provide guidance on the NIH RCR expectations in developing a plan for initial grant preparation as well as the requirements for documentation of instruction and disclosure in progress reports.

**Suggested audience:**

Faculty, staff, or administrators involved in the submission of new or renewal NIH training grants, individual fellowship awards, career development awards, research education grants and other programs with a training component.

Faculty with funded NIH projects requiring RCR instruction.

**Date:** Monday, July 26, 2010  
**Time:** 12:00 pm – 1:15 pm  
**Location:** Wethington Building Auditorium 014  
**Refreshments:** Drinks & Cookies provided. Feel free to bring your lunch.  
**RSVP:** Please respond to Stephanie Morris at 257-0582 or [samo222@uky.edu](mailto:samo222@uky.edu)