Preparing for the AAHRPP Reaccreditation
Site Visit- February 22—24, 2010

ORI is pleased to announce that the reaccreditation application for the UK Human Research Protection Program (HRPP) was submitted to and received by the Association for Accreditation of Human Research Protection Program (AAHRPP). At this point, we are preparing for the AAHRPP site visit scheduled to occur February 22-24, 2010.

Site Visit Interviews

During the site visit, AAHRPP will conduct interviews with IRB members, ORI staff, research investigators, research coordinators, Department Chairs, and possibly center directors. AAHRPP selects the individuals to be interviewed and will notify us regarding their selections just prior to the visit date.

Site Visit Preparation & Training

A series of training sessions and resource materials will be provided for all involved in human research protection. Also, look for training snapshots including sample questions and brief case studies which we will frequently send as general list serve announcements.

One of the first general training opportunities for research personnel will be in conjunction with the Clinical Research Development and Operations Center (CRDOC) January Clinical Research Update. Mark your calendar now and watch for the registration information from CRDOC for:

CRDOC Clinical Research Update
January 14, 2010 @ Noon
Topic: Hot Topics in Human Research Protection

AAHRPP Reaccreditation

Rule-of-Thumb #1 for an AAHRPP Interview: Know your resources!

AAHRPP interviewers will want to see that you are familiar with the information and services available to you, and that you know where to find help if you have questions.

The IRB Survival Handbook is a great "catch-all" resource for UK IRB/ORI policies, procedures, forms/applications, and information on special areas of research and/or populations requiring additional protections. Arranged by A-Z topic index, the IRB Survival Handbook is available on the ORI website at:

Rule-of-Thumb #2 for an AAHRPP Interview: Keeping up-to-date!

In addition to the IRB Review Newsletter, keep informed with the ORI What's New? Website. Available on the ORI website at: http://www.research.uky.edu/ori/WhatsNew2009.htm, this page offers recent news, regulatory tips, updates, and serves as the archive for the newsletter and list serve announcements.
**Study personnel ... not a likely “impartial” witness**

An informed consent witness may be required in certain situations (i.e. use of the short form oral consent presentation).

In these situations, who is best suited to serve as a witness? Best practice and ICH Good Clinical Practice (GCP) guidelines, specify that a witness should be “impartial”. ICH GCP defines an impartial witness as a person who is independent of the trial and who would not be unfairly influenced by the research personnel. By these standards, an investigator or study personnel would not likely be considered an impartial witness.

**HOLIDAY HOURS**

The Office of Sponsored Projects Administration (257-9420), the Proposal Development Office (257-2861), the Office of Research Integrity–IRB & IACUC– (257-9428), and the Survey Research Center (257-4684) will be closed Friday, 12/25/09 through Friday, 1/1/10 and will reopen on Monday, 1/4/10. If you anticipate a need for services provided by any of these offices during this time, please call the appropriate office(s) before 12/18/09 so that we may assist you before the holiday.

If you anticipate a need for services provided by any of these offices during this time, please call the appropriate office(s) before December 18 so that we may assist you before the holiday.

**Thanks and from all of us, we wish you a safe and happy holiday season!**

**Law and Order ... when conducting research outside of Kentucky**

Certain state laws may have impact on research conduct. Such situations include enrolling emancipated minors in research; determining the age of majority for a state; or identifying state laws regarding who may serve as a legally authorized representative.

In these situations, the investigator identifies the applicable state law(s) and contacts UK legal counsel for review and determination prior to approval by the IRB. If the PI is unable to identify applicable state law(s), the investigator should contact UK legal counsel at (859) 257-2936 for assistance.

**New ethics resource website in development:**