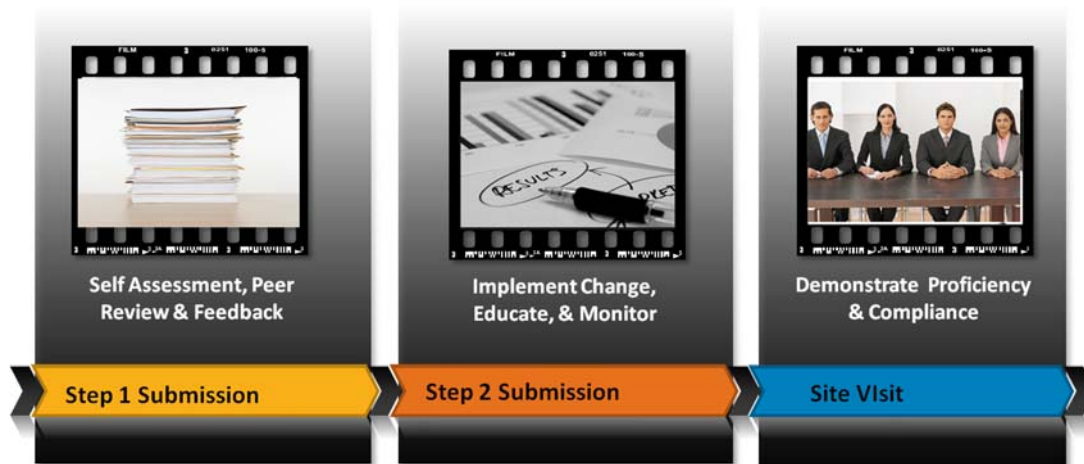


**Association for the Accreditation of
Human Research Protection Programs (AAHRPP)
Initiation of the Reaccreditation Process**

The University of Kentucky (UK) first achieved full AAHRPP accreditation in 2007. Maintaining this status through a rigorous reaccreditation process, occurring every five years, demonstrates UK's commitment to continuous improvement and the highest ethical standards in conducting human research. AAHRPP encourages effective, efficient, and innovative systems of protection for research participants. The reaccreditation process involves self-assessment, peer-review, modifications, education, monitoring, site visit interviews, reporting, and other activities culminating with the final Council determination in June 2015.



UK's Step 1 application, submitted earlier this month, was based on the AAHRPP Evaluation Instrument consisting of 3 domains, 15 standards, and 60 elements:

Domain I: Organization

8 Standards
24 Elements

Domain II: Institutional Review Board

5 Standards
25 Elements

Domain III: Researchers and Research Staff

2 Standards
11 Elements



UK's Human Research Protection Program includes all constituents involved in the conduct, review, and support of human research including institutional officials, ORI, the IRBs, and research investigators, students, and staff. **AAHRPP will select and interview individuals from each group at the site visit.** To help prepare, ORI is preparing resource materials and will offer education opportunities in advance of the site visit. Stay tuned for updates on the ongoing reaccreditation process.

IRB Member Recruitment

Interested in the ethical conduct of human research? Want to know more about the IRB process? Then become an IRB member!

The Office of the Vice President for Research and ORI appreciate volunteers and are always on the lookout for interested and committed members. Non-tenure track faculty, or tenure track Associate Professors or higher are eligible for consideration as an regular IRB member or IRB alternate member. For additional details, see the [IRB Membership](#) web page and the section on ["Nuts & Bolts" of being an IRB member](#), or contact [Judi Kuhl](#) for more information (859-257-9764).



Additional Safeguards for Children Enrolled in FDA-Regulated Clinical Investigations

When the Food and Drug Administration (FDA) published the final Subpart D regulations, they provided an [updated interpretation](#) of the requirements regarding placebo-controlled studies. The FDA concluded that it does not consider the administration of a placebo to offer a prospect of direct benefit to pediatric subjects.

For research with children, the IRB must find a study meets one of four risk-benefit categories before it may be approved. The safeguards required for each category are proportional to the risk-benefit ratio. For instance, if the research is considered minimal risk or offers potential direct benefit, the IRB may conclude that one parent is adequate to provide permission. However, the regulations require provisions to seek permission of both parents/guardians if the research is greater than minimal risk and does not offer the prospect of direct benefit.

For FDA-regulated research, a placebo control arm would not be approvable under Category 2: which involves *greater than minimal risk but presents a prospect of direct benefit to the individual subject*.

↪ See [UK IRB Form W](#) for detailed Subpart D Category descriptions.

Save the Date!

Human Subject Protection:
Friday, September 12, 2014
Northern Kentucky Convention Center
Covington, KY

Don't Stop Believin'

Conference Brochure Coming Soon!

SCHULMAN ASSOCIATES IRB

UNIVERSITY OF Cincinnati

UK UNIVERSITY OF KENTUCKY

Cincinnati Children's