

Association for the Accreditation of Human Research Protection Programs (AAHRPP)

The UK Human Research Protection Program (HRPP) is a step closer to reaccreditation. On January 23rd the AAHRPP site review team held a final close-out session to share preliminary observations about the University of Kentucky (UK) Human Research Protection Program (HRPP). The three day site visit, conducted under the direction of Office of Research Integrity (ORI) Director Ada Sue Selwitz and AAHRPP Quality Improvement Coordinator Tammi Gausepohl, involved record review and more than 70 interviews with various constituents of UK's HRPP.

It was apparent from the site team's concluding comments that UK has an exemplary program committed to protecting human research subjects. The AAHRPP Site Visit Report highlighted strengths of the University of Kentucky's HRPP.

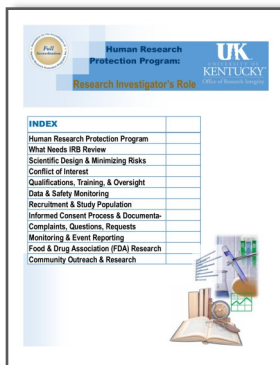
Of the three domains and sixty elements in the accreditation standards, the site review team had only one minor observation to which the ORI has responded.

"There is a strong and long-standing culture of respect and shared responsibility within the University research community."

AAHRPP Site Visit Team

AAHRPP will make a final determination at the June meeting of the Council on Accreditation.

The quality of our HRPP and success of this site visit can be attributed to the dedication to quality research and protection of our research participants exhibited by the UK research community on a daily basis.



This commitment was reflected by the number of researchers and research staff that attended ORI education programs on the researcher's role in meeting the HRPP standards.

If you were unable to attend one of the programs, but would like a copy of the Research Investigator's Training Packet, contact Belinda Smith at Belinda.smith@uky.edu or 859-323-2446.

To keep up to date regarding IRB issues and changes impacting clinical research, Ada Sue Selwitz, M.A., ORI Director and Co-Director of the Center for Clinical and Translational Sciences (CCTS) Regulatory Support and Research Ethics will present a **Human Research Protection update** at the April [CCTS Clinical Research Update program](#).

NIH revised definition of “Clinical Trial”

Effective January 25, 2015, the National Institutes of Health (NIH) revised its definition of “clinical trial” in order to make a more clear distinction between

clinical research and clinical trials. The NIH announcement indicated that the revised definition should help investigators ensure they are meeting additional obligations.



For example, NIH policy requires submission and approval of a data and safety monitoring plan (DSMP) for NIH funded clinical trials. In addition to NIH clinical trials, UK IRB policy requires a DSMP for greater than minimal risk research and FDA regulated clinical trials.

The ORI website provides resources and links to guidance for developing a DSMP that is commensurate with the research protocol—www.research.uky.edu/ori/QIP/DSMP.htm.

Look for the revised definition to appear in relevant extramural and intramural NIH policies, guidance, and instructional materials.

Additional information, question & answers, case studies, and a clinical trial decision tree is available at <http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials>.

NIH CLINICAL TRIAL DEFINITION

A research study in which one or more human subjects are prospectively assigned¹ to one or more interventions² (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.³

¹The term “prospectively assigned” refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

²An intervention is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

³Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.



To learn about newly released guidance documents, draft or final regulatory changes from NIH and other federal agencies, see the UK ORI document **Select Changes at the Federal Level Impacting IRBs** at

www.research.uky.edu/ori/human/86-ORI-Summary-of-Guidance-Documents-Resources.pdf