IRB Review A compilation of information, announcements, & updates for UK Institutional Review Board (IRB) members, investigators, and others involved in human subject research.

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New National Research Participant Website

The federal Office for Human Research Protections (OHRP) has launched a new public outreach website designed to help potential volunteers better understand research participation. The website includes a series of short videos, a printable list of questions, and links to additional resources.

Visit "About Research Participation" at www.hhs.gov/about-research-participation.

Participating in Research Video Series:

Part 1: What is Research?

This video provides basic information about scientific research, the goals of research, and discusses how clinical research differs from medical care. (3:00)

Part 2: Clinical Trials

This video discusses types of human research with a focus on clinical trials, and explains common terms that potential participants should know. (4:20)

Part 3: Questions to Ask

This video emphasizes that participating in research is voluntary and encourages potential participants to ask questions and get the information they need to decide whether to participate. (4:44)

Pre-screening Potential Subjects Using REDCap

Pre-screening of potential subjects to determine initial eligibility and interest in a study is considered part of the recruitment process and therefore requires IRB review. Using the REDCap survey application to administer a pre-screening questionnaire can be efficient for the investigator and convenient for potential participants.

The Center for Clinical and Translational Science (CCTS), Office for Research Integrity, and IRB have developed guidance and sample language that takes individual privacy, information confidentiality, and possible future contact into consideration.

The guidance is available to investigators on the CCTS Participant Recruitment webpage http://www.ccts.uky.edu/ccts/participant-recruitmentmarketing.

Email CCTS@UKY.EDU by 1/13/17 to Register

Center for Clinical and Translational Science **CCTS Clinical Research Update**

"Human Subject Protection Update: What the Future Holds"

DATE
Tuesday,
January 17, 2017

LOCATION
HG 611
(6th Floor Auditorium in Pavilion H)

TIME
Presentation:
12:30 to 1:30 p.m.
(Lunch @12:00 p.m.)

Speakers:

. **Helene Lake-Bullock, PhD, JD**	ORI Interim Director
. **Judi Kuhl, BS, CIP**	ORI E-IRB System Manager
. **Amy Kolasa, MS, CIP**	ORI Reliance Officer
. **Belinda Smith, MS, CCRC**	ORI Education Specialist

Upon completion of the program, attendees will be able to:

. Describe forthcoming regulatory changes, ongoing IRB initiatives, and evolving operational policies impacting human and clinical research.

REGISTRATION REQUIRED

To reserve your place, please email CCTS at CCTS@UKY.EDU by ***Friday, January 13, 2017.***
If you require special physical arrangements to attend this program, please call 323-8545.
Food provided by the CCTS.

Clinical Research News

Increase in One-Time Fee to Industry-Sponsors of Clinical Trials

Budgets for commercial, industry-funded clinical trial projects should include a one-time fee of $3,000, listed as "IRB Review Fee". The recent increase in the one-time fee for initial IRB review was implemented as a result of increased administrative and procedural compliance requirements. The current rate remains in line with national standards. For additional information see the IRB FAQ at |www.research.uky.edu/ori/humanFAQ&answers.htm#fee