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

Office of Research Integrity

Updated ORI Website

The ORI Website has a new format and design consistent with the Office of the Vice President for Research's website transformation initiative.

Information is organized by category and by user (researcher, IRB member, participant). As you begin to navigate the updated website, you will find new additions, such as the "Getting Started" webpage, as well as old favorites like the Survival Handbook A-Z guidance, E-IRB page, and Training & Education Resources. The Human Subject FAQs page includes answers to general questions as well as FAQs for special topics such as E-IRB, Community-Engaged Research, Informed Consent, and Continuing Review. Stay informed with the quick link to news and announcements or Subscribe to the ORI listserv to receive email announcements.

For help locating a document or resource on the updated website, contact Jen Hill at jen.hill@uky.edu or 859-257-2978. Now that the new site is launched, we appreciate your patience as we update web links in existing ORI documents.

CITI "Revised Common Rule" Course as an option for Human Subject Protection (HSP) Refresher Training

The current effective date for the New Common Rule IRB Regulation is January 21, 2019. ORI has subscribed to a *Revised Common Rule Course* on CITI which if completed, will count towards the 3-year HSP refresher requirement.

The course is available under the main IRB menu, as well as under the HSP Refresher Training menu as Group 3. Add the course any time by clicking Add a Course under the "My Learner Tools" box on your CITI main menu.

New Guidance for Researchers and IRB Members

The following documents provide ethical, regulatory, and practical considerations for researchers developing human specimen banks or data registries for use and sharing in future secondary research.

The guides provide information on what to include in the IRB submission. For instance, investigators should include a justification for developing a new bank/ registry which addresses why information or specimens cannot be obtained from existing established and IRB approved banks, repositories, data trusts, registries, or commercial vendors.

The documents also outline when additional IRB review would and would not be required for secondary research conducted by recipient researchers.

- Research Biospecimen Bank Guidance
- Research Registry Guidance

These guidance documents provide researchers and IRB members with ethical and regulatory considerations for protocols that involve digital data. Each offers a series of questions that highlight potential human subject issues for research using digital data or developing digital data products.

- IRB Review and Digital Data Considerations
- Considerations for Protocol Design Concerning Digital Data

Consent Contact for Participants in Greater than Minimal Risk Research

All informed consent documents should include the researcher's contact information for general inquiries. For greater than minimal risk research, investigators need to add contact information for participants to report injury, illness, or any other problem believed to be resulting from study participation.

For greater than minimal risks research, add at least one of the following as a contact for participants to use in case of illness or injury during their participation in the study:

- a dedicated pager number;
- a dedicated cell phone number;
- other reliable 24-hour contact option at your discretion; and
- in addition to one or more of the above, as deemed necessary, referral to 911 for an emergency.

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Human Subject Protection: Roll With It

PROGRAM SCHEDULE

Date & Location
Thursday, October 4, 2018 7:30 AM - 5:00 PM
Northern Kentucky Convention Center, Covington, KY

Overview
The purpose of this program is to provide information to researchers, IRB members/administrators, clinical investigators, research staff, research sponsors and CROs, government regulators, and members of the research community on current issues regarding the protection of human subjects.

Attendance meets the UK 3-year HSP training requirement.

Registration

An **early-registration discounted rate of $125*** is available to employees of the following co-sponsors: Advarra, NKU, UC, UK, and Cincinnati Children's. To receive this rate, select the applicable employee rate during registration and register using your UK email address.
This early registration discount ends August 31, 2018.
All payments are non-refundable.

*Includes material, CME and CEU credits, meals, and refreshments.