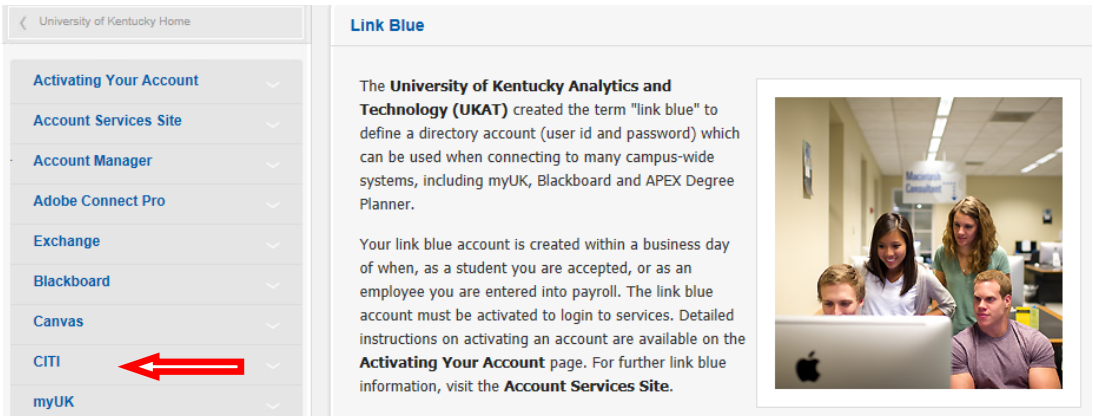
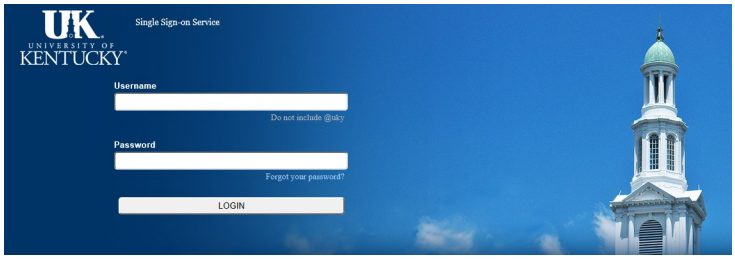
IRB Review
A compilation of 'need to know' updates for UK Institutional Review Board (IRB) members, investigators and others involved in human subject research
UK UNIVERSITY OF KENTUCKY Office of Research Integrity
September 2015, page 1 of 4

NEW UK PORTAL TO ACCESS CITI ONLINE RESEARCH TRAINING WEBSITE

The University of Kentucky is transitioning to Single Sign On (SSO) access to the Collaborative Institutional Training Initiative (CITI) website through the UK portal using UK Link Blue accounts. Link Blue is the directory account assigned to all UK employees and students. It is used to connect to many campus-wide systems including myUK, Exchange email, Canvas, etc.



The transition to the UK Portal will improve the traceability of training records and will allow UK users access to CITI without having to remember an additional username and password.



All Current and New CITI Users should follow the instructions below to access training courses on CITI:

CURRENT CITI USER INSTRUCTIONS—provides steps for a current user to link an existing CITI account with the UK Link Blue account.
NEW CITI USER INSTRUCTIONS—provides steps for **UK employees or UK students** to create a CITI account.
NON-UK PERSONNEL INSTRUCTONS—provides options for non-UK individuals listed as study personnel on a UK IRB protocol.

IMPORTANT REMINDERS:

⇒ When creating an account on CITI, it is important to use your own Link Blue ID and your own UK email address. **NEVER list someone else's UK email in your CITI account as it can result in mismatched training records.**

⇒ The UK CITI curriculum contains a number of training categories and types of training. If asked to complete training on CITI, be sure to confirm which course by name. Faculty who require completion of a CITI course as part of a class assignment will need to specify the desired course by name (e.g., Human Subject Protection, Responsible Conduct in Research). See the available courses FAQ for a partial list of courses on the UK CITI curriculum.

⇒ For additional information, see the ORI Mandatory Human Subject Training webpage at www.research.uky.edu/ori/human/Human_Research_Mandatory_Education.htm.

CITI Optional Course Offerings

ORI has added some new offerings to the *Optional Courses* Menu on CITI. The following courses join the optional HIPAA and Humanitarian Use Device (HUD) course as additional courses of interest.

New at CITI

- **Good Clinical Practice (GCP) Refresher Course for Clinical Trials Involving Investigational Drugs (ICH focus)** - *This refresher course is meant to reinforce the importance of concepts covered in the basic level GCP for Clinical Trials with Investigational Drugs and Biologics course.*
- **Phase I Research** — *Provides two new modules that identify ways in which researchers and staff involved in phase I pharmaceutical research can apply the necessary safeguards to protect subjects involved in phase I research.*
- **Information Privacy and Security**— *Includes numerous modules ranging from basics of information security to safer social networking.*
- **Students in Research**—*this overview module is suited for use as a class assignment to introduce students to human subject research. However, it does NOT meet the UK IRB human subject training requirements*.

To access an optional course, select "Add a Course or Update Learner Group" on your CITI Main Menu, then select "IRB", "Optional Courses", and "Additional courses of interest".

THERE IS STILL TIME TO REGISTER FOR THIS YEAR'S 17TH ANNUAL HUMAN SUBJECT PROTECTION CONFERENCE

Northern Kentucky Convention Center

- Day 1-
  Human Subject Protection: Takin' Care of Business
  October 1, 2015
  Registration - $150.
  **Take advantage of the discounted rate of $100 for UK Employees. This early registration discount ends August 31st.*
- Day 2 -
  Public Responsibility in Medicine & Research (PRIM&R) Conference
  October 2, 2015
  Registration - $150.

SCHULMAN ASSOCIATES IRB · Cincinnati Children's · University of Cincinnati · UK University of Kentucky · Hospital Medical Center PRIM&R Public Responsibility in Medicine and Research

*Select the appropriate employee rate during registration.

Details & Registration information available at www.research.uky.edu/ori/upcoming_events/UK-HRPP-Regional-Conference-2015.pdf

Resources for Investigator-Initiated Research with Investigational Drugs

Food and Drug Administration (FDA) Resources:

- **FDA Draft Guidance,** "*Investigational New Drug (IND) Applications Prepared and Submitted by Sponsor-Investigators*" *June 18, 2015*

  Provides guidance to sponsor-investigators in preparing and submitting complete IND applications. Describes seeking a cross-reference authorization to reference sections of a commercial sponsor's IND. Outlines required portions of Chemistry, Manufacturing, and Control (CMC) information as well as requests for waiver for complete CMC data when not available. Describes pharmacology and toxicology data needed for various study types. Includes a flow chart of the IND review process and addresses IND amendments, import-export requirements, and sponsor-investigator responsibilities.

- Investigator-Initiated Investigational New Drug (IND) Applications Table
  This table provides links to information for investigators about submitting INDs to FDA. Resources include management and ongoing reporting requirements.

IND Applications for Clinical Investigations (*Product Development*)	IND Application Reporting	IND Application Procedures	IND Applications for Clinical Treatment (*Expanded Access*)
Overview	Overview	Overview	Overview
Contents and Format	Protocol Amendments	Exemptions from IND Requirements	Contents and Format
Regulatory and Administrative Components	Information Amendments	Interactions with FDA	Treatment of a Single Patient in Emergency Setting
Non-clinical Components	Safety Reports	Clinical Hold	Treatment of a Single Patient in Non-emergency Setting
Clinical Components	Annual Reports	Investigator's Responsibilities	Treatment of a Group of Patients

- **FDA Guidance**, *"Investigational New Drug Applications (INDs) — Determining Whether Human Research Studies Can Be Conducted Without an IND"*
  This guidance describes when an IND is required, specific situations in which an IND is not required, and a range of issues that, according to FDA, have been a source of confusion or misperceptions about applying the IND regulations.

ORI Resources:

- *ORI Dietary Supplement Study FAQ*
  Outlines when a dietary supplement study may require an IND application. An IND is generally not required if a study only evaluates the supplement's effect on structure or function of the body. However, if the study investigates a therapeutic effect, such as the ability of a supplement to treat a condition or prevent a disease, an IND may be required.

Notice of Proposed Rulemaking (NPRM) regarding Revisions to the Common Rule to Improve Human Research Protections

The Department of Health and Human Services (DHHS) will be releasing on September 8, 2015 in the Federal Register the long-awaited Notice of Proposed Rulemaking (NPRM). It is currently on public display at https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-21756.pdf.

This is the second iteration of proposed revisions to the Common Rule regulations in order to enhance protections, streamline and improve efficiencies, and better calibrate the level of review to the level of potential risk.

The potential changes will impact all involved in human research. Therefore, HHS is seeking input from all stakeholders (i.e., IRB members, research investigators, the public, etc.).

As ORI begins our review, we would love to hear from any of you who would like to share your initial thoughts. Send any comments to Tammi Gausepohl (tjnewb2@uky.edu).

The following is an excerpt from the initial announcement:

The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies have announced proposed revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was promulgated as a Common Rule in 1991. A Notice of Proposed Rulemaking (NPRM) was put on public display on September 2, 2015 by the Office of the Federal Register. The NPRM seeks comment on proposals to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. It is expected that the NPRM will be published in the Federal Register on September 8, 2015. There are plans to release several webinars that will explain the changes proposed in the NPRM, and a town hall meeting is planned to be held in Washington, D.C. in October.

Some of the major changes being proposed that will better protect research subjects and help build public trust are the rules relating to informed consent. With regard to informed consent in general (such as consent to participating in clinical trials), the rules would be significantly tightened to make sure that the process becomes more meaningful. Consent forms would no longer be able to be unduly long documents, with the most important information often buried and hard to find. They would need to give appropriate details about the research that is most relevant to a person's decision to participate in the study, such as information a reasonable person would want to know, and present that information in a way that highlights the key information. In addition, to assure that these rules do indeed change current practices, there will be a one-time posting requirement for the consent forms for clinical trials, so that anyone drafting a consent form will do so knowing that it will eventually be subject to public scrutiny.

In sum, the proposed modifications described above are designed to continue to uphold the ethical principles upon which the Common Rule is based, as applied to the current social, cultural, and technological environment.