

## E-IRB Submission Pilot Progress

### Exempt Review Submission Going LIVE

### E-IRB Login

*Coming Soon!* Exempt Review applications will be first to switch to submission through the [E-IRB System](#).

Beginning June 21, 2017, the IRB will accept and conduct review of Exempt Protocols solely via E-IRB.

Use your Link Blue account to log in

Link Blue

### Initial Full and Expedited Submissions Continue in Pilot Phase

Initial Full and Initial Expedited review applications will continue in the Pilot Phase until further notice. The Pilot Phase means the system is live for select trained researchers while Research Information Services (RIS) continues to work on other components needed to round out the system.

If you have not received training but would like to participate as an E-IRB pilot researcher, you (and/or your study coordinator, if applicable) will need to participate in at least one of the online “E-IRB basics” trainings being offered via Zoom Screen Share Software.



For a list of available dates and instructions on joining live online trainings go to <http://www.research.uky.edu/ori/human/E-IRB-info.html#Training>.

## FDA & NIH Release Final Electronic Template for Clinical Trial Protocols

The final version of the template provides investigators with a standard protocol format for phase 2 or 3 clinical trials that require a Food and Drug Administration (FDA) Investigational New Drug (IND) or Investigational Device Exemption (IDE) Application.



Clinical e-Protocol Writing Tool Resources

<https://e-protocol.od.nih.gov/#/home>

The tool is designed to be compliant with good clinical practice (GCP) guidelines and provides sample text for the major protocol components. The template may be adapted for other types of human research. In addition to saving time and money, the tool is educational and provides an opportunity for collaborative writing.

## OHRP Research Community Forum in Greater Cincinnati Area

September 6-7, 2017

Northern Kentucky Convention Center

Covington, KY

**\*Registration is now open!\***[Click Here to Register](#)

This **two-day human subject protection forum** consists of an academic conference and an applied workshop relevant for institutional review board (IRB) members, IRB administrators, clinical investigators, research scientists and support staff, sponsors, contract research organizations, government regulators, and members of the research community.

Representatives from the Office for Human Research Protection (OHRP) and other federal agencies as well as research experts will provide perspectives and resources for interpreting and applying human subject protections in an evolving regulatory landscape.

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**Sessions include:***Overview of 2018 Changes to the Common Rule**Improved Exemptions: A Soloist's Perspective**Investigator Responsibilities: Striking a Chord for Compliant Innovation**Learning Health Networks: Harmonic Collaborations of Patients, Clinicians, Researchers and Health Systems**Research Consent Using Telemedicine: Acute Stroke as a Case Study**Ethical Considerations of Working with Drug-Using Patients in Clinical Research**Strategies for Rapid and Robust Ethics Review of Disaster Research**Conducting Human Subjects Research in a Basic Research Department**Why Does It Have to Be So Difficult? Let's Just Measure "Understanding"**Human Subject Protection: Perspectives from a Community-Based Participatory Researcher**From Improvisational Rifts to Symphonic Harmonies: TeleICU Research**Ask the Feds*

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Visit the forum website at [www.cincinnatichildrens.org/research/cincinnati/support/clinical-translational-research/ohrp](http://www.cincinnatichildrens.org/research/cincinnati/support/clinical-translational-research/ohrp) to view the full conference schedule, session descriptions, and register for the event.