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E-IRB System Progress

Roll-Out Schedule Mid-January 2018



The E-IRB Pilot Phase continues to gain steam as more and more Colleges and Departments transition submitting IRB applications in the E-IRB system. The pilot recently began allowing investigators to import core data for existing protocols into the system.

The goal is to launch the E-IRB system campus-wide by mid-January, which coincides with the effective date of the new Federal IRB Regulations, (see page 2). In preparation for the new rule, the Exempt Review Application will be updated mid-December with questions that address criteria for the new Exempt Review Categories.

Mandatory Implementation

We are still welcoming volunteers to participate while we are in the pilot phase, but mandatory use of E-IRB in January will affect how everyone's initial and continuation review IRB materials will be submitted to the Office of Research Integrity (ORI).

Investigators will then be required to submit all initial review applications in E-IRB, and import core data for existing IRB-approved protocols into the E-IRB system at continuation review time. Establishing an application in E-IRB can also be done with a modification request, however, Continuation Review materials will be required for review along with the modification, and a new approval period will be assigned. Materials for existing studies needing IRB review prior to establishing a protocol in E-IRB (e.g., Unanticipated Problem; Protocol Violation) can still be submitted via IRBsubmission@uky.edu.

Note, until all research applications have made the full transition into E-IRB, ORI staff will be operating under dual systems and appreciate your patience and cooperation while they are trying to manage the increased work load. To help ORI staff, we hope you can take advantage of the online resources available.

The Time to Learn is Now

To learn how to navigate in the new system prior to institution-wide implementation, review the various [E-IRB Video Tutorials](#) and online resources today. For FAQ's, known issues, training options, and to keep apprised of news and updates about this transition, please review the [E-IRB Info web page](#).



NEW “COMMON RULE” IRB REGULATIONS

Effective January 2018

The scheduled date for the majority of the revisions to the New Federal IRB Regulations is quickly approaching. The 125-page policy governing research involving human subjects involves significant changes to improve protections and streamline the IRB review process. While there is a chance of a one-year delay in implementing some of the provisions, IRBs would likely be able to proceed with implementing several “burden-reducing” changes.

The Office of Research Integrity (ORI) is preparing for the upcoming regulatory shift by revising applications, procedure/guidance documents, checklists, and even the new E-IRB submission system to take advantage of regulatory flexibility.

The goal is that the E-IRB system, currently in pilot phase, can be launched campus-wide based on the new rule. This would allow researchers to transition to a version of E-IRB that will closely mirror the future of research oversight.

A few of the changes researchers can anticipate include:

- ◆ New Exempt Review Categories for Low-Risk Research
- ◆ Streamlined Continuing Review requirement for Expedited Research Protocols
- ◆ A New approach to Consent which requires that the “Key Information” essential to decision making receive priority by appearing at the beginning of the consent form and being presented first in the consent discussion.

ORI and the Center for Clinical and Translational Science (CCTS) will continue to provide announcements and education sessions to introduce changes based on implementation of the new regulations.

Randomization Video for Potential Participant Education



The Office for Human Research Protections (OHRP) has released a new video on randomization on its public outreach website About Research Participation at www.hhs.gov/About-Research-Participation. This and other materials on this website are intended to help potential participants understand how research works, what questions they should consider asking, and things to think about when deciding whether to participate in a study. Research staff can also make use of these materials to facilitate the informed consent process.

RANDOMIZATION

This video explains the concept of randomization and what potential participants need to know when volunteering for a study with a randomized design.