Delayed Effective Date for the Revised “Common Rule” Regulation

Two days prior to the January 19, 2018 effective date for the Federal Policy for the Protection of Human Subjects, the federal agencies responsible for the rule, issued a 6-month delay in the effective and compliance dates. The delay may allow time for federal regulatory agencies to develop guidance on implementing the rule and adopting new provisions designed to streamline review and reduce regulatory burden. During the delay, human subject research will continue to comply with the current Common Rule. Institutions may, however, implement changes from the new rule that do not conflict with the current regulation. One such change involves the content, format, and process of informed consent.

Informed Consent Changes based on the New Common Rule:
To begin transitioning to the new informed consent regulatory requirements, the ORI and IRB introduced new consent form templates in December 2017. The new rule approaches informed consent using a “reasonable person standard”, which focuses on what a reasonable person would need to know, presented in a format that facilitates understanding.

New Required Elements:
Using a template to develop a consent document, helps ensure inclusion of the required elements of informed consent. The revised common rule includes additional consent elements pertinent to modern research including future use, potential gain from commercial profit, return of clinically relevant research results, and whole genome sequencing.

New Order with Key Information presented First:
Informed consent process and form must begin with a concise and focused presentation of “Key Information”. The intent is to start the process with the most important reason that a person would choose to participate and reason why a person would choose not to participate. This crucial information is front and center, rather than being dispersed somewhere in the document, buried in other details. Key information is not a cut and paste repeat of the risks and benefits. It is narrowed down to the most fundamental aspects one would weigh in making a decision whether to participate or not. See Key Information examples at www.research.uky.edu/ori/human/SampleIRBapplication.html

New Format Options:
Using a consent template may enhance compliance with required content. However, the purpose is not to create mirror images of the template. UK’s consent template provides formatting options for designing a consent that facilitates comprehension given the context of the study and potential population. Consider whether certain information is best presented as standard text paragraphs or if it would enhance participant comprehension if presented in a table, graphic, figure, illustration, or other format.

Consent Template FAQ www.research.uky.edu/ori/human/NewUKconsent-form-template-FAQ.pdf
Human Research Update at the February 27, 2018 Center for Clinical & Translational Science (CCTS) Clinical Research Update Series

At the February 27th CCTS Clinical Research Update program, ORI staff presented information on ORI operations, regulatory changes, E-IRB implementation, & IRB reliance for select multi-site research.

If you were unable to attend and would like a copy of the handout, contact ORI education coordinator Belinda Smith (belinda.smith@uky.edu).

Watch for continued updates in future newsletters and listserv announcements. Email jen.hill@uky.edu to subscribe to the UKORI-IRB-L Email Listserv.

E-IRB Update
E-IRB IS NOW IMPLEMENTED CAMPUS WIDE. ORI & Research Information Services (RIS) appreciate the participation of all researchers and IRB members! Lets keep the momentum going!

E-IRB Notes:
- All full and expedited IRB studies previously approved external to E-IRB will need to be imported and completed in E-IRB at Continuation Review time. For details, see the pertinent FAQ on the E-IRB Info web page and/or review the “Import a Full or Expedited Application” video tutorial.
- New Exempt, Expedited and Full Review Applications (Medical and Nonmedical IRB) must be submitted via the new E-IRB web-based application system.
- Please see the E-IRB Info web page for more information to assist you with your E-IRB experience, and/or visit the Video Tutorial Library (log-in with Link Blue) for "how-to" E-IRB guidance.
- Modifications and Other Reviews (Unanticipated Problem, Protocol Violation, Deviation/Exception) for existing protocols approved external to E-IRB will still be submitted electronically in PDF format to IRBSubmission@uky.edu. Go to the Human Research Forms web page to download applicable forms.

Informed Consent Workshop for UK Research Staff & Faculty

Informed Consent
From Perception to Process
Wednesday May 2, 2018
1:00 pm– 5:00 pm
Commons Room, Wethington Building

Register* at [http://j.mp/2sOvoZU] by April 24th
*Registration required due to limited room capacity

Belinda Smith, MS, RD, CCRC & Ada Sue Selwitz, M.A.
Co-sponsored by UK ORI & UK CCTS

Questions or comments regarding newsletter, email Belinda.Smith@uky.edu. To remove your name from this mailing list email Jen.Hill@uky.edu.