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

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UK Office of Research Integrity

Importing Protocols into E-IRB at Continuation Review Time

All *full* and *expedited* IRB studies previously approved external to E-IRB need to be *imported* and completed in E-IRB *at Continuation Review time*. See the video tutorial on how to "Import a Full or Expedited Application" for details and instructions for the Continuation Review component.

Getting Started — What to Include:

After importing a study originally approved external to E-IRB, upload pertinent attachments in their *currently approved state* to the appropriate application section. The contents and materials included in an imported E-IRB application should ultimately represent the *entire currently approved version*** of the research study as it is being conducted on today's date. Include documents that supported initial approval (e.g., letters of support, regulatory correspondence), and materials *still in use* (e.g., data collection tools, unstamped version of currently approved consent form(s), recruitment advertising).

**Incorporating Changes into the New Imported Application:

If the currently approved version of the research study needs modifications or updates, incorporate those changes into the appropriate section(s) of the imported E-IRB application. If the content of a previously approved document is also affected by the modification or update, attach the modified document with the changes highlighted, and assign the applicable Document Type (see the video tutorials on how to "Add attachments..." and "Add 'Informed Consent Section' Attachments" for detailed instructions). Also, describe what the changes are in the space provided at the end of the separate Continuation Review (CR) report form emailed to you and attach the form under the *Additional Info/Materials* section of your imported application.

If you make changes to your currently approved application in the newly imported version, be aware that the changes are not approved until the IRB completes and approves the study for Continuation Review (CR). For instance, new study personnel added to the imported application submission for CR, may not begin work on a protocol until the IRB has reviewed and approved the CR.

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Updated UK IRB Informed Consent Templates

Based on feedback from researchers, IRB members, and participants from the Informed Consent Workshops, we have made revisions to both the Medical and Nonmedical Informed Consent Template. The changes involve:

➲ Clarifications in instructions and simplification of the section describing storage and sharing for future secondary use.

➲ Addition of collapsed sections the user can click to open and include if applicable. If not related to the research, the user simply deletes the section.

➲ Reducing appendix examples in the nonmedical template to one, as most nonmedical consents are sufficiently concise and not enhanced by appendices that merely duplicate information.

Available now for new submissions:

The updated medical and nonmedical informed consent templates are available for use immediately. Archive any saved versions of past templates, and use the current templates available in the "All Templates" menu option of your E-IRB application, or the UK Template website for new submissions. The template updates have not prompted ORI to ask investigators to edit consents that already have IRB approval or are submitted for IRB review.

Customizing the template to fit the study:

Templates are provided as guides that include the regulatory required elements of in-formed consent. However, they should be customized to best meet the needs of the potential population and the context of the research. We encourage researchers to use conversational style, lay terminology resources and "plain language" techniques to create a consent document that facilitates understanding.

After drafting, use the Consent Checklists to assess for regulatory compliance.

For more information on using consent templates, see the updated UK consent Form Template FAQ.

Background:

The UK ORI and IRB implemented a revised informed consent template December 2017, along with newsletter announcements, FAQs, and Informed Consent Workshop offerings. This transition occurred a year in advance of the January 2019 effective date of the new "Common Rule" regulations for protecting human subjects.

The revision has provided an opportunity for researchers and IRB members to become familiar with select requirements from the new rule. In addition, the revised template included design and organization options for presenting information in a format intended to aid in understanding and help prospective subjects decide whether to participate in the research.

Human Subject Protection Training Options for NON-UK Study Personnel

As of September 26, 2018, the National Institutes of Health (NIH) will no longer be offering the Protecting Human Research Participants online course. The ORI human subject protection training FAQs provide alternate training options for NON-UK study personnel.

⇒ If external study personnel has completed Human Subject training at another institution, submit documentation to Jennifer Hill at jen.hill@uky.edu; 859-257-2978.

⇒ The Research Ethics Online Training course produced by the World Health Organization (WHO) is free and available to the public. Send a copy of the certificate for the NON-UK personnel to Jennifer Hill at jen.hill@uky.edu; 859-257-2978.

⇒ The Association of Clinical Research Professionals (ACRP) online Human Subject Protection and Ethics Training without Contact Hours is available to the public at no cost. Send a copy of the certificate for the NON-UK personnel to Jennifer Hill at jen.hill@uky.edu; 859-257-2978.

LAST CALL– Registration Closing Soon
Human Subject Protection: Roll With It

PROGRAM / SCHEDULE

Date & Location
Thursday, October 4, 2018
8:00 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.

Human Subject Protection: Roll With It

Covington, KY
October 4, 2018

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