IRBNews

Office for the Protection of Human Research Subjects *December 2018*

New Common Rule

On January 21, updates to the New Common Rule will go into effect. The Common Rule is a set of ethics used in the United States regarding biomedical and behavioral research involving research with human subjects. This is the first time this rule has been updated since it was published in 1991

Most of the changes affect the IRB Board, the staff, and the review process. However there are 4 key takeaway points for investigators:

1. An important aim is to improve the consent process. New features for Informed Consent Documents (ICDs) include:
    a. A concise, focused summary at the beginning of the ICD to give people key information right away.
    b. Informing participants regarding what will be done with their specimens or identifiable information.
    c. Organization of the consent to make it more understandable. (New templates and guidance have been created. See the following article.)
2. Focus IRB review on studies that are more risky.
    a. Minimal risk studies approved under the new rule will go through a short administrative check in as opposed to the current Continuing Review process.
    b. More studies will be eligible for Exempt status.
3. Other rules still apply such as FDA, HIPAA, FERPA, VA, etc. Also, studies approved prior to 1/21/19 will still follow the old rules with a possibility of being transitioned to the new rules at the next Continuing Review period.
4. The IRB is here to help you. Use our website, review the help text on the xForms, or contact the IRB staff and members whenever you need assistance.

For the full text of the Revised Common Rule, click here.

Updated ICD Templates

All Templates Now Include the New Requirements

Now is the time to start using the updated templates as it is possible that submissions started in December may not be approved until after 1/21/19. These new templates are also acceptable for those studies approved prior to 1/21/19. Therefore, if you have saved old versions of our templates, please replace them with these new templates.

New Social Behavioral ICD Template

A new template for Social Behavioral research has been added to the IRB website. This template incorporates all the New Common Rule guidelines and has been organized in a way to help with readability and understanding for the participant. It is written in a question/answer format and is easy to revise for the target audience.

New ICD Guidance

The IRB has posted a guidance document to help you create ICDs with or without our templates. This will help in creating ICDs with the appropriate readability level as well as help with organization of the ICD for easier understanding. Remember, templates are guidelines with suggested text. Using the templates ensures that you have all the required elements, however investigators are free to re-arrange the sections and edit the text to match the study.

To review the new guidance and access all the ICD templates, click here.

Contact us at 423-439-6053 if you have any questions or concerns about the new regulations, or email us at olivef@etsu.edu.

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