U-MIC TRANSCRIPT
The Revised Common Rule: Effective January 21, 2019

In 2018, the Department of Health and Human Services finalized revisions to its human subjects research regulations located at 45 CFR 46 subpart A, which are known as the Common Rule. The Common Rule defines responsibilities both of investigators conducting research involving human subjects and of institutional review boards in their review and approval of human subjects research.

The implementation date of the revised Common Rule is January 21, 2019. New studies with federal funding that are approved on or after this implementation date are subject to all requirements of the revised Common Rule. At UM, new studies without federal funding approved on or after this date will be subject to all provisions of the revised Common Rule except the requirement to post consent materials to a federally designated public website, which will be addressed later in this presentation.

Keep in mind that the changes within the revised Common Rule pertain only to Department of Health and Human Services regulatory requirements; the changes have no bearing on FDA or HIPAA requirements for the conduct or oversight of human subjects research.

Changes within the revised Common Rule affect numerous aspects of human subjects research conduct and review, including:

- continuing review
- exempt research
- informed consent
- other aspects of research

Continuing review

Effective January 21, 2019, continuing review is no longer required for some minimal risk research, including

- most studies that qualify for the expedited review process
- studies, whether subject to expedited or convened-board review, that have completed all subject intervention and interaction and whose remaining activity is confined to either final analysis of identifiable data or biospecimens or accessing follow-up clinical data

Keep in mind that the requirements that continuing review occur at least annually remains in effect for studies that are subject to FDA regulations and/or that are conducted in accordance with ICH-GCP E6 standards.

Exemptions

Changes to federally-defined exemption categories for human subjects research and the U-M exemption review process include:

- modification of most existing categories
- expansion in scope of several existing categories

- the addition of three new categories, only one of which—research involving only benign behavioral intervention—UM is currently implementing
- two new exempt determination processes applicable in certain circumstances:
    - limited IRB review, a process similar to expedited review
    - self-determination of exemption, whereby the principal investigator may issue a system-generated exemption determination letter based on responses to key questions. Self-determinations may be permissible for some exempt research, but not for research involving a HIPAA-covered component or for research which requires a Limited IRB review process. The eResearch system will inform researchers during the application process whether a study qualifies for self-determination of exemption.

Informed Consent

The revised Common Rule includes changes to federally required elements of informed consent, including:

- a “key information” section at the beginning of each consent document
- new required elements of informed consent
- changes to waiver criteria and documentation, as well as other process changes
- a "broad consent" option for unspecified future use of identifiable data/bisopecimens; UM is not implementing broad consent at this time

The new key information section is designed to highlight details most likely to inform potential subjects’ decision whether or not to participate in a study. Key information requirements and procedures are addressed more fully in a separate U-MIC presentation.

The revised Common Rule introduces four new required elements of informed consent:

- Regarding the collection of identifiable private information or identifiable biospecimens, the consent document must contain a statement indicating:
    - whether identifiers may be removed, and
    - whether de-identified information or biospecimens may or may not be used or shared for future research
- Regarding the use of biospecimens, the document must indicate:
    - whether biospecimens may be used for commercial profit, and
    - whether the subject will share in that profit
- Regarding clinically relevant results, the consent document must indicate:
    - whether the clinical results, including individual research results, will be returned to the subject, and
    - if so, under what conditions
- Regarding whole-genome sequencing, the document must state that the research will or might include whole genome sequencing.

IRBMED has revised its standard informed consent template, which is available for download on the IRBMED website, to comply with all revised Common Rule requirements, including a key information

section and the incorporation of all new required elements of consent.

The revised Common Rule presents two new informed consent waiver provisions:

- Waivers of consent for the use of identifiable private information or biospecimens must justify why the use of identifiers is necessary to carry out the research.
- Use of identifiable information or biospecimens to identify potential subjects for recruitment purposes is allowed under certain circumstances without informed consent; in these instances, a waiver of consent is no longer necessary. Such use, however, may still be subject to HIPAA requirements.

Additionally, the revised Common Rule requires researchers conducting federally-sponsored clinical trials to post their IRB-approved consent materials to a publicly available, federal website post-recruitment and no later than 60 days after the last study visit by any subject. Two websites have been identified to fulfill this obligation: clinicaltrials.gov and a folder on the Federal Register website.

Contact the IRB for more information about the revised Common Rule.

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