CMU CENTRAL MICHIGAN UNIVERSITY | Office of Research Compliance

Institutional Review Board

IRB NEWSLETTER – March 12, 2018

Implementation of the Revised Common Rule at CMU

The revised Common Rule for Protection of Human Subjects in Research was scheduled to become effective on January 19, 2018. However, implementation of revisions has been postponed to July 2018.

The overall aims of the revisions are to reduce the burden of developing and reviewing applications; make the regulations relevant to modern research technology; and be responsive to concerns about security of research subjects' personal information. Given these significant advantages, the IRB has decided to implement the revisions beginning on 1/12/18 when reviewing all human subjects research that is not funded by federal agency such as NIH or NSF

The IRB and the Office of Research Compliance have developed temporary standard operating procedures that describe how the revisions will be implemented. The temporary SOPs are presented on the **IRB Web Page.** Here are summaries of the revisions that will most immediately affect CMU investigators.

Exemptions: New Categories, Subcategories, and Review Procedures.

Category 2 (iii) (new) allows for research with information that identifies human subjects provided the IRB conducts a limited review to determine that "when appropriate there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data".

Category 3 (new) allows for research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and certain criteria are met. (It is anticipated that many

research projects previously classified as eligible for expedited review category 7 will be eligible for this exemption).

Category 4 (new) concerns secondary research uses of identifiable private information or identifiable biospecimens, if certain criteria are met.

Category 7 and Category 8 cover storage and secondary uses of identifiable information or biospecimens when broad consent has been, or will be, obtained.

The application form for exempt research available on IRBNet has been modified slightly to accomodate the new and revised exemption categories.

Broad Consent

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted under the revised Common Rule. The procedures and documentation are in addition to what would be required if there were no intention to use data in the future.

Investigators should be very careful about employing broad consent: records must be kept with great care and the IRB will not be able to grant waivers to use data if subjects decline to give broad consent. Very few institutions are implementing procedures from broad consent.

Continuing Review

Continuing Review is no longer required for research that qualifies for expedited review unless the IRB determines on a case by case basis that it is required and documents the rationale within the IRB record. *Local Implementation:* The CMU IRB will require a yearly Status Report indicating a project is still active and affirming that there have been no changes in procedures that have not been approved by the IRB.

We would be happy to discuss the revisions with investigators either singly or in groups.Please direct questions and comments about the revisions to either of us.

Katherine Rosier
Chair, Institutional Review Board
rosie1kb@cmich.edu

Robert Bienkowski
Director, Research Compliance
robert.bienkowski@cmich.edu

The IRB Office is located in Foust 104. The phone number is 989-774-6401.

This Newsletter is produced by the Office of Research Compliance.
Comments and suggestions are welcome and can be sent to cmuirb@cmich.edu