Implementation of the Revised Common Rule at CMU

The Revised Common Rule for Protection of Human Subjects in Research (RevCR) is scheduled to become effective on January 19, 2018. The overall aims of the revisions were to reduce the burden of developing and reviewing applications and make the regulations relevant to modern research technology and concerns about security of research subjects' personal information.

IRB staff and members have developed temporary standard operating procedures that describe how the RevCR will be implemented. The entire text of the temporary SOPs is 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 transitioned to this exemption.)

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

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 will be modified slightly to accommodate 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 is a subjects declines to give broad consent.

Continuing Review

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

Please direct questions and comments to about the revisions to either of us.

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

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

19-Jan-2108