Frequently Asked Questions about the Revised Common Rule Regulations

1. When do the revised regulations take effect?
   January 21, 2019 although there are three changes that will be implemented as of July 19, 2018

2. What three changes will be implemented in July of 2018?

   - Revised definition of "research" which specifically *excludes* the following:
     - Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research and historical scholarship)
     - Public health surveillance activities
     - Collection and analysis of information biospecimens or records by or for a criminal justice agency for activities conducted solely for criminal justice or criminal investigative purposes
     - Authorized operational activities in support of intelligence, homeland security, defense or other national security missions

   - Elimination of the requirement that institutional review boards review grant applications or other funding proposals related to the research

   - Continuing reviews will no longer be required for most expedited studies approved after July 19, 2018 but the IRB will contact you annually to determine the status of the study

     - For active studies with approval before July 19, 2018, you will be transitioned to the new regulations at the time of your next annual continuing review. This transition may require minor revisions to the consent form, this will be explained more fully in the continuing review submission form.

3. What are the additional changes in the regulations that will take effect in January 2019?

   - New and revised exempt categories
   - New broad consent requirements for data and biospecimen repositories
   - New required elements of consent
     - Specific statement about future use of data
     - If research involves biospecimens, the consent must state if the research will or might include whole genome or exome sequencing
     - A statement as to whether or not clinically relevant research results will be given to the subject and under what conditions this would occur is required, if applicable

4. What are the new exempt review categories?

    - Exempt category 3- Benign Behavioral interventions
    - Exempt category 4- use of identifiable biospecimens or private information
    - Exempt category 7-storage or maintenance of identifiable data or biospecimens for future secondary research using broad consent
    - Exempt category 8-use of data/specimens stored under exempt category 7
    - Minor revisions to exempt category 1 (educational research)
    - Minor revisions to exempt category 5 (public service programs)

5. What will change for me as an investigator on January 21, 2019?

    The short answer is not much. Submissions that were reviewed as expedited in the past may now be reviewed as exempt although you will be using the same submission form no matter how your study is reviewed. You may no longer have to request a continuing review annually, although we will still check in with you annually if the study is still active.

    At the time of your 2019 continuing review the IRB will contact the PI and faculty advisor of each expedited and full board reviewed study which was approved before January 21, 2019 to discuss moving the study forward under the revised regulations.

6. Where can I go for more information about the regulatory changes?

    - Office of Human Research Protections: https://www.hhs.gov/ohrp/
    - Public Responsibility in Medicine and Research: https://www.primr.org/commonrule/
    - Contact the Marquette IRB Manager- Jessica Rice, 288-6298, Jessica.rice@marquette.edu