

**Policy for Implementation of Changes to the Common Rule Regulations for Human Subjects Research (45 CFR 46)**

**Effective on January 21, 2019**

***Please note the Common Rule regulations are separate from FDA regulations. The FDA regulations have NOT changed. Until an update is issued by FDA, compliance is required with the current FDA regulations (21 CFR 56) as well as the Common Rule (45 CFR 46).***

Research received after **01/21/19** will be required to comply with the new rule. If a study is approved prior to the **01/21/19** effective date of the new rule, it will be evaluated for applicability to certain aspects of the new rule requirements at the time of the next Continuing Review.

**Procedures for Implementation – Studies Received after 01/21/19:**

- New Exempt Research Categories will be applied to research reviewed by the IRB after the implementation date. Exempt studies will be approved without an expiration date and will require a brief annual check-in.
- New Non-Exempt studies approved by expedited procedures will require a **brief annual status** update
- Consent forms will be evaluated for additional requirements after the implementation date as applicable.
- Studies approved by expedited procedures which meet the new requirements will require a **brief annual status** update

**Procedures for Implementation for ongoing minimal risk research studies approved prior to 01/21/19:**

- Amendments which require major revisions to the study and the consent form will be evaluated against the new requirements.
- Continuing reviews will be evaluated for applicability to certain aspects of the new requirements including:
  - Evaluation for possible exemption under the new categories
  - Elimination of future continuing reviews for studies that:
    - have completed study interventions and are analyzing study data (including identifiable data/specimens), and/or
    - involves accessing follow-up clinical data as part of clinical care;
    - were approved by expedited procedures that are not actively enrolling subjects
    - research in this category will require a **brief annual status** update