Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Research Subject to the Revised Common Rule

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Effective Date: January 21, 2019
Original Approval Date: December 14, 2018
Revision Date:

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Associate Vice Chancellor for Research

1.0 Purpose

To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research subject to the revised common rule.

2.0 Scope

The SOP applies to human subject research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

This SOP describes the variations in requirements and procedures that MU HRPP/IRB, and investigators, will adhere to for research subject to the revised common rule (45 CFR 46).

New Submissions, on or after January 7, 2019

All federally funded research, clinical trials, and/or research determined to involve greater than minimal risk will comply with the revised common rule. An approval determination will not be issued until the common rule is in full effect on January 21, 2019. Submissions prior to January 7th will follow the pre-2018 rules, but will be transitioned if required below during continuing review.

All non-federally funded research, non-clinical trials, minimal risk studies, and exempt research must comply with revised IRB policies. Some of those changes fall in line with the revised common rule, but not all revised common rule changes will apply to these studies.

Transition of Existing, Approved Research

1. Federally Funded Research, Clinical Trials, and Greater than Minimal Risk Studies

    a. Study is Open to Enrollment:

    These research projects approved before January 21, 2019 will transition to the revised common rule at the time of their continuing review. Necessary changes to the study will be made at that time.

    **Department of Justice and Consumer Product Safety Commission have not adopted the revised common rule so any study with that funding will not transition until it is adopted by those agencies.*

    **If a clinical trial is FDA regulated, FDA regulations will be followed.*

    b. Study is Closed to Enrollment or in Data Analysis Only

    These research projects approved before January 21, 2019 will not be required to transition to the revised common rule, but will be required to comply with IRB policy changes, and some of those changes fall in line with the revised common rule. However, if a study is closed temporarily, it will either need to be transitioned or be closed permanently and reopened as a new study at a later date.

2. Minimal Risk Studies (not falling under #1)

    These research projects approved before January 21, 2019 will not be required to transition to the revised common rule, but will be required to comply with IRB policy changes, and some of those changes fall in line with the revised common rule.

3. Exempt Research

    a. Existing federally funded, exempt research will comply with the revised common rule on January 21, 2019.
    b. Existing non-federally funded, exempt research will comply with the pre-2018 requirements.
    c. New exempt research will comply with the revised common rule categories for exemption because these exempt categories were adopted as local IRB policy. Limited IRB review will only be required for federally funded, exempt research.

Major Changes to the Common Rule:

1. Definitions – See Definitions SOP
2. IRB Composition – See Board Structure and Responsibilities SOP
3. Exempt Categories, Limitations, Determinations, and Limited IRB Review – See Exempt Review SOP

**The MU HRPP/IRB has decided not to adopt the option for broad consent, so these new exemptions will not be available for use.*

4. Expedited Review – See Initial Review SOP
5. Modifications to IRB Approved Research – See Amendment Review SOP
6. Continuing Review – See Continuing Review SOP
7. Criteria for IRB Approval of Research – See Initial Review SOP
8. Informed Consent Process and Documentation – See Informed Consent SOP
9. IRB Review of Grant Applications – See Initial Review SOP
10. Posting of Clinical Trial Consent Forms – See Informed Consent SOP
11. IRB Records – See Record Keeping SOP