Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Annual Review of Research

Annual Review of Research

Effective Date: January 21, 2019
Original Approval Date: January 21, 2019
Revision Date: July 12, 2019, January 21, 2020, March 1, 2020

Approved By: Michele Kennett, JD, MSN, LLM
Associate Vice Chancellor for Research

Michele Kennett

1.0 Purpose

To assure knowledge and compliance by documenting the annual administrative review and continuing IRB review of non-exempt projects for the IRB.

2.0 Scope

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

3.0 Policy/Procedure

Transition to the Revised Common Rule

All research approved before January 21, 2019 submitting for annual review must comply with the revised IRB policies. Federally funded research, clinical trials, and greater than minimal risk studies that are still open to enrollment must fully transition their study to the revised common rule at the time of annual review. Required updated information/documents will be requested on the designated annual reporting form. See "Research Subject to the Revised Common Rule" SOP for additional information regarding transitioning of existing studies.

Submission Process and Deadlines

Investigators are required to submit the Annual Update Form prior to the project expiration date for review and approval. Principal Investigators will be informed in the project approval letter of

the review interval and the study expiration date. It is the responsibility of the Principal Investigator to submit the annual report even without notification from the IRB office.

The deadlines for annual review are on the HRPP website and noted within the reminder letters to investigators. If the annual report has not been submitted by the due date, it may not be able to be reviewed and may expire on its expiration date.

If the annual review was submitted late or submitted on time, but the project cannot be re-approved by the expiration date due to time constraints (i.e. board meeting date or reviewer availability), the project status will automatically switch in eCompliance to "Closed – Annual Review Under Review" when the project expires. Investigators are not allowed to continue human subject research activities until the project is re-approved unless justification is provided by the investigator of what activities cannot cease during this time period and is subsequently approved by a primary reviewer and documented in the timeline.

Processing and Review

1. Once the annual report is generated in eCompliance, reminder notices are sent to the primary contact/primary investigator.
2. The PI or research staff must submit an annual report as long as the research:
    - Remains open to enrollment
    - Remains active for long term follow-up (even when the research is permanently closed to enrollment and all subjects have completed all research related interventions)
    - Remains partially closed or temporarily closed
    - Requires data analysis
        - Projects may be closed when activities are limited to data analysis and all data have been completely de-identified.
3. As each annual report is received, expedited and full board studies will be reviewed using a 30 day window in alignment with federal guidelines specific to the study type. Studies eligible for administrative review do not have to wait for the 30 day window to process the annual report.
4. The IRB office staff review each annual report for accuracy, completeness and whether it qualifies for administrative, expedited, or full board review. Any questions or clarifications are handled via communication with the Principal Investigator or primary contact.
5. A primary reviewer is assigned for each review unless the review can be done administratively. The IRB staff will ensure the primary reviewer has the appropriate expertise.
6. All reviewers have access to the complete annual report along with the associated attachments, if any.
7. If expedited or full board review is required, the IRB will determine the study continues to satisfy the criteria set forth by 45 CFR 46.111, 21 CFR 56.111 and 38 CFR 16.111. Subjects will be informed if there are any significant new findings that may relate to the subject's willingness to continue to participate in accordance with HHS regulations at 45 CFR 46.116(b)(5)

8. The reviewer will perform an in-depth review documenting the information on reviewer checklist. Reviewers are required to ensure that the submitted information is accurate and complete.
9. If any of the following are true, the IRB may need verification from sources other than the investigator that no material changes have occurred since the previous IRB review:
    - The investigator has a history of serious or continuing non-compliance related to continuing review in the past three years.
    - The IRB has reasons to doubt the veracity of the information provided by the investigator.
    - The information provided by the investigator is inconsistent with other information known to the IRB and the inconsistency cannot be resolved through communication with the investigator.
    - Any other reason where the IRB believes that verification should be required.

Review Levels

For studies requiring expedited or full board continuing review, the IRB conducts substantive and meaningful continuing review at intervals appropriate for the degree of risk not less than once per year. The research protocol must satisfy the criteria set forth by 45 CFR 46.111, 21 CFR 56.111 and 38 CFR 16.111 to be approved for continuation. The research cannot continue after the expiration of IRB approval as specified by 45 CFR 46.103(a), 21 CFR 56.103(a) and 38 CFR 16.103(a).

Research Eligible for Expedited IRB Review

1. DHHS regulations no longer require continuing review for research eligible for expedited review; however, the MU IRB will require an annual check-in with basic project updates to ensure reportable items are being reported as required.
    a. These will be reviewed administratively unless the study must be updated to comply with IRB revised policies, then an IRB chair or IRB member designee will be required to approve the changes.
2. FDA, Department of Justice, and Consumer Product Safety Commission regulations still require continuing review at intervals appropriate for the degree of risk not less than once per year. The MU IRB will follow the expedited review process noted below. Administrative reviews are not allowed.
    a. The study must involve only procedures described in one or more of the nine published categories of expedited research activities; and
    b. The study must involve no more than minimal risk to the subjects (45 CFR 46.110(b)).
    c. The primary reviewer may determine that the annual review does not qualify for expedited review and must be reviewed by the convened Board. If the reviewer determines the continuing review cannot be approved by expedited procedures, the study will be put on the next full board meeting agenda. The investigator will be notified in writing, and documentation must be placed in the minutes why the study cannot be approved expedited.

Research Initially Reviewed by the Full Board

1. DHHS regulations no longer require continuing review if the research has progressed to the point that it involves only one or both of the following, which are part of the IRB approved study:

    a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

    The MU IRB will require an annual check-in with basic project updates to ensure reportable items are being reported as required.

    a. These will be reviewed administratively unless the study must be updated to comply with IRB revised policies, then an IRB chair or IRB member designee will be required to approve the changes.

    DHHS requires full board review for studies not falling under the criteria listed under #1(a) or (b). These studies will follow the full board review process discussed below. The board may determine if a study was previously voted minimal risk and it fits expedited criteria, it may be transitioned to an expedited study in the future. Documentation will be placed in the minutes.

2. FDA, Department of Justice, and Consumer Product Safety Commission regulations requiring continuing review either using the expedited procedure or full board procedure. Studies may be reviewed expedited when:

    a. Continuing review of research previously approved by the convened IRB as follows:
        i. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
        ii. Where no subjects have been enrolled and no additional risks have been identified; or
        iii. Where the remaining research activities are limited to data analysis.

    b. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through (8) do not apply but the IRB has determined and documents at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified

FDA, Department of Justice, and Consumer Product Safety Commission regulations requires full board review for studies not falling under the criteria listed under a or b above. The board may determine if a study was previously voted minimal risk and it fits expedited criteria, it may be transitioned to an expedited study in the future. Documentation will be placed in the minutes.

Board members receive the material at least five days prior to the meeting. All board members are expected to have a working knowledge of all submitted materials for the continuing review and be able to engage in a meaningful discussion of the project. The annual review will comply with the full board review process outlined in the Initial Review SOP.

Actions/Approval

If no issues are raised, the project will be approved to continue for another year (or whatever interval the board determines). When the annual review is within 30 days before approval expires (when required), the study retains the anniversary date as the date by which the continuing review must occur. The new expiration date is calculated from the last approval date plus 12 months (or other time frame as specified by the board).

EXAMPLE: A project was reviewed by the convened IRB on April 14, 2004 and it expires on May 10, 2004. The new expiration date would be May 10, 2005. See OHRP guidance on continuing review dated November 10, 2010 for further clarifications.

Modifications

Only administrative changes will be reviewed on an annual report unless the board determines that a modification is necessary at continuing review time. Transitional changes to the revised common rule/IRB policies can also be made on the annual report. See "Research Subject to the Revised Common Rule" SOP for additional information regarding transitioning of existing studies. See the "Amendment" SOP regarding IRB review of changes.

Subject Complaints

If the complaint/concern does not indicate an unanticipated problem, and the complaint/concern can be resolved by the PI, then the information associated with the complaint/concern will be included as part of the annual report for review by the IRB. Complaints/concerns qualifying as unanticipated problems must be reported according to the Unanticipated Problems SOP.

Status Changes/Completion

An annual report may be used to change the status of the study if it is moving from an open to status to a closed status and the change occurs around the time the report is due; otherwise, status changes are submitted on an Amendment.

If a study has been prematurely completed or was never conducted, a Completion /Withdrawal Report should be completed and submitted to the IRB as soon as possible.

IRB Records

The IRB will maintain records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in 46.109(f)(1). Documentation will be placed in the IRB reviewer checklist.

Consent/Assent Documents

As of January 21, 2019, the IRB will no longer place an expiration date on the consent or assent documents. Only an approval date will be entered. Investigators will be asked to upload their consent or assent documents if they are still using them at annual review time so the expiration date can be removed. This will be a one-time occurrence.

Re-Opening Projects that are Expired or Closed

Projects that expire because no annual report was submitted by the expiration date may be re-activated if the annual report is submitted within a reasonable amount of time and no activities have occurred since the project expired.

Projects that are closed prematurely may be re-activated if another annual report is submitted within a reasonable amount of time and no activities have occurred since the project was closed.

Re-opening a study will be allowed on a case-by-case basis.

Expiration

If the IRB approval expires, the PI must cease all human subject research activities and may not enroll new subjects in the study. The PI must inform the IRB office if they have a subject(s) that needs to continue to stay on the study even though the IRB approval expired, and they must provide justification in writing. If the IRB finds an over-riding safety concern or ethical issue involved such that it is in best interest of the subject to continue in the research activities, the IRB may permit subjects to continue for the time required to complete the continuing review process. Documentation of this determination will be placed in the timeline of eCompliance.

Investigators are required to promptly report the expiration to the sponsor. Expiration of IRB approval does not need to be reported OHRP as a suspension of IRB approval under HHS regulations.

References:

Policy Revision Dates Prior to January 21, 2019:
July 1, 2004; August 23, 2005; February 24, 2006; December 1, 2006; June 10, 2010; July 1, 2011; July 2, 2014; March 1, 2015; July 1, 2015; January 29, 2016; June 8, 2017