



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Continuing Review Report (CRR)

Continuing Review Report (CRR)

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1.0 Purpose

To assure knowledge and compliance by documenting the continuing review procedure of approved projects for the IRB.

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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

The IRB conducts substantive and meaningful continuing review at intervals appropriate for the degree of risk at least 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 be continued 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). If the IRB approval expires, the PI must cease all research activities and may not enroll new subjects in the study. However, if the IRB determines that it is in the best interest of the subject to continue in the research activities, the IRB may permit subjects to continuing for the time required to complete the continuing review process. The IRB or IRB chair, in consultation with the VAMC Chief of Staff will determine the best interest of participants in expired VA studies (see VA Hospital Research – Special Considerations SOP). 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.

Refer to the definitions policy for a complete listing of research definitions.

Submission Deadlines

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 Continuing Review Report (CRR) even without notification from the IRB office.

The deadlines for continuing review are on the website. Notification indicating the last possible date the CRR can be reviewed is sent to the primary contact and/or the primary investigator. The CRR must be submitted by the deadlines set by the appropriate reviewing office. If the CRR has not been submitted by the due date it may not be able to be reviewed and may expire on its expiration date. (see previous section)

Processing and Review

1. Once the CRR form is generated in eCompliance, reminder notices are sent to the primary contact/primary investigator.
2. The PI must submit CRR reports as long as the research:
 - Remains open to enrollment

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- 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)
 - Requires data analysis
3. As each CRR form is received, it will be assigned using the thirty (30) day window allowed by OHRP.
 4. The IRB office staff review each CRR for accuracy, completeness and whether it qualifies for full board or expedited review. Any questions or clarifications are handled via communication with the Principal Investigator or Study Coordinator.
 5. A primary reviewer is assigned for each review. The IRB staff will ensure the primary reviewer has the appropriate expertise.
 6. All reviewers have access to the complete continuing review report along with the associated attachments (see the CRR form for a complete list of information and attachments):
 - Clean copy of the consent/assent forms (if the study is active, open to enrollment)
 - Complete copy of current protocol/ grant (if not already on file)
 - Copy of CIDB (if not already on file)
 - Data Safety & Monitoring Information or Reports
 - Certificate of Confidentiality
 - Sponsor progress report
 - Any audit reports
 - Any relevant literature
 - Any relevant multi-center trial reports
 - Any other supporting documentation

Upon request to the IRB staff, the reviewer may have access to the complete historical IRB file.

7. The IRB will determine that the risk to subjects continues to be minimized and will systematically consider physical, social, economic, legal and psychological risks. In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research).
8. The IRB will determine:
 - 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)

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- Documentation should include any actions taken by the reviewer and any findings required under the regulations.
 - Ensure the study continues to satisfy the criteria set forth by 45 CFR 46.111, 21 CFR 56.111 and 38 CFR 16.111.
9. 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.
10. If any of the following are true, the IRB will generally get 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:

Expedited Review

For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of category (8)(a), (b), or (c) are satisfied for that site. However, with respect to category 8(b), while the criterion that "no subjects have been enrolled" is interpreted to mean that no subjects have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.

Applicability: When Expedited Review Procedures May Be Used by an IRB for Continuing Review:

- Involve only procedures described in one or more of the nine published categories of expedited research activities
- Are found by the reviewers to involve no more than minimal risk to the subjects (45 CFR 46.110(b)).
- Research that meets the criteria codified in 45 CFR 46.110 (8-9) may be expedited.

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- 8) Continuing review of research previously approved by the convened IRB as follows:
 - a. 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
 - b. Where no subjects have been enrolled and no additional risks have been identified; or
 - c. Where the remaining research activities are limited to data analysis.
- 9) 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

In conducting continuing review, the reviewer must determine and document that all applicable criteria are met and that all research activities fall into one or more categories of research allowing review by the expedited procedure.

The primary reviewer may determine that the CRR 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.

Full Board Review

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.

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 review is within 30 days before approval expires, 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 CRR 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 IRB CRR dated November 10, 2010 for further clarifications.

Modifications

Typically an investigator will be asked not to make modifications at the time of continuing review but instead submit an amendment. If the board determines that a modification is necessary to protect the safety, rights and welfare of subjects, such modification may be requested at the time of the CRR and will be reviewed depending on whether the requested changes are minor modifications or major changes, see-SOP Amendments.

Subject Complaints

If the complaint/concern does not indicate an unanticipated risk or a change in the risk/benefit ratio associated with the study, or the complaint/concern can be resolved by the PI, then the information associated with the complaint/concern will be included as part of the Continuing Review submission for review by the IRB.

Status Changes/Completion

A CRR form may be used to change the status of a study yearly as necessary. If a study is “Active-open to enrollment” one year, but over the course of the following year, has changed to “Closed-data analysis only,” this change should be reflected on the CRR.

If a study has been prematurely completed, a Completion /Withdrawal Form should be completed and submitted to the IRB as soon as possible. If a Completion /Withdrawal Form has not yet been submitted at the time of study expiration, a CRR form must be submitted in lieu of the Completion Form. This eliminates the confusion often caused by submitting a Completion Form at CRR time and expedites the approval of the form.

4.0 Applicable Regulations

OHRP Guidance November 10, 2010

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