PURPOSE
To describe the policies and procedures for conducting continuing review (CR).

REVISIONS FROM PREVIOUS VERSION
Addition of description of documents provided to IRB for review and calculation of expiration dates

POLICY
For federally funded research, the IRB conducts substantive and meaningful CR at intervals appropriate to the degree of risk and at least once per year. Non-federally funded minimal risk faculty research may qualify for continuing review every two years (see SOP 205). The research protocol must satisfy the criteria set forth in 45 CFR 46.111 and 21 CFR 56.111 for the IRB to approve the protocol for continuation. The IRB may only use expedited review procedures for CR under the following circumstances:

1. The study was initially eligible and continues to be eligible for expedited review procedures; OR
2. The research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects; OR
3. Where study personnel have enrolled no subjects at UNM and no additional risks have been identified either at UNM or at any site if the research involves a multi-site study; OR
4. The only remaining research activities are limited to data analysis; OR
5. The research involves the study of drugs and/or medical devices AND either does not require an Investigational New Drug (IND) (21 CFR Part 312) and/or an Investigational Device Exemption (IDE) (21 CFR Part 812) and/or the device is approved for marketing and being used in accordance with the approved labeling. The IRB must also have determined and documented at a convened meeting that the research is no greater than minimal risk and no additional risks have been identified.

When continuing review occurs annually and the IRB performs continuing review within 30 days prior to the expiration date, the OIRB will maintain the anniversary date (original expiration date) as the date by which the continuing review must occur.

The PI may not continue research after expiration of IRB approval; conducting research activities after expiration is a violation of federal requirements specified in 45 CFR 46.103(a) and 21 CFR 56.103(a).
Lapse of IRB Approval SOP.) 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 there is an overriding safety concern and/or ethical issue or that it is in the best interests of the individual subjects to continue participating in the research activities, the IRB may permit the subjects to continue in the study for the time required to complete the CR process.

RESPONSIBILITIES
Execution of SOP: Researchers, IRB Chair, IRB, OIRB.

PROCEDURE
Submission and Screening of Continuing Reviews
1. Using the notifications generated by IRBNet, the PI is sent CR requests and reminders before the end of the IRB approval period. The PI is responsible for responding to those requests in a timely manner.
2. The PI is responsible for submitting a CR request at least 30 days prior to the study expiration date.
3. To submit the CR, the PI completes the IRB Continuing Review application (progress status report) according to the instructions on the form and submits the form to the OIRB via IRBNet including any additional documents required for CR (e.g. last signed consent forms, protocol deviations log, interim findings, reports to funders, etc.). Newly proposed consent forms must be submitted as an amendment and cannot be submitted at the time of continuing review.
4. The PI must submit continuing review reports for studies as long as the research:
   - Remains open to enroll new subjects;
   - 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); and/or
   - Requires analysis of data with identifiers.
   See the Study Closure SOP for details on circumstances in which a PI may close a study.
5. Upon receipt of the CR materials, OIRB staff conduct a preliminary screening of the materials submitted and of the IRB’s protocol records to ensure the materials are complete and consistent with IRB requirements.
6. OIRB staff screen to determine whether the study is eligible for expedited review.
7. OIRB staff screen the application to ensure compliance with selected federal requirements, such as need for prisoner representative review.
8. If the CR submission includes an event report, OIRB staff process it under separate cover. OIRB staff write a note to accompany the separated event materials indicating that the PI originally submitted them with CR materials. The IRB Chair reviews the event report using standard procedures. (See Reporting and Review of Events SOP.)
9. OIRB staff contact ad hoc and cultural consultants regarding issues for which the IRB does not have the appropriate expertise, using the procedures outlined in the IRB Use of Outside Expertise SOP.
10. OIRB staff may request additional information or materials from the PI if the application is not complete. If the PI does not respond, OIRB staff will make attempts to contact the PI and/or research staff for additional information/materials, provided there is sufficient time before the end of the approval period.
11. If the OIRB does not receive a response from the PI, the OIRB sends the CR to the IRB. If the approval period limits the amount of time available to resolve outstanding issues, OIRB staff may schedule the protocol for IRB review “as is” to help avoid a lapse of approval. OIRB staff forward notes detailing the missing or incomplete materials to the IRB.

**IRB Review**

1. Studies that require full committee review are reviewed at regularly scheduled convened meetings according to the IRB Meeting Conduct SOP.

2. Studies that can undergo expedited review are reviewed according to the Initial Expedited Review SOP.

3. IRB members, regardless of the type of review, receive all documents submitted for CR and can have access to all previous reviews conducted for the study, including any amendments and relevant multi-center trial reports.

4. The IRB reviews the current consent form document to determine whether it is still accurate and complete.

5. The IRB determines whether the protocol needs verification from sources other than the researchers that no material changes occurred since the previous IRB review.

6. The IRB reviews the protocol deviation log to determine if any events occurred that meet the definition of an unanticipated problem involving risks to participants or others.

7. The OIRB procedures for notifying the PI of the review outcome, obtaining follow up correspondence, and issuing approval letters are outlined in the Initial Full Review SOP.

8. Once the IRB reviewer(s) approves the study, he/she assigns the approval period at intervals appropriate to the degree of risk.

9. Approval expiration dates are calculated based on the date of full committee review or the date of the final expedited review.

10. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit his/her concerns to the IRB reviewer via a written document that includes justification for changing the IRB decision.

**Lapse of Approval**

If a PI fails to submit the CR report form or the IRB has not completed review by the end of the approval period, OIRB staff notify the PI in writing that the approval will lapse or has lapsed according to the Lapse of IRB Approval SOP.

**REFERENCES**

21 CFR 56.108(a)(1)&(2)
21 CFR 56.109(f)
21 CFR 56.110
21 CFR 56.111
21 CFR 56.115(a)(3)&(7)
45 CFR 46.103(b)(4)
45 CFR 46.108(b)
45 CFR 46.109(e)
45 CFR 46.110
45 CFR 46.111
45 CFR 46.115(a)(3)&(7)
45 CFR 160
45 CFR 164