OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #305.6 Revision 6	**TITLE: Continuing Review**	Effective Date: 1/21/2019
Approved By: OIRB Director	Signature	Date 1/21/2019
Approved By: IRB Chair	Signature	Date 1/21/2019

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

REVISIONS FROM PREVIOUS VERSION
Updates relevant to revised common rule

POLICY
For research that is greater than minimal risk and reviewed by the full board or is regulated by the FDA, the IRB conducts substantive and meaningful CR at intervals appropriate to the degree of risk and at least once per year. Federally funded and non-federally funded minimal risk research may or may not require continuing review as determined by the reviewer. All projects must satisfy the criteria set forth in 45 CFR 46.111 or 21 CFR 56.111 for the IRB to approve the protocol for continuation. Projects reviewed at full board may undergo expedited or minimal risk CR procedures (dependent on funding) under one or more of the following circumstances:

1. The project is greater than minimal risk, no participants have enrolled and no additional risks have been identified;
2. The project is limited to data analysis, including the analysis of identifiable provide information or biospecimens or accessing follow-up clinical data from procedures that participants would undergo as part of clinical care;
3. The research involves the project 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 were identified.

When CR occurs annually and the IRB performs CR within 30 days prior to the expiration date, the OIRB will maintain the anniversary date (original expiration month and day) 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) (see Expiration of IRB Approval SOP). If the IRB approval expires, all research activities must cease and no new participants can be enrolled. 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 participants to continue participating in the research activities, the IRB may permit the participants to continue in the research 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 expiration date.
3. To submit the CR, the PI completes the 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. protocol deviations log, interim findings, reports to funders, etc.). Amendments and CRs cannot be submitted at the same time.
4. If CR is required, the PI must submit CR reports as long as the project remains open to enrollment of new participants and/or is actively collecting data unless the IRB has determined otherwise. See SOP 410 Project Closure for details on circumstances in which a PI may close a project.
5. Upon receipt of the CR materials, OIRB staff conduct a pre-review of the materials submitted and of the IRB's project records to ensure the materials are complete and consistent with IRB requirements.
6. OIRB staff screen to determine whether the project is eligible for expedited or minimal risk review.
7. OIRB staff screen the project 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 may ask the PI to submit it as a separate package. The IRB reviews the event report using standard procedures (see Reporting and Review of Events SOP).
9. OIRB staff contact consultants regarding issues for which the IRB does not have the appropriate expertise, using the procedures outlined in SOP 204 IRB Use of Outside Expertise.
10. OIRB staff may request additional information or materials from the PI if the package is not complete. Failure to respond may result in expiration of IRB approval.

IRB Review

1. Projects that require full board review are reviewed at regularly scheduled convened meetings according to SOP 103 IRB Meeting Conduct.
2. Projects that can undergo expedited review are reviewed according to SOP 304 Expedited Review of Federally Funded Research.
3. Minimal risk non-federally funded projects are reviewed according to SOP 205 Review of Minimal Risk Research Not Covered by FWA.
4. 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 project, including any amendments and relevant multi-center trial reports.
5. The IRB reviews the current consent form document, if applicable, to determine whether it is still accurate and complete.
6. The IRB determines whether the protocol needs verification from sources other than the researchers that no material changes occurred since the previous IRB review.

7. The IRB reviews the protocol deviation log, if submitted, to determine if any events occurred that meet the definition of an unanticipated problem involving risks to participants or others.
8. The OIRB procedures for notifying the PI of the review outcome, obtaining follow up correspondence, and issuing approval letters are outlined in SOP 303 Initial Full Review.
9. When approved, continuing review, if required, is at intervals appropriate to the degree of risk.
10. Approval expiration dates are calculated based on the date of full board review or the date of the final expedited or minimal risk review.
11. If the PI has concerns regarding the IRB decision/recommendations for changes in the project, they may submit their concerns to the IRB reviewer via a written document that includes justification for changing the IRB decision.

Expiration 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 or has expired according to SOP 408 Expiration of IRB Approval.

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