



Weill Cornell Medicine

Research Integrity

Human Research Compliance

Policy Number: 205.1
Effective Date: 09/01/2022
SOP Owner: HRC

Continuing Review

I. Purpose

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

II. Revisions from Previous Version

None.

III. Definitions

None.

IV. Policy

For research that is regulated by the FDA or for research that is greater than minimal risk, the Institutional Review Board (IRB) conducts substantive and meaningful CR at least once per year or at intervals appropriate to the degree of risk. 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 the full board may undergo expedited CR procedures under one or more of the following circumstances:

1. The project is greater than minimal risk, no participants have enrolled locally, and no additional risks have been identified,
2. The project is greater than minimal risk and the research is permanently closed to the enrollment of new participants, all participants have completed all research-related interventions, and the research remains active only for long-term follow up (note: Follow up procedures must be research interactions and minimal risk to qualify under this category (e.g. quality of life survey), and/or must be standard of care, regardless of whether they are described in the protocol to qualify under this category; research interventions not performed for clinical purposes, even if minimal risk, do not qualify under category),
3. The project is greater than minimal risk and the remaining research activities are limited to data analysis, or
4. Research, not conducted under an investigational new drug application or investigational device exemption, not covered by expedited categories, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

When CR occurs annually and the IRB performs CR within 30 calendar days prior to the expiration date, the IRB can maintain the anniversary date (original expiration month and day) as the date by CR must occur for the following year.

The PI may not continue research after the 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) and considered to be noncompliance. If the IRB approval expires, all research activities must cease and no new participants can be enrolled. Research activities include recruitment, participant enrollment, informed consent, data collection, data analysis and data storage of identifiable data, and sharing of identifiable data. If the IRB determines that there is an overriding safety concern and/or ethical issue or that it is in the best interest of the individual participants to continue participating in the research activities, the IRB Chair or their designee may permit the participants to continue in the research for the time required to complete the CR process. If research activities must cease, research procedures must be safely discontinued.

Procedure

Submission and Screening of Continuing Reviews

1. Using the notifications generated by WRG-HS, the Principal Investigator (PI) is sent CR requests and reminders 30-, 60-, and 90-days before the end of the IRB approval period.
2. The PI is responsible for submitting a CR request at least two months prior to the expiration date.
3. To submit the CR, the PI will complete the Continuing Review form via WRG-HS, including any additional documents required for CR (e.g. deviations log, interim findings, reports to funders, etc.). Amendments and CRs should not be submitted at the same time.
4. If CR is required, the PI must submit CR reports as long as research activities as described above are active, unless the IRB has determined otherwise. See Project Closure SOP for details on circumstances in which a PI may close a project.
5. Upon receipt of the CR materials, the IRB staff will conduct a pre-review of the materials submitted and review the IRB's project records to ensure the materials are complete and consistent with IRB requirements.
6. The IRB staff will determine whether the project is eligible for expedited review.
7. The IRB staff will review the project to ensure compliance with applicable federal, state, and institutional requirements, such as the need for a prisoner representative review.
8. If the CR submission includes a reportable event, the IRB staff may ask the PI to submit them separately. The IRB reviews the reportable event using standard procedures.
9. The IRB staff may contact consultants regarding issues for which the IRB does not have the appropriate expertise.
10. The IRB 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 the IRB Meeting Conduct SOP.
2. Projects 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 have access to all previous reviews conducted for the project, including any amendments and relevant multi-center trial reports.
4. The IRB will review the current informed consent/assent form document(s), if applicable, to determine whether they remain accurate, complete, and meet regulatory and institutional requirements.
5. The IRB will determine whether the protocol needs verification from sources other than the researchers to confirm that no material changes have occurred since the previous IRB review.
6. The IRB will review 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.
7. The following actions are applicable to CR review:
 - a. Approval – the research is approved to continue.
 - b. Modifications Required – more information is needed prior to continuing (note that all modifications must be resolved and approval granted to avoid expiration of IRB approval).
 - c. Disapproval – the research no longer meets the criteria for approval and the research must stop. This can only be determined at a convened meeting.
 - d. Suspension/Termination – temporary or permanent interruption in the enrollment of new participants, activities involving previously enrolled participants, or other research activities.
8. The IRB procedures for notifying the PI of the review outcome, obtaining follow up correspondence, and issuing approval letters are outlined in the Initial Full Review and Initial Expedited Review SOPs.
9. When approved, continuing review, if required, is at intervals appropriate to the degree of risk as determined by the IRB.
10. If the PI has concerns regarding the IRB's decision/recommendations for changes in the project, they may submit the concerns to the IRB reviewer via a written document that includes justification for changing the IRB's decision.

Expiration of Approval

If a PI fails to submit the CR report form or the IRB has not completed CR by the end of the approval period, the IRB staff will notify the PI in writing that the approval has expired.

VI. 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