

Guidance: IRB Review Type – Continuing Review

(last updated February 26, 2019)

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Overview

Federal regulations require an IRB to conduct substantive and meaningful continuing review of human subjects research that is within the jurisdiction of the IRB. This guidance outlines the criteria for continuing review, and investigator and IRB responsibilities.

Continuing Review Frequency

- Pre-2018 Rule: Continuing review, sometimes referred to as “renewal,” of all non-exempt federally funded projects involving human subjects is required *at least annually* (see [45 CFR 46.109\(d\)](#) and [21 CFR 56.109\(d\)](#))
 - Even if no changes are made,
 - Even if the only study activity is participant follow-up, and
 - Even if the only study activity is data analysis of data that are identifiable.
- The IRB may require more frequent review depending on the level of risk.
- Extended approvals issued prior to January 21, 2019: The UCLA Office of the Human Research Protection Program (OHRPP) implemented a procedure for granting approval for up to 3 years for research projects that involve no more than [minimal risk to participants](#) (as defined by [45 CFR 46.102](#)) and are not subject to federal oversight. See OHRPP Guidance: [Extended Approval for Minimal Risk Research Not Subject To Federal Oversight](#).
- 2018 Revised Common Rule: For research reviewed and approved by Expedited Review procedures on or after January 21, 2019, unless an Expedited Reviewer determines otherwise, continuing review of research will be replaced with Annual PI Assurances. Please see the “Level of Review” section below.
- If the researcher does not wish to continue the study, then he or she should submit a closure report. See OHRPP Guidance: [Closure of Human Subjects Research Studies](#).

Level of Review

A study that requires continuing review may be reviewed at one of two levels:

Full Committee Review: Human research which does not meet the criteria for expedited review or exemption from IRB review must be reviewed by the Full Committee at a convened meeting. Continuing review of a protocol which initially required Full Committee review will continue to be reviewed by the convened Board unless:

- the study meets the requirements for expedited review under federally defined expedited review categories 8¹ or 9² (see [45 CFR 46.109](#) or [21 CFR 56.110](#));
- changes to the protocol are included with the continuing review application such that the entire study now meets the criteria for expedited review, and the convened Board determines that future reviews of the study may be reviewed using expedited review procedures; or
- the convened Board determines that the study meets the criteria for expedited review, i.e., research poses no more than **minimal risk** to subjects and all study procedures fall within one or more of the [DHHS Expedited review categories 1-7](#).

Expedited Review: Research which meets the criteria for expedited review is reviewed by the Chair or his/her designee. A protocol which initially was reviewed using expedited review procedures may be reviewed for continuing review using expedited review procedures. However, research protocols that previously met the criteria for expedited review will require Full Committee review if changes to the protocol are proposed which: (1) present more than minimal risk to human subjects or (2) involve procedures which do not meet the criteria for expedited review.

webIRB Annual PI Assurances Check In – NEW IN JANUARY 2019

The 2018 Revised Common Rule does not require annual continuing review in the following circumstances:

- Research eligible for expedited review in accordance with § .110;
- Research reviewed by the IRB in accordance with the limited IRB review described in §.104(d)(2)(iii), (d)(3)(i)(C), (d)(7), or (d)(8);
- Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
 - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

In order to collect the information needed by the University to be able to identify active research projects, UCLA Principal Investigators of projects that are eligible for no annual continuing review **will** be required to complete a brief Annual PI Assurances process request issued by the webIRB submission system. This process will be applicable to research approved for the first time by Expedited Review procedures and to greater than minimal risk research that has reached certain milestones on or after January 21, 2019.

¹ **Expedited Category 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.

² **Expedited Category 9:** Continuing review of research, not conducted under an investigational new drug application or investigation device exemption, where categories two (2) through eight (8) do not apply 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.

As a courtesy, webIRB will send out Annual PI Assurances **reminders 90, 60, and 30 days before the anniversary date of the initial approval.**

If no response is received by the Principal Investigator, the application will be considered to be abandoned and will be administratively closed. Once administratively closed, **All Research Activities Involving Human Subjects Must Stop!** See OHRPP Guidance: [Closure of Human Subjects Research Studies](#).

Investigator Responsibilities

Sufficient Time: For multi-year research, the principal investigator is responsible for submitting a continuing review application through webIRB with sufficient time prior to the expiration of the current IRB approval so that there will be no lapse in the study approval. Allow **at least** one month for a full committee continuing review and two weeks for an expedited continuing review.

Submit the Continuing Review via webIRB: webIRB will direct you through the process.

Materials for Review: For an outline of the materials required for all continuing review submissions, please refer to the webIRB Application and OHRPP Guidance: [Materials Required for IRB Review and Approval](#).

Status or Progress Report: webIRB will ask for information regarding the status or progress of the research during the last year. The information will include: the number of participants accrued, the number of withdrawals and the reasons for withdrawals, unanticipated problems including complaints about the research, amendments to the research, any relevant recent literature, any interim findings, any relevant multi-center trial reports if applicable, and an assessment by the researcher of the current risk-potential benefit based on study results to date.

Amendments to the Protocol: Changes to the protocol or study documents may be submitted at the same time as the continuing review. Although the continuing review application and the amendment will be reviewed at the same time, webIRB requires that these be submitted as separate applications. See: [webIRB Quick Reference Guide: Submitting Amendments, CRs \(Including study closures\), and PARs](#).

An investigator may not implement proposed modifications until the changes are reviewed and approved by the IRB.

Avoiding Lapses in Approval

If an IRB approval expires, All Research Activities Involving Human Subjects Must Stop! These activities include subject contact, data collection and data analysis. The only exception to this requirement is for activities that are needed for participant safety. Contact the IRB at 310-825-5344 if this occurs. **No new subjects may be enrolled.**

In cases of the need for continuing study activities for participant safety, the information that the IRB needs to allow this exception is included in the Continuing Review Application. The IRB determines on a case-by-case basis whether treatment may continue for currently enrolled subjects. The IRB will notify the investigator if it is permissible under federal guidelines to continue limited research activities.

If project activities occur or continue after the expiration date, the investigator is out of compliance with both federal regulations and University policy. The IRB cannot grant retroactive approval for work done after the expiration date. Even if the continuing review application has been submitted to the IRB, all activities must stop until approval is granted.

The application for continuing review will ask for details about any lapses and will also ask for a corrective action plan to ensure such lapses do not occur in the future.

IRB Review Responsibilities

Review Criteria: Continuing review of research must be substantive and meaningful. The criteria for continuing review are the same as those for initial review. Therefore, the IRB (or the Chair or his/her designee for protocols reviewed using expedited review procedures) must determine that all of the following requirements are satisfied:

- Risks to subjects continue to be minimized and reasonable in relation to anticipated benefits;
- Selection of subjects continues to be equitable;
- Informed consent is sought or waived in accordance with 45 CFR 46.116 as well as 21 CFR 50.25 for FDA-regulated research.
- Informed consent will be documented or documentation waived in accordance with 45 CFR 46.117 and 21 CFR 50.27 for FDA-regulated research.
- The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, when appropriate;
 - There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, when appropriate; and
 - Appropriate safeguards for vulnerable subjects are provided.
 - If multi-site research, the study management of information relevant to protection of subjects is adequate.

Review of Recruitment, Screening and Consent Documents: When reviewing the recruitment, screening and/or consent documents, the IRB will ensure the following:

- The currently approved or proposed documents are complete, accurately reflect the information in the study application, and meet all the regulatory and University criteria for approval.
- Any new findings that may relate to the subject's willingness to continue participation are provided to the subject in an updated informed consent form or addendum to the informed consent form.

Determining Appropriate Interval for Continuing Review: The IRB will determine which projects require review more often than annually in order to ensure the continued protection of the rights and welfare of the research subjects. The IRB considers the following factors, along with any other factors deemed relevant by the IRB, in determining the frequency of review: the nature of the study, the degree of risk involved and the vulnerability of the study subject population.

The IRB will communicate to the investigator in writing any determinations of a requirement for review more often than annually and also indicate this in the minutes for the meeting.

Verification from Other Sources: The IRB will determine which projects need verification from sources other than the investigators that no material changes have occurred since the prior IRB review on a case-by-case basis.

Continuing Review Reminders and Notices

- As a courtesy, webIRB sends out **continuing review reminders 90, 60, and 30 days before studies expire**. A notice of expiration is issued on the date of expiration of each study.
- Investigators are advised to complete the Continuing Review Application via webIRB and submit the required accompanying documentation within thirty days from the date of the first reminder notice.
- It is ***ultimately the investigator's responsibility*** to submit a continuing review application and to allow sufficient time for the review and re-approval process to be completed before the current approval expires.
- The expiration date listed on the Approval Notice and within webIRB is the last date on which research activities may occur.

References

Federal

- [OHRP Guidance on IRB Continuing Review of Research – November 10, 2010](#)
- [FDA Information Sheets: Continuing Review After Study Approval, Frequently Asked Questions: IRB Procedures](#)

UCLA OHRPP Guidance and Procedures

- [Closure of Human Subjects Research Studies](#)
- [Extended Approval for Minimal Risk Research Not Subject To Federal Oversight](#)
- [Materials Required for IRB Review and Approval](#)

Change history:

2/26/2019: Updated to reflect 2018 Revised Common Rule requirements.