UCLA Research Administration
Human Research Protection Program

Guidance and Procedure: Levels and Types of IRB Review
(last updated March 22, 2023)

Brief Summary

This document describes the three federally-defined levels of IRB review, the three types of review within each of those levels, and provides an overview of the UCLA IRB review procedures. This information is designed to help you plan the amount of time needed to prepare and submit your application to ensure timely IRB review and approval of your study. IRB review and approval or certification of exemption must be obtained *prior* to any contact with human subjects or any use of their specimens, records, or data.

See Getting Started for a quick guide of how to get started with the IRB application process.

Levels of IRB Review

The webIRB application requires that researchers perform a risk-benefit assessment (see: Assessing Risks).

The IRB confirms your assessment during its review process and evaluates whether the proposed research meets federal criteria for the requested level of review. The levels of IRB review may change throughout the course of a study depending on the nature and risk level of subsequent amendments or the stages of the research.

LEVELS OF HUMAN SUBJECTS RESEARCH REVIEW	
Expedited Review	Expedited Review is the most common method of review at UCLA. The IRB may review protocols using expedited procedures if the protocol meets the requirements outlined at 45 CFR 46.110, i.e., the research involves no more than minimal risk *and* falls within the categories published in the November 9, 1998 Federal Register list of research eligible for expedited IRB review. See: IRB Review Process – Expedited Review.
Full Committee Review	Protocols that do not qualify for expedited review or exempt certification (see below) require review by a convened meeting of the Full Committee. See: IRB Review Process – Full Committee Review.
Certification of Exemption from IRB Review	Only a small percentage of human research conducted at UCLA qualifies for a certification of exemption. To qualify, research activities must fall within one or more of the categories outlined at 45 CFR 46.101(b). The

	UCLA OHRPP reviews the investigator's preliminary determination of exemption, and then makes the final determination prior to certification.
	See Level of Review – Certification of Exemption from IRB Review for the exempt categories and process of review.

Types of IRB Review

Within each level of IRB there may be three types of review.

TYPES OF HUMAN SUBJECTS RESEARCH REVIEW	
Initial	This refers to a study being submitted and reviewed for the first time. See OHRPP Guidance noted above in review levels.
Continuing	This refers to a study being reviewed at the time of continuation, sometimes referred to as a "renewal." Continuing review frequency is determined based upon level of review. See OHRPP Guidance and Procedure: Continuing Review.
Amendment	This refers to a change, also referred to as a "modification" to the current approved study. Amendments to currently approved research must be approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the human subjects. Depending upon the nature of the amendment, the IRB may conduct an Expedited or Full Committee review. See OHRPP Guidance and Procedure: Amendments.

Approximate IRB Review and Approval Turnaround Times

A number of factors enter into IRB review and turnaround times, including but not limited to the quality of the IRB submission, the complexity and/or novelty of the study, whether or not there are unusual and/or difficult ethical issues to consider, the time it takes for an investigator to respond to IRB requests for additional information and/or revisions as well as the time of year. For example, reviews during holiday periods will take longer. Because IRB review is a deliberative process, it is not possible to provide exact turnaround times. However, investigators might want to consider the following as rough guides:

Level	Type	IRB Review
Full Committee	Initial	4 – 8 weeks
	Continuing and/or Amendments	3 - 4 weeks
Expedited	Initial	2 - 4 weeks
	Continuing and/or Amendments	1 - 2 weeks
Exempt	Initial	1 - 2 weeks

For more information about IRB Statistics including Approval Counts, Review Cycle Times and Award Dollars, see the UCLA Research Administration ORA Research Portal reports section or click on the links in this paragraph.

IRB Selection and Meeting Dates

Discipline-specific IRBs: The review focus of each of UCLA's five IRBs is described on the "About UCLA IRBs" page of the OHRPP website. These disciplines may change slightly depending on current membership expertise.

IRB Assignment: Investigators can make a preliminary request for IRB assignment when completing an application in webIRB. Once a protocol is received by the UCLA OHRPP (via webIRB), the confirmation or revision to IRB assignment is made by the OHRPP staff, based on the available review expertise of the IRBs.

Meeting Dates and Submission Deadlines: Each of the UCLA IRBs holds a convened meeting of the full committee twice a month. See Meeting Calendars and Deadlines for Submission. There are no submission deadlines for applications undergoing expedited IRB review or applications considered for certification of exemption from IRB review.

Overview of IRB Application and Review

Materials Required: As you complete your webIRB submission, the application will branch based upon the research methods and participant populations described. As such, the materials required for your submission may vary. See Materials Required for IRB Review for an overview of the various materials that may be required.

Protocol ID Assignment: webIRB assigns the official IRB protocol identifier ("IRB number") to the protocol at the time of submission. The UCLA "IRB number" is formatted as: YY-######. The first element is the two-digit year in which the protocol was originally submitted, the second element is a six-character accession number, representing the order in which the protocol was received in the year.

Criteria for Approval: Federal regulations require that the IRB apply the same criteria for initial review, amendments (modifications), and continuing review of human research protocols. See OHRPP Guidance: Requirements for IRB Review.

Communications with Investigators Regarding IRB Actions: Researchers are notified in writing via webIRB of the results of any IRB reviews, which may include requests for revisions, requests for additional information, or a final review determination. See Communication of Results of IRB Review.

Review Frequency: All protocols reviewed by full committee are reviewed at least once annually. Some projects require review more often than annually in order to ensure the continued protection of the rights and welfare of the research subjects. Protocols reviewed using the expedited review process are reviewed at the interval determined at the time of initial review, which may not include annual continuing review, under the terms of the 2018 Revised Common Rule. In determining the frequency of review, the IRB will consider the nature of the study, the degree of risk involved and the vulnerability of the study subject population, along with any other factors deemed relevant by the IRB. The IRB will communicate in writing and indicate in the minutes of the meeting any determinations of requirements for review more often than annually. For more information, see the OHRPP guidance document on IRB Review Types - Continuing Review.

Studies that are certified as exempt do not require annual continuing review. Principal Investigators are required to complete Annual Principal Investigator ("PI") Assurances in webIRB in order to confirm that the research is still active.

Period of Approval for Amendments: The approval period does not normally change following IRB approval of an amendment to a protocol. For example, if the new, renewal, or continuing approval is issued on January 1, 2010, the protocol will have an expiration date of December 31, 2010. If an addendum is approved during the approval period time, the protocol will still have an expiration date of December 31, 2010, unless an amendment is submitted at the time of

continuing review, or the investigator requests a change in expiration date as part of the continuation review.

Related UCLA OHRPP Guidance

- [Communication of Results of IRB Review](#)
- [IRB Review Type – Continuing Review](#)
- [IRB Review Type – Amendment Review](#)
- [IRB Review Level – Expedited Review](#)
- [IRB Review Level – Full Committee Review](#)
- [Certification of Exemption from IRB Review](#)

Change history:
3/22/2023: Updated the Portal links on page two.
4/12/2019: Updated to reflect January 1, 2019 procedure change for no exempt expiration date and to reflect Revised Common Rule changes to continuing review requirements (effective January 21, 2019).