

Guidance and Procedures Number: 9
Title: IRB Review Process – Full Committee Review
Date of Last Revision: July 5, 2007

I. Introduction

UCLA's Institutional Review Boards (IRBs) are charged to protect the rights and welfare of human research subjects by reviewing all University affiliated human subject research conducted by or under the auspices of UCLA, regardless of funding, to ensure the rights, welfare, and protection of all subjects. Federal regulations¹ require that initial and continuing reviews of research be conducted by the IRB at convened meetings at which a quorum consisting of the majority of the members of the IRB is present, including at least one member whose primary concerns are in nonscientific areas, unless expedited review is appropriate.²

II. Submission Deadline Calendar

Each of the five UCLA IRBs meets biweekly; the UCLA OPRS publishes on its website a calendar of deadline dates for submission to each of the five UCLA IRBs. Investigators are required to submit a complete application, including all required supporting documentation, to the UCLA OPRS by 5:00 p.m. on the published deadline date, for the submission to be considered for review at the subsequent scheduled IRB meeting. Deadlines for submission are approximately two weeks prior to the date of each meeting.

III. Quorum Requirements

A majority of the IRB members must be present (or participating via teleconference), including at least one member whose primary concerns are in non-scientific areas. Approval of research is by a majority vote of this quorum. IRB staff in attendance are responsible for monitoring the maintenance of quorum. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests or early departures, or absence of a nonscientist member), discussion of protocols may continue, but the IRB may not take further actions or votes unless the quorum can be restored. Please refer to [HRPP Guidance & Procedure # 68: IRB Meeting Administration](#) and [HRPP Guidance & Procedure # 69: IRB Meeting Minutes](#) for details.

¹ 45 CFR 46.108(b) and 21 CFR 56.108(c)

² For details regarding the categories of research that may be reviewed by the IRB through an Expedited Review procedure, please refer to the [HRPP Guidance & Procedure #8: IRB Review Process—Expedited Review](#).

IV. Primary Reviewer System

- A. IRB Staff assigns primary and secondary [and occasionally tertiary] reviewers based on the scientific and non-scientific expertise required for each submission.

Definitions:

1. The primary reviewer is always the person with the most applicable scientific expertise in the area of research.
 2. Secondary and tertiary reviewers include individuals with additional expertise required for the study and/or non-scientific members. For studies involving vulnerable populations, special subject population representatives [members who are knowledgeable about and experienced in working with the specific vulnerable population] are assigned as secondary or tertiary reviewers if they are not the primary reviewer.
 3. For the purpose of this guidance, primary, secondary, and tertiary reviewers are considered “primary reviewers”.
- B. IRB Staff may request consultation from the Chair when assigning reviewers. If it is determined that appropriate expertise is not available within the IRB, an internal or external consultant is sought at this time. Please refer to [HRPP Guidance & Procedure #16: IRB Process— Consultant Review](#) for details.
- C. Please refer to [HRPP Guidance & Procedure #7: Materials Required for IRB Review](#) for an outline of the materials provided to *primary reviewers*. All materials provided to *primary reviewers* are also available to all other IRB members for review upon request directed to the IRB Administrator.

V. Materials for Review

Please refer to [HRPP Guidance & Procedure #7: Materials Required for IRB Review](#) for an outline of the materials required for full committee review.

VI. Full Committee Review Process

- A. The submission and related study materials are distributed to the *primary reviewers* and all Board members sufficiently in advance of the meeting date to allow review of the material. Materials are generally distributed approximately one week prior each scheduled meeting.
- B. All members are expected to review and be familiar with all protocols. The primary reviewers are responsible for providing a brief summary of the study and identifying significant concerns. All members are expected to participate in the discussion of the significant concerns, raise additional concerns, provide necessary clarifications and/or propose resolutions.

- C. Please refer to OPRS/IRB Policies on *IRB Review Process – Initial Review, IRB Review Process—Continuing Review, and IRB Review of Modifications to Previously Approved Research* for additional related guidance.

VII. Possible IRB Actions

The convened Board may vote on one of the following determinations:

- A. **Approval:** The submission is approved, and no changes to the submission are required or recommended.
- B. **Conditional Acceptance, contingent upon the Chair’s or his/her designee’s acceptance of requested modifications:** The convened IRB stipulates specific revisions requiring simple concurrence by the investigator. The IRB Chair or another IRB member designated by the Chair may subsequently review and approve the revised research protocol on behalf of the IRB under an expedited review procedure.
- C. **Conditional Acceptance, contingent upon the primary reviewers’ acceptance of requested modifications:** The convened IRB stipulates specific revisions requiring simple concurrence by the investigator. The primary reviewers may subsequently review and approve the revised research protocol on behalf of the IRB under an expedited review procedure.
- D. **Deferral:** When the convened IRB requests substantive clarifications or modifications regarding the protocol or informed consent documents that are directly relevant to the determinations required by the IRB under HHS regulations at 45 CFR 46.111 or FDA regulations at 21 CFR 56.111, IRB approval of the proposed research is deferred, pending subsequent review by the convened IRB of responsive material.
- E. **Consultant Review:** If the IRB does not have a member with expertise adequate to the scope and complexity of the proposed research, the Board will request consultant review from an expert in the field. Please refer to [HRPP Guidance & Procedure #16: IRB Process— Consultant Review](#) for details.
- F. **Tabled:** A submission may be tabled due to one of the following reasons: (1) Lack of appropriate expertise in attendance; (2) Lack of sufficient information to conduct an adequate review; and/or (3) Lack of time/loss of quorum. IRB staff will re-distribute the application materials for full Committee review. The Board may vote on any of the possible determinations listed in Section VII.
- G. **Disapproval:** When the convened IRB identifies significant concerns about potential risk to subjects and a lack of scientific evidence to support the proposed research activities, it may decide to disapprove proposed research. The investigator will receive a statement of the reasons for the IRB’s decision, and an opportunity to respond in person or in writing. The convened IRB will review responses to all disapproval communications. A mechanism exists for advisory reviews of disapprovals- please refer to [HRPP Guidance & Procedure #13: IRB Review Process—Executive Committee](#) for additional information.

VIII. Review Frequency

The convened IRB is responsible for determining which protocols require review more often than annually in order to ensure the continued protection of the rights and welfare of the research subjects. The IRB shall consider 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. *All determinations of requirements for review more often than annually will be communicated to the investigator in writing, and documented as a codicil on the approval notice for the research.*

IX. Communication with Investigators Regarding IRB Actions

The IRB communicates concerns and suggestions regarding human subject protection issues to investigators following each step of its review. In accordance with federal regulations, IRB communications regarding the approval, disapproval or modifications required to secure IRB approval of research activities are in the form of written correspondence.³

IRB staff are responsible for drafting IRB communications regarding proposed research and any modifications or clarifications required by the IRB as a condition for IRB approval of proposed research. All IRB communications are reviewed and approved by the IRB Chair and/or designated IRB member prior to dissemination to the Investigator.

Upon receipt of an investigator's response to IRB communications, staff will prepare a written evaluation of the response to include any regulatory or administrative guidance. Staff will distribute the evaluation, along with applicable regulatory checklists and relevant historical information from the study file for review in accordance with the prior determination of the IRB.

See [HRPP Guidance & Procedure #12: IRB Review Process—Communication of IRB Actions](#) for further details.

X. Timely Review Defined

Ideally, given that all necessary resources⁴ are available, the IRB and the staff aim to complete each action within two weeks of the date of the meeting.

Regulations:

21 CFR 56.108
21 CFR 56.111
45 CFR 46.108
45 CFR 46.111

References:

OHRP Guidance on Written IRB Procedures, January 15, 2007.
<http://www.hhs.gov/ohrp/humansubjects/guidance/irbqd107.pdf>

³ 45 CFR 46.109(d) and 21 CFR 56.109(e)

⁴ Necessary resources may include but are not limited to required Board member expertise and staff.