UCLA Research Administration
Human Research Protection Program

Guidance and Procedure: IRB Review Level – Full Committee Review

(last updated May 29, 2021)

Introduction

This guidance outlines the criteria and process for IRB review conducted by Full Committee review.

Initial, continuing and amendment (modification) ***applications that involve greater than minimal risk to subjects***, must be reviewed via the Full Committee review process. For detail regarding the categories of research that may be reviewed by Expedited Review, please refer to IRB Review Process – Expedited Review.

Examples of applications that may warrant Full Committee review include randomized, double-blind, placebo controlled studies for safety and efficacy of a investigational agent, or social-behavioral studies that involve disclosure of highly sensitive information or enrollment of vulnerable subject populations.

Also reviewed via the Full Committee review process are ***unanticipated problems, and allegations of serious and/or continuing noncompliance***. These may include failure to follow the approved protocol, failure to consent subjects as indicated in the approved protocol, breach of confidentiality or privacy, and serious unexpected adverse events.

What is Full Committee Review?

Full Committee review is conducted 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.

Meeting Frequency: Each of the five UCLA IRBs meets twice a month. The UCLA OHRPP publishes on its website a calendar of meeting dates with submission deadlines to each of the five UCLA IRBs.

Quorum Requirements:

- A majority of the IRB members must be present (or participating via teleconference).
- At least one member whose primary concerns are in non-scientific areas must be present.
- At least one member who represents the perspective of research participants must be present.
- Unaffiliated members and/or non-scientist members represent the perspective of research participants. The unaffiliated member, the member representing the general perspective of participant, and the non-scientific member may be the same person or they may be represented by two or three different persons.
- Approval of research is by a majority vote of the quorum.
- IRB staff in attendance are responsible for documenting quorum in the meeting minutes and monitoring the maintenance of quorum during the meeting.
- 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 IRB Documentation of Activities for details.

Primary Reviewer System: IRB Staff assigns primary and secondary (and occasionally tertiary) reviewers based on an appropriate balance of scientific and non-scientific expertise required for each submission.

- The primary reviewer is always the person with the most applicable scientific expertise in the area of research.
- 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, such as children, cognitively impaired, or prisoner populations) are assigned as secondary or tertiary reviewers if they are not the primary reviewer.
- For the purpose of this guidance, primary, secondary, and tertiary reviewers are considered "primary reviewers."

External Consultants: 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 IRB Membership for details.

Minutes: Meeting minutes include at minimum the committee discussions including resolution of any controverted issues, regulatory determinations and votes for each study, the list of studies reviewed prior to the meeting via Expedited Review, member attendance, and disclosure of any member conflicts of interests.

Initial Review Process and Communications

Submission: Investigators are required to submit a complete application via webIRB, including all required supporting documentation, to the UCLA OHRPP on the published deadline date.

Materials for Review: All documents outlined in Materials Required for IRB Review are provided to *primary reviewers* and are available to all other IRB members for review via webIRB.

IRB Review Process:

- IRB staff will conduct an initial pre-review for completeness, and determine whether a submission warrants Full Committee review.
- 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, generally one week prior to each scheduled meeting.
- All members are expected to review and be familiar with all protocols.
- Members provide comments for review into the webIRB application.
- The primary reviewers are responsible for providing a brief summary of the study and identifying concerns.
- All members are expected to participate in the discussion of the significant concerns, raise additional concerns, provide necessary clarifications and/or propose resolutions.

Possible IRB Actions: The convened Full Committee may make one of the determinations listed below. Votes are taken by show of hands and/or voice vote by members participating by teleconference. The IRB Chair and Vice Chair(s) participate as voting members.

- ***Approved*:** Acceptable as is. No changes are required--criteria for IRB approval met.
- ***Accepted Pending Modifications:*** Minor specific changes are required.
- ***Deferred for Re-review:*** Substantial modifications and/or additional information required that are directly relevant to the Criteria for IRB approval.

- ***Disapproved:*** Criteria for IRB approval are not met. Only the Full Committee may disapprove a study.
- ***Tabled:*** Criteria for a convened Full Committee meeting are not met, and/or appropriate expertise is not available at the meeting.
- ***Not Human Subjects Research***
- ***Not Engaged in Human Subjects Research***

Communication with Investigators Regarding IRB Actions: Approvals, concerns and suggestions are communicated to investigators following each step of review; see IRB Review Process and Communication of Results of IRB Review for details.

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, the vulnerability of the study subject population, the experience of the clinical investigator in conducting clinical research, previous experience with the researcher or sponsor (e.g., compliance history, previous problems with the researcher obtaining consent, prior complaints from participants), the projected rate of enrollment, and whether the study involves novel therapies . *The IRB will communicate to the investigator in writing and document on the Approval Letter all determinations of requirements for review more often than annually.*

Timely Review: The performance standard for the IRB and the staff aim to respond to the investigator is within one week of the date of the meeting. Depending upon the type of review (i.e., initial, amendment, continuation) the investigator should allow at least one month and up to two for review and final approval.

IRB Approval Netter: The Approval Notice will contain all regulatory determinations, the IRB approval period, and the list of funding sources for the research in addition to PI and study identifying information and other information as needed.

Post-Initial Review

Continuing Review: The IRB must review ongoing research at least annually, unless the IRB requires more frequent review for a particular protocol. For more information, please see IRB Continuing Review.

Amendments to Approved Research: All 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. For more information, please see IRB Review of Amendments to Previously Approved Research

Post-Approval Reporting: The Principal Investigator must submit to the IRB all post approval reports that meet the submission criteria within the proper timeframe, as described in the OHRPP guidance: Post Approval Reporting Requirements (PAR).

References

DHHS Regulations

- IRB Functions and Operations: 45 CFR 46.108
- Criteria for IRB Approval of Research: 45 CFR 46.111

FDA Regulations

- IRB Functions and Operations: 21 CFR 56.108
- Criteria for IRB Approval of Research: 21 CFR 56.111

OHRP Guidance

- Guidance on Written IRB Procedures – July 1, 2011

UCLA OHRPP Guidance

- Materials Required for IRB Review
- IRB Review Process and Communication of Results of IRB Review
- Post Approval Reporting Requirements (PAR).

Change Log:
05/29/2021: Added information to review frequency about the investigators experience, compliance history, rate of enrollment, and novel therapies.