UCLA Research Administration
Human Research Protection Program

Guidance and Procedure: Communication of Results of IRB Review

(updated July 7, 2020)

Overview

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

This guidance outlines the possible IRB Actions, the process for IRB review, and the process of communicating results to researchers and other institutional officials.

Possible IRB Actions

Specific determinations will be made following Full Committee or Expedited Review, including limited IRB review, as noted below. Additionally, an IRB Chair/designee conducting a review under Expedited procedures may refer an application for Full Committee Review.

Possible IRB Actions: Full Committee, Expedited Review, or Limited Review		
Approval	• Full Committee • Expedited Review	Acceptable as is. ***No changes are required***. Criteria for IRB approval have been met.
Accepted Pending Modification	• Full Committee • Expedited Review • Certification of Exemption	***Criteria for IRB approval have been met, though specific, non-substantial revisions are required.*** Upon receipt of the required changes, the Committee Chair or another member designated by the Chair will verify that the appropriate additions/corrections were made and will approve the study.
Deferral	• Full Committee only	***Substantial modifications and/or additional information*** (e.g., details, clarifications, justifications) ***are required*** that are directly relevant to the criteria for IRB approval. The revised application must be returned for Full Committee deliberation.
Tabled	• Full Committee only	***Criteria for a convened Full Committee meeting are not met*** (e.g., loss of quorum; non-scientific

		member not present) and/or appropriate expertise is not available at the meeting. Study will return to Full Committee for review when criteria are met.
Disapproval	• Full Committee only	***Criteria for IRB approval are not met***. Disapprovals are rare and may occur in one of two ways: • After multiple attempts (i.e., typically at least two deferrals) have been made to resolve the issues, the Committee and the investigator reach an impasse. At the discretion of the IRB, the investigator may be invited to a meeting, or the IRB may assign a subcommittee to meet with the investigator. The IRB may also honor a request from the investigator to present his or her case to the convened IRB or a subcommittee. • The study is disapproved outright because the convened IRB determines that the science is clearly inadequate, the resources to conduct the study are not available, or that the research is inappropriate. In the first case, the IRB may ask the investigator to seek scientific review and redesign the project and submit an application for a new project.
Not Human Subjects Research	• Full Committee • Expedited Review	Please see Guidance Document Determining Which Activities Require UCLA OHRPP/IRB Review
Not Engaged in Human Subjects Research	• Full Committee • Expedited Review	Please see Guidance Document Determining Which Activities Require UCLA OHRPP/IRB Review

Approval Notices and Approval Periods

- Unless otherwise indicated, the approval period for research requiring Full Committee review will end one year from the date of the meeting. The approval period for research reviewed under expedited review procedures will not require a continuing review, unless the expedited reviewer determines otherwise. See OHRPP Guidance and Procedure: IRB Review Level – Expedited Review for additional information.
    - All FDA and DOJ regulated studies require annual continuing reviews.

- ***IRB approvals are valid until 11:59 p.m. on the expiration date listed on the approval notice. Investigators are therefore allowed to conduct research activities on the expiration date listed on their approval notices.***

- Approval of amendments to previously approved research will not change the previously assigned expiration date unless the amendment is submitted with a continuing review application.

- The IRB can approve a protocol for a shorter period if warranted by the risks presented to participants. See OHRPP Guidance: Type of Review – Continuing Review for additional discussion.

Communication of Results of IRB Review to Researchers

All IRB communications are reviewed and approved by the IRB Chair and/or designated IRB staff prior to dissemination to the Investigator.

Written IRB requests and IRB approval notices are issued electronically via webIRB.

Notification of IRB requests and IRB approval are provided to:
- the Principal Investigator (PI),
- faculty sponsor if applicable, and
- persons designated by the PI as PI Proxy or study contact person.

Communication of IRB Actions to Institutional Offices and Officials

- Relevant IRB findings and actions are made available - either by allowing access to webIRB or providing copies of materials - to offices and committees such as the Office of Contract and Grant Administration (OCGA), the Conflict of Interest in Research Committee (CIRC), Medical Radiation Safety Committee (MRSC), JCCC Internal Scientific Peer Review Committee (ISPRC), and the Embryonic Stem Cell Research Oversight (ESCRO) Committee.

- For particular situations in which notification of institutional offices or officials are warranted (such as non-compliance), OHRPP will copy relevant offices and officials on resultant correspondence according to OHRPP Guidance and Procedure: IRB Reporting Procedures for Unanticipated Problems, Noncompliance, Suspension, or Termination.

- The Vice Chancellor for Research may request copies of relevant documentation, such as correspondence and meeting minutes, as needed for investigations, quality assurance or other purposes.

- The Associate Vice Chancellor for Research is provided copies of the IRB minutes.

References

DHHS Regulations and References
- IRB Review of Research: 45 CFR 46.109
- OHRP Guidance on Written IRB Procedures, July 1, 2011

FDA Regulations and Guidance
- IRB Review of Research: 21 CFR 56.109

UCLA OHRPP Guidance
- Getting Started with an IRB Application – A Guide for Investigators and Research Staff
- IRB Membership
- IRB Reporting Procedures for Unanticipated Problems, Noncompliance, Suspension, or Termination
- Materials Required for IRB Review and Approval

- Requirements for IRB Review and Approval

Change history:
07/07/2020: Updated to reflect 2018 Revised Common Rule; updated links.