

CHLA IRB REVIEW OUTCOMES FOR NON-EXEMPT RESEARCH

This guidance outlines the possible IRB Actions following IRB review of non-exempt research.

Specific determinations will be made following Full Committee or Expedited 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 or Expedited Review		
Approved	<ul style="list-style-type: none"> • Full Committee • Expedited Review 	Criteria for approval are met. The IRB determined the submission meets the criteria for approval. The IRB may add specific changes; however, no action is required from the PI related to the submission.
Approve with Contingencies	<ul style="list-style-type: none"> • Full Committee • Expedited Review 	Criteria for IRB approval have been met, but specific, non-substantial revisions are required. The submission will meet the criteria for approval with minor or prescriptive changes or requirements that can be verified without considering the criteria for approval. IRB reviewer comments will be directive requesting simple concurrences or specific, non-substantial changes. Upon receipt of the required changes, the IRB staff or a designated reviewer will verify that the appropriate additions/corrections were made and can approve the study.
Deferred	<ul style="list-style-type: none"> • Full Committee only 	Criteria for approval are not met. The submission does not meet the criteria for approval and does not meet the criteria for “Disapprove”. Substantial modifications and/or additional information (e.g., details, clarification, justifications) are required that are directly relevant to the criteria for approval. Deferring a protocol requires that the study with the additional information or modifications be reviewed by the IRB at a convened meeting.
Tabled	<ul style="list-style-type: none"> • Full Committee only 	Criteria for a convened full Board meeting are not met (e.g., loss of quorum; inadequate expertise; no non-scientific member). “Table” may also be used to set aside a submission that will be considered later in the meeting or at another meeting to get more information to better discuss the issue and assess criteria for approval.

Disapproved	<ul style="list-style-type: none">• Full Committee only	Criteria for IRB approval are not met. The submission does not meet the criteria for approval and the IRB considers the research to have extensive deficiencies. Only the convened IRB may disapprove research. Disapproval is done after more than one attempt (e.g., two deferrals) is made to resolve the issues including, at the discretion of the IRB, inviting the Investigator to the IRB meeting.
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