

University of California, Los Angeles
Office for Protection of Research Subjects
INSTITUTIONAL REVIEW BOARD

POLICIES AND PROCEDURES FOR REVIEW OF CONTINUATION APPLICATIONS

POLICIES

Federal regulations and University policies require that all research involving human subjects be reviewed by the Institutional Review Board (IRB) *at least* once a year. Review of a continuation application must be substantive and meaningful to ensure adequate protection of the rights and welfare of research subjects.

The IRB must review ongoing research with respect to potential benefits, risks, adequacy of consent forms and other criteria for safeguarding human subjects. Comprehensive review is mandatory at the time of continuing review as well as initial application. New subjects may not be enrolled and all research activities may be suspended if a continuing approval is not issued before the expiration date of the most current approval.

REVIEW AND APPROVAL PROCEDURES

Full Committee Review: Continuation applications that were originally processed by full committee review (i.e., did not qualify for expedited review) will be submitted to the full Committee for review and approval.

An application requiring full Committee review is assigned to one or more IRB members who present the application during a convened meeting. Primary readers also review the original application, including any modifications previously approved by the IRB. Each IRB member also receives copies of all documents submitted for continuing review.

Expedited Review: Continuation applications originally approved by expedited review (involving no more than minimal risk) may be processed for expedited review and approval, providing there have been no reports of adverse events. Applications that include proposed modifications that change the level of risk to more than minimal or add procedures that do not fall within expedited categories will be sent to full Committee.

An Expedited application is assigned to one or more experienced IRB members for review. Approval by the designated IRB member(s) may be issued, with subsequent notification to the full committee.

Administrative Review: Submissions limited to administrative issues may be approved by the Chair, Vice Chair or authorized OPRS staff, with subsequent notification to the full IRB. Administrative approvals primarily involve Training Grants, Program Project Grants, and Center Grants. Administrative approval is also appropriate if the grant proposal does not yet define human subjects involvement. However, all interventions involving human subjects must be reviewed and approved by the IRB or certified exempt from IRB approval prior to initiation.