
Yale University Institutional Review Boards

100 PR.2 Expedited Review

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Overview

Under the federal regulations and at the discretion of the IRB, projects meeting the criteria for expedited review described in Policy 100, IRB Review of Research Proposals are not required to be reviewed by a convened IRB. This procedure describes the requirements and process for review of projects qualifying for the expedited review mechanism.

Submission Requirements

New Protocols, Continuing Review, and Amendment Requests

If an investigator believes that his or her research activities may qualify for the expedited review process, he or she must submit an IRB application for review. When the protocol is submitted electronically to the IRB, the appropriate documents must be uploaded under the relevant sections for the protocol, consent forms, and/or supporting documents. Expedited review requests require submission of the complete set of documents that are required for convened IRB review as described in 100 PR.1. The IRB Chair or designated IRB single member reviewer is responsible for ultimately determining whether or not a study qualifies for expedited review.

Response to Requests for Specific Minor Revisions

Protocols which have been reviewed by a convened IRB or via expedited review and determined to require specific minor revisions require submission of the documents incorporating the requested changes or providing sufficient justification from the PI for not making the changes in “track changes” format to facilitate review of modifications.

Review Process

Single IRB Member Reviewer Qualifications

Under the expedited review process, research proposals are assigned by the IRB regulatory analyst for primary review by the Chair, by one or more experienced members of the IRB or by a regulatory analyst who also serves as an IRB member, under the delegated authority of and oversight by the IRB Chair. These primary reviewers are required to have at least one year of experience working with the IRB and have demonstrated competence in thorough and rigorous review of the specific types of studies to be assigned as determined by the IRB Chair or IRB Manager. Qualification includes a thorough working knowledge of ethical principles, federal regulations and guidance, and IRB policies and procedures as demonstrated in the conduct of accurate and timely review of protocols and protocol related materials. Single IRB member primary reviewers must also demonstrate ability to identify substantive issues that require consultation with the Chair, IRB Manager, their designee, or convened IRB and to communicate and negotiate appropriate resolution with investigators. Primary reviewers need not necessarily have direct training in the areas of research under review and may compensate by utilizing consultants for scientific or human participant considerations as necessary. Reviewers with a potential conflict of interest must decline from reviewing a study related to the potential conflict and must inform the Chair or designee of the recusal.

Other Review Committees and Consultants

Research subject to review by other, additional oversight committees must be approved by the applicable committee(s) commensurate with the same approval requirements described for full board review (see IRB Procedure 100PR1).

When the study is not subject to additional review committee oversight and the single IRB member primary reviewer does not have adequate expertise, either in the judgment of the IRB regulatory analyst assigning the primary reviewer or as determined by the IRB itself, the Chair or IRB regulatory analyst will identify a consultant who can review the project and provide an assessment to the IRB regarding the adequacy of protection of participant rights and welfare.

Determination of Qualification for Expedited Review

Studies may only be reviewed through the expedited review procedure if they meet the requirements described in IRB Policy 100 IRB Review of Research Proposals. Single IRB member (Expedited) reviewers should consult the Non-Committee or expedited review checklist to ensure that all aspects of the research proposal are limited to one or more of the expedited review categories. The reviewer(s) must document which category(ies) are applicable on the checklist. Studies which do not meet the criteria may not be reviewed through expedited review and should be referred to the convened IRB.

Criteria for Approval – New Protocols, Continuing Review, and Amendment Requests

Approval criteria are the same as that for research reviewed by the full IRB (see IRB Policy 100 and Procedure 100 PR.1 Review by Convened IRB) and primary reviewers should refer to the appropriate checklists in the course of review. The reviewer(s) will confirm completeness of the submission by referencing the IRB review checklist and any applicable additional checklists such as checklists for research involving vulnerable populations, for example, children, prisoners or pregnant women. For continuing review of research, at least one IRB member is provided and reviews the complete protocol, including any protocol modifications previously approved by the IRB. The reviewer(s) will contact the principal investigator (PI) regarding any missing documents or items that are unclear. The reviewer(s) may also seek consultation from IRB members or other consultants to obtain additional expertise as necessary for thorough review of the project. The reviewer(s) may seek verification from sources other than the PI to ensure that no material changes have occurred since the previous IRB review, if necessary. The reviewer(s) may take any action that the full IRB may take except disapproval of the research proposal. The reviewers may thus approve or request clarifications or modifications to the protocol and/or consent form to secure approval or defer action pending additional information. When a reviewer concludes that disapproval may be warranted, the research protocol must be referred to the convened IRB for review

Criteria for Approval – Response to Specific Minor Revisions

When an investigator re-submits a protocol or supporting documents due to specific minor revisions required of either the convened IRB or single IRB member reviewer, the expedited reviewer must ensure that all IRB stipulations have been met or that the investigator sufficiently justified their not being met, in consultation with the IRB Chair as necessary. The investigator's response must either conform to the revisions required by the convened IRB or single IRB member reviewer, or constitute modifications that render the stipulations irrelevant, such as removing the procedure that was questioned by the convened IRB or single IRB member reviewer, in order for the reviewer to approve the response via expedited review.

Approval Periods

For federally funded and FDA-overseen research, new and continuing review applications approved via expedited review may be approved on the date that the reviewer determines that the research qualifies for approval and ending no more than 364 days from that date, unless a set anniversary date is

maintained; in such a case, upon renewal, the IRB approval may be granted within a 30-day period prior to the protocol's expiration while still maintaining the anniversary date going forward. The IRB may determine that a renewal period shorter than one year is appropriate given the nature of the study, IRB requirements, or specific milestones that must be met and evaluated by the IRB before extending the study's duration. The IRB may also determine that a renewal period longer than one year is appropriate if the protocol qualifies for an extended (two-year) renewal period (see Guidance on Approval and Expiration Dates, 100 GD2).

Protocols approved via expedited review following the convened IRB's request for specific minor revisions may be approved for the period determined by the convened IRB. Once the expedited reviewer determines that the IRB stipulations have been met, approval of the project is granted. Approval of new protocols expires after the time specified by the IRB, with the approval period calculated from the date of the approved revisions. (See <http://www.hhs.gov/ohrp/policy/continuingreview2010.html#section-g>.)

IRB approval for studies under continuing review expires on the anniversary of the expiration date previously assigned by the IRB unless the expiration date going forward is shortened or extended by the IRB. If the IRB reviews and approves a renewal submission earlier than 30 days prior to expiration, the IRB will assign a new anniversary date for the protocol renewal.

Amendments approved via expedited review are approved on the date the reviewer determines that the criteria required for approval have been satisfied. Expiration of the IRB approval for the research project remains the date assigned by the IRB at the time of the study's initial approval or renewal of approval, and does not change due to the amendment.

Vulnerable Populations

Research involving pregnant women, prisoners, children, individuals with impaired consent capacity or other potentially vulnerable populations may be reviewed through expedited review if they meet the criteria described in IRB Policy 100: IRB Review of Research Proposals. Whenever possible, the expedited review should be conducted by reviewers or involve consultants with experience in protecting the particular vulnerable population proposed to be involved in the research.

Notification and Documentation Requirements

The IRB Chair or designated single IRB member will provide written notification to the investigator regarding the outcome of the expedited review or of any clarifications or modifications required to obtain approval.

IRB records will include documentation regarding the actions taken by the reviewer, any findings required by laws, regulations, codes, and guidance, determination of permissible category(ies) for expedited review and the determination of minimal risk if appropriate, through notes included in the IRB record. IRB records will include the approval and expiration dates of the protocol.

A list of all human research proposals approved using the expedited review procedures will be provided to the IRB members at convened meetings. Summaries of expedited review activities are available electronically to the Institutional Official.