
Yale University Institutional Review Boards

100 PR.2 Expedited Review

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Overview

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. Two copies of the application along with all attachments should be submitted to the IRB. Should the protocol be submitted electronically, the appropriate documents must be uploaded into Coeus eIRB under the Attachments tab. Expedited review requests require submission of the complete set of documents that are required for convened IRB review as described in 100 PR.1 and the application instructions. The IRB Chair or designee 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 two copies of the documents incorporating the requested changes or providing sufficient justification from the PI for not making the changes, and one copy of the documents in “track changes” format to facilitate review of modifications. Should the revisions be submitted electronically, the track changed version should be uploaded using Word and a clean copy with the changes incorporated should also be uploaded in Word.

Review Process

Primary Reviewer Qualifications

Under the expedited review process, research proposals are assigned by the IRB coordinator for primary review by the Chair or by one or more experienced members of the IRB 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 Director. 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. Primary reviewers must also demonstrate ability to identify substantive issues that require consultation with the Chair, IRB Director, 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 participants 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 meet 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 IRB primary reviewer does not have adequate expertise, either in the judgment of the IRB coordinator assigning the primary reviewer or as determined by the IRB itself, the IRB, Chair or IRB coordinator 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. Expedited reviewers should consult the 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 or on the Regulatory Review Checklist. Studies which do not meet the criteria may not be reviewed through expedited review and should be referred to the convened IRB at its next available meeting.

Criteria for Approval

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 (see 100 CH.3 Reviewer Checklist for IRB Approval and 200 CH.1: Informed Consent Checklist). 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 children, prisoners or pregnant women. The reviewer(s) will contact the 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 take any action that the full IRB may take except disapproval of the research proposal. The reviewers may thus approve or request modifications in 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 proposal must be referred to the convened IRB for review at its next available meeting.

When an investigator re-submits a protocol or supporting documents due to specific minor revisions required of a convened IRB, 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 constitute modifications that render the stipulations irrelevant, such as removing the procedure that was questioned by the convened IRB, in order for the reviewer to approve the response via expedited review.

Approval Periods

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 one year from that date.

Protocols approved via expedited review following an IRB request for specific minor revisions may be approved for the period determined by the convened IRB. Approval of the project begins on the day that the expedited reviewer determines that the IRB stipulations have been met. Approval of new protocols expires after the time specified by the IRB, with the approval period calculated from the date of the convened IRB meeting and not from the date of approval. IRB approval for studies under continuing review expires on the anniversary of the expiration date previously assigned by the IRB. The IRB will not review renewal submissions earlier than 30 days prior to expiration. Renewal submissions reviewed more than 30 days after expiration will generate a new expiration date.

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.

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 designee will provide written notification to the investigator regarding the outcome of the expedited review or of any modifications required to obtain approval.

IRB records will include documentation regarding the determination of permissible category(ies) for expedited review and the determination of minimal risk if appropriate, through notes included in the IRB file. 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 reported and available electronically to the Institutional Official.