

SOP-G-009: TC IRB Standard Operation Procedures (SOP) on IRB Actions, Failure to Respond, Appeals

IRB Actions

In conducting its review of research, the IRB may take any of the following actions. With the exception of disapproval, the actions listed below may be used for either expedited or convened board review, including limited IRB review under the 2018 requirements. An action of disapproval can only be taken at a convened IRB meeting.

Approval. The research, proposed modification to previously approved research, or another item is approved. The IRB has made all of the determinations required for approval (i.e., approval criteria and any applicable special determinations (e.g., waivers, alterations, vulnerable population determinations, etc.)). No further action is needed.

Conditions Required for Approval. The research, proposed modification to the previously approved research, or other item is approved but conditions must be satisfied before the approval becomes effective.

The IRB may approve research with conditions if, given scope and nature of the conditions, the IRB is able, based on the assumption that the conditions are satisfied, to make all of the determinations required for approval (i.e., approval criteria and any applicable special determinations (e.g., waivers, alterations, vulnerable population determinations, etc.)). Any time the IRB cannot make one or more of the determinations required for approval ([45 CFR 46.111](#)), the IRB may not approve the study with conditions.

The IRB may require the following as conditions of approval of research:

1. Confirmation of specific assumptions or understanding on the part of the IRB regarding how the research will be conducted (e.g., confirmation that research excludes children);
2. Submission of additional documentation (e.g., certificate of training);
3. Prescriptive language changes to the study, consent, or other study documents along with clearly stated parameters that the changes must satisfy.

When the IRB approves research with conditions, the conditions will be documented in the IRB minutes for research reviewed at a convened meeting or in the applicable reviewer checklist for research reviewed under an expedited review procedure.

When the convened IRB approves research with conditions, the IRB may designate the IRB Chair (and/or other qualified individual(s)) to review responsive materials from the investigator and determine that the conditions have been satisfied. If the conditions have not been satisfied, or are only partially satisfied, the responsive materials must be referred to the convened IRB for review. When an expedited reviewer approves research with conditions, the original expedited reviewer (and/or other qualified individual(s)) will receive the response materials.

After verification, the following will be documented in IRB records and written communication to the investigator:

1. The date when the IRB determined that the criteria for approval were satisfied (i.e., the "approval date");

2. The date when verification was made that all IRB conditions have been satisfied (i.e., the “effective date”), and;
3. For initial approval and continuing reviews, the date by which continuing review must occur (i.e., the “expiration date”)

Partial Approval or Approval with Limitations or Restrictions.

This action may be taken when the IRB only approves some but not all components of the research while other components of the research that require modification or clarification cannot begin or continue until approved by the IRB. For example, the IRB could determine that a study may begin but that children cannot be enrolled until the investigator submits, and the IRB approves, a plan for assent; the IRB could stipulate that the approval for the local site only includes adult subjects; the IRB could approve one phase of the research but require that a modification is submitted before future phases begin; or the IRB could limit the research responsibilities of an investigator due to a COI.

Defer (Table). This action is taken by the IRB when modifications are required of the nature or amount that the full IRB cannot make or specify exact changes or parameters, or additional information or clarification is needed in order to determine that one or more criteria for approval are satisfied (e.g., the risks and benefits cannot be assessed until additional information is provided.).

The deferral is documented in the IRB minutes (for convened review) or reviewer checklist (for expedited review) and is communicated to the investigator in writing.

When the convened IRB defers approval, the responsive materials from the investigator will be provided to the convened IRB for review at a subsequent meeting. When an expedited reviewer defers approval, the original expedited reviewer will review the response materials whenever possible. When the original expedited reviewer is unavailable, the response will be reviewed by the IRB Chair or other qualified IRB member who has been designated to conduct expedited review.

Disapprove. This action is taken when the convened IRB determines that the proposed research activity does not satisfy the criteria for approval and that it cannot be modified to render it approvable (or the sponsor or investigator will not make necessary modifications that would render the research approvable).

Approval in Principle. Per HHS regulations at [45 CFR 46.118](#), there are circumstances in which a sponsoring department or agency may require certification of IRB approval as a condition of submitting for or releasing funds but before definitive plans for the involvement of human subjects have been developed (e.g., grants in which the procedures involving human subjects are dependent on preliminary activities such as the completion of animal studies or development of instruments). In these circumstances, the IRB may grant “approval in principle” without having reviewed the yet undeveloped procedures or materials. The IRB Chair or designee will review the available information (i.e., the grant or proposal and any supplemental information provided by the investigator) and, if appropriate, will provide certification of IRB approval in principle. Any approvals in principle will note that IRB approval must be obtained before any activities involving human subjects may commence.

Additional Actions. In addition to the above actions, the IRB may **acknowledge** reports and other items that do not involve prospective changes to already approved research. For example, the IRB may acknowledge the report of a protocol deviation but approve, require modifications in, or disapprove any associated corrective action plan. Further, the IRB may approve an item but include comments noting certain requirements, restrictions, or understandings. For example, with collaborative research, the IRB may note

that approval must also be obtained from another IRB with jurisdiction and that the letter documenting that approval must be submitted to the TC IRB before human research activities involving the collaborating organization or personnel may commence.

Failure to Respond

Upon review of a research study, the IRB may require changes or request certain information from an investigator. Failure to respond to IRB required changes or requests for information within 60 days (or fewer if the IRB determines that the information must be submitted earlier to ensure protection of the research subjects) may result in suspension or termination of IRB approval for the study. For studies that have not yet been approved, the study submission may be administratively withdrawn. At its discretion, the IRB may grant an extension beyond 60 days if the investigator contacts the IRB office prior to the deadline and presents sufficient cause for delay.

Reporting IRB Actions

All IRB actions are communicated to the investigator, and/or designated contact person for the research study, via notification/letter in the Mentor IRB within ten (10) working days, whenever possible, of the review. When applicable, a stamped copy of the approved consent form, parental permission form, and/or assent form will also be published. For IRB actions of conditions required for approval or deferral, the notification will include a listing of the conditions or requirements that must be satisfied or responded to. For a disapproval, suspension, or termination, the notification will include the basis for the action and will offer the investigator an opportunity to respond in person or in writing.

The IRB reports its findings and actions to the organization in the form of its minutes, which are distributed by the Research Compliance Director to the TC Institutional Official (IO).

Appeal of IRB Decisions

When the IRB suspends, terminates, or disapproves research, the IRB letter communicating the decision will include the basis for the action and will offer the investigator the opportunity to respond in person or in writing. Additionally, whenever an investigator disagrees with an IRB requirement or decision or believes that providing the IRB with additional information may result in a different outcome, they may request that the IRB reconsider its decision by submitting a memo and other supportive materials via Mentor IRB. The investigator may be invited to attend the IRB meeting to discuss the request and provide information but will be asked to leave prior to the IRB's final deliberations and vote.

Documentation and Record-Keeping

All reports, correspondence, and relevant documentation are retained in accordance with TC's policies for research record retention. Records include copies of the initial report, any follow-up communications, and final resolutions, if applicable.