
Yale University Human Research Protection Program

700 PR.4 Suspension and Termination of Human Research

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Overview

The IRB has the authority to suspend or terminate approval of all or part of the research that is not being conducted in accordance with the IRB's requirements, University policy or that has been associated with, or has the potential to be associated with unexpected risk to subjects. Likewise, the sponsor, other appointed University oversight committees and the local Yale principal investigator have the authority to suspend research activities whenever they believe it is necessary to do so in order to protect the safety or welfare of research participants or the integrity of the research. This procedure explains the steps necessary for the orderly suspension or termination of a research protocol.

Suspensions or Terminations by the IRB

Formal Suspension: The IRB or IRB Chair may suspend a protocol when it is believed to be in the best interest of participants to stop some or all protocol related activities temporarily. Studies may be suspended during an investigation of noncompliance or following a protocol deviation, adverse event or unanticipated problem involving risks to participants or others. Suspended protocols are still considered to be active studies and hence require continuing review by the IRB.

Formal Termination: A fully convened IRB may terminate a protocol when it is believed to be in the best interest of participants to stop protocol related activities permanently. Studies may be terminated following an investigation of noncompliance, protocol deviation, adverse event or unanticipated problem involving risks to participants or others.

Expiration and Administrative Closure: Any research protocol that has not been subjected to ongoing review and approval by the end of its approval period is automatically considered expired and all research activity must cease. Investigators will receive notice from the IRB that their protocol has expired. Failure by the investigator to immediately request that the study be re-activated and receive re-approval by the IRB will lead to the protocol being closed administratively by the IRB.

The IRB will notify the principal investigator in writing of the reason for the suspension, termination or closure. The IRB also will notify Grant and Contract Administration of protocols formally terminated by the IRB.

Suspensions or Terminations by the Investigator, Sponsor or Other Oversight Body

Sponsors, investigators, and other oversight bodies such as Data Safety and Monitoring Boards (DSMBs) or Yale's Quality Assurance, Compliance and Safety (QUACS) have the authority to suspend their own research study at any time they believe it is necessary to protect the safety and welfare of research participants or the integrity of the study. Studies may be voluntarily suspended after review or monitoring of study data, upon recommendation from Data and Safety Monitoring Boards or Committees, prior to or during an investigation of noncompliance or protocol deviation, adverse or unanticipated problem involving risks to research participants or others.

When a principal investigator, sponsor, or other oversight body determines that it is in the best interest of the participants to suspend or terminate a protocol, the principal investigator must notify the IRB of the decision within five days of the principal investigator deciding to or learning of the suspension or termination. The principal investigator must provide the IRB with the reasons why the study is being suspended or terminated. If only some of the study activities will be suspended (such as suspension of enrollment) then the principal investigator must include a description of what activities will continue and why it is appropriate to do so. The IRB will review the notification and determine if additional protection of research subjects, corrective actions, or investigation is required. The IRB will notify the principal investigator in writing of whether or not the IRB concurs or if additional actions are required.

Obligations to Participants During Suspension or Following Termination

Following a determination that a protocol must be suspended or terminated, several steps must be taken to ensure the protection of research participants as described below:

1. If the protocol is terminated or the suspension will require that current participants be withdrawn from some or all research related activities, then the principal investigator must submit to the IRB proposed procedures for withdrawal of currently enrolled participants that considers their rights and welfare. The IRB will review the proposed procedures and, if circumstances of the suspension or termination should warrant, the IRB may mandate oversight or transfer responsibility to another investigator to assure implementation of these procedures.
2. If the suspension will involve continuing some of the research procedures, the principal investigator must submit to the IRB proposed procedures for adequate oversight of those aspects of the research which will continue.
3. The principal investigator must submit to the IRB a proposed script or letter notifying all currently enrolled participants who are affected by the suspension or termination. The IRB will review the proposed script or letter. If follow-up activities are permitted or required by the IRB, participants should be so informed.
4. During the suspension period or after the termination of the research project, the principal investigator must report any events to the IRB or sponsor that would have required reporting had the former participants continued to be enrolled in the research. If circumstances of the suspension or termination should warrant, the IRB may mandate oversight or transfer responsibility to another investigator to ensure implementation of these procedures.

Activities During Suspension

In the event a research project or protocol is suspended, all research activities must cease unless the project involves therapeutic treatment or intervention and interrupting that treatment, in the opinion of the treating physician and with the approval of the IRB, would be detrimental to the research participant(s). Only in this case may the principal investigator continue to apply treatment. In all other cases, no protocol related activities may continue unless explicitly authorized by the IRB including no further enrollment of new subjects, administration of the research drug, device and/or therapy, and use of data in which a subject identifier is attached.

A principal investigator may request to re-open a research project when the study design, investigation and/or corrective actions are appropriately revised by submitting an amended protocol incorporating these changes.

Re-opening and Reapproval of Expired or Suspended Protocols

Re-opening and reapproval of a protocol following expiration or suspension requires that the IRB review and approve a request for reapproval, including a submission of the full protocol with all amendments incorporated therein and the following supporting documentation:

1. an explanation of the circumstances that led to the failure to submit the reapproval at an appropriate time or to otherwise fail to comply with the reapproval requirements.
2. a statement indicating whether subjects were enrolled during the period that the protocol was not approved.
3. a statement indicating whether any research participants were maintained on a therapeutic intervention after the expiration of the study's IRB approval, the number of participants , and why cessation of that therapy would have been detrimental to the health of the research participant.

References

<http://yalecancercenter.org/intranet/oprm/quality.html>