

Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2009-003.0
Policy Title: Imposing and Lifting Suspensions of Institutional Review Board (IRB) Approval or Imposing Terminations of IRB Approval

Purpose

The purpose of this policy is to identify the individuals and entities within the institution with authority for imposing and lifting suspensions of IRB approval (in whole or in part), for imposing terminations of IRB approval, and to describe the mechanism for doing so.

Definitions

See policy 2011-007.0 for definitions of:

IRB Approval Suspension Termination

Policy

It is the policy of the HSPP that the IRB Chair, convened IRB or any Administrative Officer defined in institutional policy 2002-42 may suspend IRB approval for a study (in whole or in part), inclusive of the need to do so urgently. With the exception of the Vice Chair, the authority to suspend approval for studies cannot be delegated to other individual members of the IRB. Only the IRB can reinstate approval.

The convened IRB or Administrative Officers designated in policy 2002-42 may terminate IRB approval of a study, inclusive of the need to do so urgently.

Reasons for imposing a suspension or terminations include, but are not limited to, learning that 1) research is not being conducted in accordance with the IRB's requirements, 2) the research has been associated with unexpected serious harm to participants or 3) findings from the continuing review or internal monitoring process.

Procedure

Imposing a Suspension or Termination of IRB Approval

The IRB or Administrative Officer may seek advice from other institutional areas (e.g. legal counsel, risk management, research compliance) in determining whether to impose a suspension or termination of IRB approval. In addition, when imposing a suspension or termination, the Chair, the convened IRB or Administrative Officer will give consideration to the impact that the suspension or termination may have on subject safety and/or welfare. Consideration will include, but is not limited to:

- whether participation can be stopped safely;
- whether subjects should be transferred to another physician for clinical care;
- whether subjects can be kept on study under the same PI;
- if kept on study under the same PI, whether additional monitoring is required;
- whether subjects can be kept on study under another PI.
- actions to protect the rights and welfare of currently enrolled participants.
- informing current participants of the termination or suspension.
- having any adverse events or outcomes reported to the IRB.

In the event of a suspension or termination of approval, the person/entity imposing the suspension will inform the investigator in writing. If immediate action is required the person/representative of the entity imposing the suspension or termination may give the directive verbally to the Principal Investigator (PI) and the letter will follow. Letters to the PI are to be sent within 5 working days prior to the effective date of suspension or termination (unless PI was notified verbally). Such letters will include:

- the effective date of suspension or termination;
 - if notification was initially done verbally the letter will reference the date of verbal notification;
- the reason for the suspension or termination;
- for suspension, identification of the research activity, in whole or in part, that must stop;
- any corrective action or clarification that must occur;
- if the reason for suspension may bear on the subjects decision to continue participation, a directive that currently enrolled subjects be informed of the suspension;
- for terminations, a directive that all currently enrolled subject be informed of the termination;
- if applicable a directive of how to deal with any currently enrolled subjects; and;
- a direction to the PI regarding to whom to submit responses.

The person/entity imposing the suspension or termination will send a copy of the letter to:

- the applicable Administrative Officers identified in policy 2002-42; and
- the applicable IRB Chair and Vice Chair
- the IRB Regulatory Specialists (RS)

Letters issued by the IRB will be prepared by the IRB RS; reviewed, approved and signed by the IRB Chair; and sent to the PI by the IRB staff through the electronic system. If imposed by another Administrative Officer identified in Policy 2002-42, that individual is responsible for the preparation and sending of the letter, including notification to the IRB. The IRB RS will include any notice of suspension or termination on the next meeting agenda for presentation to and review by the convened board. The IRB RS will update the Study Status field within the electronic submission system to reflect Suspension or Termination accordingly.

The investigator is to direct a written response to the person/entity who imposed the suspension/termination and copy the other individuals noted on the initial suspension/termination letter.

If an activity for which a suspension or termination has been imposed must continue, e.g. a research related treatment because it is in the best interest of the subject, the investigator must write a letter to the IRB Chair. The letter shall include:

- a justification as to why continuation is in the best interest of the subject;
- a request for approval for continuation of the specific activity either until the suspension is lifted or until alternate arrangements can be made for the subject;
- for terminations, confirmation that alternate arrangements are actively being sought and provide the anticipated time frame by which the arrangements should be finalized;
- confirmation that the investigator will inform subjects that the study has been suspended or terminated but that permission for the activity has been obtained;

- confirmation that the investigator will direct subjects to continue to report adverse events or unanticipated problems;
- confirmation that the investigator will continue to report all activity in accordance with policy.

Lifting a Suspension of Approval

Only the IRB can lift a suspension using either the expedited review process or review by the convened board. If someone other than the IRB imposed the suspension, that person is responsible for notifying the IRB Chair in writing when s/he is satisfied that all concerns that led to the suspension have been satisfied and to recommend lifting the suspension. That person must attach a copy of the responses from the PI to the letter to the IRB. The IRB Chair may use the expedited review process to lift a suspension:

- that was imposed by the Chair;
- that was imposed by an Administrative Officer, providing the documentation noted above is received; or
- that was imposed by the convened board when the board specifically delegates to the chair the authority to lift the suspension.

Otherwise, the convened IRB will determine whether to lift a suspension.

The IRB will send written notification to the PI when the suspension is lifted and will change the study status accordingly. The letter will be prepared by the IRB RS reviewed and signed by the Chair, and sent to the PI through the electronic system. The IRB staff will also send a copy of the letter lifting the suspension to the individuals identified above.

Informing the IRB of Suspensions or Termination Imposed by Other Institutional Officials

The IRB Chair is responsible for providing the IRB staff with information from other institutional officials who imposed a suspension or termination of IRB approval. The IRB RS will note the suspension/termination on the agenda of the next regularly schedule meeting as a discussion item. The IRB RS will ensure that, at a minimum, each member to be present will receive the letter of suspension or termination. The Chair will determine what additional supporting documentation, if any, should be made available to IRB members. The IRB may require additional corrective actions as noted in the policy for “Reporting Non-Compliance to the IRB.”

Related Policies

- #2009-001 Reporting Unanticipated Problems to the Institutional Review Board
- #2009-002 Reporting Non-Compliance to the Institutional Review Board
- #2009-004 Required Reporting to Institutional Official and External Agencies

Basis

- 45 CFR 46 – Protection of Human Subjects
- 21 CFR 56 – Institutional Review Boards

Document Attributes

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Date: