



IRB Policy Number: 2301 Version: 3.0 Effective Date: 08/15/25	Suspensions and Terminations	Supersedes Document Dated: 12/01/16, 07/26/19
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HRPP 2301: Suspensions and Terminations

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23.1 Reasons for Suspension or Termination

Common reasons for suspending or terminating a research protocol or research activities include, but are not limited to, instances when the research:

1. Has led to or is associated with an unexpected increase in risks of harm to subjects.
2. Is associated with subject injuries.
3. Is not being conducted in accordance with IRB requirements (researcher noncompliance).

The IRB may suspend or terminate research based on information received during its continuing review, from the findings of a post-approval monitoring visit, or from complaints made to the IRB.

23.2 Authority to Suspend or Terminate Research Activities

23.2.1 Principal Investigator

As the “front line” in subject protections, a principal investigator (PI) should always be aware of subject safety issues and should suspend research activities on a study in order to remove immediate hazards to subjects. If it is apparent that hazards cannot be eliminated by modification of various aspects of the study (e.g., the study design or inclusion/exclusion criteria), the study should be terminated. PIs must notify the IRB immediately after suspending research activities or terminating a study. The notification should contain information on the facts leading to the decision for the action, a plan for notifying and safely withdrawing current subjects, if applicable, that considers whether the plan takes the subjects rights and welfare into account and, if applicable, a plan for notifying former subjects of the suspension/termination and any follow-up that may be required to assure their ongoing safety. The IRB will review reports of suspensions or terminations, determine what, if any further actions are required on the part of the PI, and report the suspension/termination to the IO and others as described in [Section 27](#) of this manual.

23.2.2 IRB Chair

The IRB Chair can suspend or terminate IRB approval of a study, prior to discussion by the IRB, to remove immediate hazards to subjects or in the event there is evidence of noncompliance by the research team and that the noncompliance results in increased risk for subjects. The IRB Chair must consider protection of the rights and welfare of currently enrolled subjects (e.g., coordinating for medical or other care of subjects). The



PI will be notified of the decision immediately and be required to submit a response to the IRB Chair's concerns. At a convened meeting of the IRB, the IRB Chair will report the suspension/termination, discuss the reasons for the decision, review the PI's response to the suspension/termination, and lead an IRB discussion of the action, response, and possible further required actions. Possible further actions imposed by the IRB may include requiring the PI to submit a plan for notifying and safely withdrawing current subjects, a plan for notifying former subjects of the suspension/termination and any follow-up that may be required to assure their ongoing safety, if applicable, and a requirement that all adverse events or outcomes resulting from the research or the suspension/termination are reported to the IRB. A report of the suspension/termination will be submitted to the Institutional Official (IO) and others as described in [HRPP 2701](#) of the HRPP Policies and Procedures Manual.

23.2.3 IRB

The IRB, at a convened meeting, may suspend research activities or terminate them as a result of the following:

1. Reports of unanticipated problems involving risks to subjects and others (including adverse events).
2. Other reports that relate to subject safety in a particular protocol.
3. Reports of serious or ongoing noncompliance by the PI and/or research team.

The PI will be notified of the decision immediately and be required to submit a response to the IRB's concerns. At a subsequent convened meeting of the IRB, the IRB will review the PI's response to the suspension/termination, discuss the response, and possible further actions required to lift the suspension or rescind the decision to terminate the research. Possible further actions imposed by the IRB might include requiring the PI to submit a plan for notifying and safely withdrawing current subjects and a plan for notifying former subjects of the suspension/termination and any follow-up that may be required to assure their ongoing safety, if applicable, and a requirement that all adverse events or outcomes resulting from the research or the suspension/termination are reported to the IRB. A report of the suspension/termination will be submitted to the IO and others as described in [HRPP 2701](#) of the HRPP Policies and Procedures Manual.

23.2.4 Institutional Official

The Institutional Official may suspend a research activity or study.

23.3 Notification of Suspension or Termination

In the event of a suspension or termination of approval, the IRB or person directing the suspension or termination will inform the investigator in writing. If immediate action is required, the person imposing the suspension or termination may give the directive verbally to the PI, and the letter will follow. If the IRB did not suspend or terminate the research, members will be notified at the next convened meeting. Letters to the PI will be sent within five working days of the effective date of suspension or termination. Such letters will include:

1. The effective date of suspension or termination.
2. If the notification was initially done verbally, the letter will reference the date of verbal notification.
3. The reason for the suspension or termination.
4. Identification of the research activity, in whole or in part, that must stop or be suspended.
5. Any corrective action or clarification that must occur.
6. If the reason for suspension may bear on the participant's decision to continue participation, a directive that currently enrolled participants will be informed of the suspension.
7. For terminations, a directive that all currently enrolled participants will be informed of the



- termination.
8. If applicable, a directive of how to deal with any currently enrolled participants.
 9. A direction to the PI regarding to whom to submit responses.

23.4 Lifting a Suspension or Termination

Only the IRB can lift a suspension using either the expedited review process or full board review. If the IO imposed the suspension, that person is responsible for notifying the IRB Chair in writing, via email or in hard-copy format, when they are satisfied that all concerns that led to the suspension have been satisfied and 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 directed under the following conditions:

1. That was directed by the Chair.
2. That was directed by the IO, providing the documentation noted above is received.
3. That was directed by the convened board when the board specifically delegates to the IRB Chair the authority to lift the suspension.

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

The IRB will send a notification to the PI via IRBNet when the suspension is lifted. The letter will be prepared by the IRB staff, reviewed and approved by the Chair, and posted in IRBNet. The IRB staff will also forward a copy of the letter lifting the suspension to all entities that received a copy of the notification of suspension (see [section 23.3](#)).