

The CHS is required to report to OHRP “any serious or continuing noncompliance with this policy [45 CFR § 46 and its subparts B, C and D] or the requirements or determinations of the IRB”, and thus the ORSP Director will forward decisions of the CHS within five working days to the Director of Compliance at OHRP and to the following other agencies or institutional officials, as appropriate:

- The Investigator’s Faculty of Medicine Department Head (and any additional Department Heads where the Investigator holds multiple professional appointments)
- The Faculty of Medicine Institutional Official. The IO will contact any additional institutional authorities, such as the Dean of the Faculty of Medicine, the President of the University, the Associate Provost for Research, the representative from the Office of the General Council, and Risk Management and Audit Services;
- The Sponsored Research Administration representative (where grants are supporting the research), and the Office of Technology Development (where corporate/company contracts are supporting the research). SPA or OTD will notify the study sponsor.
- Any additional University departments involved in the conduct of the research;
- Any additional IRBs and institutions involved in the research (for multi-site studies, subcontracts, IRBs and institutions relying on CHS review);
- The FDA, when the research is FDA-regulated; and
- Any additional federal agencies involved when the research is subject to those agencies.

Suspensions and terminations of research will be handled and managed as outlined in Section 15 of this policy document.

14.9. Retaliation

The CHS will inform Investigators that, in accordance with University policy and the law, they are prohibited from engaging in any kind of retaliatory action following allegations of research non-compliance or misconduct.

15. Suspension or Termination of Research

The CHS is authorized to suspend or terminate the approval of research that:

1. Is not being conducted in accordance with the CHS’s requirements; and
2. Has been associated with unexpected or serious harm to participants.

Suspension of research approval means a halt in all research activities until the CHS determines whether the research may commence (with or without modifications to the research), or whether it shall be terminated.

Termination of research approval means a permanent stop to the research and all related activities.

Suspensions or terminations of approval of research are determined at a convened CHS meeting. When the CHS votes to suspend or terminate the CHS approval of a research study based on a

serious adverse event, unanticipated problem or serious or continuing non-compliance, it must consider whether the suspension or termination requires that current participants be withdrawn from the study and/or whether other measures must be taken to protect them.

If the CHS determines that participants must be withdrawn from a clinical study involving a drug, test article or treatment of any kind, the CHS must determine the necessary steps to be taken to ensure the safety, welfare and rights of those participants, e.g., drug taper, final visit, lab tests, continuation of treatment, other follow-up. Additionally the Investigators will be reminded that arrangements will need to be made for continued care by the participant's physician, another Investigator, or through appropriate referrals.

If the CHS determines that the suspension or termination of the research will place participants at risk of harm, the CHS must determine what participants are to be told, by whom, the manner in which they are to be notified (e.g., in writing or by telephone), and the timing of notifications.

In addition to the CHS, the study DSMB, the Dean of the Faculty of Medicine, the President or Provost of Harvard, and the Committee on Biological Safety (COMS) may suspend or terminate research; all such suspensions and terminations must be reported to the CHS Office within 24 hours by the official or Committee suspending or terminating the research, and must be evaluated by the convened CHS. Additionally, in the event of an extreme or immediate emergency, the CHS Chair or IO may suspend the research until it can be further evaluated by the convened CHS, and any other appropriate entity responsible to review the research or activities of the Investigator. These suspensions must also be reported to the CHS Office within 24 hours and evaluated by the convened CHS.

15.1. Notification to Participants

Depending upon the reasons for the suspension or termination and the design of the protocol, the CHS may require that participants who have been consented or enrolled in the study be notified of the suspension or termination.

Ordinarily, participants will be notified by the Investigator of a study termination and reason for the termination, however depending on the reasons of the termination, the notification may come from another party (such as a Co-Investigator or the Department Chair). Participant notification will be given in a manner so as not to arouse concern but to fully inform them of the situation. Letters will:

- Be written and signed by the Investigator and must additionally be reviewed and signed by the CHS Chair and the ORSP Director, before being sent by the Investigator to participants;
- Contain the contact information of the Investigator, ORSP Director, and the study sponsor for the participant to contact for further information;
- Inform the participants of any follow-up procedures that are needed or required for their safety and a recommendation made as to how this follow-up can be done and by whom.
- Direct participants to notify the ORSP Director, the Investigator or the Sponsor of any adverse event or problem that occurs during the follow-up period.

15.2. Notification of CHS Determinations to Investigator, Institutional Officials, and Regulatory Agencies

Whenever the CHS suspends or terminates the approval of a study due to serious or continuing non-compliance or an unanticipated problem involving risks to participants or others, the ORSP Director will draft a report of the suspension/termination. The report will include the circumstances surrounding the suspension or termination, the findings of the CHS in making the determination to suspend or terminate the research, any necessary steps to be taken to ensure the safety, welfare and rights of past or present study participants (e.g., drug tapers, continuation of treatment, notification to participants, etc.), and any corrective actions for the Investigator. The report is reviewed and approved by the CHS Chair (and other CHS members, as the Chair determines) prior to distribution.

The following individuals and entities receive a copy of the suspension or termination report, ordinarily the next business day (and not later than 5 business days) after the CHS determination to suspend or terminate the research, by the ORSP Director:

- The Investigator and Co-Investigator;
- The Investigator's Faculty of Medicine Department Head (and any additional Department Heads where the Investigator holds multiple professional appointments)
- The Faculty of Medicine Institutional Official. The IO will contact any additional institutional authorities, such as the Dean of the Faculty of Medicine, the President of the University, the Associate Provost for Research, the representative from the Office of the General Council, and Risk Management and Audit Services;
- The Sponsored Research Administration representative (where grants are supporting the research), and the Office of Technology Development (where corporate/company contracts are supporting the research). SPA or OTD will notify the study sponsor.
- Any additional University departments involved in the conduct of the research;
- Any additional IRBs and institutions involved in the research (for multi-site studies, subcontracts, IRBs and institutions relying on CHS review);
- FDA, when the research is FDA-regulated;
- Any additional federal agencies involved when the research is subject to those agencies; and
- OHRP, as appropriate.

Investigators shall have the opportunity to respond to the suspension or termination and offer new procedures or a new research plan to protect the rights and welfare of the participants.

16. CHS Records

The CHS maintains the following documentation in its office: (1) discussions and decisions of reviews by the convened CHS; (2) discussions and decisions that take place by an expedited review procedure; (3) discussions and decisions that take place by an exempt review procedure; (4) communications between CHS members or CHS staff and Investigators and/or their staff; (5) study files; (6) CHS Membership Rosters; and (7) Policies and Procedures of the CHS.