Termination and Suspension of Research

Definitions:

Suspension: temporary cessation of IRB approval of research activities

Termination: permanent cessation of IRB approval of research activities

Authority of the Institutional Review Board (IRB) to suspend or terminate research

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the Common Rule (45CFR46) or the IRB's requirements or that has been associated with unexpected serious harm to participants. The IRB's authority to suspend or terminate research is retained regardless of whether the research was initially approved by the convened IRB, through expedited procedures, through limited IRB review, or is exempt. The IRB retains this ability to suspend or terminate research even when continuing review is not required.

IRB suspension or termination of research

Suspension or termination of IRB approval of research may be done by the convened board or, in instances where a study should be suspended or terminated immediately for subject safety, the IRB Chair may initiate suspension or termination and the IRB will be notified. Any immediate suspension or termination of research implemented by the IRB Chair will be reviewed at the next convened meeting.

The IRB may suspend or terminate research involving human subjects if it finds that:

1. The information submitted to the IRB for review by the investigator (or sponsor) omits pertinent information required by the IRB to review and evaluate the proposed research protocol.

2. The report of previous or on-going investigations concerning the study treatments or interventions, assessment procedures, investigational new drugs (INDs), medical devices, or other articles are inadequate to support a conclusion that it is reasonably safe to continue the investigation.

3. The available facilities, including those for the clinical laboratory, inpatients, outpatients, fitness activities, affiliate or collaborative sites, and/or the medical support have become inadequate to assure that the investigation will be conducted properly and in conformity with the proposed clinical protocol.

5. The investigational research does not conform to and/or is not being conducted in accordance with the approved protocol and/or the requirements of the IRB, FDA, Woman's Hospital, WHF, Woman's Health Research Center or other affiliate or collaborative site pertaining to human subject research.

6. The research exposes or may expose subjects to new unacceptable risks.

7. There is serious or continuing noncompliance.

8. There is notification of an unmanageable financial Conflict of Interest related to the research.

9. Disqualification of the Principal Investigator by OHRP, the FDA, the study sponsor, the Institutional Official, or other groups involved in oversight of human subjects research activities.

The IRB will consider the following:

- Any actions necessary to protect the rights and welfare of currently-enrolled participants
- The rights and welfare of participants when determining procedures for withdrawal of those enrolled (such as continuing the research under independent monitoring, arranging medical care outside of the research, etc.)
- Informing current and former participants of the suspension or termination
- Any adverse events or outcomes reported to the board

Reporting to agencies

The IRB will report the suspension or termination to the sponsor, FDA (if applicable), and OHRP (if applicable) within three working days. Any subsequent actions, such as changing or lifting a suspension or termination, will also be reported. Please note that only IRB suspensions or terminations of approved research are required to be reported to OHRP. If an investigator or an institutional official suspends or terminates approved research, such actions are not required to be reported to OHRP under 45 CFR 46.113.

Investigator responsibilities for suspended or terminated research

When the IRB terminates or suspends approval of a research study, the investigator will be notified in writing of this decision promptly. Any suspension or termination of approval will include a statement of the reasons for the Chair's and/or IRB's actions.

The investigator will be expected to submit a plan within one week for study termination outlining procedures for notification and safe withdrawal of participants enrolled. If follow-up or continued monitoring of participants for safety reasons is permitted or required by the IRB, the participants should be so informed and any adverse events reported to the IRB and sponsor.