
Yale University Institutional Review Boards

710 PR.3 IRB Review of Reports of Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others

Overview	1
Initial Review of Reports	1
Full Committee Review	2
Suspension or Termination of a Study	3

Overview

Reports of adverse events and unanticipated problems involving risks to subjects or others which are reported to the IRB will be promptly reviewed and resolved in a fair process and in accordance with all applicable regulatory requirements.

Initial Review of Reports

1. The IRB Chair or Compliance Manager, in consultation with the Chair, will initially assess the report and make a preliminary determination as to the seriousness or continuing nature of the event. The seriousness and risks to participants are evaluated on a case-by-case basis. In making the initial determination, the Chair or Compliance Manager will consider such issues as to what degree subjects were harmed or placed at an increased risk of harm, the risk level of the study, and specifics of the research protocol and research population.
2. If it is determined that the report concerns an adverse event that is not serious, unanticipated, or related to participation in the study or does not present an unexpected risk to subjects or others then the matter will be dismissed. If it is determined that the matter would be more appropriately handled by another body, then it will be referred as appropriate.
3. If subjects are at immediate risk of harm and may be placed at further risk while awaiting the further analysis or outcome of a convened IRB meeting and the investigator has not already suspended the protocol, then the Chair(s) may place the study on an administrative suspension pending further investigation.
4. If the report concerns an event that may be serious, unanticipated, and related to involvement in the protocol or which involves risks to subjects or others then the Chair or other experienced IRB designee will undertake further inquiry. The Chair will notify the Institutional Official and when appropriate, the Office of Human Research Protections, and the Food and Drug Administration, of the event.

The purpose of the inquiry is fact-finding, and may involve examination of study records and discussion with the research team, other personnel, research participants, witnesses, and others as appropriate. The results of the inquiry will be shared as below.

a) Dismissal of the report:

If the report is found to concern an event that is not serious, unanticipated, or related to participation or an unanticipated problem that does not place, or have the potential to place research subjects or others at risk of harm following the inquiry and review by the Chair or designee, then the findings will be noted in the protocol file and, where appropriate, written notice provided to the principal investigator.

b) Forward of the report to the fully convened IRB:

Adverse event or unanticipated problem involving risks to participants:

If the incident is determined to be serious, unanticipated and related to participation, or an unanticipated problem involving risks to subjects or others (as defined in IRB Policy Section 710.2), then the matter will be reported to a full Committee.

Full Committee Review

The Committee will review the incident at a convened meeting and make its own determination of the severity and relatedness of the AE or the potential for harm to participants. The Committee may determine that:

1. More information is required and may request that the IRB designee undertake a further investigation and then report back to the Committee.
2. The incident does not meet the criteria for serious, unanticipated and related to participation and recommend that it be dismissed.
3. The incident constitutes a serious, unanticipated, and related event or an unanticipated problem involving risks to subjects or others.

If the Committee determines that the incident constitutes a serious, unanticipated and related event or an unanticipated problem involving risks to subjects or others as defined in Policy 710.2, it may take any action it deems necessary to protect the rights and/or welfare of the subjects involved, including, but not limited to:

1. Remediation or educational measures required of the research team
2. Monitoring of research activities by appropriate person(s).
3. Monitoring of the informed consent process by appropriate person(s).
4. Notification of past or current research participants.
5. Requiring re-consenting of participants.
6. Modification of the research protocol.
7. Increased reporting by the researcher of his/her human participants research activities to the IRB.
8. Requiring a more frequent continuing review (renewal of approval) schedule.
9. Requiring periodic audits by the Compliance Manager or other quality assurance/quality improvement auditors.
10. Restrictions the investigator's research practice, such as limiting the privilege to minimal risk or supervised projects.
11. Suspension of approval for one or more of the researcher's studies.
12. Termination of approval for one or more of the researcher's studies.
13. Referral to other University authorities or committees for possible further review and resolution by those bodies including possible disciplinary action up to and including termination in accordance with the appropriate disciplinary procedures for faculty, staff, and students.

For all incidents determined by a full Committee to be serious, unanticipated and related to participation in the study or to be an unanticipated problem involving risks to subjects or others (as defined in IRB Policy 710.2) the following individuals will be notified within 7 days: the PI and Faculty Advisor, where applicable, the Department Chair involved in the research, and the Institutional Official. Where applicable, the IRB will also notify within 30 days University Grant and Contract Administration; OHRP; FDA; the funding agency and for other institutions participating in the research, the HRPP Administrator(s) and the IRB Chair(s) of those institutions.

The Committee's determination and required actions will be communicated to the PI in writing. The PI is responsible for ensuring written documentation of completion of any required actions is received by the IRB within 30 days. Once the appropriate actions are taken, the matter will be considered resolved. A final report detailing the nature of the event, any findings made and actions taken, and the resolution of the matter will be communicated, in writing, to the Investigator and others as appropriate. A copy of all correspondence and the final report will be maintained at the IRB.

Suspension or Termination of a Study

If a study is suspended or terminated, new participants may not be enrolled and no study procedures may take place unless the IRB or IRB Chair determines that continuation of study procedures is in the best interest of currently enrolled participants. See Procedure 700 PR.4 Suspension and Termination of Human Research.