
Yale University Human Research Protection Program

700 PR.3 IRB Review and Investigation of Reports of Noncompliance

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Overview

Reports of noncompliance which are reported to the IRB will be promptly reviewed and resolved in a fair process and in accordance with all applicable regulatory requirements and Yale policies.

Sources of Reports of Noncompliance

Information regarding noncompliance may come to the attention of the IRB from a number of different sources, including new applications, research summaries and progress reports from investigators, internal audits, FDA audit reports, monitoring activities by sponsors, adverse event/safety reports, members of the research team, participants or their family members, community members, and other sources. Each complaint or concern is taken seriously and reviewed by the IRB Chair or designee in a consistent, prompt, and professional manner. Care is taken to maintain confidentiality. See also Procedure 700 PR.2: Soliciting and Responding to Research Participant Feedback and Concerns.

Initial Review of Reports of Noncompliance

1. The IRB Chair, Compliance Manager, or other qualified designee will initially assess the report or allegation of noncompliance and make a preliminary determination as to the seriousness or continuing nature of the noncompliance.
 2. The degree of noncompliance is evaluated on a case-by-case basis. In making the initial determination, the Chair, Compliance Manager or other qualified designee will consider such issues as to what degree participants were harmed or placed at an increased risk of harm, the risk level of the study, willfulness of the noncompliance, and specifics of the research protocol and research population. Consideration will also be given as to whether or not the incident compromises the integrity of the study or the validity of the data collected.
 3. If it is determined that the allegation or investigator report is unjustified, or does not meet the threshold for minor, serious or continuing noncompliance, then the matter will be dismissed. If it is determined that the matter would be more appropriately handled by another body within the IRB or Yale, then it will be referred as appropriate. If it is determined that the allegation or investigator report may constitute minor noncompliance, serious noncompliance, or continuing noncompliance, then a formal inquiry will be conducted as described below.
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Inquiry and Further Action

The Compliance Manager, the Chair or other experienced designee will undertake the inquiry of the allegation(s) or investigator report within 5 working days of the allegation being reported to the IRB. 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, the complainant (if not anonymous), and others as appropriate. The PI will be notified in writing of the allegation and have an opportunity to respond to the allegation(s) during this initial inquiry. The results of the inquiry will be shared with the Principal Investigator and others as described below.

1. Dismissal of the allegation or complaint as unjustified:

If the allegation or complaint is found to be unjustified following the inquiry and review by the Chair or designee, then the findings will be noted in the IRB records and, where appropriate, written notice provided to the principal investigator. Dismissal of allegations or complaints will be subject to periodic evaluation to ensure consistency in making determinations.

2. Referral of the allegation or complaint to more appropriate authority:

If the allegation or complaint is found during the inquiry to potentially violate other University policies, such as academic misconduct or financial mismanagement, then the complaint will be shared or referred to the appropriate University authority(ies) for resolution. If the allegation or complaint is found to involve noncompliance as well as violation of other University policies, then the appropriate authority will be notified of the findings by the IRB. The IRB will cooperate and coordinate its reviews with the other University authorities to avoid duplication of effort.

3. Minor noncompliance:

If the noncompliance is determined to be minor, then the issue may be resolved between any combination of the IRB Chair or designee, Compliance Manager, principal investigator and Department Head(s). The Compliance Manager will document and compile the information and make recommendations for resolution of the issue. Possible recommendations may include:

- a. Resolution through corrective actions;
- b. Resolution through educational measures appropriate to the nature and degree of the noncompliance.

If resolution through corrective or educational measures is required, then the investigator must provide written documentation of completion of the measures to the IRB within 30 days of the investigator being notified.

The Compliance Manager will notify the investigator in writing that corrective action plan is adequate and that the matter has been resolved.

4. Serious and/or Continuing Noncompliance:

If the inquiry suggests that the incident may constitute serious or continuing noncompliance, then the matter will be considered by a fully convened IRB. The Chair or designee will notify the investigator and the Institutional Signatory Official of the incident and its possibility of constituting serious or continuing noncompliance. The Chair or designee may also provide preliminary notice to the Office of Human Research Protections and/or the Food and Drug Administration, as appropriate.

If research participants are at immediate risk of harm or have the potential to be placed at further risk while awaiting the outcome of a convened IRB meeting, then the Chair(s) may place one or all aspects of the study on suspension pending the decision of the full IRB.

Review of Potentially Serious and/or Continuing Noncompliance by a Fully Convened IRB

The fully convened IRB will review the incident and make its own determination. The IRB may determine that:

1. The incident does not meet the criteria for serious or continuing noncompliance and recommend that it be handled as minor noncompliance described in #3 above; or
2. More information is required and may request that the Compliance Manager undertake a further investigation and then report back to the Committee; or
3. More information is required and may request that an ad hoc panel of three IRB members (other than the Chair) undertake further investigation. This ad hoc panel will consist of IRB

members whose areas of expertise are suited to reviewing the complaint and area of study. The ad hoc panel may also include the IRB member or the Compliance Manager who conducted the initial inquiry in lieu of a third IRB member. The ad hoc panel may conduct further interviews or other methods of information gathering. The researcher under investigation will be given an opportunity to submit written comments and to appear before the ad hoc panel on at least one occasion prior to an investigative report being issued. The ad hoc panel will provide a written report to the fully convened IRB following their inquiry, including a summary of the information gathered, conclusions and recommendations. The fully convened IRB will review the report in the same manner as the initial report; or

4. The incident constitutes serious and/or continuing noncompliance.

If the IRB determines that the incident constitutes serious and/or continuing noncompliance, it may take any action it deems necessary to protect the rights and/or welfare of the participants 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 the fully convened IRB to be serious or continuing noncompliance the IRB will notify the following individuals within 7 days: the PI and Faculty Advisor, where applicable, the Department Chair involved in the research, and the Institutional Signatory 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 IRB's determination and required actions will be communicated to the investigator in writing. The investigator must provide written documentation of completion of any required actions to the IRB within 30 days. Once the appropriate corrective actions are complete, the matter will be considered resolved. A final report detailing 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 in the IRB records.

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.

Revision History

October 25, 2010, June 17, 2010 and January 26, 2009