Overview

Reports of noncompliance which are reported to the Yale Institutional Review Boards (IRBs) 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, noncompliance/protocol deviation 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, Human Research Protection Program (HRPP) 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 IRB Chair, HRPP 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 HRPP or Yale, then it will be referred as appropriate. If it is determined that the allegation or investigator report may constitute minor, serious, or continuing noncompliance, then a formal inquiry will be conducted as described below.

Inquiry and Further Action

The HRPP Compliance Manager, or other experienced designee will promptly undertake the initial fact-finding and inquiry of the allegation(s) or investigator report after an allegation has been 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. If the allegation is made by someone other than the Principal Investigator (PI), 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 PI 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, then the findings will be noted in the IRB records and, where appropriate, written notice provided to the PI. 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, HRPP Compliance Manager, PI and Department Head(s). The HRPP Compliance Manager will document and compile the information and make recommendations for resolution of the issue. Possible recommendations may include:
   a. Resolution through corrective and/or preventive 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 PI must provide written documentation of completion of such measures to the IRB within 30 days of being notified.

   Following receipt of such written documentation from the PI, the HRPP Compliance Manager or designee will confirm in writing that corrective and preventive 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 IRB Chair, HRPP Compliance Manager or designee will notify the PI and the Institutional Signatory Official of the incident and its possibility of constituting serious or continuing noncompliance. The IRB Chair, HRPP Compliance Manager or designee may also provide preliminary notice to any applicable Federal agency, such as the Office of Human Research Protections (OHRP) and/or the Food and Drug Administration (FDA), 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 IRB Chair(s) may place one or all aspects of the study on hold 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 PI will be informed that he/she is welcome to attend that meeting to discuss the concerns and clarify the fact-finding information. 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 HRPP Compliance Manager undertake a further investigation and then report back to the IRB; or
3. More information is required and may request that an ad hoc panel of three IRB members (other than the IRB 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 HRPP 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 its 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 research 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. Re-consenting of participants.
6. Modification of the research protocol.
7. Increased reporting by the PI of his/her human participants research activities to the IRB.
8. More frequent continuing review (renewal of approval) schedule.
9. Periodic audits by the Compliance Manager or other quality assurance/quality improvement auditors.
10. Restrictions to the PI's research practice, such as limiting the privilege to minimal risk or supervised projects.
11 Suspension of approval for one or more of the PI's studies.
12 Termination of approval for one or more of the PI'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 seven (7) days of such determination: the PI and Faculty Advisor, where applicable, the PI’s Department Chair, and the Institutional Signatory Official. Where applicable, the IRB will also notify within 30 days of such determination, Yale 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 any required remediation or corrective and preventive actions (CAPA) will be communicated to the PI in writing. The PI must provide written documentation of completion of any CAPA to the IRB in the time frame designated in the CAPA. Once the PI (and others, as applicable) have satisfied the requirements of the CAPA, the matter will be considered resolved. A final report detailing resolution of the matter will be communicated, in writing, to the PI 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, no new participants may 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