

Series 802 IRB Review of Noncompliance | Institutional Review Board

Review of Noncompliance by the Convened IRB from Series 802 of the Standard Operating Procedures

I. Definitions

Noncompliance is any situation, incident, or process during the conduct of human subjects research that is inconsistent with any of the following: applicable local, state, or federal law; USU Policies, IRB SOPs; approved IRB protocols; or any directive from the USU IRB.

Serious Noncompliance is any noncompliance which, in the judgment of the IRB, places human subjects at elevated or unreasonable risk; decreases potential benefits to participants; jeopardizes the safety, welfare, or rights of research participants or others; compromises the integrity of the human research protection program; or compromises a research participant's ability to render informed consent.

Continuing Noncompliance is any action or omission which, in the judgment of the IRB Chair or Convened IRB, demonstrates a pattern of noncompliance over time and/or across research projects. Such a pattern suggests that the likelihood of noncompliance will continue without intervention.

II. Review of Noncompliance by the Convened IRB

The convened Utah State University Institutional Review Board shall, based on the findings provided by the investigative team and materials provided by the investigator(s), make the final determination of whether the allegations of noncompliance constitute noncompliance, and if so:

1. Whether the noncompliance is serious; and/or
2. Whether the noncompliance is continuing.

The investigators about whom the allegations pertain shall be notified in writing of the IRB's determinations regarding the existence and nature of noncompliance. If the noncompliance is not serious or continuing, it shall be handled as outlined in SOP 801.IV. If serious or continuing noncompliance is present, the IRB shall also notify the cognizant Dean and Department Head, as well as the Institutional Official, and any other party the IRB deems appropriate (e.g. participants, research staff, etc.). Sponsor notifications are addressed in Section V, below. All notifications should be delivered only after the time frame for notice of appeal, outlined in SOP 803, has passed.

If the research project was suspended by the IRB Chair during the inquiry or investigatory process, the IRB shall review the IRB Chair's suspension determination at the same meeting.

III. Corrective Action

If the Convened IRB finds noncompliance, it shall require a Corrective Action Plan (CAP). Such plans may include, but are not limited to:

1. Referral to the IRB Chair and/or HRP Director for minor corrective action in cases of minor noncompliance;
2. Referral to the investigator for a proposed Corrective Action Plan;
3. Temporary suspension of the protocol pending further corrective action;

4. Temporary suspension of enrollment of new participants pending further corrective action;
5. Termination of a protocol or all human subjects research activity related to the noncompliance;
6. Destruction or sequestration of data;
7. Mandated additional training in the protection of human subjects in research for investigators and research staff;
8. Required supervision of the research or investigator by a qualified mentor;
9. Suspension of the individual investigator(s) or staff responsible for the noncompliance from the research activities;
10. Recommend Suspension or termination of the investigator's ability to oversee or conduct human subjects research;
11. Notification to research participants of the noncompliance;
12. Required modifications to the protocol and accompanying documents in order to regain approval;
13. Mandated process for obtaining the continued informed consent of the participants;
14. More frequent review of one or more of the noncompliant investigator's protocols;
15. IRB or third party monitoring of the consent processes;
16. IRB or third party monitoring of the data collection process;
17. IRB or third party monitoring of data storage and maintenance; and
18. Recommendation of further action by the Vice President for Research, Dean, Department Head, or Tenure and Promotion Committee, which may include but is not limited to:
 - a. Retraction of published or presented work related to the noncompliant research;
 - b. Retraction of submitted work related to the noncompliant research;
 - c. A letter of reprimand to be placed in the investigator's or student's file;
 - d. Reporting to the appropriate professional organization regarding the noncompliant behavior of a member.

At all times, the IRB shall act in accordance with its ethical and legal mandate to ensure the protection of human subjects participating in research. The Corrective Action Plan shall be delivered to all relevant investigators, in writing, and may be combined with the finalized findings of the Convened IRB.

III. Findings

Once the Convened IRB has reviewed the preliminary report and findings, they shall finalize the findings and deliver those findings to the Principal Investigator and other relevant members of the research team, in writing. The delivery of these finalized findings shall begin the tolling of the time period for appeal.

IV. External Reporting of Noncompliance

Reports of serious or continuing noncompliance shall be submitted to federal agencies and/or other relevant parties (such as a covered entity in the event of a HIPAA violation) in compliance with applicable regulations. The IO shall ensure delivery within an appropriate time frame – usually, 15 days following the resolution of the issue by the IRB, which in the case of noncompliance, is the resolution of the appeal or the passage of the time frame for appeal.

The HRP Director shall have responsibility for coordinating with the principal investigator, gathering any additional required information and writing the initial report, which shall include:

- The nature of the event or problem
- The findings of USU
- The action taken by the IRB and USU
- Facts which support the underlying actions taken by the IRB and USU
- Any plans or recommendations for a continuing inquiry or investigation

The HRP Director shall submit the draft report in a timely manner to the IRB Chair and IO. The IO shall have responsibility for final approval of the report, and for its submission to the appropriate agency or entity. Copies of the reports shall be distributed to the IRB and to other federal agencies when research is overseen by those agencies and such agencies require reporting separate from reports to OHRP.

V. Efforts to Enhance Understanding

In the course of processing noncompliance, the HRP Director, IRB Chair, IO, or IRB might identify educative or guidance measures that could be taken to prevent the recurrence of similar issues with other investigators. When these individuals or bodies identify an area where investigator understanding or education could be enhanced, those recommendations should be delivered to the HRP Director, in writing, and the HRP Director shall consider these recommendations and implement them, where appropriate and feasible. This might include modifications of the protocol template, the creation of a new educational resource, the creation of a new template document, delivery of in-person training, or other measures that fit within the HRPP's responsibility to continuously educate members of the HRPP