

Series 801 Noncompliance

Noncompliance from Series 801 of the Standard Operating Procedures

I. Definitions

Out of Compliance is a status wherein an approved protocol has been discovered to have a passive lapse that can be easily corrected, and which does not impact the rights or welfare of research participants or any of the approval criteria documented by the IRB.

Noncompliance is a 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. Managing a Protocol that is Out of Compliance

When information provided to researchers, the IRB, or HRP staff indicates that a protocol is out of compliance, the HRP Director may determine that the protocol is out of compliance. When such a discovery is made, the HRP Director will work with the Principal Investigator to bring the protocol back into compliance within five business days of the discovery, or a shorter timeframe if the situation (in the opinion of the HRP Director) warrants. A protocol that remains out of compliance for more than five business days shall be considered noncompliance, and will be processed under Section III (Processing Allegations of Noncompliance) of this Standard Operating Procedure, absent extenuating circumstances.

Examples of a protocol that is out of compliance such that it can be corrected include:

- Lapse in CITI Training for one of the study team members in a minimal risk protocol, where that study team member has not interacted with participants or their identifiable information since the expiration date;
- A slight delay in the destruction of identifying information or specimens based on the timeline shared with participants where the information has not been used or analyzed since the approximate approved date of destruction;
- Research data not having been deleted from a personal device following movement to the approved storage mechanism; and
- Failure to remove a research assistant or co-investigator whose information was not on recruitment or informed consent material and who recently ceased work on the protocol.

Several instances of a protocol being out of compliance may result in referral to the noncompliance process, if the lapses indicate a pattern of ineffective oversight, regardless of the timeline for correcting the lapses

III. Processing Allegations of Noncompliance

When any Utah State University employee, student, or affiliate receives information related to Noncompliance and those activities appear to be related to research being conducted by USU personnel or under USU's purview, those allegations shall promptly be reported to the IRB Chair, the IO, the HRP Director, or HRP staff. All allegations of Noncompliance received by someone other than the IRB Chair shall be expeditiously reported to the IRB Chair.

The IRB Chair shall receive the Noncompliance allegation and, using the information available, make an initial determination of whether

1. The activities constitute human subjects research; and if so
2. Whether the substance of the allegation is likely to constitute serious or continuing Noncompliance.

The IRB Chair may also determine that the activities described in the allegation do not constitute human subjects research Noncompliance.

Utah State University does not tolerate retaliation against individuals who come forward in good faith with allegations of Noncompliance. Retaliation will be immediately reported to University administration.

IV. Suspension of Research Pending Disposition

The IRB Chair or Institutional Official may take action to suspend the research that is the subject of the Noncompliance allegation, pending a formal inquiry and/or determinations by the convened IRB. The IRB Chair or Institutional Official may suspend the research if:

1. The activities appear to be human subjects research; and
2. The alleged Noncompliance appears to raise the level of risk to the research participants. Suspension of research should not be implemented if the suspension would cause new or increased risks to participants.

V. Processing Allegations of Noncompliance

After the IRB Chair has received the allegation of Noncompliance and made the initial determinations described in Section II (Managing a Protocol that is Out of Compliance), the IRB Chair shall determine:

1. That sufficient information exists to find that no human subjects research Noncompliance has occurred;
2. That sufficient information exists to find that the Noncompliance is not serious or continuing, and develop a corrective action plan for the Principal Investigator;
3. That more information is needed before findings can be made regarding whether the allegations constitute serious or continuing Noncompliance, or regarding the jurisdiction of the IRB, and refer the matter for further inquiry;
4. That sufficient information exists to find serious or continuing Noncompliance and refer the matter for investigation; and/or
5. That the allegation is sufficiently serious to be turned over to the Institutional Official, cognizant dean, and/or department head for immediate action.

If the IRB Chair determines that the matter should be referred for further inquiry or investigation as described in Sections 3) or 4), above, the IRB Chair shall refer the matter to the Human Research Protections Director. When an investigation is requested, the HRP Director shall, in consultation with the Institutional Official and IRB Chair, identify appropriate membership of the investigative team, which may consist solely of the HRP Director.

Inquiries shall be conducted by the HRP Director, and findings regarding whether an investigation is warranted will be reported to the IRB Chair for further action, i.e. whether moving to an investigation in line with Section D, above, is appropriate.

Except when suspension of the research is appropriate under Section III (Processing Allegations of Noncompliance), the Principal Investigator might not be contacted until the inquiry or investigative team has had an opportunity to sequester documents related to the alleged noncompliant research activities.

Investigations shall be carried out expeditiously and thoroughly, using approved IRB forms and processes. Utah State University's Scientific Misconduct Guidelines should serve as guidance for carrying out the investigation, especially as to procedures for conducting interviews, appropriate evidentiary standards, standards for notifying parties, and other procedural issues.

During the course of the investigation, additional areas of Noncompliance may be uncovered; those areas of Noncompliance should be investigated alongside the initial allegations.