Series 803 Appeal of Noncompliance Determinations

Appeal of Noncompliance Determinations from Series 803 of 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. Procedures for Appeal

Investigators who wish to appeal any determinations of the IRB Chair or Convened IRB may do so. Procedures for appealing noncompliance determinations are outlined here, and supersede the provisions of the SOPs in Series 400 regarding appeals, due to the time-sensitive nature of processing issues of noncompliance.

If an investigator disagrees with an IRB Determination related to Noncompliance, the Investigator may submit the appeal and any information supporting the appeal within 10 business days of being notified of the determination. Investigators have ten business days from the receipt of the final findings to submit a written appeal to the IRB, at irb@usu.edu or in hard copy, to 1450 Old Main Hill, Suite 155, Logan, UT 84322. If hard copy will be utilized, the materials must be received by close of business on the tenth business day.

Notice of the intent to appeal must be submitted in writing within five business days, using the same delivery mechanisms. The appeal will be reviewed at the next available meeting of the Convened IRB. The written appeal must clearly present:

1. Which finding(s) of the Convened IRB or IRB Chair are being disputed;
2. All evidence supporting the investigator's claim that the finding(s) should be overturned; and
3. All relevant reasoning supporting the investigator's claim that the finding(s) and determination(s) should be overturned.

Investigators are welcome to combine their individual appeals into one written appeal, or may file them separately for separate consideration. The Investigator may also request to be in attendance at a convened meeting to provide clarification or additional information to the IRB. The Investigator may not be present for the vote on the appeal. The Convened IRB may accept the appeal, or deny the appeal. The Investigator is notified in writing of the decision. In the event that the appeal is successful, the IRB will automatically review the Corrective Action plan. If the appeal is denied, the IRB decision is final and the original determination stands.

Notifications of the noncompliance will not be sent to the cognizant Dean, Department Head, or other parties until the period for informing the IRB of the intent to appeal has passed without notice, or until the appeal has been heard by the Convened IRB, whichever occurs first.