

Noncompliance

Noncompliance to the Common Rule or to the requirements of the IRB increases risks to participants in human research. Investigators are encouraged to report to the IRB chair or administrators situations in which agreed upon procedures have not been implemented as expected. Noncompliance may also come to light during continuing reviews, or through monitoring of research activities. In many cases non-compliance that is neither serious nor ongoing will be corrected through an agreement between the investigator and the IRB chair. When the chair determines that non-compliance is serious or ongoing the convened IRB meets to discuss the risks posed by the non-compliance and considers actions that would be appropriate. The existing form for reporting of Unanticipated Problems has been expanded to provide for a means of reporting noncompliance and determining whether it is serious or ongoing. Noncompliance can result in the IRB suspending or terminating the research.

The terms “serious” and “ongoing” have not been rigorously defined in the Common Rule. An example of serious noncompliance at USU might be failure to obtain informed consent when the IRB has not waived this requirement. Ongoing noncompliance might be a pattern of not securing study data appropriately as required by the Common Rule or the IRB. Another example might be a pattern of not submitting Protocol Status Report Forms in a timely manner. Noncompliance would also extend to other activities, such as financial malfeasance or research misconduct. In cases that extend beyond the IRB’s jurisdiction, the IRB chair may refer the noncompliance to the Federal Compliance Manager.

USU Procedures for considering noncompliance

k. Investigating Noncompliance.

The IRB shall expeditiously process all reported instances of noncompliance as set forth in Policy #308, “Human Participants in Research.” Upon receiving information indicating possible non-compliance, the IRB chair shall make a determination if the non-compliance involves Human Research, and if so, whether the non-compliance is serious or continuing. If the non-compliance is neither serious nor continuing, the IRB chair shall take steps to correct the non-compliant behavior with the investigator and shall report the incident to the cognizant dean, department head, and the IO and FCM.

If the noncompliance is found by the IRB Chair to be serious or continuing, the non-compliant behavior may be reported to the OCA for investigation. The FCM, together with the IRB Chair and the IO shall assess the information available immediately to determine if there is an elevated risk of harm to participants, and if so, what steps will be taken to protect the rights and welfare of participants. ...

When the OCA has been delegated responsibility for conducting the inquiry and investigation, documentation and other pertinent information shall be provided to the FCM in order to carry out these processes.