

I5D PR1 Reporting Noncompliance to the IRB

Overview

This procedure describes the process for reporting allegations of noncompliance with University of Nevada, Reno (the University) and federal and state requirements for the protection of human participants including noncompliance with approved Institutional Review Board (IRB) protocols.

It is recognized that noncompliance with IRB-approved protocols as well as with established regulations, policies and procedures may occur during the course of a research study. Some sponsors and investigators refer to such incidents as deviations, while others would consider all such events as noncompliance. The University IRBs consider all instances of protocol deviations as instances of noncompliance with the approved protocol and processes them as such.

Where to Report

Individuals who are uncertain if an incident or occurrence constitutes noncompliance should contact the Office of Human Research Protection (OHRP) by phone at 775.327.2368 to discuss their concerns and preferable next steps.

Unexpected problems, incidents, or events including situations that may indicate noncompliance has occurred must be reported to the Office of Human Research Protection (775.327.2368) within five working days.

Reports of noncompliance involving the conduct of a University IRB, IRB Chair or members, or the OHRP Director or staff should be reported to the Vice President for Research by phone 775.327.2363 or email research@unr.edu.

How to Report

Allegations of noncompliance are best submitted in writing by completing I12F FO2 Investigator Form for Reporting Unexpected Problems or Events; however, they may be presented orally to OHRP staff or an IRB member.

To the extent possible, the report should include the following:

- the study title, protocol number, and name of the principal investigator;
- a description of the event, or the sequence of events that led to the potential noncompliance and the reason why the events are considered noncompliance (e.g., references to the specific procedures as outlined in the approved protocol);

- an assessment of why the event occurred or may have occurred;
- an assessment of whether participants may have been adversely affected by the event or exposed to increased risk or reduced benefits or whether the event compromises the integrity of the study;
- a description of any changes to the protocol that will be made as a result of the event;
- a description of any corrective actions that can be, or have been implemented to ensure that similar events do not occur in the future; and
- the name of the individual reporting the event (although anyone wishing to remain anonymous may refrain from giving her or his name).

Note: The name of the individual reporting an allegation of noncompliance will be maintained confidentially by the OHRP and the IRB to the fullest extent possible (see I5D PR2 IRB Investigation and Review of Reports of Noncompliance).