

II2F PR3 IRB Review and Reporting Requirements: Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others

Overview

Reports of adverse events and unanticipated problems involving risks to subjects or others (henceforth referenced as Unanticipated Problems) which are reported to the University of Nevada, Reno (the University) Institutional Review Board (IRB) will be promptly reviewed and resolved in a fair process and in accordance with all applicable regulatory requirements and University policy.

Note: Additional reporting requirements for VA and Department of Defense (DoD) research are noted in separate subsections under section II2F3.

II2F1 Initial Review of Reports

The IRB Chair or Vice Chair, or IRB Program Manager in consultation with the Chair will initially assess the report and make a preliminary determination as to the seriousness or continuing nature of the event. She or he will evaluate the seriousness and risks to participants on a case-by-case basis. In making the initial determination, the Chair or Program Manager will consider such issues as to what degree subjects were harmed or placed at an increased risk of harm, the risk level of the study, specifics of the research protocol and characteristics of the research population.

1. If it is determined that the report concerns an adverse event that is neither serious nor unanticipated and it is not an Unanticipated Problem (see Policy II2F for definitions of these terms) the matter will be dismissed. The investigator making the report will be notified and the event will be closed. If it is determined that the matter would be more appropriately handled by another body, it will be referred as appropriate and this action will be noted in the protocol file.
2. If subjects are at immediate risk of harm and may be placed at further risk while awaiting the analysis or outcome of a convened IRB meeting and the investigator has not already suspended the protocol, then the Chair may place the study on an administrative suspension pending further investigation (see Procedure II2F PR 4 Suspension and Termination of Human Research).
3. If the report concerns an internal event (i.e., event that occurred locally) that may be serious and was not anticipated, and is associated with an participant's involvement in the protocol but is not necessarily drug-related, or which involves risks to subjects or others, the Chair or other experienced IRB designee will undertake further inquiry.

The purpose of the inquiry is fact-finding, and may involve examination of study records and discussion with the research team, other personnel, research participants, witnesses and others as appropriate. The inquiry generally results in one of two outcomes.

- a. The Chair or designee determines that the event is not serious, unanticipated or associated with participation in the research, nor is it an Unanticipated Problem and dismisses the report. The findings of the inquiry will be noted in the protocol file and, where appropriate, written notice will be provided to the principal investigator.
- b. The Chair or designee determine that the event serious, unanticipated and associated with participation in the research, or it constitutes an Unanticipated Problem (as defined in IRB Policy II2F) and forwards the report and summary of findings from the inquiry for review at a convened IRB meeting.

II2F2 Review at Convened IRB Meeting

The IRB will review the incident at a convened meeting and make its own determination of the severity and relatedness of the AE, the potential for harm to participants and whether or not the incident constitutes an Unanticipated Problem.

The convened IRB may determine that

1. more information is required and may request that the IRB designee undertake a further investigation and then report back to the Board;
2. the AE does not meet the criteria for serious, unanticipated and associated with participation, and is not an Unanticipated Problem and may recommend that it be dismissed; or
3. the incident constitutes a serious, unanticipated adverse event that is associated with participation in the research (even if not drug-related) or it is an Unanticipated Problem.

If the IRB determines that the incident constitutes a serious and unanticipated event that is associated with participation in the research or it is an Unanticipated Problem as defined in Policy II2F, it may take any action it deems necessary to protect the rights and/or welfare of the subjects involved, including, but not limited to the following:

1. remediation or educational measures required of the research team;
2. monitoring of research activities by appropriate persons;
3. monitoring of the informed consent process by appropriate person;
4. notification of past or current research participants;
5. requirement to re-consent participants;

6. modification of the research protocol;
7. requirement for increased reporting by the researcher of her or his human participants research activities to the IRB;
8. requirement for a more frequent continuing review (renewal of approval) schedule;
9. requirement for periodic audits by the who is the Quality Improvement IRB Program Manager or other quality assurance or quality improvement auditors;
10. restrictions on the investigator's research practice, such as limiting her or his research privileges to minimal risk or supervised projects;
11. suspension of approval for one or more of the researcher's studies;
12. termination of approval for one or more of the researcher's studies; or
13. referral to other University authorities or committees for possible further review and resolution by those bodies including possible disciplinary action up to and including termination in accordance with the appropriate disciplinary procedures for faculty, staff, and students.

The IRB's determination, with required actions, will be communicated to the PI in writing. Within 30 days of receipt of the IRB's determination, the PI will submit a corrective action plan to the IRB. Once the appropriate actions are taken, the matter will be considered resolved. A final report detailing the nature of the event, any findings made and actions taken, and the resolution of the matter will be communicated, in writing, to the Investigator and others as appropriate. A copy of all correspondence and the final report will be maintained in the protocol file.

II2F3 IRB Reporting Requirements

II2F3a IRB Reporting Requirements for Unanticipated Problems

For all incidents determined at a convened IRB meeting to be serious, unanticipated and associated with participation in the study or to be an Unanticipated Problems (as defined in IRB Policy II2F) the following individuals will be notified within seven days: the PI; student investigator and Faculty Advisor, where applicable; the Department Chair involved in the research and the Institutional Official. Where applicable, the IRB will also notify within 30 days University Office of Sponsored Projects; DHHS OHRP; FDA; the funding agency and for other institutions participating in the research, the HRPP Administrator(s) and the IRB Chair(s) of those institutions.

II2F3b IRB Reporting Requirements for VA Research

Reporting Local, Serious Adverse Events in VA Research

If the convened IRB or the IRB reviewer determines that the problem or event was serious, unanticipated, and related to the research, the IRB chair or designee must report the event in writing, within five business days after the determination to the

- Medical Center Director,
- Associate Chief Of Staff For Research, and
- Research and Development Committee.

Reporting Unanticipated Problems in VA Research

For VA research, if the IRB categorized the event or problem as unanticipated, serious, and related, (i.e., the event constitutes an Unanticipated Problem), a report of the problem must be sent to the following entities:

- Office of Research and Development,
- Regional Office of Research Oversight,
- VA Privacy Office (when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information), and
- VHA Information Security Officer when the report involves violations of VA information security requirements.

II2F3c Reporting Unanticipated Problems for Department of Defense-supported Research

For DoD-supported research, reports of unanticipated problems involving risks to participants or others must be promptly reported to the DoD human research protection officer.

II2F4 Suspension or Termination of a Study

If a study is suspended or terminated, new participants may not be enrolled and no study procedures may take place unless the IRB or IRB Chair determines that continuation of study procedures is in the best interest of currently enrolled participants (see Procedure II2F PR4 Suspension and Termination of Human Research).