Noncompliance and Research Misconduct

Standard

The IRB shall use the OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events for the determination and reporting of unanticipated problems and adverse events.

An *unanticipated problem* is unexpected given the protocols described in the proposal, and given the characteristics of the subject population; related or possibly relate to participation in the research; and suggest that the research places the subjects at greater risk of harm than was previously known or recognized.

An *adverse event* is any untoward or unfavorable medical occurrence in a human subject that is temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events can be physical or psychological harms.

Serious or continuing noncompliance is defined in accordance with federal guidance as a deviation from the approved protocol, institutional policies, or applicable regulations that may increase risks to participants or affect the integrity of the research. Noncompliance may be minor or serious, and may occur as a single incident or as part of a pattern of repeated behavior.

Procedures

How to determine which adverse events are unanticipated problems:
Category A (Do Not Report): Adverse events that are not unanticipated problems (i.e. an expected adverse event)

Category B (Report): Adverse events that are unanticipated problems (i.e. an unexpected adverse event)

Category C (report): Unanticipated problems that are not adverse events

Guiding Questions

1. Is the adverse event unexpected?
2. Is the adverse event related or possibly related to participation in the research?
3. Does the adverse event suggest that the research places subjects or others at a greater risk of harm that was previously known or recognized?

Is the answer to *all three questions* is *yes*, then the adverse event is an unanticipated problem and must be reported.

Timeline for Reporting Unanticipated Problems

Unanticipated problems that are serious adverse events should be reported to the IRB within 1 week of the Investigator becoming aware of the event.

Any other unanticipated problem should be reported to the IRB within 2 weeks of the investigators becoming aware of the problem.

Serious or Continuing Noncompliance

Investigators may only conduct the human subjects research activities that have been approved by the IRB. Deviation from the approved protocol is considered noncompliance with the scope of the IRB approval. Noncompliance may be intentional or unintentional.

Serious or continuing noncompliance also includes intentional or unintentional research misconduct that violates the ethical norms of the investigators field of study and the ethical norms of human subjects research. Some examples of serious or continuing noncompliance include:

- Adding research activities that are not part of the approved protocol;
- Coercing subjects into participation in the research;
- Refusing to allow a subject to withdraw from a study;
- Conducting research activities at an external facility without permission or support from that facility;
- Releasing confidential information or data; and
- Not reporting serious adverse events

How to Report

- Investigators should submit reports of protocol deviations (violations) or noncompliance using the **Protocol Violation** form in eProtocol. If the deviation impacts the approved research plan, the investigator should submit an **Amendment** at the same time to ensure the protocol remains up to date and in compliance with IRB approval.
- Adverse events, whether serious or otherwise, should be reported using the **Serious Adverse Event** form in eProtocol.
- These reports serve as an essential record-keeping mechanism, ensuring that research activities align with ethical guidelines and that necessary modifications to protocols are documented and reviewed.
- Participants, research personnel, or other concerned individuals may report unanticipated problems, serious adverse events, or instances of serious or continuing noncompliance via email to the IRB, direct communication with an IRB member, phone calls, meetings, or

anonymous reporting through the IRB webpage. All reports will be treated confidentially, and federal whistle-blower protections apply.

Confidentiality of Reports

All reports of adverse events, unanticipated problems, or research misconduct will be confidential. The anonymity of the reporter will be maintained.

Review of Information About Unanticipated Problems, Serious or Continuing Noncompliance

Reports of adverse events, unanticipated problems, or research misconduct will initially be reviewed by the IRB chair. Serious adverse events or serious noncompliance may result in an immediate suspension of approval to allow the full IRB to convene to determine if the approval of the project should be terminated or suspended pending revisions to the protocol. A decision to terminate approval shall only be made on the recommendation of the full IRB.

Handling Serious or Continuing Noncompliance

The IRB has the authority to suspend or terminate approval of a study if serious or continuing noncompliance is identified. However, for researchers with repeated episodes of noncompliance or misconduct, the IRB may require additional oversight, such as **shortening the approval period for more frequent review** or mandating **regular check-ins**. These measures function as enhanced mentoring and monitoring to help researchers align their practices with ethical and regulatory standards, rather than as punitive actions.

In cases of serious or continuing noncompliance or research misconduct, the **FWA Institutional Official** will be notified. The Institutional Official will determine whether additional institutional actions are warranted, including notifying department chairs, deans, or other relevant administrators as necessary. This ensures that appropriate leadership is informed while maintaining confidentiality and due process for the investigator.

By implementing these structured reporting and review procedures, the IRB strives to ensure that research remains compliant, transparent, and up to date while providing appropriate guidance and oversight to investigators.

Document Attributes

Last approved by IRB: May 2025