Required Reporting of Unanticipated Problems and Protocol Deviations

Table of Contents: Required Reporting of Unanticipated Problems and Protocol Deviations

Policy Statement

Consistent with federal regulations, UIW IRB requires prompt reporting of unanticipated problems that may pose risks to participants or others. The policy applies to social, behavioral, educational and biomedical research.

Definitions

Unanticipated Problem: For the purposes of this policy, the following criteria exist:

a. was not anticipated or foreseen;
b. involves potential risk or harm to participants or others; AND
c. was deemed to be related to or caused by the research activity, including practices not directly involving the intervention.

Description and Procedures

A. Scope of Unanticipated Problems

The scope of what qualifies as an unanticipated problem may include one or more of the following:

1. an adverse event (including on-site or off-site injuries, side effects, deaths or other problems), which in the opinion of the primary investigator meet the definition of reportable events above;
2. an unexpected increase in the frequency or severity of an otherwise expected event;
3. new information from the literature, sponsor, or safety monitoring board that indicates an increased risk to participants;
4. protocol suspension by sponsor(s) due to increased risk(s) to participants;
5. changes in labeling or withdrawal from the marketing of any drug, device, or biologic used in the research protocol;
6. breach of confidentiality involving risk or harm to participants or others;

7. protocol deviation in that changes were made to the protocol without prior IRB review in order to eliminate apparent immediate hazards to participants;
8. protocol deviation in that accidental or unintentional changes were made to the IRB-approved protocol that involve harm to participants or an increased risk of harm;
9. any complaint by a participant that indicates an unanticipated risk that cannot be resolved by the research team; and/or
10. enrollment of incarcerated participants or other designated vulnerable populations in a protocol that is not approved specifically for their enrollment.

The above must be reported regardless of whether they occur during the study, after study completion, or after participant withdrawal or completion.

B. Process for Reporting

1. The principle investigator is responsible for ensuring completion of the online *Unanticipated Problem/Protocol Deviation Form* and a comprehensive and accurate accounting of the event to the IRB office. Federal regulations state that all unanticipated problems are to be promptly reported to the IRB. The window for promptly reporting unanticipated problems to the UIW IRB is 5 working days (Monday-Friday).

2. The report should include relevant dates, event description, actions taken, and next actions as a result of the event.

3. In addition to the report, the current protocol, consent form if applicable, and any study materials should be supplied, if they differ from the IRB-approved documents.

4. The items are routed to the Chair of the IRB (or designee) who will evaluate the unanticipated problem, consult with other members of the IRB, or the investigator as necessary. The Chair may act independently in cases of urgency, to protect the safety of research participants.

5. If determined that the event is NOT an unanticipated problem, no further action will be taken.

6. All or some of the following actions may be necessary to ensure the ongoing safety of participants:

    a. modification of the research protocol,
    b. modification of the information provided within the consent process,
    c. additional information provided to past participants,
    d. notification of current participants (when the information may be related to willingness to continue to participate in the study),
    e. current participants may need to be re-consented,
    f. modification of the continuing review schedule,
    g. monitoring of the research,
    h. monitoring of the consent process,
    i. suspension of all or some of the research,
    j. termination of the research,
    k. convening an emergency panel to discuss,
    l. referral to legal counsel and/or other institutional official, and/or
    m. no action (if appropriate).

7. Non-exempt protocols must be referred for review to the next meeting of the IRB, regardless of whether the protocol was initially approved through a Full Board process. The IRB will then make the following determinations:

    a. confirm that the designation of unanticipated problem applies;
    b. evaluate the adequacy of the immediate actions taken by the investigator to protect participants from further risk;
    c. determine the status of actions taken by the Chair and/or the designee;
    d. determine if actions are indicated (changes to research protocol and/or consent form);
    e. indicate for non-exempt research whether a report will be submitted to other University officials, state and/or federal agencies; and
    f. if the unanticipated problem is a result of a protocol violation, the IRB will determine whether the protocol violation described serious or continuing non-compliance. If so, appropriate reports to local, state, and federal agencies will be generated.

C. Protocol Deviations

If the IRB Chair and/or designee determines that a protocol deviation does not constitute an unanticipated problem involving risks to participants or other, the IRB still must determine whether the protocol deviation constituted a serious or continuing non-compliance.

Protocol deviations for non-exempt protocols must be referred to the IRB for review regardless of whether the initial protocol was approved through a Full Board review process. The IRB board must make the following determinations:

a. confirm that a protocol deviation occurred;
b. evaluate the adequacy of the immediate actions taken to protect the participants or other from risks;
c. determine whether other or additional actions are required, to include changes to the research protocol and/or consent process/form; and
d. determine if a corrective action plan is indicated for the protocol deviation. A report may be generated in accordance with federal oversight agency requirements.

D. Documentation of Reviews of Reported Events

Decisions of the IRB Chair and designees will be promptly reported and documented in writing within the IRB minutes. The UIW Office of Research and Sponsored Projects Operations will report all unanticipated problems involving risks to participants and others as well as serious or continuing non-compliance in accordance with the federal oversight agencies.

E. Responsibility to Monitor ALL Problems

It is the responsibility of the primary investigator to monitor ALL problems that involve risk to the research participants or others, both anticipated and unanticipated. The investigator should maintain a log of unanticipated problems, participant questions and complaints, as well as other issues that arise within the conduct of the research effort that she/he deems do not require reporting to the IRB.

The investigator and/or research team should:

1. record the occurrence of any problem within the study log,
2. consider the need for clarification of the problem within the consent document (amending the consent with IRB approval as necessary),
3. consider the need to further review and analyze event trends,
4. consider the need to change research procedures (submitting any changes to the IRB as amendments to the research protocol for review and approval),
5. consider consulting with the IRB Chair and/or designee as needed, and
6. recognize that the IRB may request some or all of the investigator logs and/or related documentation during a continuing review or audit process.

Effective Date

August 24, 2020

Revision History

References

Guidance on Reporting and Reviewing Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others
Suspension or Termination of Previously Approved Research
Reporting to Regulatory and Oversight Agencies