



WESTERN INSTITUTIONAL REVIEW BOARD®
3535 SEVENTH AVENUE, SW • OLYMPIA, WA 98502-5010
P.O. BOX 12029 • OLYMPIA, WA 98508-2029
(360) 252-2500 • 1-800-562-4789 • FAX (360) 252-2498

WIRB Reporting System for Unanticipated Problems that are Not Adverse Events

Federal Regulation 21 CFR 56.108(b)(1) and 45 CFR 46.103(b)(5) require the IRB to “follow written procedures for ensuring prompt reporting to the IRB...any unanticipated problems involving risks to human subjects or others...”

An unanticipated problem is defined as any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, or the Investigator Brochure; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the drugs, devices or procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

All reports to the IRB of unanticipated problems should explain clearly why the event is "unanticipated" and clearly explain why the event represents a “problem involving risks to human subjects or others.”

WIRB expects reports to the IRB of unanticipated problems to include a corrective action plan to address the issue, or written justification for why none is provided.

Please note that unnecessarily reporting problems that do not meet the criteria outlined above may impair the Board’s ability to review and respond in a timely manner to actual situations where subject rights, welfare or safety are threatened. Such reports will be returned to the sender.

Instructions for reporting unanticipated problems that are not adverse events.

Use the Report Form for Unanticipated Problems that are Not Adverse Events to report the following unanticipated problems:

- Unanticipated problems that do not fit the definition of an adverse event, but which may, in the opinion of the investigator, involve risk to the subject, affect others in the research study, or significantly impact the integrity of research data. For example, report occurrences of breaches of confidentiality, accidental destruction of study records, or unaccounted-for study drug.
- *Unplanned* protocol deviations/violations that have already occurred, that may adversely affect the rights, safety or welfare of subjects or the integrity of the research data, AND for which you did not seek WIRB pre-approval.

Report occurrences within 10 days of becoming aware of them.

Note: *Planned protocol deviations* that may adversely affect the rights, safety or welfare of subjects or the integrity of the research data should be submitted to WIRB for review and approval **prior to implementation** except where necessary to eliminate apparent immediate hazards to the human subjects [(DHHS 45 CFR § 46.103(b)(4); (FDA 21 CFR § 56.108(a)(4); ICH 3.3.7)]. Use the **WIRB Change in Research and Subject Recruitment (Ads) Submission Form** to request approval of a *planned* protocol deviation prior to implementation. (Deviations necessary to eliminate apparent immediate hazards to the human subjects should be reported within 10 days on the attached **Report Form for Unanticipated Problems that are Not Adverse Events.**)



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Report Form for Unanticipated Problems that are Not Adverse Events
(due within 10 days of determining that a problem is an unanticipated problem that is
NOT an adverse event)

Principal Investigator Name: _____
WIRB Protocol No.: _____
Sponsor Protocol No.: _____
Sponsor: _____
Study Drug/Device: _____
Date of this Report: _____
Date of Occurrence: _____
Subject ID _____
(If applicable)

1. Describe the problem and explain why it occurred:

2. Why do you consider the event “unanticipated”?

3. Why do you consider the event a “problem involving risks to human subjects or others”?

For protocol variances, explain how this event might adversely affect the rights, safety or welfare of subjects or the integrity of the research data.

Report Form for Unanticipated Problems that are Not Adverse Events (continued)

4. Were there adverse effects to those involved? If so, please describe.

5. Describe what action you have taken or will take to prevent recurrence:

Printed or Typed Name of Person Completing This Form

Company/Title

Phone number

Fax number

E-mail