



Western Institutional Review Board®
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OHRP/FDA Parent Organization number: IORG0000432
IRB registration number: IRB00000533



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 that meet the definition of an unanticipated problem (i.e., it involves risk to subjects or other people).

Report occurrences within 10 days of becoming aware of them.

Note: Planned protocol deviations

Due to differing regulatory requirements, WIRB reporting requirements for planned protocol deviations differ depending on whether your research federally funded or is covered by a federal-wide assurance (FWA):

- If the research is **not** federally funded and the research is **not** conducted under an FWA, 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].
- If the research **is** federally funded or **is** conducted under an FWA, **all** planned protocol deviations must 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].

The reason for these different requirements regarding planned protocol deviations is that the Office for Human Research Protections (OHRP) has adopted the regulatory interpretation that every planned protocol deviation is a change in research that needs prior IRB review and approval before implementation. However, the Food and Drug Administration (FDA) has not adopted this interpretation.

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:

2. Why did the problem occur?

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. **If your answer is “it does not,” then the event does not need to be reported to WIRB.**



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

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

5. What specific action(s) have you taken to correct the error?

If this report involves errors in obtaining and or documenting **consent**, please indicate whether you have corrected the error. For example, if you have obtained the subject's signature on the correct consent form, please provide that information.

6. Describe what specific action you have taken or will take to prevent similar occurrences:

Printed or Typed Name of Person Completing This Form

Company/Title

Phone number

Fax number

E-mail