

Information Sheet for Researchers

Unanticipated Problems Involving Risks to Participants or Others

What is an unanticipated problem involving risks to participants or others?

Unanticipated Problems Involving Risks to Participants or Others

- Any event that:
1. is unexpected
 2. suggests that participants or others are at greater risk than was previously known or recognized, **and**
 3. is related to the research procedures

Definitions:

Unexpected: An event is “unexpected” when its specificity and severity are not accurately reflected in the informed consent document or other information available (e.g., protocol, investigator’s brochure)

Related to the research procedures: An event is “related to the research procedures” if in the opinion of the principal investigator, it was more likely than not to be caused by the research procedures or if it is more likely that not that the event affects the rights and welfare of current participants.

IMPORTANT NOTE: An adverse event, protocol deviation, or other problem may also be an unanticipated problem involving risks to participants or others.

- We created the Reportable Event Form to help researchers consistently consider whether a reportable event might also be an unanticipated problem involving risks to participants or others.
- The form asks researchers to also assess the reported event based on the definitions above.

Why must I report unanticipated problems involving risks to participants or others?

Reports of unanticipated problems involving risks to participants or others are required by BRANY IRB policy and applicable local, State and Federal regulations governing research.

Which form do I use to report the above to BRANY IRB?

The *NEW* Reportable Event Form

Effective **Monday, November 16, 2009**, all reports of the events described above, including SAEs, deviations, exceptions, violations, unanticipated problems involving risks to participants or others must be made using the **Reportable Event Form**. The previous separate forms will be removed from circulation as of that date.

As of November 16, 2009, the **Reportable Event Form** will be available for download on BRANY IRB’s Web site: www.branyearb.com, and it will be available as a generated document in *IRBManager* (BRANY IRB’s electronic protocol tracking system).

Reports to BRANY IRB must contain a sufficient amount of information to permit the reviewer to judge whether the event raises new questions about risks to participants. Additional relevant documents should be included, as necessary.

How do I to transmit reports?

Telephone: 516-470-6900 – Monday through Friday, 9am – 5pm (EST)

Telephone: 516-318-6877 – after regular business hours

Fax: 516-470-6926

Email: rhart@brany.com

Who do I call if I have a question about the new Reportable Event Form?

Any questions or feedback regarding the new Reportable Event Form may be directed to Raffaella Hart, IRB Director at rhart@brany.com or by calling 516-470-6909.