

## 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 Reportable Event xForm.

To submit reports of the events described above, including SAEs, deviations, exceptions, violations, unanticipated problems involving risks to participants or others, use the **Reportable Event xForm**.

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.

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

Any questions or feedback regarding the Reportable Event xForm may be directed to BRANY IRB at [rhart@brany.com](mailto:rhart@brany.com) or by calling 516-470-6909.