The JHSPH requires researchers to comply with all applicable local, state, and federal regulations in the conduct of research studies. As part of this requirement, researchers are required to submit to the JHSPH IRB written reports of events that meet the definition of “unanticipated problems involving risks to participants and others.” Principal investigators must report such problems/events to the IRB promptly, as well as to applicable regulatory agencies, sponsors, and institutional officials.

Events labeled as “reportable events” in research involving investigational drugs or devices may or may not meet the definition of an “unanticipated problem.” In such cases, the PI must report the event to the JHSPH IRB if it meets the definition of an unanticipated problem or if a sponsor or regulatory authority requires report to the IRB.

Definitions

A. “Unanticipated problems involving risks to participants or others” is defined as:

(1) The information is unexpected in terms of nature, severity, or frequency, given:

a) the research procedures described in the protocol and informed consent document; and

b) the characteristics of the subject population being studied;

and

(2) The information about the event indicates that participants or others are at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
B. “Prompt reporting” is defined to be “as soon as possible after the PI learns of the event”, but in all cases within 10 working days.

C. Reportable Problem/Events

The JHSPH PI must promptly report the following unanticipated problems or events:

1. **Event** (including on-site and off-site adverse event reports, injuries, side effects, breaches of confidentiality, or other problems) that occurs any time during or after the research study, which in the opinion of the principal investigator:
   
   a. Involved harm to one or more participants or others, or placed one or more participants or others at increased risk of harm;
   
   b. Is unexpected (an event is “unexpected” when it is not described with specificity in the protocol and informed consent document; or if described with specificity, it occurs beyond the expected frequency and/or severity identified); and
   
   c. Is 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.)

2. Information that indicates a change to the risk:benefit ratio of the research. For example:
   
   a. An interim analysis indicates that participants have a lower rate of response to treatment than initially expected
   
   b. Safety monitoring indicates that a particular side effect is more severe, or more frequent than initially expected
   
   c. A paper is published from another study that shows that an arm of the research study is of no therapeutic value

3. Change(s) in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.

4. Change(s) to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant

5. Incarceration of a participant

6. Event that requires prompt reporting to the sponsor

7. Complaint of a participant when the complaint indicates unexpected risks or the complaint cannot be resolved by the research team
8. Protocol violation (a term often used by NIH or commercial sponsors, meaning an accidental or unintentional change to the IRB approved protocol) that placed one or more participants at increased risk, or has the potential to occur again.

9. An unanticipated adverse device effect as defined by FDA at 21 CFR Part 812.3(s).

**Form of Report**

The PI should submit a written report of the unanticipated problem/event to the JHSPH IRB using the Problem/Event Report Form. Reports may be accepted by hard copy, e-mail, or phone (if the report is of an urgent nature) with a report form to follow.

**Review of Problem/Event Reports**

The JSHPH IRB will review each reported problem/event to determine if it meets the definition of an unanticipated problem involving risks to participants or others. Review of a problem/event may require use of a consultant, or assistance from the division or department chair, to collect additional information before a determination is made.

Action will be taken to address the problem. The range of actions may be taken by the Institutional Official, other senior JHSPH officials charged with taking action, or the IRB. The range of actions includes items listed below, but the list does not preclude taking additional actions as determined on a case-by-case basis.

- Administrative hold on the study pending IRB receipt of further information from the PI in a time period not to exceed 90 days
- Modification of the protocol
- Modification of the information disclosed during the consent process
- Providing additional information to current participants (this must be done whenever the information may relate to participants’ willingness to continue participation)
- Making arrangements for clinical care outside the research or additional follow-up for participants
- Providing additional information to past participants
- Requiring current participants to re-consent to participation
- Alteration of the frequency of continuing review
- Observation of the research or the consent process
Requiring additional training of the investigator

Notification of investigators at other sites

Obtaining additional information

Termination or suspension of the research. Such action will be reported to the Institutional Official (IO).

The IO will be informed when a determination has been made that a problem/event meets the definition of an unanticipated problem involving risks to participants or others. The IO will fulfill the requirements to report the action to federal departments or agencies as required by regulation and with JHSPH policy.

If a determination is made that a problem/event reported to the IRB does not meet the definition of an unanticipated problem involving risks to participants or others, no further action needs to be taken and a report to the IO is not required.