

## **Adverse Events and Unanticipated Problems**

**Summary/Purpose:** This policy describes the process that the Institutional Review Board (IRB) follows to deal with reports and findings of adverse events and unanticipated problems in research studies.

### **Definitions:**

**Adverse Event:** Any undesirable effect (unfavorable physical or psychological harm) occurring in a human subject, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Examples include but are not limited to an abnormal physical exam or laboratory finding, unusual symptoms or occurrence of disease, and psychological reactions such as intense sadness or transient anxiety.

**Serious Adverse Event:** An adverse event that results in any of the following: death, hospitalization, significant disability, congenital anomaly or birth defect, a life-threatening situation, or concerns about the physical health or future health of the subject.

**Unanticipated Problem:** An incident or experience occurring during the course of research that meets all of the following criteria:

- Is not described in the protocol or consent form or is unexpected in nature, severity, or frequency;
- May possibly be related to participation in the research; and
- Suggests that the research places subjects or others at a greater physical, psychological, economic, or social risk of harm than was described in the consent form or protocol.

### **Prompt Reporting of Unanticipated Problems or Adverse Events:**

- Unanticipated Problems that are serious adverse events should be reported to the IRB within 1 week of an investigator becoming aware of the event or effect.
- Any other Unanticipated Problems should be reported to the IRB within two weeks of an investigator becoming aware of the incident or experience.
- The form to be used when reporting incidents or events to the IRB is the Incident Report Form.

### **Process for Handling Reports of Unanticipated Problems or Adverse Events:**

1. An incident report form is sent to the Director of Research Integrity and Compliance, the IRB Chair, or the IRB Office.
2. The IRB Executive Committee determines whether the report involves an Unanticipated Problem, an Adverse Event, or both.
3. The IRB Executive Committee may notify the Full IRB at any time during the process of examining reports of Unanticipated Problems or Adverse Events. All events and final outcomes will be reported to the Full IRB at the regular monthly meetings.
4. If the report is determined to be an Adverse Event, but not an Unanticipated Problem, further reporting to appropriate institutional officials, the department or agency head (or

designee), and OHRP is not required under HHS regulations at 45 CFR 46.103(a) and 46.103(b)(5).

5. If the report is determined to be an Unanticipated Problem, whether Adverse Event or not, the IRB must promptly (within one month) report the incident, experience, or outcome to appropriate institutional officials, any supporting department or agency head (or designee), and OHRP (for DHHS funded studies). The types of actions that the IRB may consider taking for any event include, but are not limited to:
  - Acknowledgement/acceptance without further recommendation;
  - A request for further clarification from the investigator;
  - Modification of the research protocol or procedures;
  - Modification of the consent/assent process or consent/assent form;
  - Providing additional information to current and past research participants;
  - Additional monitoring of the research protocol or consent process;
  - Education for the investigator or research staff;
  - Limitations on the research activities;
  - Suspension or termination of the research.
6. The IRB will notify the investigator upon receipt of the report as well as after a decision has been made regarding actions to be taken (including acknowledgement/acceptance without further recommendation).
7. If the investigator has concerns regarding the actions to be taken, he may submit these to the IRB in writing for consideration.
8. A follow-up report detailing the outcome of any event (whether Unanticipated Problem or Adverse Event) may be submitted to appropriate institutional officials, any supporting department or agency head (or designee), OHRP, and the full IRB.