NOTE: Principal investigators are required to submit written reports of the following events to the HRPP/IRB, using FORM: Report of Protocol Deviation/Unanticipated Problem/Adverse Event. SEE POLICY: Reportable Events: Protocol Deviations, Unanticipated Problems, and Adverse Events Involving Risks to Participants and Others for definitions of terms, reporting procedures, timeframes, and IRB processes.

NOTE: FATAL OR LIFE-THREATENING EVENTS MUST BE REPORTED WITHIN 48 HOURS. THIS MAY BE BY TELEPHONE OR e-MAIL, TO BE FOLLOWED BY THE WRITTEN REPORT. Events involving unanticipated life-threatening experiences must be reported within 7 calendar days of the investigator’s receipt of the information. All other serious and unanticipated problems—short of death or life-threatening experiences—must be reported within 14 calendar days of the investigator’s receipt of the information. Reportable events are not limited to medical studies.

If you need assistance in deciding whether to report an event, please contact a research compliance specialist at 8-5069 (Medical IRB) or 8-6457 (Non-Medical IRB).

REPORT THESE EVENTS:

1. Internal or External Adverse Event reports, injuries, side effects, breaches of confidentiality (e.g., loss of a laptop with identifiable participant data, opening of confidential mail to participants by an unauthorized person, release of the identities of persons with HIV/AIDS), or other problems that occur any time during or after the research study, which, in the opinion of the Principal Investigator or Project Director:

   a. Involve harm to one or more participants or others (such as research staff), or placed one or more participants or others at increased risk of harm;
   b. Are unexpected (unanticipated in the description of risks and safeguards); and
   c. Are possibly related to the research procedures.
2. Information that indicates a change to the risks or potential benefits of the research in terms of frequency or severity. 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 published from another study shows that an arm of your study is of no therapeutic value.

3. A change in FDA labeling (package inserts/instructions for use) or withdrawal from marketing of a drug, device, or biological used in a research protocol.

4. A change in the protocol made without prior IRB review to eliminate an apparent immediate hazard to a research participant.

5. Incarceration of a research participant in a study not approved to enroll prisoners.

6. Event that requires prompt reporting to the sponsor.

7. Sponsor or investigator-imposed suspension of a study.

8. Sponsor-imposed suspension of the UA investigator.

9. A complaint from a participant that indicates unexpected risks or a complaint that cannot be resolved by the research team.

10. A protocol deviation (an accidental or unintentional change to the IRB-approved protocol once a participant has been enrolled or a change made to a protocol to protect participants or staff from an immediate hazard) that puts one or more participants at increased risk OR has the potential to occur again. NOTE: Enrollment of more subjects than the sample size approved by the IRB is a protocol deviation and a reportable event.

11. Unanticipated adverse device effect: Any serious adverse effect on health or safety or any life threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previous identified in nature, severity, or degree of incidence in the application—initial, continuing review, or modification—, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.
12. A report from a sponsor (e.g., DSMB report).

13. Any fatal or life-threatening experience of a research participant, whether expected or unexpected, must be reported as long as the protocol is active.

14. Reports of a fatal or life-threatening experience of a research participant at any site that was “unexpected”, was a risk of participation that was not identified in the consent document, and was more likely than not caused by the research procedures must be reported to the IRB within 48 hours of when the PI/PD is first informed of the event.

15. Any other event in a particular study that the investigator believes should be reported in the interests of disclosure or protection of human participants.