GUIDELINE TO RSRB CATEGORIES OF REPORTABLE EVENTS

OHSP Policy 801 describes the requirement for the Investigator to determine whether an event or problem must be reported to the RSRB or another non-UR Reviewing IRB (i.e., a reportable event) and the Guideline for Reporting Research Events outlines the process for determining whether additional reporting is required. The RSRB has several categories of reportable events to which the Investigator may report and document an event or problem. This guideline details each category to assist Investigators in making the appropriate reporting action.

1. TYPE 1 – Serious Adverse Events
   If a subject is enrolled by a UR Investigator, the Investigator must report to the RSRB any unexpected adverse event which is determined to have a serious outcome and is assessed as related (i.e., definitely, probably, possibly) to the study (e.g., drug, biologic, device, procedure or assessment). If the event is also determined to be a risk to subjects or others, see “Type 4” below for reporting requirements.

2. TYPE 2 – Not in Use

3. TYPE 3 – Not in Use

4. TYPE 4 – Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO)
   A UPIRTSO includes any event that was not expected given the nature of the research, the population under study, and the approved procedures or protocol for conduct of the study (i.e., a UPIRTSO may or may not involve an adverse event). The event involves risks to subjects or others (e.g., research staff, family members, or others not directly involved in the research) and is related (i.e., definitely, probably or possibly related) to the research (i.e., intervention, procedures, and/or conduct of the study). The risks (e.g., physical, financial, legal, social, emotional, psychological well-being, subject privacy, or data confidentiality) may affect the rights, safety, or welfare of subjects or others. When a research study includes investigational drugs or devices, some unanticipated problems may also meet the definition of an unexpected adverse drug experience, or an unanticipated adverse device effect.

   Investigators must report any UPIRTSO regardless of whether the event occurred during the study or after study completion (e.g., event is discovered in the analysis phase). The report should include a description of the event, the date of occurrence, whether it is a UR or non-UR event, the type of harm or risk, and its effect on subjects and/or others.
Note: If known in advance that a protocol revision is needed (e.g., to change the risks in the consent), file an Amendment along with a Reportable Event report.

Examples of unanticipated problems reported to the RSRB:

From OHRP Guidance on Unanticipated Problems and Adverse Events (Appendix B)

1) An investigator conducting behavioral research collects individually identifiable sensitive information about illicit drug use and other illegal behaviors by surveying college students. The data are stored on a laptop computer without encryption, and the laptop computer is stolen from the investigator’s car on the way home from work. This is an unanticipated problem that must be reported because the incident was (a) unexpected (i.e., the investigators did not anticipate the theft); (b) related to participation in the research; and (c) placed the subjects at a greater risk of psychological and social harm from the breach in confidentiality of the study data than was previously known or recognized.

2) As a result of a processing error by a pharmacy technician, a subject enrolled in a multicenter clinical trial receives a dose of an experimental agent that is 10-times higher than the dose dictated by the IRB-approved protocol. While the dosing error increased the risk of toxic manifestations of the experimental agent, the subject experienced no detectable harm or adverse effect after an appropriate period of careful observation. Nevertheless, this constitutes an unanticipated problem for the institution where the dosing error occurred that must be reported to the IRB, appropriate institutional officials, and OHRP because the incident was (a) unexpected; (b) related to participation in the research; and (c) placed subject at a greater risk of physical harm than was previously known or recognized.

3) Subjects with cancer are enrolled in a phase 2 clinical trial evaluating an investigational biologic product derived from human sera. After several subjects are enrolled and receive the investigational product, a study audit reveals that the investigational product administered to subjects was obtained from donors who were not appropriately screened and tested for several potential viral contaminants, including the human immunodeficiency virus and the hepatitis B virus. This constitutes an unanticipated problem that must be reported because the incident was (a) unexpected; (b) related to participation in the research; and (c) placed subjects and others at a greater risk of physical harm than was previously known or recognized.

Additional “Non-Medical” Reports:

1) An interview subject begins to cry uncontrollably when asked about high school experiences.
2) A breach of confidentiality, such as a laptop computer with unencrypted research data stolen from the Investigator’s car. [Note: According to University policy, all laptops, external memory storage devices that have identifiable information on them should be encrypted or otherwise made unreadable by persons who are not authorized access.]

3) “Anonymous” results of a study of alcohol abuse in a defined population were published; however, several subjects complained to the Investigator that because of the location and small community size, it was clear who the population was and even the identity of individuals who were in the study.

Additional “Medical” Reports:

1) A subject in a study of diabetes grabs his chest and shows signs of a heart attack. In the emergency response, it is discovered that the CPR equipment wasn’t working.

2) After the administration of a reconstituted vaccine, it was discovered that the test vaccine was contaminated on the research unit because of faulty procedures.

3) Part-way through a study, it is discovered that the research procedures or test equipment gives an unexpected rate of false positives that required medical referrals, work-ups and expense.

5. TYPE 5 – Monitoring Reports

Formal monitoring bodies (e.g., Data and Safety Monitoring Board, Data Monitoring Committee, Independent Safety Monitor, Coordinating Center, Study Group Center) are established to conduct ongoing monitoring and analysis of study information, such as adverse events and data to assure the continuing safety of research subjects. These groups distribute summary reports on the status of studies (e.g., keep open, close early, make study changes, etc.). [See OHSP Policy 506 Data and Safety Monitoring]

Monitoring reports that indicate an increased risk to subjects (usually reflected as a revision to the consent and/or protocol), whether an internal or external event, must be submitted to the RSRB as a reportable event, and an amendment if there are changes to any protocol materials. Monitoring reports that allow the study to continue unchanged may be submitted; however, will be reviewed at the time of the next continuing review.

6. TYPE 6 – New Information

Note: This category may be used as a mechanism to obtain RSRB review for reporting study results after a study has been closed. If study is not yet closed, and it is known in advance that a protocol revision is needed (e.g., to change the risks in the consent), file an Amendment instead of a Reportable Event.

During the course of a study, researchers may become aware of new information that might affect a subject’s decision to participate, or continue participating in the research study. For example, interim analyses of data may identify an adverse safety trend, or may identify early
efficacy (benefit). In addition, results from other published research studies or changes in standards of practice or care may affect the conduct of a study and would need to be communicated to research subjects. Investigators must report any new information that may impact the willingness of subjects to participate, including a description of the new information and its potential effect on subjects (prospective, current and former), and the Investigator’s proposed method for providing this information to subjects.

7. **TYPE 7 – Changes Without Approval**
   This category should be used to report one-time change(s) made to the research without prior RSRB approval, in order to eliminate apparent immediate harm to the subject(s). This change does not call for permanent changes (amendments) to the study, but rather reporting that a single incident occurred. If permanent changes to the study are a result of this event, then an amendment to make study revisions should be submitted as well.

8. **TYPE 8 – Non-Compliance**
   Investigators should self-report non-compliance with federal regulations, state law, the requirements or determinations of the RSRB, or University policy pertaining to research that affect the rights, safety, or welfare of subjects or others, including but not limited to protocol deviations. A protocol deviation would not be considered a reportable event, for example, for an out of window visit or the wrong survey was used (as long as the event does not impact subject safety or increase risk to subjects or others). [See Policy 802 Non-Compliance and the Guideline for Review of Allegations of Non-Compliance and for more details.]

9. **TYPE 9 – Voluntary Suspension**
   Investigators may suspend all or part of a research study (e.g., enrollment, study procedures, a certain arm or phase) to consider changes to the research, for temporary funding constraints, to investigate risks to subjects or others, or to address issues with non-compliance. These reports keep the RSRB appraised of the status of approved research and do not require automatic reporting to regulatory authorities outside the institution.

   *NOTE:* This is not the mechanism to close a study. Request for closure of a study is made by submitting a final progress report.