

# Guidance for Reporting Reportable Events to the RSRB

This document is meant to clarify RSRB reportable event submission requirements.

## **LOCAL EVENTS**

A local event is an incident, experience, or outcome that occurs to a subject participating in a RSRB-approved research study. A **local event** is **only** reportable to the RSRB as an individual event report when the event is **SERIOUS, UNEXPECTED AND RELATED TO PARTICIPATION IN THE STUDY.**

These individual events must be reported within 10 calendar days and will typically be reported as a Type 1 “adverse event” or a Type 4 “unanticipated problem involving risks to subjects or others (UPIRTSO)”. *See below for examples of UPIRTSOs.*

If a local event **does not** meet this definition, **DO NOT REPORT UNTIL THE TIME OF CONTINUING REVIEW.** Local adverse events that do not require immediate reporting should be submitted as a summary of events with an assessment of risk (e.g., no change, greater/less than expected, etc.) through question 5.7 in the progress report “Adverse events/overall risk.”

When reporting a summary of events, the PI should answer the progress report form question based upon the study’s approved data and safety monitoring plan (DSMP).

- If the DSMP is to have a data and safety monitoring board (DSMB) – then the PI should comment on the DSMB reports. *If you have not received the DSMB reports from the previous year at the time of your continuing review...contact your sponsor; you should receive these in a timely fashion.* [Note: DSMB reports that do not require changes to the protocol or consent are reported when received as a “Type 5” monitoring report.]
- If the DSMP is to have a Medical Monitor review the data – then the PI should comment on the Medical Monitor’s reviews and there should be documentation (letter, e-mail, etc.) from the Medical Monitor providing summary information related to the review of the data. [Note: Medical Monitor reports that do not require changes to the protocol or consent are reported when received as a “Type 5” monitoring report.]
- If the DSMP is to have the PI review the data – then the PI should include the summary information related to the review of the data. Wording should be customized to the situation but **at a minimum** PI should comment on: 1) the number of serious vs. non-serious adverse events, 2) most common serious and non-serious adverse events, 3) relatedness and 4) expectedness. Sample wording would be...“Overall, there were # serious adverse events and # non-serious adverse events, all of which were probably related to the subject’s participation in the study. The most common serious adverse event was \_\_\_\_\_. The most common non-serious adverse event was \_\_\_\_\_. All adverse events were expected. There was no change in the overall risk to subjects.”
- If a DSMP was not required (minimal risk study) the PI should include summary information, as stated above.

If an investigator believes that a pattern of local events is occurring, which is unexpected, the reports should be combined into one submission through ROSS and reported as a UPIRTSO (Type 4) or as an amendment, if this pattern requires a change to the consent form or protocol.

## **NON-LOCAL EVENTS**

Non-local events need only to be submitted to the RSRB if they represent an increased risk to the subjects who are participating locally, i.e., they require a change in the protocol or consent form. Non-local (or off-site) reports that generate a change in the protocol, consent forms, etc.

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should be submitted as an amendment. These amendment-generating events must be reported within 10 calendar days.

Common examples of these are:

- “Dear Investigator” letter notifying the site of a trend based upon adverse events reported in the entire study.
- DSMB reports that require an action to the study (e.g., terminate the study, terminating an arm of the study, adding risks to the consent form, etc.). [Note: DSMB reports that do not require action are reported as a “Type 5” monitoring report.]
- Annual Manufacturer HUD Reports. [Note: Manufacturer HUD reports that do not require action should be reported as a “Type 5” monitoring report.]

For non-local events/reports that have **no effect on the risks to subjects** participating at the University of Rochester; **DO NOT SUBMIT** to the RSRB; they will not be reviewed.

Common examples of these non-reportable events/reports are:

- Manufacturer IND safety reports.
- Reports of Serious Adverse Events (SAEs) that took place at other sites (i.e., sites not under the responsibility of the Investigator or the RSRB).

**POINTS TO CONSIDER:** When submitting a Reportable Event, it is helpful to use the “Report Title” to further clarify what is being submitted, e.g.:

- Rather than use “Reportable Event #1 for RSRBXXXX” change the title to:
  - DSMB report dated XX/XX/XXXX
  - UPIRTSO – Laptop computer stolen on XX/XX/XXXX”

**Examples of UPIRTSOs include:**

- Research 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. [Note: 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.]
- As a result of a processing error, a subject enrolled in a clinical trial receives a life-threatening dose of an experimental agent that is 10-times higher than the dose dictated by the approved protocol.
- After the administration of a reconstituted test vaccine, a subject had to be hospitalized overnight for a fever spike because the vaccine was contaminated on the research unit because of faulty procedures.
- Research procedures/test equipment gave an unexpected rate of false positives that resulted in unnecessary medical referrals, work-ups and expense (and worry).
- “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.

For further information see RSRB website [RSRB Reportable Event Definitions](#) or the [RSRB Investigator Guidance](#).