

GUIDELINE FOR REPORTING RESEARCH EVENTS

OHSP Policy 801 defines the requirement for the Investigator, or any research staff, to determine whether an event or problem must be reported to the RSRB or another external Reviewing IRB (i.e., a report of new information). This guideline outlines the procedures for determining whether a research event or problem is reportable and the process for submission and review of the reported information. This guideline also describes the procedures the RSRB will follow to report applicable events to institutional and regulatory authorities. When considering whether an event needs to be reported to an external Reviewing IRB, the Investigator should follow guidelines from the Reviewing IRB.

1. Investigator Review and Assessment of Event

- a) Investigators and research staff are responsible for reporting a research incident, experience, or outcome, including but not limited to:
- Adverse event or injury from drug, device or non-medical procedure or activity.
 - Breaches of confidentiality.
 - Data and Safety Monitoring Board (DSMB) reports, interim analyses, or other oversight committee/monitoring reports altering the risk/benefit profile.
 - Investigator's brochure updates/revisions to safety information (excluding routine updates).
 - New information indicating an unanticipated change in risks or potential benefits (e.g., literature/scientific reports or other published findings).
 - Protocol deviations, violations, or other changes (intentional or otherwise) to the protocol or procedures involving risks or with the potential to recur.
 - Subject complaints or complaints that cannot be resolved by the research staff.
 - Note: Researchers must also take into account any additional departmental policies and procedures when resolving any complaints or concerns arising from the conduct of research.
 - Changes made to the research to eliminate an apparent immediate hazard to a subject(s).
 - Other problem or finding (e.g., loss of study data or forms, a subject becomes a prisoner while participating in research, etc.).
 - Other events that may prompt reporting requirements according to the protocol, sponsor, or funding agency.
- b) The Investigator is responsible for assessing whether an event is considered **unanticipated, related, and serious**, or **involves increased risks to subjects or others** than was previously known or expected, or meets both of these definitions. If the event is determined to meet either or both definitions, the event must be reported to the RSRB. Internal and external events involving subjects participating in research under the University of Rochester's Human Subject Protection Program should be given this assessment.

2. Timeframe for Reporting to RSRB

- a) If an Investigator or research staff determines that an event requires reporting, it should be reported to the RSRB using the 'Report New Information' form in the RSRB online submission system **within 10 calendar days** of the Investigator's or research staff member's learning of the event. All internal and external events should be promptly reported, regardless of whether they occur during or after the study, or involve a subject who has withdrawn from or completed study participation.
 - i. The report should include a description of the event, the date of occurrence, the type of harm or risk, whether the event was internal or external, unanticipated, the outcome, and an assessment of degree of relatedness to the research. The report should also include effect on subjects and/or others, as applicable, and any corrective and preventive action plan the Investigator has implemented.
 - ii. At the time of reporting, if changes to the research or consent process are proposed as a result of the event, or if additional information will be provided to current and/or past subjects, complete an Amendment request along with the Reportable Event form. The Amendment will be reviewed according to the amendment review procedures outlined in *Policy 502 Types of RSRB Submissions*.
- b) Events resulting in temporary or permanent interruption of study activities by the Investigator or sponsor to avoid potential harm to subjects should be reported **within 48 hours** of awareness of the event whenever possible.
- c) When a problem occurs in a study reviewed and approved by an external Reviewing IRB, the event is reported directly to that external Reviewing IRB. Additional investigation of the event might be conducted by the RSRB; however, as necessary, any required external reporting will be conducted by the RSRB Director.

Examples of External Reportable Events:

- "Dear Investigator" letter notifying the site of a trend based upon adverse events reported in the entire study.
- Data Safety Monitoring 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.).
- Annual Manufacturer HUD Reports.

3. Events Not Requiring Prompt Reporting to RSRB

- a) If a local event is **NOT** deemed **unanticipated, and serious, and related**, or it does not additionally involve increased risks to subjects or others, it may be reported at the time of Continuing Review. Include a summary of the event(s) with an assessment of risk (e.g., no change, greater/less than expected, etc.). Non-local events are submitted to the RSRB only if they represent an increased risk to the subjects who are participating locally (i.e., event requires a change in the protocol or consent form).

- b) For external events that have no effect on the risks to subjects participating at University of Rochester (and affiliates), **do not submit** to the RSRB.

Examples of external, non-reportable events:

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

4. RSRB Review Process

Reports of new information will initially be reviewed by the RSRB Director (or designated RSRB Specialist) to determine whether additional information and review by the Board Chair is necessary. If a report of new information is related to a specific submission, the report will be cross-referenced with the respective submission. The RSRB Director (or designated Specialist) may acknowledge a report of new information that does not require additional review, or send to the Board Chair to determine whether the event might require convened board (Committee) review. Based on the initial assessment of the report, the event may be assigned directly to Committee review.

a) Non-Committee Review of Reports of New Information

The Chair or designee assigned to review the event will determine if the report raises new concerns about risks and will recommend further review by the convened board, as necessary, for a final determination. The Chair or designee may suspend or terminate approval of an Investigator's research if necessary to assure the protection of research subjects. The Chair or designee will consider the rights and welfare of subjects when suspending, terminating, or modifying research. If, during non-committee review, the event is determined not to be an unanticipated problem involving risks to subjects or others (UPIRTSO), the reviewer will make any necessary recommendations for action or request for more information (see section 5 below), which will be communicated to the submitter of the report by the RSRB Specialist. A determination requiring no further action/acknowledged will be documented and the submitter of the report will be notified of this outcome.

b) Committee Review of Reports of New Information

Any report of new information deemed to require Committee review will be forwarded to a subsequent convened board meeting. The Chair, or other member with relevant expertise, will serve as the primary reviewer. All relevant information pertaining to the report is accessible to the reviewer and board members in the online submission system, as well as information about any related submission(s), as applicable.

5. RSRB Review Determination

- a) The RSRB will determine by convened review whether the event meets the criteria of an unanticipated problem involving risks to subjects or others. In addition, the board will also determine if any further action is necessary. Action(s) will be based on the nature of the event, degree to which research subjects are placed at risk, occurrence of previous problems, etc. The

board will consider the rights and welfare of subjects when suspending, terminating, or modifying research.

- The RSRB's convened board determination and action(s), including any votes taken, will be recorded in the meeting minutes. The requirements for quorum and majority vote apply. Suspended RSRB approval may be reinstated, as appropriate, based on the outcome of the convened review. Investigators (and others as necessary) will be notified of RSRB actions regarding events determined to be unanticipated problems involving risks to subjects or others as described in Section 6 below.
- b) The range of possible actions that the RSRB may consider for any reported event include, but are not limited to the following, all of which will be communicated to the Investigator:
- No action / acknowledged
 - Modification of the protocol and/or consent
 - Providing additional information to former subjects
 - Notification of current subjects when such information may relate to subjects' willingness to continue to take part in the research
 - Requirement that current subjects re-consent to participation
 - Modification of the continuing review schedule, or adding the requirement for continuing review when the study receives non-committee review
 - Monitoring of the research
 - Monitoring of the consent process
 - Suspension of the research approval
 - Termination of the research approval
 - Referral to other organizational entities (e.g., OHSP, University Audit, UR Office of Counsel)
 - Corrective and Preventative Action plan (CAPA) to explain what has been done to correct the event or occurrence, as well as a plan to prevent such an event from occurring again.

6. Institutional and Regulatory Reporting

If the RSRB determines that an event is an unanticipated problem involving risks to subjects or others, or if the Board suspends or terminates approval of research that is associated with unexpected serious harm to subjects, notification to the Investigator, institutional officials, regulatory authorities, and others will be completed as required following the *Guideline for RSRB Institutional and Regulatory Reporting of Suspension, Termination and Non-Compliance*.