

University of Rochester	Office for Human Subject Protection		
	Research Subjects Review Board		Effective Date: 02/27/2019
	Reporting Research Events		Policy 801
			Version: 1.2

POLICY

1. Purpose

This policy outlines the process for the Investigator's assessment of untoward research events or problems, such as adverse events or unanticipated problems, and subsequent reporting requirements to the RSRB.

2. Scope

This policy applies to all Investigators and study staff conducting human subject research, the RSRB, and the RSRB office.

3. Definitions

- 3.1. *Event or Problem*: An incident, experience, or outcome that occurs during the conduct of a research study that may require reporting to the RSRB, an external Reviewing IRB, the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and/or the Sponsor.
- 3.2. *Internal Event*: An event occurring in a research study conducted by employees or agents of the University of Rochester (UR). The study may be approved by the RSRB or an external Review IRB.
- 3.3. *External Event*: An event occurring in a research study conducted by non-UR employees or agents. The study may be approved by the RSRB or an external Reviewing IRB.
- 3.4. *Adverse Event*: Any undesirable and unintended (although not necessarily unexpected) event occurring as a result of interventions, interactions, or collection of identifiable private information in research. In medical research, any untoward physical or psychological occurrence in research, including abnormal laboratory findings or newly identified or worsening symptom(s) or disease(s) that occurs during the conduct of a research study.
- 3.5. *Serious Adverse Event*: An adverse event that is fatal or life threatening, permanently disabling, requires or prolongs hospitalization, or results in significant disability, congenital anomaly, or birth defect. Also, an adverse event that causes a prolonged or permanent harm that is psychological, social, legal, or financial.
- 3.6. *Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO)*: Any incident, experience, or outcome that meets all of the following criteria:
 - i. unexpected (in terms of nature, severity, or frequency) given the research procedures and subject population being studied; and
 - ii. related to a subject's participation in the research; and

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iii. suggests that the research places subjects, research staff, family members or other individuals not directly participating in the research at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or expected.

3.7. *Unanticipated (Unexpected)*: An experience that was not expected or previously observed, or is not consistent in nature, severity, or frequency with existing risk information, such as in the investigator’s brochure, device manual, research protocol, consent form, or other available information (e.g., IND application for an investigational drug or IDE application for an investigational device). Interchangeable with “unexpected”. An event/problem occurring in one or more subjects in a research project that is not consistent with the expected natural progression of any underlying disease, disorder, or condition of the subject experiencing the event/problem.

3.8. *Related to the Research*: There is some aspect of the study (e.g., research procedure, existence of a laptop database) that is directly related to or associated with the event (e.g., physical harm/adverse event, breach of confidentiality). “Directly” means possibly, probably, or definitely related to the study drug, the device, a study procedure or participation in the study.

3.9. *Non-Compliance*: Failure to follow the federal, state, or local regulations or laws governing the protection of human subjects in research, institutional policies related to human subject research, or the requirements or determinations of the RSRB/IRB of record with respect to the conduct of the research as approved.

3.10. *Reviewing IRB*: The Institutional Review Board (IRB) designated to review and approve human subject research as per 45 CFR 46.111 and in accordance with the Reliance Agreement.

3.11. *Relying IRB*: The IRB that delegates the responsibility of IRB review and approval to another IRB.

4. References

4.1. FDA 21 CFR 312.32(a); FDA 21 CFR 812.150; International Conference on Harmonization E-6 Guidelines for Good Clinical Practice; OHRP Guidance on Reviewing and Reporting UPIRTSO and Adverse Events

4.2. [Guideline for Reporting Research Events](#)

5. Responsibilities

5.1. The Investigator is responsible for determining whether an internal or external event is required to be reported to the Reviewing IRB, and if so, that prompt reporting of the

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event occurs in order to protect human subjects from avoidable harms while reducing unnecessary burden.

- 5.2. The Reviewing IRB is responsible for the timely review of reportable event notifications received from the Investigator in order to protect the safety, welfare, and rights of human subjects or others.
- 5.3. When the RSRB is the Relying IRB, the RSRB is responsible for reporting events to the Reviewing IRB according to the established Reliance Agreement

6. Requirements

- 6.1. The RSRB will provide written procedures to guide prompt reporting to the RSRB, appropriate institutional officials, and any supporting department or agency head of any unanticipated problem involving risks to subjects or others [45 CFR 46.103(b)(5)].
 - 6.1.1. The RSRB office will promptly report any reportable events (e.g., unanticipated problems) to OHRP [45 CFR 46.103(a)] or other institutional or regulatory authority as applicable (see *Guideline for Reporting Research Events*).
- 6.2. The Investigator (or any research staff) will notify the Reviewing IRB of a reportable event according to the *Guideline for Reporting Research Events*.
- 6.3. The RSRB office will consult with the Office of Counsel for guidance regarding pertinent state, local and international laws and regulations related to reportable events such as unanticipated problems and adverse events as applicable.

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Appendices:

None

Revision History:

08/2016: Add hyperlinks, Sect 3.2 and 3.3 revised, Sect 3.10 added, editorial changes
02/2019: Sect 3.11 definition added, Sect 4.2 Guideline for RSRB Categories of Reportable Events deleted – archived no longer in use; Sect 5.3 added; Sect 6.2 updated to reflect current online review system; editorial changes; remove T. Gommel from signatures

Supersedes Date:

08/04/2016

Approved By:



Kelley A. O'Donoghue
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Date