

Columbia University and Columbia University Medical Center IRB Policy

Adverse Events and Unanticipated Risks Reporting Policy

This policy applies to all research involving human subjects, including behavioral, biomedical, and social sciences.

The researcher shall submit reports of [adverse events](#) or other [unanticipated problems](#) involving risks to subjects or others as outlined below.

Summary

Adverse Events

INTERNAL: The following Adverse Events shall be reported to the IRB within **48 hours** of the event or the investigator being notified of the event:

- Adverse events that meet all of the following criteria:
 - Serious and Unanticipated; *and*
 - Occurred at a site [under the purview of a CU IRB](#) (*i.e., internal*).

EXTERNAL: The following Adverse Events shall be reported to the CU IRB within **5 business days** of the event or the investigator being notified of the event:

- Adverse events that meet all of the following criteria:
 - Serious and Unanticipated; *and*
 - Possibly related to study procedures; *and*
 - Occurred at a site that is ***not under the purview of a CU IRB*** (*i.e., external*).

Events that do not meet the above criteria shall **ONLY** be reported in summary form at the time of continuing review. If reported as they occur, the reports will be returned to the researcher without IRB review.

Unanticipated Problems

Unanticipated problems (other than adverse events) involving risks to subjects or others, occurring at any site, shall be reported to the IRB within 5 business days using the Adverse Event Report form in RASCAL.

If an Adverse Event Report is required: The Investigator shall submit for IRB review a detailed Adverse Event Report in RASCAL¹ in the time frame indicated above. In filing the report, the investigator must make the preliminary determination whether revision(s) to the

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protocol and/or consent document(s) is/are necessary. If a change is required, a modification must be submitted promptly in RASCAL.

If a report in Summary Format is Indicated: The Investigator shall submit for IRB review a summary report with the submission of the scheduled continuation application

¹Protocols that exist only in paper form must be validated in RASCAL before an Adverse Event report may be submitted.

Adverse Events		
	Not serious	Serious
Anticipated	Report in summary at time of continuing review.	Report in summary at the time of continuing review.
Unanticipated	Report in summary at the time of continuing review.	Report promptly in accordance with terms of this policy.

Unanticipated Problems	
Nature	Action
Involves risk to subjects or others.	Report promptly in accordance with terms of this policy.
Does not involve risk to subjects or others.	No report required.

Detailed Policy and Procedures

Internal Adverse Events

The Investigator shall report all internal adverse events that are determined to be [serious](#) and [unanticipated](#) to the IRB within 48 hours of the event, or notification of its occurrence.

Reporting within RASCAL, using the Adverse Event Report form, is preferred. If access to RASCAL is not available in the designated time frame, submission of a written report by fax, hand delivery, or express mail delivery to the IRB office is acceptable, as long as the complete report is submitted in RASCAL as soon as possible.

The IRB Chair or designee will review reports of adverse events. Reports of all internal adverse events that are serious and unanticipated will also be reviewed by the full Board.

If the investigator believes a change in the protocol or consent document is warranted, he/she should submit a modification request in RASCAL. The Chair or designee will forward the modification, when received, for appropriate review (i.e., expedited review if the change(s) is/are minor or full Board review if the change(s) is/are substantive).

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If the investigator has indicated that no change is required and the Board disagrees, the investigator will be asked to submit a modification.

Reports of internal adverse events that are not serious and unanticipated will be returned without review if they are submitted as they occur. These should only be reported in summary form at the time of continuing review.

External Adverse Events

All external adverse events that are determined by the Principal Investigator to be [serious](#), [unanticipated](#), and possibly related must be reported to the IRB with a report in RASCAL within 5 business days of notification.

A detailed Adverse Event Report must be submitted in RASCAL¹ within 5 business days of the event or notification. The IRB Chair or designee will review the report of adverse events or unanticipated problems.

Reports of all external adverse events that are serious, unanticipated, and possibly related will also be reviewed by the full Board.

In filing the report, the investigator must make the preliminary determination whether revision(s) to the protocol and/or consent document(s) is/are necessary. If a change is required, a modification must be submitted promptly in RASCAL.

The Chair or designee will forward the modification, when received, for appropriate review (i.e., expedited review if the change(s) is/are minor or full Board review if the change(s) is/are substantive).

If the investigator has indicated that no change is required and the Board disagrees, the investigator will be asked to submit a modification.

Reports of external adverse events that are not serious, unanticipated and possibly related will be returned without review. These should only be reported in summary form at time of continuing review.

Unanticipated Problems (Internal or External) Involving Risks to Subjects or Others

All unanticipated problems involving risks to subjects or others must be reported promptly to the IRB, via submission of an Adverse Event form in RASCAL.

A detailed Adverse Event Report must be submitted in RASCAL¹ within 5 business days of the event or notification, whether the problem was internal or external. The IRB Chair or designee will review all reports of unanticipated problems, and make a determination of whether additional review, by the full IRB, is required.

In filing the report, the investigator must make the preliminary determination whether revision(s) to the protocol and/or consent document(s) is/are necessary. If a change is required, a modification must be submitted promptly in RASCAL.

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The Chair or designee will forward the modification, when received, for appropriate review (i.e., expedited review if the change(s) is/are minor or full Board review if the change(s) is/are substantive).

Reports of unanticipated problems that do not involve risks to subjects or others will be returned without review. These should only be reported in summary form at the time of continuing review.

Other Adverse Events

A summary of adverse events and unanticipated problems that occur during the approved study period must be submitted with other required materials at the time of continuing review. The summary for each type of adverse event should include, at a minimum:

- number of subjects who experienced the event;
- investigator's determination of whether or not the event is serious;
- investigator's determination of the event's relationship to the study procedures (e.g., definitely, probably, possibly, probably not, definitely not related);

Data Safety and Monitoring Board (DSMB) Reports

All DSMB reports that the investigator receives should be promptly reported to the IRB and submitted in RASCAL as a modification to the protocol.

Definitions

Adverse Event

Any experience or abnormal finding that has taken place during the course of a research project and was harmful to the subject participating in the research, or increased the risks of harm from the research, or had an unfavorable impact on the risk/benefit ratio. Note that the Food and Drug Administration (FDA) also includes in its definition abnormal preclinical or laboratory findings which may not yet have resulted in direct harm to subjects (e.g. a bacteria is identified in a culture from the same batch of cells used to produce a vaccine which has been administered, even if no cases of infection have been reported).

Note that the FDA characterizes adverse events resulting from devices as adverse device effects. Only unanticipated adverse device effects that are serious need to be reported promptly. The Columbia policy encompasses this regulatory requirement.

CU Site

Any site at which the research is conducted under the direction or supervision of a Columbia University investigator.

External

Occurring in a study at a site for which a Columbia University investigator is not responsible for the conduct of the study.

Internal

Occurring in a study approved by a Columbia University IRB at a site for which a Columbia University investigator is responsible for the conduct of the study.

Serious Adverse Event (SAE)

Any experience occurring that results in any of the following outcomes: death; life-threatening experience; requires in-patient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse experience when, based upon appropriate medical judgment, they may jeopardize the subject and may require medical or surgical intervention to prevent one of these outcomes.

Unanticipated Problems

Any unexpected event that affects the rights, safety, or welfare of subjects or others that results from the study. The event could be physical, such as an adverse event or experience. The event could also involve social harm or risk, or psychological or legal harm or risk. Examples include, but are not limited to, breach of confidentiality, protocol violations and deviations, and complaints about the research procedures or treatments by key personnel on the research team.

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Unanticipated Adverse Event

Any (adverse) drug, device, or intervention experience for which the specificity, frequency, or severity is not consistent with the current investigator's brochure; or, if an investigator's brochure is not required or available, the specificity, frequency, or severity of which is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended.

Note that the FDA characterizes adverse events resulting from devices as adverse device effects. Only unanticipated adverse device effects that are serious need to be reported promptly. The Columbia policy encompasses this regulatory requirement.