

SOP-R-003: TC IRB Standard Operation Procedures (SOP) on Unanticipated Problems Involving Risks to Subjects or Others

Purpose

This section provides definitions and procedures for the reporting of UAPs to the Teachers College (TC) IRB. Investigators conducting research under the oversight of an external IRB must comply with the reporting requirements of the external IRB and the internal reporting requirements outlined in the IRB Reliance SOP.

Policy

Regulations require an organization to have written procedures for ensuring prompt reporting of “unanticipated problems involving risk to subjects or others” (also referred to as UPs, UAPs, and UPIRTSOs).

In conducting its review of protocol deviations, noncompliance, subject complaints, and other reportable events, the IRB will also consider whether the event or issue was caused by, contributed to, or otherwise related to an UAP.

Definitions

Unanticipated problems involving risk to participants or others: Unanticipated problems involving risks to subjects or others (UAPs) refer to any incident, experience, outcome, or new information that:

1. Is unexpected; **and**
2. Is at least possibly related to participation in the research; **and**
3. Indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, legal or social harm) than was previously known or recognized

Unexpected: The incident, experience or outcome is not expected (in terms of nature, severity, or frequency) given the research procedures that are described in the study-related documents, such as the IRB-approved research protocol/research plan and informed consent documents; and the characteristics of the subject population being studied.

Related: There is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.

Adverse Event: For the purposes of these policies and procedures, an adverse event (AE) is any untoward or unfavorable occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research. Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

Procedures

Reporting

Investigators must report the following events or issues to the IRB as soon as possible but within **7 working days** after the investigator first learns of the event using the “Event Report” form in Mentor IRB.

If investigators are uncertain but believe that the event might represent an UAP, a report should be submitted.

Examples of UAPs include:

1. Events involving direct harm to subjects enrolled by the local investigator which in the opinion of the investigator or sponsor, may represent an UAP;
2. Sponsor or lead investigator/coordinating center-imposed suspension or termination of some or all research activities;
3. An unanticipated event related to the research that exposes subjects or others to potential risk but that does not involve direct harm;
4. A breach of confidentiality or loss of research data (e.g., a laptop or thumb drive is lost or stolen);
5. An unanticipated event related to the research that results in actual harm or exposes individuals other than the research subjects (e.g., investigators, research assistants, students, the public, etc.) to potential risk;
6. New information that indicates increased risk, new risk(s), or decrease to potential benefit from what was previously understood. Examples include:
 - a. An interim analysis or safety monitoring report indicates that the frequency or magnitude of harms or benefits may be different than initially presented to the IRB;
 - b. A report or publication that indicates the risks, benefits, or merit of the research are different from what was previously understood.

Review Procedures

1. Upon receipt of the Event Report, the IRB staff pre-reviews the submission and, if needed, contacts the investigator for corrections or additional information.
2. The IRB Chair or designated reviewer receives and reviews the report and makes an initial determination as to whether the event represents an UAP. If needed, the Chair or designee may request additional information from the investigator, sponsor, or others (including study committees, such as data monitoring committees, data safety monitoring boards, or steering committees).
 - a. If the reviewer determines that the problem does not meet the definition of an UAP, they will determine whether any additional actions are necessary to ensure the protection of human subjects. As warranted, the reviewer may refer the matter to the convened IRB for review. The results of the review will be recorded in review notes in Mentor IRB and communicated to the investigator.
 - b. If the reviewer determines that the event may be an UAP, the report will be referred for review by the convened IRB. The convened IRB will determine whether the event is a UAP and whether any additional actions are necessary to ensure the protection of human subjects. If needed, the IRB may request additional information from the investigator, sponsor, or others. The results of the review will be recorded in the IRB minutes and communicated to the investigator.
3. Based upon the circumstances, the IRB may take any of the following actions, or others, to ensure the protection of human subjects:

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- a. Requiring modifications to the protocol or plan or procedures for implantation of the research (Research Plan) as described in the application and other materials submitted to the IRB;
- b. Revising the continuing review timetable;
- c. Modifying the consent process;
- d. Modifying the consent document;
- e. Providing additional information to current participants (e.g., whenever the information may relate to the subject's rights, welfare, or willingness to continue participation);
- f. Providing additional information to past participants;
- g. Requiring additional training of the investigator and/or study staff;
- h. Requiring that current subjects re-consent to participation;
- i. Monitoring the research;
- j. Monitoring consent;
- k. Reporting or referral to appropriate parties (e.g., the IO, General Counsel, IT);
- l. Suspending IRB approval;
- m. Terminating IRB approval;
- n. Other actions as appropriate given the specific circumstances.

When the IRB determines that an event is an UAP, the IRB staff will follow the procedures for reporting to regulatory agencies, sponsors, and organizational officials in Reporting to Federal Agencies, Departments, and Organizational Officials. When appropriate, a preliminary report may be submitted while more information is obtained to inform the determination or actions.

Documentation and Record-Keeping

All reports, correspondence, and relevant documentation are retained in accordance with TC's policies for research record retention. Records include copies of the initial report, any follow-up communications, and final resolutions, if applicable.