

SOP-R-010: TC IRB Standard Operation Procedures (SOP) on Other Reportable Information

Policy

When research is under the oversight of the Teachers College (TC) IRB, in addition to UAPs, noncompliance, and complaints, any change to the research implemented without IRB approval and any information that may impact the rights, safety, or welfare of subjects or inform the IRB's oversight of the research must be reported to the IRB within **7 working days** of discovery using the Incident Report form in Mentor IRB, as applicable.

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.

Other reportable information includes, but is not limited to, the following:

1. Changes made to the research without prior IRB approval to eliminate apparent immediate hazards to the subject(s);
2. Protocol Deviations - any variation from the IRB approved research plan that happens without prior review and approval of the IRB and is not necessary to eliminate apparent immediate hazards to the subject(s);
3. Monitoring, audit, and inspection reports in accordance with the Quality Assurance & Post-Approval Monitoring SOP;
4. Notice of:
 - a. Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters and any corresponding compliance actions taken under non-US authorities related to human research protections.
 - b. Any litigation, arbitration, or settlements initiated related to human research protections.
 - c. Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding human subjects research conducted at or by TC or TC's program for the protection of human research participants.

NOTE: The above events (4.a, b, and/or c) must be reported to the IRB office by phone or email **as soon as anyone becomes aware**, with the formal submission within the 7-day timeline as noted above. See Investigator Responsibilities SOP for more information.

5. Sponsor or coordinating center reports;
6. Enrollment or inclusion of vulnerable populations not previously approved by the IRB for the study (e.g., prisoner, pregnant woman, neonate, child, adult with impaired decision-making capacity);
7. When an existing subject becomes a member of a vulnerable population not previously approved by the IRB for inclusion in the study (e.g., incarceration, pregnancy, or change in decision-making capacity of an already enrolled subject);
8. Holds, suspensions, or terminations of a study, in part or in full, by an investigator, sponsor, or others;

9. Changes that impact the ability of the PI to conduct or supervise the study, temporarily or permanently;
10. Changes that impact the qualifications of investigators or research staff members; e.g., actions taken by regulatory authorities or licensing boards;
11. New information that may impact the rights, welfare, or willingness of subjects to continue in the research.

Procedures

1. Upon receipt of the report, the IRB staff pre-reviews the submission and, if needed, contacts the investigator for corrections or additional information. If the information provided suggests that subjects may be at risk of harm without immediate intervention or that research misconduct may have occurred, the Research Compliance Director, IRB Chair, and, when appropriate, the IO or designee, will be notified so that they can take any necessary steps to ensure the safety of subjects or investigate the matter.
2. The IRB Chair or designated reviewer receives and reviews the report and if the report may represent an UAP or noncompliance, reviews the report as described in Unanticipated Problems Involving Risks to Subjects or Other or Non-Compliance SOPs. When circumstances warrant, the Research Compliance Director or Research Compliance Manager may bypass this step and assign the report for convened board review.
3. If the reviewer determines that the event or issue is not noncompliance or an UAP, they will review the event or issue, any proposed corrective and preventative action plans, and determine if any additional actions are needed to ensure the protection of human subjects.
4. As warranted, the reviewer may refer the matter to the convened IRB for review. The results of the review will be recorded in Mentor IRB and communicated to the investigator.

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.