SOP-R-007: TC IRB Standard Operation Procedures (SOP) on Reporting to Federal Agencies, Departments, and Organizational Officials

Purpose

This SOP outlines the procedures for reporting unanticipated problems, serious or continuing noncompliance, and suspensions or terminations of IRB approval to federal agencies, departments, and institutional officials as required by federal regulations.

Policy

Federal regulations require prompt reporting to appropriate institutional officials and, as applicable, the federal department or agency (e.g., OHRP, FDA), of (i) any unanticipated problems involving risks to subjects or others; (ii) any serious or continuing noncompliance with the applicable federal regulations or the requirements or determinations of the IRB; and (iii) any suspension or termination of IRB approval. Teachers College (TC) IRB complies with this requirement as follows.

When research is under the oversight of an external IRB, the terms of the agreement with that IRB will guide reporting.

Procedures

IRB staff will initiate these procedures as soon as the IRB takes any of the following actions:

1. Determines that an event may be considered an unanticipated problem involving risks to participants or others
2. Determines that noncompliance was serious or continuing
3. Suspends or terminates approval of research

The Research Compliance Director or designee is responsible for preparing reports in accordance with the instructions of the Federal department or agency (e.g., OHRP).

The Research Compliance Director or designee sends a copy of the report to:

1. The IRB Chair
2. The IO
3. Federal departments or agencies, as follows:
    a. OHRP, if the research is conducted or supported by DHHS, or if an engaged institution's FWA has been voluntarily extended to all non-exempt human subjects research
    b. If the research is conducted or supported by a Common Rule Dept. or Agency other than DHHS, the report is sent to the party identified by the Dept. or Agency. A list of contacts is available on OHRP's Reporting Incidents webpage.
    c. If the study is conducted or supported by a federal dept. or agency that has not adopted the Common Rule, and reporting is required, the report is sent to the party identified by the dept. or agency.

Teachers College, Columbia University
Institutional Review Board
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Reports are not submitted to federal departments or agencies such as OHRP unless the research is subject to federal regulations or another mandate that necessitates such reporting.

4. Sponsor, if applicable
5. Principal Investigator, when applicable
6. Others as deemed appropriate by the IO

The Research Compliance Director ensures that all steps of this policy are completed within 30 working days of the determination. For more serious actions, the Research Compliance Director expedites reporting. If additional time is needed to gather facts, or determine corrective actions, a preliminary report will be submitted within 30 days, to be followed by a final report as described above.

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.

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