SOP-R-011_TC IRB Standard Operation Procedures (SOP) Post-Approval Monitoring and Auditing of IRB-Approved Research

Purpose

This SOP establishes the process for conducting post-approval monitoring (PAM) and audits of human research studies overseen by the Teachers College IRB (TC IRB). These processes ensure the ongoing compliance with federal regulations, institutional policies, and the protection of research participants.

Policy

Primary Investigators (PIs) of human research projects approved by the Teachers College IRB are required to participate in post-approval monitoring activities. Audits of approved projects may be conducted either for cause or randomly at any time. In accordance with regulations that govern human research (45 CFR §46.109(e) and 21 CFR §56.109(f)), TC IRB has the authority to conduct:

- Observation of the informed consent process.
- Observation of research procedures, including interactions and/or interventions with participants.
- Surveying participants enrolled in the project about the informed consent process and their experience as a participant.
- Review of all documents and materials pertaining to the permission for or conduct of research activities.

Responsibilities

- **Compliance Team**: Conducts routine and for-cause post-approval monitoring.
- **Principal Investigator (PI)**: Ensures study compliance with IRB-approved protocols, attends audits, and provides required documents and information.
- **IRB Chair/Research Compliance Director**: Oversees the audit process and reviews findings.

Procedure

Types of Audits

1. **Audits for Cause:**
   - Initiated if a concern or complaint about the conduct of a project is discovered or reported to TC IRB staff, any IRB member, or other administrative officials.
   - Determination of the need for an audit for cause is made by the IRB Chair in consultation with the Research Compliance Director.
   - Audits can be project-oriented (focused on a specific project) or researcher-oriented (focused on all projects of a particular researcher).
   - Audits may include all project documents or be limited to consent forms or other specified areas.

2. **Full On-Site (Routine) Assessments:**
   - Full assessments of any active project may occur at any time for quality assurance oversight with a focus on:
     - Recruitment of vulnerable populations.
     - Federal funding.
     - Large numbers of participants.
     - PI with a large number of active projects and a history or pattern of noncompliance.
     - Procedures that are greater than minimal risk to participants.

- IRB Reviewer recommendations.

Conducting an Audit or Assessment

1. The TC IRB has primary responsibility for conducting audits and assessments. Assistance may be requested from the IRB Chair, Institutional Official (IO), IT staff, or other experts.
2. The PI must be present for the opening interview but is not required for the entire audit/assessment. A project team member should be available if the PI is not present.
3. TC IRB staff may review the researcher's files, participant research records, signed consent/assent forms, and other documents to determine compliance.
4. On-site records may be reviewed and compared to TC IRB office records to ensure compliance.
5. Research staff's written SOPs or procedures and plans may be reviewed.
6. Interviews with the PI, project team members, or research participants may be conducted.
7. Findings will be recorded and reviewed with the research staff at the end of each assessment day when feasible.
8. External sponsors may conduct audits, investigations, site visits, or evaluations as detailed in the sponsor contract, coordinated in advance through the TC IRB.

Confidentiality

Knowledge of audit/assessment procedures and findings will be kept confidential. A signed confidentiality agreement may be requested.

Notification to Researchers

- PI of a project randomly selected for a full assessment will be notified at least five (5) working days in advance.
- PI of a project selected for an audit for cause will be notified at least one (3) working day in advance.

Audit and PI Presence

- Generally, an audit should include the presence of the PI to ensure accurate and comprehensive responses to any questions and to facilitate the verification of procedures and documentation.
- However, if there is a significant risk to subjects identified, the audit should proceed regardless of the PI's availability to mitigate potential risks and ensure participant safety.
  - A designated co-investigator or another knowledgeable and responsible member of the research team must be present during the audit.
- If no risk to subjects has been identified, it is acceptable to delay the routine audit until the PI is available. This ensures your active participation and a thorough review process.

Contingency Plan for PI Absence

- A designated co-investigator or another knowledgeable and responsible member of the research team should be present.
- The IRB should be notified in advance about the PI's absence and the temporary delegation of responsibilities.

Response to Findings

- Upon completion, TC IRB will prepare an TC IRB Audit Findings Report.
- If no findings are noted, the report will be published in Mentor IRB for PI access.
- If findings are noted, the report will be reviewed by the IRB Chair, who will determine any required actions or additional monitoring.

Review by the IRB

- The Research Compliance Director will review the Findings Report.

- The IRB Chair or Vice Chair will review the Findings Report and determine the compliance status:
    - Full compliance with no deficiencies.
    - Objectionable practices but no major departures.
    - Major departures from regulations and policies, requiring submission of a Protocol Deviation and/or Adverse Event form for review by a fully convened IRB meeting.
- Noncompliance findings will be reviewed according to the TC IRB Reportable New Event Reviewer Checklist, with possible additional stipulations or required training for the PI.
    - PIs must address any findings of non-compliance within 30 days, and follow-up monitoring may be required.
    - Non-compliance may result in additional corrective measures, including protocol amendments, re-training, or study suspension. Continued non-compliance may affect future submissions.

Reports

An annual summary report of all findings, including corrective actions and preventive measures (excluding personal identifiers), will be made available to the IRB and Institutional Official (IO)/Provost.

Resources

TC IRB Audit Reviewer Checklist
TC IRB Audit Findings Report
TC IRB Audit Notification to Researchers Email Template
TC IRB Researcher Guidance Audit Preparation Checklist
TC IRB Reportable New Event Reviewer Checklist

References

45 CFR 46.109(e)
21 CFR 56.109(f)

Rev 0
Effective Date: 06/21/2024

3

Teachers College, Columbia University
Institutional Review Board
525 W. 120th St. Box 151, New York, NY 10027
212-678-4105 | IRB@tc.edu | RH 13 | tc.edu/IRB