SOP-A-009: TC IRB Standard Operation Procedures (SOP) on Quality Assurance & Post-Approval Monitoring

Policy

Teachers College (TC) IRB performs Quality Assurance and Improvement activities for the purposes of monitoring the safety of ongoing studies and measuring and improving human research protection effectiveness, quality, and compliance with organizational policies and procedures and applicable federal, state, and local laws.

External Monitoring, Audit, and Inspection Reports

The TC IRB should be notified in advance, whenever possible, of upcoming audits or inspections of research whether the study is reviewed by the TC IRB or an external IRB on TC's behalf. IRB representatives may participate in entrance and exit interviews and otherwise observe or support the audit or inspection. Likewise, TC representatives may assist in the development of any responses to audits or inspections.

When research is under the oversight of the TC IRB, all reports from external monitors, auditors, or inspectors must be submitted to the IRB for review. The IRB Chair or designee will review such reports to monitor for issues that could impact the rights or welfare of human subjects and for issues indicative of possible serious or continuing noncompliance. If such issues are identified, the report will be forwarded to the convened IRB to determine what additional actions are necessary, if any.

When TC is engaged in research reviewed by an external IRB, all reports from audits or inspections must be submitted to the TC IRB for review. The TC IRB may require corrective and preventative actions (CAPA), a follow up review, or other actions as needed to ensure the protection of human subjects and to support compliance.

Reports indicative of any negative actions by a government oversight office regarding research conducted at or by TC, must be immediately reported to the IRB office by phone or email regardless of whether the research is reviewed by an internal or external IRB. See Investigator Responsibilities SOP for more information.

Investigator Compliance Reviews (aka Post-Approval Monitoring)

The QA & Education & Specialist or, on occasion, other internal or external staff, conduct post-approval directed (for cause) and routine (not for cause) compliance reviews of human subject research conducted under the auspices of TC. Additionally, the IRB may appoint a subcommittee for the purpose of conducting a for-cause or not for-cause compliance review of one or more research plans under its oversight. The subcommittee may be composed of IRB members and staff from within, or individuals from and outside of the organization.

Compliance reviews are conducted to assess investigator compliance with federal, state, and local law, and TC policies, and to identify areas for improvement, and to provide recommendations based on existing policies and procedures. The results of compliance reviews will be reported to the Research Compliance Director, the internal IRB (when the internal IRB is the IRB of record), the investigator, and other TC leadership, as appropriate. Any IRB reporting and evaluation of noncompliance will be handled according to the procedures of the IRB of record.

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If it is identified during a review that subjects in a research project may have been exposed to unexpected serious harm or risk of harm, the reviewer will promptly report such findings to the Research Compliance Director and the IRB of record.

If issues are identified that indicate possible misconduct in research, the procedures in the Teachers College *Research Misconduct Policy and Procedures* will be initiated. Compliance reviews may include:

- Requesting progress reports from investigators
- Reviewing source documentation
- Reviewing the recruitment process and materials
- Reviewing consent materials and the documentation of consent
- Observing the consent process and other research activities
- Verifying HIPAA authorization
- Interviewing investigators and research staff
- Interviewing research subjects
- Reviewing projects to verify from sources other than the investigator that no unapproved changes have occurred since previous review
- Conducting other monitoring or auditing activities as deemed appropriate by the IRB.

IRB Compliance Reviews

The QA & Education & Specialist, Research Compliance Manager, Research Compliance Director, or, on occasion, other internal or external staff, will periodically review the activities of the IRB to assess compliance with regulatory requirements and to identify areas for improvement; this will include a review of IRB records at least annually.

Review activities may include:

- Review of the IRB minutes to evaluate whether adequate documentation of the meeting discussion and any required determinations has occurred, and that quorum was met and maintained
- Reviewing IRB files to evaluate whether adequate documentation of exemptions, expedited review, and other outside of committee reviews has occurred
- Reviewing consent forms to evaluate whether all required elements are included
- Reviewing the IRB databases to evaluate whether all required fields are completed accurately
- Verifying IRB approvals for external sites or investigators
- Reviewing metrics (for example, time from submission to first review) to evaluate the quality, efficiency, and effectiveness of the IRB review process
- Reviewing the workload of the IRB and IRB staff
- Other review activities as appropriate

The Research Compliance Director and IRB Chair will review the results of IRB compliance reviews with the IRB and the Institutional Official. If substantive deficiencies are identified in the review, a corrective action plan will be developed by the Research Compliance Director and approved by the IO. The Research Compliance Director will have responsibility for implementing and reporting progress on the corrective action plan, the results of which will be evaluated by the IO.

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Quality Assessment and Improvement

Annually, a meeting is held by the Research Compliance Director to establish a quality assessment/ improvement (QA/QI) plan to assess compliance, and the quality, efficiency, and effectiveness, of the IRB. The plan will include, at a minimum, the following:

- The goals of the plan with respect to achieving and maintaining compliance
    - At least one objective to achieve or maintain compliance
    - At least one measure of compliance
    - The methods to assess compliance and make improvements
- The goals of the plan with respect to achieving targeted levels of quality, efficiency, and effectiveness
    - At least one objective of quality, efficiency, or effectiveness
    - At least one measure of quality, efficiency, or effectiveness
    - The methods to assess quality, efficiency, or effectiveness and make improvements.

The Research Compliance Director will meet regularly throughout the year with the staff responsible for performing the assessments called for in the plan to review progress and to identify opportunities for improvement. At the end of each year, the Director and IRB Chair will evaluate whether the respective goals were achieved and determine if any additional actions or monitoring are necessary.

If at any time substantive or concerning issues or trends are identified, the Research Compliance Director will report those issues or trends to the appropriate parties (e.g., the IO, the IRB Chair, General Counsel) and, if appropriate, a proposed CAPA plan.

In addition to the above, the QA & Education & Specialist is responsible for tracking internal data and metrics that are informative when considering IRB efficiency, effectiveness, workload, and resources. Metrics reports will be provided to the Research Compliance Director and IRB Chair at least twice per year.

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