SOP-R-002: TC IRB Standard Operation Procedures (SOP) on Investigator Responsibilities

Policy

Principal Investigators (PIs) are ultimately responsible for the conduct of research. PIs may delegate tasks to appropriately trained and qualified members of their research team. However, PIs must maintain oversight and retain ultimate responsibility for the proper conduct of the research.

Definitions

Within the regulations, the term 'investigator' refers to individuals involved in the design, conduct, or reporting of the research. Such involvement could include one or more of the following:

- Designing the research
- Obtaining information about living individuals by intervening or interacting with them for research purposes
- Obtaining identifiable private information about living individuals for research purposes
- Obtaining the voluntary informed consent of individuals to be subjects in research
- Studying, interpreting, or analyzing identifiable private information or data for research purposes.

Responsibilities

Investigators who conduct research involving human subjects must:

1. Develop and conduct research that is in accordance with the ethical principles in the Belmont Report;
2. Develop a research plan that is scientifically sound and minimizes risk to the subjects;
3. Develop a research plan that ensures the just, fair, and equitable recruitment and selection of subjects;
4. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, include additional safeguards in the study to protect the rights and welfare of these subjects;
5. Ensure that the research plan includes adequate provisions for the monitoring of subjects and data to ensure the safety of subjects;
6. Ensure that there are adequate provisions to protect the privacy interests of subjects;
7. Ensure that there are adequate provisions to protect the confidentiality of data;
8. Have sufficient resources necessary to protect human subjects, including:
    a. Access to a population that would allow recruitment of the required number of subjects;
    b. Sufficient time to conduct and complete the research;
    c. Adequate numbers of qualified staff;
    d. Adequate facilities;
    e. Necessary equipment;

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f. A plan to ensure proper supervision of the research including a plan for periods of absence or decreased availability; and

g. When appropriate, a plan to ensure the availability of medical, psychological, or other services that subjects might require as a result of their participation.

9. Ensure that all procedures in a study are performed with the appropriate level of supervision and only by individuals who are qualified to perform them under the laws of New York and the policies of TC;
10. Ensure that all study personnel are educated in the regulatory requirements regarding the conduct of research and the ethical principles upon which they are based;
11. Ensure that all persons assisting with the research are adequately trained and informed about the protocol and research implementation plan and their specific duties and functions;
12. Promptly report any changes in, addition to, or departure of investigators or research staff to the IRB for evaluation and approval (note that investigators and staff may not begin work on the research until IRB-approved);
13. Protect the rights, safety, and welfare of participants;
14. Ensure that the language in the consent form is consistent with that in the protocol, any associated grant or contract;
15. Obtain and document informed consent and ensure that no human subject is involved in the research prior to obtaining consent or consent/permission from their LAR, unless a waiver of the requirement has been approved by the IRB;
16. Have a procedure to receive questions, complaints, or requests for additional information from subjects and respond appropriately;
17. Ensure that all information provided to the IRB is accurate and complete so that the IRB may fulfill its responsibilities to review the research and make the required determinations;
18. Ensure that all research involving human subjects receives IRB review and approval in writing or a determination of exemption before the research begins;
19. Ensure that all required reviews and approvals are in place before initiating the research;
20. Comply with all IRB decisions, conditions, and requirements;
21. Ensure that studies receive timely continuing IRB review and approval;
22. Report unanticipated problems, deviations, complaints, noncompliance, suspensions, terminations, and any other reportable events to the IRB and the organization, as required by regulations and policy;
23. Notify the IRB if information becomes available that suggests a change to the potential risks, benefits, merit, or feasibility of the research;
24. Obtain IRB review and approval before changes are made to the research unless a change is necessary eliminate apparent immediate hazards to the subject(s);
25. Seek IRB assistance when in doubt about whether proposed research requires IRB review;

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26. Retain records for the time-period and in the manner described to and approved by the IRB and as required by required by regulations, agreements, and policies.

Record Retention

Investigator research records, including, but not limited to, signed consent forms, subject records and data, IRB records (submission materials, IRB determinations and associated documentation, correspondence to and from the IRB, etc.), and sponsor/grant records must be retained in accordance with regulatory, organizational, IRB, sponsor or grantor, and journal or publication standards. Records must be maintained securely with limited access. Disposal of investigator records must be done in such a manner that no identifying information can be linked to research data. When research is sponsored or grant-supported, consult the contract, grant terms, or other relevant agreements prior to destroying or transferring any records. If there are questions or allegations about the validity of the data or the appropriate conduct of the research, all records must be retained until such questions or allegations have been completely resolved.

For research supported by federal agencies, research records must be retained for at least 3 years after the completion of the research.

HIPAA Retention Requirements

For research subject to the Health Insurance Portability and Accountability Act (HIPAA), records must be kept for 6 years after completion (45 CFR 164.530(j)). This includes records of IRB determinations of waivers of authorization (45 CFR 164.512(i)(2)(ii)), written HIPAA authorizations, and records of disclosure not listed in the consent and authorization document (e.g. secondary analysis of data studies conducted under a waiver).

Destruction of Records

Investigators are responsible for periodically ensuring the appropriate destruction of all records that have reached the end of their retention period. Acceptable destruction methods include:

1. Recycling: Generally appropriate for all paper records that do not contain personal, certain financial, or confidential information. Examples include public records of other organizations, magazines, annual reports, newsletters, and announcements.
2. Secure destruction: Using a shredder or shredder service for all records that contain personal, financial, or confidential information. This includes, but is not limited to, all records that contain attorney-client communications, student education records, health-related information, and certain financial information.

Investigators should consult with TCIT regarding the destruction of electronic records.

Investigator Concerns

Investigators who have concerns or regarding the conduct of research at TC, the TC IRB or the external IRBs TC relies upon should convey them to the Research Compliance Director, the Institutional Office (IO) or other responsible parties (e.g., faculty advisor, supervisor, Department Chair), when appropriate. The recipient of the concern will consider the issue, and when deemed necessary, seek additional information and convene the parties involved to form a response for the investigator or make necessary procedural or policy modifications, as warranted. In addition, the IRB Chair and IRB Manager are available to address investigators' questions, concerns, and suggestions.

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The College also operates a website and telephone hotline that permit the anonymous reporting of concerns. To make a report, contact EthicsPoint at 888-329-6420 or here.

Consistent with TC policies, there will be no retaliation against employees, faculty, students or staff who report concerns in good faith.

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