Albert Einstein College of Medicine

Principal Investigator Responsibilities

I. Purpose

The purpose of the Policy is to outline the responsibilities of Principal Investigators ("PIs") who conduct research involving human subjects at Albert Einstein College of Medicine ("Einstein") and Montefiore Medical Center ("MMC"), in regards to the protection of human subjects and compliance with Office of Human Research Affairs (OHRA) policies and procedures.

II. Scope

This Policy applies to all Principal Investigators conducting human research at Einstein or MMC that is under the purview of the Einstein Institutional Review Board ("IRB"). For Principal Investigator responsibilities when engaged in multi-site research involving a Single IRB ("sIRB") arrangement, refer to the policy, "sIRB Principal Investigator Responsibilities."

III. Definitions

Principal Investigator ("PI"): The individual who is personally responsible for the overall conduct of a specified human research study or clinical investigation.

IV. Policy

Through the act of being named as the Principal Investigator ("PI") of a study, the PI is agreeing to assume the overall responsibility for the study conduct at Einstein/MMC. Primary responsibility for protecting the rights and welfare of human subjects participating in research rests with the PI.

The PI may delegate authority to make decisions about the study but may not delegate the responsibility for proper conduct of the study. The PI is responsible for the actions of all co-investigators and research staff involved with the research.

The PI is responsible for conducting human research in compliance with all applicable federal and state regulations and institutional policies, including the following:

- Obtaining IRB approval or an exempt determination prior to initiating human research, and ceasing all research activities if IRB approval expires before continuing review and approval occur;[1]
- Ensuring that all members of the study team have a) been trained to conduct the study in accordance with the approved protocol, b) completed mandatory human research training as required by the Office of Human Research Affairs ("OHRA"), and c) completed all required conflict of interest disclosures in accordance with Einstein and MMC policies on conflicts of interest;
- For clinical research, ensuring that clinical staff have appropriate licensing and credentialing;
- Obtaining Department/Division approval and applicable ancillary committee approval in accordance with institutional policies;
- Overseeing the conduct of the research, including recruitment, obtaining consent and protocol procedures, managing data collection to ensure adequate and accurate records, storage, security and backup, and ensuring accurate analysis of study data;
- Ensuring that the research is conducted in accordance with the study's IRB-approved protocol, and any conditions that are set in order to receive IRB approval;
- Obtaining and documenting informed consent in accordance with regulatory and institutional requirements, unless waived by the IRB;
- Delegating responsibilities to qualified study team members that are commensurate with their training and qualification;
- Maintaining documentation for each study in compliance with federal and institutional policy.[2]
- Retaining research records after study completion in compliance with federal and institutional policy.[3]

The PI is responsible for reporting the following information to the IRB:

- Any proposed changes to the research activity including amendments to the previously approved protocol or proposed changes to study documents or procedures;[4]
- Progress reports, in accordance with institutional policies and procedures;
- Closure information once human research is completed;
- All unanticipated problems involving risks to subjects or others, and other events that require prompt reporting in accordance with federal regulations and institutional policies;

[1] Except where they judge that it is in the best interests of already enrolled subjects to continue to participate. When investigators make this judgment, they must promptly notify the IRB. See the procedure, "Protocol Exception Requests."

[2] See the policy "Required Documentation for the Conduct of Research Involving Human Subjects."

[3] See the policy "Research Record Retention Policy."

[4] The only exception is when it is necessary to eliminate apparent immediate hazards to subjects. Once the change has been made, the IRB must be immediately informed of the event that required this emergent change. See the procedure "Other Reportable Events."

- Any noncompliance with regulations, IRB-approved protocol, IRB conditions, and institutional policies and procedures;
- Any other information that must be promptly reported per institutional policies;[5]
- Change in PI.

PIs conducting human research will ensure that they fulfill their ethical obligations to protect the research participants via the following:

- Providing reasonable access to needed medical care, either by the investigator or by another identified, qualified individual (e.g., when the investigator is unavailable, when specialized care is needed);
- Ensuring that human research subjects are kept informed of any new information that may affect their willingness to continue to participate in the research study.
- Ensuring that there are adequate resources available to safely conduct the research and to ensure the safety of research participants, including:
    - Access to a population that will allow you to recruit the required number of subjects in a reasonable amount of time
    - Sufficient time to conduct and complete the research
    - Adequate staff to carry out, monitor, and compile the research
    - Adequate facilities for the type of research to be conducted
    - Institutionally approved access to systems and appropriate training
    - Appropriate medical or psychological resources as outlined in the data safety and monitoring plan;
- Ensuring that s/he or another specific qualified individual is available to study subjects to answer questions during the conduct of the research;
- Addressing any concern or question raised by a research subject (or parent, legal guardian, Legally Authorized Representative, as applicable) before, during, or after the conduct of a research study.
- Informing the subject's primary physician about the subject's participation in the clinical trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.
- Although a subject is not obliged to give his or her reasons for withdrawing prematurely from a clinical trial, the investigator must make a reasonable effort to ascertain the reason for a subject withdrawal, while fully respecting the subject's rights.

When conducting FDA-regulated drug or device trials, the PI will be responsible for the following:

- In the case of drug/device trials, the PI must ensure that the study is conducted according to the signed investigator statement for clinical investigations of drugs, including biological products, or agreement for clinical investigations of medical devices, the investigational plan, and applicable regulations;

[5] See the procedure "Other Reportable Events."

- When drugs, biological products, and devices are being investigated or used, they must be managed and controlled as required by institutional policy and, when applicable, FDA regulations 21 CRF 312 and 21 CFR 812;[6]
- The PI must maintain adequate and accurate case histories on each subject's participation in the trial, and adequate records of the disposition of the drug or device;
- The PI must provide the Investigational New Drug ("IND") or Investigational Device Exemption ("IDE") holder with progress reports, safety reports, deviations from the investigational plan, the final report, and financial disclosure reports;
- Investigators who submit protocols involving FDA test articles and for which they hold the IND or IDE are considered by FDA to be sponsor-investigators. A sponsor-investigator must adhere to the same federal regulatory responsibilities as any other sponsor of an IND or IDE.

When serving as the lead PI for a multi-site study in which each site is under separate IRB review, the Einstein/MMC PI assumes the responsibility for overall data management, monitoring and communication among all sites, and general oversight of the conduct of a human subject's research project. They must ensure all of the following:

- Investigators and sites are qualified by virtue or training and experience to conduct the research;
- Investigators have adequate resources—space, time and potential for enrolling the requisite number of subjects—to ensure that it is feasible to conduct the study at their site;
- All sites conduct the research in accordance with the study's IRB-approved protocol;
- All sites obtain IRB approval prior to local initiation of the study;
- A valid consent is obtained using an IRB-approved informed consent form that contains the required elements of consent, unless consent has been waived;
- All required study materials are distributed and accounted for, including investigational test articles, case-report forms, etc.;
- The data that is collected is accurate, valid, and securely stored;
- All use and disclosure of Protected Health Information is compliant with HIPAA regulations and institutional policies;
- Analyses are accurate and carried out in conformance to the pre-specified statistical analysis plan (as applicable and specified in the protocol);
- Safety of subjects is assured by continual assessment throughout the conduct of the study;
- Unanticipated problems are reported to the relevant regulatory authorities, funding agencies, and all local sites;
- Authorship of results is equitably apportioned to investigators in accordance to the requirements of the ICJME.

[6] See the procedures "Investigational Device Procedure" and "Investigational Drug Procedure" for more information on FDA regulations, including the criteria for IND and IDE exemption. See the "Guidelines for Storage and Dispensing of Investigational Drugs" for more information on the management and control of investigational drugs.

Budget Development and Approval

The PI is responsible for working with appropriate offices to ensure that the budget is in accordance with institutional requirements and includes appropriate rates for all items and services, and that sponsor agreements and contracts include proper rates as approved by the institution.

The PI is responsible for ensuring accurate study billing and timely reimbursement to subjects.

Contract Review and Negotiations

The PI is responsible for ensuring that all agreements, including clinical trial agreements and confidentiality/non-disclosure agreements are reviewed by institutional legal counsel.

ClinicalTrials.gov

If the PI is the Responsible Party for a clinical trial that must be registered on ClinicalTrials.gov, the PI is responsible for ensuring the trial is registered, submitting results, and promptly making updates as required by all applicable regulations and policies.[7]

V. Effective Date

Effective as of: March 10, 2020

Revised as of: August 22, 2023

VI. Policy Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this Policy. The Executive Dean is the Responsible Executive for this Policy. The OHRA Director is the Responsible Officer for the management of this Policy.

VII. Approved (or Revised)

Responsible Executive

12/19/23

Date

[7] Refer to the policy "Clinical Trials Registration and Results Reporting" for more information about ClinicalTrials.gov requirements and registration.