

# Human Research Protection Program Policy

## I. Purpose

This Policy describes the plan of the Albert Einstein College of Medicine (“Einstein”) and Montefiore Medical Center (“MMC”) to comply with ethical and legal requirements for the conduct and oversight of Human Research.

## II. Scope

The HRPP applies to all Human Research that engages Einstein or MMC, and all Human Research submitted to the Einstein Institutional Review Board (“Einstein IRB”) for review.

## III. Definitions

**Human Research:** Any activity that is either:

- “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS; or
- “Research” as defined by FDA and involves “Human Subjects” as defined by FDA

**Research as Defined by DHHS:** Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

**Research as Defined by FDA:** FDA has defined "clinical investigation" to be synonymous with "research". "Clinical investigation" means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA...or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

**Human Subject as defined by DHHS:** Human subject means a living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable confidential information or identifiable biospecimens.

- Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- Interaction includes communication or interpersonal contact between investigator and subject.

- Privileged information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- Identifiable privileged information is confidential information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

**Human Subject as Defined by FDA:** An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

**Engaged in Human Research:** Einstein or MMC are engaged in Human Research when its employees or agents are interacting or intervening with Human Subjects for the purpose of conducting research. Einstein and MMC follow OHRP guidance on “Engagement of Institutions in Research” to apply this definition.

**Institutional Official (“IO”):** The IO is the organizational official responsible for ensuring that the HRPP has the resources and support necessary to comply with all federal regulations and guidelines that govern Human Research. The IO is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the terms of its Federal-wide Assurance.

**Institutional Review Board (“IRB”):** A specifically constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral/social science research.

**Investigator:** The person responsible for the conduct of Human Research at one or more research sites. Suppose the Human Research is conducted by a team of individuals at a research site. In that case, the investigator is the responsible leader of the team and may be called the principal investigator.

## **IV. Policy**

To ensure the highest standards of human subject protection, Einstein and Montefiore have developed and supported a Human Research Protection Program (“HRPP”). Einstein and MMC pride themselves on their commitment to excellence in all research activities and recognize the institutional responsibility for the ethical conduct of research. Such standards are vital for the success of the research enterprise, participant safety, and public trust.

The HRPP shall ensure compliance with all Einstein policies as well as all federal, state, and local laws and regulations.

The HRPP includes mechanisms to:

- Establish a formal process to monitor, evaluate, and continually improve the protection of human research participants.
- Provide guidance to investigators and research staff for the ethical conduct of research.
- Dedicate resources sufficient to do so.

- Exercise oversight of research protection.
- When appropriate, intervene in research and respond directly to the concerns of research participants.

The HRPP will adopt operating procedures to implement this, Policy.

### Ethical Principles

The HRPP will be guided by the principles set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (often referred to as the Belmont Report). These principles include respect for persons, beneficence, and justice.

Einstein applies its ethical principles to all Human Research regardless of support or geographic location. Policies and procedures applied to research conducted domestically are applied to international research.

The following categories of individuals are expected to abide by these ethical requirements:

- Investigators
- Research Staff
- IRB members, IRB chairs, and IRB vice-chairs
- HRPP staff members
- Institutional Officials
- Employees and agents

### Legal Requirements

Einstein applies FDA regulations, the Original Common Rule, the Revised Common Rule, and 45 CFR 46 Subparts B, C, and D to human research, as described in the table below:

Category of Research	Research initially reviewed or determined exempt:	
	Before January 21, 2019	On or after January 21, 2019
FDA-regulated research that is NOT emergency use, compassionate use, or device research on anonymous tissue specimens	FDA regulations Original rule Subparts B, C, D	FDA regulations Original rule Subparts B, C, D
Emergency use, compassionate use, or device research on anonymous tissue specimens	FDA regulations	FDA regulations
Research regulated by a federal department that is a Common Rule Signatory	Original rule Subparts B, C, D	Revised rule Subparts B, C, D
Unregulated research	Original rule Subparts B, C, D	Revised rule Subparts B, C, D

Einstein applies other federal regulations, when applicable. Einstein does not apply New York State law Article 24-A regarding the protection of human subjects, as it applies federal regulations to all human research.

### **Periodic Evaluation**

As part of the annual budget review, the directors of the component offices of the HRPP review budget, personnel, and office space in consultation with the Dean's Office to ensure adequate resources to support HRPP operations, including IRB, COI, and community outreach operations. A portion of the OHRA budget is dedicated to education and development for IRB members and OHRA staff and is also reviewed annually. Educational needs for the research community are assessed twice per year with input from administrative leadership, the Dean's Office, investigators, OHRA staff, IRB members, and research support staff. The OHRA education specialist then runs a comprehensive HRPP education program for Einstein Montefiore based on these assessments.

OHRA leadership regularly confers to discuss potential areas for evaluation and improvement. Based on such discussions, the Director of the OHRA creates an annual quality improvement plan that is reviewed by the Dean's Office. The OHRA coordinates with other component offices of the HRPP as necessary to develop appropriate educational initiatives to meet compliance and quality improvement goals.

### **Components of the HRPP:**

#### **Institutional Officials**

The Executive Dean at Einstein and the Director of the Office for Research at MMC serve as the Institutional Officials ("IOs") for Einstein and MMC, respectively. The IOs have overall responsibility for the HRPP.

The IOs are authorized to take the following actions or delegate these authorities to a designee:

- Create the HRPP budget and allocate resources within the budget
- Appoint and remove IRB members, IRB chairs, and IRB vice-chairs
- Hire and fire research review staff
- Determine the IRBs that the organization will rely upon
- Limit or condition investigator or research staff privileges to conduct Human Research
- Sign IRB authorization agreements
- Suspend or terminate IRB approval of research
- Disapprove research approved by the IRB

The IOs have the responsibility to take the following actions or delegate these responsibilities to a designee:

- Oversee the HRPP
- Ensure the independence of the review process
- Ensure that complaints and allegations regarding the HRPP are appropriately handled
- Ensure that the HRPP is provided the resources necessary to conduct the activities under its jurisdiction and adjust resource allocation as needed

- Establish a culture of compliance with HRPP requirements
- Investigate and correct allegations and findings of undue influence on the Human Research Review process
- Ensure that officials of the organization cannot approve research that has not been approved by an IRB designated by the organization
- Investigate and correct systemic problems related to the HRPP
- Periodically review HRPP policies and procedures
- Assume the obligations of the Federal wide Assurance of Compliance for the Protection of Human Subjects on behalf of Einstein and MMC
- Encourage participant outreach activities to further the understanding of and support for human subject research.

### **All members of the organization**

All individuals within the organization have the responsibility to:

- Understand the definition of Human Research
- Consult the IRB when there is uncertainty about whether an activity is Human Research
- Not conduct Human Research or allow Human Research to be conducted without review and approval by an IRB designated by the Institutional Official.
- Report allegations of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to the Institutional Official.
- Report allegations or findings of noncompliance with the requirements of the Human Research Protection Program to the IRB.

### **Office of Human Research Affairs**

The Office of Human Research Affairs (“OHRA”) is the central administrative office of the HRPP. This office serves as the central repository of all information affecting the protection of human subjects in research.

The mission of the OHRA is to enhance and facilitate the ethical conduct of human subject research conducted by Einstein and MMC faculty and staff, regardless of location. The OHRA will perform this mission through its review of human subject research, its educational and training initiatives, compliance oversight, and quality improvement programs.

The OHRA is responsible for the management and oversight of the Einstein IRB and Conflict of Interest Committee, as well as the reporting of all safety and noncompliance issues regarding research involving human subjects. The OHRA is responsible for ensuring that all relevant information affecting the safety and welfare of human subject research is reported to the Einstein IRB, and, as appropriate, to Institutional Officials, federal regulatory agencies, and sponsors. The OHRA also oversees other related research administration functions, such as ClinicalTrials.gov registration.

### **Einstein Institutional Review Board**

The OHRA has designated the Einstein Institutional Review Board (IRB) to review the Human Research conducted under the auspices of the HRPP.

The Einstein IRB has the authority to:

- Approve, require modifications to secure approval, and disapprove all Human Research activities overseen and conducted by Einstein and MMC
- Suspend or terminate approval of Human Research not being conducted in accordance with HRPP requirements, or that had been associated with unexpected serious harm to participants
- Observe, or have a third party observe, the consent process and the conduct of the Human Research
- Determine whether an activity is Human Research
- Determine whether Einstein or MMC are engaged in Human Research
- Decide whether fiscal interests related to the research and the management, if any, allow approval of the Human Research

### **Conflict of Interest Committee**

Einstein and MMC strive to ensure objectivity, balance, transparency, and scientific rigor in all research activities. The Conflict of Interest (“COI”) Committee reviews and determines the appropriate management or mitigation of any potential conflict of interest in accordance with Einstein and MMC’s COI policy. The Conflict-of-Interest Committee is composed of a balanced representation of the institutions’ clinical and pre-clinical faculty and ex-officio representatives from the College of Medicine and Montefiore administration.

### **Research Compliance**

Research Compliance is responsible for conducting audits of clinical research to ensure subject safety, protection of subject rights, verification of accurate and complete data collection, identification of deficiencies, and development and implementation of appropriate corrective action plans. In addition, Research Compliance conducts audits to ensure compliance by investigators with applicable Einstein and Montefiore policies and procedures, policies and procedures of the reviewing IRB, ICH Good Clinical Practice guidelines, and OHRP and FDA requirements. Research Compliance may also conduct audits of the Einstein IRB to ensure that the IRB is adhering to federal regulations governing human subject research.

### **Office of Grant Support**

The Einstein Office of Grant Support is responsible for the administration of most of the HHS-sponsored research conducted by Einstein and MMC. The Office works closely with the OHRA staff to ensure that all human subject research has obtained appropriate IRB approval.

### **Office of Research Sponsored Programs**

The Office of Research and Sponsored Programs (“ORSP”) at Montefiore is the centralized administrative office that oversees the sponsored program applications and award processes and provides support to faculty regarding research activities. ORSP documents policy provides ongoing information to faculty regarding sponsorship, policy changes, and funding opportunities, and generally assists faculty in all aspects of the award process. ORSP collaborates with the OHRA staff to ensure that all human subject research has been reviewed and approved.

## **Office of Clinical Trials**

The Office of Clinical Trials (“OCT”) negotiates and manages sponsor agreements and contractual financing for private industry clinical trials. Their mission is to encourage and support investigators at Einstein and Montefiore in the conduct of clinical research by providing resources, expertise, and best practices to facilitate efficient, compliant, and ethical study conduct and management.

## **Institutional Biosafety Committees**

The Institutional Biosafety Committees (“IBC”) at Einstein and Montefiore are responsible for the review and approval of the handling of hazardous materials in research, such as potentially infectious tissues or bodily samples, and research involving gene transfer. The IBCs also reviews any research involving the transfer of gene material, complementary DNA, full-length genes, RNA, or oligonucleotides into humans.

## **Protocol Review and Monitoring Committee**

The Protocol Review and Monitoring Committee (“PRMC”) serves as the scientific review committee for the Cancer Center. The authority and responsibilities of the PRMC include:

- Determining whether a protocol is scientifically sound
- Assurance that a protocol is appropriately designed
- Evaluation of whether protocol accrual goals are feasible for completion
- Monitoring of all cancer protocols for sufficient accrual and scientific progress
- Review and approval of amendments to active protocols

## **Institute for Clinical and Translational Research**

The Institute for Clinical and Translational Research (“ICTR”) provides resources to foster and support new collaborative, multidisciplinary human subject research at Einstein and Montefiore. Resources provided include consultation for biomedical informatics, research design and biostatistics, and regulatory considerations. The Institute also administers the Clinical Research Center, which allows investigators to conduct both inpatient and outpatient studies involving adults and children.

## **Pharmacy**

The Department of Pharmacy at Montefiore Medical Center and the OHRA work together to ensure that all investigational drugs, including those administered for emergency use, are administered in accordance with federal regulations and institutional policies.

## **Privacy Office**

The IRB serves as the Einstein and Montefiore Privacy Board for research-related HIPAA activities. The Privacy Office provides review, support, and oversight for the research of HIPAA requirements for protocols submitted to the IRB.

## **Office of General Counsel**

The Office of General Counsel serves the IRB and the OHRA, advising on such legal issues as regulatory matters, consent issues, state and federal law, and other research-related areas. Legal counsel serves as an

ex officio member of both IRB committees and works closely with IRB chairs, OHRA staff, and the IO's in reviewing legal issues affecting human research, assessing, and monitoring research practices, and assisting the institution in maintaining compliance with pertinent federal and state legal requirements. When there are any conflicts between legal requirements, Legal Counsel will determine the appropriate resolution.

### **Relationships with External Entities**

Einstein and MMC maintains Institutional Authorization Agreements ("IAAs") with various external institutions to rely on their IRBs for certain types of research projects. Einstein and MMC provide IRB and other research administration services to various external institutions, as defined in corresponding agreements and contracts.

## **V. Effective Date**

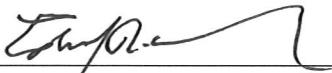
Effective as of: 10 July 2020

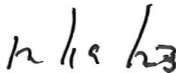
Revised as of: 18 September 2023

## **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)**

  
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Responsible Executive

  
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Date