



Albert Einstein College of Medicine

Research Involving Employees as Subjects

I. Purpose

This Policy describes the requirements for involving employees of Montefiore Medical Center (“MMC”) and/or Albert Einstein College of Medicine (“Einstein”) as subjects in human research that is under the auspices of the Einstein Institutional Review Board (“IRB”).

II. Scope

This Policy applies to all human research involving MMC or Einstein employees that is under the auspices of the Einstein Institutional Review Board (“IRB”).

III. Definitions

Employee: an individual who is contracted to receive a salary or other compensation from Montefiore or Einstein, or any subsidiary thereof in return for services performed on a full-time, part-time, limited-time, temporary, contracted, or casual basis

Direct Supervision: the authority to evaluate performance, recommend pay raises and/or promotions, or hire and terminate employees.

IV. Policy

MMC and Einstein employees may enroll in research studies approved by the Einstein IRB, subject to the safeguards and considerations set forth in this policy. Both the Principal Investigator and the IRB must ensure that employees who wish to serve as research subjects are protected from perceived coercion, lack of privacy, and other risks.

1. **Coercion or appearance of coercion prohibited**. An employee may not be required to participate in research as a condition of employment. An employee’s decision about research participation may not affect (favorably or unfavorably) performance evaluations, career advancement, or other employment-related decisions made by peers or supervisors.
2. **Studies looking at issues affecting employees as a group**. Investigators should not plan on targeting employees as subjects unless the study hypothesis involves one or more aspects of employment. Employees as a group should not be selected solely on the basis of convenience when they would not otherwise be appropriate for inclusion.
3. **Recruitment**. Proposed methods of recruitment of employees must be approved by the IRB. Recruitment must be designed to minimize the possibility of coercion or undue influence.

Potential participants should be recruited from a broad base of individuals meeting the eligibility criteria for the study, rather than from individuals in the same department of the study team or who report directly to the investigator(s). Recruitment should be through someone who is not in a supervisory relationship with the employee, and/or in the same department than the employee. Postings or sign-up sheets, or other methods that require an employee interested in participation to initiate contact with the investigator(s), are preferable to direct contact between the investigator and the employee.

4. **Enrolling employee under direct supervision of the investigator.** Investigators and IRBs must consider strategies to ensure voluntary participation when the subjects of research include employees who are directly supervised by the investigator(s). Except in unusual circumstances, investigators should not enroll employees under their direct supervision into research studies that involve greater than minimal risk without the prospect of direct benefit. Such studies should proceed only where the IRB determines that adequate provisions have been made to minimize the possibility of coercion, and the research is of significant importance and cannot be conducted without the enrollment of these employees.
5. **House staff.** Interns, residents, and fellows (collectively, “residents”) are particularly vulnerable to coercion, because their career is contingent on successful completion of post-graduate training. For research studies in which residents are being recruited as subjects, including surveys and other minimal risk research involving residents, the Vice President/Associate Dean for Graduate Medical Education or designee/s must review the proposed study in advance of submission to the IRB. This should include review of the recruitment plan. Participation by residents in studies may not interfere with their training program or duty hours.
6. **Volunteers.** Volunteers at Montefiore and Einstein may not be enrolled in research studies by virtue of their status as volunteers. They may participate as subjects, but not in connection to their role as volunteer.
7. **Privacy considerations.** Privacy requirements must be described in detail in the protocol and approved by the IRB. Additional safeguards may be needed to protect the privacy interests of employees who are also research participants. Workplace conditions, including the size of the site and number and presence of coworkers may make it difficult for investigators to keep an individual’s participation confidential, which could pose privacy risks to participants. The mere fact that an employee is participating as a research subject is confidential and should never be disclosed except for study-related purposes as described in the protocol. Overt or subtle pressure on employees to participate, for altruistic reasons or because coworkers are participating, must be avoided. In such situations, research should be conducted off-site and/or outside of regular work hours to minimize these risks.

Protecting the confidentiality of research participants’ personal information when the participants are employees may also present additional challenges. The extent to which medical information and/or research data may be accessible to supervisors or others not directly involved in the

research must be considered and disclosed to potential participants in the informed consent process.

Employee data obtained in research may never be disclosed (favorably or unfavorably) for use in performance evaluations, career advancement, or other employment-related decisions made by peers or supervisors.

8. **Research within the scope of employment.** Research activities must be conducted separately from employment activities. Employees may not perform research-related activities within the scope of employment or during work hours. Employees are not eligible for employment-related benefits if they are performing study-related activities. These benefits may include but are not limited to malpractice and other insurance coverage, workers' compensation, disability and regular or overtime pay.
9. **Compensation.** Compensation for employees who are research subjects should be in accordance with the Einstein IRB's "Subject Compensation Guidelines." Compensation may not be based in whole or in part on employment status.
10. **Access to medical and/or employment information about employees for use in research.** Occupational Health Services records are confidential and shall not be disclosed to an investigator for research-related purposes, except with prior written approval by the Medical Director of Occupational Health Services. Access to medical records of employees generally requires written informed consent as determined by the IRB. Access to employment files maintained in a department or by Human Resources is prohibited.

V. Effective Date

Effective as of: November 20, 2020

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	12/03/2020 _____ Date
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