

# Participation of Research Personnel as Research Subjects

## I. Purpose

The purpose of the Procedure is to describe the requirements for enrolling research personnel or employees of Albert Einstein College of Medicine (“Einstein”) or Montefiore Medical Center (“MMC”) as subjects in human research conducted at Einstein or MMC under the purview of the Einstein Institutional Review Board (“IRB”).

## II. Scope

The Procedure applies to human research conducted at Einstein or MMC under the purview of the Einstein Institutional Review Board (“IRB”).

## III. Definitions

None.

## IV. Procedure

1. The human research protocol must be fully approved by the Einstein IRB prior to any participation of research personnel or employees as research subjects.
2. It is the responsibility of the Principal Investigator (“PI”) to determine whether potential bias or conflict of interest on the part of research personnel who serve as research subjects should preclude their inclusion in the protocol database.
3. Potential inclusion of research personnel as research subjects must be stated on the IRB application form and research protocol, stipulating the reason(s) for such inclusion.
4. The inclusion of the PI and/or co-investigators as research subjects does not require special IRB approval.
5. The proposal to include other key personnel as research subjects will be reviewed by the Einstein IRB on a case-by-case basis and is generally not permitted. A compelling justification is required to support such requests. Einstein IRB approval is required prior to enrollment.
6. The inclusion of employees other than Key Personnel, who are part of or closely associated with the PI’s team, will be reviewed by the Einstein IRB on a case-by-case basis and is generally not permitted. A compelling justification is required to support such requests. Einstein IRB approval is required prior to enrollment.

7. A qualified member of the research team must monitor the participation of the PI, co-investigator, or other Key Personnel who serve as research subjects, in the same fashion as any other research subject.

## **V. Effective Date**

Effective as of: August 14, 2020

## **VI. Procedure Management and Responsibilities**

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