

IRB Membership and Appointment Procedure

I. Purpose

This Procedure establishes the Albert Einstein College of Medicine (“Einstein” or “College of Medicine”) requirements for Institutional Review Board (IRB) membership and the process for appointing Chairs, Vice-Chairs, and members.

II. Scope

This Procedure applies to the Einstein IRBs and Office of Human Research Affairs (OHRA) staff.

III. Definitions

None.

IV. Procedure

1. IRB membership will comply with federal requirements outlined in 45 CFR 46.107 and 21 CFR 56.107.
 - 1.1. Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. Consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with the vulnerable populations the IRB regularly reviews.
 - 1.2. Each IRB includes at least one non-scientific member, one scientific member, one non-affiliated member (a member who is not affiliated with Einstein or Montefiore and who is not an immediate family member of a person affiliated with Einstein or Montefiore), and one physician (for review of FDA-regulated research). One member may satisfy more than one membership category.
 - 1.3. The membership of each IRB includes both primary members and designated alternate members. The appointment and function of alternate members is the same as that for primary members. The function of alternate members is to serve as a voting member of the panel when the regular member is unavailable to attend a convened meeting. Alternate members have qualifications comparable to the primary member they are designated to serve in place of, but they may only vote if the primary member is absent.

- 1.4. Individuals responsible for business development may not serve as IRB members and may not be involved in daily operations of the review process, and may not discuss business development with IRB members.
2. Each IRB has a Chair and a Vice-Chair who are respected individuals with knowledge of research ethics, regulations, guidance, and HRPP policies and procedures.
3. Appointment of Executive Chairs, Chairs, and Vice-Chairs
 - 3.1 The Institutional Official appoints IRB Executive Chairs, Chairs, and Vice-Chairs, after consultation with the OHRA Director and any other senior staff, as applicable.
 - 3.2 IRB Executive Chairs, Chairs, and Vice-Chairs should be highly respected individuals, with sufficient IRB experience and scientific expertise.
 - 3.3 IRB Executive Chairs, Chairs, and Vice-Chairs are initially appointed for a term of two years. The appointment may be evaluated periodically by the OHRA Director, in consultation with the Institutional Official. Appointments are automatically renewed for two-year terms. The Institutional Official, in consultation with the OHRA Director, may dismiss Executive Chairs, Chairs, and Vice-Chairs if necessary.
 - 3.4 The IRB Executive Chairs, Chairs, and Vice-Chairs may resign by providing notice to the OHRA Director.
4. Appointment of Members
 - 4.1 The OHRA Director and Chairs will periodically review the membership of the IRB and recommend re-appointments or modifications as necessary to ensure adequate review of research and regulatory compliance.
 - 4.2 The OHRA Director and Chairs will identify potential candidates for IRB membership as needed.
 - 4.3 The OHRA Director, in consultation with the Chairs and the Institutional Official, makes the final decision in appointing new members.
 - 4.4 Members are initially appointed through the end of the next calendar year. The appointment may be evaluated periodically. Appointments are automatically renewed for two-year terms.
 - 4.5 New members are required to provide the IRB with a current CV or summary of experience and complete the board's COI and confidentiality form.
 - 4.6 Members may resign by providing notice to the OHRA office.

V. Effective Date

Effective as of: 22 August 2019

Implementation Period: Six months from the effective date.

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.