

IRB Member and Consultant Conflicts of Interest

I. Purpose

The document describes the procedure for handling potential Conflicts of Interest in the Einstein Institutional Review Board (“IRB”) review process.

II. Scope

The following Procedure applies to all submissions reviewed by the Einstein IRB, regardless of type of review procedure (full board, expedited, limited, or exempt), or type of submission (initial, continuing review, reportable event, etc.).

III. Definitions

None.

IV. Procedure

1. IRB review activities, and the implementation of IRB policies and procedures, are to be conducted objectively and without undue influence over deliberations or processes.
2. At the time of appointment, IRB members will sign the Confidentiality and Conflict of Interest Assurance form.
3. For full board review, IRB members and consultant reviewers will not participate in confidential deliberations and votes with which they have a conflict of interest, except to provide information as requested by the IRB.
4. For expedited, limited, and exempt review, designated reviewers will not review any submissions with which they have a conflict of interest.
5. IRB members or consultants may have a conflict of interest when:
 - 5.1. The member or consultant has a personal relationship with the investigator (e.g., immediate family relationship or other close personal relationship).
 - 5.2. The member or consultant is involved in the design, conduct, supervision, or reporting of the research.
 - 5.3. The member or consultant holds significant financial interests in the research or sponsor of the research.
 - 5.4. The member or consultant has any other interest that he or she believes conflicts with his or her ability to objectively review the research.

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6. It is the responsibility of IRB members to recuse themselves from review and approval of a study if they have any conflicts of interest, except to provide information as requested by the IRB.
 - 6.1. At the convened meeting, the IRB Chair reminds members to recuse themselves from the confidential deliberations and vote on any protocols in which they have a conflict of interest.
 - 6.2. The recused member will not be counted toward quorum, and their absence during confidential deliberations and vote will be noted in the meeting minutes.
 7. For full board review, consultant reviewers are required to sign the Confidentiality and Conflict of Interest Assurance Form.
 - 7.1. If a consultant reviewer has a conflict of interest, the protocol is not assigned to them and another consultant reviewer is selected.
 8. IRB members, IRB Chairs, Office of Human Research Affairs (“OHRA”) staff, investigators, or research participants who believe that an attempt has been made to unduly influence the IRB, its review processes, or application of its policies and procedures may contact the Institutional Official (“IO”), OHRA Director, or Executive Chair to report a concern.
 - 8.1. Depending on the nature and origination of the concern, the IO, OHRA Director, or Executive Chair or independent designees will review reports.
 - 8.2. The outcome of the review will be documented, the complainant provided with a response, and a corrective action plan instituted if deemed necessary.

V. Effective Date

Effective as of: March 10, 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.