Albert Einstein College of Medicine

Exempt Research Procedure

I. Purpose

This Procedure describes the requirements for Institutional Review Board ("IRB") review of human research that is exempt from the requirements set forth in 45 CFR 46 and 21 CFR 56.

II. Scope

This Procedure applies to all human research conducted under the auspices of the Einstein IRB.

III. Procedure

1. The IRB will review the human research to determine whether it meets one or more of the exemption categories described in the federal regulations and complies with the Institution's ethical standards. The exemption categories are posted on the Office of Human Research Affairs ("OHRA") website.
2. The determination that human research is exempt must be made by the IRB, not an individual investigator.
3. For exempt submissions, the Principal Investigator ("PI") is required to submit a protocol; consent form, if applicable; and other materials, as applicable.
4. IRB staff pre-reviews the submission and requests clarifications or revisions, as necessary.
5. An IRB Chair or one or more experienced reviewers from among members of the IRB will review exempt submissions to confirm if one or more exemption categories are applicable to the research. The assigned reviewer may not have any conflict of interest or direct involvement with the proposed research.
6. The reviewer will conduct a limited IRB review of the privacy and confidentiality measures, if such limited review is a condition of exemption.
    a. Reviewers conducting limited IRB review may not disapprove research.
    b. When conducting a limited review for exempt categories 2 and 3, the reviewer must document in the reviewer checklist that there are adequate protections for privacy interests of subjects and the confidentiality of identifiable data.
7. Using the reviewer checklist as a guide, the reviewer will determine that the research meets the ethical standards of the Institution.
8. If the reviewer finds that the research is greater than minimal risk, the reviewer must document the rationale for this determination and the rationale for review by the convened IRB in the reviewer checklist.
9. IRB staff will issue a notification of exemption status to the PI.
10. Exempt research is given a 3-year institutional approval period, inclusive of research approved with a limited IRB review. Exempt research approved with limited IRB review is not subject to regulatory continuing review requirements.

11. Amendments to the study only need to be submitted if they have the potential to alter the exemption status, if they change the PI, or if they are adding a new site or funding source.
12. The IRB retains the authority to suspend or terminate approval of research approved with a limited review.

IV. Effective Date

Effective as of: 11 August 2019

Revised as of: 18 September 2023

V. Procedure Management and Responsibilities

Einstein's Office of Human Research Affairs ("OHRA") 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.