Albert Einstein College of Medicine

Expedited Review Procedure

I. Purpose

This Procedure describes the requirements for human research to be eligible for expedited review by the Institutional Review Board ("IRB").

II. Scope

This Procedure applies to the Einstein IRB and all human research under its oversight.

III. Procedure

1. The Department of Health and Human Services ("DHHS") and the Food and Drug Administration ("FDA") regulations for the protection of human subjects recognize that not all research warrants review by the IRB at a convened meeting. Accordingly, 45 CFR 46 and 21 CFR 56 permit certain types of research that involve no greater than "minimal risk" to be reviewed and approved through the expedited review process.
2. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories listed in Appendix A, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110.
   2.1. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protection will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
   2.2. The expedited review procedure may not be used for classified research involving human subjects.
3. For expedited submissions, the Principal Investigator ("PI") is required to submit the same materials as for full board studies (including protocol, consent form(s), recruitment materials, and other materials as applicable).
4. Upon receipt of the application, the IRB staff reviews the submission for completeness. If the submission is incomplete or requires any corrections prior to review, IRB staff will return the submission to the PI with a list of stipulations to be addressed. Upon receipt of a complete submission, IRB staff assigns it to the IRB Chair or other Board Member for Expedited Review.
5. The Application will be reviewed by one of the IRB Chairs or designated IRB members who possess the expertise needed to review the proposed research. If the person assigned to review the protocol has a declared conflict of interest with that study or investigator then the protocol will be reassigned to another reviewer.
6. The Executive Director/Assistant Directors or Chair approves the designation of IRB members for the role of Expedited reviewers as needed based on workflow. Expedited reviewers must be a board member and have undergone one-on-one training.
7. Reviewers will evaluate whether research is eligible for initial or continuing review using the expedited procedure by considering whether the research:

7.1. Does not involve more than minimal risk
7.2. Represents one or more of approvable categories of research
7.3. When research involves vulnerable populations, additional safeguards have been included in the study to protect the rights and welfare of these participants

8. The reviewer conducting initial or continuing review should receive and review all documentation that would normally be submitted for a full-board review. The reviewer completes the appropriate checklists to determine whether the research meets the criteria for expedited review and, if so, whether the research can be approved according to the same criteria for approval as for full board reviews. If deemed necessary by the reviewer, he or she may request a second reviewer or request review by an expert consultant to the IRB.
9. In reviewing the research, the reviewer may exercise all of the authority of the IRB committee except that the reviewers may not disapprove the research. If the reviewer believes that there is reason for disapproval, or the nature of the project is not suitable for expedited review, then the reviewer must defer any decision and refer the application for review at a convened panel meeting.
10. Research appearing on the list of expedited review categories is deemed to be no more than minimal risk. If the reviewer finds that research appearing on the expedited review list is greater than minimal risk, the reviewer must document the rationale for this determination and the rationale for review by the convened IRB.
11. Reviewers will indicate approval, require modifications, reclassify the project as Exempt/Not Human Subject Research, or defer to full board. A notification of the determination, the reason for the determination, and, if applicable, any required changes or outstanding items is sent to the PI.
12. If the reviewer determines that continuing review by the IRB is required, they will justify the decision to conduct continuing review of research originally reviewed using the expedited procedure in the reviewer checklist. Otherwise, research approved via expedited procedure will be given either an institutional approval period or an approval period required for regulatory reasons.
13. Once the IRB reviewer approves the study, he or she assigns the approval period at intervals appropriate to the degree of risk. Studies that require IRB continuing review may not have an approval period greater than one year.
14. Research approved via expedited procedure that does not require regulatory continuing review is given a 1-year institutional approval period. The research team must submit a progress report to renew institutional approval. OHRA staff reviews the progress report and assigns a new institutional approval period of 1 year. Institutional approval is required for the duration of active human research. If institutional approval expires, research activities must cease until institutional approval has been renewed.
15. The date the expedited reviewer signs off final approval on the study is the date the approval period starts. Einstein IRB staff document the approval period dates in the approval notification to the PI.

IV. Effective Date

Effective as of: 11 August 2019

Revised as of: 20 September 2023

V. Policy 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.

Appendix A: Expedited Categories

The activities listed below should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

- The categories in this list apply regardless of the age of subjects, except as noted.
- The standard requirements for informed consent apply regardless of the type of review--expedited or convened--utilized by the IRB.
- Categories one (1) through seven (7) pertain to both initial and continuing IRB review. Categories eight (8) and nine (9) pertain to continuing studies only.

COMMON RULE 45 CFR 46.110 Expedited Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
    b. from other adults and children , considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally

eligible for expedited review, including studies of cleared medical devices for new indications). Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Note: The Following applies to Continuing review of research only.

8. Continuing review of research previously approved by the convened IRB as follows:
    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
    b. where no subjects have been enrolled and no additional risks have been identified; or
    c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.