Albert Einstein College of Medicine

Initial Full Board Review Procedure

I. Purpose

This Procedure describes the requirements for full board review of initial protocol submissions by the Institutional Review Board ("IRB").

II. Scope

The following Procedure applies to the review of human research that is non-exempt and not eligible for expedited review under federal regulations and/or institutional policy.

III. Procedure

1. All human research that does not qualify for expedited review or exemption from federal regulations, that is referred to full board during expedited review by an IRB member, or that involves the randomization of standard of care requires review by a convened IRB. To meet quorum, a majority of the IRB members must be present at the convened meeting, including at least one member whose primary concern is in a non-scientific area. For review of FDA-regulated research, at least one licensed physician must be included in the quorum. Alternate members may attend in place of absent primary members in order to meet a quorum. The convened IRB will assess whether the research complies with federal criteria for approval as set forth in 45 CFR 46.111 and/or 21 CFR 56.111.
   1.1. To ensure at least one unaffiliated member is generally present at convened meetings, unaffiliated members are expected to attend 10 meetings per year. Attendance of the unaffiliated members is documented in the minutes.

2. Meeting Scheduling

2.1. On an annual basis, senior IRB staff develop the schedule of IRB meetings and submission deadlines in accordance with the expected volume of submissions. The schedule, including the timing of the meetings, is made publicly available.

2.2. There are no limits on the number of items on the agenda, but IRB staff may schedule additional meetings on an ad hoc basis if required due to an increased volume of submissions.

3. Meeting Preparation

3.1. Upon receipt of the initial protocol submission, IRB staff performs an administrative review. If a submission is incomplete or requires revisions, IRB staff may return the submission to the Principal Investigator ("PI") to obtain any necessary documents or revisions by a specified deadline. IRB staff will confirm that documentation of all ancillary reviews required by Einstein or MMC is included in the submission before proceeding to assign the submission to an agenda.

3.2. IRB administrative staff assigns submissions to an agenda based on workload and submission timing. If a submission requires review by a particular committee prior to IRB review, it should not be placed on the agenda until the committee review has been completed.[1]

3.3. IRB staff evaluates each submission and assigns reviewers based on the expertise needed for the review of the protocol and availability to attend the meeting. If a research protocol involves vulnerable participants, IRB staff ensure a member who is knowledgeable about that population or is experienced in working with that population is assigned to review the protocol. Experts are consulted when board members do not have expertise in the research topic of a submitted protocol.

3.4. Protocols are assigned primary and secondary review. If deemed necessary by the IRB Chair or Staff, an additional reviewer may be selected. Both the primary and secondary reviews perform an in-depth review of the protocol and all application materials. Both the primary and secondary reviewers complete a reviewer's checklist to consider the approval criteria set forth in federal regulations and to identify any potential issues regarding those criteria.

3.5. When a protocol has undergone a peer review or equivalent process (e.g., for NIH or NSF funding), the IRB will generally accept that the design is sound. When there is an IDE or IND for the study, the IRB may consider the scientific scrutiny of the FDA as confirmation of scientific merit.

3.6. For investigator-initiated unfunded projects, unless they have been reviewed by the FDA for the purposes of an IND or IDE application, the IRB must consider the soundness of the research design, to the degree necessary to ensure that statistically valid results may be possible. In making this determination, the IRB may draw on its own knowledge and disciplinary expertise. In general, investigator-initiated protocols that have not received a full peer review receive an additional review by a statistician.

3.6.1.1. If the research involves investigational products, the IRB must ensure the evaluation of the available nonclinical and clinical information on an investigational product is adequate to support the proposed clinical trial.

3.7. Prior to the meeting, IRB staff sends the board members a copy of the meeting agenda and review assignments. For initial review submissions, IRB members are provided access to the full protocol; application; consent form, if applicable; the PI's current curriculum vitae; the investigator's brochure, if applicable; and any other applicable study documents. Consultant reviewers are provided with the same study documents that are provided to IRB members. IRB members are expected to review submitted materials ahead of the meeting.

3.8. IRB staff sends all IRB members the final minutes from the previous month's meeting includes all submissions reviewed and approved under the expedited procedure. IRB members have the right to bring expedited review submissions to the full board for discussion or to request additional information.

3.9. Prior to the meeting, the primary and secondary reviewers should communicate with the PI, IRB Chair, and IRB staff regarding any issues or areas of concern. Revisions to the protocol and/or consent document that may occur prior to the meeting are provided to the IRB administrative

[1] Please see the Office of Human Research Affairs ("OHRA") website for the current list of approvals required prior to IRB review.

staff, distributed to IRB members who will be attending, and included in the review at the IRB meeting.

4. Meeting Conduct

4.1. The IRB Chair and administrative staff determine that an appropriate quorum has been reached before the IRB Chair calls the meeting to order. IRB staff monitor quorum and document attendance in meeting minutes. If a quorum is lost, or if a required member leaves the meeting, no further action requiring a vote may be taken until the quorum is restored.

4.1.1. If the number of primary board members is even, a quorum is defined as half of the membership plus one. If the number of primary board members is odd, a quorum is defined as half of the number of board members rounded up to the next whole number.

4.2. Convened meetings may be held either in-person or remotely using teleconferencing technology, provided that IRB members have received all pertinent material prior to the meeting and can actively and equally participate in the discussion of all protocols.

4.3. 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. Members who recuse themselves due to a conflict of interest do not count toward quorum. Members attending virtually who are in conflict are placed into virtual waiting rooms where they may not participate in deliberation and voting.

4.4. The primary reviewer presents a summary of the protocol at the meeting, and the secondary reviewer raises any additional concerns not covered in the primary reviewer's presentation. The IRB Chair then leads the discussion. The IRB Chair encourages input from the non-scientific member for all protocols.

4.5. For the initial full review, representatives for protocols on the agenda (either the PI or qualified designees) are invited to attend the meeting to participate in the discussion and respond to any additional questions that arise during the board's discussion. Representatives are requested to leave before the confidential discussion and vote.

4.6. Following the discussion and prior to the vote, the IRB Chair confirms applicable regulatory findings.

5. Determinations

5.1. Studies reviewed by the full board may be approved, approved pending (with non-substantive revisions), deferred, tabled, or disapproved. The minutes for each full review item record the number in favor of, opposed to, and abstaining from the action, and those who recused themselves due to a conflict of interest.

5.2. **Approval**: A study may be approved if the board determines that it meets federal criteria for approval as defined in 45 CFR 46.111 and 21 CFR 56.111. For research to be approved, a majority of members present must vote in favor of approval. The criteria for approval are as follows:

5.2.1. Risks to subjects are minimized: (i) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

5.2.2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result from the study.

5.2.2.1. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (i.e., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

5.2.3. Selection of subjects is equitable.

5.2.3.1. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, individuals with impaired decision-making ability, or economically or educationally disadvantaged persons.

5.2.4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative (LAR), in accordance with, and to the extent required by, 45 CFR 46.116 and 21 CFR 50.25.

5.2.5. Informed consent will be appropriately documented, in accordance with, and to the extent required by, 45 CFR 46.117 and 21 CFR 50.27.

5.2.6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

5.2.7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

5.2.8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

5.3. **Approved Pending:** A study may be "approved pending" if only non-substantive changes are necessary to gain final approval. Those changes can be reviewed and approved by a board member. The results of the review of such materials are recorded in the agenda and minutes for the IRB members' information. Examples of such non-substantive requested changes include:

5.3.1. Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted (e.g., confirmation that the research excludes children);

5.3.2. Submission of additional documentation (e.g., certificate of ethics training);

5.3.3. Directed language changes to the protocol or informed consent documents; or

5.3.4. Directed changes to the protocol or informed consent documents along with clearly stated parameters that the changes must satisfy.

5.3.4.1. If approved or approved pending, the full board determines the approval period of a research study based on its risk level. The approval period cannot exceed 365 days from approval by the full board (e.g., if the date of board review is 06/01/2018, the final day of the approval period cannot be later than 05/31/2019). The board may determine that a shortened review cycle is necessary due to concerns about high levels of risk or vulnerable populations, or other circumstances that warrant more frequent review.

5.3.4.2. For research approved at the convened meeting, the start date of the approval period is the day the protocol was approved by the full board. For approval pending, the start date of the approval period is the date on which all the required changes made by the PI were approved via expedited review. For both approvals and approvals

pending modifications, the expiration date is calculated from the date on which the protocol was reviewed by the full board.

5.4. **Deferred**: A study may be deferred because of substantive changes requested by the board, or other issues related to the criteria for approval. Such substantive changes or requests for more information cannot be reviewed under the expedited procedure. Deferred studies may be re-submitted for review.

5.5. **Tabled**: A study may be tabled if the full discussion was not able to occur (e.g. quorum was not met, the board ran out of time, the board did not have enough information to make a decision, or lack of representation for the study at the convened meeting). Tabled studies are rescheduled for a later meeting.

5.6. **Disapproval**: A study may be disapproved because the risks outweigh the benefits, or if it does not meet federal criteria for approval.

5.7. Determinations are documented in the Minutes. Checklists completed by reviewers are not retained and do not represent official IRB determinations. In the case of controverted issues that arise from checklists that contain different opinions from reviewers, the controverted issues are discussed at the meeting. The controverted issues and resolutions are documented in the Minutes.

5.8. A notification of the determination, the reason for the determination, and, if applicable, any required changes or outstanding items is sent to the PI.

IV. Effective Date

Effective as of: August 11, 2019

Revised as of: January 5, 2024

V. Procedure Management and Responsibilities

Einstein's Office of Human Research Affairs ("OHRA") is the Responsible Office for 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.