Full Board Initial Review Procedures

Table of Contents: Full Board Initial Review Procedures

Policy Statement

All human subjects research protocols that are considered to pose more than minimal risk to subjects are reviewed by a convened full board meeting of the IRB. The full board initial review will be conducted by a quorum of IRB members and in accordance with 45 CFR 46.

Description and Procedures

A. Full Board Meeting Conduct

In order to review research protocols via the full board, the convened meeting will be conducted in accordance with the requirements described in the Conduct of Full Board Meetings policy.

B. Assignment of Primary and Secondary Reviewers

Primary and secondary reviewer assignments are made by IRB staff in conjunction with the IRB Chair(s) according to their expertise with the research proposed and the populations involved.

C. Full Board Meeting Actions/Review Process

a. Preliminary Document Review

All materials necessary to review convened submissions and verify that the approval criteria are met are distributed to reviewers and attending IRB members in sufficient time prior to the meeting to allow for adequate review (minimum of two weeks), including the pre-review forms and all submitted materials, including but not limited to the full protocol, consent document(s), recruitment materials, and other supporting materials.

b. Primary and Secondary Reviewer Responsibilities

Each protocol will be assigned to a primary reviewer who will be responsible for reviewing the protocol in detail and for leading a discussion of the protocol. Each protocol will be assigned a secondary reviewer, whose major responsibility is to review the protocol in detail and provide input for panel discussion.

Members who have a conflict of interest must recuse themselves from a review assignment (see IRB Conflict of Interest Policy).

At times, the IRB may invite individuals with competence or necessary expertise to determine the scientific soundness of a research protocol or make an accurate determination of the risk to subjects. When required, the IRB Chair, or the primary reviewer after consultation with the IRB Chair, may request the assistance of an external subject matter expert to perform an in-depth review of the study. (see IRB Confidentiality Policy regarding the use of external subject matter experts)

If the primary and secondary reviewers disagree with the necessity for full board review, they may recommend expedited or exempt review by notifying IRB staff of their recommendation.

The primary and secondary reviewers may contact the investigator, co-investigator, other IRB members, or outside sources as necessary for protocol-related information requiring clarification, to ensure a thorough evaluation of the risks and benefits of the proposed research.

c. Primary and Secondary Reviewer Comments

Reviewer comments are presented by the primary and secondary reviewers. Comments are documented in electronic writing via the reviewer comments function on the Ethical Review Manager reviewer website prior to the convened meeting to prepare for a full discussion of the protocol.

d. Full Board Meeting Discussion

For protocols undergoing initial review, a full discussion regarding ethical concerns, risks and benefits, and issues likely to impact research subjects takes place, in which the following are discussed in detail (this list is not all-inclusive):

- confirmation that the regulatory criteria for approval at 45 CFR 46.111 or 21 CFR 56.111 are met;
- confirmation that the research meets the requirements for informed consent and assent (if applicable);
- confirmation that when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects;
- review of any recruitment procedures and materials;
- a risk level determination or other justification to warrant full board review;
- approval period dates, if less than annual continuing review is recommended. The interval for continuing review will be at least once per year, calculated based on the date of the convened meeting at which the IRB approves the protocol or approves the protocol with modifications. The following conditions may lead the IRB to require review more often than annually:
    - High degree of risk to subjects;
    - Risks are unknown at the current stage of research;
    - Proposed procedures have not been used in humans;
    - Previous confirmed instances of serious or continuing noncompliance;
    - Other reasons for which the IRB requests more frequent monitoring.

- *Full Board Review Motions and Voting*

  After a full and complete discussion of the protocol undergoing initial review, a motion, a second motion, and a final vote may be called. See Conduct of Full Board Meetings for a full description of the motions of the IRB.

f. Documentation of Full Board Review Outcome

The actions of the panel are recorded by IRB staff in the Minutes and communicated in writing to the principal investigator via the Ethical Review Manager reviewer website.

Effective Date

August 24, 2020

Revision History

References

45 CFR 46
21 CFR 56
Conduct of Full Board Meetings
IRB Confidentiality Policy
IRB Conflict of Interest Policy