CHAPTER 5 The Full Board Meeting

Full board meetings can be intellectually demanding. The credibility and integrity of the IREC review process depends upon the committee's ability to identify and address ethical issues in human subjects research. All IREC members must pay attention to written material and meeting discussions, voice their opinions when appropriate, and ask questions when they need clarification. This chapter guides a new member's initial experience of a full board meeting by describing the review process, defining voting options, and providing tips for reviewing a study.

SEQUENCE OF EVENTS AT MEETINGS

What follows is a basic order of a full board IREC assessment.

- The primary reviewer summarizes important issues they noted related to research ethics, safety, and/or science. The reviewer may decide not to discuss all the study details because other IREC members/reviewers are expected to have read the materials and time is limited for many IRECs. The presentation ends with a summary of unresolved issues and/or issues requiring revision. The reviewer makes a recommendation for how the committee should vote on the protocol.
- The secondary reviewer comments on the protocol. The secondary reviewer does not repeat the information presented by the first reviewer, but indicates where he or she agrees or disagrees with the issues as outlined by the first reviewer. The secondary reviewer adds or clarifies information and ends with a recommendation that may or may not agree with the primary reviewer's recommendation.
- If there are three (or more) assigned reviewers, the tertiary/other reviewers, provide additional information or raise other questions. Discussion begins after the reviewers have had a chance to complete their presentation.
- It is the responsibility of the chair to open the discussion, make sure every issue and question is addressed, and to ensure the meeting is carried out in a courteous and productive manner. The chair ends the discussion and calls for a vote to approve, accept with contingencies, table, or disapprove.

An ideal environment is one that promotes an open discussion and encourages all members to express their views in a warm atmosphere, and all IREC members participate in identifying and discussing the issues. There is no formula for this process so it is essential that the IREC chair manage this aspect of the meeting. Some IRECs let a discussion continue until an IREC member seconds a motion for a vote. In other committees, the chair determines when all of the important issues have been raised, declares the discussion over, and calls for the vote. Questions of regulatory or policy matters are often addressed by the Chair or IREC Director as IREC members are not expected to be as expert in these areas.

VOTING OPTIONS AT MEETINGS

Voting options differ by institution and are chosen to meet individual IREC needs. Common voting options include:

- approved
- conditionally approved
- approved pending modifications

- table
- disapprove
- substantive revisions required
- not approved
- abstain
- recuse

Voting options used by Nazarbayev University's IREC are:

Approved
The application has secured approval, thus the investigator is not required to make changes to the protocol or IREC application. IREC approval is valid for one year, unless the committee designates a shorter period due to higher levels of risk. An approval letter is sent to the investigator. The consent documents (if any) are stamped with the IREC approval dates. The investigator may start enrolling subjects.

Conditionally Approved
"Contingencies" are IREC's request for clarification, modification or additional information.

Disapprove
This term is used when the magnitude and/or number of concerns, questions, and problems are such that "Accepted/Approved with contingencies" is not appropriate. A letter describing reasons the study was not approved is sent to the investigator.

The investigator must make significant changes and may resubmit the study. On occasion, the investigator may be invited to answer committee questions in person. If a study is resubmitted for full review and approved at a subsequent meeting, the date of approval is the date of the subsequent meeting.

Defer
This is used when the IREC application lacks sufficient information to make an appropriate determination. When a study is deferred, the investigator's response must be reviewed by the full committee.

Recuse
If an IREC member is listed in a study under IREC review or has any other conflict of interest, they may not participate in the initial or continuing review of the study except to provide information requested by the IREC. The IREC member must leave the room (e.g. "recuse" themselves for the discussion and vote). The meeting minutes will reflect this. The chair requests IREC members with a conflict of interest to leave the room and not participate in the vote or discussion. Conflicts of interest include financial interest, active participation in the trial as principal investigator or co-investigator, or any other issue for which the member feels his or her vote could be potentially conflicted.

Abstain
If an IREC member does not have a "conflict" but is unable to vote (e.g., left the room during discussion, does not comprehend the study or the issues) the member may "abstain" from voting. A vote to "abstain" will be included as part of the voting quorum. The meeting minutes will reflect this.

WHEN MIGHT I BE ASKED TO BE A PRIMARY REVIEWER?

When the IREC Chair determines that a new member is ready to take on assigned reviewer responsibilities, they are assigned to be secondary or tertiary reviewers, or review informed consent documents. The following requirements and scenarios may indicate readiness to serve as a primary reviewer:

- Attended a sufficient number of IREC meetings to feel comfortable
- Attended IREC education sessions
- A sufficient knowledge of IREC policies and procedures to give a meaningful review
- Completed satisfactory reviews as a secondary reviewer
- Expertise in the area of the study
- Adequate time to prepare for the meeting and give a thorough review
- Achieved sufficient confidence to proceed with a review
- Availability when other members are unavailable, on vacation, or have a large number of items pending review
- Spoken up at a meeting with concern about the study or consent form

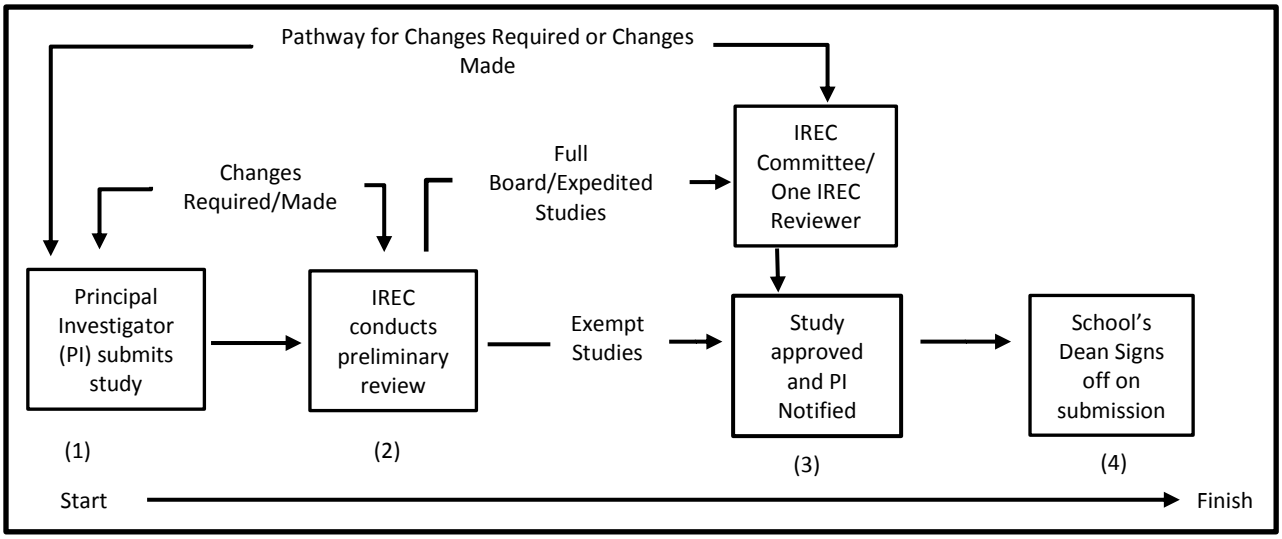
STUDY REVIEW

What follow is an overview of the IREC review and approval process, an introduction to the IREC application system, and a list of points to consider when reviewing research protocols. This information is provided to help the new community member understand the IREC review process.

IREC Review and Approval Process Overview

The chart below provides an outline of the IREC review process, starting with the online IREC submission by the researcher and ending with the IREC granting approval of the research.

Schematic of IREC Approval Process: non-NUSOM Schools



Reviewer Checklists

Reviewer checklists have been created to help identify requirements and to note the ethical expectations that must be met. It is highly recommended that these checklists be used while reviewing IREC applications. The complete set of reviewer checklists is included in Appendix C.

Points to Consider When Reviewing a Project

Being mindful of certain requirements will help you identify ethical and regulatory issues while reviewing the IREC application. Here are some points to consider:

- What are the subjects required to do? Will they take a drug, fill out a survey, or be interviewed about criminal activity? Are the research activities potentially harmful or embarrassing?
- Would you participate in this study, or would you want your parents, children, spouse or other family members to participate?
- Does the study make sense as written?
- Is the informed consent document easy to understand and an accurate reflection of the study procedures?
- Who are the subjects and are they vulnerable to coercion (e.g. children)?
- Is it necessary to keep the identifying information? Is more information being requested than is needed?
- If identifying information is collected, is there a mechanism in place to protect the subjects' identities or other private information? If so, is it adequate?
- Is the information provided in the protocol, consent, and recruitment materials consistent?
- Are there adequate safeguards to protect the subjects if an untoward event occurs? What action will the PI/researchers take if something goes wrong?
- If the intervention/treatment proves beneficial, will those subjects not in the intervention/treatment group (i.e. control group) be able to partake in the intervention or receive the treatment once the study has been concluded?
- What "gut" feelings do you get after reading the protocol? Sometimes, something about the study seems questionable and may make you feel uneasy. Express this unease and attempt to get the issue resolved, or vote "no" when the vote is taken.

Criteria for IREC Approval

In order to approve research, reviewers must evaluate whether the rights and welfare of the human subjects are being protected. While reviewing a project, reviewers will be asked to determine that the criteria below are met. If the criteria are not met, the study will not receive IREC approval until the study is amended to meet the requirements or the IREC receives the missing information. The details of these requirements are provided in Chapter 2: "What criteria must be met to approve a protocol."

Approval Criteria

1. Minimized Risks
2. Reasonable risk/benefit ratio

3. Equitable Subject Selection
4. Obtain Oral or Documented Informed Consent
5. Data Monitored for Safety
6. Confidentiality/privacy maintained