

CHAPTER 1 IREC Members: Roles, Responsibilities and Purpose

This chapter provides basic information for new members on Nazarbayev University's IREC and is designed to answer common questions. It outlines a member's role within IREC.

WHAT IS RESEARCH AND WHO ARE HUMAN SUBJECTS?

IREC members need to understand human subjects research, which differs in many ways from other kinds of research. When humans voluntarily enroll in research studies, a high level of respect is required to honor that choice. Ethics committees worldwide define "human subject" and "research" in a way that differs from common use of those terms.

The following are the definitions:

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

A **human subject** is a living individual **about** whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual; or (2) Identifiable private information.

These definitions may seem straightforward to new members, but with experience, the meanings and subtle nuances become more important.

WHAT IS AN INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)?

The IREC is an oversight committee charged with reviewing all research involving human subjects to ensure research complies with university policies and Kazakhstan laws. IREC has the authority to approve, require changes to the study procedures, or disapprove proposed research projects.

IREC functions as a surrogate "human subject advocate." Its role is to safeguard the rights and welfare of research subjects by evaluating the research to assure an acceptable balance of risks to benefits.

IREC members are faculty and staff from NU, and members from the local community.

WHAT IS A COMMUNITY MEMBER?

An IREC community member is someone from outside NU. They come from a variety of backgrounds and are chosen for their particular experience, knowledge, or relationship to the types of studies reviewed by the IREC.

Roles unique to Community Members:

- Provide non-biased opinion in relation to the institution

- Provide the voice of the participant in the research process
- Provide balance to pro-research viewpoint
- Provide unique viewpoint not biased by employment
- Provide values of the community, neighborhood, patients, public, and society to the research process

WHAT IS EXPECTED OF ME AS AN IREC MEMBER?

A considerable **time commitment** is required when serving as an IREC member. IREC members need to set aside blocks of time to review IREC applications and protocols, attend meetings, and avail themselves to educational opportunities. The amount of time needed will gradually lessen as the process becomes familiar. Keep in mind - some studies are so technical, complex, and dense, that other IREC members or consultants will need to review the most technical sections in addition to your review.

IREC Members are expected to:

- Have completed “IREC Members – Basic/Refresher” CITI training within the last three years
- Review and Critique Research Applications
 - Review all materials (IREC application, informed consent, questionnaires, recruitment documents, etc.) on the meeting agenda.
 - Review minutes linked to the agenda, and if issues or errors are found resolve them with the IREC staff.
 - Assure that applications include adequate protections for human subjects in the research plan.
 - When assigned as a reviewer on an expedited review, complete the review within two weeks.
 - Voice issues that are noted while reviewing the protocol.
- Attend Meetings and Education Sessions
 - **Attend a majority** of the IREC committee meetings
 - Attend **educational events** (such as web-based training, guest speakers, and conferences), which are in addition to educational sessions presented at IREC meetings.
 - Allot time to read about human subjects protections, and avail yourself of education, IREC documents, and the experience of your colleagues, and the IREC staff or other members.
- Review monthly meeting minutes for accuracy and promptly notify the IREC Chair and/or staff of any corrections or additions.
- Absent yourself from discussion and voting on any project where there is a potential or real **conflict of interest**.
- **Maintain confidentiality** for all discussions, reviews, meeting minutes, and proprietary information you will encounter as an IREC member.

WHAT CHALLENGES MIGHT I FACE?

Adjusting to being an IREC member will take time as challenges faced will vary from person to person. As members grow more experienced, their comfort level will increase, anxiety level will decrease, and overall participation in the review process will increase.

Below are potential challenges:

- You will be expected to provide and defend your opinions. Discussions may get heated, but realize you are not under attack.
- You might question whether your opinions are valid or your suggestions are feasible, and they may not always be. Be open-minded to learning, but be persistent if you remain unconvinced.
- You may find that you are alone in your vote.
- You may struggle with trying to find how the research actually benefits or is related to the community or the people who are participating in the research. IRECs have a tendency to discuss risks in depth and yet gloss over possible benefits. But benefits should also be noted and real. Ask if there are any benefits!
- You might not understand everything you read or hear. IREC members tend to use medical, scientific and regulatory jargon, making it difficult to follow discussions. Your understanding will increase as you become more comfortable with the terminology.
- You might be disappointed in the quality of some of the research applications.