

Preparing the human research ethics application for IREC

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Objectives

- Upon completion of this presentation, you should be able to:
 - Define Research and Human Subjects
 - Complete Required Training
 - Navigate the IREC
 - Create an IREC application and be familiar with the IREC process
 - Describe the Informed Consent Process
 - Discuss Common IREC issues

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

- Primary Function

to protect the rights, welfare, and safety of human subjects participating in research being performed by Nazarbayev University faculty, staff and students.

HOW DO YOU KNOW IF YOU'RE DOING RESEARCH?

- **Research**

is defined by IREC as a systematic investigation designed to develop or contribute to generalizable knowledge or to contribute to the general body of knowledge.

HOW DO YOU KNOW IF YOU ARE USING HUMAN PARTICIPANTS?

- **Human Participants**

are defined by IREC as living individuals about whom an investigator conducting research obtains

- Data through intervention or interaction with the individual
- or
- Identifiable private information

DOES YOUR PROJECT MEET THE DEFINITION OF RESEARCH WITH HUMAN SUBJECTS?

- All of the following activities may be considered research:
 - Interviews
 - Surveys
 - Observation
 - Case studies
 - Analysis of existing data

EXAMPLES OF HUMAN SUBJECTS RESEARCH

- Dissertations or thesis
- Publications, poster presentations, conference proceedings
- Human Subjects Data – medical records, school records, past research
- Interaction with humans – online surveys, interviews, observations, classroom research, focus groups, asking opinions, interventions

DESIGNATIONS OF NON-HUMAN SUBJECTS RESEARCH

- If using secondary analysis of publically available or de-identified data
- For examples: data (e.g. past studies, census data) that have no identifiers or codes linking to humans, studies only for quality assurance that will not be published or presented, studies that only gather data that is not about humans (e.g. company statistics)

WHAT ABOUT STUDENT RESEARCH?

- Ask yourself these questions:
 - Do the results have the potential to be published or presented outside the classroom or off campus?
 - Is the activity defined as a research project with a research question or hypothesis?
- If the answer is “**Yes**” to any of these questions, the student should submit an application to the IREC.

CLASS-RELATED ACTIVITIES THAT DO NOT REQUIRE REVIEW

- Course activities that involve human participants, but have no connection to research beyond the instructional function.
- The collection of information from respondents for the purpose of class discussions or for the purpose of training in research or research methods.
- In these situations, **instructors are responsible** for the protection of human subjects. Faculty instructors must have completed CITI training and have filed a classroom activity application with the IREC.

HUMAN SUBJECTS EDUCATION

- Citiprogram.org – widely used by many universities
- All members with interaction with human subjects or access to data must complete the training
- Register selecting your own username and password; and select NU as your institution
- Be sure to complete the social and behavioral basic course or the biomedical basic course.
- Series of modules with text and questions at the end of each module
- Takes about 4 – 6 hours, but you can log-out and log-in as necessary

WHAT DOES THE IREC LOOK FOR IN A RESEARCH PROJECT?

- Risks are minimized
- Risk vs. benefits ratio
- Equitable participant selection
- Informed consent process is appropriate
- Privacy, confidentiality, and safety are maximized
- Safeguards are in place to protect vulnerable subjects

WHAT YOU NEED TO KNOW

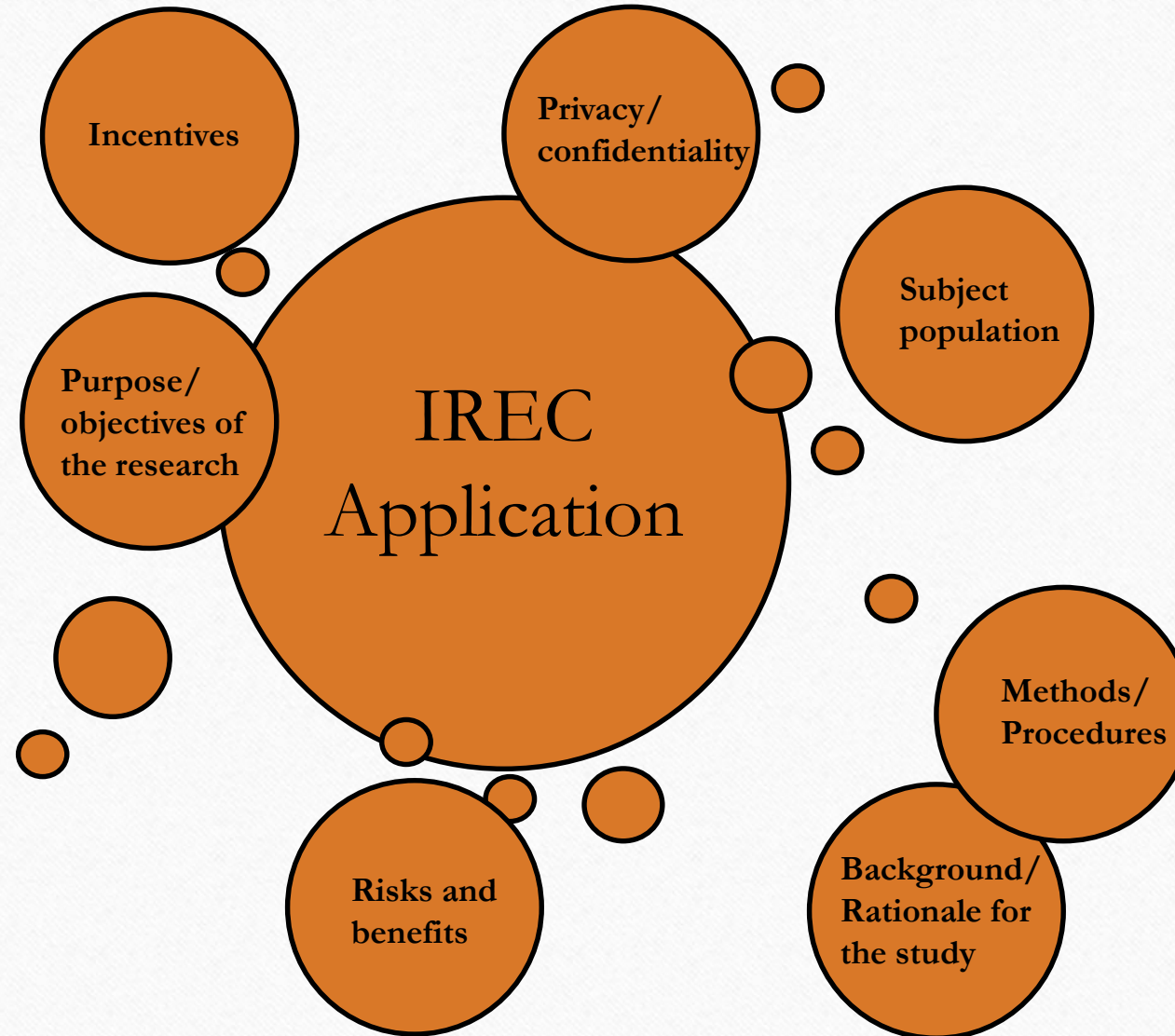
All faculty, staff, and students who conduct research involving human subjects are required to have prior approval from the IREC **BEFORE** research begins

***SO YOU NEED IREC APPROVAL.
WHAT DO YOU DO NEXT?***

HOW TO APPLY FOR IREC APPROVAL

- Forms may be downloaded from the IREC website:

<https://nu.edu.kz/about-us/institutional-research-ethics-committee>



PURPOSE/OBJECTIVES OF RESEARCH

- State the purpose of the research and the problem to be investigated. When possible, state specific hypotheses to be tested or specific research questions to be answered.

RELEVANT BACKGROUND AND RATIONALE FOR THE RESEARCH

- This section should present the context of the work by explaining the relation of the proposed research to previous investigations in the field. Include citations for relevant research.
- Provide at least twice as many peer reviewed citations as “lay” citations.

METHODS/PROCEDURES

- Describe what you are going to do and how you are going to do it.
- Be specific.
- If part of a larger project, describe in detail only the research procedures that involve human subjects.

SUBJECT POPULATION

- Provide the number of participants that will be involved in the research.
- State who the study participants will be and how they will be recruited.
- Vulnerable populations require special care and considerations. These include:
 - Children
 - Mentally impaired persons
 - Pregnant women

INCENTIVES

- What incentives will be offered, if any?
- Payment should not be so great as to encourage participation that would not otherwise be undertaken.
- Professors, be careful if you want to offer extra credit!

RISKS/BENEFITS TO PARTICIPANTS AND PRECAUTIONS TO BE TAKEN

- List all possible risks and discomforts from participation in the study, indicating both severity and likelihood of occurrence.
- Discuss how these risks will be minimized.
- If subjects are vulnerable populations, or if risks are more than minimal, please describe what additional safeguards will be taken.

CONSIDER ALL THE RISKS



PRIVACY/CONFIDENTIALITY

- Describe how the privacy/confidentiality of the participants will be maintained.
- Anonymous vs. Confidential
- Think about the **DATA** generated
 - What are they?
 - Physical AND Electronic
 - How and where will they be stored?
 - Who will have access to the data?
 - What will happen to the data following the conclusion of the study?

ADDITIONAL ATTACHMENTS

- Survey/research instruments (in English and language of participants)
- Informed Consent Forms (in English and language of participants)
- Recruitment materials (in English and language of participants)
- CITI Training certificates
- Permission letters (in English and language of participants)
- Anything that is relevant!

HOW TO APPLY FOR IREC APPROVAL

- For 1) all faculty and staff human subject research and 2) student-led research that requires full board review (more later on this):

**Applications are completed and submitted electronically to:
reethics@nu.edu.kz**

- For student-led minimum-risk research (more later on this):

**Applications are completed and submitted electronically to
School-based IRECs**

HOW LONG WILL IT TAKE TO HAVE MY PROJECT APPROVED?

The length of time for review depends on a number of factors:

- The category of review required
- The completeness of your application
- The volume of applications being reviewed by the IREC

HOW LONG WILL IT TAKE TO HAVE MY PROJECT APPROVED?

Expedited

Up to 2 weeks once the IREC officially accepts the application (i.e., the application is full and complete)

Full Board
Review

Approximately 1 month once the IREC officially accepts the application (i.e., the application is full and complete)

PROCESS OF REVIEW: EXPEDITED REVIEW

1. NU IREC or School-based IREC receives the application via email.
2. NU IREC or School-based IREC conducts initial review and may request changes.
3. When application is clear and complete, NU IREC or School-based IREC sends the application to an IREC member for review.
4. IREC member contacts either NU IREC or School-based IREC to request additional changes. NU IREC or School-based IREC requests researcher to make modifications.
5. Revised applications are then re-reviewed by NU IREC or School-based IREC committee and approved.
6. NU IREC or School-based IREC sends out approval letter.

PROCESS OF REVIEW: FULL-BOARD REVIEW

1. NU IREC receives the application via email.
2. NU IREC conducts initial review and may request changes.
3. When application is clear and complete, NU IREC sends the application to all IREC members for review.
4. NU IREC members meet and discuss the application and request additional changes.
5. Revised applications are then re-reviewed by NU IREC members and approved.
6. NU IREC sends out approval letter.

WHAT ARE THE CATEGORIES OF REVIEW?

1. Exempt
2. Expedited
3. Full Board Review

HOW IS THE CATEGORY OF REVIEW DETERMINED?

The IREC determines the category of review based on the following factors:

- The level of risk to the participants
- The vulnerability of the participant population
- Nature of research methods
- The selection process of the participants
- Whether sensitive or medical information will be collected

GREATER THE RISK = GREATER THE REVIEW

EXEMPT RESEARCH

Research may qualify as exempt if:

- Low-risk research involving normal educational practices
- Low-risk, anonymous tests, surveys, or public observations
- Research on existing public or anonymous data or specimens

SOME EXAMPLES OF EXEMPT



Comparison of
instructional techniques or
curricula in a classroom



Anonymous surveys
conducted on Qualtrics of
student perceptions

EXCEPTIONS



Any study that uses vulnerable populations is not eligible for exemption. Research on these populations requires at a minimum expedited review.

WHAT TYPE OF RESEARCH IS CONSIDERED EXPEDITED?

- Research that is determined to place a human subject at minimal risk in a research setting. “Minimal risk” is defined by the IREC as risk no greater than that ordinarily encountered in daily life.
- Most social and behavioral science research, certain specific non-invasive methods of specimen collection, and surveys or studies where the participants’ information will be kept confidential.

Most research at NU falls into this category.

EXPEDITED REVIEW EXAMPLES



Clinical studies that do not include investigational new drugs or new medical devices



Collection of voice, video, or digital data for research purposes



Individual or group behavior, surveys, interviews, or oral histories that are confidential, but not anonymous

EXPEDITED REVIEW PROCEDURES

- Review is carried out by two IREC committee members.
- The reviewers may approve the application, request changes, or refer the application to the full IREC committee for review.
- Both reviewers must agree to approve the application or the application will be sent to the full IREC committee for review.

EXPEDITED REVIEW PROCEDURES

- Research classified as Expedited is approved for 1 year only. At the end of the year, investigators may apply for renewal if no changes to the study or participant population are anticipated.
- All changes to the research design or the subject population must be reported to the IREC; if deemed substantial, the IREC may require the submission of a new IREC application. .

WHAT TYPE OF RESEARCH REQUIRES FULL BOARD REVIEW?

Any research that involves more than minimum risk to participants or vulnerable groups requires full-board review

FULL BOARD REVIEW PROCEDURES

- Review is carried out by a full quorum of the IREC members (at least half of the members). Members receive the application at least 1 week prior to the meeting.
- One member of the IREC will present the research project
- All members participate in discussion and make comments.
- Decision is rendered by a majority of the assembled quorum.

FULL BOARD REVIEW PROCEDURES

- The Board may approve the research, require modifications before approval, or deny the applicant's request for approval.
- Projects approved under the full board review process require an annual review by the full board committee.

INFORMED CONSENT

INFORMED CONSENT

- Voluntary participation and informed consent are at the very core of the IREC.

Informed consent is a process, not a form.

CORE PRINCIPLES OF INFORMED CONSENT

- Informed consent must be obtained **before** the research begins.
- Information must be understandable.
- Subjects must have time to consider whether they want to participate.
- Consent must be given without coercion or undue influence.
- Subjects must not be made to give up legal rights.

STANDARD ELEMENTS OF INFORMED CONSENT

- A. Heading and Title
- B. Identify Principal Investigator(s)
- C. Purpose and Background
- D. Procedures
- E. Risks and/or Discomforts
- F. Confidentiality
- G. Benefits
- H. Costs/ Financial Considerations
- I. Reimbursement/Payment
- J. Questions
- K. Tissue and/or Blood Banking or Storage
- L. Ask for Consent
- M. Signature Section

INFORMED CONSENT TYPES

- **Signed consent**
 - Signature on a piece of paper
- **Waiver of documentation of consent (i.e., oral consent)**
 - All the elements of consent but no signature
 - Online studies or simple surveys
 - If risky, no record linking the subjects to the research
- **Waiver of consent**
 - No consent
 - Removing any required element of consent – deception and concealment

THINGS TO CONSIDER

IMPLICATIONS FOR YOU

- The Principal Investigator has ultimate responsibility for ethical conduct.



- Respect the time and process necessary for review. **IREC approvals are not retroactive.**

THINGS TO CONSIDER

- The IREC is there to assist by raising issues and asking questions that the PI may have overlooked or failed to consider.

The researcher and the IREC should be considered collaborators.

FOR MORE INFORMATION...

- NU IREC Website:

<https://nu.edu.kz/about-us/institutional-research-ethics-committee>

- Additional information: Full NU IREC procedures; Definitions; Forms; Instructions for completing and submitting the application

FOR MORE INFORMATION...

NU IREC Office

Email: resethics@nu.edu.kz

Peter Howie, NU IREC Chair

Email: irecchair@nu.edu.kz

QUESTIONS?

YES

NO

MAYBE