WHAT IT TAKES TO BE AN IREC MEMBER – VERSION 1

A RESOURCE HANDBOOK

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Institutional Research Ethics Committee (IREC)

Peter Howie, *Chair*

Assel Narymbetova, *Research Compliance Officer*

This handbook is an adaptation of the "What it takes to be an IRB Community Member" developed by the University of Southern California Office for the Protection of Research Subjects. It also uses information from the "Handbook: A Guide to Conducting Human Subject Research" developed by the Nazarbayev University Institutional Research Ethics Committee.

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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 5 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.

CHAPTER 2 IREC 101

This chapter provides a short introduction to IREC regulations, policies, procedures, research terminology, and the roles of research personnel. It also provides tips on how to review a protocol.

WHAT POLICIES AND PROCEDURES SHOULD I BE FAMILIAR WITH?

IREC is expected to follow Kazakhstan laws, as well as Nazarbayev University policies. In addition to these requirements, IREC examines ethical issues when reviewing research projects. For NU's IREC, a comprehensive set of policies and procedures is available at https://nu.edu.kz/about-us/institutional-research-ethics-committee. IREC members should familiarize themselves with these policies and procedures and refer to them when completing reviews.

WHAT IS INFORMED CONSENT?

Informed consent is the process of informing potential subjects about the key facts of a research study and what their participation will involve. The human subjects in the study must participate willingly, after having been adequately informed about the research. If the subjects are from a vulnerable population such as children, additional protections are required.

WHAT ARE THE REGULATORY LEVELS OF IREC REVIEW?

There are three levels of review for human subjects research: exempt, expedited and full board.

Exempt Review: protocols commonly involve less than minimal risk (e.g. anonymous survey) to subjects and fall within at least one of the four defined categories. This level of review has no continuing IREC oversight requirements. The exempt categories are:

- **Exemption 1:** Research conducted in commonly accepted educational settings involving normal educational practices
- **Exemption 2:** Educational tests, surveys, interviews, or observation of public behavior unless subjects can be identified and disclosure of data could place subject at risk
- **Exemption 3:** Collection/study of existing data, documents, records, specimens, if publicly available or if the information is not identifiable
- **Exemption 4:** Research and demonstration projects conducted/approved by Department/Agency heads designed to study/evaluate public benefit or service programs

Expedited Review: protocols involve minimal risk (e.g. blood draw, longitudinal study on attendance and graduation outcomes) and fall within one of six defined categories. These projects are reviewed by one designated, well trained IREC member. This level of review has ongoing IREC oversight requirements. The expedited categories are:

- **Category 1:** Clinical Studies that do not involve an investigational drug or device exemption
- **Category 2:** Blood sample collection (routine methods-small amounts)
- **Category 3:** Prospective collection of biological samples through noninvasive means

- **Category 4:** Data collected through noninvasive means (routinely practiced in clinical settings)
- **Category 5:** Collection of voice, video or digital data for research purposes
- **Category 6:** Individual or group behavior, surveys, interviews

Full Board Review: protocols involving greater than minimal risk (e.g. drug, device, biologics, and collecting/recording private information). These projects are reviewed by a fully convened IREC committee. This level of review is extensive and has continuing IREC oversight requirements.

WHAT ARE THE TYPES OF IREC RESEARCH SUBMISSIONS/INTERACTIONS?

There are a variety of types of IREC submissions and various reasons that may warrant IREC – researcher interaction. The following is a list of the different types of IREC submissions:

Common types of submissions include:

- *Full Board*: more than minimal risk, requires IREC review
- *Expedited*: minimal risk, requires review by one designated IREC reviewer
- *Exempt*: less than minimal risk, can be reviewed by IREC staff
- *Continuing Review*: yearly review required for full board and expedited projects
- *Amendment*: any change in risk, personnel, scope, procedures, etc.
- *Reportable Event*: adverse events and unanticipated problems involving risks to subjects or others, protocol deviations, noncompliance

Other IREC – research interactions include:

- *Suspension*: temporary hiatus of study procedures resulting from decision of IREC, PI, or sponsor
- *Termination*: IREC decision to halt a study, and usually requires a new submission to reactivate

HOW TO REVIEW A PROTOCOL

Using the NU IREC reviewer checklist is the required method to review protocols, support materials, and consent documents. The reviewer checklist helps organize thoughts, provides reminders of issues to be addressed, and gives useful formats to present the review. The complete set of NU IREC reviewer checklists can be found in Appendix A.

Once a member establishes a system for review research that work well for her/him, the process will become easier over time. IREC members may always call the IREC staff or another IREC member if something is unclear, missing or prompts questions about the proper course of action.

Tips for Reviewing

1. Establish a review routine by using a **systematic approach** to review each new protocol in the same way.
2. Read the **consent document** to understand the important aspects of the study. The consent document should serve as a good introduction to the study protocol. It should also orient you to the overall design of the study.
3. Read the **abstract** in the IREC application which provides key aspects of the study.
4. Read the **full protocol** and **supporting materials** carefully. The investigator provides the IREC with detailed information such as the study background and rationale, methodology, inclusion/exclusion criteria for subject enrollment, and other documents. Funding documents provide additional information. Take notes as needed.
5. Reread the consent document. **Record suggested corrections or questions** for the investigator, and ensure that the consent form adequately describes the actual study design and procedures in a language that can be understood by the subject.
6. Contact the IREC secretary or IREC Chair if there is information missing that is needed for full board review.

WHO ARE VULNERABLE SUBJECTS?

The term "vulnerable subjects" refer to research subjects that have been designated as vulnerable by federal regulations. Federal regulations outline special protections investigators must incorporate into their research when enrolling and conducting research with vulnerable subjects. Vulnerable subjects are:

- pregnant women, human fetuses, and neonates
- prisoners
- children

IRECs and researchers must bear in mind that vulnerability extends beyond the regulatory definitions. Vulnerability is an important consideration in all IREC deliberations. Individuals, as well as entire cohorts of subjects, may be susceptible to coercion depending on the particular study. Adequate justifications must be provided for studies that enroll vulnerable subjects.

WHAT CRITERIA MUST BE MET TO APPROVE A PROTOCOL?

The "Common Rule" sets forth certain criteria that must be met in order for the IREC to approve a protocol. Proposed research must satisfy each requirement below:

(1) Minimized Risks

Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which 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.

(2) Reasonable risk/benefit ratio

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. In evaluating risks and benefits, the IREC 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 IREC should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Equitable subject selection

Selection of subjects is equitable. In making this assessment the IREC 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, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Obtain Informed Consent

Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

(5) Document Informed Consent

Informed consent will be appropriately documented unless documented informed consent is waived

(6) Data monitored for safety

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

(7) Confidentiality/privacy maintained

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

Additional safeguards must be included 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.

WHAT IS CONFLICT OF INTEREST

The term “conflict of interest” (COI) refers to situations in which financial or other personal considerations compromise, or have the potential to compromise, an individual’s professional judgment or objectivity. Conflict of interest may occur with the researcher, IREC member, or the institution. All three types of COI must be reviewed and managed by the institution or its designated committee.

Researcher COI may occur in proposing, conducting or reporting research. The bias caused by such conflicts may affect collection, analysis, and interpretation of data, hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human subjects, and the use of statistical methods.

Institutional COI is a growing issue that is increasingly being noted by institutions and regulatory bodies. Finding those projects where the institution has interests that may conflict with the research outcome is of special concern in human-subjects research. Institutional COI is a difficult issue to identify and resolve because of the variety of ways an institution can be an "interested stakeholder" or have other interest in the conduct or outcome of a project.

IREC Members who have an "outside" interest or relationship to a research project or investigator are prohibited from participating in the vote and discussion of the project. IREC members are both required to recuse themselves (leave the meeting room) before the discussion and prohibited from voting on a study in which they have a COI. In some cases, IREC may request a member to be present in order to provide information to the committee. Unless an IREC member declares a conflict of interest, their unbiased ability to review a project is assumed.

THE DIFFERENCE BETWEEN BIOMEDICAL AND SOCIAL/BEHAVIORAL RESEARCH

IREC members may review biomedical or social and behavioral research, or both. IREC will make every effort to review social/behavioral research in an appropriate context. In order to feel comfortable understanding the differences between social/behavioral and biomedical research, the following matrix illustrates some typical differences:

	Social Behavioral	Biomedical
Terms commonly used to describe the research	interpretative, qualitative, action, observational, community based, emergent	quantitative, positivist, objective
Intended Research Outcome	produce rich description or theory	use of controlled/limited variables to test a biomedical outcome
Validity of Outcome Provided by	a research strategy utilizing verification/validation measures and reliable observation techniques	fixed procedures
Interaction with Subjects	social scientist is often an involved participant	researcher is a non-participant
Methods Used	observations, surveys, interviews, focus groups, comparisons, internet	drugs, medical procedures, interventions, test devices, biologics
Hypothesis Driven?	can be yes or no	yes
Interpretation by Experimenter vs. Experiment	experimenter and experiment	experiment
Social Distance between Researcher and Subjects	can be close relationship	should be more distant relationship
Dynamic/flexible/iterative Study Design?	yes	no
Power Differential Perception of PI over Subject	can be minor or major	usually major
Risk of Physical Harms (e.g. illness, death, etc.)?	no (though yes rarely)	yes
Risk of Social Harms (e.g., embarrassment, employability, etc.)?	yes	yes
Generalizable to other settings/populations?	can be yes or no	yes
Requires IREC review?	can be yes or no	yes

WORDS TO LEARN

As a new IREC member, you will come across terminology you may not be familiar with. Don't worry; this is common for anybody who is new to IREC. The list below includes definitions/descriptions of some of the common terms used in human subjects research. This section on terminology provides:

1. Project review terms
2. Study related personnel terms
3. IREC related personnel terms
4. Research related statistics terms

PROJECT REVIEW TERMS

Amendments – These are changes to an IREC approved research protocol and must be submitted and approved by the IREC before implementation (e.g. revised consent document, change in personnel, additional risks). Amendments involving more than minor changes or changes that pose more than minimal risk will be reviewed by the full committee.

Coded Data – Replacing identifiable data/private information (e.g., name) with a 'code' (e.g., letters, symbols or numbers). The goal is to protect the identity of the subject. The key is that the code is not kept with the data.

Common Rule – United States federal rules and regulations that IRECs must adhere to were codified in 1991 Policy for the Protection of Human Subjects (45 CFR 46).

Confidentiality – Describes the protections taken to safeguard data/information obtained from a subject.

Continuing Review – Periodic re-review of a research study by IREC to evaluate if risks to participants remain reasonable in relation to potential benefits, and to evaluate if the study continues to meets regulatory and institutional requirements.

Deception – Deception is the intentional misleading of subjects or intentional withholding of information about the nature of a study. Deception limits the ability of subjects to provide truly 'informed consent'; however, it is sometimes necessary for certain types of behavioral research. Deception is often justified because humans act differently depending on study circumstances, and full disclosure of study information/goals may bias the results.

De-identified Data – Data is considered de-identified when unique identifiable information (e.g., name, address, etc.) is removed from the data so that the subjects/source cannot be identified.

Exempt Research – Certain kinds of research involving minimal or less than minimal risk may be "exempt" from IREC oversight when the activities fall into one or more of the exempt categories.

Expedited Review – Regulations allow for an expedited review (one reviewer only) for certain kinds of research involving no more than minimal risk. For a list of the expedited research categories, click here. IREC Chairs and other experienced/trained IREC members designated by the IREC chair may conduct expedited reviews.

Full Board Review – Research involving greater than minimal risk must be reviewed at a fully convened meeting, where a majority of the committee members are present.

Human Subject – Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

Human Subjects Training Certification – Human subjects training certification is required for research approval at many institutions, including NU. NU uses an online educational program called CITI Human Subjects Research.

Informed Consent – A person's voluntary agreement to participate in research, once they've understood the possible risks and benefits of participation. Consent may be written or oral in defined circumstances, or translated from a language other than English.

Minimal Risk – A risk is minimal when the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the participant's daily life or during the performance of routine physical or psychological examinations or tests.

Multi-site research – A research study conducted at more than one institution (nationally and/or internationally) using the same protocol, each with its own Principal Investigator. Many clinical trials involving drugs/devices/biologics are conducted at more than one site.

Privacy – Privacy refers to the subject and his/her control over the extent, timing and circumstances of sharing oneself (physically, emotionally, behaviorally, or intellectually) with others.

Protocol – The formal design of an experiment or research activity. The protocol includes a description of the research methodology, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data. Research involving drugs, devices, or biologics will have a formal clinical protocol, which is submitted with an IREC application. For non-clinical social and/or behavioral research, a properly completed IREC application can serve as the protocol.

Reportable Events – At NU, the term "reportable events" refers to: adverse events, unanticipated problems involving risk to subjects or others, protocol violations, and data safety monitoring reports. Reportable events are submitted to the IREC in a reportable events form.

Research – Regulations define research as "a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102(d)). Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.

Sponsored/funded research – Sponsored or funded research is research that is financially supported by an outside entity. The funding may come from a pharmaceutical company, from a foundation, a donor, or the government.

Study Sample – The number of subjects the investigator wishes to enroll in a particular study. This number can change, depending on the stage and goal of the study. For example, a pilot study may have 5 subjects, and a Phase III clinical trial may have 500 subjects. A social and behavioral study could have a whole tribe or selected individuals. Target accrual must be justified in IREC applications.

STUDY RELATED PERSONNEL TERMS

Co-Principal Investigator (Co-PI) – In addition to the principal investigator, the co-principal investigator is the scientist or scholar who shares responsibility for the design and conduct of a research project. The Co-PI may be involved with a large portion of the research, or a small portion. The type and amount of study involvement depends on the responsibilities agreed upon by the PI and the Co-PI.

Data Manager – An individual who handles the data gathered during a study. Responsibilities may also involve managing data entry, database generation and/or maintenance, compliance with regulations, and protection and integrity of private information and study data.

Faculty Advisor – Faculty advisors are faculty members who supervise and oversee research being conducted by students. Advisors are responsible for guiding students through the IREC process, helping with research design, methodology, and ethical considerations.

Principal Investigator (PI) – The lead scientist or scholar who holds the ultimate responsibility for the conduct of a research project. The PI is the signatory authority of the study.

IREC RELATED PERSONNEL TERMS

IREC Chair – The role of IREC chairs vary by institution, but commonly IREC chairs direct the proceedings of IREC meetings. IREC chairs also review and approve research qualifying for expedited and exempt review. Furthermore, the IREC chair plays a leadership role in creating IREC policies and procedures.

IREC Secretary – An administrative staff person, who is responsible for screening and reviewing IREC applications prior to committee review. This job also includes agenda preparation, taking minutes and drafting correspondence between the PI and IREC.

IREC Vice-Chair – The role of the Vice-Chair is to fulfill the IREC Chairs responsibilities when the Chair is unavailable. Vice-Chairs also may review and approve research qualifying for expedited and exempt review.

CHAPTER 3 Developing into an Experienced Member

Members may face additional challenges as their IREC membership progresses. This chapter provides tips and strategies for overcoming challenges and transitioning from an inexperienced member into a confident and well-trained one.

MENTORING A NEW MEMBER

New members need guidance from the IREC staff and other IREC members. Because new members may not yet familiar with the institution's culture, assistance and advice from a mentor can be very beneficial. IREC chairpersons, IREC members, and/or IREC staff should provide mentoring to new community members. Ideal mentor qualities include knowledge, patience, and a willingness to share their personal experience with serving on the IREC.

A mentor should be available to help the new member review their first protocol. Having another person go over the review will help boost the new member's self-confidence and assure that the important points have been captured in the review.

BUILDING NEW MEMBER SKILLS

Achieving confidence, familiarity, and understanding of the IREC review process can come from a variety of sources. Below are recommendations for building new member skills:

a. Observe research activities

A useful way to become familiar with human subjects research is to observe the conduct of research as it is occurring. Getting a sense of what subjects undergo while participating in research will not only make reviewing a protocol easier, but it will help the new member empathize with the subject portion of the review. In addition, witnessing the informed consent process may influence reviewer recommendations.

b. Don't be afraid to ask questions

If it is discomforting to raise questions during a meeting, submit questions and/or concerns to the IREC staff or Chair either before or after the meeting. Providing insight into protocol review depends partly on the new member's willingness to seek out explanations about unfamiliar procedures/concepts/methodology. Note: agreement is assumed if no questions are asked, or concerns are raised.

c. Learn about regulations and controversial research and ethics issues

Read articles given out at meetings and/or related articles online or in newspapers.

d. Join an internet community/listserv

Join a group that shares common interests in the IREC process such as IREC Forum (http://www.IRECforum.org/). With these groups, members can ask questions and get opinions and

thoughts from other IREC members outside of NU. Joining will provide supplementary education on important debates and new programs/initiatives from IRECs around the world.

e. Keep a notebook

Taking notes on important, sometimes controversial issues gives a permanent resource for reference. It will allow you to refer back to a previous meeting's discussion where a particular issue was discussed. The notebook can also provide important information for reviewing protocols because issues often recur.

f. Foster relationships with other board members

The IREC Chair should create an environment where ALL members feel empowered to contribute opinions. Attending more full board meetings will result in becoming comfortable with the other committee members. Interacting with other members outside of the meeting fosters the exchange of IREC related information and many will be willing to offer assistance outside meeting sessions.

CHAPTER 4 Online Education

This section describes the required training (CITI).

CITI: ONLINE HUMAN SUBJECTS TRAINING

To access the CITI course:

1. Go to the "CITI Login and Registration Page": www.citiprogram.org
2. If you already registered for CITI, enter your username and password. If you have not registered for CITI, proceed below.
3. Click "Register Here"
4. Under the "Participating Institutions" drop down menu, select Nazarbayev University. Click the "submit" button.
5. Choose a unique username and password (username DOES NOT have to be your NU username). Click the "submit" button.
6. Enter your name and email address in the appropriate fields.
7. Fill in the required fields in the "Member Information" page. Only asterisked fields are required. Click the "submit information" button.
8. Select a group appropriate to your research activities. Unsure of what user group applies to you?
9. You can begin the course from the "Learner's Menu" page. Click "Enter", located under the "Status" header.
10. You can elect which modules to complete. Some users choose to complete modules related to their research, or modules that their department or advisor may require, or modules that are of interest. Yet it is mandatory that users obtain a cumulative score of at least 80% on the quizzes before a certificate is issued. You can retake any quiz as many times as you would like to improve your score.
11. Log in as many times as necessary to complete the course. Once you have completed the course, a certificate will be issued and stored in your CITI account.

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

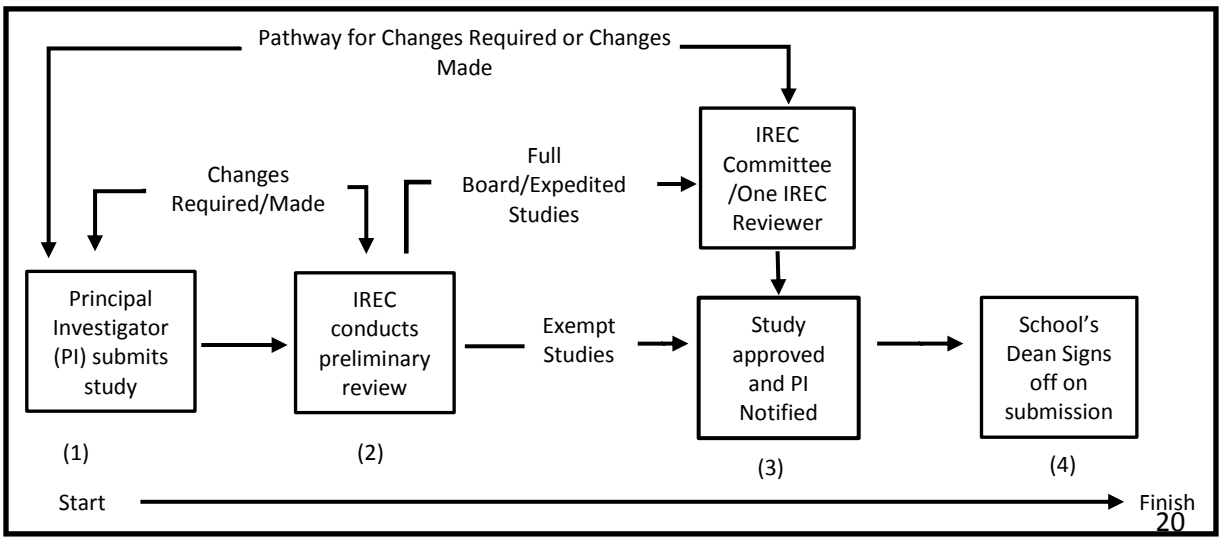
STUDY REVIEW

What follows 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

CHAPTER 6 Types of IREC Review: Exempt, Expedited, and Full Board

Research involving human subjects requires IREC review under one of the following three levels: exempt, expedited, or full-board. Studies involving minimal risk* (or less than minimal risk) generally qualify for review at the exempt or expedited level. For studies that are deemed greater than minimal risk, review by the full-board is required. An explanation of each review level is described below.

** "Minimal risk" is defined as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests".*

EXEMPT REVIEW

Exempt research involves research with human subjects, but because of its nature and "minimal risk" it is "exempt" from IREC oversight. The following are exempt categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.**
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.**
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement).
4. Research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

***Studies involving children can only be exempt if the PI plans to only observe and not interact with the children.*

Exempt 2 may not be used for minors.

EXPEDITED REVIEW

If the level of risk in a research project is considered to be no greater than minimal, and the research meets at least one of the expedited categories below, the IREC may review the project as expedited. Expedited review covers the same considerations as a full committee review; however the project

can be reviewed and approved by the IREC Chair or one Designated Reviewer, rather than the whole convened IREC committee. In reviewing research, expedited reviewers may exercise all of the authorities of the IREC, except the reviewer may not disapprove the research. In this case, the expedited reviewer must defer review to the full IREC committee. The expedited categories include:

1. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
2. Prospective collection of biological specimens for research purposes by noninvasive means.
3. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).
4. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt.)
5. Collection of data from voice, video, digital, or image recordings made for research purposes.
6. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

FULL BOARD REVIEW

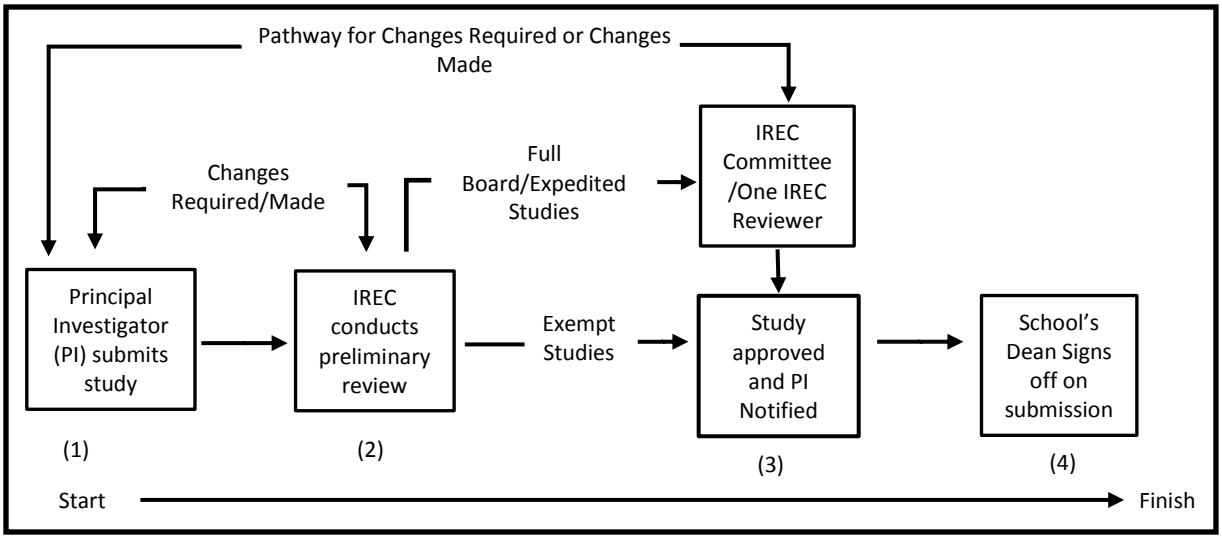
Studies that involve more than minimal risk require full board review at a convened meeting, at which a quorum of IREC members is present, including a community member. For the research to be approved, it must receive the approval of a majority of those members present. While federal regulations do not specifically list categories that would fall under full board review, below are certain criteria that may require full board review.

1. Clinical procedures involving drugs, devices, or biologics;
2. Studies using vulnerable populations;
3. Studies where information may be disclosed to researchers that could require mandatory legal reporting (e.g., child/elder abuse, drugs, etc.);
4. Studies involving deception which raise the risk level;
5. Studies where the IREC chair determines to be greater than minimal risk.

CHAPTER 7 IREC Review Process

What follows is a basic overview of each stage in the IREC review process from online submission to IREC approval. A description of each stage is provided below the flowchart.

Schematic of IREC Approval Process: non-NUSOM Schools



KEY:

(1) Principal Investigator Principal Investigator (Faculty/Staff/Student) Designs and Submits Study:

Faculty and staff investigators design their protocol and submit it via email to resethics@nu.edu.kz. Student investigators submit protocols to School-based IRECs. Investigators must indicate if the application requires expedited or full board review. The final determination of the review category is made by the IREC.

NOTE: Faculty investigators, student investigators, key personnel and faculty sponsors must fulfill the University's CITI online training requirement before the IREC will review applications.

(2) IREC:

After school Dean's approval is obtained, an initial review of the application is conducted by the IREC staff. At Nazarbayev University, the IREC staff conducts a thorough pre-review of the application to verify the correct type of review, and to evaluate the protocol and supporting documents (e.g., consent documents, recruitment materials, letters of support/permission, surveys, questionnaires, etc.). If a study is approved as **exempt** or determined to be "**not human subject research**," no further review is required by the IREC. A letter will be issued to the investigator indicating that the work does not require IREC review.

For studies designated as **expedited** or **full board**, IREC review is required by a designated reviewer or the full board, respectively. (For more information on the IREC Review categories see Chapter V: Types of IREC Review).

The possible determinations/outcomes that can be made on a study are as follows:

- ***Approved*** – the application is complete, the risks to subjects are minimal/minimized, and the procedures are appropriate. The IREC gives approval for the research to be conducted.
- ***Approved with Conditions*** – the application is complete but there are specific conditions that must be satisfied before the project can begin. Once a satisfactory response to these conditions is received the IREC will grant final approval and the research may then be initiated. **Conditional approval is used in very rare circumstances.**
- ***Deferred*** – applications that are found to have deficiencies (risk to subjects, unclear procedures, serious omissions, ethical issues, or major contingencies) will be deferred. The researcher is sent a memorandum listing the concerns that must be addressed for approval to proceed. The researcher's response is reviewed by the IREC and will be approved or deferred until all issues are addressed satisfactorily.
- ***Disapproved*** – Applications that are found to have risks that outweigh the potential benefits to subjects and/or society will receive a non-approval and the research will not be allowed. This determination can only be made by the full board at a convened meeting. Institutional administrative officials may not override this decision.

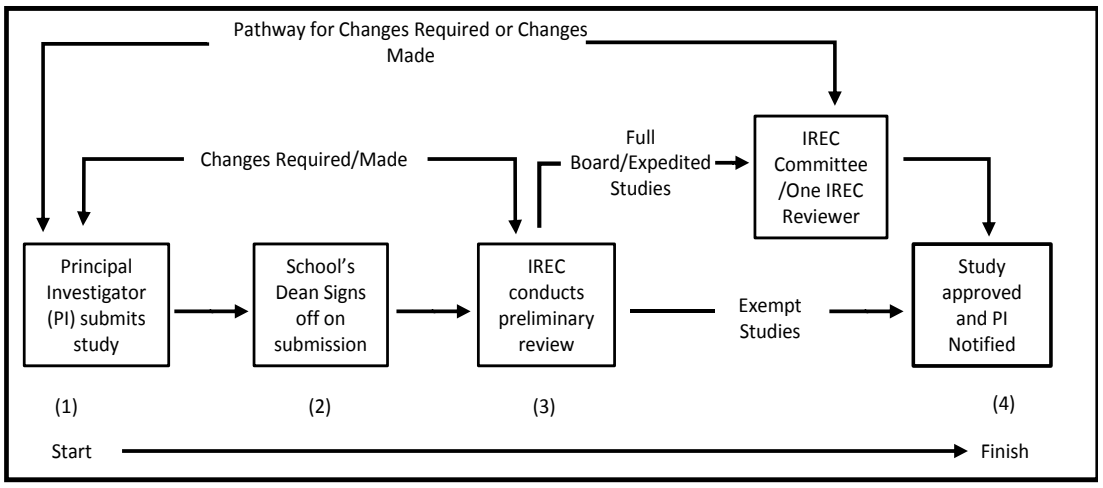
(3) Study Approved and PI Notified:

The researcher will be notified through an email when the study has been approved.

(4) Dean Sign-Off:

Once the application is completed, the principal investigator's Dean must review and sign off on the application. This sign-off represents consideration of scientific merit, availability of resources, or other issues at the department level.

Schematic of IREC Approval Process: NUSOM



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(4) Study Approved and PI Notified:

The researcher will be notified through an email when the study has been approved.

IREC APPROVAL CRITERIA: KEY POINTS

When reviewing proposed research, the IREC must consider the 7 regulatory requirements, provided below. Among the concepts that must be well understood to review human subjects research are

informed consent (elements and process), privacy and confidentiality, and risk and benefit. The information below is not all inclusive and is provided to establish familiarity with these critical topics.

Regulatory Criteria for IREC Approval

NU investigators proposing a research project that involves human subjects must submit an application to the IREC. The IREC shall determine that all of the following requirements are satisfied before approving the research:

1. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which 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.
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. In evaluating risks and benefits, the IREC 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 IREC should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment the IREC 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, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
5. Informed consent will be appropriately documented, unless investigator requests oral consent or waived informed consent for research involving deception.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Additionally, 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.

Informed Consent

Informed consent is the process of informing potential subjects about the key facts of a research study and what their participation will involve. The human subjects in the study must participate willingly, after having been adequately informed about the research. If the subjects are from a

vulnerable population, such as pregnant women, prisoners or children, additional protections are required.

Consent documents must be clearly written and at a level understandable by the subjects. The language must be non-technical (comparable to the language in a newspaper or general circulation magazine). Scientific, technical, and medical terms must be plainly defined. It is often recommended that the informed consent be written at the sixth to eighth grade reading level. Assent forms for minors and any related recruitment materials must reflect the reading level of the minors.

What elements should be included in an informed consent?

For human subjects to participate in a research study, they need to have enough information to give a truly voluntary informed consent. Information subjects must be given include:

- *Purpose* of the research
- *Procedures* involved in the research
- *Alternatives* available should a subject decide not to participate in the research
- All reasonably *foreseeable risks and discomforts* to the subject

  Note: these include not only physical injury but also possible psychological, social, or economic harm, discomfort, or inconvenience.

- *Benefits* of the research to the individual human subject and society
- *Length of time* the subject is expected to participate
- *Payment* for participation (if applicable)
- *Person to contact* for answers to questions or in the event of a research-related injury or emergency
- Statement that *participation is voluntary* and that refusal to participate will not result in any consequences or any loss of benefits that the person is otherwise entitled to receive
- Subjects' *right to confidentiality* and *right to withdraw* from the study at any time without any consequences

There are three types of consent:

- **Consent** – An adult subject, capable to give permission to participate in a research study, can provide consent. The subject must be 18 years of age and competent to make the decision to participate.

- **Parental Permission** – When children/minors are included in research, the parent/guardian must sign a parental permission consent document. Some situations require permission from at least one parent, while other situations require permission from both parents.

- **Assent** – Assent is a child's affirmative agreement to participate in research. If the subject is 7-17 years of age, assent must be obtained. The assent form must include simple language written at the appropriate reading level of the youngest subject in the age range.

Informed consent templates and guides can be found in Appendix C:

Privacy/Confidentiality

The protection of privacy and confidentiality are important issues in the protection of human research subjects. The investigator must describe plans to protect the subject's identity as well as the confidentiality of the research records. Privacy and confidentiality are extensions of the principles of autonomy (respect for persons) and beneficence from the Belmont Report.

Privacy

Can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Care should be taken to explain the mechanisms that have been devised to protect the privacy of the subjects. The concept of privacy relates to the means for obtaining the data from subjects. For example, when a researcher is interviewing a participant, they must make provisions to protect what is being discussed. Holding the interview in a private office is one method to protect the participant's privacy. Another consideration for privacy is limiting the data being obtained to essential data only. For example, collecting information not related to the research hypothesis is inappropriate.

Confidentiality

Pertains to the treatment of information that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others (without permission) in ways that are inconsistent with the understanding of the original disclosure.

The investigator must provide a plan to keep research records confidential. For example, storing research records in locked file cabinets and password protecting electronic files helps to ensure confidentiality. Investigators should also describe, in their IREC application, who has access to the research records. Without appropriate safeguards, problems may arise from a long-term retention of records. In some cases, to prevent potential criminal or civil prosecution of the research subjects, the IREC may require the destruction of all data that can identify the subjects. Subjects should be informed of whether the data collected will be retained, and if so, for what purpose and for what period of time. Video and audio taped data, as well as photographs require specific plans for confidentiality since these media can provide additional means for subject identification.

Risk/Benefit

When reviewing research studies, IREC must assess the risks and benefits (if any) to subjects who participate in the research. The IREC's assessment of risks and anticipated benefits involves a series of steps. IREC must: (1) identify the risks associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in research; (2) determine that the risks will be minimized to the extent possible; (3) identify the probable benefits to be derived from the research; (4) determine that the risks are reasonable in relation to the benefits to subjects, if any, and the importance of the knowledge to be gained; (5) assure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits; and (6) determine intervals of periodic review, and, where appropriate, determine that adequate provisions are in place for monitoring the data collected.

Risk

Defined as the probability of harm or injury (physical, psychological, social, or economic) occurring as the result of participation in a research study. Risks also include possible breaches of confidentiality. Both the probability and magnitude of possible harm may vary from minimal to significant.

Harms

Medical research often involves exposure to pain, discomfort, or injury from invasive medical procedures, or harm from possible side effects of drugs. All of these should be considered "risks" for purposes of IREC review. Some of the adverse effects that result from medical procedures or drugs can be permanent, but most are transient. Procedures commonly used in medical research usually result in no more than minor discomfort (*e.g.*, temporary dizziness, the pain associated with venipuncture). Some medical research is designed only to measure more carefully the effects of therapeutic or diagnostic procedures applied in the course of caring for an illness. Such research may not entail any significant risks beyond those presented by medically indicated interventions. On the other hand, research designed to evaluate new drugs or procedures may present more than minimal risk, and can cause serious or disabling injuries.

Psychological Harms. Participation in research may result in undesired changes in thought processes and emotion (*e.g.*, episodes of depression, confusion, or hallucination resulting from drugs, feelings of stress, guilt, and loss of self-esteem). These changes may be transitory, recurrent, or permanent. Most psychological risks are minimal or transitory, but IREC members should be aware that some research has the potential for causing serious psychological harm.

- Subjects may feel stress caused by certain research questions or procedures such as surveys or face-to-face interviews. Some questions may raise painful memories or unresolved issues. Questions about at-risk behaviors may cause embarrassment, feelings of guilt, or legal liability when that behavior is generally illegal or socially unacceptable.

- Provisions for psychological support and referrals can be built into studies when emotional distress may be an outcome. Consent forms describing the kinds of questions the researcher will ask allows participants to choose whether they are comfortable with answering certain types of questions or exploring certain issues.
- A breach of confidentiality may be damaging to a subjects reputation, their employability may be negatively affected, and/or their ability to obtain insurance coverage may be jeopardized if confidentiality is not maintained.
- Information about certain behaviors may place subjects at risk of legal action. For example, if subjects divulge information about illegal activities or stigmatized activities, any disclosure of that information could place the subjects at risk of significant harm.

Benefit

Defined as a valued or desired outcome; an advantage. The benefits of research fall into two major categories: benefits to subjects and benefits to society. Frequently, the research subjects are undergoing treatment, diagnosis, or examination for an illness or abnormal condition. This kind of research often involves evaluation of a procedure that may benefit the subjects by ameliorating their conditions or providing a better understanding of their disorders. Patients and healthy individuals may also agree to participate in research that is either not related to any illnesses they might have or that is related to their conditions but not designed to provide any diagnostic or **therapeutic** benefit. Such research is designed principally to increase our understanding and store of knowledge about human physiology and behavior. Research that has no immediate therapeutic intent may, nonetheless, benefit society as a whole. These benefits take the form of increased knowledge, improved safety, technological advances, and better health. IREC should assure that the anticipated benefits to research subjects and the knowledge researchers expect to gain are clearly identified.

CHAPTER 8 Investigator Reporting

Responsibilities

After a research project is approved, there are many situations requiring communication with IREC during the conduct of the research. These communications result from events that unfold (and may or may not be expected) as the research is taking place. Investigators are required to submit reports or communication on: adverse events, unanticipated problems, changes, study continuing reviews, expiration of approval period, study completion, and terminations/suspensions. This chapter provides an introduction to each of these sections.

REPORTABLE EVENTS: ADVERSE EVENTS AND UNANTICIPATED PROBLEMS

After an Adverse Event or an Unanticipated Problem occurs, the principal investigator is required to submit a reportable event form as soon as possible to IREC. The principal investigator's report should contain enough information for IREC to determine whether the event increases the level of risk to participants, requires a research design change or necessitates modification to the informed consent form.

Definitions

Adverse Events are defined as any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Serious Adverse Events (**SAEs**) are those that: are fatal or life threatening, result in significant or persistent disability, require or prolong hospitalization, result in a congenital anomaly/birth defect, or in the opinion of the investigators, represent other significant hazards or potentially serious harm to research subjects or others.

Unanticipated or **Unexpected** refers to adverse events or other problems in the research, the specificity or severity of which is not consistent with the information already provided to the IREC, including the investigator's brochure, research protocol or consent form.

Unanticipated Problems Involving Risks to Subjects or Others (**UPX**) includes any incident, experience, or outcome that is unexpected, related or possibly related, and suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

CHANGES TO PREVIOUSLY APPROVED RESEARCH

Any proposed change to a previously IREC approved research project must be submitted to and approved by IREC before the change is implemented, except when necessary to eliminate apparent immediate hazards to the subjects. Amendment submissions will be reviewed by the IREC Chair amd

may require review by the expedited review procedure or require review by the fully convened IREC depending on the assessment of associated risk. Typically, minor changes are reviewed and approved by the NU IREC Chair. Minor changes do not alter the risk/benefit ratio in previously approved research (e.g. correction of typos, adding PIs to the project, etc.).

All NU investigators proposing modifications to a previously approved human subject research project must submit an amendment application. The amendment application serves as a "form" that lists/details the proposed changes to the study. In addition to the amendment application, investigators must make the changes to the originally submitted new study application. In reviewing amendments, IREC analyzes whether the changes pose additional risks to subjects or represents a significant change in study procedures and may impose additional contingencies before approving the amendment.

CONTINUING REVIEW

In accordance with NU regulations, all non-exempt research protocols undergo continuing review at intervals appropriate to the degree of risk, but not greater than once per year. The frequency and extent of continuing review for each study is based upon the nature of the study, the degree of risk involved, the novelty of the research procedures, and the vulnerability of the study's subject population. After a careful consideration of each of these factors, each protocol is assigned an approval period, after which the study must be re-reviewed by IREC.

Each investigator must abide by the approval period imposed by IREC at the time of the most recent IREC approval. Each IREC approval notice designates a period of time during which activities involving human research subjects may be *undertaken*. No research project may continue to recruit, enroll, or treat subjects or analyze data after the IREC approval expiration date (except where doing so would cause harm to the subjects).

It is the investigator's responsibility to ensure that approval for an active protocol remains current.

EXPIRATION OF APPROVAL PERIOD

In the event that a protocol expires and the withdrawal of research interventions may place study subjects at risk, the investigator may request that IREC grant permission to allow the continuation of activities. If subject safety would be compromised by study closure, investigators can request that the IREC allow continuation of study activities for currently enrolled subjects. If research-related interventions have been continued with subjects on an expired protocol, IREC must be immediately informed of the circumstances that necessitated this action.

Requests justifying continuation of currently enrolled subjects will be forwarded to the IREC Chair for consideration. If the IREC Chair grants permission to allow the continuation of research interventions with previously enrolled subjects for reasons related to subject safety, the IREC will send written notification to the investigator. Other research activities (such as recruitment, enrollment, data analysis, etc.) may only be resumed after the investigator receives continuing approval for the research.

STUDY COMPLETION

A research project is closed when subject accrual, subject follow-up and data analysis are completed at NU. Once a study is closed, no further research activity, including data analysis, may occur.

TERMINATION/SUSPENSION OF A STUDY

Termination is when IREC permanently withdraws approval of ALL research activities for a particular study. Terminated research is no longer required to undergo continuing review. The convened IREC, IREC Chair, and IREC Vice Chair (in the absence of the Chair) are authorized to suspend or terminate research. If there is an urgent situation requiring suspension or termination of a study, the IREC Chair or Vice Chair may make this determination. If the IREC Chair or Vice Chair terminates or suspends a study on his/her own, IREC is notified by the Chair at the next IREC meeting.

Suspension is when the IREC temporarily or permanently withdraws approval of some or all research activities**.** Suspended research is still under the jurisdiction of IREC.

APPENDIX A IREC Reviewer Checklists

IREC has developed comprehensive reviewer checklists to assist IREC staff and members in performing thorough protocol reviews. Those submitting applications may also find these checklists useful to learn regulatory expectations. The checklists are meant to be used as a guide regarding essential content, but not as an official set of rules. The following checklists are included in this chapter:

1. New IREC Applications – Expedited Reviews
2. New IREC Applications – Full-board Reviews

PI:	
Title:	**Date:**
Reviewed By:	

Brief Description of the Protocol:	
• **Does the Research Qualify for Expedited Review? (Yes, check all that apply.)**	☐ No →STOP. A full IREC review is required. ☐ Yes
☐ 1: Research participants do not comprise children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons	
☐ 2: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. This listing refers only to research that is not exempt.)	
☐ 3: Collection of data from voice, video, digital, or image recordings made for research purposes.	
☐ 4: Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.	
☐ 5: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.	

☐ 6: Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

☐ 7: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

COMPLETENESS CHECK	
☐ No ☐ Yes	All required CITI training complete? Note:
☐ No ☐ Yes	Informed consent documents in the respondents' language(s) and English *or* Assent Forms and Parental Permission Forms in the respondents' language(s) and English submitted?
☐ No ☐ Yes ☐ NA	Supporting documents submitted in the respondents' language(s) and English? (e.g., recruitment materials, questionnaires, interview questions)
☐ No ☐ Yes	Conflict of interest reported?

ASSESSMENT OF THE REVIEW SUBMISSION BY REVIEWER	
☐ No ☐ Yes ☐ Resolved	**Risks are minimized:** Risks are minimized by using procedures which are consistent with sound research design and which do not expose subjects to unnecessary risk; and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. COMMENTS/Stipulations/Recommendations:
☐ No ☐ Yes	**Risks are reasonable:** Risks to subjects are **reasonable** in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result. Will the research achieve the objectives proposed? In evaluating risk, IREC should consider only those risks and benefits that may result from the research, not risks and benefits of therapies subjects would receive even if not participating in the research. IREC should not consider possible long range effects

☐ Resolved	of applying knowledge gained in the research (e.g., effects of results on public policy.) What is the risk level? Is there prospect of benefit to subjects? COMMENTS/Stipulations/Recommendations:
☐ No ☐ Yes ☐ Resolved	**Subject selection is equitable:** IREC should also take into account: • The purposes of the research. • The setting in which the research would be conducted. • Whether prospective participants would be vulnerable to coercion or undue influence. • The inclusion/exclusion criteria. • Participant recruitment and enrollment procedures. • The influence of payments to participant Are recruitment materials free from exculpatory language? *Exculpatory language is any language that actually or apparently releases investigators, sponsors, institutions and their agents from liability of negligence.* Who will be enrolled? Pregnant women? Children? Prisoners? Decisionally impaired? Economically or educationally disadvantaged persons? Are these subjects appropriate for the protocol? Are protections appropriate? COMMENTS/Stipulations/Recommendations::
☐ No ☐ Yes ☐ N/A ☐ Resolved	**Data monitoring:** When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure safety of subjects. COMMENTS/Stipulations/Recommendations::
☐ No ☐ Yes ☐ Resolved	**Privacy and Confidentiality:** Does the protocol describe adequate provisions to protect the privacy interests of participant? When appropriate, there are adequate provisions to protect subject privacy & maintain confidentiality of the data. Will personal identifiable research data be protected to the extent possible from access or use? Are any special privacy & confidentiality issues properly addressed? COMMENTS/Stipulations/Recommendations:
☐ No ☐ Yes	**Adequate Resources:** Will the investigator have access to a population that will allow recruitment of the required number of subjects?

☐ Resolved	Will the investigator have adequate numbers of qualified staff? Will the investigator have adequate facilities? Will the investigator have an adequate process to ensure that all persons assisting with the research are adequately informed about the protocol and their related duties? Availability of medical or psychological resources that participants might need as a consequence of the research? Sufficient time to conduct and complete the research? COMMENTS/Stipulations/Recommendations:
☐ No ☐ Yes ☐ Waived ☐ Resolved	**Informed consent process:** Will the investigator obtain the legally effective informed consent of the subject or the subject's legally authorized representative? Will the circumstances of the consent process provide sufficient opportunity for the subject to consider whether or not to participate? Will the circumstances of the consent process minimize the possibility of coercion or undue influence? COMMENTS/Stipulations/Recommendations:
☐ No ☐ Yes ☐ Waived ☐ Resolved	**Informed consent form:** Informed consent is obtained from research subjects or their legally authorized representative(s) in accordance with Nazarbayev University procedures. Does the informed consent document include the basic element of consent? Is the consent document understandable to subjects? Is the consent form free of exculpatory language that asks the subject to waive or appears to waive the subjects' legal rights or language that waives or appears to release the investigator, sponsor, or the institution form liability for negligence? COMMENTS/Stipulations/Recommendations:
☐ No ☐ Yes ☐ N/A ☐ Resolved	**Survey Instruments** Were survey instruments included in the submission? COMMENTS/Stipulations/Recommendations:

CONSENT WAIVERS	
REQUEST FOR WAIVER OF WRITTEN DOCUMENTATION OF CONSENT: ** MUST MEET (1) AND (2) BELOW **	
☐ **Waived**	**(1)** The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.
☐ **Waived**	**(2)** That the research presents no more than minimal risk of harm to subjects.
Provide protocol specific justification for waiver of written documentation of consent:	
Does the PI should provide subjects with a written statement (information sheet) regarding the research? ☐ Yes ☐ No Review script or information sheet. COMMENTS/Stipulations/Recommendations:	

REVIEWER'S FINAL ASSESSMENT/OPINION	
Approve	☐ Without changes
Approve	☐ With minor changes
IREC Chair review needed	☐ Contact IREC Chair for consultant information.
Reject	☐ Numerous issues in protocol file and accompanying documents
Referred for full review by IREC	☐ Does not qualify for expedited review. ☐ Risks significantly outweigh the benefit or value of the knowledge to be gained. ☐ There are significant ethical concerns or questions that deem the study unacceptable.

Reviewed by:

Date:

1. PROJECT DESCRIPTION AND METHODOLOGY	Yes / No / N/A
a. Are the aims and underlying hypotheses of the research stated clearly?	
b. Does the research use procedures consistent with sound research design?	
c. Does the research design allow the proposed research question to address the proposed study objectives and result in scientifically and statistically valid results?	
d. Does the research contribute to generalizable knowledge?	
e. Is there an adequate justification for involving human subjects?	
f. Is there an adequate explanation of the research issues?	
g. Is there an adequate description of the activities involving human subjects?	
h. Is there a detailed description of the data collection and methods of recording?	
i. Have the questionnaires and interview tools been provided?	
j. Is there an adequate justification for the sample size?	

2. RISK AND BENEFIT CONSIDERATIONS	Yes / No / N/A
a. Are the risks (physical, psychological, legal, economic, and social) to subjects minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk?	
b. Are the risks minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes?	
c. Are the risks to subjects reasonable in relation to anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonably be expected to result?	
d. Are the risks to subjects reasonable in relation to the importance of the knowledge that may reasonably be expected to result?	
e. Are both risks and anticipated benefits accurately identified, evaluated, and described?	
f. Have the risks and benefits of the research interventions been evaluated separately from those of the therapeutic interventions?	

3. SELECTION OF SUBJECTS	Yes / No / N/A
a. Is the subject selection equitable?	
b. Are the criteria for inclusion/exclusion equitable?	
c. Will the recruitment process alter equitable selection?	
d. Does the nature of the research justify using the proposed subject population?	
e. Are there adequate procedures for identifying those who might be more susceptible to the risks and who therefore ought to be excluded?	
f. Has there been appropriate consideration of any special physiological, psychological, or social characteristics of the subject group that would pose special risks?	
g. Are some or all of the subjects likely to be vulnerable to coercion or undue influence, such as children prisoners, pregnant women, mentally disabled persons or economically disadvantaged persons?	
h. If yes to question 3g, have additional safeguards been included in the study to protect the rights and welfare of these subjects?	
i. If there is a special population (children, prisoners, pregnant women and fetuses), has the appropriate justification been provided?	
j. Is the exclusion of study subjects justified and appropriate?	

4. PRIVACY AND CONFIDENTIALITY	Yes / No / N/A
a. Are there adequate provisions to protect the privacy interests of participants?	
b. Are there adequate provisions for protecting the confidentiality of the data through coding, destruction of identifying information, limiting access to the data, or whatever methods that may be appropriate to the study?	
c. If the information obtained about subjects might interest law enforcement or other government agencies, has a certificate of confidentiality been obtained?	
d. Are the investigator's disclosures to subjects about confidentiality adequate?	

5. MONITORING	Yes / No / N/A
a. Does the research plan make adequate provision for monitoring the data collected to ensure the safety of subjects?	

b. Is there documentation indicating appropriate reporting to the IREC in the event that unexpected results are discovered or there are adverse events?	
c. If appropriate has a data safety monitoring committee been established?	
d. If the study is a multi-center study and USC is the coordinating center, is the plan for the management of information that is relevant to the protection of participants, such as reporting of unexpected problems, protocol modifications, and interim results adequate?	
e. If the PI is conducting research at an external site, is their an adequate management and communication plan among the IRECs involved?	

6. INCENTIVES FOR PARTICIPATION	**Yes / No / N/A**
a. Are the incentives offered reasonable, based upon the complexities and inconveniences of the study and the particular subject population?	
b. Is the compensation or reimbursement appropriately prorated?	

7. CONFLICT OF INTEREST	**Yes / No / N/A**
a. Is there a conflict of interest that requires management?	

8. INFORMED CONSENT PROCESS AND CONTENT	**Yes / No / N/A**
a. Do the proposed explanations of the research provide an accurate assessment of its risks and anticipated benefits? Is the possibility (or improbability) of direct benefit to the subjects fairly and clearly described?	
b. Is the language and presentation of the information to be conveyed appropriate to the subject population?	
c. Are the timing of and setting for the explanation of the research and obtaining informed consent conducive to good decision making?	
d. Is it clear who is authorized to obtain informed consent for the study?	
e. Have the informed consent issues for secondary study subjects been addressed?	
f. Will the investigator obtain legally effective informed consent of the participant or the participant's legally authorized representative?	

g. Will the circumstances of the consent process provide the prospective participant or the representative sufficient opportunity to consider whether to participate?	
h. Will the circumstances of the consent process minimize the possibility of coercion or undue influence?	
i. Will the individuals communicating information to the participant or the representative during the consent process provide the information in language understandable to the participant or the representative (individuals talking to the participants and answering questions will be able to communicate in a manner that is understandable to the participant)?	
j. Did the PI report that they plan to enroll non-English speaking subjects?	
k. If yes, did the PI report that they will use the short form? *Reminder to IREC staff: PI's must be notified in IREC correspondence regarding the IREC requirements when using the short form.	
l. Will the information being communicated to the participant or the representative during the consent process not include exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights?	
m. Will the information being communicated to the participant or the representative during the consent process not include exculpatory language through which the participant or the representative releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence?	
n. Are subjects informed to take as much time necessary to read the consent form?	
o. Are subjects informed that they will receive a copy of the consent form?	
p. The consent from contains contact information for a person independent of the research team for the following: • To obtain answers to questions about the research • In the event the research staff could not be reached • In the event they wished to talk to someone other than the research staff?	

9. BASIC ELEMENTS OF INFORMED CONSENT (REQUIRED)	**Yes / No / N/A**
a. A statement that the study involves research	
b. An explanation of the purposes of the research	

c. The expected duration of the subject's participation	
d. A description of the procedures to be followed	
e. Identification of any procedures which are experimental	
f. A description of any reasonably foreseeable risks or discomforts to the subject	
g. A description of any benefits to the subject or to others which may reasonably be expected from the research	
h. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	
i. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained	
j. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained	
k. An explanation of whom to contact for answers to questions about the research	
l. An explanation of whom to contact for answers to questions about injury	
m. An explanation of whom to contact concerning rights as a research subject.	
n. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits and the subject may withdraw without penalty.	
ADDITIONAL ELEMENTS OF INFORMED CONSENT	**Yes / No / N/A**
o. A statement that the particular treatment or procedure may involve risks to the subject or to the embryo or fetus, if the subject is or may become pregnant which are currently unforeseeable.	
p. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.	
q. Any additional costs to the subject that may result from participation in the research.	
r. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.	
s. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.	
t. The approximate number of subjects involved in the study.	
u. The storage and use of research specimens disclosed.	

v. Agreement and spaces for signatures/dates for subject, and/or representative (if applicable) and person obtaining consent.	
w. Is a witness signature required?	
x. If FDA Regulated, a statement that the FDA may inspect the records. (Include if the research is subject to FDA regulations)	
y. Are subjects informed to take as much time necessary to read the consent form?	
z. Are subjects informed that they will receive a copy of the consent form?	
aa. The consent from contains contact information for a person independent of the research team for the following: • To obtain answers to questions about the research • In the event the research staff could not be reached • In the event they wished to talk to someone other than the research staff?	

10. ASSENT FROM CHILDREN	**Yes / No / N/A**
a. Is assent required? (Assent is required unless the child is not capable (due to age, psychological state, sedation), or the research holds out the prospect of direct benefit that is only available within the context of the research.)	
b. Will assent be documented?	
c. Is the process of obtaining/documenting assent adequate?	

11. PARENTAL PERMISSION	**Yes / No / N/A**
a. Is consent of one parent appropriate?	
b. Is consent of both parents required? (Consent from both parents is required when the research is greater than minimal risk, without potential for benefit.)	

12. CONSENTING COGNITIVELY IMPAIRED PERSONS	**Yes / No / N/A**
a. Does the research involve greater than minimal risk?	
b. If the research involves greater than minimal risk does it present the prospect of direct benefit to the individual subjects?	

c. Are the risks to subjects reasonable in relation to anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonable be expected to result?	
d. Is the relation of the anticipated benefit to the risk at least as favorable to the subjects as that presented by available alternative approaches?	
e. Are there adequate provisions for soliciting the assent of the subject and permission of their legally authorized representative?	
f. Is the proposed plan for the assessment of the capacity to consent adequate?	

13. RESOURCES	**Yes / No / N/A**
a. Does the IREC have the appropriate expertise to review this research? If no to question , should a consultant be used to assist in the review of the research	
b. Will the Investigator have access to a population that will allow recruitment of the required number of participants?	
c. Will the Investigator have sufficient time to conduct and complete the research?	
d. Will the Investigator have adequate numbers of qualified staff?	
e. Will the Investigator have adequate facilities?	
f. Does the Investigator have an adequate process to ensure that all persons assisting with the research are adequately informed about the protocol and their research related duties and functions?	
g. Will the Investigator have adequate medical or psychological services available that participants might require as a consequence of the research, when applicable?	

Additional Comments (optional):

Appendix B: IREC Application Form

Institutional Research Ethics Committee (IREC) Application Form Directions:

- This form must be approved prior to any student (undergraduate or graduate), faculty, or staff conducting research. *Data collection/analysis may not begin until there has been IREC approval of this project.*
- Handwritten forms will not be accepted. *For your benefit, save your completed form in case it needs to be revised and resubmitted*.
- This is a professional document; please check spelling, grammar and punctuation.
- Fill in the form and verify that you have included all necessary documents (consult the Checklist of Submission Documents on the final page of the form).
- Submit the complete IREC Application Form, without required signatures and materials attached, in electronic form to resethics@nu.edu.kz .
- Once the project has been approved, submit original paper documents, with required signatures and required materials attached.
- All investigators (and students, staff affiliated with a protocol) who submit an IREC protocol to NU IREC will need to complete the CITI basic course on Human Subjects Research or provide verification that this course has been completed within the past 3 years.

NOTE: If your project **does not** involve human subject research (e.g. literature reviews) you are **not required** to submit an IREC application. Researchers may request that the IREC conduct the review to verify that no human subjects are involved.

IREC examines the information provided in the application documents to determine whether approval can be granted, and under what conditions. If IREC cannot determine the status based on the information provided, the application will be returned to the investigator with a request for additional information. It is in the investigator's interest to provide thorough information. Delays are most likely to occur if the investigator does not provide the information needed for IREC to conduct its review. It may take up to five (5) business days or more

to initially review an application that falls within the exempt or expedited category statuses. The review of applications that fall within the full board category status occurs at the monthly IREC meetings.

Please remove this page before submitting form

Part 0: Do I Submit an IREC Application?

Is this research?

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

a. Is this project being conducted solely to fulfill course requirements with no intention to share the results beyond the classroom in which it is assigned?

Yes ☐ No ☐

b. Is this project a quality assurance activity or program improvement activity with no intention to share the results beyond the University community?

Yes ☐ No ☐

c. Is this project a pilot study, or would you like to use this study to launch future investigations in which you would re-use this data?

Yes ☐ No ☐

d. Would you like to consider using this study for publication or dissemination at a later date, including at research presentations on- or off-campus?

Yes ☐ No ☐

If you answered "yes" to "a" or "b" and:

- If you answered "***no***" to "c" *and* "d," then you are not conducting research under the Nazarbayev University IREC definition. You may stop here and you do not need to submit this to the IREC.

- If you answered "***yes***" to "c" *or* "d," then you are conducting a type of research. Please continue with this form.

e. Do the proposed activities involve *a systematic approach*? A "systematic approach" involves a predetermined method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A systematic approach incorporates collection of data, either quantitative or qualitative, or specimens; and analysis of the collected information.

Yes ☐ No ☐

If **NO,** explain why the proposed activities do not involve a systematic approach:

f. Is the intent of the proposed activities to *develop or contribute to generalizable (scholarly) knowledge*?

Yes ☐ No ☐

If **NO**, explain the intent of proposed activities and explain how the proposed activities are not intended to contribute to generalizable knowledge:

If you answered "no" to <u>all</u> questions "a" through "f," you may *stop here and do not submit an IREC application*.

g. Are Human Subjects involved?

A **human subject** is defined by NU IREC as a living individual about whom an investigator obtains either 1) data through intervention or interaction with the individual; or 2) identifiable private information.

Does your research involve human subjects or official records about human subjects?

Yes ☐ No ☐

If you answered "no" to question "g", do not submit an IREC application.

Decision:	Protocol #: _____

Institutional Research Ethics Committee (IREC) Application Form
Part 1: Cover Sheet

Are you seeking an Expedited Review Yes ☐ No ☐

Project Title: _____

Principal Investigator:
Name: _____ ID: _____ Daytime Phone #: _____ School/Depart.: _____
Graduate Student: ☐ Undergraduate Student: ☐ Faculty: ☐ Staff: ☐
E-mail address: _____
Mobile phone: _____
Have you completed the CITI basic course on Human Subjects Research? Yes ☐ No ☐
CITI Training completion date: _____
Signature: _____

Additional Investigator(s): *(Use additional pages if necessary)*
Name: _____ ID: _____ Daytime Phone #: _____ School/Depart.: _____
Graduate Student: ☐ Undergraduate Student: ☐ Faculty: ☐ Staff: ☐ Other: ☐ _____
E-mail address: _____
Have you completed the CITI basic course on Human Subjects Research? Yes ☐ No ☐
CITI Training completion date: _____

Name: _____ ID: _____ Daytime Phone #: _____ School/Depart.: _____
Graduate Student: ☐ Undergraduate Student: ☐ Faculty: ☐ Staff: ☐ Other: ☐ _____
E-mail address: _____

Have you completed the CITI basic course on Human Subjects Research? Yes ☐ No ☐

CITI Training completion date: _____

*By signing this form, the **Principal Investigator** certifies that:*

a) You have read and understand NU's policies regarding the protection of human subjects in research;

b) You have not begun recruitment or testing of research participants and will not do so until formal notification of IREC approval of the proposed project has been received;

c) You will seek approval from the IREC prior to implementation of any changes in procedures or the consent process/forms for this project; and

d) You will immediately inform the IREC of any adverse events or other negative consequences incurred by participants in this research.

For students:

Research Advisor:

Name: _____ Daytime Phone #: _____ School/Department: _____

Signature: _____ Date: _____

Have you completed the CITI basic course on Human Subjects Research?

Yes ☐ No ☐

CITI Training completion date: _____

*By signing this form, the **Research Advisor** designated above certifies that:*

a) You have provided appropriate training in the ethics of human research to the student signing above;

b) You have reviewed this protocol and take responsibility for the research design, and for the student investigator's compliance with the requirements of the Nazarbayev University IREC; and

c) You will provide adequate supervision of the above student in the conduct of this research.

Additional Signatures (as required by School-level policies):

Department Chair:

Name: _____ School/Department: _____

Signature: _____ Date: _____

School Dean/Director:

Name: _____ School/Department: _____

Signature: _____ Date: _____

Part 2: General Information

2.1 What is the purpose of the research? (Approximately 250-500 words.) What question(s) do you hope to answer? Summarize the proposed research/activity stating the objectives, significance, and detailed methodology. Briefly describe your data collection method (for example: observations, survey, experimental design, psychological tests, interviews, etc.) Copies of all data collection instruments must be attached to this application.

2.2 How do you intend to analyze the data? (2 - 3 sentences.) For all studies, provide a description of the statistical or qualitative methods used to analyze the data.

2.3 When is the data collection for the research *intended* to begin and end?
_____ to _____ (enter month/year).

Please note that research cannot begin until this project has been approved by the IREC. Furthermore, IREC will only approve projects for one year. Please note that any point in time that substantive modifications to a protocol occur would require another review.

2.4 Location of where research is to be conducted: _____

2.5 Funding/Sponsor Information

Is this project being supported by any funding sources within NU?
Yes ☐ No ☐

Is this project being supported by any funding source outside of NU?
Yes ☐ No ☐

Name of granting agency/sponsor: _____
Name of contact person: _____

E-mail address: _____

Duration of grant/sponsorship: _____

2.6 Exemption

Do you believe that your project may fall under one of the categories of research that are exempt from NU IREC oversight? If you wish to request an exemption from IREC oversight in one of the approved categories, please select the category below that applies and continue with the form. If you have questions, more information about the exemption categories can be found by contacting IREC at resethics@nu.edu.kz .

The following categories of research are exempt from this policy:

☐ (1)Research conducted in ***established or commonly accepted educational settings***, involving ***normal educational practices***, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ (2/3)Research involving the ***use of educational tests*** (cognitive, diagnostic, aptitude, achievement), ***survey procedures, interview procedures or observation of public behavior***, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; ***and*** (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

☐ (4)Research involving the collection or study of ***existing*** data, documents, records, pathological specimens, or diagnostic specimens, ***if these sources are publicly available OR if*** the information is recorded by the investigator in such a manner that ***subjects cannot be identified***, directly or through identifiers linked to the subjects.

The IREC will determine qualification for exemption based on information detailed in the remainder of this form.

Part 3: Participants

3.1 Special Populations

Do participants belong to a group for which special protections are required? Special precautions must be included in your research procedures if any of these special populations or research areas are included.

Are any of the subjects:

(a) minors (under 18 years of age)?

Yes ☐ No ☐

(consent from parent & possibly subject required)

(b) legally incompetent?

Yes ☐ No ☐

(c) prisoners?

Yes ☐ No ☐

(d) pregnant women, if affected by the research?

Yes ☐ No ☐

(e) institutionalized?

Yes ☐ No ☐

(f) mentally incapacitated?

Yes ☐ No ☐

Does the research deal with questions concerning:

(a) sexual behaviors?

Yes ☐ No ☐

(b) drug use?

Yes ☐ No ☐

(c) illegal conduct?

Yes ☐ No ☐

(d) use of alcohol?

Yes ☐ No ☐

3.2 Participant Pool: Expected number of participants or sample size: _____

3.3 Describe your intended participant pool in terms of:

a. Languages of communication:

b. Gender, race or ethnic group, age range, etc.:

c. Affiliation of participants (e.g., institutions, hospitals, general public, students, etc.):

d. Participants' general state of mental health:

e. Participants' general state of physical health**:**

3.4 Explain why you have chosen this particular group for study. If participants belong to one of the protected classes above, this justification is especially important. If participants are affiliated with a particular institution, please explain:

3.5 What is your relationship to the participants? (e.g., are you their classroom instructor, a nurse in a clinic whose participants are seeking medical care, etc.? If your only relationship is as a researcher or student researcher, then there is likely no relationship.)

3.6 Participant Recruiting

a. Will participants be recruited?

Yes ☐ No ☐

If not, please explain (recruitment may not be involved in some types of classroom research):

b. Describe the method for recruiting participants. If recruitment will involve advertising, posters, or scripts, please provide copies:

3.7 **Exclusions:** If certain populations will be excluded from this study, please describe and justify the criteria for exclusion. Describe the method you will use to identify and exclude the individuals from the study. For example, if you are excluding pregnant women from a nutrition study due to health concerns for the fetus, describe that here.

Part 4: Detailed Procedures

4.1 Procedures: Describe how subjects will be involved in detail. Describe the setting in which the participants' involvement will take place. Where will they be? Will they be alone or in a group? Will there be any specific conditions? How long will it take?

4.2 Will you be the one administering the procedure, or will someone else do it for you? If someone else, describe how they will be involved and what type of oversight, training, and instructions they will have in order to conduct this procedure.

1.3 Will the participants experience any discomfort?

Yes ☐ No ☐

If yes, please explain. (Discomfort may include physical or emotional discomfort.)

1.4 Will deception or false or misleading information be used in your procedures? Will you withhold information such that the ability of the subject to understand the true nature of the study would be affected?

Yes ☐ No ☐

If yes, explain why deception is necessary for this study and describe how you will debrief participants, and procedures you will follow if a participant decides to withdraw his/her consent.

4.5 Electronic/Internet/Online research

a) Are you conducting a survey using any electronic media?

Yes ☐ No ☐

If "no," please skip to Part 5.

b) How will data be transmitted? Is a survey host (Qualtrics, Select Survey, Survey Monkey, etc.) used? Will the host retain identifiable data? Will the data be encrypted?

c) Explain how data are maintained. Will it be in individually identifiable form, aggregate form, anonymized?

d) Will data be shared?

Yes ☐ No ☐

How? With whom?

e) Will aggregated anonymized data be made publicly available?

Yes ☐ No ☐

If yes, will subjects be re-identifiable? Why or why not?

f) Describe the data security plan (e.g., how you will keep your data secure):

g) Will survey results be posted on a website that could be accessed by individuals other than the investigators?

Yes ☐ No ☐

If yes, please explain:

h) If a survey link is sent to participants, will the URL for the survey include information that could identify individuals?

Yes ☐ No ☐

What is the URL? _____

i) If you are sending out an email invitation to subjects to complete a survey:

Will you assure that the participant will only see his/her name?
Yes ☐ No ☐

Will you have the "read receipt" function turned off?
Yes ☐ No ☐

If you answered “No” in question “i”, please explain:

j) If your survey contains questions where the subjects choose from a drop-down menu, do they have the option to choose “no response” or to leave the question blank?

Yes ☐ No ☐ No drop-down questions ☐

Part 5: Risk/Benefit Analysis

5.1 **Risks:** Describe all risks, perceived and actual, that participants might encounter during this study. Risks may be physical, social, psychological, legal, or risks to employment or economic well-being. A response of "Not Applicable" will not be accepted.

5.2 **Is the research Minimal Risk?**

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Do you believe those risks will be no greater than minimal?

Yes ☐ No ☐

Explain why:

5.3 **If risks are greater than minimal, describe the following:**

N/A ☐

a) Explain why these risks are essential to your study.

b) What have you done to minimize risks without compromising your research objectives?

c) What protections have you put in place to minimize the potential consequences to the subjects if the risks become realized?

d) What procedures have you established for reporting adverse events should they occur?

5.4 Will the participants directly or indirectly benefit from your study?

Yes ☐ No ☐

Please explain:

5.5 What are the benefits to society at large as a result of this project? Are there other benefits?

5.6 Will you offer incentives, reimbursement of costs, or other compensation to participants?

Yes ☐ No ☐

If yes, what will you offer as incentive, reimbursement, or compensation and under what conditions will participants receive it?

Part 6: Confidentiality/Anonymity

6.1 Can the subjects be identified directly or through any type of identifiers?

Yes ☐ No ☐

If "yes," please explain:

6.2 If the data collected in your research will be anonymous, explain the procedures you will use to create and preserve anonymity:

N/A (My research does not involve anonymous data.) ☐

Anonymity occurs when the identity of the subject to whom a particular set of data pertains is completely unknown, even to the researcher.

6.3 If the data will not be anonymous, explain the procedures you will use to protect the confidentiality of your data:

a) During the data collection process:

b) While results are being analyzed:

c) In publication or other reporting of results:

d) In storage after research is complete and results are reported (Note: all materials must be retained and available for inspection by the faculty advisor and/or IREC audit for a minimum of three years).

Part 7: Consent

7.1 Describe how you will obtain informed consent from your participants: In what setting? Who will be present? Will there be an opportunity for questions to be asked and answered?

7.2 Describe how you will assure that participation is voluntary:

PLEASE NOTE: If subjects are children and they are capable of assent, they must give their permission, along with that of their parent, guardian, or authorized representative. ***ALSO NOTE:*** A school's personnel cannot give permission or consent on behalf of minor children.

7.3 Are you requesting a Waiver of Documentation of Informed Consent?

Yes ☐ No ☐

If you wish to request a waiver of documentation of informed consent (that is, you are requesting oral consent), explain how your research plan meets each of the criteria below.

a. The research involves no more than minimal risk to the subjects:

b. The waiver will not adversely affect the rights and welfare of the subjects:

c. The research could not practicably be carried out without the waiver:

Requesting a waiver of documentation of informed consent does NOT guarantee that the IREC will grant it. All researchers must submit consent forms or oral consent script with their application materials in order for the IREC to determine whether the informed consent process may be modified.

Please include a copy of informed consent forms in all languages intended to be used and in English even if your subjects are not expected to speak English.

CHECKLIST OF SUBMISSION DOCUMENTS

☐ **Typed and Completed IREC Application**

- Application must be signed by all investigators and advisors.
- Direction page should be removed prior to submission.

☐ **Consent form(s)**

- Standard consent form(s) should include explanation of procedures, risks, safeguards, freedom to withdraw, confidentiality, offer to answer inquiries, third party referral for concerns, and participant (and/or guardian) signature. Consent forms need to be provided in all languages intended to be used and in English even if your subjects are not expected to speak English. Sample consent forms can be found at the official IREC page on the University website.

☐ **Questionnaire/Survey Instrument**

- The final version of the Questionnaire/Survey instrument must be attached. Also, if the survey is being conducted verbally, a copy of the introductory comments and survey questions being asked must be attached to this form.
- If your survey includes focus group questions, a complete list of the questions should be attached.
- For research using a published/purchased instrument, a photocopy of the complete survey will suffice.

☐ The CITI basic course on Human Subjects Research must be completed by all individuals involved in conducting this research project before this form is submitted.

☐ **Other Forms as Needed**

- Other forms may include recruitment materials, advertising documents, debriefing scripts, etc.

Please do not staple your submissions documents.

APPENDIX C Consent and Assent Forms

Written Informed Consent Form Template

Introduction. You are invited to participate in a research study entitled *add name of study*.

Procedures. *Provide a thorough statement regarding the purpose and methodology of the research, the expected duration, and the procedures of the subject's participation*. This *survey/interview* will take approximately [time] to complete.

R**isks.** The potential risks of participating in this study are: *Outline the possible risks (e.g. risk of breach of confidentiality*.

Benefits. Anticipated benefits from this study are add the potential benefits to *Nazarbayev University, science, and possibly the participants*.

Compensation. No tangible compensation will be given. A copy of the research results will be available at the conclusion of the study (*explain how*).

Confidentiality & Privacy. Any information that is obtained during this study will be kept confidential to the full extent possible. All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. *[Insert a description of how records and data/specimens will be stored and maintained and who will have access. Describe any study specific issues that may increase the risk of breach of confidentiality.]*

Voluntary Nature of the Study. Participation in this study is strictly voluntary, and if agreement to participation is given, it can be withdrawn at any time without prejudice.

Points of Contact. It is understood that should any questions or comments arise regarding this project, or a research related injury is received, the Principal Investigator, *Dr. Joe Researcher*, *+8.778.656.9999*, *joe.researcher@nu.edu.kz* should be contacted. Any other questions or concerns may be addressed to the Nazarbayev University Institutional Research Ethics Committee, resethics@nu.edu.kz.

Statement of Consent.

I,_____,

Give my voluntary consent to participate in this study.

The researchers clearly explained to me the background information and objectives of the study and what my participation in this study involves.

I understand that my participation in this study is voluntary. I can at any time and without giving any reasons withdraw my consent, and this will not have any negative consequences for myself .

I understand that the information collected during this study will be treated confidentially.

Signature: _____ Date: _____

Researcher:

Signed_____ Date_____

Informed Consent Form Template for Internet Survey

Introduction. You are invited to participate in a research study entitled *add name of study*.

Procedures. *Provide a thorough statement regarding the purpose and methodology of the research, the expected duration, and the procedures of the subject's participation*. This *survey/interview* will take approximately [time] to complete.

R**isks.** The potential risks of participating in this study are: *Outline the possible risks (e.g. risk of breach of confidentiality*.

Benefits. Anticipated benefits from this study are add the potential benefits to *Nazarbayev University, science, and possibly the participants*.

Compensation. No tangible compensation will be given. A copy of the research results will be available at the conclusion of the study (*explain how*).

Confidentiality & Privacy. Any information that is obtained during this study will be kept confidential to the full extent possible. All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. *[Insert a description of how records and data/specimens will be stored and maintained and who will have access. Describe any study specific issues that may increase the risk of breach of confidentiality.]*

Voluntary Nature of the Study. Participation in this study is strictly voluntary, and if agreement to participation is given, it can be withdrawn at any time without prejudice.

Points of Contact. It is understood that should any questions or comments arise regarding this project, or a research related injury is received, the Principal Investigator, *Dr. Joe Researcher*, *+8.778.656.9999*, *joe.researcher@nu.edu.kz* should be contacted. Any other questions or concerns may be addressed to the Nazarbayev University Institutional Research Ethics Committee, resethics@nu.edu.kz.

Statement of Consent.

By clicking “I agree” below you are indicating that you are at least 18 years old, have read and understood this consent form and agree to participate in this research study.

□ I Agree

□ I Disagree

Oral Consent Script

[Insert Title of study here]:

Researcher: [*Insert your name here]*

Oral Consent Script

[Note to Researcher: Please adapt this sample to match your specific study. Delete all italicised instructions and sample wording that doesn't apply to your study, before submitting.]

Introduction:

Hello. I'm *[insert your name].* I am conducting surveys about [*insert topic(s)*]. I'm conducting this as part of research for [*insert: master, or PhD studies etc.*] at Nazarbayev University's [*insert department, school, or program*].

I located/found your name by *[insert such wording as: visiting the websites of [insert website name]; searching for persons working in the area of [insert topic]; by having your name suggested to me by [possibly insert name of contact here, if appropriate]; by people who know about [insert topic].*

Study procedures: *[Alternate wording:* **What will happen during the study?]**

I'm inviting you to do a survey that will take about [*??*] minutes. The survey will ask you questions about [*insert topic(s) here*] such as [*insert 2-3 short sample questions from your interview guide if appropriate to your study].*

Risks: **[***Alternate wording:* **Are there any risks to doing this study?]**

[Describe to participants any reasonably foreseeable risks, discomforts, inconveniences that might occur, and how they will be dealt with. Make sure that whatever level of risk you represent in this letter reflects what you described in your application form.]

You do not need to answer questions that you do not want to answer or that make you feel uncomfortable…. And you can withdraw (stop taking part) at any time. I describe below the steps I am taking to protect your privacy.

Benefits:

It is unlikely that there will be direct benefits to you, however, by better understanding [*insert the topics to be studied*] researchers and others may be able to [*insert your description of benefits to the participant, science or society at large here*].

I will keep the information you tell me during the interview confidential. Information I put in my report that could identify you will not be published or shared beyond the research team unless we have your permission. Any data from this research which will be shared or published will be the combined data of all participants. That means it will be reported for the whole group not for individual persons. *[Insert alternate wording as needed].*

Voluntary participation:

- Your participation in this study is voluntary.
- You can decide to stop at any time, even part-way through the questionnaire for whatever reason.
- If you decide to stop participating, there will be no consequences to you.
- If you decide to stop we will ask you how you would like us to handle the data collected up to that point.
- This could include returning it to you, destroying it or using the data collected up to that point.
- If you do not want to answer some of the questions you do not have to, but you can still be in the study.
- If you have any questions about this study or would like more information you can call or email [*insert name of researcher]* at *[insert your telephone number here*] or [*insert your email address here]*.

This study has been reviewed and cleared by the Nazarbayev University Institutional Research Ethics Committee. If you have concerns or questions about your rights as a participant or about the way the study is conducted, you may contact:

Nazarbayev University Institutional Research Ethics Committee

E-mail: resethics@nu.edu.kz

Consent questions:

- Do you have any questions or would like any additional details? *[Answer questions.]*

- Do you agree to participate in this study knowing that you can withdraw at any point with no consequences to you?
  [If yes, begin the interview.]

  [If no, thank the participant for his/her time.]

Assent Form Template

[*Insert title of the study*.]

You are asked to participate in a research study conducted by [*insert name of Principal Investigator—Faculty Sponsor as appropriate*] from the [*insert department affiliation*] at the Nazarbayev University (NU). You were selected as a possible participant in this study because [*explain why the potential participant is eligible to participate*]. Your participation in this research study is voluntary.

Why is this study being done?

[*Using a language that is easily understandable by the participants in the study and avoiding jargon and technical terms state what the study is designed to assess or establish - in approximately 2 sentences*]

What will happen if I take part in this research study?

Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say “yes” you can still decide not to do this.

If you volunteer to participate in this study, the researcher will ask you to do the following:

[*List and describe the procedures/tests/activities and their frequency chronologically using simple language, short sentences and short paragraphs. Use bullets or number the paragraphs as appropriate. If there are questionnaires or interviews, describe types of questions. Specify location of the study activities, if appropriate. If the study will include experimental and non-experimental procedures, please specify which procedures are experimental.*]

How long will I be in the research study?

[*Short-term/simple study:*] Participation in the study will take a total of about XX hours [*over a period of XX days/weeks*].

[*Long-term/complex study:*] You will be asked to XXX every XXX for [*months, weeks/until a certain event*]. [*When appropriate, state that the study will involve long-term follow-up and specify time frames and requirements of follow-up*].

Are there any potential risks or discomforts that I can expect from this study?

[*List and describe any reasonable foreseeable risks, discomforts, inconveniences, and how these will be managed. If there are significant physical or psychological risks to participation that might cause the researcher to end the participant's participation in the study, please describe them. If there are no anticipated risks or discomforts, please state "There are no anticipated risks or discomforts."*]

Are there any potential benefits if I participate?

You may benefit from the study ... [*Describe benefits to participants expected from the research. If the participants will not directly benefit from participation, please state, "You will not directly benefit from your participation in the research."*]

The results of the research may ... [*Describe the potential benefits, if any, to science or society expected from the research.*]

Alternatives to participation

NOTE: If the research does not involve treatment (e.g., behavioral therapy), this section is NOT required.

If the research includes treatment, please describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that should be considered before the subjects decide whether or not to participate in the study. If applicable, explain why these procedures are being withheld. If there are no efficacious alternatives, state that an alternative is not to participate in the study.

Will I receive any payment if I participate in this study?

You will receive … [*describe amount of payment and how and when payment will be received. If participant will not receive payment, say "You will receive no payment for your participation."*].

Will information about me and my participation be kept confidential?

Any information that is obtained in connection with this study and that identify you will remain confidential. It will be disclosed only with your permission or as required by law.

Confidentiality will be maintained by means of ... [*describe coding procedures and plans to safeguard data, including where data will be kept, who will have access to it, etc.*]

Withdrawal of participation by the investigator

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If [*describe include examples of the circumstances in which you would withdraw subjects from participation in the research*], you may have to drop out, even if you would like to continue. The investigator will make the decision and let you know if it is not possible for you to continue. The decision may be made [*include if applicable: either to protect your health and safety or*] because [*explain*].

What are my rights if I take part in this study?

You may withdraw your assent at any time and discontinue participation without penalty or loss of benefits to which you were otherwise entitled.

You can choose whether or not you want to be in this study. If you volunteer to be in this study, you may leave the study at any time without consequences of any kind. You are not waiving any of your legal rights if you choose to be in this research study. You may refuse to answer any questions that you do not want to answer and still remain in the study.

Who can answer questions I might have about this study?

In the event of a research related injury, please immediately contact one of the researchers listed below. If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact [*add the name of the PI and faculty sponsor as approriate*] at [*phone number(s) and email address if appropriate*].

If you wish to ask questions about your rights as a research participant or if you wish to voice any problems or concerns you may have about the study to someone other than the researchers, please write an email to IREC at resethics@nu.edu.kz.

SIGNATURE OF STUDY PARTICIPANT

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

Name of Participant

Signature of Participant | Date

SIGNATURE OF PERSON OBTAINING ASSENT

In my judgment the participant is voluntarily and knowingly agreeing to participate in this research study.

Name of Person Obtaining Assent | Contact Number

Signature of Person Obtaining Assent | Date

If you wish to ask questions about your rights as a research participant or if you wish to voice any problems or concerns you may have about the study to someone other than the researchers, please please write an email to IREC at resethics@nu.edu.kz