Appendix № 1 to the minutes of the IREC meeting № 60, Dated February 20, 2018

AUTONOMOUS ORGANIZATION OF EDUCATION
"NAZARBAYEV UNIVERSITY"

INSTITUTIONAL RESEARCH ETHICS COMMITTEE PROCEDURES

Approved by the resolution of the Research Council of the autonomous organization of education “Nazarbayev University”
Minutes № 60 of 20.02.2018
1. Definitions

1. Terms and abbreviations used in Institutional Research Ethics Committee Procedures:
   1) “University” refers to the autonomous organization of education “Nazarbayev University”;
   2) “Committee” refers to the Institutional Research Ethics Committee;
   3) “School/division committee” refers to IREC committees located in university subdivisions.
   4) “Procedures” refers to the procedures of Institutional Research Ethics Committee;
   5) “Charter” refers to Charter of the autonomous organization of education “Nazarbayev University”;
   6) “Bylaws” refers to the Bylaws of the Institutional Research Ethics Committee;
   7) “Secretary” refers to the Secretary of Institutional Research Ethics Committee.
   8) “Members” refers to university IREC committee members
   9) “Reviewers” are members selected by the Chair to conduct expedited reviews.
   10) “Expert” refers to a scientist or nonscientist from within or external to Nazarbayev University who has special expertise to act — at the request of IREC — as an ad hoc reviewer of a research project application. These individuals have access to all documents relevant to the specific project under review, may participate in the deliberations and make recommendations on the project, but may not vote and are not counted toward quorum.
   11) “Protocol” refers to all documents that need to be provided for the review of the Committee to determine the risks of the research.
   12) “Initiator” – person, who submitted the Protocol for Committee review.
   13) “PI” is the principle investigator, who is responsible for the content and submission of their protocol.
   14) “Human subjects research” is any research or clinical investigation that involves human subjects. Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. A human subject is as a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual; or (2) identifiable private information.
   15) “Minimal risk research” refers to research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research.
16) “Course-based research,” which is subject to IREC review, includes course activities when: 1) the objective of project/data collection is for the student to acquire skills involved with conducting academic and scholarly research in a rigorous manner; 2) the student is not the primary beneficiary of the activity; 3) the results or findings are written in a format that would be acceptable for a research journal or academic conference presentation; 4) primary data is collected and organized for analysis; and 5) results may be shared with classmates or professors and are intended to generate generalizable (and new) knowledge from which others might benefit even if this does not actually occur.

17) “Course projects,” which are not subject to IREC review, include assignments when: 1) the intent is to use the information to provide advice, diagnosis, identification of appropriate interventions, or general advice for a client; 2) the intent is to develop skills which are considered standard practice within a profession (e.g., observation, assessment, intervention, evaluation, auditing); or 3) the information gathering process is part of the normal relationship between the student and the participants (e.g., teacher and students, nurse and patient, lawyer and client).

2. General Provisions

1. These procedures of the Institutional Research Ethics Committee (IREC) of the University have been prepared in accordance with the University Charter (hereinafter – Charter) and the Bylaws of the Institutional Research Ethics Committee (hereinafter - Bylaws).

2. The purpose of these procedures is to define a single approach for submitting to and reviewing human subject research conducted in Nazarbayev University (hereinafter – University) by the Institutional Research Ethics Committee (hereinafter – Committee) and to establish a single approach in preparation of the materials for the meetings of the Committee and recording its actions.

3. The Committee follows the ethical principles set out in the report “Ethical Principles and Guidelines for the Protection of Human Subjects of Research” also known as “The Belmont Report”:

- Respect for Persons-- Informed consent is obtained unless the requirements for waiver of informed consent are met by adequate and appropriate methods in accordance with the provisions of applicable regulations;
- Beneficence--The sum of the benefits to the subject and the importance of the knowledge to be gained so outweigh the risks to the subjects as to warrant a decision to allow the subject to accept these risks;
Justice--The selection of subjects is equitable and is representative of the group that will benefit from the research.

The Committee applies The Belmont Report ethical principles to all human research regardless of source of support or geographic location.

Thus, the intention of the Committee is to ensure that, in research involving human participants:

- participants are treated with dignity;
- the selection of participants is fair and equitable;
- participants have the opportunity for free and informed consent;
- vulnerable persons are protected from abuse, exploitation and discrimination. This group comprises children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons;
- standards for privacy and confidentiality are observed with respect to access, control and dissemination of personal information;
- the ethics review process is fair and effectively independent of the University’s other academic and administrative decision-making processes;
- foreseeable harms will not outweigh the anticipated benefits;
- research participants will not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientific and societal aims that cannot be realized without the participation of human subjects; and
- actual, potential, or perceived conflicts of interest of researchers and individuals in the review process are made known and dealt with appropriately.

The following categories of individuals are expected to abide by these ethical requirements when reviewing or conducting human subjects research:

- Investigators
- Research assistant, student and research staff
- Committee member, Committee chairs, and Committee deputy-chair

3. Responsibility of Investigators and Researchers

Each PI and Investigator is responsible to:

1. Read and be aware of ethics of research involving human participants policies and procedures.
2. Assess each planned research project, including student and classroom-based initiatives, for applicability and compliance.

3. Submit an application to IREC Office using the current form specified by IREC.

4. Promptly inform the Committee of any similar or equivalent proposal to research ethics boards or similar bodies at other institutions. The Committee shall determine if concurrent applications are necessary.

5. Ensure that any modifications to the study personnel, funding, protocol, consent form or any recruitment procedures are cleared by the Committee prior to implementation, except where necessary to eliminate apparent immediate hazards to participants.

6. Investigators must report all unanticipated problems to IREC. Unanticipated problems (UPs) are defined as any incident, experience or outcome that meets all of the following criteria: 1) Unexpected (unforeseen by the researcher or the research participant) in terms of nature, severity, or frequency, given the research procedures and the subject population being studied; 2) Related or probably related to participation in the research, or if the event or problem probably or definitely affects the safety, rights and welfare of current participants; and 3) 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.

7. In the case that an adverse event occurs in interventional health research, the investigator is requested to refer to the appropriate IREC document.

4. Consent

1. Researchers are responsible for ensuring that participants have provided consent for participation in this project.

2. Consent shall be given voluntarily, and can be withdrawn at any time. If a participant withdraws consent, the participant can also request the withdrawal of their data.

3. Consent shall be informed, meaning prospective participants should be provided all information necessary, in understandable language, for making an informed decision to participate in a research project.

4. Consent shall be an ongoing process, meaning that researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research.

The following elements of consent must be included in the consent form document:

- A statement identifying research purpose and procedures
• An outline of risks and discomfort associated with research
• Potential benefits from research participation
• The provisions for data confidentiality and safeguarding privacy
• Contacts for additional information
• Voluntary participation and the right to discontinue participation without penalty
• Approximate duration

5. The Committee may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IREC finds and documents that: i) the research involves no more than minimal risk to the subjects; ii) the waiver or alteration will not adversely affect the rights and welfare of the subjects; and iii) the research could not practically be carried out without the waiver or alteration

5. Permission

1. The Nazarbayev University faculty, investigators, students, and staff who plan to conduct research at institutions or organizations—schools, businesses, etc.—that are unaffiliated with the University are required to seek written permission from those outside groups to utilize them for research studies. This will involve requesting permission in person or writing a permission request letter to the appropriate party. It is the responsibility of the PI, investigator and researcher to determine from whom to seek permission. The permission request letter does not need to be submitted to IREC.

6. Committee Review Scope and Standards

1. The Committee will determine if it is the appropriate body to review the application and whether the application is within its jurisdiction or expertise;
2. The Committee will consider methodological aspects of the research only as necessary to assess the risks and benefits;
3. The Committee will determine whether proposals are acceptable on ethical grounds;
4. The Committee will determine that free and informed consent will be obtained and maintained;
5. The Committee will determine if the research is in compliance with principles found in the Belmont Report. Specifically, respect for persons, beneficence, and justice.
6. The Committee will determine if the PI has declared and managed any conflicts of interest;
7. Informed consent form shall be provided with IREC Protocol Form according to Annex 2;

8. Besides a completed IREC protocol form, the PI is required to submit CITI diplomas of all NU-associated research team members, consent forms, assent forms when required, recruitment materials, survey questionnaire instruments when used, interview questions when used, operating procedures for experiments when used, and funding proposals (these items are indicated in IREC Protocol Application Checklist, which is provided in Annex 3). Non-Nazarbayev University researchers involved in research led by Nazarbayev University faculty or staff may complete either the NIH (National Institutes of Health) Protecting Human Research Participants or the Global Health Training Centre training in place of CITI training. A copy of these certificates must be included in the IREC application prior to IREC assessing an application. In addition, any other documents that could allow the Committee to better estimate the risk and benefit of the research can be provided;

9. The protocol shall be provided in English;

10. The protocol may be revised by the school/division committees, or other relevant departments of the Schools or the Centers according to school/division procedures according to the internal procedures of each school/division, prior to the submission to the Committee.

**7. Review of Student-led Research**

1. Nazarbayev University encourages student-led research involving human subjects. These activities are subject to the same review requirements as faculty research, but may be delegated to School-based IREC committees. The Committee has a responsibility to ensure that delegated reviewers have the appropriate expertise, training, and resources required, and special attention should be given to the assessment of real, potential, or perceived conflicts of interest.

2. Research involving human participants undertaken by students during the completion of thesis, capstone course, or project such as a Directed Study must be supervised by a faculty member, who is ultimately responsible for the ethics of the project and should provide appropriate mentorship regarding ethics and methodology. In these projects, the regular IREC protocol form is used. The level of risk will determine the nature of the review.

3. When a student is the PI, it is student’s responsibility to prepare his/her IREC application. Student researchers forward the completed and signed form and accompanying documents to their research advisors for review and signature. Research advisors then forward the application package to his/her Department Chair or School Dean, as appropriate, for review and signature. Upon receiving all signatures, the student
submits the application to the Committee for review. The application package must include both the student’s and his/her advising professor’s CITI certificate of completion or equivalent. Note, the Committee will not process any application without the required signatures or without the appropriate CITI certificates of completion.

4. It is strongly recommended that for all but experienced undergraduate student researchers, projects be designed so that they are “minimum risk research”.

8. Course-Based Research

1. A Course Based Student Research Ethics (CBSRE) is meant for instructors of courses where the assignment(s) might include the use of human subjects. The Instructor applies through the Committee and takes on the role of overseeing all projects within their course. Ethical approval for class projects is valid for up to three (3) years, provided that there are no changes to the course assignment(s). Outlined below are details surrounding what type of research ethics one might need in the classroom. Projects that can obtain CBSRE Approval include:
   a. Course-related activities that are, in the opinion of the Committee, greater than Minimal Risk to participants shall be subject to full Committee review.
   b. Course projects, as a general rule, are not systematic data collection efforts intended to develop or contribute to generalizable knowledge and, thus, do not meet IREC’s definition of research. Therefore, as a rule, student class assignments do not fall under the jurisdiction of the Committee and do not require IREC application, approval, or oversight.

9. Delegated Ethics Committees

1. The Committee may choose to delegate review of minimal risk student research as well as course-based research involving human subjects to a school/division-level IREC. Such arrangements are beneficial for both the University and school/division, as it reduces the burden on the Committee, and empowers the schools/division to establish procedures and guidelines that are discipline-specific and pedagogically relevant.

2. Research which is considered above “minimum risk” must be submitted to the university-level IREC.

3. Those conducting the delegated review are accountable to the Committee and must comply with any directions from them regarding their procedures or decisions.

4. The process for reconsideration of delegated reviews is review by the Committee.
10. Deferral of IREC Oversight

1. In limited cases, the Committee may cede IREC oversight to another university institutional research ethics board, particularly when the research involves researchers from partner universities. The research ethics board at the partner institution that will serve as IREC of record for Nazarbayev University. However, University co-researchers must submit: i) a copy of the protocol ii) a copy of the approval letter; and iii) complete the necessary parts of the Nazarbayev University form “Request to Defer IREC Oversight”.

11. Procedures for investigator to request reconsideration or to appeal decisions made by IREC

1. Researchers have the right to request, and IREC has the obligation to provide, reconsideration of decisions. In cases where IREC and the researcher cannot reach an agreement, the researcher has the right to file an appeal.

2. Researchers wishing to file an appeal shall make a written request to the Office of the Provost. Please refer to the relevant NU documents to determine the required materials and information to be included in the appeal request.

12. Procedures for material submission and review

1. After the submission of the protocol to the Committee, the Chair shall assess the risk of the proposed research and either approve the request for an expedited review, send the protocol for full review, or grant exemption from IREC oversight according to the categories listed below.

12.1 Exempt Research

2. The following research is exempt from the Committee’s oversight:

3. 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.
4. 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.

5. 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.

6. Research in which interviews are with experts about a particular policy, agency, program, technology, technique, or best practice. The questions are not about the interviewee themselves, but rather about the external topic.

7. Studies focused on quality assurance and quality improvement, program evaluation, and performance or studies implemented within normal educational requirements when used exclusively for assessment, management or improvement purposes.

12.2 Expedited Review

8. In case the research involves minimal risk the Chair assigns 1 or 2 members including himself/herself to conduct an expedited review. Reviewers should be assigned normally within 2 days from the day of receiving of the material by the Chair.

9. Each appointed member including Chair should submit his/her comments and feedback for the assigned protocol to the Secretary of the Committee (hereinafter – Secretary) via email normally within 2 weeks from the day of the appointment.

10. The Secretary sends the received suggestions and feedback to the PI, who is recommended to make changes to his/her materials in a timely manner after the receiving the Committee’s suggestions.

11. The Secretary sends the amended protocol to the Chair for the approval.

12. Once approved, the initiator brings the signed hardcopy of the protocol to the Secretary within one week.

13. The Secretary records the approved research protocol in minutes every last week of the month.

14. The minutes are signed by the Chair and the Secretary.

15. The whole process of review should not normally take more than 4 working weeks.

12.3 Full Review
16. In case the research involves more than minimal risk or involves a vulnerable group, the materials are distributed to all members for the suggestions and feedback.

17. All members have to submit their suggestions and feedback to the Secretary via email normally within 2 weeks from the day of receiving materials.

18. The Secretary sends the received suggestions and feedback to the PI, who is recommended to make changes to his/her materials in a timely manner after receiving the Committee’s suggestions.

19. The Secretary sends the amended materials to Committee and schedules a meeting for the final approval of the amended materials. A template for Agenda is provided in Annex 3.

20. Once approved, the initiator brings the signed hardcopy of the protocol to the Secretary within one week.

21. The Secretary records the approved research protocol in minutes every last week of the month.

22. The minutes are signed by the Chair and the Secretary.

23. The whole process of review should not normally take more than 6 working weeks.

13. Consequences with non-compliance with these procedures

1. It is in the best interests of all parties (Nazarbayev University, the PI, and the research participant) to have all human subject research reviewed by the Committee. Such review helps to ensure that the ethical principles of beneficence, respect for persons, and justice have been honored. Participation in research should be protected as a matter of ethics, not merely as a matter of “compliance” with Nazarbayev University rules.

2. In instances when the PI intentionally or unintentionally avoids ethical review procedures, the PI should be aware that serious consequences could result. PIs who fail to comply with Nazarbayev University’s IREC policies and procedures will be subject to appropriate disciplinary action.


1. The Secretary shall record all actions taken by the Committee in the abstracts of minutes. A template for Minutes is provided in Annex 5 and Annex 6.

2. The Minutes shall be signed by the Chair and the Secretary.

3. In case any member of the Committee has objections or suggestions to the Minutes, the concerns should be discussed between all members, who should make a
collegial decision on whether to include these objection or suggestions to the Minutes or not.

4. As part of the University’s commitment to ethical research, these procedures will be reviewed every 3 years, or more frequently in the event of a major policy change by a significant stakeholder or the identification of a significant weakness in the procedures as they stand.
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 all 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.*
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:  

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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;

![Warning]

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;

![Warning]

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: _____
Signature: ________________________

School/Department: _____
Date: __________

School Dean/Director:
Name: _____
Signature: ________________________

School/Department: _____
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.

4.3 Will the participants experience any discomfort?

Yes ☐  No ☐

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

4.4 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? ☐

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.
(This template is for research interventions that use questionnaires, interviews or focus group discussions)

(language used throughout form should be at the level of a local student of class 6th)

Notes to Researchers:

1. It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. The logo of the Institution must be used on the ICF.

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. This template is long only because it contains guidance and explanations, which you will not include in the ICFs that you develop for your research.

4. This template includes examples of key questions that may be asked at the end of each section that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions- the investigators must modify the questions depending upon their study.

5. In this template:
   - square brackets indicate where specific information is to be inserted
   - bold lettering indicates sections or wording which should be included
   - standard lettering is used for explanations to researchers only and must not
be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

6. This template and instructions are derived from the World Health Organization’s form.
[Informed Consent Form for ________________________]

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example counselors, community members, clients of services - it is important that you identify which group this particular consent is for.

(Example: This informed consent form is for social service providers in the community X and who we are inviting to participate in research Y, titled "The Community Response to Malaria Project").

You may provide the following information either as a running paragraph or under headings as shown below.

[Name of Principle Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Project and Version]

This Informed Consent Form has two parts:
• Information Sheet (to share information about the study with you)
• Certificate of Consent (for signatures if you choose to participate)

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Introduction
Briefly state who you are and that you are inviting them to participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions at anytime.

(Example: I am X, working for the Y organization. I am doing research on the disease malaria which is very common in this country and in this region. I am going to give you
information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.)

Purpose of the research
Explain the research question in lay terms which will clarify rather than confuse. Use local and simplified words rather than scientific terms and professional jargon. In your explanation, consider local beliefs and knowledge when deciding how best to provide the information. Investigators however need to be careful not to mislead participants, by suggesting research interests that they do not have. For example, if the study wants to find out about treatments provided by local practitioners, wording should not suggest that they want to find out about how the practitioners are advertising themselves. Misleading participants may be essential and justified in certain circumstances, but that needs to be carefully argued, and approved by an ethics committee.

(Example: Malaria is making many people sick in your community. We want to find ways to stop this from happening. We believe that you can help us by telling us what you know both about malaria and about local health practices in general. We want to learn what people who live or work here know about the causes of malaria and why some people get it. We want to learn about the different ways that people try to stop malaria before someone gets it or before it comes to the community, and how people know when someone has it. We also want to know more about local health practices because this knowledge might help us to learn how to better control malaria in this community.)

Type of Research Intervention
Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a questionnaire, or a series of finger pricks.

(Example: This research will involve your participation in a group discussion that will take about one and a half hour, and a one hour interview).

Participant Selection
Indicate why you have chosen this person. People may wonder why they have been chosen and may be fearful, confused or concerned.
(Example: You are being invited to take part in this research because we feel that your experience as a social worker (or as a mother, or as a responsible citizen) can contribute much to our understanding and knowledge of local health practices.)

➤ **Example of question to elucidate understanding:** Do you know why we are asking you to take part in this study? Do you know what the study is about?

**Voluntary Participation**
Indicate clearly that they can choose to participate or not. State, only if it is applicable, that they will still receive all the services they usually do if they choose not to participate. Explanation: It may be more applicable to assure them that their choosing to participate or not will not have any bearing on their job or job-related evaluations. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Although, if the interview or group discussion has already taken place, the person cannot 'stop participation' but request that the information provided by them not be used in the research study.

(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services you receive at this Centre will continue and nothing will change.

OR

The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.)

➤ **Examples of question to elucidate understanding:** If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?

**Procedures**
A. Provide a brief introduction to the format of the research study.

(Example: We are asking you to help us learn more about malaria in your community. We are inviting you to take part in this research project. If you accept, you will be asked to.....)

B. Explain the type of questions that the participants are likely to be asked in the focus group, the interviews, or the survey. If the research involves questions or discussion which may be sensitive or potentially cause embarrassment, inform the participant of this.
(Example 1 (for focus group discussions)
take part in a discussion with 7-8 other persons with similar experiences. This discussion will be guided by [name of moderator/guiders] or myself.
The group discussion will start with me, or the focus group guide or moderator (use the local word for group discussion leader), making sure that you are comfortable. We can also answer questions about the research that you might have. Then we will ask you questions about the malaria and give you time to share your knowledge. The questions will be about malaria in your community, how is it recognized, what people do to stop it from spreading to other people, who people go to for help and what happens when people become sick with it.
We will also talk about community practices more generally because this will give us a chance to understand more about malaria but in a different way. These are the types of questions we will ask...... We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing.
The discussion will take place in [location of the FGD], and no one else but the people who take part in the discussion and guide or myself will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after ______ number of days/weeks.

Example 2 (for interviews)
participate in an interview with [name of interviewer] or myself.
During the interview, I or another interviewer will sit down with you in a comfortable place at the Centre. If it is better for you, the interview can take place in your home or a friend's home. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present unless you would like someone else to be there. The information recorded is confidential, and no one else except [name of person(s)] will access to the information documented during your interview. The entire interview will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after ______ number of days/weeks.

Example 3 (for questionnaire surveys)
fill out a survey which will be provided by [name of distributor of blank surveys] and collected by [name of collector of completed surveys]. OR You may answer the questionnaire yourself, or it can be read to you and you can say out loud the answer you want me to write
down.

If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. [Describe how the survey will be distributed and collected]. The information recorded is confidential, your name is not being included on the forms, only a number will identify you, and no one else except [name of person(s) with access to the information] will have access to your survey.)

Duration
Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

(Example: The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, we will visit you three times for interviewing you at one month interval and each interview will last for about one hour each. The group discussion will be held once and will take about one and a half hour.)

- **Examples of question to elucidate understanding:** If you decide to take part in the study, do you know how much time will the interview take? Where will it take place? Do you know that we will be sending you transport to pick you up from your home? Do you know how much time will the discussion with other people take? If you agree to take part, do you know if you can stop participating? Do you know that you may not respond to the questions that you do not wish to respond to? Etc. Do you have any more questions?

Risks
Explain and describe any risks that you anticipate or that are possible. The risks depend upon the nature and type of qualitative intervention, and should be, as usual, tailored to the specific issue and situation.

(If the discussion is on sensitive and personal issues e.g. reproductive and sexual health, personal habits etc. then an example of text could be something like "We are asking you to share with us some very personal and confidential information, and you may feel uncomfortable talking about some of the topics. You do not have to answer any question or take part in the discussion/interview/survey if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview"
OR If for example, the discussion is on opinions on government policies and community beliefs, and in general no personal information is sought, then the text under risks could read
something like "There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the discussion/interview/survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable."

Benefits
Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

(Example: There will be no direct benefit to you, but your participation is likely to help us find out more about how to prevent and treat malaria in your community).

Reimbursements
State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the research. These may include, for example, travel costs and reimbursement for time lost. The amount should be determined within the host country context.

Example: You will not be provided any incentive to take part in the research. However, we will give you [provide a figure, if money is involved] for your time, and travel expense (if applicable).

Examples of question to elucidate understanding: Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?

Confidentiality
Explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any limits to confidentiality. Inform the participant that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and therefore more likely to be stigmatized. If the research is sensitive and/or involves participants who are highly vulnerable - research concerning violence against women for example - explain to the participant any extra precautions you will take to ensure safety and anonymity.
(Example: The research being done in the community may draw attention and if you participate you may be asked questions by other people in the community. We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)

The following applies to focus groups:
Focus groups provide a particular challenge to confidentiality because once something is said in the group it becomes common knowledge. Explain to the participant that you will encourage group participants to respect confidentiality, but that you cannot guarantee it.

(Example: We will ask you and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each of you to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.)

➢ Example of question to elucidate understanding: Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you understand that the we cannot guarantee complete confidentiality of information that you share with us in a group discussion Do you have any more questions?

Sharing the Results
Your plan for sharing the findings with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You may also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

(Example: Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. The knowledge that we get from this research will be shared with you and your community before it is made widely available to the public. Each participant will receive a summary of the results. There will also be small meetings in the community and these will be announced. Following the meetings, we will publish the results so that other interested people may learn from the research.)

Right to Refuse or Withdraw
This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a community social worker. Participants should have an opportunity to review their remarks in individual interviews and erase part or all of the recording or note.

(Example: You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the [discussion/interview] at any time that you wish without your job being affected. I will give you an opportunity at the end of the interview/discussion to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with my notes or if I did not understand you correctly.)

Who to Contact
Provide the name and contact information of someone who is involved, informed and accessible - a local person who can actually be contacted. State also the name (and contact details) of the local ethics committee that has approved the proposal.

(Example: If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/email]
This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact _____.

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find out more about the IRB, contact [name, address, telephone number]. It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.

- **Example of question to elucidate understanding:** Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?
Part II: Certificate of Consent

This section must be written in the first person. It should include a few brief statements about the research and be followed by a statement similar the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the informed consent and not a stand-alone document, the layout or design of the form should reflect this. The certificate of consent should avoid statements that have "I understand...." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

Example: I have been invited to participate in research about malaria and local health practices.

(This section is mandatory)
I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Print Name of Participant ______________________
Signature of Participant ______________________
Date ______________________
    Day/month/year

If illiterate¹

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness __________  Thumb print of participant

Signature of witness __________

¹ A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.
Date __________________________

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. 
2. 
3. 

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.
Print Name of Researcher/person taking the consent __________________________

Signature of Researcher/person taking the consent __________________________

Date __________________________

Day/month/year
IREC Protocol Application Checklist

Use this checklist to ensure your application package is complete.

All Submissions:

☐ IREC Protocol in electronic format, or in hard copy with all required signatures if required by your school (i.e. NUSOM)

☐ Consent forms in the respondents’ language(s) and English or Assent Forms and Parental Permission Forms in the respondents’ language(s) and English

☐ Instrument(s) (Interviews, questionnaires, telephone scripts, etc.) in the respondents’ language(s) and English

☐ Copy of CITI diplomas for PIs and Advisors for student research

If Applicable:

☐ Conflict of Interest form completed

☐ Request for waiver of written informed consent process
☐ Recruitment material (letters to professionals, letters to prospective participants, brochures, flyers, etc.) in the respondents' language(s) and English

☐ Debriefing statement in the respondents' language(s) and English

☐ Participant information sheet in the respondents' language(s) and English

☐ Permission letter from the organization where the research will be conducted
REQUEST TO DEFER IREC OVERSIGHT

This form is to be utilized if a protocol from an external institution is being submitted in lieu of the Nazarbayev University’s protocol template. If requesting that Nazarbayev University’s IREC defer oversight to an external institution, complete and submit this form along with the external institutions current approval and all supporting documents.

<table>
<thead>
<tr>
<th>Submission Type</th>
<th>NU will NOT be the IREC of Record</th>
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<tbody>
<tr>
<td>External Study ID# (if issued)</td>
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<tr>
<td>Study Title</td>
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<tr>
<td>Principal Investigator</td>
<td></td>
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<tr>
<td>Email Address</td>
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<tr>
<td>School</td>
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<tr>
<td>Department, Program, Unit, Center, or Institute</td>
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<tr>
<td>Primary Intent</td>
<td>□ Publication/presentation OR □ Thesis/dissertation</td>
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</table>
1. Name of external institution where ethics approval was granted:

2. Name of PI at external institution:

3. Role of Nazarbayev University personnel:

<table>
<thead>
<tr>
<th>Study Team Member(s)</th>
<th>Role in Project</th>
<th>NU Email Address</th>
<th>Copy on Correspondence</th>
<th>Ethics Training Completed</th>
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<tr>
<td></td>
<td>Principal Investigator</td>
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<td>Yes □ No □</td>
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4. Details of Nazarbayev University involvement:

Provide summary and check all applicable boxes.

Collection of data or samples □ Yes □ No □ Pre-existing
Receipt of data or samples for analysis
□ Identifiable □ De-identified/coded □ Not Receiving
Recruitment □ Yes □ No
Obtaining consent □ Yes □ No

5. Data/sample transfer and storage procedures at Nazarbayev University:
6. Explanation of any discrepancies between external protocol and local procedure:

7. Nazarbayev University Study Team Assurance Statement
   □ I attest that the information contained in this application is accurate and complete.
   □ I agree to notify the NU IREC immediately of the development of any potential conflict of interest not already disclosed and when applicable, the external institution of record.
   □ I understand that if NU has deferred ethic oversight to an external institution, I am responsible for ensuring that the content of the NU IREC file matches the external institution’s file within 30 days of any approvals, changes, or other actions.

<table>
<thead>
<tr>
<th>Name of NU Study Team Member:</th>
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<tbody>
<tr>
<td>Signature of NU Study Team Member:</td>
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<td>Date:</td>
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Annex 5 to the Procedures of the Institutional Research Ethics Committee of The autonomous organization of education "Nazarbayev University"

Institutional Research Ethics Committee Meeting Agenda

<table>
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<tr>
<th>Date of Meeting:</th>
<th>IREC000-00</th>
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<tbody>
<tr>
<td>Time:</td>
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<tr>
<td>Location:</td>
<td>Room #</td>
</tr>
<tr>
<td>Board/Committee:</td>
<td>Institutional Research Ethics Committee</td>
</tr>
<tr>
<td>Meeting Called by:</td>
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MEMBERS

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
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<tr>
<td>1.</td>
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<tr>
<td>2.</td>
<td></td>
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<tr>
<td>3.</td>
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AGENDA

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<tr>
<th>№</th>
<th>Topic</th>
<th>Presented by</th>
<th>Associated Documents</th>
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<tr>
<td>1.</td>
<td>Items for approval</td>
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<tr>
<td>2.</td>
<td>Items for information</td>
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<tr>
<td>3.</td>
<td>Any Other Business</td>
<td></td>
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</tr>
</tbody>
</table>
Institutional Research Ethics Committee Meeting Minutes

Date
Time
Location

Voting Members Present:

№  Full Name           Affiliation
1.

Apologies for Absence:

№  Full Name           Position
1.

Minutes:

1. *Items for Approval:*

1.1

2. *Items for information:*

2.1

3. *Any other business:*

Chair  ____________________  Full name

Secretary ____________________  Full name
Institutional Research Ethics Committee Minutes for Expedited Review

Date:

Approved items:

1.
2.

Chair ______________________ Full name

Secretary ____________________ Full name

Annex 6 to the
Procedures of the Institutional Research Ethics Committee of
The autonomous organization of education
"Nazarbayev University"