NU IREC Human Research Ethics Review Form

Use this form to apply for an ethical review of research involving people, to be carried out by researchers at Nazarbayev University (NU). Ethical review of research is a NU requirement for research involving humans. This includes research that studies data about people and observations of people.

Directions

- This application must be approved **prior to** beginning any aspect of **data collection or data analysis** (unless it relates to a pilot study that will not be published or presented).
- If your project does not involve human subjects or human subject data (e.g., literature reviews) you are not required to submit an NU IREC application. If you are not sure if you require NU IREC approval, you may request a consultation using the form on the NU IREC website.
- Fill in this application form and verify that you have included all necessary documents. Consult the Checklist of Submission Documents on the final page and ensure that **all documents are labeled as directed.**
- All investigators affiliated with this application (i.e., faculty, research staff, students, and external collaborators) need to be listed on the application form and submit completion certificates for The **C**ollaborative **I**nstitutional **T**raining **I**nitiative (CITI Program) Basic Course on Human Subjects Research. Alternative ethics training certificates will be accepted. Certificates must be valid - completed within the last three years. See information available on the NU IREC website.
- Save your completed form using naming protocols for all documents as stipulated at the end of this form. The correct naming of your documents will hasten the review process.
- This is a professional document; please check spelling, grammar, and punctuation. Documents containing errors, especially on documents for public dissemination (e.g., consent forms), will be returned for correction.
- Submit the complete NU IREC Application in electronic form to resethics@nu.edu.kz, with all required documents attached, the signature of a supervisor or email of support is required for student research. All other signatures are only required **after approval** of the application.
- Once the project has been approved, a signed original hard copy of the application form must be delivered to the NU IREC secretary within three weeks.

NU IREC examines the information provided in your application to determine whether approval can be granted, and under what conditions. The application should be completed in terminology readily understood by an informed layperson. The project, as described in the application, should be complete with no additional documentation required other than requested by the Committee and listed in the checklist at the end of the application form. If your research cannot be understood, the application will be returned with a request for additional information or simplified language. Delays occur when the requested information is not provided in the application.

Review Timelines

Comprehensive and accurate applications, containing all the required information and supporting documents may be approved in the approximate times listed below:

- *Requests for exemption, amendment, and extension*– usually within one week.
- *Expedited review* – three to four weeks.
- *Full board application*s – normal processing time is up to five weeks for complete, accurate, and language-appropriate applications. The review of full board applications occurs at biweekly NU IREC meetings.

Part 0: Do I Submit an NU IREC Application?

Does this research involve human subjects?

NU IREC defines

- **Research** as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- **Human subject** as a living individual about whom an investigator obtains: 1) data through intervention or interaction with the individual; or 2) identifiable private information.
  a) Does your research involve human subjects or official records about human subjects?
  Yes ☐ No ☐ If No – No application needed.
  b) 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 ☐ If Yes – No application needed.
  c) Is this project a quality assurance activity or program improvement activity with no intention to share the results beyond the University community?
  Yes ☐ No ☐ If Yes – No application needed.
  d) Would you like to use this study to launch future investigations in which you would re-use this data?
  Yes ☐ No ☐ If Yes – Application needed.
  e) Would you like to disseminate or publish findings from this study at research presentations on- or off-campus, or in published works (including online media)?
  Yes ☐ No ☐ If Yes – Application needed.
  f) Do you think this research is eligible for an Exemption from Research Ethics Review?
  Yes ☐ No ☐

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

The following categories of research are exempt from this policy:

f1 ☐ Research conducted in ***established or commonly accepted educational settings***, involving ***normal educational practices***, such as (i) research on education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

f2 ☐ 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 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 damage the subjects' financial standing, employability, or reputation.

f3 ☐ 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 in such a manner that ***subjects cannot be identified***, directly or through identifiers linked to the subjects.

NOTE: "**Publicly available**" refers to data and/or biospecimens that are accessible to anyone in the general public, without the need for special qualifications, permissions, or privileges. Examples include data/biospecimens available for public purchase or searchable online.

FOR NU IREC USE ONLY: Application #:	Decision:	Date of Approval:

NU IREC Human Research Ethics Application Form

Part 1: Cover Sheet

Principal Investigator: Application Date:
Nazarbayev University Unit (School):
Primary Research Discipline:
Application Title:

Type of Review (Please refer to the link for more information):
I am seeking (choose one category only):

- An Expedited Review Yes ☐ No ☐
- A Full Board Review Yes ☐ No ☐
- An Exemption Yes ☐ No ☐
  - If Yes for Exemption, please check below (refer to categories on page 2):
    - f1 ☐ ***normal educational practices*** in ***established or commonly accepted educational settings.***
    - f2 ☐ ***use of educational tests.***
    - f3 ☐ ***existing*** data, documents, records, pathological specimens, or diagnostic specimens, ***if these sources are publicly available OR de-identified***.
    - f4 ☐ ***other.***

Outline the reasons why your study should be considered exempt:

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

Part 2: Research Team Details

Principal Investigator
Name: NU ID:
NU School:
Department:
Position:
E-mail address:
Daytime Phone: Mobile phone:
Have you completed the CITI basic course on Human Subjects Research?
Yes ☐ No ☐ If No – You cannot submit this application until CITI training is completed.
CITI Training completion date:

NOTE: The application will only be reviewed if valid course completion certificates for all research team members are submitted.

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 collection of data from research participants and will not do so until formal notification of NU IREC approval of the proposed project has been received.
c) You will seek approval from the NU IREC prior to implementing any changes in procedures or the consent process/forms for this project; and
d) You will immediately inform the NU IREC of any adverse events or other negative consequences incurred by participants in this research.

Signature:_____ (to be completed on hard copy for final submission only)

Additional Investigator(s): *(Use additional pages if necessary)*
Name: NU ID:
NU School:
Department:
Position:
E-mail address:
Have you completed the CITI basic course on Human Subjects Research or, for non-NU researchers, alternative accepted by NU IREC? Yes ☐ No ☐
If No – This application cannot be submitted until CITI training is completed.
CITI or alternative training completion date:

Additional Investigator(s): *(Use additional pages if necessary)*
Name: NU ID:
NU School:
Department:
Position:
E-mail address:
Have you completed the CITI basic course on Human Subjects Research or, for non-NU researchers, alternative accepted by NU IREC? Yes ☐ No ☐
If No – This application cannot be submitted until CITI training is completed.
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Additional Investigator(s): *(Use additional pages if necessary)*
Name: NU ID:
NU School:
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Position:
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Have you completed the CITI basic course on Human Subjects Research or, for non-NU researchers, alternative accepted by NU IREC? Yes ☐ No ☐
If No – This application cannot be submitted until CITI training is completed.
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Additional Investigator(s): *(Use additional pages if necessary)*
Name: NU ID:
NU School:
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Have you completed the CITI basic course on Human Subjects Research or, for non-NU researchers, alternative accepted by NU IREC? Yes ☐ No ☐
If No – This application cannot be submitted until CITI training is completed.
CITI or alternative training completion date:

Additional Investigator(s): *(Use additional pages if necessary)*
Name: NU ID:
NU School:
Department:
Position:
E-mail address:
Have you completed the CITI basic course on Human Subjects Research or, for non-NU researchers, alternative accepted by NU IREC? Yes ☐ No ☐
If No – This application cannot be submitted until CITI training is completed.
CITI or alternative training completion date:

For students:
Undergraduate ☐ Masters ☐ PhD ☐ Other ☐
Course:

Research Advisor:
Name: NU ID:
NU School:
Department:
Position:
E-mail address:
Have you completed the CITI basic course on Human Subjects Research or, for non-NU researchers, alternative accepted by NU IREC? Yes ☐ No ☐
If No – This application cannot be submitted until CITI training is completed.
CITI or alternative training completion date:

By signing this form, the **Research Advisor** 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 NU IREC; and
c) You will provide adequate supervision of the above student in the conduct of this research.

Signature:_____ Date:

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

Department Chair/Vice Dean of Research:
Name:
NU School:
Department:

Signature: _____ Date:

School Dean/Director/Chair of Research Committee:
Name:
NU School:
Department:

Signature: _____ Date:

Part 3: Research Design

This application must be written in language that can be understood by academics who are not specialists in the field of this study. The provision of clear information will assist with the prompt processing of your application.

3.1 What is the purpose of the research? (Approximately 250-300 words)
What question(s) do you hope to answer? Summarize the objectives and significance of the study.

3.2 Describe the data collection methodology in language that will be understood by researchers outside your field. Briefly describe your data collection method. For example: qualitative (interviews, focus groups, observations, action research), quantitative (surveys, clinical trials, existing data sets, human genetics) and mixed methods). **Copies of all data collection instruments must be attached to this application, in the required languages**. (**Approximately 250-300 words**).

3.3 Briefly describe the data analysis processes. (Approximately 150-300 words).

3.4 Briefly describe the research sites.

Part 4: Participants

4.1 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 your human subjects:

a) Minors (under 18 years of age)? Yes ☐ No ☐
If "Yes", consent from parents and assent from the child will be required. These documents must be supplied with the application.

b) Legally incompetent? Yes ☐ No ☐

c) Prisoners? Yes ☐ No ☐

d) Perinatal women, if affected by the research? Yes ☐ No ☐

e) Institutionalized? Yes ☐ No ☐

f) Mentally incapacitated? Yes ☐ No ☐

Does the research deal with sensitive subjects, for example, questions concerning:

g) Sexual behaviors? Yes ☐ No ☐

h) Drug use? Yes ☐ No ☐

i) Illegal conduct? Yes ☐ No ☐

j) Use of alcohol? Yes ☐ No ☐

k) Other (please specify)

4.2 **Participant Pool.** Expected number of participants or sample size:

4.3 **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:

4.4 **Explain why you have chosen this particular group for study.** N/A ☐

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:

4.5 **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).
Does your relationship potentially create any power over the potential participant?

4.6 **Participant Contact (Recruitment)**

a) Will participants be recruited? Yes ☐ No ☐
b) How will you contact potential participants to solicit their involvement in your study? N/A ☐

c) Describe the method for recruiting participants. Provide copies of recruitment emails, presentations, advertising, posters, scripts, or other materials.
N/A ☐

4.7 **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. N/A ☐

4.8 **Procedures in the event of a participant withdrawing from the study.** Outline any follow up actions which will occur if a participant withdraws from the study.

Part 5: Detailed Procedures

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

NOTE: The research cannot begin until this project has been approved by the NU IREC. Projects will only be approved for **one year**. Requests for extension should be submitted one month before the approval expiry date.

5.2 **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?

5.3 **Will you be the one administering the data collection 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.

5.4 **Will the participants experience any discomfort?** Yes ☐ No ☐

If "Yes", please explain. (Discomfort may include physical or emotional discomfort).
N/A ☐

5.5 **Will deception or false or misleading information be used in your procedures?** Will you withhold information that will influence the subjects' understanding of the true nature of the study?
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.
N/A ☐

Part 6: Data Management Plan

All materials must be retained and available for inspection by the faculty advisor and/or NU IREC audit **for a minimum of three years from the date of dissemination or final reporting**. PIs are responsible for the disposal of data or transfer to continuing safe storage repository.

6.1 **Are you conducting a survey using any electronic media?**
Yes ☐ No ☐
If "No," please skip to Part 6.5.

6.2 **If you are sending out an email invitation to subjects to complete a survey:**
a) Will you assure that the participant will only see his/her name?
Yes ☐ No ☐

b) Will you have the "read receipt" function turned off?
Yes ☐ No ☐
If you answered "No" to these questions, please explain why:

6.3 If your survey contains questions where the subjects choose from a dropdown menu, do they have the option to choose "No response" or to leave the question blank?

Yes ☐ No ☐ No dropdown menu ☐

6.4 How will data be transmitted? Is a survey host (Qualtrics, Select Survey, Survey Monkey, etc.) used? If a survey link is sent to participants, will the URL for the survey include information that could identify individuals? Will the host retain identifiable data? Will the data be encrypted?

What is the URL?

6.5 Where will data be stored?

6.6 How will data be maintained? Will it be in an individually identifiable form, aggregate form, anonymized?

6.7 Will data be shared? This includes posting survey results or aggregated anonymized data on a website or publicly available location that could be accessed by individuals other than the investigators.
Yes ☐ No ☐
How? With whom? Will subjects be re-identifiable? Why or why not?

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

Part 7: Risk/Benefit Analysis

7.1 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:

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" or "No risk" will not be accepted.

7.2 If risks are greater than minimal, describe the following:

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?

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

Yes ☐ No ☐

Please explain:

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

7.5 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 8: Confidentiality/Anonymity

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

Confidentiality is necessary when anonymity is not possible – when the identity of the participant is known to the researcher in any way.

8.1 Will you make video, photograph, or audio recordings? Yes ☐ No ☐

8.2 Do your consent forms include a request for permission to obtain video, photographic or audio recordings? Yes ☐ No ☐

8.3 Can the subjects be identified by the researchers directly or through any identifiers?

Yes ☐ No ☐

If "Yes," please explain:

8.4 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) ☐

8.5 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:

Part 9: Consent

If subjects are under the age of 18 (a minor), a parent, guardian, or an authorized representative must give consent for participation. A school's personnel cannot give permission or consent on behalf of minors. In addition, the minor must give their assent. Consent forms and assent scripts must be provided. Samples are available on the NU IREC website.

9.1 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?

N/A ☐ ***If "N/A", please explain why?***

9.2 Describe how you will assure that participation is voluntary:

9.3 Are you requesting Oral Consent Only (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 NU IREC will grant it. All researchers must submit consent forms or oral consent scripts with their application materials for the NU 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.

Part 10: Project Funding

10.1 Funding/Sponsor Information:

a) Is this project being supported by any funding sources?

Yes ☐ No ☐

b) What is the source of funding?

For external funding provide: N/A ☐

Name of granting agency/sponsor:
Name of contact person:
E-mail address:
Duration of grant/sponsorship:
Commencement date of grant/sponsorship:

Part 11. Protocol for naming of documents and attachments

Correct naming of documents helps the reviewers to complete the review quickly. Ensure that all your documents are labelled as outlined below. Applications will be returned if documents are not identifiable as outlined.

Application form:
Surname of PI_IREC Application Date (month– day – year)
e.g., Sinclair_ IREC Application_04172020

Instruments:
Surname of PI [description of the instrument - language] Date (month– day – year)
e.g., Sinclair_ Interview Questions-Eng_04172020
or Sinclair_Online Survey_04172020

Consent Forms/Assent Scripts:
Surname of PI [description of the form - language] Date (month– day – year)
e.g., Sinclair_Participant consent-Eng_04172020
or Sinclair_Parent Consent-Kz_04172020

Recruitment Documents:
Surname of PI [description of the form - language] Date (month– day – year)
e.g., Sinclair_Recruitment email-En_04172020
or Sinclair_Recruitment poster-Kz_04172020

Ethics Training document:
Surname of investigator [Training body_completion date month–day –year]
e.g., Sinclair_CITI_04172020
or Sinclair_TRREE_04172020

Other:
Surname of PI [Description of the document - language] Date of document (month – day – year)
e.g., Sinclair_hospital authorization - Ru_04172020

CHECKLIST OF SUBMISSION DOCUMENTS:

☐ **Completed NU IREC Application**

☐ **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 NU IREC website.
- ☐ Parental consent form or child assent script. ☐ N/A
- ☐ Consent forms are named according to the protocol described above.

☐ **Data Collection Instruments**

- ☐ The final version of the data collection 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. ☐ N/A
- ☐ If your data collection includes focus group questions, a complete list of the questions should be attached. ☐ N/A
- ☐ For research using a published/purchased instrument, a copy of the complete survey will suffice. ☐ N/A
- ☐ Data collection instruments are named according to the protocol described above.

☐ **Human Subject Ethics Training Certificates** (CITI basic course on Human Subjects Research or approved alternative) must be completed by all individuals involved in conducting this research project before this form is submitted.

- ☐ Current, valid certificates, named according to the required protocol, are attached for all project participants (staff, students, partners in external organizations).

☐ **Recruitment Documents** ☐ N/A

- ☐ Information sheets or letters/emails explaining the purpose of the research for recruitment, Information presentations, posters.

☐ **Other Documents as Needed** ☐ N/A

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