

## VIII. What Investigators Need to Know About the IREC Review Process

The Nazarbayev University IREC offers assistance for investigators navigating the Institutional Research Ethics Committee (IREC) process. Whether conducting human subject research as part of a research project, honors project, thesis or dissertation project, or an independent study, the IREC staff is available to help!

The first step is to determine whether your project needs to be reviewed by the IREC or if it qualifies as a class project that does not require IREC review. Please refer to [Chapter IV](#) for guidance on determining whether or not your project needs to be reviewed by the IREC.

If it is determined that your project DOES require IREC review, you will be required to submit an IREC application.

**IREC members are available to consult with faculty and students regarding their research projects. If it has been determined that your project requires IREC review and you would like assistance navigating the IREC submission process, please fill out a consultation form that is available in [Appendix I](#).**

PLEASE NOTE: IREC staff cannot assist in the *development* of your research project. IREC staff will assist you with your IREC application and other materials required as part of the application process.

### Preparation Submission by Student Investigators

Nazarbayev University student investigators must have a faculty sponsor who serves as an advisor on research projects. Faculty sponsors bear ultimate responsibility for their students and the ethical conduct of the research. They are responsible for ensuring students are adequately trained in human subject protections and understand the ethical principles underlying the ethical conduct of research.

Once the faculty sponsor has approved the research topic, design, and methods, the project is ready for IREC submission. Both the student and faculty sponsor must complete CITI training. The student and the faculty sponsor can work together to determine whether the project requires **expedited**, or **full board review**. However, the final determination of the review type is made by the IREC.

Students should seek study-related assistance from their faculty sponsors before submitting to the IREC to assure study risks are minimized and that faculty sponsors

are prepared to monitor the ethical conduct of the project. Students can seek guidance from the IREC for help pertaining to the IREC submission process.

Please note that student investigators and their faculty sponsors must fulfill the University's CITI online training requirement before IREC approval for a study can be obtained. Students whose projects are determined to **not** qualify as human subject research **do not** need to complete CITI.

### **Before You Begin:**

- Complete the required CITI online training (required of all study personnel: faculty investigator, student investigator, Faculty Sponsor, and research staff)
- Determine appropriate type of IREC review. If uncertain, it is always best to consult with the IREC.
- Allot enough time for the IREC submission and review process. An expedited IREC review takes approximately 3 business weeks.
- Answer each question on the IREC Application form. Do not leave questions blank. If you believe a question does not apply to your study, answer "Not Applicable".
- If your study is being conducted off-site (for example, at a school, hospital or other organization), you may need permission from the site to conduct research there. Site permission should be requested prior to submitting your IREC application.

NOTE: As part of your IREC application you may need to submit a letter of support/permission from the site. The letter of support must be on the official letterhead of the site where you're conducting research. Alternatively, you may submit a letter of support/permission from an official email address at that site.

### **Human Subjects Training**

All Nazarbayev University research team members engaged in human subject research must complete an online training program called the Collaborative Institutional Training Initiative (CITI) Program. This is to ensure that all individuals conducting research with humans are properly trained in human subject protections. The CITI training course is available at <https://www.citiprogram.org/index.cfm?pageID=14&languagePreference=English&region=1>. The required training modules are divided in two learner groups: **Group 1**

## **“Biomedical Research Investigators and Key Personnel” and Group 2 “Social Behavioral and Education Research Investigators and Key Personnel”.**

The Biomedical Research course is required for medical, physiological, or pharmacological studies. This includes but is not limited to, research with drugs, devices, or other interventions. The Social Behavioral and Education Research (SBER) course is required for studies on sociological, psychological, anthropological or educational phenomena including observational and survey research and work with population and/or epidemiological studies.

CITI training must be completed *before* a research application is submitted to the IREC for review. Training is valid for a 3 year period.

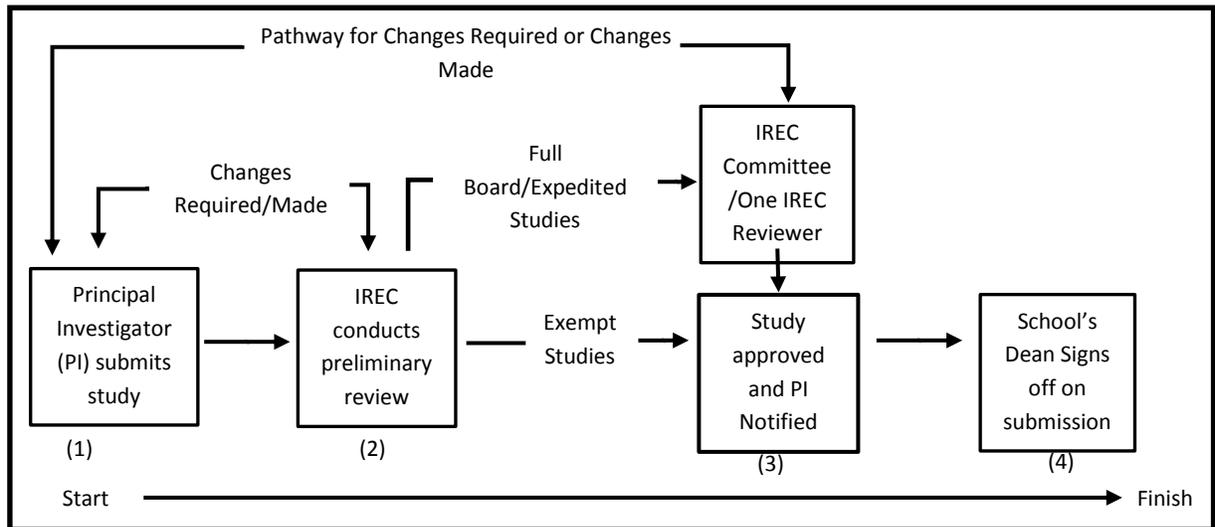
### **Application Submitted to IREC for Review**

Before the application is submitted electronically via email to [resethics@nu.edu.kz](mailto:resethics@nu.edu.kz), for some School's (i.e., School of Medicine) the principal investigator's Dean must review and sign-off on the application before the IREC will assess the study. For other Schools, the principal investigator's Dean must review and sign-off on the application immediately after the IREC has contacted the principal investigator to state that his/her research has been approved. Through this process, the principal investigator attests to the scientific merit of the submission, the availability of needed resources, and the department acceptance of the study.

Upon submission, the application is routed to the IREC staff for preliminary review. The IREC grants the final approval of IREC protocols. If a study is exempt or does not qualify as human subjects research, as determined by IREC staff, no further review is required. However, any study changes must be submitted and approved by the IREC staff prior to initiation of changes as changes could modify the initial determination made by the IREC.

The charts below provides an outline of the IREC review process, starting with online IREC submission by the researcher and ending with the IREC granting approval of the research.

## Schematic of IREC Approval Process: non-NUSOM Schools



### KEY:

#### (1) Principal Investigator Designs and Submits Study:

Investigators design their protocol and submit it via email to [resethics@nu.edu.kz](mailto:resethics@nu.edu.kz). Investigators must indicate if the application requires expedited or full board review. The final determination of the review category is made by the IREC.

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

#### (2) IREC:

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

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

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

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

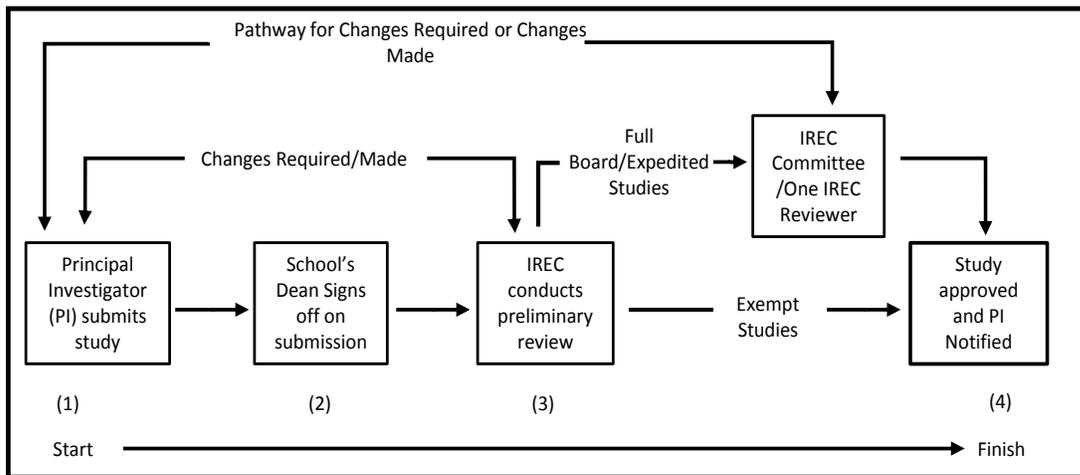
### **(3) Study Approved and PI Notified:**

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

### **(4) Dean Sign-Off:**

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

## Schematic of IREC Approval Process: NUSOM



### KEY:

#### (1.) Principal Investigator Designs and Submits Study:

Investigators design their protocol and submit it via email to [resethics@nu.edu.kz](mailto:resethics@nu.edu.kz). Investigators must indicate if the application requires expedited or full board review. The final determination of the review category is made by the IREC.

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

#### (2.) Dean Sign-Off:

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

#### (3.) IREC:

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

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#### **(4.) Study Approved and PI Notified:**

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

#### **Revisions and Reportable Events**

Once the application is approved, the researcher may begin recruiting subjects and conducting the study. The researcher must let the IREC know if any of the following subsequently occur:

- Changes to the original study must be reviewed and approved by the IREC using an **IREC Protocol Amendment Form** (Appendix G) via e-mail before they are implemented, unless the subject is at immediate risk.
- Adverse Events and Unanticipated Problems Involving Risks to Subjects or

Others (harm to subjects or others resulting from the study) must be reported to the IREC promptly using an **IREC Reportable Events Form (Appendix H)**.

- Complaints regarding human subject research (any complaints from the subjects or the study staff must be reported to the IREC promptly).
- Breach of Confidentiality (Confidential data that has been disclosed by any member of the study staff must be reported to the IREC immediately, for example, the theft of a laptop containing research data with names and addresses of participants).

### **Continuing Review**

All active expedited or full board studies must be reviewed at least once a year. Investigators must submit a renewal application (a **Request for Continuing IREC Approval form**, which is available in Appendix F) via email to [resethics@nu.edu.kz](mailto:resethics@nu.edu.kz) prior to the study expiration date. The renewal form asks the investigator to indicate the status of the study (e.g. enrolling new subjects, enrollment closed/data analysis only).

### **Summary of Principal Investigator Responsibilities**

#### **The Principal Investigator is responsible for:**

- ensuring the description of the proposal study in the IREC application is accurate and complete prior to IREC submission
- obtaining IREC approval before initiating any research activities
- ensuring the research activity is conducted in accordance with the IREC-approved protocol
- informing the IREC of all proposed changes or additions to the previously approved study before implementing them unless there is immediate risk of harm to the subject
- submitting required continuing review to the IREC
- promptly reporting unanticipated problems involving risks to subjects or others and adverse events to the faculty sponsor and IREC.