IX. Investigator Reporting Responsibilities after IREC Approval

After IREC approval is obtained, the Principal Investigator must keep the IREC informed about study changes or problems. Certain events or circumstances require reporting within a specified amount of time depending on the risk they may pose to study participants. These requirements and guidelines are described below.

Reportable Events

Adverse Events (AE) and Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO)

In the event of a **Serious Adverse Event (SAE)** or an **Unanticipated Problem (UP)**, the student investigator is required to submit a written report to the IREC within 5 business days. The investigator's report must contain enough information for the IREC to determine whether the event increases risks to participants or requires a change to the research design.

Definitions

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

Adverse events (AE) are undesirable and unintended, though not necessarily unanticipated, physical, or emotional harm, or occurrences in a human subject.

Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) includes any incident, experience, or outcome that meets **all** of the following criteria:

• **Unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IREC-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied.

• **Related or possibly related** to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research) and suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

• **Unexpected or unanticipated** refers to any adverse event occurring in one or more research subjects where the nature, severity, or frequency of the event(s) is not consistent with the known/foreseeable risk associated with the study procedures described in the IREC approved study, any related study documents, and the IREC approved informed consent document.

• **Protocol Deviation** refers to those occasions when the procedures described in the protocol are accidentally or intentionally not adhered to. Deviations can result when new staff are not adequately trained, or when records are not properly maintained. Protocol deviations should be promptly reported to the IREC.

Reporting of an adverse event or protocol deviation, must be submitted through email to resethics@nu.edu.kz.

The IREC also has a form that is to be filled out in the event of an **unanticipated problem** - **IREC Reportable Events Form** available in **Appendix H**. Once you have submitted information regarding an incident (event or deviation) that has occurred, you will be notified regarding whether or not the unanticipated problem form should be submitted as well.

Proposing Changes to Previously Approved Research Projects

Revisions

A revision is a change to an IREC approved research project. IREC review and approval of revisions are required before investigators can modify IREC approved research projects, except when modification is necessary to eliminate apparent immediate hazards to the subjects. Any proposed change to a previously approved full board or expedited study must be submitted to the IREC as a revision to that project using the **Protocol Amendment Form** (Appendix G). It may be reviewed by the expedited review procedure (i.e. by one reviewer) or by the convened IREC (i.e. reviewed by a committee), depending on the risk associated with the change. Minor changes are those that do not significantly alter the project's risk/benefit ratio and these may qualify for expedited review. All revisions must be submitted through email to resethics@nu.edu.kz.

Continuing Review

Investigators can request the IREC for continuing review of Nazarbayev University human subject research studies at intervals appropriate to the degree of risk.

Investigators should submit a continuing review application (**Request for Continuing IREC Approval form, which is available in Appendix F)** before the end of the approval period for their study in order to avoid lapses in IREC approval. Once the approval period for a given study has expired, it is considered a lapsed study and all research-related procedures must stop, except in situations in which doing so would jeopardize the welfare of the subjects. **If a study expires, no subjects may be enrolled in the research, no data may be collected, and data analysis must stop.**

Once a renewal form is submitted and approved by the IREC, a new approval period is established and the study activities may resume.

Protocol Deviations and Noncompliance

Failure to follow the regulations governing human research, requirements or determinations of the IREC, or institutional policies constitutes noncompliance. This definition may include action of any University employee or agent, such as investigators, research staff, IREC member, IREC staff, employees or institutional officials.

Protocol deviations that occur during the course of research are considered a form of noncompliance and may be considered significant when the deviation compromises the rights and welfare of subjects. Principal investigators should report all protocol deviations and noncompliance to the IREC as soon as it is discovered.

All reports of alleged noncompliance or inappropriate involvement of human subjects in research may come to the attention of the IREC from different sources and by various means. Alleged noncompliance reports may come from an IREC member, an investigator, a subject or subject's family member, institutional personnel, institutional committees, the media, anonymous sources, or the public. Reports of alleged noncompliance or inappropriate involvement of humans in research will be investigated by the IREC.

Study Suspension and Termination: PI and IREC Role

Suspension of a Study by the IREC

In cases of Serious Adverse Events (SAEs), Unanticipated Problems Involving Risks to subjects or others (UPIRTSO), researcher noncompliance, or protocol violations reported to the IREC, the IREC may suspend a study to ensure subject safety.

Termination of a Study by the IREC

Upon investigation of any SAE, UPIRTSO, noncompliance, or protocol violations, the convened IREC may vote to terminate a study. A PI can address the issues that caused a termination via a revision in e-protocol unless the IREC specifically requires that the PI submit a new study.