I. Human Subject Research at a Glance

Research involving human subjects conducted by personnel affiliated with Nazarbayev University must be reviewed and approved by the Nazarbayev University Institutional Research Ethics Committee (IREC) prior to research activities being initiated.

All investigators, whether staff, students, or faculty are required to adhere to university policies and ethical principles when conducting human subject research.

All investigators must follow the study procedures approved by the IREC. If deviations from the IREC approved protocol or violations occur, they must be reported promptly to the IREC.

Revisions (changes) to an IREC-approved research study must be reviewed and approved by the IREC prior to implementation, unless subjects are at immediate risk of harm. These changes are submitted as revisions using the **Protocol Amendment Form** which is available in Appendix F.

The informed consent process is a central element of the ethical treatment of human research subjects. During this process the investigator informs the potential participant about the research as well as any possible risks or benefits associated with it. The goal is to ensure prospective participants have all of the information they need in order to make an informed decision about whether or not they would like to participate in the study. Investigators must be forthright and realistic when describing the benefits and risks of research participation and when answering questions posed by subjects. For sample consent documents, please refer Nazarbayev University's **Informed Consent Template documents** which are available in Appendices B, C, and D.

Reporting Adverse Events and Unanticipated Problems Involving Risk to Subjects or Others

Although not specifically defined in the regulations, an adverse event is generally defined as any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events may encompass both physical and psychological harms.

They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

Unanticipated Problems are unexpected events related or possibly related to the research that places subjects or others at a greater risk of physical or psychological harm. These unanticipated events must be reported promptly in accordance with IREC policy using the **Reportable Events Form** which is available in Appendix H. For more information on reportable events please see Chapter VIII of this document.

Approval Period and Continuing Review of Research by the IREC

Research studies are approved by the IREC for a period of 12 months. The IREC approval letter for a research project will contain an expiration date not to exceed 12 months from the date of approval and therefore ongoing research studies must undergo continuing review by the IREC at a minimum of every 12 months. Requests for renewal (continuing review) are made submitting a **Request for Continuing IREC Approval Form** which is available in Appendix F. In the event renewal is not approved prior to the expiration date, all research activities associated with the research must stop until renewal is approved (this includes recruiting additional subjects, analyzing data, etc.)