Appendix J: Glossary of Common IREC Terminology

ADVERSE EVENT/EFFECT (AE)

Any untoward physical or psychological occurrence in a subject participating in research. An AE can be any unfavorable or unintended event including an abnormal laboratory finding, or a symptom/disease associated with the research. Adverse events may or may not have a causal relationship with the research.

ASSENT FORM

An assent form is used when subjects are between 7-17 years of age. Assent is a minor's affirmative agreement to participate in research. The assent form must include simple language written at the appropriate reading level of the youngest subject in a given age range.

BENEFITS

Most research does not provide direct benefit to subjects. Furthermore, it may be many years before the results of the research are publicly known and/or made useful to society or to affected subjects. Vague promises to benefit science or society are not adequate descriptions of benefit whether in a consent form or a research application.
When there is no direct benefit, subjects should be told that they will not benefit from participation. However, they can also be so informed when their participation may benefit society. Compensation to subjects is not considered a benefit.

BIAS

Occurs when objectivity is impaired by personal gain or personal judgment. In clinical studies, bias is minimized by blinding and randomization.

BIOLOGICS (OR BIOLOGICAL PRODUCTS)

Biologics, as regulated by the U.S. Food and Drug Administration, are made from a variety of natural sources. Like drugs, biologics are used for the prevention, treatment, or cure of disease or injury. Examples include vaccines, blood and blood products, allergenic extracts, human cells and tissues, gene therapies and test to screen potential donors for infectious agents.

CERTIFICATES OF CONFIDENTIALITY

Certificates of Confidentiality constitute an important tool to protect the privacy of research study participants. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifiable information from research participants to any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants.

COGNITIVELY IMPAIRED

Having a disorder (psychiatric or developmental) that affects cognitive or emotional functions that impair the capacity for sound judgment and reasoning. Other conditions that may impair judgment and reasoning are: being under the influence of drugs or alcohol, having a degenerative disease, having a terminal illness or disability.

CODED PRIVATE INFORMATION

Coded private information means that all identifying information that would enable anyone to ascertain the identity of the individual to whom private information or specimens belongs to is coded with a letter or symbol.

Note: A key to the code enables linkage of private information or specimens. A study may qualify as not human subjects research (NHSR) if the coded data was not collected for the proposed study AND the investigator does not have access to unlink the coded information. The IREC must make this determination. Guidance regarding coded private information and the IREC process can be found at: http://www.hhs.gov/ohrp/policy/cdebiol.html.

CONFIDENTIALITY

Confidentiality refers to the process of protecting private data or specimens and its use. Plans for managing data in a confidential manner must be appropriate to the study being proposed.

Care should be taken to explain a plan to maintain confidentiality in the e-protocol form
(e.g., the use of numbering or code systems, encryption of data, the use of passwords for electronic data access, or safely locked files in private offices). Replacing names with pseudonyms or codes also adds protection. Furthermore, the investigator should describe who has access to the data and under what circumstances, if any, a code system may be broken. Subjects should be informed whether the data collected will be retained, and, if so, for what purpose, what period of time, and whether (and when) data will be de-identified or destroyed.

CONSENT FORM

A consent form is used in a study when the subject is 18 years of age or older and competent to make the decision to participate. Parents/legal guardians of minors must provide permission to allow their children to participate in a study.

CONTINUING REVIEW

A periodic IREC review of a research study to evaluate whether risks to participants remain reasonable in relation to potential benefits and to verify that the study continues to meet regulatory and institutional requirements. Continuing review should be conducted at intervals appropriate to the degree of risk but not less than once per year. (45 CFR 46.109(e); 21 CFR 56.109(f))

DEBRIEFING

Occurs when subjects are provided with previously undisclosed information about the research project.

DECEPTION

Deception is the intentional misleading of subjects or the withholding of full information about the nature of the study. Use of deception increases ethical concerns of a study because it interferes with the ability of the subject to give informed consent. Deception is arguably necessary for certain types of behavioral research, because full knowledge by the subject might bias the results.

Subjects have the right to full disclosure as soon as possible after participation in deception research. In exceptional circumstances, the full or true purpose of the research may not be revealed to the subjects until the data collection is complete. In such cases, subjects must still receive full disclosure of the purpose of the study as soon as possible. Deception in research should be used rarely and may only be employed with the approval of the IREC.

DEVICE/MEDICAL DEVICE

A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Examples of devices are diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic equipment.

ELIGIBILITY CRITERIA

These are defined requirements for subject inclusion in a given experiment. Eligibility criteria examples are age, sex, state of health, a defined range for a biologic measure (e.g. glucose level or cholesterol), blood cell counts, etc.

ETHNOGRAPHIC (FIELDWORK/ANTHROPOLOGY RESEARCH)

Ethnography is the study of people and culture. Ethnographic research involves observation of a person or group in their own environment, often for long periods of time.

EXEMPT RESEARCH

Exempt research is Human Subjects Research that meets one of the minimal risk categories in the federal regulations (45 CFR 46).

EXPEDITED REVIEW

A review of proposed or continued research involving no more than minimal risk and/or for minor changes in approved research. Review is performed by IREC Chair or designee, rather than the full board.

FULL BOARD REVIEW

Review of proposed or continuing research (primarily greater than minimal risk research) by a convened IREC meeting, at which a majority of the voting membership is present.

GRANT

Financial support provided for a research study. Fund givers typically do not exercise strict control over the grants they have awarded (whereas contracts are prescriptive).

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

HIPAA's Privacy Rule of 2003 prohibits health care providers such as health care practitioners, hospitals, nursing facilities and clinics from disclosing protected health information without written authorization from the individual (HIPAA Authorization).

IDENTIFIABLE PRIVATE INFORMATION

Identifiable private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place," (such as a public restroom) "and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public" (for example, a health care record) (45 CFR 46.102(f)(2)).
"Identifiable" means the information contains one or more data elements that can be combined with other reasonably available information to identify an individual (e.g.Social Security #).

INCLUSION/EXCLUSION CRITERIA

The pre-determined conditions of a clinical trial that allow or excludes subject participation. These criteria are factors such as age, gender, type and stage of a disease, previous treatment history, and/or other medical conditions.

INFORMED CONSENT

Informed consent is the process of informing potential subjects about the key facts of a research study. Subjects in a study must be informed of the details of their participation, the possible risks and benefits of study participation and the voluntary nature of their participation. The process of informing and discussing research with potential subjects is a critical ethical principle in human subject research. The informed consent document serves as documentation that consent was provided by the subject or legal representative, before any study procedures took place.

INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

A specially constituted review body designated by an entity to review human subject research protocols to protect the welfare of human subjects participating in research.

INTERNATIONAL STUDIES

International research must adhere to recognized ethics codes or regulations such as: 45 CFR 46 (Policy for the Protection of Human Research Subjects), the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report. Consent and recruitment documents must be in the language of the subjects and be readable and understandable by the subjects.

Ethical regulatory responsibilities for research involving human subjects may differ outside Kazakhstan from those set forth Nazarbayev University institutional policies.

The investigator is encouraged to contact the IREC to discuss these issues. Investigators will be required to obtain a research ethics review board (IREC equivalent) approval letter for research conducted outside Kazakhstan for studies that are more than minimal risk.

Many institutions outside of Kazakhstan have ethics committees to review and approve research. For minimal risk studies an approval letter or permission letter from the research site may be acceptable by the Nazarbayev University IREC; however, this decision will be determined on a case-by-case basis.

MINIMAL RISK

The federal regulatory definition of minimal risk is 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"(45 CFR 46).

MINORS

Persons who have not attained the legal age to consent to treatment or procedures in research, as determined under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.401(a)].

PLACEBO

A chemically inert substance used in controlled clinical trials to provide data that helps distinguish and determine whether improvement and side effects reflect imagination or anticipation rather than the actual power of a drug.

PRIMARY DATA

Primary data is data obtained from direct contact with, or observation of, one or more people for the purpose of collecting data from or about them.

PRINCIPAL INVESTIGATOR (PI)

The scientist or scholar with ultimate responsibility for the design and conduct of a research project.

PRIVACY

Privacy refers to a research participant's willingness to allow access to themselves and their personal information. Privacy considerations include the timing and setting where private information is obtained, the nature of the information requested or obtained, and who receives/uses this information.

The IREC considers the protection of subject data/privacy during all stages of a study. The manner in which subjects are identified and approached for participation in research may be also be of concern. For example, a participant might not want to be identified in a place that could potentially embarrass them, such as a pregnancy counseling center or drug rehabilitation facility.

The IREC requires investigators, or other relevant parties, to explain how the privacy of study participants and their private data will be maintained during the course of the study and how study data will be retained after study closure. Investigators are required to provide this information in the IREC application.

PROSPECTIVE STUDIES

A study designed to follow groups of subjects for an extended period of time with defined outcomes.

PROTECTED HEALTH INFORMATION (PHI)

PHI is health information transmitted or maintained in any form or medium that includes
ALL of the three following parts:

- identifies or could be used to identify an individual; and
- is created or received by a healthcare provider, health plan, or healthcare clearinghouse; and
- relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.

PROTOCOL

The formal design or plan of an experiment or research activity.

RANDOM ASSIGNMENT (RANDOMIZATION, RANDOMIZED)

A method of assigning subjects to different treatment groups based on chance.

RECRUITMENT/RECRUITMENT MATERIALS

Recruitment is a process by which potential subjects are informed about study participation. Recruitment materials, such as fliers, email messages, newspaper ads, and phone calls, must accurately describe the study and be non -coercive. The use of all recruitment materials in a non-exempt research project must be approved by the IREC before use.

RESEARCH

Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge [45 CFR 102(d)].

RETROSPECTIVE STUDIES

Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews, surveys or measurements.

RISK

Risk is the probability of harm or injury (physical, psychological, social, or economic) occurring as the result of participation in a research study. Both biomedical and behavioral research may entail some levels of risk to a person's health or physical or social well being. Student researchers must consider the following risks when conducting their study:

STRESS FROM STUDY QUESTIONS/SURVEYS

Subjects may feel stress caused by the research questions or procedures. Questions can raise painful memories, embarrassment, or unresolved issues.

Interviews with survivors of personal or state violence may be at risk. Questions about illegal behaviors or immigration status may cause embarrassment, feelings of guilt or distress or raise legal concerns.

Although most psychological risks are minimal and transitory, investigators must be aware of the potential for harm. The IREC will want to know how such outcomes will be minimized or addressed.

BREACH OF CONFIDENTIALITY

A breach of personal confidentiality is often the greatest risk to participants in social and behavioral human subject research. Reputation or employment may be affected if confidentiality is compromised.

Information about subjects' activities may place them at risk of legal action. For example, if a researcher asks children about discipline, information about child abuse may be disclosed and must be reported to the appropriate authorities. Similarly, if subjects divulge information about gang activities, disclosure of that information could place the subjects at risk of harm or legal action.

RISK/BENEFIT RATIO

A comparison of the potential benefits to the risks of participating in a research study.

SECONDARY DATA

Data that has already been obtained, either individually or in aggregate form. Use and sharing of secondary data which contains personal identifiers are subject to the requirements set forth under federal regulations. Secondary data, which do not contain personal identifiers, are exempt from these requirements (the IREC must make this determination).

SERIOUS ADVERSE EVENT (SAE)

A SAE is defined by the FDA as an undesirable experience associated with the use of a medical product in a subject that results in death, a life threatening experience, hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly and/or birth defects or requires intervention to prevent permanent impairment or damage.

SPONSOR

A person, federal agency, corporation, or other entity that provides funds for a research project.

STUDY ARM

Any of the treatment groups in a randomized trial.

SUSPENSION/TERMINATION

IREC approval is suspended/terminated and all research activity is halted as the result of: unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with 45 CFR Part 46, or not following IREC requirements/determinations.

UNANTICIPATED PROBLEM INVOLVING RISKS TO SUBJECTS OR OTHERS (UPX)

Any event that is unexpected, related or possibly related, and suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.

VOLUNTARY

Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's willingness to participate (or to continue to participate) in a research activity.

VULNERABLE POPULATIONS

Any subject may be “vulnerable” when a power differential exists between researcher and subject.

Federal regulations specifically define only groups as vulnerable: pregnant women/fetuses/neonates (45CFR46, Subpart B), prisoners (45CFR46, Subpart C), and children (45CFR46, Subpart D).

Pregnant women, fetuses, and neonates (Subpart B)
Pregnant women, fetuses, and neonates are considered vulnerable because of the shared risk and/or compromised health status.

Prisoners (Subpart C)
Prisoners are considered vulnerable because incarceration impacts their ability to make a voluntary and non-coerced decision regarding whether to participate as subjects in research.

Children (Subpart D)
Children are considered vulnerable because they may not be able to completely understand the information presented, nor the risks and benefits the study may entail.

People who cannot competently understand the information regarding a study and cannot give true consent, (e.g., individuals with psychiatric, cognitive, or developmental disorders, substance abusers, students, and workers) may also be considered vulnerable populations in certain human subject research.