Types of IREC Review

Regulations provide for two types of IREC review: **expedited, and full-board**. The following chapter provides an explanation of each type of review and examples of studies that represent each type. The IREC conducts reviews using the criteria contained in the United States Federal Policy for the Protection of Human Subjects (CFR45; Part 46, Section 46.111).

1. Expedited Review

Expedited review applies to those research projects that do not fit an exempt category but do not present more than minimal risk to subjects. These projects must meet one of the nine categories for expedited review. Expedited review requires the same approval criteria as a full board study, but because these studies entail less risk, they are reviewed by the IREC Chair or a Designated Reviewer, rather than the convened IREC. During this process, designated reviewers exercise all of the authorities of the IREC except that they may ***not*** disapprove the research.

Expedited Review Categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
(a) Research on drugs for which an investigational new drug application is not required. (b) Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

The following expedited categories apply only to projects that have been initially reviewed and approved by a convened IREC that require continuing review (renewal):

8. Continuing review of research previously approved by the convened IREC as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IREC has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

2. Full Board Review

Studies that involve **more than minimal risk** to subjects require full board review at a convened meeting at which a quorum (more than 50%) of the membership is

present. For the research to be approved, it must receive the approval of a majority of those members present.

IREC regulations do not specifically list categories that require full board review since the criteria for full board review is determined by the risk to subjects potentially being greater than minimal. Studies such as those listed below are normally sent to full board for review when part of the study design involves greater than minimal risk to participants (risks can be physical, psychological, social, economic) and may be determined to be greater than minimal by the investigator or the IREC.

- studies involving clinical procedures with drugs, devices, or biologics, or innovative research into new medical or surgery procedures
- studies taking place internationally (particularly countries with little or no provisions for protection of human subjects) where subjects may be at physical, psychological or legal risk
- studies in which disclosed information could require mandatory legal reporting (e.g., child/elder abuse, etc.)
- studies involving deception which increase the risk to subjects or others
- studies in which the IREC staff, chair, member, or designee determines risk to subjects or others to be greater than minimal risk
- studies using certain "vulnerable" populations requiring extra protections.

A Reminder…

Investigators should consult with the IREC if unsure which type of review is required for their research.

All human subject research whether conducted by student investigators, faculty or staff must obtain IREC approval prior to initiation of any research activity (presuming the study fits the IREC definition of "human subjects" and "research" and is not solely a classroom exercise).

Retroactive approval for data previously collected for an unapproved study is **not allowed**. **Failure to seek IREC approval for research may invalidate a study. Many journals will not accept a human subject research paper without proof of IREC approval.**

IREC Review Exceptions

Some research that involves investigator interaction with people does not meet the definition(s) of "human subjects" and/or "research." When uncertainty exists, Nazarbayev University requires that investigators contact IREC so that a determination can be made as to whether the study is or is not human subject research.

Coded Data/Specimens

Studies using **coded private information** or **coded biological specimens** not collected by the current investigator, nor collected for the currently proposed project**, do not** require IREC review provided that the current investigator is not able to link the coded data/specimens to individual subjects. Further, if the data/specimen provider has access to the identity of the subjects, the investigator must confirm that under no circumstances will the identity of the subjects be released to him/her.

For additional guidance on coded data/specimens use, please refer to the U.S Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/policy/cdebiol.html.

IREC Approval

IREC project approval for research is valid for a maximum period of 12 months. If the research is planned to continue for more than a year, a renewal application (also called a continuing review or application) must be submitted to the IREC to extend approval for an additional year.