

**REGULATION**  
**on the Local bioethics commission**  
**of the non-profit joint-stock company**  
**“National center for children’s Rehabilitation”**

**Astana city, 2025**

1. This Regulation on the Local Bioethics Commission of the non-profit joint stock company “National center for children’s rehabilitation” (hereinafter - the Regulation) has been developed in accordance with the legislation of the Republic of Kazakhstan, international acts in the field of bioethics and internal documents of the non-profit joint-stock company “National center for children’s rehabilitation” (hereinafter - the Society).

2. Local Bioethics Commission of the Company (hereinafter - the Commission) is an independent expert body of the Company conducting bioethical examination of documents related to biomedical research, at the stage of their planning, during execution and after completion in order to ensure the safety and protection of the rights of participants in biomedical research.

3. In its activities, the Commission is guided by the Constitution Republic of Kazakhstan, the Code of the Republic of Kazakhstan on the health of the people and the health care system, the laws of the Republic of Kazakhstan in the field of the Helsinki Declaration of the World Medical associations, national and international standards and ethics and regulatory operational guidelines and this Commission Regulation.

4. The following terms are used in this Regulation:

1) biomedical research (hereinafter - research) - research, the purpose of which is to obtain by scientific methods new knowledge about life, human health, diseases, their diagnosis, treatment and prevention, as well as genetic and environmental factors related to life processes, diseases and health;

2) bioethics - interdisciplinary scientific direction, uniting biomedical and humanities for the purpose of analyzing moral, social, legal aspects of the application of the latest achievements of the sciences of lives;

3) bioethical expertise - review of a biomedical study and issuance of a justified opinion of the Bioethics Commission from the point of view of ethical acceptability, safety for participants and the feasibility of this study;

4) applicant - individuals and legal entities who applied for an independent bioethical examination;

5) interventional study - a study involving a human subject in which the study doctor assigns a special intervention to the subject based on the protocol of the interventional clinical trial corresponding to the procedure for conducting clinical trials;

6) investigator - the individual responsible for conducting the study at the investigating center;

7) clinical study - a study involving a person as a subject, conducted to identify or confirm the safety and effectiveness of means, methods and technologies for the prevention, diagnosis and treatment of diseases;

8) independent expert - a person who has special knowledge and experience and is involved by the Commission to provide expert advice on certain issues; invited experts are not counted in the quorum and do not take part in the voting;

9) study protocol - document describing the objectives, design, methodology, statistical aspects and organization of the study;

10) sponsor - an individual or legal entity that initiates a clinical trial and is responsible for its organization and/or funding;

11) authorized body in the field of health (hereinafter -the authorized body) - the central executive body that carries out leadership and intersectoral coordination in the field of health protection of citizens of the Republic of Kazakhstan, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological well-being of the population, circulation of medicines and medical devices, quality of medical services (assistance);

12) study participant - a person who participates in the study, either as a direct intervention subject, or as a control group participant, or as a subject under observation. Such a person may be a healthy person who voluntarily agrees to participate in the study, or a person whose health condition is not related to the nature of the study being conducted and who voluntarily agrees to participate in the study.

## **2. Aim and goals of Commission**

5. The aim of the Commission is to conduct an independent bioethical examination of documents related to biomedical research at the stage of their planning, during execution and after completion in order to ensure the safety and protection of the rights, dignity, safety and well-being of the study subjects (patients and volunteers) and researchers participating in clinical trials, medical and biological experiments, as well as moral and ethical and legal assessment of clinical study materials.

6. The tasks of the Commission are:

1) independent bioethical examination of clinical study protocols and issuance of opinions for biomedical research planned on the basis of the Company, including those submitted from other research organizations with the permission of the authorized body;

2) determination of the need (expediency) for bioethical and moral-legal examination of materials of preclinical (non-clinical) tests, clinical trials and medical-biological experiments using new medical technologies, medicines, biologically active additives, medical equipment and medical devices, new means and methods of prevention, diagnosis, treatment and rehabilitation of diseases when conducting research in the Company;

3) bioethical monitoring of the progress of medical research, for which the conclusions of the Commission were issued, permission of the authorized body;

4) submission of an annual report on activities to the Central Bioethics Commission in accordance with its established procedure.

### **3. Functions of the Commission**

7. To implement the tasks assigned to it, the Commission performs the following functions:

1) conducting an expert evaluation of the study from the point of view of ethical acceptability, safety for participants and feasibility; legal assessment of research materials;

2) assessment of compliance of the protocol and accompanying study materials with the standards of good clinical and scientific practice; compliance with the qualifications and competence of the investigators to perform the study;

3) establishing the need for bioethical examination of studies (exemption from examination);

4) monitoring compliance with ethical principles during the study, as well as after its completion;

5) providing recommendations on amendments and modifications to the protocol and related study materials submitted to the Commission; examination of supplements, amendments to study protocols;

6) Advising researchers and funders on applicable bioethics policies and procedures;

7) engaging experts, including independent experts in various fields, to clarify specific issues; specialists in various fields to clarify specific issues;

8) conducting ethical review of studies planned in the Society by non-affiliated researchers from other organizations;

9) осуществление независимой биоэтической экспертизы протоколов исследований, представленных из других организаций independent bioethical review of study protocols submitted from other organizations;

10) consideration of disputes arising before, during or after the studies;

11) regulation of interest conflicts of the Commission members;

12) interaction with the Central commission on bioethics, national and international organizations on bioethics issues, as well as with public organizations;

13) participation in the development of documents on bioethics;

14) preparation of an annual report to the management of the Company on the work of the Commission.

Functions of the Chairman of the Commission:

1) responsible for the organization and conduct meetings of the Commission;

2) invites independent consultants for specific expertise on a specific study;

3) Approves the decisions of the Commission.

Functions of the Secretary of the Commission:

a. organizes paperwork for each received application;

b. organizes regular meetings of the Commission;

c. prepares agendas and keeps minutes of the Commission meetings;

d. documents and archives the materials of the Commission;

- e. liaises with members of the Commission and applicants;
- f. organizes the preparation, review, revision and distribution of manuals and other documents;
- g. provides updates on relevant current research ethics issues.

#### **4. Commission members**

8. The composition of the Commission is formed on an interdisciplinary basis and consists of representatives of medical, humanitarian professions, public organizations and legal specialists.

9. The composition of the Commission shall be approved by order of the Chairman of the Board of the Company or a person authorized by him.

10. The commission consists of at least 7 people, including the chairman, deputy chairman, secretary and members who are appointed for a term of three years with the right to re-election for a subsequent term.

11. The Commission regularly rotates members in order to ensure a balance of experience and freshness of views.

12. To ensure independence, the composition of the Commission must include at least one person who is not affiliated with the Company. Persons who are members of the Company's management may not be members or chairman of the Commission.

13. Membership in the Commission may be terminated early on the basis of an order of the Chairman of the Management Board of the Company or a person authorized by him.

#### **5. Rules of procedure of the Commission**

14. The meeting of the Commission shall be held at least once a quarter and shall be deemed competent if at least two thirds of the total number of members of the Commission are present at the meeting.

15. Depending on the type of study, the Commission shall conduct an expedited or complete examination of the protocol and documents related to the conduct of the study. A quorum is required for all decisions requiring full expertise.

16. Members of the Commission participating in the planned study are not involved in the discussion of study documents and are not allowed to make a decision.

17. Applicant and researchers may be invited to the Commission meeting solely to provide answers to questions from members of the Commission.

18. The Commission seeks to make decisions by consensus. In cases where consensus is not achievable, a vote is taken. Members may vote for, against, or abstain. In case of equality of votes, the chairman's vote is decisive. The Secretary of the Commission shall not participate in decision-making.

19. The Commission, based on the results of the examination of the submitted documents and data, may make the following options for conclusions:

- 1) approve the conduct of studies;
- 2) approve the conduct of studies with a recommendation on amendments and additions to the study materials within ten calendar days after the issuance of the Commission's opinion;
- 3) postpone the decision until the comments are eliminated by the subsequent consideration of the study materials at the next meeting of the Commission;
- 4) not to recommend the study.

20. The Commission performs a bioethical peer review of clinical trial protocols, patient information and informed consent form, professional experience of investigators, study sites, health insurance documents of persons participating in the patient/volunteer studies, and other materials up to 30 days.

21. The appeal of the applicant who disagrees with the results of the bioethical examination is considered by the Commission with the participation of the applicant himself and the involvement of independent experts.

22. If necessary, the Commission may engage independent experts to provide expert advice on specific issues.

The Commission informs the mass media about the ongoing work, goals and objectives of the Commission and its role in protecting the rights of subjects, together with public organizations takes part in the discussion of ethical aspects of research, maintains and develops contacts with local ethical committees and the central commission on bioethics.

## **6. Rights and responsibilities of the Commission**

23. The Commission shall ensure:

- 1) quality and objectivity of examination of protocols and materials of biomedical research;
- 2) safety and justification of possible risk and inconvenience for study participants in comparison with the expected benefit;
- 3) regular monitoring of compliance with ethical principles during the study, as well as after its completion;
- 4) confidentiality of any information submitted to the Commission;
- 5) inadmissibility of the start of the study before the Commission issues a written opinion on the controversial issues that have arisen for its conduct;
- 6) documentation and storage of documentation relating to the activities of the Commission;
- 7) high-quality and timely performance of functions stipulated by this Regulation.
- 8) professional development through online and offline courses/trainings/seminars/training programs.

24. Commission have rights:

1) approve, approve with recommendations, postpone the decision or not recommend the study; require changes to the study materials, changes and additions to the protocol or other materials of the current study;

2) request additional information from the applicant regarding the planned study if it is necessary;

3) Suspend or withdraw prior approval of a study that does not meet ethical requirements or is associated with unexpected serious harm to study participants;

4) initiate inquiries regarding compliance with ethical and legal aspects of the study;

5) ask for help from other independent experts and consultants who are specialists in various fields of science;

6) give explanations, recommendations, instructions and make decisions on issues within his competence;

7) exercise other rights in accordance with the legislation of the Republic of Kazakhstan.

25. The Commission does not have the authority to:

1) prohibit the study;

2) make public information concerning the study without the consent of the applicant and/or the sponsor of the study, except as required by applicable law.

## **7. Organizational support of the Commission's activities**

26. Organizational and material and technical support of the Commission's activities is carried out by the relevant structural unit of the Company, whose competence includes issues of scientific activity.

27. The Company shall provide the Commission with sufficient funding for the effective functioning and performance of its duties.

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## **8. Final provisions**

29. All disputes not settled in this Regulation shall be regulated by the legislation of the Republic of Kazakhstan, the Charter and internal documents of the Company.

30. If, as a result of changes in the legislation of the Republic of Kazakhstan, certain norms of this Regulation conflict with them, then these norms become invalid and until the moment of amendments to this Regulation, the members of the Commission are guided by the laws and regulatory legal acts of the Republic of Kazakhstan.