

Approved
by decision of the Board of NJSC
«National center for
children's rehabilitation»
from «31» January 2025 year № 1
(Appendix № 7)

**Changes and additions
to the Regulation of the Local bioethics commission
of noncommercial joint-stock company
«National center for children's rehabilitation»**

1. Make the following changes and additions to the Regulation of the Local bioethics commission of noncommercial joint-stock company «National center for children's rehabilitation» (hereinafter - the Regulation):

- state clause 5. of Chapter 2. The purpose and objectives of the Commission as follows "The purpose 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 subjects (patients and volunteers) and researchers participating in clinical trials, medical and biological experiments, as well as moral, ethical and legal assessment of clinical trial materials";

- supplement paragraph 7 of chapter 3 with the following paragraphs.
Functions of the Commission:

«Functions of the Chairman of the Commission:

- 1) responsible for the organization and conduct of meetings of the Commission;
- 2) invites independent consultants to conduct a specific examination of a specific study;
- 3) approves the decisions of the Commission;
- 4) convenes an absentee meeting (upon reconsideration of the application) or an online meeting.

Functions of the secretary of the Commission:

- 1) organizes paperwork for each received application;
- 2) organizes regular meetings of the Commission;
- 3) prepares agendas and keeps minutes of meetings of the Commission;
- 4) documents and archives the materials of the Commission;
- 5) communicates with members of the Commission and applicants;
- 6) organizes the preparation, review, revision and distribution of manuals and other documents;

7) provides updates on relevant current research ethics issues»;
- change in Chapter 5. «Rules of procedure of the Commission»: amend paragraphs 19 and 20:

«19. The Commission, based on the results of the examination of the submitted data documents, 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 with the subsequent consideration of the study materials at the next meeting of the Commission;
- 4) do not 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 centers, health insurance documents for persons participating in the patient/volunteer studies, and other materials within 30 days»;

- supplement paragraph 22 with the following paragraph:

«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»;

- supplement subparagraph 8) of paragraph 23 of chapter 6 Rights and obligations of the Commission:

«8) professional development through online and offline courses/trainings/seminars/training programs».

2. Validity period - constantly

3. These amendments are effective from the date of their adoption.

**Deputy Chairman of the Board
for medical affairs**

A. Altynbekova

Head of management of science and education

S. Mukasheva

Chairman of Local bioethics commission

M. Shakenov