

APPROVED BY  
General Director

“Research Institute for Biological Safety  
Problems” LLP



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## REGULATION on the Local Bioethics Committee

REVIEWED

at the meeting of the Local Bioethics Committee

Minutes No. 1

dated “19” 03 2026

**REGULATION**  
**on the Local Bioethics Committee**  
**of the “Research Institute for Biological Safety Problems” LLP**

**1. General Provisions**

1.1. The Local Bioethics Committee (hereinafter referred to as the *Committee* or *LBC*) is a permanent advisory and expert body established under the Limited Liability Partnership “Research Institute for Biological Safety Problems” (hereinafter referred to as the *Institute*) with the purpose of ensuring compliance with ethical principles in the conduct of scientific research.

1.2. In its activities, the Committee shall be guided by:

1) Laws and regulatory legal acts of the Republic of Kazakhstan:

– The Constitution of the Republic of Kazakhstan;  
– The Code of the Republic of Kazakhstan dated July 7, 2020 “On Public Health and the Healthcare System”;

– Order of the Minister of Health of the Republic of Kazakhstan dated December 21, 2020 No. KR DSM-310/2020 “On approval of the Rules for conducting biomedical research and requirements for research centers”;

– Order of the Minister of Health of the Republic of Kazakhstan dated December 11, 2020 No. DSM-248/2020 “On approval of the Rules for conducting clinical trials of medicinal products and medical devices, clinical and laboratory testing of medical devices, preclinical in vitro diagnostic studies, requirements for clinical bases, and the provision of the public service ‘Issuance of permission to conduct clinical trials and/or testing of pharmacological and medicinal products and medical devices’”;

– Good Laboratory Practice (GLP) Standard, Annex 1 to the Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated February 4, 2021 No. DSM-15 “On approval of Good Pharmaceutical Practices”;

– Good Clinical Practice (GCP) Standard, Annex 2 to the Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated February 4, 2021 No. DSM-15 “On approval of Good Pharmaceutical Practices”.

2) International guidelines:

– World Medical Association Declaration of Helsinki “Ethical Principles for Medical Research Involving Human Subjects”;

– WHO Operational Guidelines for Ethics Committees that Review Biomedical Research (TDR/PRD/ETHICS/2000.1);

– CIOMS International Ethical Guidelines for Health-related Research Involving Humans;

– Report of CIOMS Working Group VI “Management of Safety Information from Clinical Trials”;

– CIOMS International Ethical Guidelines for Epidemiological Studies;

– CIOMS International Guidelines for Ethical Review of Epidemiological Studies;

– ICH GCP (Good Clinical Practice) — international standard for the conduct of clinical research;

– Convention on Human Rights and Biomedicine (1997);

– European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes (1986).

3) The Charter of the Institute;

4) This Regulation;

5) Internal regulatory documents of the Institute.

1.3. In its activities, the Committee shall be guided by generally accepted international principles for the protection of the rights, safety, and well-being of research participants.

1.4. The Committee conducts an independent ethical review of scientific research to assess its compliance with bioethical principles, biosafety requirements, and applicable legislation.

1.5. The Committee reviews research conducted by:

– employees of the Institute;

– students and applicants for academic degrees;

– researchers and students of other scientific and educational organizations;

– external research organizations.

1.6. The Local Bioethics Committee may conduct ethical review of scientific research upon requests from individuals and legal entities, including researchers and students from other scientific and educational organizations, in accordance with the procedures established by the Institute.

1.7. The Committee operates based on the following principles:

– independence;

– objectivity;

– scientific validity;

– confidentiality;

– protection of the rights and interests of research participants.

The Committee makes decisions independently and free from administrative, financial, or any other undue influence.

1.8. In its activities, the Local Bioethics Committee is guided by the following fundamental bioethical principles:

– Principle of respect for persons: recognition of the dignity, rights, and freedoms of research participants, ensuring voluntary participation and obtaining informed consent.

– Principle of beneficence and risk minimization: ensuring maximum scientific and societal benefit of the research while minimizing potential risks to research participants, personnel, and the environment.

– Principle of non-maleficence: prevention of research that may result in unjustified risks to the health of research participants, animals, personnel, or the environment.

– Principle of justice: ensuring equal and fair treatment of research participants and preventing discrimination or unjustified distribution of risks and benefits.

– Principle of researcher responsibility: ensuring that researchers comply with ethical standards, biosafety requirements, and applicable legislation when conducting scientific research.

The Committee also follows international recommendations on the ethics of biomedical research.

## **2. Purpose of the Committee**

2.1. The primary purpose of the Committee is to ensure compliance with bioethical standards in the conduct of scientific research.

2.2. The Committee ensures the protection of:

- the rights, safety, and well-being of research participants;
- humane treatment of laboratory animals;
- compliance with biosafety principles when working with biological agents.

2.3. The Committee promotes the implementation of international standards of bioethics and responsible conduct of scientific research.

## **3. Tasks of the Committee**

The main tasks of the Committee are:

3.1. Conducting ethical review of scientific research.

3.2. Assessing the scientific validity of research from the perspective of bioethics.

3.3. Evaluating the balance between potential risks and the expected benefits of research.

3.4. Assessing compliance with the rights and interests of research participants.

3.5. Reviewing research involving the use of:

- biological samples;
- cell cultures;
- genetic materials;
- laboratory animals;
- pathogenic biological agents.

3.6. Assessing biosafety measures in the conduct of research.

3.7. Monitoring compliance with ethical requirements during the implementation of approved research.

3.8. Reviewing reports of violations of bioethical standards and incidents arising during the conduct of research.

3.9. Where necessary, the Committee may review issues related to compliance with bioethical requirements in the preparation of scientific publications.

## **4. Scope of Competence of the Committee**

The Committee reviews and conducts ethical evaluation of the following types of research:

4.1. Biomedical research.

- 4.2. Research involving human participants.
- 4.3. Research involving the use of human biological materials.
- 4.4. Research involving laboratory animals.
- 4.5. Research involving microorganisms, viruses, and other biological agents.
- 4.6. Research involving cell cultures, biological samples, and genetic materials.
- 4.7. Research involving the processing of personal data.

## **5. Composition and Qualification Requirements for Committee Members**

5.1. The Local Bioethics Committee shall be composed of specialists from various fields of expertise with experience in scientific and expert activities.

5.2. The Committee shall generally consist of 7 to 15 members.

5.3. The Committee may include:

- specialists in biology, medicine, or veterinary science;
- specialists in biosafety;
- specialists in bioethics;
- legal professionals;
- representatives of the public.

5.4. To ensure independence and objectivity of the review, the Committee must include at least one independent member who is not an employee of the Institute.

5.5. Where necessary, the Committee may engage external experts with specialized knowledge.

5.6. Members of the Local Bioethics Committee must possess the necessary knowledge and experience to conduct ethical review of scientific research.

5.7. Members of the Committee must have:

- higher education in a relevant field;
- experience in scientific, medical, biological, or expert activities;
- knowledge in the field of bioethics and principles of scientific research.

5.8. Members of the Committee shall improve their qualifications in the fields of bioethics, biosafety, and research ethics.

## **6. Procedure for Forming the Committee**

6.1. The composition of the Committee shall be approved by an order of the Director of the Institute.

6.2. Proposals for the composition of the Committee may be submitted by:

- the management of the Institute;
- the Academic Council;
- structural divisions of the Institute.

6.3. The term of office of Committee members shall be three years.

6.4. Committee members may be reappointed.

6.5. The authority of a Committee member may be terminated early:

- upon the member's own request;
- by decision of the Director of the Institute;
- in case of systematic non-participation in the activities of the Committee.

## **7. Chair and Secretary of the Committee**

7.1. The activities of the Committee shall be organized by the Chair of the Committee.

7.2. The Chair of the Committee shall:

- lead and coordinate the activities of the Committee;
- organize Committee meetings;
- sign the decisions of the Committee;
- represent the Committee in its interactions with the Institute and other organizations.

7.3. A Secretary of the Committee shall be appointed to provide organizational support for the activities of the Committee.

7.4. The Secretary of the Committee shall:

- receive and register applications for ethical review;
- prepare materials for consideration at Committee meetings;
- record minutes of Committee meetings;
- ensure the proper storage of Committee documentation.

## **8. Conflict of Interest**

8.1. Members of the Committee shall avoid situations of conflict of interest when reviewing research.

8.2. In the event of a conflict of interest, the Committee member shall inform the Chair of the Committee.

8.3. A Committee member with a conflict of interest shall not participate in the discussion or voting on the relevant research project.

## **9. Committee Meetings**

9.1. Meetings of the Committee shall be held as necessary, but at least once per quarter.

9.2. Meetings may be held:

- in person;
- remotely using communication technologies.

9.3. A meeting of the Committee shall be considered valid if a quorum is present, consisting of at least half of the total membership of the Committee.

9.4. Decisions of the Committee shall be adopted by a simple majority of the members present.

9.5. In the event of a tie vote, the Chair of the Committee shall have the casting vote.

## **10. Rights of the Committee**

The Committee shall have the right to:

- request additional materials and information from applicants necessary for conducting ethical review;
- require amendments to the research protocol in order to ensure compliance with bioethical principles and biosafety requirements;
- engage independent specialists and experts with the necessary knowledge and experience for expert evaluation;
- return research proposals for revision if non-compliance with bioethical requirements is identified;
- refuse approval of research that does not comply with bioethical standards or biosafety requirements;
- request progress reports on research that has received Committee approval;
- review reports of violations of bioethical standards and adverse events occurring during the conduct of research;
- recommend to the Institute’s management the suspension or termination of research in the event of serious violations of bioethical requirements.

## **11. Responsibility of the Committee**

The Committee shall be responsible for:

- ensuring the objectivity and independence of the ethical review conducted;
- ensuring compliance with bioethical principles when reviewing scientific research;
- maintaining the confidentiality of information obtained during the review process;
- ensuring the protection of the rights, safety, and well-being of research participants;
- ensuring compliance with the legislation of the Republic of Kazakhstan and the internal regulatory documents of the Institute.

## **12. Limitation of the Committee’s Responsibility**

12.1. The Committee conducts ethical review of scientific research solely for the purpose of assessing compliance with bioethical principles and biosafety requirements.

12.2. Approval of a research project by the Committee does not entail the imposition on the Committee of liability for the conduct of the research, its scientific outcomes, the safety of the methods used, or any potential consequences arising from its implementation.

12.3. Responsibility for the conduct of the research, compliance with applicable legislation, and ensuring the safety of research participants, personnel, and the environment rests with the principal investigator and the organization conducting the research.

### **13. Submission and Review of Applications**

13.1. To undergo ethical review, the applicant shall submit to the Committee a package of documents established by the internal regulatory acts of the Institute.

13.2. The Committee reviews research:

- conducted by employees of the Institute;
- carried out on the premises or facilities of the Institute;
- conducted by other scientific and educational organizations.

13.3. The procedure for submission, review, and ethical evaluation of applications shall be determined by the Committee's internal procedures (SOPs).

### **14. Conduct of Ethical Review**

14.1. The Committee conducts an independent ethical review of scientific research to assess its compliance with bioethical principles, biosafety requirements, and applicable legislation.

14.2. When reviewing research proposals, the Committee evaluates:

- the scientific justification of the research;
- the balance between potential risks and expected benefits;
- compliance with the rights and interests of research participants;
- compliance of the research with applicable ethical standards;
- measures to ensure biosafety.

14.3. The Committee reviews submitted research materials, including:

- the research protocol;
- description of the methodology;
- information on potential risks;
- measures for risk minimization;
- documents confirming compliance with ethical requirements.

14.4. Where necessary, the Committee may request additional materials and clarifications from the applicant.

### **15. Biosafety Review**

15.1. When reviewing research involving the use of biological agents, the Committee evaluates compliance with biosafety requirements.

15.2. Biosafety review includes assessment of:

- the biosafety level of laboratories;
- working conditions with microorganisms, viruses, and other biological agents;
- personnel protection measures;
- systems for handling biological waste.

15.3. Where necessary, the Committee may engage biosafety specialists to conduct expert evaluation.

## **16. Review of Research Involving Laboratory Animals**

16.1. The Committee reviews research involving the use of laboratory animals.

16.2. During the review, the following aspects are assessed:

- the scientific necessity of using animals;
- justification for the choice of animal species;
- compliance with the principles of humane treatment of animals;
- measures to reduce pain and suffering of animals;
- conditions of animal housing and care.

16.3. The Committee may request additional materials confirming compliance with ethical principles in research involving animals.

## **17. Engagement of Experts**

17.1. For the review of specific research projects, the Committee may engage external specialists possessing the necessary knowledge and experience.

17.2. Invited experts participate in the expert evaluation of research materials but do not participate in voting when the Committee makes its decision.

17.3. Invited experts shall comply with confidentiality requirements and conflict-of-interest prevention rules.

## **18. Decisions of the Committee**

18.1. Based on the review of research materials, the Committee shall adopt one of the following decisions:

- approve the conduct of the research;
- approve the research subject to amendments or clarifications;
- return the research materials for revision;
- refuse approval of the research.

18.2. The Committee's decision shall be documented in the meeting minutes and the corresponding ethical review conclusion.

18.3. The Committee's conclusion shall be provided to the applicant in accordance with the established procedure.

## **19. Monitoring of Research**

19.1. The Committee may monitor the conduct of research that has received its approval.

19.2. Within the framework of monitoring, the Committee may:

- request progress reports on the research;
- receive information on adverse events that have occurred;
- review amendments to the research protocol.

19.3. If violations of bioethical requirements are identified, the Committee may recommend suspension or termination of the research.

## **20. Amendments to the Research Protocol**

20.1. Any amendments to the research protocol must be submitted to the Committee for review.

20.2. Amendments may be implemented only after they have been reviewed and approved by the Committee.

## **21. Confidentiality**

21.1. Members of the Committee shall maintain the confidentiality of information obtained during the review of research materials.

21.2. Research materials submitted to the Committee shall be used exclusively for the purpose of ethical review.

21.3. Members of the Committee and invited experts shall not disclose information containing:

- scientific information related to the research;
- personal data of research participants;
- commercial or other confidential information.

21.4. Confidentiality requirements also apply to external experts engaged by the Committee.

## **22. Documentation and Archiving**

22.1. All meetings of the Committee shall be documented in meeting minutes.

22.2. The minutes of the Committee meeting shall be signed by the Chair and the Secretary of the Committee.

22.3. Documents related to the activities of the Committee shall be systematically recorded and stored.

22.4. Research materials, Committee decisions, and meeting minutes shall be stored in the archive of the Institute in accordance with the established procedure.

22.5. The retention period for Committee documents shall be determined by the internal regulatory acts of the Institute.

## **23. Funding of the Committee's Activities**

23.1. The activities of the Committee may be funded from the Institute's resources as well as from other sources not prohibited by the legislation of the Republic of Kazakhstan.

23.2. Ethical review of scientific research may be conducted on a paid basis.

23.3. The cost of the review shall be determined in accordance with the price list for paid services approved in accordance with the procedures established by the Institute.

23.4. Funds received for conducting ethical reviews shall be used to support the organizational activities of the Committee and to provide remuneration to experts.

23.5. Payment for the ethical review shall not affect the independence or objectivity of the Committee's decisions.

23.6. The procedure for conducting ethical review on a paid basis shall be determined by the internal regulatory documents of the Institute.

## **24. Final Provisions**

24.1. This Regulation shall be approved by the Director of the Institute.

24.2. Amendments and additions to this Regulation shall be introduced in accordance with the procedures established by the Institute.

24.3. Organizational procedures of the Committee's activities shall be regulated by the Committee's Standard Operating Procedures (SOPs).

24.4. Matters not regulated by this Regulation shall be governed by the internal regulatory documents of the Institute.

24.5. This Regulation shall enter into force from the date of its approval.