



Research institute for biological safety problems
Local Bioethics Commission

SOP-07 Conduct of Bioethical Review of Research
Version 1.0 | page 1 / 4

APPROVED BY
General Director
“Research Institute for Biological Safety
Problems” LLP

_____ K.D. Zhugunissov
« _____ » _____ 20 _____

Conduct of Bioethical Review of Research SOP-07

REVIEWED
at the meeting of the Local Bioethics Committee
Minutes No. ____
dated “ ____ ” _____ 20 _____



Conduct of Bioethical Review of Research

1. General Provisions

1.1. This Standard Operating Procedure establishes the procedure for conducting the bioethical review of research studies by the Local Bioethics Committee (hereinafter referred to as the Committee or LBC).

1.2. The bioethical review is conducted in order to assess whether the research complies with:

- principles of bioethics;
- biosafety requirements;
- the current legislation of the Republic of Kazakhstan;
- internal regulatory documents of the Institute.

1.3. The review is conducted after submission of the application and completion of the initial administrative review.

2. Scope of Application

2.1. This SOP applies to the following types of research:

- biomedical research;
- laboratory studies involving biological materials;
- research involving microorganisms and viruses;
- research involving laboratory animals;
- research involving biological agents;
- other studies subject to bioethical review.

3. Responsible Persons

3.1. The organization of the bioethical review shall be ensured by the Chair of the Committee.

3.2. Preparation of materials for the review shall be ensured by the Secretary of the Committee.

3.3. The expert evaluation shall be conducted by the members of the Committee.

4. Submission of Materials for Review

4.1. After the administrative review, the research materials are submitted to the Chair of the Committee.

4.2. The Chair of the Committee:



- determines the procedure for reviewing the research;
- appoints a rapporteur from among the members of the Committee;
- if necessary, decides on the engagement of independent experts.

5. Preparation for the Review of Research

- 5.1. Members of the Committee shall review the research materials in advance.
- 5.2. During the preparation stage, the following aspects are assessed:
 - scientific justification of the research;
 - objectives and aims of the research;
 - research methods used;
 - potential risks associated with the research;
 - measures to minimize risks;
 - compliance with biosafety requirements.

6. Review of the Research at the Committee Meeting

- 6.1. The research review shall be conducted at a meeting of the Committee.
- 6.2. The rapporteur presents a brief description of the research.
- 6.3. During the discussion, members of the Committee consider:
 - the scientific justification of the research;
 - bioethical aspects of the research;
 - potential risks and methods for their minimization;
 - compliance with biosafety requirements;
 - protection of the rights and interests of research participants (if applicable).

7. Engagement of Experts

- 7.1. If necessary, the Committee may engage independent experts.
- 7.2. The expert may provide a written opinion or participate in the discussion of the research.
- 7.3. The expert does not participate in the voting process of the Committee.

8. Decision Making

- 8.1. Based on the results of the review, the Committee may adopt one of the following decisions:
 - approve the conduct of the research;
 - approve the research subject to required modifications;
 - return the research materials for revision;
 - refuse approval of the research.



8.2. Decisions are adopted by a majority vote of the members present at the Committee meeting.

9. Documentation of Review Results

9.1. The results of the research review are recorded in the minutes of the Committee meeting.

9.2. Based on the Committee's decision, a formal opinion on the results of the bioethical review is issued.

9.3. The opinion is communicated to the applicant.

10. Final Provisions

10.1. Compliance with this SOP shall be supervised by the Chair of the Committee.

10.2. The Secretary of the Committee shall ensure the storage of documents related to the review process.

10.3. This SOP shall enter into force by order of the Head of the Institute.