



Research institute for biological safety problems
Local Bioethics Commission

SOP-20 Bioethical Review of Research Involving Laboratory Animals
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APPROVED BY
General Director
“Research Institute for Biological Safety
Problems” LLP

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« _____ » _____ 20 _____

Bioethical Review of Research Involving Laboratory Animals SOP-20

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



Bioethical Review of Research Involving Laboratory Animals

1. General Provisions

1.1. This Standard Operating Procedure establishes the procedure for conducting bioethical review of research involving laboratory animals.

1.2. This SOP applies to all research in which laboratory animals are used.

1.3. The purpose of the review is to ensure humane treatment of animals and compliance with bioethical and biosafety requirements.

2. Scope of Application

2.1. This SOP applies to research involving:

- use of laboratory animals;
- experimental procedures performed on animals;
- infection of animals with biological agents;
- collection of biological materials from animals.

2.2. The review is conducted regardless of whether the research is carried out by:

- employees of the institute;
- students and trainees;
- external organizations.

3. Submitted Materials

3.1. For bioethical review, the applicant shall submit:

- research protocol;
- justification for the use of animals;
- description of experimental procedures;
- information on the species and number of animals;
- description of housing conditions;
- description of measures to minimize pain and distress in animals.

3.2. If necessary, additional documents related to animal housing and use may be submitted.

4. Assessment of Bioethical Aspects

4.1. During the review, the Committee evaluates:

- the scientific justification for the use of animals;
- the necessity of using the particular animal species;



- the possibility of using alternative methods;
- compliance with principles of humane treatment of animals;
- compliance with biosafety requirements.

5. Assessment of Animal Housing Conditions

5.1. The Committee evaluates:

- housing conditions of laboratory animals;
- qualifications of personnel working with animals;
- compliance with sanitary and veterinary requirements;
- availability of measures ensuring animal welfare.

6. Engagement of Experts

6.1. If necessary, the Committee may engage specialists in veterinary medicine or laboratory animal science.

6.2. Invited experts provide expert opinions.

7. Committee Decisions

7.1. Based on the review, the Committee may decide to:

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

8. Documentation

8.1. Decisions of the Committee are recorded in the minutes of the meeting.

8.2. Documents related to the review of research involving animals are attached to the materials of the respective research.

9. Final Provisions

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

9.2. The Secretary of the Committee ensures storage of documents related to the review of research involving laboratory animals.

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