



Research institute for biological safety problems
Local Bioethics Commission

SOP-19 Bioethical Review of Research Involving Pathogenic Biological Agents
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APPROVED BY
General Director
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« _____ » _____ 20 _____

Bioethical Review of Research Involving Pathogenic Biological Agents SOP-19

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



Bioethical Review of Research Involving Pathogenic Biological Agents

1. General Provisions

1.1. This Standard Operating Procedure establishes the procedure for conducting bioethical review of research involving pathogenic biological agents.

1.2. This SOP applies to research conducted using:

- microorganisms;
- viruses;
- bacterial cultures;
- genetic material of microorganisms;
- other biological agents.

1.3. The purpose of the review is to assess compliance with bioethical principles and biosafety requirements during research.

2. Scope of Application

2.1. This SOP applies to:

- laboratory research involving microorganisms;
- research involving viruses;
- research using cell cultures;
- research involving biological samples.

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;
- description of the biological agents used;
- information on methods of working with biological agents;
- description of biosafety measures;
- information on the biosafety level of the laboratory.

3.2. If necessary, additional documents confirming compliance with biosafety requirements may be submitted.



4. Assessment of Biological Risks

4.1. During the review, the Committee evaluates:

- the type of biological agents used;
- the potential hazard level of the biological agents;
- methods of handling biological agents;
- measures to prevent the spread of biological agents;
- personnel protection measures.

5. Assessment of Research Conditions

5.1. The Committee evaluates:

- compliance of the laboratory with biosafety requirements;
- availability of appropriate equipment;
- qualifications of research personnel;
- availability of biosafety instructions.

6. Engagement of Experts

6.1. If necessary, the Committee may engage specialists in biosafety.

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 additional biosafety requirements;
- 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 are attached to the materials of the respective research project.

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 pathogenic biological agents.

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