



Research institute for biological safety problems
Local Bioethics Commission

SOP-06 Initial Administrative Review of Applications for Bioethical Review
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APPROVED BY
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« _____ » _____ 20 _____

Initial Administrative Review of Applications for Bioethical Review SOP-06

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



Initial Administrative Review of Applications for Bioethical Review

1. General Provisions

1.1. This Standard Operating Procedure establishes the procedure for conducting the initial administrative review of applications submitted to the Local Bioethics Committee (hereinafter referred to as the Committee or LBC).

1.2. The initial administrative review is conducted before the materials are submitted for consideration by the Committee.

1.3. The purpose of the administrative review is to verify the completeness and correctness of the submitted documentation.

2. Responsible Persons

2.1. The initial administrative review of applications shall be carried out by the Secretary of the Committee.

2.2. Oversight of the administrative review process shall be exercised by the Chair of the Committee.

3. Review Timeline

3.1. The administrative review shall be conducted after the application has been registered.

3.2. The review shall be carried out as soon as possible after the documents are received.

4. Verification of Document Completeness

4.1. The Secretary of the Committee verifies the presence of the following documents:

- an application for bioethical review;
- the research protocol;
- a description of the research methodology;
- information on potential risks and measures for their mitigation;
- documents confirming compliance with bioethical and biosafety requirements.

4.2. Where applicable, the presence of additional documents shall also be verified, including:

- informed consent forms;
- biosafety documentation;



- documentation related to the use of laboratory animals;
- a cover letter from the scientific supervisor or advisor (for student researchers).

5. Verification of Document Format and Compliance

5.1. The Secretary of the Committee verifies:

- the presence of signatures of responsible persons;
- the availability of the researcher's contact information;
- the correct formatting of the research protocol;
- compliance of the submitted documents with the Committee's requirements.

5.2. The review is conducted without evaluating the scientific content of the research.

6. Results of the Administrative Review

6.1. Based on the results of the review, the application shall either:

- be accepted for further review;
- be returned to the applicant for revision.

6.2. If deficiencies are identified, the applicant shall be notified and provided with a list of required corrections.

7. Transfer of Materials for Further Review

7.1. Applications that have passed the administrative review are forwarded to the Chair of the Committee.

7.2. The Chair of the Committee determines the procedure for further review of the research.

8. Documentation

8.1. Information on the results of the administrative review shall be recorded by the Secretary of the Committee.

8.2. The documents shall be stored within 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 shall ensure the storage of documents related to the administrative review of applications.

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