



Research institute for biological safety problems
Local Bioethics Commission

SOP-05 Submission of Applications for Bioethical Review
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APPROVED BY
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« _____ » _____ 20 _____

Submission of Applications for Bioethical Review SOP-04

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



Submission of Applications for Bioethical Review

1. General Provisions

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

1.2. This procedure applies to all research studies subject to bioethical review.

1.3. Submission of an application for bioethical review is mandatory prior to the commencement of the research.

1.4. This SOP applies to research studies:

- conducted by employees of the Institute;
- conducted by students and applicants for academic degrees;
- conducted in collaboration with other organizations;
- conducted by external organizations upon request to the Institute's LBC.

2. Persons Eligible to Submit an application

2.1. An application for bioethical review shall be submitted by the Principal Investigator.

2.2. The Principal Investigator may be:

- an employee of the Institute;
- the scientific supervisor or advisor of a student;
- a researcher from another scientific or educational organization.

2.3. The Principal Investigator is responsible for the accuracy and completeness of the submitted materials.

3. Application Document Package

3.1. To obtain bioethical review, the applicant shall submit the following documents to the Committee:

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

3.2. Depending on the nature of the research, additional documents may be required, including:

- informed consent forms for research participants;



- biosafety documentation;
- documentation related to the use of laboratory animals;
- information on biological materials.

4. Requirements for the Research Protocol

4.1. The research protocol shall include:

- the title of the research study;
- the objectives and aims of the research;
- a description of the research methods;
- a description of the biological materials used;
- a description of potential risks;
- measures for risk mitigation;
- information on compliance with biosafety requirements.

4.2. The research protocol shall be signed by the Principal Investigator.

5. Specific Requirements for Applications Submitted by Students

5.1. When research is submitted by students (Master's students, PhD candidates, or other students), the application shall be accompanied by a letter from the scientific supervisor or advisor.

5.2. The scientific supervisor or advisor confirms:

- scientific supervision or consultation of the research;
- approval of the research topic;
- responsibility for the scientific guidance of the research.

6. Applications Submitted by External Organizations

6.1. The Institute's LBC may conduct bioethical review of research carried out in other organizations upon an official request from the researcher or the organization.

6.2. When an application is submitted by an external organization, the following additional documents shall be provided:

- an official request letter from the organization;
- information about the location where the research will be conducted;
- information about the research conditions;
- information about the responsible researcher.

7. Application Submission Procedure

7.1. The application and the document package shall be submitted to the Secretary of the Committee.



7.2. The Secretary of the Committee shall:

- register the application;
- verify the completeness of the submitted documents;
- assign a registration number.

7.3. If the document package is incomplete, the application shall be returned to the applicant for revision.

8. Registration of Applications

8.1. Each application shall be assigned a registration number.

8.2. Applications shall be recorded in the Bioethical Review Registration Log.

8.3. The registration number shall be used in the subsequent review of the research and in the documentation of the Committee's decisions.

9. Transfer of Materials for Committee Review

9.1. After registration, the Secretary of the Committee submits the materials to the Chair of the Committee.

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

9.3. The research may be referred:

- for review at a Committee meeting;
- for expedited review (in cases provided for by the SOP).

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 registration of applications and the storage of relevant documents.

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