



Research institute for biological safety problems
Local Bioethics Commission

SOP-10 Review of Amendments and Modifications to Research Protocols
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APPROVED BY
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« _____ » _____ 20 _____

Review of Amendments and Modifications to Research Protocols SOP-10

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



Review of Amendments and Modifications to Research Protocols

1. General Provisions

1.1. This Standard Operating Procedure establishes the procedure for reviewing amendments and modifications to research protocols previously approved by the Local Bioethics Committee (hereinafter referred to as the Committee or LBC).

1.2. Any amendments to a research protocol must be reviewed by the Committee before their implementation.

1.3. Amendments to a research protocol without review by the Committee are not permitted.

2. Grounds for Amendments

2.1. Amendments to a protocol may be introduced in the following cases:

- modification of research methods;
- change in the scope of the research;
- change in the biological materials used;
- change in the conditions under which the research is conducted;
- clarification or adjustment of research procedures.

3. Submission of Amendment Request

3.1. The Principal Investigator shall submit a request to the Committee for review of the proposed amendments.

3.2. The request shall include:

- a description of the proposed amendments;
- an updated version of the research protocol;
- justification for the proposed changes.

4. Administrative Review of Documents

4.1. The submitted documents undergo administrative review by the Secretary of the Committee.

4.2. The following aspects are verified:

- the presence of all required documents;
- correctness of document formatting.



5. Procedure for Reviewing Amendments

5.1. The Chair of the Committee determines the procedure for reviewing the proposed amendments.

5.2. Amendments may be reviewed:

- at a meeting of the Committee;
- through the expedited review procedure.

5.3. During the review of amendments, the Committee evaluates:

- the impact of the amendments on the bioethical aspects of the research;
- potential changes in the level of risk;
- compliance with biosafety requirements.

6. Decisions Following Review

6.1. Based on the review, the Committee may adopt one of the following decisions:

- approve the amendments;
- return the amendments for revision;
- reject the proposed amendments.

6.2. The decision of the Committee shall be documented in accordance with established procedures.

7. Implementation of Amendments

7.1. Amendments to the protocol may be implemented only after approval by the Committee.

7.2. After approval, the updated version of the protocol becomes the valid version.

8. Documentation

8.1. All protocol amendments are recorded in the Committee documentation.

8.2. The documents are stored together with the materials of the respective research study.

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 the storage of documents related to protocol amendments.

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