



Research institute for biological safety problems
Local Bioethics Commission

SOP-13 Review of Protocol Violations
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APPROVED BY
General Director
“Research Institute for Biological Safety
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« _____ » _____ 20 _____

Review of Protocol Violations SOP-13

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



Review of Protocol Violations

1. General Provisions

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

1.2. A protocol violation is defined as any deviation from the research protocol approved by the Committee.

1.3. Review of violations is conducted to ensure compliance with bioethical requirements and biosafety standards.

2. Types of Violations

2.1. Protocol violations may include:

- conducting procedures not предусмотренных in the approved protocol;
- changing research methods without approval from the Committee;
- failure to comply with biosafety requirements;
- failure to comply with bioethical requirements;
- other deviations from the approved protocol.

3. Reporting a Violation

3.1. The Principal Investigator must immediately inform the Committee about any identified protocol violation.

3.2. The report of violation must include:

- description of the violation;
- causes of the violation;
- possible consequences of the violation;
- measures taken to eliminate the violation.

4. Review of the Violation

4.1. The received information is reviewed by the Committee.

4.2. During the review, the Committee evaluates:

- the nature and severity of the violation;
- the impact of the violation on the bioethical aspects of the research;
- the impact of the violation on research safety.



5. Decisions of the Committee

5.1. Based on the review results, the Committee may decide to:

- acknowledge the reported violation;
- require correction of the identified violations;
- require amendments to the research protocol;
- consider suspension of the research;
- consider termination of the research.

6. Documentation

6.1. Information about protocol violations is recorded in the Committee documentation.

6.2. Documents related to the review of the violation are attached to the materials of the respective research.

7. Final Provisions

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

7.2. The Secretary of the Committee ensures storage of documents related to protocol violation review.

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