



Research institute for biological safety problems
Local Bioethics Commission

SOP-11 Monitoring of Research Progress
Version 1.0 | page 1 / 3

APPROVED BY
General Director
“Research Institute for Biological Safety
Problems” LLP

_____ K.D. Zhugunissov
« _____ » _____ 20 _____

Monitoring of Research Progress SOP-11

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



Monitoring of Research Progress

1. General Provisions

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

1.2. Monitoring is conducted to ensure compliance with bioethical requirements and biosafety standards during the conduct of research.

1.3. Monitoring applies throughout the entire period of the research.

2. Forms of Monitoring

2.1. Monitoring of research progress may be carried out in the following forms:

- review of interim reports submitted by researchers;
- analysis of information on the progress of the research;
- review of reports on problems or violations that have occurred;
- requests for additional information from the researcher.

3. Responsibilities of the Researcher

3.1. The Principal Investigator shall inform the Committee about the progress of the research.

3.2. The researcher shall report to the Committee about:

- significant changes in the conditions of the research;
- the occurrence of unforeseen risks;
- identified violations of the research protocol;
- early termination of the research.

4. Review of Information on Research Progress

4.1. The Committee reviews incoming information regarding the progress of the research.

4.2. During the review, the Committee evaluates:

- compliance with the approved research protocol;
- compliance with bioethical requirements;
- compliance with biosafety requirements.

5. Response to Identified Violations

5.1. In case violations are identified, the Committee may:



- request additional explanations from the researcher;
- require correction of identified violations;
- consider suspension of the research;
- consider termination of the research.

6. Documentation of Monitoring

6.1. Information on research monitoring is recorded in the Committee documentation.

6.2. All materials related to research monitoring are stored in the documentation of the respective project.

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 the storage of documents related to research monitoring.

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