



Research institute for biological safety problems  
Local Bioethics Commission

SOP-02 Development, Approval and Revision of Standard Operating Procedures (SOP)  
Version 1.0 | page 1 / 4

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

\_\_\_\_\_ K.D. Zhugunissov  
« \_\_\_\_\_ » \_\_\_\_\_ 20 \_\_\_\_\_

## **Development, Approval and Revision of Standard Operating Procedures (SOP) SOP-02**

REVIEWED  
at the meeting of the Local Bioethics Committee  
Minutes No. \_\_\_\_\_  
dated “ \_\_\_\_\_ ” \_\_\_\_\_ 20 \_\_\_\_\_

Gvardeyskiy, 2026



## SOP-02

# Development, Approval and Revision of Standard Operating Procedures (SOP)

## 1. General Provisions

1.1. This Standard Operating Procedure establishes the procedure for the development, formatting, approval, dissemination, and revision of the Standard Operating Procedures (SOPs) of the Local Bioethics Committee (hereinafter referred to as the Committee or LBC).

1.2. SOPs are intended to regulate the activities of the Committee and ensure the consistent implementation of ethical review procedures.

1.3. All procedures of the Committee's activities shall be performed in accordance with approved SOPs.

1.4. The requirements of this SOP apply to:

- members of the Committee;
- the Secretary of the Committee;
- independent experts engaged by the Committee.

## 2. Purpose of Standard Operating Procedures

2.1. Standard Operating Procedures establish unified rules for:

- organization of the Committee's activities;
- ethical review of research studies;
- documentation of the Committee's decisions;
- documentation management and archiving of materials.

2.2. The implementation of SOPs ensures:

- transparency of the Committee's work;
- consistency of research review procedures;
- compliance with bioethical and biosafety requirements;
- alignment of the Committee's activities with international standards of ethical review.

## 3. Development of SOPs

3.1. SOPs are developed based on the decision of the Committee or at the request of the Chair of the Committee.

3.2. Draft SOPs may be prepared by:

- members of the Committee;
- the Secretary of the Committee;
- a working group appointed by the Chair of the Committee.



3.3. The development of SOPs takes into account:

- the legislation of the Republic of Kazakhstan;
- international recommendations in the field of bioethics;
- the Regulations of the Local Bioethics Committee of the Institute;
- practical needs of the Committee's activities.

#### **4. Structure of SOPs**

4.1. Each Standard Operating Procedure is prepared according to a unified structure.

4.2. An SOP includes the following sections:

- SOP number;
- title of the procedure;
- scope of application;
- description of the procedure;
- responsibility for implementation;
- final provisions.

4.3. Each SOP is assigned a unique number.

Example designation: SOP-01, SOP-02, SOP-03, etc.

#### **5. Review and Approval of SOPs**

5.1. Draft SOPs are reviewed at a meeting of the Committee.

5.2. Following the review, the Committee adopts one of the following decisions:

- approve the SOP;
- return the SOP for revision.

5.3. Approved SOPs enter into force upon approval by order of the Director of the Institute.

#### **6. Registration of SOPs**

6.1. All approved SOPs are subject to registration.

6.2. SOP registration is carried out by the Secretary of the Committee.

6.3. The Secretary maintains the register of Standard Operating Procedures, which includes:

- SOP number;
- title of the procedure;
- date of approval;
- date of entry into force.



## **7. Dissemination of SOPs**

7.1. After approval, the SOP is communicated to the members of the Committee.

7.2. Current versions of SOPs are stored:

- by the Chair of the Committee;
- by the Secretary of the Committee;
- in the Committee archive.

7.3. The use of outdated versions of SOPs is not permitted.

## **8. Revision of SOPs**

8.1. SOPs are subject to periodic revision.

8.2. SOP revision is carried out:

- as necessary;
- when legislation changes;
- when the structure or functions of the Committee change.

8.3. The decision to revise an SOP is made by the Committee.

8.4. Amendments to SOPs are approved in accordance with the established procedure.

## **9. Final Provisions**

9.1. Compliance with this SOP is supervised by the Chair of the Committee.

9.2. Responsibility for maintaining the SOP register and storing documents is assigned to the Secretary of the Committee.

9.3. This SOP enters into force upon approval by the order of the Director of the Institute.