



Research institute for biological safety problems  
Local Bioethics Commission

SOP-00 Structure and Numbering of Standard Operating Procedures of the Local  
Bioethics Committee  
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APPROVED BY  
General Director  
“Research Institute for Biological Safety  
Problems” LLP

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

## **Structure and Numbering of Standard Operating Procedures of the Local Bioethics Committee SOP-00**

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



## **Structure and Numbering of Standard Operating Procedures of the Local Bioethics Committee**

### **1. General Provisions**

1.1. This Standard Operating Procedure establishes the structure, numbering system, and classification of Standard Operating Procedures (SOPs) of the Local Bioethics Committee (hereinafter referred to as the Committee or LBC).

1.2. Standard Operating Procedures (SOPs) constitute the primary internal regulatory documents governing the activities of the Committee.

1.3. This SOP applies to all standard operating procedures used in the activities of the Committee.

### **2. Purpose of SOPs**

2.1. Standard Operating Procedures establish unified rules for:

- organization of the Committee’s activities;
- ethical review of research studies;
- monitoring of ongoing research;
- conduct of Committee meetings;
- documentation and archiving of materials.

2.2. The implementation of SOPs ensures:

- consistency of the Committee’s procedures;
- transparency of the Committee’s activities;
- compliance with bioethical principles;
- compliance with biosafety requirements.

### **3. SOP Numbering System**

3.1. Each Standard Operating Procedure is assigned a unique number.

3.2. The SOP number consists of the designation SOP followed by the sequential number of the procedure. Example: SOP-01, SOP-02, SOP-03, etc.

3.3. SOP numbering is assigned sequentially.

### **4. Classification of SOPs**

4.1. Standard Operating Procedures of the Local Bioethics Committee are grouped into the following categories.

Organization of Committee activities



- SOP-01 Organization of the activities of the local bioethics committee
- SOP-02 Development, approval and revision of SOPs
- SOP-03 Confidentiality of information and prevention of conflict of interest
- SOP-04 Engagement of independent experts

#### Application processing

- SOP-05 Submission of applications for bioethical review
- SOP-06 Initial administrative review of applications for bioethical review

#### Ethical review procedures

- SOP-07 Conduct of bioethical review of research
- SOP-08 Expedited ethical review
- SOP-09 Review of resubmitted applications for bioethical review
- SOP-10 Review of amendments and modifications to research protocols

#### Monitoring of research

- SOP-11 Monitoring of research progress
- SOP-12 Review of final research reports
- SOP-13 Review of protocol violations
- SOP-14 Suspension or termination of research

#### Committee meetings

- SOP-15 Preparation of the agenda for meetings of the Committee
- SOP-16 Conducting of extraordinary meetings of the Committee

#### Documentation management

- SOP-17 Documentation management of the Committee
- SOP-18 Storage and archiving of documents of the Committee

#### Specialized procedures

- SOP-19 Bioethical review of research involving pathogenic biological agents
- SOP-20 Bioethical review of research involving laboratory animals
- SOP-21 Use of LBC decisions in international scientific publications
- SOP-22 Issuance of ethical approval certificate

## **5. Amendments to the SOP System**

5.1. The Committee may develop additional Standard Operating Procedures when necessary.

5.2. New procedures are incorporated into the SOP system by assigning the next sequential number.

5.3. Amendments to the SOP structure are approved in accordance with the established procedure.

## **6. Final Provisions**

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



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6.2. The Secretary of the Committee maintains the register of Standard Operating Procedures.

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