



Research institute for biological safety problems  
Local Bioethics Commission

SOP-01 Organization of the Activities of the Local Bioethics Committee  
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APPROVED BY  
General Director  
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« \_\_\_\_\_ » \_\_\_\_\_ 20 \_\_\_\_\_

## **Organization of the Activities of the Local Bioethics Committee SOP-01**

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



## **Organization of the Activities of the Local Bioethics Committee**

### **1. General Provisions**

1.1. This Standard Operating Procedure (SOP) establishes the procedure for organizing the activities of the Local Bioethics Committee (hereinafter referred to as the Committee or LBC) of the Research Institute for Biological Safety Problems.

1.2. This SOP defines:

- the organization of the Committee’s work;
- the distribution of responsibilities among Committee members;
- the procedures for preparation and conduct of meetings;
- the procedures for decision-making by the Committee;
- the procedures for interaction between the Committee and researchers.

1.3. This procedure applies to all types of research subject to ethical review by the Local Bioethics Committee of the Institute.

1.4. The Committee performs its activities in accordance with:

- the legislation of the Republic of Kazakhstan;
- internationally recognized bioethical principles;
- the Regulations on the Local Bioethics Committee of the Institute;
- these Standard Operating Procedures.

### **2. Fundamental Principles of the Committee’s Activities**

The Committee performs its activities based on the following principles:

- independence in decision-making;
- objectivity and scientific validity of ethical review;
- compliance with bioethical standards;
- protection of the rights and safety of research participants;
- compliance with biosafety requirements;
- confidentiality of information.

### **3. Composition of the Committee**

3.1. The composition of the Committee is approved by the order of the Director of the Institute.

3.2. The Committee typically consists of 7 to 15 members.

3.3. The Committee includes specialists from different fields of expertise to ensure comprehensive evaluation of research studies.

3.4. The Committee includes:

- specialists in biology, medicine, or veterinary sciences;



- specialists in biosafety;
- specialists in bioethics;
- legal experts;
- representatives of the public.

3.5. At least one member of the Committee shall be independent and not affiliated with the Institute.

3.6. The Committee may involve independent experts in the review of specific research studies.

#### **4. Chair of the Committee**

4.1. The activities of the Committee are organized by the Chair of the Committee.

4.2. The Chair:

- organizes the activities of the Committee;
- approves the meeting agenda;
- presides over meetings;
- signs the Committee's decisions;
- represents the Committee in interactions with the Institute's administration and external organizations.

4.3. The Chair ensures adherence to the principles of independence and objectivity in ethical review.

#### **5. Secretary of the Committee**

5.1. Administrative support of the Committee is provided by the Secretary of the Committee.

5.2. The Secretary:

- receives and registers applications for ethical review;
- conducts an initial administrative review of submitted documents;
- prepares materials for consideration by the Committee;
- prepares the meeting agenda;
- records minutes of meetings;
- ensures proper storage of Committee documents.

5.3. The Secretary maintains:

- the register of applications for ethical review;
- the register of Committee decisions;
- the archive of Committee documentation.



## **6. Members of the Committee**

6.1. Members of the Committee participate in the activities of the Committee and in the review of research studies.

6.2. Members of the Committee are required to:

- participate in Committee meetings;
- conduct expert evaluation of submitted materials;
- maintain confidentiality;
- prevent conflicts of interest.

6.3. In the event of a conflict of interest, a Committee member must inform the Chair and refrain from participating in the discussion of the relevant research project.

## **7. Preparation of Committee Meetings**

7.1. Committee meetings are held as necessary, but at least once per quarter.

7.2. Meeting preparation is carried out by the Secretary of the Committee.

7.3. During preparation of the meeting, the Secretary:

- registers incoming applications for ethical review;
- verifies the completeness of submitted documents;
- prepares a list of research projects for review;
- prepares materials for Committee members;
- prepares the draft meeting agenda.

7.4. Materials for review are distributed to Committee members in advance for preliminary consideration.

## **8. Conduct of Committee Meetings**

8.1. Committee meetings are conducted under the leadership of the Chair.

8.2. In the absence of the Chair, the meeting is conducted by the Deputy Chair or a Committee member designated by the Chair.

8.3. A Committee meeting is considered valid if a quorum is present.

8.4. The quorum constitutes at least half of the total membership of the Committee.

8.5. Committee meetings may be held:

- in person;
- using remote communication technologies.

8.6. During the meeting the Committee:

- reviews the submitted research materials;
- discusses the bioethical aspects of the study;
- evaluates potential risks;
- evaluates biosafety measures;
- makes a decision based on the review.



## **9. Review of Research Materials**

9.1. When reviewing a study, the Committee evaluates:

- the scientific justification of the research;
- compliance of the research with bioethical principles;
- the balance between potential benefits and possible risks;
- compliance with biosafety requirements;
- protection of the rights and interests of research participants (if applicable).

9.2. If necessary, the Committee may:

- request additional materials from the applicant;
- invite the researcher to clarify specific issues;
- involve independent experts.

## **10. Decision-Making by the Committee**

10.1. Decisions of the Committee are made by voting.

10.2. A decision is considered adopted if supported by a simple majority of the members present at the meeting.

10.3. In the event of a tie, the vote of the Chair is decisive.

10.4. Based on the review of a research project, the Committee may adopt one of the following decisions:

- approve the research;
- approve the research with required modifications;
- return the research materials for revision;
- refuse approval of the research.

## **11. Documentation of Committee Decisions**

11.1. Committee decisions are documented in the minutes of the meeting.

11.2. The meeting minutes include:

- date and place of the meeting;
- list of members present;
- meeting agenda;
- brief description of the research reviewed;
- voting results;
- the adopted decision.

11.3. The minutes are signed by:

- the Chair of the Committee;
- the Secretary of the Committee.

11.4. Based on the decision of the Committee, the applicant is provided with the conclusion of the ethical review.



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## **12. Final Provisions**

12.1. This procedure applies to all meetings of the Local Bioethics Committee.

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

12.3. Amendments and additions to this procedure are made in accordance with the established procedure.

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