



Research institute for biological safety problems  
Local Bioethics Commission

SOP-17 Documentation Management of the Local Bioethics Committee  
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APPROVED BY  
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« \_\_\_\_\_ » \_\_\_\_\_ 20 \_\_\_\_\_

## Documentation Management of the Local Bioethics Committee SOP-17

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



## **Documentation Management of the Local Bioethics Committee**

### **1. General Provisions**

1.1. This Standard Operating Procedure establishes the procedure for maintaining documentation of the Local Bioethics Committee (hereinafter referred to as the Committee or LBC).

1.2. The documentation of the Committee is maintained to ensure transparency of the Committee's activities and proper record-keeping of bioethical review materials.

1.3. Committee documents shall be registered, systematized, and stored.

### **2. Responsible Persons**

2.1. Documentation management of the Committee is carried out by the Secretary of the Committee.

2.2. Oversight of documentation management is carried out by the Chair of the Committee.

### **3. Main Types of Documentation**

3.1. The following documents are maintained by the Local Bioethics Committee:

- register of applications for bioethical review;
- register of Committee decisions;
- minutes of Committee meetings;
- conclusions of bioethical review;
- documents submitted by applicants;
- expert opinions.

3.2. Committee documents are organized separately for each research study.

### **4. Registration of Documents**

4.1. All incoming documents shall be registered.

4.2. Registration is carried out in the appropriate record registers.

4.3. The following information is recorded during registration:

- document registration number;
- date of registration;
- title of the document;
- information about the applicant.



## **5. Preparation of Meeting Minutes**

5.1. Minutes shall be prepared following each Committee meeting.

5.2. The minutes shall include:

- date and place of the meeting;
- list of Committee members present;
- meeting agenda;
- issues discussed;
- decisions taken.

5.3. The minutes shall be signed by the Chair and the Secretary of the Committee.

## **6. Storage of Documents**

6.1. Committee documents shall be systematized and stored in accordance with established procedures.

6.2. Documents are organized into separate files for each research study.

6.3. Access to Committee documentation is provided in accordance with confidentiality requirements.

## **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 registration, systematization, and storage of Committee documents.

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