



Research institute for biological safety problems
Local Bioethics Commission

SOP-18 Storage and Archiving of Documents of the Local Bioethics Committee
Version 1.0 | page 1 / 3

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

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

Storage and Archiving of Documents of the Local Bioethics Committee SOP-18

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



Storage and Archiving of Documents of the Local Bioethics Committee

1. General Provisions

1.1. This Standard Operating Procedure establishes the procedure for storage and archiving of documents of the Local Bioethics Committee (hereinafter referred to as the Committee or LBC).

1.2. Document storage is carried out to ensure preservation of bioethical review materials and the possibility of future reference.

1.3. Committee documents shall be subject to systematic recording, storage, and archiving.

2. Responsible Persons

2.1. The Secretary of the Committee is responsible for the storage and archiving of documents.

2.2. Oversight of compliance with document storage rules is carried out by the Chair of the Committee.

3. Documents Subject to Storage

3.1. The Committee archive shall contain:

- applications for bioethical review;
- research protocols;
- expert opinions;
- minutes of Committee meetings;
- Committee decisions;
- documents related to research monitoring;
- final research reports;
- documents related to protocol violations;
- other materials related to the activities of the Committee.

4. Systematization of Documents

4.1. Documents are systematized for each research study.

4.2. Research materials are compiled into separate files.

4.3. Each file is assigned a registration number.



5. Retention Period

5.1. Documents of the Local Bioethics Committee are stored for the period established by the internal regulations of the institute.

5.2. Documents shall be stored in a manner that ensures their preservation and accessibility.

6. Access to Archived Documents

6.1. Access to archived documents is provided in accordance with confidentiality requirements.

6.2. Access to documents may be granted to:

- members of the Committee;
- the management of the institute;
- other persons in cases provided for by legislation.

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 systematization, storage, and archiving of Committee documents.

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