



Research institute for biological safety problems  
Local Bioethics Commission

SOP-09 Review of Resubmitted Applications for Bioethical Review  
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APPROVED BY  
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## Review of Resubmitted Applications for Bioethical Review SOP-09

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



## **Review of Resubmitted Applications for Bioethical Review**

### **1. General Provisions**

1.1. This Standard Operating Procedure establishes the procedure for the review of resubmitted applications for bioethical review by the Local Bioethics Committee (hereinafter referred to as the Committee or LBC).

1.2. Resubmission review is conducted when previously submitted research materials were returned by the Committee for revision.

1.3. The repeated review is conducted after the applicant has introduced the required changes to the research documentation.

### **2. Grounds for Resubmission Review**

2.1. Resubmission review is conducted in the following cases:

- modification of the research protocol as required by the Committee;
- submission of additional information requested by the Committee;
- correction of deficiencies identified during the previous review.

2.2. The resubmitted application shall be submitted by the applicant after the identified deficiencies have been corrected.

### **3. Documentation for Resubmission**

3.1. When resubmitting an application, the applicant shall provide:

- a revised research protocol;
- a list of changes made;
- additional documents requested by the Committee.

3.2. The list of changes shall include a description of corrections made to the research materials.

### **4. Administrative Review of the Resubmitted Application**

4.1. The resubmitted application undergoes administrative review in accordance with the relevant SOP.

4.2. The Secretary of the Committee verifies:

- the presence of revised documents;
- whether the submitted changes correspond to the comments of the Committee.



## **5. Procedure for Reviewing the Resubmitted Application**

5.1. The Chair of the Committee determines the procedure for reviewing the resubmitted application.

5.2. The resubmitted application may be reviewed:

- at a meeting of the Committee;
- through the expedited review procedure.

5.3. During the repeated review, the Committee evaluates:

- whether previously identified deficiencies have been corrected;
- whether the updated materials comply with bioethical and biosafety requirements.

## **6. Decisions Following Resubmission Review**

6.1. Based on the results of the resubmission review, the Committee may adopt one of the following decisions:

- approve the conduct of the research;
- return the materials for further revision;
- refuse approval of the research.

6.2. The decision of the Committee shall be documented in accordance with established procedures.

## **7. Documentation**

7.1. Information on the resubmission review shall be recorded in the Committee documentation.

7.2. The documents of the resubmitted application shall be attached to the materials of the respective research study.

## **8. Final Provisions**

8.1. Compliance with this SOP shall be supervised by the Chair of the Committee.

8.2. The Secretary of the Committee ensures the storage of documents related to resubmitted applications.

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