



Research institute for biological safety problems
Local Bioethics Commission

SOP-08 Expedited Bioethical Review
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APPROVED BY
General Director
“Research Institute for Biological Safety
Problems” LLP

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« _____ » _____ 20 _____

Expedited Bioethical Review SOP-08

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



Expedited Bioethical Review

1. General Provisions

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

1.2. Expedited review is applied to research studies presenting minimal bioethical risk.

1.3. Expedited review is conducted without consideration of the research at a full meeting of the Committee.

2. Grounds for Expedited Review

2.1. Expedited review may be applied in the following cases:

- in vitro studies;
- research using previously collected biological materials;
- studies that do not involve intervention in the human body;
- laboratory studies involving minimal risk;
- minor amendments to previously approved research protocols.

2.2. Expedited review shall not be applied to studies:

- involving human participants;
- associated with increased biological risk;
- involving high-risk pathogenic biological agents.

3. Responsible Persons

3.1. The decision to conduct an expedited review is made by the Chair of the Committee.

3.2. The expert evaluation is conducted by:

- the Chair of the Committee;
- one or more members of the Committee appointed by the Chair.

4. Conduct of Expedited Review

4.1. Research materials are submitted to the designated members of the Committee for expert evaluation.

4.2. The experts review the submitted materials and assess:

- the scientific justification of the research;
- compliance with bioethical principles;



- compliance with biosafety requirements;
- the presence of potential risks.

5. Decisions Following Expedited Review

5.1. Based on the results of the expedited review, one of the following decisions may be made:

- approve the conduct of the research;
- return the research materials for revision;
- refer the research for review at a full meeting of the Committee.

5.2. The decision shall be documented in accordance with established procedures.

6. Informing the Committee

6.1. Information about the conducted expedited review shall be communicated to the members of the Committee.

6.2. The decision shall be recorded in the Committee documentation.

7. Documentation

7.1. The results of the expedited review are formalized in the form of a written opinion.

7.2. The opinion is stored together with 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 registration and storage of documents related to expedited review.

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