



Research institute for biological safety problems
Local Bioethics Commission

SOP-04 Engagement of Independent Experts
Version 1.0 | page 1 / 3

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

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

Engagement of Independent Experts SOP-04

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



Engagement of Independent Experts

1. General Provisions

1.1. This Standard Operating Procedure establishes the procedure for engaging independent experts to conduct the bioethical review of research studies considered by the Local Bioethics Committee (hereinafter referred to as the Committee or LBC).

1.2. Independent experts are engaged when the evaluation of a research study requires specialized scientific, technical, or expert competence.

1.3. Independent experts are engaged in order to ensure the objectivity and scientific validity of the bioethical review.

2. Grounds for Engaging Experts

2.1. The Committee engages independent experts in the following cases:

- when specialized scientific evaluation of a study is required;
- when complex biological technologies are used;
- when studies involve pathogenic biological agents;
- when studies involve the use of laboratory animals;
- when evaluation of biosafety issues is required;
- when assessment of specific research methods is necessary.

2.2. The decision to engage an expert is made by the Chair of the Committee or by the Committee during a meeting.

3. Requirements for Independent Experts

3.1. An independent expert may be a specialist possessing the necessary qualifications and experience in the relevant field of science.

3.2. The expert must have:

- higher education in the relevant field;
- scientific or professional experience related to the research under review;
- competencies required to conduct expert evaluation.

3.3. An independent expert must not have a conflict of interest in relation to the research under review.

4. Procedure for Engaging Experts

4.1. A proposal to engage an expert may be made by:

- the Chair of the Committee;



- members of the Committee;
 - the Secretary of the Committee.
- 4.2. The Secretary of the Committee is responsible for:
- sending the research materials to the expert;
 - receiving the expert opinion;
 - registering the expert opinion.
- 4.3. The expert opinion shall be submitted in written form.

5. Participation of an Expert in Committee Meetings

- 5.1. An independent expert may be invited to attend a Committee meeting to present an expert opinion.
- 5.2. The independent expert:
- participates in the discussion of the research study;
 - provides expert clarifications to the members of the Committee.
- 5.3. The independent expert does not participate in voting when the Committee makes its decision.

6. Confidentiality and Conflict of Interest

- 6.1. An independent expert shall comply with confidentiality requirements.
- 6.2. Prior to the commencement of the expert review, the expert signs a confidentiality agreement.
- 6.3. The expert must disclose any potential conflict of interest.
- 6.4. If a conflict of interest exists, the expert shall not be involved in the review of the research.

7. Documentation of Expert Evaluation

- 7.1. The expert opinion shall be attached to the materials of the research review.
- 7.2. The expert opinion shall be stored together with the documents of the respective research study.
- 7.3. Information about the engagement of the expert shall be recorded in the minutes of the Committee meeting.

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 shall ensure the storage of documents related to the engagement of experts.
- 8.3. This SOP shall enter into force by order of the Head of the Institute.