**Appendix 6**

**Standard operating procedure**

**for reviewing applications from third-party organizations to the local**

**ethics commission**

**Package of documents to be submitted to the Commission for consideration**

The dossier should include the following documents:

1. List of submitted documents with version numbers and dates;

2. Test or experiment report;

3. List of scientific centers where research, testing or experiment is planned to be conducted;

4. Curriculum vitae (CV) of the researcher (brief description of professional activity).

5. Previous decisions of the domestic ethics committees in relation to this planned research, test or experiment, if any.

**For clinical studies, trials or experiments involving a person as an object of research, trial or experiment, the following set of documents must be submitted to the Commission:**

1. Signed by the applicant and dated application addressed to the Chairman of the Commission. The application specifies the full name of the study, test or experiment, provides a list of submitted documents, contact person details to clarify emerging issues on the part of the Commission (for example, the coordinator of the study).

2. Abstract to the planned research, test or experiment (signed by the executor and the scientific director of the project), in which the goals, objectives, materials and methods of research, testing or experiment, justification of scientific novelty and expediency, expected results are formulated.

3. A list of criteria for inclusion, non-inclusion and exclusion of volunteers in a study, trial or experiment, a plan (scheme) of a study, trial or experiment. Basic information about the studied means or method (including instructions for the use of the studied means).

4. Information for the patient and the patient's informed consent form.

5. The form of the individual registration card of the patient (if any).

6. Diaries, questionnaires to be filled out by patients participating in a study, trial or experiment (if any).

7. Curriculum vitae (CV) of researchers, dated and signed by researchers (Principal Investigator);

8. List of clinical research centers where it is planned to conduct a study, trial or experiment;

9. Information about insurance documents, compensations and payments provided for the subjects of the study, trial or experiment during the study, trial or experiment;

10. Materials, including advertising, informing about the study, trial or experiment and used to attract patients to participate in it.

At the discretion of the applicant, other documents relevant to compliance with ethical standards during the planned research, test or experiment may be additionally submitted and considered.

When submitting additions and amendments to previously approved protocols for examination, annotations (a summary of the essence of the changes and their causes) are submitted.

Note: documents are provided in a folder, separated by separators, with a detailed description (dates and version numbers) in paper and electronic form.