**Application 2**

**Form A. Research application**

**LIST AND SAMPLES OF DOCUMENTS**

The dossier documents must be sent online through the main website of the University, the Science section, then the Bioethical Commission (BC), and also submitted in a file folder, through separators. A detailed list of documents (dates and version numbers) in paper (1 copy) and electronic form by e-mail [lbk\_zkmu@mail.ru](mailto:lbk_zkmu@mail.ru).

1. Application addressed to the Chairman of the BC **(Form A-1)**

2.Research application **(Form A-2)**  
3. Informed consent with information for a participant in the official and Russian languages **(Form A-3).**

**3.1** for clinical trials of medicinal products, a “Information leaflet of a patient participating in a clinical trial of a medicinal product” is required;

**3.2.** in cases of research work with databases, it is sufficient to provide a document confirming the consent of the head to receive the data. When conducting surveys of respondents, information is written for the participant at the beginning of the survey, answering which the participant agrees to participate in the study.

4. Abstract (Form A-4)

5. Scales, questionnaires, algorithms or other datas, used in scientific work, attached in the original language.

6. Investigator's brochure on clinical trials.

8. The current Curriculum vitae (CV) of the researchers, signed by the researchers and dated. Copies of GCP and GLP certifications for Principal Investigators (required) and Research Team Members (if available). GLP certificate, if available.

List of members of the research team with their current qualifications. For the Principal Investigators - documents confirming their medical specialization in the research being carried out and at least five years of experience in clinical research.

When submitting an application for reconsideration (when changing the plan and protocol of the study), attach the documents of the new version and indicate that the application is repeated (attach the previous version of the decision of the Local Bioethics Commission). For those who continue Research Work, interim reports are submitted annually by form, for those who complete research – the final report by form. For interim and final reports, attach previous versions of the LBC decision. You can find the report forms in the appendices.

3. The application for interim and final reports is filled out in accordance with the requirements (Appendix 7)

4. When carrying out research work on laboratory animals, it is obligatory to fill in the appropriate forms of documentation (Appendix 3).