


ОНТҮСТІК-ҚАЗАҚСТАН MEDISINA AKADEMIASY «Оңтүстік Қазақстан медицина академиясы» АҚ		SOUTH KAZAKHSTAN MEDICAL ACADEMY АО «Южно-Казахстанская медицинская академия»
Local bioethics commission	044-65/	
Application	1 стр. из 1	

Bioethical review of the planned research

1. Dated Application for ethical review, signed by the head of the department (supervisor) indicating whether the set of patients started the study (in Kazakh, Russian and English).
2. Abstract of the thesis (in Kazakh, Russian and English).
3. Protocol of the planned research (in Kazakh, Russian and English).
4. The brief summary on the drugs used (if used).
5. Signed and dated by professional autobiography researcher and his supervisor (in Kazakh and Russian language), with contact telephone.
6. The form of informed consent and patient information.
7. Written and other forms of providing information to potential research participants in a language understood by the potential research participants.
8. Individual registration card, diaries and questionnaires, which will fill the patients, research participants.
9. In the presence of the test product (drug or medical device) - a proper description of its data on the safety, pharmacology, pharmaceutical, and toxicological data, together with a description of the existing to date clinical experience with the product (eg, a valid version of the Investigator's Brochure, publication, description product properties).
10. List of clinical centers, where it is planned to conduct a study.
11. Signed and dated current versions of professional autobiographies of researchers.
12. Document safeguards the rights of patients in the study in the case of harm to their health during the study (insurance certificate or a letter sponsor of compensation to patients in the event of damage to their health during the study).
13. A description of any compensation for participating in the research for the study participants (including costs and medical care).
14. Materials, including advertising, informing about the study and used to attract patients to participate in it.
15. Resolution of the Pharmacological Committee for the study.
16. At the discretion of the applicant can be further presented and discussed other documents relevant to ethics in the course of the planned research.
17. Certificate for Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) - if available. (FileFolderred)

Note: The submission of documents according to the list and to the peculiarities of the survey research.