NON-COMMERCIAL JOINT STOCK COMPANY
"WEST KAZAKHSTAN MARAT OSPANOV MEDICAL UNIVERSITY»

Approved by the decision
of the Board of the NJSC
"West Kazakhstan Marat Ospanov
Medical University"
(minutes No. 14 of May 17 2021)

POSITION

ABOUT THE LOCAL BIOETHICS COMMISSION

Code	Edition	Developed by
P WKMU 01-05-07	Fourth	D.Ayaganov Аяганов Д 12 05 2021

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1. GENERAL PROVISIONS

1.1. Ethical examination of research works (RW) is carried out in accordance with the Code of the Republic of Kazakhstan "On the Health of the People and the Health Care System", according to which the ethical evaluation of research materials is a prerequisite for conducting clinical trials.

1.2. Ethical expertise of RW is carried out by the Local Bioethics Commission (hereinafter referred to as the LBC), which was established under the Non-Profit Joint-Stock Company "West Kazakhstan Marat Ospanov Medical University" (hereinafter referred to as the University) in accordance with the decision of the Academic Council of the University and approved by the order of the Rector). The Commission is an independent advisory body.

1.3. The Commission was established in accordance with international research standards and is registered in the international system of Health and Human Services (HHS) (IRB00003734 Kazakh Natl Med U-Kazakhstan Ethical Committee #1). The LBC at the ZKMU named after Marat Ospanov (IRB00010636 Local IRB Committee West-Kazakhstan State Medical University named after Marat Ospanov, the Republic of Kazakhstan), is registered in the international database of the Office Office for Human Research Protections (OHRP) IORG0008911 (dated 14.07.2016). LBC at the ZKMU named after Marat Ospanov is registered in the unified database of the LBC of the Republic of Kazakhstan with the assignment of the identification number LEC-I / 2010-07-014.

1.4. All research projects planned for execution with the participation of University employees, or conducted at the University's clinical, laboratory and other bases, regardless of the source of funding, are subject to preliminary ethical examination. Examination of the LBC is a mandatory stage of planning research conducted by employees and students (doctoral students, undergraduates) University. Any preclinical, clinical study or biomedical experiment carried out with the participation of humans and (or) laboratory animals must pass a preliminary examination of the University's LBC.

1.5. Commission should consider the plans of all research projects that involve treatment or examination of patients conducted in contact with the subject (including post-mortem), as well as non-clinical studies without contact with the subject (according to medical records, laboratory tests, etc.).

1.6. It is unacceptable to include a person in the study before the approval of the study protocol by the Commission, except in exceptional cases stipulated by the GCP.

1.7. Commission guidance documents: The Constitution of the Republic of Kazakhstan; the Code of the Republic of Kazakhstan dated July 7, 2020 No. 360-VI "On the health of the people and the health care system" (as amended as of 08.01.2021); The Standard of Good Clinical Practice (GCP), approved by the Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated May 27, 2015 No. 392 " On the approval of good pharmaceutical practices»; Rules for conducting medical and biological experiments, preclinical (non-clinical) and clinical studies, as well as requirements for preclinical and clinical databases, approved by Order No. 142 of the Minister of Health of the Republic of Kazakhstan dated April 2, 2018; Rules for the use of new methods of diagnosis, treatment and Medical Rehabilitation, approved by Order No. 272 of the Acting Minister of Health of the Republic of Kazakhstan dated May 20, 2014; The Helsinki Declaration of the World Medical Association "Recommendations for Doctors engaged in Biomedical Research involving People", adopted by the 18th World Medical Assembly (Finland, 1964) and all its subsequent editions; Other existing international regulations and acts of the Republic of Kazakhstan related to the activities of ethics committees and clinical research, as well as orders and orders for the University, this Regulation and standard Operating Procedures (SOP), which are a mandatory annex to the Regulation.

1.8. The Commission has its own stamp "APPROVED BY the LBC".

1.9. The Commission's decisions are aimed at protecting human rights and dignity in conducting research, ensuring humane treatment of animals in research, promoting the development of science, and improving the quality of research with human participation conducted within the framework of

research. The Commission's decisions are guided by the principles of objectivity and independence from political, administrative and managerial, departmental, collegial, and financial and economic influences.

1.10. Consideration of applications from the University staff is carried out free of charge. When considering requests from third-party organizations, the customer compensates the University for administrative costs on contractual terms, and the payment does not depend on whether the application is approved or any other decision has been made regarding the study.

1.11. The Commission is an open body. Information about the schedule of its work and the list of approved projects is published on the official website of the University.

1.12. The Commission, on the initiative of its members represented by authorized representatives, may interact with organizations and other ethical commissions or committees.

1.13. The Commission develops the Regulations on the Commission and the Standard Operating Procedures (hereinafter referred to as SOPs), which are discussed at the meeting of the Commission and approved by the Chairman of the LBC.

1.14. This Regulation gives effect to the following forms:

F P WKMU 01-05-07-01-21	Confidentiality and Conflict of Interest Statement
F P WKMU 01-05-07-02-21	Project appraisal form
F P WKMU 01-05-07-03-21	Activity reporting form
F P WKMU 01-05-07-04-21	Standard operating procedures
F P WKMU 01-05-07-05-21	list and samples of documents
F P WKMU 01-05-07-06-21	Statement
F P WKMU 01-05-07-07-21	Request for ethical expertise bc
F P WKMU 01-05-07-08-21	Declaration of conflict of interest of the principal investigator
F P WKMU 01-05-07-09-21	Information for the study participant
F P WKMU 01-05-07-10-21	Consent of the advanced participant
F P WKMU 01-05-07-11-21	Permission by parents or legal representative of the research participant
F P WKMU 01-05-07-12-21	Oral consent of the child
F P WKMU 01-05-07-13-21	Research protocol
F P WKMU 01-05-07-14-21	Information on the state of industrial building for research on laboratory animals
F P WKMU 01-05-07-15-21	Equipment and facilities available in the studies institution in laboratory animals
F P WKMU 01-05-07-16-21	laboratory animals and their conditions of detention
F P WKMU 01-05-07-17-21	list of methods used in conducting studies on laboratory animals
F P WKMU 01-05-07-18-21	list of standard operating procedures of the research laboratory used in the research
F P WKMU 01-05-07-19-21	Guarantee obligation
F P WKMU 01-05-07-20-21	Research interim report form
F P WKMU 01-05-07-21-21	Final research report form

2. GOALS AND OBJECTIVES OF THE COMMISSION

2.1. The purpose of the Commission is to protect the rights and dignity of people invoived in scientific research as test subjects, to protect animals from inhumane treatment in scientific research, to consider the ethical aspects stated by research and to ensure safety guarantees.

The tasks of the Commission are:

2.2. Independent expert evaluation of research documents with the participation of humans as test subjects, research using laboratory animals in accordance with international and national standards of good clinical and laboratory practice and the recommendations of this Commission for compliance with ethical requirements for research.
2.3. Assessment of compliance with the qualifications of researchers based on their scientific biography and/or other documentation and technical equipment of the health organization conducting the study.
2.4. Development of recommendations for amendments and changes to the documents and research materials submitted for ethical review.
2.5. Making an opinion on the approval or disapproval of planned and ongoing research.
2.6. Organization of the audit of compliance of the conducted research with the legal norms and ethical standards required for such research.

3. COMMISSION STRUCTURE

Composition:

3.1. The composition of the Commission is formed by the Vice-Rector for Strategic Development, Science and International Cooperation on the basis of proposals from University officials and members of the Local Bioethics Commission. The composition of the Commission is approved by the order of the Rector of the University.
3.2. The Commission is headed by a chairman appointed by the Rector of the University for 3 (three) years. The term of office of the Chairman may be extended, but not for more than two terms. The Chairman of the Commission appoints the Deputy and Executive Secretary from among the members of the LBC at its next meeting by open voting for the term of their powers as members of the LBC. The issue of early release from the duties of the chairman (Deputy Chairman or executive Secretary) of the Commission is considered at the meeting on his personal application. In case of early termination of the powers of the chairman (Deputy Chairman or Executive Secretary), the Commission shall elect a new chairman (Deputy Chairman or Executive Secretary).
3.3. The Commission from among its members. The Commission consists of persons who are not directly dependent on the researchers and the customer. Members of the Commission may be specialists in the field of health, science, law, representatives of religious denominations and public associations. At the same time, the following conditions are met: gender balance, the presence of an expert who is not engaged in scientific work in the field of biomedicine and an expert who is not affiliated with the institution where the Commission was established.
3.4. The number of the Commission is 12 people, including the executive secretary (without the right to vote). The number of members of the Commission can be increased depending on the volume and complexity of the tasks to be solved.
3.5. The duration of membership in the Commission is 3 (three) years. This period may be extended for a further 3-year period if the Commission member continues to meet all the qualification requirements.

Rights:

The powers of a member of the Commission are terminated in the following cases:

3.6. Expiration of the term of office of the Commission.
3.7. Submission by a member of the Commission of an application to the Vice-Rector for Strategic Development, Science and International Cooperation of the University to resign from the Commission.
3.8. Making a decision of the Commission on the violation of ethical standards by a member of the Commission when conducting research with the participation of people as test subjects or using laboratory animals.

3.9. If necessary, the Commission has the right to involve independent experts from among the university staff in the ethical examination without the right to vote and subject to their confidentiality.
3.10. Members of the Commission perform their expert functions regardless of their official position.
3.11. Have equal rights in the discussion and decision-making of the Commission.
3.12. Any pressure on the members of the Commission or on the participants of the study is a gross violation of the ethics of scientific research and harms the reputation of the University. The Commission immediately notifies the Rector of the University of any attempts at pressure.
3.13. Members of the Commission studying the submitted documents have the right to request from the head and the contractor additional information about the planned research, if it is necessary to protect the rights and health of the subjects.
3.14. It is the responsibility of the members of the Commission to give a comprehensive and exhaustive review of the ways to resolve ethical problems proposed in the research plan, based on the submitted documents, or arising in the course of the study.

Governance and accountability:

3.15. The officers of the Commission are the Chairman, the Vice-Chairman and the Executive Secretary, who represent the working body of the Commission.
3.16. The Chairman directs the activities of the Commission, conducts meetings, and is responsible for the implementation of this Regulation and the requirements of the SOP. The Chairman is authorized to assign individual tasks to the members of the Commission.
3.17. The Vice-Chairman performs the functions of the chairman in his absence or on his behalf.
3.18. The Executive Secretary is responsible for keeping the minutes of the meetings of the Commission, record keeping and maintaining the archive of the Commission. In the absence of the Secretary of the Commission at the meeting, the chairman entrusts the minutes to one of the members.
3.19. In order to promptly resolve issues related to the inclusion of medicines in a clinical trial, additional centers, replacement of researchers, amendments to the protocol of a clinical trial of a drug and other biomedical research, information for the patient, etc., a Bureau is formed as part of the Commission.
3.20. The composition of the Bureau of the Commission and its rules of procedure shall be approved by the Chairman of the Commission.

4. FUNCTIONS, DUTIES AND POWERS OF THE COMMISSION

The Commission's responsibilities include:

4.1. Review of the study protocol, methods and forms of informed consent of the study participants.
4.2. Review of the report on ongoing projects (at least once a year).
4.3. Review of the report on deviations from the protocol (report on the progress of the study).
4.4. Issuance of a written opinion on the results of the review. Consideration of the submitted materials is carried out within 1 month from the date of submission of the materials to the Commission.
4.5. All members of the Commission are obliged to keep confidential the information received during the ethical examination or in connection with it, and also sign the corresponding agreement (Appendix 1).
4.6. The Commission accepts for consideration the set of documents specified in Appendices 2, 3.
4.7. Dissertations and initiative research works are subject to ethical examination by the Commission. The Commission accepts for consideration the set of documents specified in Appendices 2, 3. Dissertations and initiative research works are subject to ethical examination by the Commission. The procedure of ethical examination of dissertations should be carried out before the approval of the topic at the Academic Council of the University, but can also be carried out in the course of the work, if the work has already begun. In the latter case, an ethical examination is carried out only for the amount of research that is only planned to be performed.

4.8. Clinical trials in humans can only be conducted by persons admitted to medical practice in the Republic of Kazakhstan.

4.9. In order to protect the subjects, they should be provided with sufficient information, which is reflected in the forms of informed consent. If the consent to participate in the study is given by the legal representative of the subject, the Commission must make sure that the provided protocol and/or other documentation fully reflects the ethical aspects of this study. If the protocol indicates that it is impossible to obtain consent from the subject or his legal representative before inclusion in the study, the Commission must ensure that the provided protocol and/or other documentation fully reflects the ethical aspects of this study.

4.10. The Commission has the right to request the suspension or termination of the study in the event of unforeseen difficulties of an ethical nature or violations of ethical standards at any stage of the study.

4.11. If the applicant does not agree with the results of the ethical examination, the Commission re-examines the materials of the study with the participation of the applicant and the involvement of independent experts.

4.12. Reports of undesirable side effects that are both serious and unexpected that have occurred in the research centers of the University should be considered as they arise at the next meeting of the Commission.

4.13. If the chief researcher refuses to inform about the progress of the study, the Commission reserves the right to request the rector and / or the project sponsor to suspend the activities of this center or exclude it from the study.

4.14. It is unacceptable to deviate from the protocol without the approval of the Commission of the relevant amendments, except in cases specified in the GCP.

In cases of conducting an ethical examination of research performed on laboratory animals.

4.15. The Chairman of the Commission forms the Bureau for Animal Research, which consists of 3 people, including a veterinarian. The composition of the Bureau and the schedule of work are approved by the Chairman of the Commission.

4.16. The applicant submits to the Bureau of the Commission for Animal Research the documents listed in Annex 3.

4.17. The Bureau of the Commission for Animal Research conducts an ethical examination of research using laboratory animals in accordance with the following aspects:

4.17.1. The compliance of the design of the study the objectives of the study, including the validity of the study on laboratory animals, aimed at obtaining results unattainable by other means, and the engagement of the minimum possible number of laboratory animals;

4.17.2. Qualifications and relevant experience of the researcher, supervisor (consultant) and co-researchers planning studies, including the adequacy of analgesia and control the state of the animal;

4.17.3. Availability of laboratory facilities and staff providing care for laboratory animals;

4.17.4. Suggestions for improvement of experimental techniques to reduce (eliminate) negative (pain, stress, etc.) effects on laboratory animal;

4.17.5. The presence of measures to avoid unnecessary damage and physical suffering of laboratory animals;

4.17.6. Compliance with precautions to ensure the safety of researchers, staff and excluding the negative impact on the environment;

4.17.7. Sources of funding of the study.

5. MANAGEMENT, REGULATIONS OF THE COMMISSION

5.1. The Commission considers the issue of compliance of research with the principles of ethics of biomedical research, the requirements of the GCP and carries out ethical expertise after the

approval of the research plan at the meeting of the department, and in some cases, the problem commission.

5.2. The Academic Council of the University and the problem commissions accept for consideration research plans and other plans that provide for research involving humans or animals, only if there is a conclusion of the Local Commission on Bioethics.

5.3. The Commission determines the compliance of the research with the principles of ethics and scientific research, makes recommendations for its improvement, or agrees with proposals for resolving ethical issues of the authors of the research.

5.4. The Commission evaluates the compliance of the researcher's qualifications with the planned research on the basis of his/her scientific biography and / or other documentation.

5.5. The Commission considers the risk associated with the research and possible scientific results, but does not consider the social, political, economic aspects that are taken into account by the administration or funding institutions.

5.6. Based on the results of the reviewed research plans, the Commission issues a reasoned conclusion to the head or responsible executor, according to the form (Appendix 4). If there are recommendations of the Commission on the research plan, the identified shortcomings should be eliminated by the applicants, the changes to the plan are approved by the meeting of the department, and the updated plan should be submitted to the Commission.

5.7. At the request of the sponsor, the chief researcher and with the consent of the Central Commission on Bioethics (CCB) under the Ministry of Health of the Republic of Kazakhstan, the Local Commission on Bioethics under the WKMU named after Marat Ospanov may delegate to the CCB the authority to monitor and analyze information on safety and adverse events as it becomes available; to review reports on serious adverse events provided by the sponsor of a clinical trial. At the same time, the LBC at the Marat Ospanov ZKMU reserves all other issues of ethical support for the study.

5.8. The Commission does not have the authority to prohibit the conduct of research, but if it turns out that the recommendations of the Commission are not taken into account, or that the research is carried out without any participation of the Commission, the Commission has the right to report these violations to the management of the University, the medical institution, the contracting authority, the sponsor company and the appropriate licensing authority.

5.9. If situations arise in the course of a study approved by the Commission that are questionable or contrary to ethical standards, due to the fault of the researcher or sponsor, or an organization participating in the research, the Commission has the right to point this out to the above-listed subjects, inform the University rector and the appropriate licensing authority, and consider suspending the approval previously given by the Commission.

5.10. The results of all research projects that have passed a preliminary ethical examination, when submitted to the press, must contain a reference to the ethical examination, as well as in the case of registration of the research results in the form of a dissertation. When submitting a dissertation to the Dissertation Council, it is advisable to attach to the documents copies of the conclusions of the Local Bioethics Commission obtained during the planning and completion of the work.

5.11. The Commission is obliged to submit annual reports summarizing the results of its work to the Academic Council of the University.

5.12. Organization and holding of meetings of the Commission.

5.13. The Commission has its own regulations and work plan, which are developed and approved in accordance with this Regulation. The meetings of the Commission are held in accordance with the approved schedule or are appointed by the Chairman of the Commission as necessary, but at least once a month.

5.14. The meetings of the Commission are held in closed form in compliance with the quorum. The meeting is considered competent if there are at least half of the members of the Commission (50%) plus 1 member of the Commission.

5.15. The Commission makes decisions at the meeting only if there is a quorum. Quorum requirements: a) at least 5 members of the Commission (men and women), b) at least 1 member of the Commission is a non – medical employee, c) at least 1 member of the Commission who is not subordinate to the university administration.

5.16. The members of the Commission participating in the research under consideration are not involved in the discussion of the submitted materials of the research and are not allowed to vote.

5.17. The decisions of the Commission are taken by a simple majority of the votes of the members by open voting in the presence of a quorum and are drawn up in minutes. The minutes of the meetings of the Commission are signed by the chairman and the secretary.

5.18. The current results of the work of the Commission are made out in the form of extracts from the minutes of meetings.

5.19. The results of the Commission's work are drawn up in the form of annual reports, which are stored in the Commission (Annex 5).

5.20. The Commission develops and strictly follows its own standard operating procedures (SOPs), approved by the Chairman of the LCB (Annex 6).

5.21. The Commission maintains and stores the necessary documentation. The conditions for storing documentation should ensure confidentiality.

5.22. Any R & D submitted for examination must be considered by the Commission within a period of no more than one month.

5.23. The Commission holds public meetings, at which all interested persons have the right to attend. In the case of an investigation of ethical issues, as a follow-up to the current study, the Commission may limit the number of participants in the meeting in the interests of confidentiality, but only until a final decision is made. If there are significant contradictions on the proposal of the Commission members or researchers who submitted the research plan, it is possible to hold a joint meeting of the Local Commission on Bioethics and the problem commission on the relevant specialty at the university.

5.24. The meetings of the Commission may be regular (scheduled) and extraordinary (additional). Scheduled meetings of the Commission are held at least once a month, with the exception of July and August (vacation time). The date and time of the meetings are determined by the chairman, and a schedule for the current year is drawn up, which is displayed on the university's website. The Secretary of the Commission informs the members of the time, place and agenda of the next meeting 15 days prior to its holding and receives confirmation of their presence. If necessary, the Chairman may change the date of the next meeting or appoint an extraordinary meeting. Information on changes in the date of the meeting is communicated by the secretary to all members and participants of the meeting.

5.25. The agenda of the meeting of the Commission is formed by the chairman on the basis of the documents and materials received from the applicants.

5.26. The schedule of scheduled meetings of the Commission is published on the official website of the University at the beginning of the year. Information about unscheduled meetings of the Commission is posted on the official website of the University no later than 10 days before the meeting day.

5.27. At least 5 days before the meeting, the Secretary submits the R & D documents to the members of the Commission (the number of experts involved is at the discretion of the chairman of the LCB, depending on the complexity of the examination and the degree of risk) for preliminary examination, in accordance with the distribution of responsibilities among the members. Additional documents and / or materials prepared by the members may be distributed directly on the day of the meeting.

5.28. The meeting is opened and conducted by the Chairman of the Commission. In the absence of the Chairman or in the event of a conflict of interest, the meeting is chaired by the Vice-Chairman. In

the absence of the Deputy Chairman or if he has a conflict of interest, the meeting is conducted by an authorized person selected by the members of the Commission.

5.29. Before the meeting, the agenda is presented to the members of the Commission. A member of the Commission who has received the documents for examination makes a report on the study under consideration at the meeting. If necessary, the members, in consultation with the Chairman of the Commission, involve independent consultants in the discussion, who may attend the meeting in person or submit their opinion in writing, subject to confidentiality.

5.30. The Commission takes a decision by consensus. If it is not possible to reach a consensus, the Commission will resort to voting. A decision of the Commission adopted by a simple majority of votes in the presence of at least five of its members is considered valid, and in the event of a tie, the Chairman's vote is decisive. The opinion of a minority of the members, as well as the special opinions of the members of the Commission, should be reflected in the minutes of the meeting and an extract from the minutes of the meeting.

5.31. In the event of a conflict of interest, a member of the Commission does not participate in the meeting and voting and leaves the meeting room for the duration of the discussion and voting. An exception is when such a member of the Commission is present at the meeting at the request of the Commission in order to provide additional information about the study. In agreement with the chairman, the meeting may be attended by medical researchers, representatives of the contracting authority, the sponsor company, and University staff. If the chief researcher or co-researchers disagree with the decision of the Commission, they have the right to request that the Commission re-examine this study with the involvement of agreed experts in the field under study, or a joint meeting with the problem commission.

5.32. The meeting of the Commission begins with the inclusion of the present members and invited persons (if any) in the minutes of the meeting of the Commission. If the invited persons are present before the discussion of the issues included in the agenda of the meeting of the Commission, the Chairman of the Commission (or another person leading the meeting of the Commission) explains to the invited persons their rights.

5.33. The members of the Commission shall address the meeting in the order determined by the Chairman.

5.34. The Commission takes into account the results of the previous scientific examination, if any, the requirements of the relevant laws and other regulatory legal acts of the Republic of Kazakhstan, as well as the recommendations of international and national organizations. The Commission has the right to request additional information necessary for making a decision. If necessary, the Commission may involve independent experts and specialists in the work, subject to confidentiality.

5.35. Based on the results of consideration of the issues on the agenda of the meeting, the Commission may make decisions in the form of conclusions, proposals and appeals.

5.36. A member of the Commission who does not agree with the conclusion of the Commission may express in writing his dissenting opinion, which is attached to the conclusion.

5.37. The decisions of the Commission are drawn up in the form of a protocol, which is signed by the chairman (or other person leading the meeting of the Commission) and the executive secretary.

5.38. The documents must be submitted in electronic format by e-mail specified on the official website of the University and in printed form to the Secretary of the Commission. In case of submission of an incomplete set of documents, consideration of the application is suspended until the applicant submits the missing documents and materials.

6. FINAL PROVISIONS

6.1. This regulation presents the main rules governing the legal status of the Commission in the overall structure of the University. In the scope of its activities, changes, clarifications or additions may be made in the process of production and economic activities of the University. These changes are

fixed by internal regulatory documents and organizational and administrative acts of the University administration, issued in accordance with the established procedure.

6.2. The function of monitoring the implementation of this regulation is assigned to the Secretary of the Commission, who ensures its communication to the members of the Commission and interested persons of the University, control over the implementation and timely updating of the regulation.

6.3. Changes and additions to this Regulation are made by drawing up the Regulations on the Commission in a new version, or by making changes (additions) in the form of annexes to this Regulation on the basis of an order of the Rector or other authorized official of the University, and are brought to the attention of the members of the Commission and interested persons.

6.4. This regulation comes into force from the date of its approval and is valid until its cancellation in accordance with the established procedure.

6.5. If the Commission is abolished or the Regulations on the Commission are approved in a new version, this Regulation becomes invalid and becomes invalid.

Appendix A
(required)

F PRO WKMU 401-04-19

INTRODUCTION SHEET

№	Full name, position	Personal signature	Date	Note