On approval of the rules for conducting biomedical research and requirements for research centers

Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan dated December 21, 2020 No. ҚР DSM-310/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on December 22, 2020 No. 21851

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On approval of the rules for conducting biomedical research and requirements for research centers

In accordance with paragraph 10 of Article 227 of the Code of the Republic of Kazakhstan dated July 7, 2020 On Public Health and Health Care System I hereby ORDER:

1. Approve the attached rules for conducting biomedical research and requirements for research centers.

2. Invalidate Order No. ҚR DSM-64 of the Minister of Healthcare of the Republic of Kazakhstan dated May 4, 2019 "On approval of the Rules for conducting medical research, and also requirements for research centers" (registered in the Register of State Registration of Regulatory Legal Acts under No. 18630, published 14 May 2019 in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan).

3. The Department of Science and Human Resources of the Ministry of Healthcare of the Republic of Kazakhstan, in accordance with the procedure established by the legislation of the Republic of Kazakhstan, shall:

1) provide the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;

2) post this order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

3) within ten working days after the state registration of this order, report to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan on execution of the actions provided for in subparagraphs 1) and 2) of this paragraph.

4. Control over the execution of this order shall be assigned to Vice-Minister of Healthcare of the Republic of Kazakhstan, A.Giniyat.

5. This order shall be enforced upon expiry of ten calendar days after the date of its first official publication.

Minister of Healthcare
of the Republic of Kazakhstan *A. Tsoi*

Approved
by order No. ҚR DSM-310/2020
of the Minister of Healthcare
of the Republic of Kazakhstan
of December 21, 2020

Biomedical research Rules and requirements for research centers

Chapter 1. General provisions

1. The rules for conducting biomedical research and requirements for research centers (hereinafter -the Rules) have been developed in accordance with paragraph 10 of Article 227 of the Code of the Republic of Kazakhstan dated July 7, 2020 On Public Health and Health Care System (hereinafter -the Code) and define the procedure for conducting biomedical research, and also establish requirements for research centers.

2. These Rules shall apply to all types of biomedical research, except for:

1) clinical trials of medicines and medical devices, including clinical trials of the simultaneous use of several medicines (without and (or) having state registration);

2) clinical and laboratory tests of medical devices for in vitro diagnostics;

3) preclinical (nonclinical) studies of medicines;

4) research (testing) assessment of the biological effect of medical devices.

3. The following terms and definitions shall be used in these Rules:

1) informed consent - a procedure for a person to voluntarily confirm his consent to medical assistance and (or) participation in a specific study after receiving information on all aspects of the medical assistance and (or) research that are significant for making a decision;

2) biomedical research - research, purposed to obtain new knowledge by scientific methods about life, human health, diseases, their diagnosis, treatment or prevention, as well as genetic and environmental factors associated with life processes, diseases and health;

3) bioethics - a cross-disciplinary scientific field that combines biomedical and humanitarian sciences to analyze the moral, social, legal aspects of application of the latest achievements of life sciences;

4) bioethical examination - a preliminary examination of the biomedical study materials and issuance of a substantiated conclusion of the Bioethics Commission from the standpoint of ethical acceptability, safety for participants and feasibility of this study;

5) sponsor - an individual or legal entity initiating a biomedical research and organizing and (or) financing it.

6) authorized body in health care (hereinafter -the authorized body) - the central executive body that exercises management and cross-sectoral coordination in health protection of the

citizens of the Republic of Kazakhstan, medical and pharmaceutical science, medical and pharmaceutical education, sanitary-epidemiological welfare of the population, circulation of medicines and medical devices, quality of medical services (assistance);

7) research subject - a living human or animal participating in a medical research;

8) non-interventional clinical research - a research that is carried out after the state registration of a medicinal product or medical device and is prescribed within the framework of medical practice;

9) interventional research - a research involving a human being as a research subject, in which a researching physician, on the basis of an interventional clinical research protocol, corresponding to the procedure for conducting clinical research, prescribes a special intervention for the research subject;

10) preclinical (nonclinical) study - chemical, physical, biological, microbiological, pharmacological, toxicological and other experimental studies or a series of researches to study the researched substance (medicinal product) by applying scientific assessment methods in order to examine the specific action and (or) obtain evidence of safety for human health;

11) clinical research - a study with human participation as a subject, conducted to identify or confirm the safety and efficacy of means, methods and technologies for the prevention, diagnosis and treatment of diseases;

12) applied biomedical research - biomedical research aimed at achieving specific goals in diagnosis, treatment or prevention of diseases, ensuring public health;

13) biomedical experiment - a study based on reproduction (modeling) of the structural and functional complex of the studied condition or disease in a simplified form on laboratory animals to find out the causes, conditions and mechanisms of the onset of the condition or development of the disease, to develop treatment and prevention methods;

14) monitoring - a procedure for progress monitoring of biomedical research and ensuring its conduct, data collecting and presenting the research results in accordance with the protocol , plan, programme, standard operating procedures, good clinical practice;

15) audit of a clinical trial of the tested methods and (or) means - a systematic, independent and documented check of the documentation and activities of the parties involved in the clinical trial of the tested methods and (or) means, which is carried out by experts independent of the clinical trial and the research center to confirm the fact of implementation of these activities, as well as for compliance assessment of the procedures of collecting, processing and presenting data, requirements of the clinical trial protocol, standard operating procedures, good clinical practice and regulatory requirements;

16) good clinical practice - a standard for planning, organizing, conducting, monitoring, auditing, documenting of clinical trials, as well as analyzing and presenting their results, which serves as a guarantee of the reliability and accuracy of the data obtained and the results presented, and also ensuring protection of the rights, health and confidentiality of research subjects;

17) protocol synopsis - a summary of the clinical trial protocol;

18) fundamental biomedical research - biomedical research conducted with the aim of expanding basic knowledge and understanding of the physical, chemical and functional mechanisms of life processes and diseases.

Chapter 2. Procedure for conducting biomedical research

4. Biomedical research shall be conducted on living humans and animals (research subjects), biological samples of living and deceased humans and animals, and also on the basis of the use of clinical-epidemiological data and other medical information.

Biomedical research shall include fundamental and applied biomedical research. Applied biomedical research shall include biomedical experiments, preclinical (non-clinical) research, clinical research, and public health research.

5. Biomedical research shall be conducted in the presence of the following documents:

1) a positive opinion of the Central (hereinafter - the Central Commission) or local (hereinafter - the Local Commission) commission on Bioethics, conducting bioethical expertise;

2) a positive opinion of an advisory-consultative body authorized to consider issues of scientific and (or) research and development activities (academic, scientific, scientific-clinical , expert council) in a research center (hereinafter -the Council);

3) documents on life and health insurance of the research participant for interventional clinical trials.

6. Central Commission shall be established under the authorized body according to the order laid down in paragraph 5 of Article 228 of the Code.

Local commissions shall be established at healthcare organizations for an independent assessment of research carried out on their basis.

Central and local commissions on bioethics shall be established on a cross-disciplinary basis and consist of representatives of the medical, humanitarian professions, public organizations and legal specialists.

7. Research sponsor (hereinafter - sponsor) or research leader shall:

1) receive the conclusion of the Central (hereinafter - the Central Commission) or local (hereinafter - the Local Commission) commission of bioethical expertise in the manner prescribed by the requirements of the Standards of the bioethics commissions' activity approved by the Central Commission on Bioethics in accordance with subparagraph 4) of paragraph 3 of Article 228 of the Code of the Republic of Kazakhstan dated 7 July 2020 No. 360-VI On Public Health and Health Care System (hereinafter - the Standards);

2) receive the opinion of the Research Center Council in the manner prescribed in the Regulations on the Research Center Council and the internal regulatory documents of the research center approved by the head leader of the research center.

8. Biomedical research shall be carried out under the guidance of the sponsor or the research leader according to the research plan approved by the Central or Local Commission and the Research Center Council, with drawing up of a research protocol and a report containing the research results. Control over the execution of the plan shall be assigned to the research leader.

9. Biomedical research shall be carried out on the basis of the research center that avails of the required material-technical resources and qualified professionals in the relevant field of research.

10. Documents drawn up during biomedical research in accordance with these Rules shall be subject to registration in electronic and (or) paper form by the organization that issued them, in the registration log (s).

11. Persons responsible for conducting biomedical research shall:

1) ensure timely collection of the results obtained, registration of deviations from the research plan, indicating the reasons and assessing the impact of the changes made on the results obtained, and also take measures to eliminate the identified deviations;

3) ensure interpretation and analysis of the results obtained, preparation of a report on the biomedical research results, confidentiality of the results obtained.

12. The biomedical research quality shall be backed up by:

1) material and technical provision of biomedical research, ensured by the head of the research center;

2) availability of supervision (observance of the biomedical research protocol at all stages of biomedical research; observance of standard operating procedures adopted at the research center level (for clinical trials));

3) planning of the biomedical research parameters;

4) paperwork execution system (work logs with primary data, final report, archives);

5) quality guarantee system to ensure reliability of the study and validity of the results obtained.

The equipment on which the biomedical research is conducted shall have an appropriate quality certificate, indicating the warranty service period, with a schedule for checking the equipment operation attached to it.

13. Quality control shall be carried out at all stages of the work to ensure reliability of biomedical research data and validity of their processing.

Quality control of biomedical research shall be carried out through monitoring, and for clinical research also through inspection and audit.

14. The head of the research center shall ensure that the requirements established by the research plan are met, the objectivity and independence of the research, reliability of the results obtained.

15. The audit of the study shall be carried out by a protocol decision of the Council by specialists with a certificate of completed training in good clinical practice.

16. Documents drawn up in the course of biomedical research in accordance with these Rules shall be kept by the research leader.

17. Documents drawn up by a research center when conducting a biomedical research in accordance with these Rules must be stored in an electronic version for three years.

18. All biomedical research conducted on the territory of the Republic of Kazakhstan, the procedure for which is governed by these Rules, as well as clinical trials of drugs and medical devices, clinical and laboratory tests of medical devices for in vitro diagnostics, preclinical (non-clinical) studies of medicinal products, research (testing) assessing of the biological effect of medical devices shall be subject to registration.

Registration shall be performed by the working body, determined by the authorized body, to record, monitor the biomedical research progress and coordinate research processes between the parties involved based on information on the research that is being performed.

Chapter 3. Requirements for research centers

19. The requirement for research centers on whose basis biomedical research is conducted shall be:

1) presence of accreditation as a subject of scientific and (or) research and development activities;

3) availability of personnel with education corresponding to the field of the conducted research.

20. Along with the requirements specified in paragraph 19 of these Rules, the following demands shall be set to the research centers on whose basis clinical trials are conducted:

1) availability of a license to carry out medical activities;

2) availability of standard operating procedures for conducting clinical trials, adopted at the research center level;

3) presence of personnel with medical education and a document on completed training in good clinical practice;

4) availability of conditions for intensive therapy and resuscitation (for conducting interventional clinical trials).