



## On approval of the Rules for creation and activities of biobanks

### *Unofficial translation*

Order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated December 24, 2020 no. ҚР ДСМ-328/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on December 28, 2020 no. 21927.

### Unofficial translation

In accordance with paragraph 3 of Article 229 of the Code of the Republic of Kazakhstan "On the health of the people and the health care system" **I hereby ORDER:**

**Footnote. Preamble - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 17.04.2023 № 74 (shall enter into force upon expiry of ten calendar days from the date of its first official publication).**

1. To approve the attached Rules for creation and activities of biobanks.
2. 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 ensure:
  - 1) state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;
  - 2) placement of 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 with the Ministry of Justice of the Republic of Kazakhstan, submission to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan of information about execution of measures, stipulated by subclauses 1) and 2) of this clause.
3. Control over execution of this order shall be entrusted to the supervising Vice-Minister of Healthcare of the Republic of Kazakhstan.
4. This order shall come into force upon expiry of ten calendar days from the date of its first official publication.

*Acting Minister of Healthcare  
of the Republic of Kazakhstan*

*M. Shoranov*

"AGREED"

Ministry of Education and Science  
of the Republic of Kazakhstan

Approved  
by the order of the acting  
Minister of Healthcare of the

## **Rules for creation and activities of biobanks**

### **Chapter 1. General Provisions**

1. The Rules for the creation and operation of biobanks (hereinafter referred to as the Rules) have been developed in accordance with paragraph 3 of Article 229 of the Code of the Republic of Kazakhstan "On the health of the people and the health care system" (hereinafter referred to as the Code) and shall determine the procedure for the creation and operation of biobanks.

**Footnote. Paragraph 1 – in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 17.04.2023 № 74 (shall enter into force upon expiry of ten calendar days after the date of its first official publication).**

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

1) biobank - a specialized storage of biological materials for scientific and medical purposes;

2) biological material - any substance or part thereof obtained from an organic object, such as an individual, animal, plant, microorganism (s) or multicellular organisms that shall be neither animals nor plants.

**Footnote. Paragraph 2 - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 17.04.2023 № 74 (shall enter into force upon expiry of ten calendar days after the date of its first official publication).**

3. Biological materials stored in biobanks shall be collected in accordance with the legislation of the Republic of Kazakhstan, bioethics standards, in compliance with all requirements for sample preparation, transportation, laboratory processing and storage.

**Footnote. Paragraph 3 - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 17.04.2023 № 74 (shall enter into force upon expiry of ten calendar days after the date of its first official publication).**

### **Chapter 2. Procedure for creation of biobanks**

4. A biobank is created on the basis of a healthcare organization, organization of higher and (or) post-graduate education and scientific organization (hereinafter referred to as the research center) on the basis of:

1) a positive opinion of the Central Commission for Bioethics (hereinafter referred to as the Central Commission), issued in accordance with the Standards for Activities of Bioethics Commissions, approved by the Central Commission (hereinafter referred to as the Standards) according to subclause 4) of clause 3 of article 228 of the Code;

2) a positive opinion from the Biosafety Commission of the research center (if any) or a biosafety expert from a third party in the absence of a Biosafety Commission at the research site.

5. The following requirements shall be imposed on the research center on the basis of which the biobank shall be created:

1) accreditation as a subject of scientific and (or) scientific and technical activities and (or) a license for medical activities;

2) availability of standard operating procedures for biological and clinical studies (when using biological materials for biomedical purposes and/or clinical studies) and for working with biobanks;

3) availability of personnel having specialized education and a document on training in good clinical practice (Good Clinical Practice) of standards of good pharmaceutical practices approved in accordance with subparagraph 9) of Article 10 of the Code (hereinafter referred to as the GCP standard) when using biological materials for medical purposes and/or clinical studies);

4) positive opinion of the Central commission, positive opinion of the Biosafety commission and/or biosafety expert;

5) availability of a protocol for assessing the biological risks of the procedures performed;

6) regulation on the Biosafety commission of the research center;

7) the presence of a three-level system of physical protection (when storing biological materials belonging to groups 1-2 of pathogenicity);

8) availability of permission to work with pathogenicity groups I, II, III and/or IV (in accordance with the pathogenicity group of stored biological materials).

**Footnote. Paragraph 5 - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 17.04.2023 № 74 (shall enter into force upon expiry of ten calendar days after the date of its first official publication).**

6. To receive an opinion of the Central Commission, the research center submits an application for creation of a biobank to the Central Commission and attaches the following documents:

1) application indicating the name of a biobank;

2) legal and financial details of the biobank owner;

3) information on the location and methods of storing and coding biological samples, as well as the data associated with these samples, and the conditions for managing this data;

4) a description of the field (s) of biobank activity, principles and conditions that apply to the collection and storage of biological samples and data; providing access to them for research and other uses of biological samples, information and restrictions regarding the use of biological samples;

5) approved form of the informed consent;

6) information about procedures of record-keeping, destruction of biological samples and personal data;

7) information about available trained personnel, responsible for collection and storage of biological samples and data, provision of access to them, conducting the research.

7. The term for consideration by the Central Commission of an application for creating a biobank does not exceed thirty calendar days after receiving the request.

8. If necessary, the Central Commission requests clarifications from the research center on specific provisions in the submitted list of documents. The time required for the submission by the research center of the data is not included in the processing time of the application by the Central Commission and does not exceed sixty calendar days.

9. The Central Commission shall make one of the following decisions:

1) on approval of creation of a biobank;

2) on the need to finalize the application documents for the creation of a biobank;

3) on refusal to issue an approval for creation of a biobank.

10. Based on the positive opinion of the Central Commission, the head of the research center issues an act on the creation of a biobank.

### **Chapter 3. Procedure for activities of biobanks**

11. Activity of a biobank shall include:

1) collecting, the entering visual quality control, storage of samples of biological materials ;";

2) delivery of biological materials to researchers by the criteria of inclusion developed by them;

3) accounting of the stored samples of biological materials and the medical, demographic and laboratory information associated with them, maintaining the electronic database;

4) storage of collected collections of samples of biological materials with observance of temperature conditions, with existence of the reserve sources of power supply guaranteeing full safety of the saved-up biomaterial;

5) rendering services of collecting, processing, storage and analysis of biological materials to researchers and scientific personnel of the research center;

6) interaction with other Kazakhstan and foreign biobanks;

7) exchange of samples of biological materials between biobanks and the medical organizations.

**Footnote. Paragraph 11 - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 17.04.2023 № 74 (shall enter into force upon expiry of ten calendar days after the date of its first official publication).**

12. A biobank shall be governed in its activity by the current legislation of the Republic of Kazakhstan in the field of healthcare and science, personal data and their protection, international and national bioethic standards and good practices of conducting biomedical

research, these Rules, internal regulatory documents of the research center, orders and instructions of the first head of the research center.

13. The general management of the biobank's activities is carried out by the deputy first head for scientific work (in the organization of higher and (or) postgraduate education and in the scientific organization), the deputy first head for the medical part (in the health organization).

The direct management of the biobank is carried out by the head of the biobank, appointed by the order of the first head of the research center.

14. The structure and staffing of the biobank is approved by the first head of the research center.

15. Collection, recording, storage, use and destruction of biological materials and personal data in the biobank shall be carried out in accordance with standard operating procedures.

**Footnote. Paragraph 15 - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 17.04.2023 № 74 (shall enter into force upon expiry of ten calendar days after the date of its first official publication).**

16. When collecting biological materials, the biobank ensures obtaining the informed consent from the donor of biological materials or his/her legal representative. The transfer of biological materials and personal data by the biobank for their further use in research is carried out on the basis of the informed consent of the donor of biological materials or his/her legal representative, provided that the research is approved by the Local Commission on Bioethics (hereinafter referred to as the Local Commission).

17. Obtaining and documenting the informed consent of the donor of biological materials or his legal representative is provided in accordance with the GCP Standard and bioethical principles.

18. The written informed consent of the donor of biological materials or his/her legal representative is obtained prior to collection of biological material for research purposes for storage in a biobank, use in research, indicating specific tasks.

19. Researchers and biobank managers ensure that the privacy and confidentiality of donors of biological materials and their personal information is protected, including information received from donors about others.

20. When using biological materials, researchers and biobank managers take into account the religious and cultural views and traditions of people or groups of people in communities with respect to the human cell.

21. The donor who signed the informed consent at any time prohibits the use of his data and (or) biological material stored in the biobank in particular studies.

22. The local commission reviews and approves all agreements on the provision of access to data and / or biological samples stored in the biobank to ensure the best ethical use of biological samples and data from donors in accordance with their consent.

23. The activity of the biobank is subject to internal and external monitoring.

The Research Center, which is creating the biobank, provides an internal monitoring procedure. Internal monitoring is carried out annually in accordance with the procedure established in the quality management system manual. External monitoring is carried out by the Central Commission once every 5 years.

The procedures for the collection, storage and use of biological samples, collection, registration, storage, protection and transmission of personal data are subject to monitoring..

24. When the research center decides to close the biobank or destroy biological samples, personal data stored in the biobank, the research center:

1) notify the Central commission;

2) ensure the destruction of personal data, as well as biological samples in accordance with the procedure for the collection, storage, transportation and disposal of medical waste in accordance with the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated December 25, 2020 № RK MH-331/2020 "On approval of sanitary Rules" Sanitary and epidemiological requirements for the collection, use, neutralization, transportation, storage and disposal of production and consumption waste;

3) ensure the transfer of biological samples, personal data on material carriers to another biobank operating on the basis of a research center - a resident of the Republic of Kazakhstan.

**Footnote. Paragraph 24 - in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 17.04.2023 № 74 (shall enter into force upon expiry of ten calendar days after the date of its first official publication).**