

On approval of the rules for the issuance and validity of the certificate of compliance with the requirements for the activities of bioethics commissions

Unofficial translation

Order № KR DSM-243/2020 of the Minister of Healthcare of the Republic of Kazakhstan as of December 9, 2020. It is registered with the Ministry of Justice of the Republic of Kazakhstan on December 14, 2020 under № 21774.

Unofficial translation

In accordance with paragraph 10 of Article 228 of the Code of the Republic of Kazakhstan "On public health and health care system" **I HEREBY ORDER:**

Footnote. The preamble as amended by the order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated 31.03.2023 № 51 (shall be enforced upon expiry of ten calendar days after its first official publication).

1. To approve the appended rules for the issuance and validity of the certificate of compliance with the requirements for the activities of bioethics commissions.

2. In the manner prescribed by the legislation of the Republic of Kazakhstan, the Department of Science and Human Resources of the Ministry of Healthcare of the Republic of Kazakhstan shall ensure:

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

2) the posting of this order on the website of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

3) the submission of information on the implementation of the measures provided for in subparagraphs 1) and 2) of this paragraph to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan within ten working days of the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan.

3. Control over the execution of this order shall be entrusted to A.Giniyat, deputy minister of healthcare of the Republic of Kazakhstan.

4. This order comes into effect ten calendar days of its official publication.

*Minister of Healthcare of
the Republic of Kazakhstan*

A.Tsoi

Approved by Order
№ KR DSM-243/2020
of the Minister of Healthcare
of the Republic of Kazakhstan
as of December 9, 2020

Rules f

or the issuance and validity of the certificate of compliance with the requirements for the activities of bioethics commissions

Chapter 1. General provisions

1. The Rules for the issuance and validity of the certificate of compliance with the requirements for the activities of bioethics commissions (hereinafter – the Rules), have been developed in accordance with the Code of the Republic of Kazakhstan "On public health and health care system" (hereinafter – the Code) and shall determine the procedure for the issuance and validity of the certificate of compliance with the requirements for the activities of bioethics commissions (hereinafter – the certificate).

Footnote. Paragraph 1 as amended by the order of the Actng Minister of Healthcare of the Republic of Kazakhstan dated 31.03.2023 № 51 (shall be enforced upon expiry of ten calendar days after its first official publication).

2. Local bioethics commissions (hereinafter - LBC) have the right to issue opinions on conducting biomedical research, provided that they have a certificate of compliance with the standards of activity of bioethics commissions issued by the Central Bioethics Commission on (hereinafter - CBC).

Chapter 2.

Procedure for the issuance and validity of the certificate of compliance with the requirements for the activities of bioethics commissions

3. certificate of compliance with the requirements for the activities of bioethics commissions shall be issued on the basis of conducting LBC inspections, which include the following stages:

1) self-assessment conducted by the LBC using a self-assessment form in accordance with the requirements of the Standards for the activity of bioethics commissions approved by the CBC in accordance with subparagraph 4) of paragraph 3 of Article 228 of the Code of the Republic of Kazakhstan;

2) on-site verification of the compliance of the LBC with the requirements of the activities of bioethics commissions, carried out by the inspector within the framework of an on-site visit to the LBC (hereinafter referred to as on-site verification);

3) observation of an LBC meeting, conducted by the inspector as part of the visit to the LBC.

In order to conduct an inspection of an LBC and issue a certificate of compliance with the requirements of the activities of bioethics commissions, the CBC shall form a base of independent inspectors and train them in accordance with the requirements of the Standards.

Footnote. Paragraph 3 as amended by the order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated 31.03.2023 № 51 (shall be enforced upon expiry of ten calendar days after its first official publication).

4. To obtain a certificate, the LBC submits an application to the CBC secretariat for the issuance of a certificate of the LBC's compliance with the requirements for the activity of bioethics commissions in accordance with the form in the requirements of the Standards;

5. Based on the applications received, the CBC Secretariat:

1) develops the schedule of LBC certification for a calendar year;;

2) at least 240 calendar days prior to the date of the inspection, informs the LBC of the submission of the self-assessment form.

6. The LBC submits a self-assessment form at least 28 calendar days prior to the date of the visit.

7. The CBC Secretariat within 5 working days:

1) checks the completeness of the information provided in the form of self-assessment and requests the missing information;

2) in agreement with the CBC Chairperson, selects at least two inspectors from the base of independent inspectors and sends them a self-assessment form for preliminary assessment.

8. The inspectors pre-evaluate the self-assessment form and agree with the LBC on the final date and plan for the LBC inspection, including all on-site verification activities and the time of the LBC meeting to be observed.

Inspectors sign a confidentiality agreement prior to the commencement of inspections in accordance with the requirements of the Standards.

9. As part of the on-site inspection, inspectors:

1) hold an introductory meeting with LBC representatives;

2) hold a semi-structured interview with the LBC Secretary to discuss answers in the self-assessment form;

3) verify that the LBC's standard operating procedures are consistent with actual operating procedures;

4) verification of the location of the LBC and the existing conditions for the functioning of the commission;

5) check samples of research files (at least 6 files);

6) hold a meeting with the employees of the organization housing the LBC, where they explain the results of the inspection, identified positive aspects, inconsistencies and corrective actions (it is held on the last day of the on-site inspection).

Footnote. Paragraph 9 as amended by the order of the Actng Minister of Healthcare of the Republic of Kazakhstan dated 31.03.2023 № 51 (shall be enforced upon expiry of ten calendar days after its first official publication).

10. The LBC meeting is supervised:

1) as part of the on-site inspection (if the date of the next LBC meeting coincides with the on-site inspection);

2) separate from the on-site inspection (if the dates of the LBC meeting and the on-site inspection do not coincide).

The LBC shall provide inspectors with a copy of the relevant agenda for the observed meeting 3 working days prior to the meeting.

Inspectors do not take part in the meeting and attend as an observer only.

The results of the LBC meeting observation shall be included in the inspector's report (hereinafter referred to as the report) and recommendations for the corrective action plan (hereinafter referred to as the action plan)

Footnote. Paragraph 10 as amended by the order of the Actng Minister of Healthcare of the Republic of Kazakhstan dated 31.03.2023 № 51 (shall be enforced upon expiry of ten calendar days after its first official publication).

11. After completing the on-site inspection and observing the LBC meeting, the inspectors prepare a report and recommendations for an action plan within 7 calendar days.

12. Before sending a draft report and recommendations for an action plan to the CBC, inspectors send them to the LBC that was inspected.

13. When there is a large amount of incompliances in the LBC's activities, the CBC involves an external auditor. The draft report and recommendations for the Action Plan are sent to the external auditor for initial review prior to submission to the LBC.

14. The LBC draws up an action plan with a timeline for implementation not exceeding six months from the date of receipt of the inspection report. Upon the expiration of the deadlines for the implementation of measures to eliminate non-conformities, LBC, within 7 calendar days, sends information on the implementation of the action plan to the CBC in electronic form signed by the LBC Chairman and attaches supporting documents.

15. Inspectors review information on the implementation of the LBC's action plan and related documents and advise the CBC on the certification status of the inspected LBC.

16. Inspectors shall provide the following uniform set of documents to the CBC:

- 1) transfer act;
- 2) report on the results of LBC inspection;
- 3) an action plan with information on its implementation;
- 4) a self-assessment form;
- 5) checklist for inspection of research files;
- 6) checklist for observation of the LBC meeting.

Footnote. Paragraph 16 as amended by the order of the Actng Minister of Healthcare of the Republic of Kazakhstan dated 31.03.2023 № 51 (shall be enforced upon expiry of ten calendar days after its first official publication).

17. The documents submitted by the inspector are checked by the CBC within 14 calendar days of the documents' receipt.

18. The inspector's report is heard at the next meeting of the CBC, which, taking into account the results of the inspection, makes a decision:

- 1) on full certification (with the issuance of a certificate of the LBC's compliance with the standards of bioethics commissions for a period of 3 years);
- 2) on incomplete certification for a period of up to 1 year (with the issuance to the LBC of the CBC protocol decision on incomplete certification with an action plan to achieve full certification).

19. The CBC sends a letter confirming the full certification status to the head of the organization, the secretary and chairman of the LBC, and to the authorized health authority within 14 calendar days of the decision.

20. The validity period of the certificate of compliance with the requirements for the activities of bioethics commissions is three years with full certification of the local bioethics commission and one year with incomplete certification of the local bioethics commission.

21. After the expiry of the LBC's certificate of compliance with the standards of activity of bioethics commissions, the re-certification of the LBC is carried out within one month of the certificate's expiration.

22. The LBC with incomplete certification shall apply for full certification no earlier than 60 calendar days before the expiration of the incomplete certification.

23. The CBC annually hears a report from the CBC Secretary on certification applications reviewed, inspections carried out and decisions taken.