

On approval of the Rules for ascertaining irreversible brain death and the Rules for termination of the artificial measures to maintain organ functions in case of irreversible brain death

Unofficial translation

Order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated October 27, 2020, No. ҚР ДСМ-156/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on October 29, 2020, No. 21531

Unofficial translation

In accordance with paragraph 4 and subparagraph 2) of paragraph 6 of Article 153 of the Code of the Republic of Kazakhstan dated July 07, 2020 "On public health and healthcare system", **I HEREBY ORDER:**

1. To approve:

1) The Rules for ascertaining irreversible brain death in accordance with Annex 1 to this Order;

2) The Rules for termination of the artificial measures to maintain organ functions in case of irreversible brain death in accordance with Annex 2 to this Order;

2. To recognize as invalid some orders of the Ministry of Healthcare of the Republic of Kazakhstan in accordance with Annex 3 to this Order.

3. The Department for Organization of Medical Aid of the Ministry of Healthcare of the Republic of Kazakhstan, in the manner prescribed by law, shall ensure:

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

2) posting 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, the submission to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan the information on the implementation of the measures provided for in subparagraphs 1), 2) of this paragraph.

4. Control over the execution of this Order shall be entrusted to the Supervising Vice-Minister of Healthcare of the Republic of Kazakhstan.

5. This Order shall come into effect upon the expiration of ten calendar days from the date of its first official publication.

*Acting Minister of Healthcare of the
Republic of Kazakhstan*

M. Shoranov

Annex 1
to the Order of the Acting

The Rules for ascertaining irreversible brain death

Chapter 1. General Provisions

1. These Rules have been developed in accordance with paragraph 4 of Article 153 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and healthcare system" and shall determine the procedure for ascertaining irreversible brain death (hereinafter referred to as the Rules).

2. Irreversible death of the brain is the cessation of the activity of the brain in connection with the death of the brain substance, in which artificial measures are taken to maintain the functions of the organs.

Chapter 2. Procedure for ascertaining irreversible brain death

3. To ascertain the irreversible death of the brain, a council of a medical organization shall be created, consisting of: an anesthesiologist-resuscitator with at least 5 years of experience in resuscitation and a neuropathologist with at least 5 years of experience in the specialty. When carrying out special studies (registration by electroencephalography, angiography), an appropriate specialist with at least 5 years of experience in the specialty, including those invited from other medical organizations on a consultative basis, shall be included in the council. The appointment of the composition of the council and the approval of the conclusion on the ascertaining of brain death shall be carried out by the chairman of the council, represented by the chief physician or deputy chief physician for the medical work of the medical organization where the patient is.

4. Irreversible brain death shall be ascertained by a council of a medical organization based on a combination of the following signs of termination of the functions of the central nervous system, as well as clinical tests and other diagnostic studies (hereinafter referred to as the Set of signs):

- 1) complete and stable lack of consciousness;
- 2) atony of all muscles;
- 3) disappearance of any reactions to external irritation and any types of reflexes (no reaction to strong painful irritations in the area of trigeminal points, corneal, oculocephalic, oculovestibular, pharyngeal, tracheal), which are closed above the level of the spinal cord:

to induce oculocephalic reflexes, the doctor shall take a position at the head of the bed so that the patient's head is held between the doctor's hands, and the thumbs raise the eyelids. The head rotates 90 degrees to one side and is held in this position for 3 - 4 seconds, then in the opposite direction for the same time. If, when turning the head, eye movements do not

occur and they persistently maintain a middle position, then this indicates the absence of oculocephalic reflexes;

oculocephalic reflexes shall not be investigated in the presence or suspicion of traumatic injury to the cervical spine;

to study oculovestibular reflexes, a bilateral caloric test shall be performed. Before carrying out it, one must make sure that there is no perforation of the tympanic membranes. The patient's head shall be raised 30 degrees above the horizontal level. A small catheter shall be inserted into the external auditory canal, and the external auditory canal is slowly irrigated with cold water (temperature $+ 20^{\circ} \text{C}$, 100 milliliters) for 10 seconds. If the function of the brain stem is intact, nystagmus or deviation of the eyes towards the slow component of nystagmus appears in 20-25 seconds. The absence of nystagmus or deviation of the eyeballs in a caloric test performed on both sides indicates the absence of oculovestibular reflexes;

the study of pharyngeal and tracheal reflexes shall be performed by moving the endotracheal tube in the trachea and upper airways, as well as by advancing the catheter in the bronchi for aspiration of secretions.

4) stable dilation and non-reactivity of the pupils and their fixation in the middle position (it should be known that no drugs that dilate the pupils were used, the eyeballs are motionless);

5) a tendency to hypotension - 80 mm. Hg and lower for an adult;

6) spontaneous hypothermia;

7) sustained lack of spontaneous breathing. Disconnection of the patient from the ventilator shall be performed using a specially designed disconnection test (apnea test).

The disconnection test shall be carried out after the results for subparagraphs 1) -6) of this paragraph are obtained. To monitor the blood gas composition (PaO and PaCO), one of the arteries of the limb is cannulated. The test consists of three steps to monitor blood gases.

Initial monitoring of blood gases shall be performed using conventional mechanical ventilation.

Next, mechanical ventilation is switched to a mode that provides normocapnia (PaCO - 35 -45 mm Hg) and hyperoxia (PaO not less than 200 mm Hg) - $\text{FiO} = 1.0$, that is, 100% humidified oxygen is supplied at a rate of at least 6 liters per minute. At this time, the accumulation of endogenous carbon dioxide occurs, controlled by taking arterial blood samples. Blood gases shall be monitored 10-15 minutes after the start of mechanical ventilation with 100% oxygen.

The ventilator is turned off, then every 10 minutes the blood gases are monitored until PaCO reaches 60 mm Hg.

If at these or higher values of PaCO spontaneous respiratory movements are not restored, the disconnection test indicates the absence of functions of the respiratory center of the brain stem.

When minimal respiratory movements appear, ventilation is immediately resumed.

5. Irreversible brain death in adults shall not be established when:

- 1) intoxication, including drug;
- 2) primary hypothermia;
- 3) hypovolemic shock;
- 4) metabolic endocrine coma;
- 5) action of narcotic drugs and muscle relaxants;
- 6) patient has a specific posture (decerebration or decorticate).

6. Irreversible death of the brain in children shall not be established when:

- 1) intoxication, including drug;
- 2) primary hypothermia (in children, the body temperature is below 35 C);
- 3) hypovolemic shock;
- 4) metabolic, endocrine coma;
- 5) action of narcotic drugs and muscle relaxants;
- 6) the patient has a specific posture (decerebration or decorticate);
- 7) arterial hypotension:

in children from 1 to 3 years old, when determining the signs of brain death, the level of systolic pressure is not lower than 75 mm Hg.

in children from 4 to 10 years old, when determining the signs of brain death, the level of systolic pressure is not lower than 85 mm Hg.

in children from 11 to 18 years old, when determining the signs of brain death, the level of systolic pressure is not lower than 90 mm. Hg.

- 8) hypoxemia;
- 9) hyponatremia or hypernatremia;
- 10) hypokalemia;
- 11) hypoglycemia or hyperglycemia.

7. Diagnosis of irreversible brain death in children under 1 year of age shall not be performed.

8. In the presence of clinical signs of irreversible brain death, spinal automatisms and reflexes are observed, specified in Annex 1 to these Rules.

9. If there is a suspicion of injury to the cervical spine, perforation of the tympanic membranes after identifying the clinical signs described in subparagraphs 1) -7) of paragraph 4 of these Rules, to ascertain irreversible brain death, the council of a medical organization shall conduct one or more of the following instrumental diagnostic methods that carry auxiliary character:

1) an electroencephalogram (hereinafter referred to as EEG) shall be performed to confirm the clinical diagnosis of brain death in all situations where there are difficulties in identifying injuries or suspicion of injury to the cervical spine, perforation of the eardrum.

For electrical silence of the brain, an EEG recording shall be taken, in which the amplitude of activity from peak to peak does not exceed 2 microvolts (hereinafter referred to

as mkV), when recording from scalp electrodes with a distance of at least 10 centimeters between them and with a resistance of up to 10 kilo-ohms (hereinafter referred to as kOhm), but not less than 100 ohms. Needle electrodes are used, at least 8 located according to the 10-20 scheme and 2 ear electrodes. The interelectrode resistance is not less than 100 Ohm and not more than 10 kOhm, the interelectrode distance is not less than 10 centimeters. Before conducting the study, it is necessary to make sure that the commutations are safe and that there is no inadvertent or deliberate creation of electrode artifacts.

The recording shall be carried out on the channels of the encephalograph with a time constant of at least 0.3 seconds with a sensitivity of no more than 2 mkV / millimeter (the upper limit of the frequency bandwidth is at least 30 hertz). Apparatus with at least 8 channels are used. EEG is recorded with bipolar and monopolar leads. Electrical silence of the cerebral cortex is maintained for at least 30 minutes of continuous recording.

If there is any doubt about the electrical silence of the brain, the EEG is re-recorded. Evaluation of EEG reactivity to light, loud sound and pain: the total time of stimulation with light flashes, sound stimuli and painful stimuli are not less than 10 minutes. The source of flashes fired at a frequency of 1 to 30 Hz is located 20 centimeters from the eyes. The intensity of sound stimuli (clicks) is 100 decibels. The speaker is located near the patient's ear. Maximum intensity stimulants are generated by standard photo-stimulants and phonostimulants. For painful irritations, strong injections of the skin with a needle are used;

2) contrast angiography of four main vessels of the head (common carotid and vertebral arteries) to determine cerebral circulation shall be performed twice with an interval of at least 30 minutes. The mean arterial pressure during angiography should be at least 80 mm Hg. Art. The absence of filling of the intracerebral arteries with a contrast agent during angiography indicates the cessation of cerebral circulation.

10. The observation period in adults with primary brain damage is at least 12 hours from the moment a set of signs is detected, with the signs remaining for more than 12 hours, is the basis for ascertaining irreversible brain death. The observation period is shortened after determining the set of signs (one or several) during angiography, which records the cessation of the cerebral circulation, and (or) EEG, which records the complete absence of spontaneous and evoked electrical activity of the brain. If it is impossible to use EEG and angiography, the observation period is extended to 24 hours, from the moment a set of signs is detected.

11. The observation period in adults with secondary brain damage is at least 24 hours from the moment of detection of a set of signs. In the presence of toxic substances in the blood, the duration of observation is increased to 24 hours from the moment the toxic substances in the blood disappear, confirmed by laboratory tests, or to 72 hours if laboratory tests for the presence of toxic substances in the blood shall not be carried out.

12. The observation period in children shall be at least 24 hours from the moment of revealing a set of signs with intervals between examinations of at least 12 hours.

13. The patient is under constant supervision, with the frequency of neurological examination at least 1 time in 2 hours at 12 and 24 hours of observation and at least 3 hours at 3 days of observation.

14. The members of the council shall draw up and sign an opinion on the ascertaining of irreversible brain death in accordance with Annex 2 to these Rules. The conclusion shall be approved by the head of the intensive care unit or the person performing his duties

Annex 1 to the Rules for
ascertaining irreversible brain
death

Spinal automatisms and reflexes

Part of the body	Occurring signs
Cervical spine	Tonic cervical reflexes: spastic contracture of the neck muscles, flexion in the hip joint in response to head rotation, flexion in the elbow joint in response to head rotation, lowering of the shoulder in response to head rotation, spontaneous head rotation to the side.
Upper limbs	Unilateral extension - pronation. Isolated twitching of the fingers. Flexion and lifting of the shoulder described the case with the connection of the arms.
Torso	Asymmetric opisthotonic body position. Flexion of the trunk in the lower back, simulating a sitting position. Abdominal reflexes.
Lower limbs	Flexion of fingers in response to tapping. Triple flexion phenomenon. Babinsky symptom.

Annex 2 to the Rules for
ascertaining irreversible brain
death

Conclusion on ascertaining irreversible brain death

Last Name _____ First Name _____ Partonymic (if any) _____

— Date of Birth _____ Age _____ Medical Record No. _____

The diagnosis of the disease, leading to irreversible brain death

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The commission consisting of: a doctor - anesthesiologist - resuscitator

— (surname, first name, patronymic (if any)) a neurologist

— (surname, first name, patronymic (if any)) other involved specialists

— (surname, first name, patronymic (if any).)

— for _____ hours examined the patient and concluded that:

1. Excluded following factors impeding the establishment of the diagnosis of irreversible brain death

(ascertaining factors shall be noted the word "excluded"): intoxication,

including medicinal _____

primary hypothermia _____

hypovolemic shock _____

metabolic or endocrine coma _____

relaxants _____

anesthetics _____

specific posture (decerebration or decorticate) _____

arterial hypotension _____.

2. The following signs were registered, indicating the cessation of the function of the cerebral

hemispheres and the brain stem (the statement of signs and these additional tests is marked with the word "yes" or "no"):

complete and stable absence of consciousness

(coma) _____

atony of all muscles _____

_____ lack of response to strong pain stimuli

(pressure on the trigeminal points, sternum) and any other reflexes that close above the cervical spinal cord _____

the pupils do not respond to light _____

pupil diameter _____

absence of corneal reflexes _____

absence of trachiocephalic reflexes _____

absence of oculovestibular reflexes _____

absence of oculovestibular when the endotrachea moves tube and airway sanitation)

lack of spontaneous breathing during the separation test:

PaCO₂ before the start of the test in mm Hg. _____

(insert numbers)

PaCO₂ in the middle of the apnea test in mmHg. _____

(indicate in numbers)

PaO₂ at the end of the apnea test in mm Hg. _____.

(indicate in numbers)

3. Additional (confirmatory) tests (statement of these additional tests is marked with the word "yes" or "no"):

electroencephalogram (complete electrical silence of the brain) _____

angiography of the great vessels

of the brain (no filling of intracerebral arteries) _____

4. Comments: _____

5. Conclusion: Having considered the above results and guided in their interpretation by the Rules for establishing

irreversible brain death based on the diagnosis of irreversible brain death, we certify the patient's death _____

(last name, first name, patronymic (if any))

Date _____ Time of death _____ (number , month, year)
(hour, minute)

Signatures of doctors included in the commission:

Signature of the head of the intensive care unit: _____
(last name, first name, patronymic (if any))
Signature of the chairman of the council: _____

(last name, first name, patronymic (if any))

Annex 2
to the Order of the Acting
Minister of Healthcare of the
Republic of Kazakhstan
dated October 27, 2020
No. КР ДСМ -156/2020

The Rules for termination of the artificial measures to maintain organ functions in case of irreversible brain death

Chapter 1. General Provisions

1. These rules are developed in accordance with subparagraph 2) of paragraph 6 of Article 153 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and healthcare system" (hereinafter referred to as the Code) and shall determine the procedure for terminating artificial measures to maintain the functions of organs in the event of irreversible death of the head brain.

2. Artificial measures to maintain the functions of organs are aimed at restoring vital functions, including the functions of respiration and blood circulation of a person, in case of irreversible death of the brain.

Chapter 2. The procedure for termination of the artificial measures to maintain organ functions in case of irreversible brain death

3. Artificial measures to maintain the functions of organs shall be terminated by the attending physician resuscitator only when:

- 1) statements of biological death;
- 2) irreversible brain death, ascertained by the council, in accordance with paragraph 4 of Article 153 of the Code, with the written consent of the spouse, in his (her) absence, one of the close relatives, and (or) legal representative.

After ascertaining the irreversible death of the brain, a record of the measures taken shall be made in the medical record of the inpatient and the time of death shall be recorded.

Annex 3
to the Order of the Acting
Minister of Healthcare of the
Republic of Kazakhstan
dated October 27, 2020
No. ҚР ДСМ-156/2020

The list of some Orders of the Ministry of Healthcare of the Republic of Kazakhstan that have become invalid

1. Order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated August 11, 2010 No. 622 "On approval of the Rules for the determination of biological death or irreversible brain destruction (brain death)" (registered in the State Register of Normative Legal Acts under No. 6449, published in the newspaper "Kazakhstanskaya Pravda" dated October 2, 2010 No. 260-261 (26321-26322)).

2. Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated June 8, 2015 No. 459 "On amendments to the Order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated August 11, 2010 No. 622" On approval of the Rules for establishing biological death or irreversible brain destruction (death brain)" (registered in the State Register of Normative Legal Acts under No. 11621, published in the Legal Information System "Adilet" on July 20, 2015).

3. Order of the Minister of Healthcare of the Republic of Kazakhstan dated September 25, 2018 No. ҚР ДСМ-18 "On Amending the Order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated August 11, 2010 No. 622 "On Approval of the Rules for the statement of biological death or irreversible brain destruction (death brain), and the termination of artificial measures to maintain the vital functions of organs after the detection of biological death or irreversible brain destruction (brain death)", (registered in the State Register of Normative Legal Acts under No. 17740, published the Reference Control Bank of normative legal acts of the Republic of Kazakhstan in electronic form on November 30, 2018)