Ministerial Decree No. 550 of 2017 on the Declaration of Death

Minister of Health and Prevention:

- Having taken cognizance of Federal Law No. (1) of 1972 Concerning the Mandates of Ministries, Powers of Ministers and its amendments;
- Federal Law No. (7) of 1975 Concerning the Practice of Human Medicine Profession;
- Federal Law No. (4) of 2015 on Private Health Facilities;
- Federal Decree-Law No. (4) of 2016 on Medical Liability;
- Federal Decree-Law No. (5) of 2016 on the Regulation of Human Organs and Tissues Transplantation;
- Cabinet Resolution No. (6) of 2013 Concerning the Organizational Structure of the Ministry of Health;
- **And based on the requirements of public interest …**

Has decided as follows:

Article (1)

Death shall be declared upon complete cardiac-respiratory arrest, complete and irreversible loss of all brain functions, and upon physicians' decision that such arrest and cessation is complete and irreversible as per the criteria contained in the Annex attached to this Decree.

Article (2)

This Decree shall be published in the Official Gazette and shall come into force as of the day following its publication date.

H.E. Abdul Rahman Mohammed Al Owais

Minister of Health and Prevention

Issued in the Main Office of the Ministry

On: Sha'ban 10, 1438 H

Corresponding to: 7/5/2017 G

*In case of any misinterpretation, the Arabic version of this legislation prevails.

Annex to the Decree of the Ministry of Health and Prevention on the Declaration of Death

First: Declaration of death resulting from complete cardiac-respiratory arrest:

This diagnosis is made after ensuring that death has absolutely happened due to complete, definitive, and irreversible cardiac-respiratory arrest as per the medical standards applicable in this regard to declare the death, as per the following:

1. Spontaneous Respiratory Arrest (SRA)
2. Absence of pulse and Low Blood Pressure (Hypotension)
3. Absence of heartbeats while using the stethoscope

Second: Declaration of death resulting from complete and irreversible loss of all brain functions:

This diagnosis is made through specific cerebral guides, it is available at any hospital with an intensive care unit, and it is applied for any patient who meets the characteristics of death using the cerebral criteria.

1. Who is allowed to diagnose death through cerebral criteria?

A neurologist, neurosurgeon, internal medicine specialist, intensive care specialist, anesthesiologist, pediatrician, or any specialist physician with sufficient experience to diagnose brain death can make the diagnosis.

It is strictly forbidden for an organ transplant doctor or surgeon to be involved in diagnosing brain death in any way whatsoever.

2. Medical aspects of death through cerebral criteria:

2.1 Definition:

Brain death is defined as an irreversible cessation of all functions of all parts of the brain, including the brain stem.

2.2 Conditions and exceptions for diagnosing death through cerebral criteria.

2.3 Prerequisites for diagnosing death though cerebral criteria:

The following conditions must be met before starting the process of diagnosing death though cerebral criteria:

a. The patient is in state of coma due to specific and known cause;
b. The patient is under a ventilator and his respiration is not spontaneous;
c. That at least 6 hours have passed since the occurrence of accident that led to brain death, clearly mentioning the cause of death (for example, head injury, brain hemorrhage, … etc.);
d. The patient should not be in a state of cardiovascular stroke;
e. That all metabolic and endocrine disrupting have been cured;
f. There should be no response to any type of stimulants;
g. Total absence of reflexes, though some simple spinal reflexes may appear;

2.2.2 **Exceptions**:

a. The patient should not be hypothermic and the internal body temperature must be more than 34 °C before the brain death is diagnosed, if it is less than that degree, the patient's body must be warm to raise the temperature;
b. It must be excluded that the patient is under the influence of sedatives, hypnotics, drugs, nervous system depressants, muscle relaxants and antidepressants. The blood levels of such substances or the patient's medical history file must not indicate the presence of explicit levels of sedative drugs or muscle relaxants and the patient did not receive sedative treatment in the past five days. A toxicological test should be performed, especially in cases of traffic accidents, drug poisoning and cases of unknown coma, and in all cases that the doctor thinks there is an indication for that. In case this is not available, the clarification of death must be made after five days;
c. Exclude patients with metabolic and endocrine disrupting;
d. The patient does not make any action indicating cerebral activity, such as seizures, decerebrate and decorticate posturing;

2.3 How to diagnose death through cerebral criteria?

After making sure that the prerequisites are met and exceptions are excluded, it is necessary to proceed to the clinical examination as per the death diagnosis document through cerebral criteria and record the clinical findings in that document. After that, the examining physician signs that document and the case shall be re-examined after the specified monitoring period is passed and the death diagnosis document shall be signed again.

2.3.1 Initial Clinical Examination:

1. Ensure that the patient is a state of coma;
2. Assess the patient in terms of the presence of brain activity, such as seizures or movements indicating the presence of decerebrate and decorticate posturing as the patient with brain death does not show any of that. The presence of spinal reflexes and/ or myoclonus does not preclude brain death;
3. Examine the motor response to painful stimuli; for example, pressing on the frontal sinus area does not lead to any kind of furrowed brow or grimacing (Figure 1).

Figure (1): Examining the motor response to painful stimuli

2.3.2 Brainstem reflexes test

After carrying out the aforementioned initial assessment, the necessary tests must be performed to ensure the absence of brainstem reflexes according to the following order (the presence of any of following reflexes obviate the need to complete the remaining examinations):

a. Pupillary response to light/ pupillary light reflex (PLR):

A good and strong light source should be directed towards the open eye in a manner does not lead to any reaction, whether directly or indirectly, in the other eye of the person that is suffering from brain death.

Both eyes should be tested, making sure not to use any kind of eye drops or medicine causing the pupil to dilate before the test.

Figure No. (2): Pupillary response to light/ pupillary light reflex (PLR)

b. Corneal reflex:

Touch the cornea with a wick of cotton (Figure 3), you will notice that the eye does not blink in case of brain death. The test must be performed for both eyes and the pressure on the cornea must be heavier in potential brain death patients.

Figure No. (3) Corneal Reflex Test

c. Vertical vestibulo-ocular reflex (VOR):

Stand at the head of the patient's bed, hold the patient's head steadily with both hands in a middle position, suddenly move the head to the right side, then move it to the left side.

Monitor the movement of the eyes during the stages of the test by lifting the eyelids up using your thumbs.

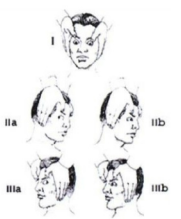

Figure No. (4)

Positive vertical vestibulo-ocular reflex (notice the eye position for the head movement direction)

Photo No. 1: Head and eyes are in a neutral position

Photo No. 2a and 3a: Eyes are squinting towards a direction opposite to the movement of the head, if the movement is to the left or to the right side

Photo No. 2b and 3b: Eyes are returning back to the neutral position

The test is considered positive in case the eyes are moving towards the opposite direction of head movement, and the brain stem is alive in this case and there is no need to complete the rest of the tests. If the brain stem is dead, eyes and head will to the same direction.

This test should not be performed if it is suspected that a patient with a recent injury is suffering from fractured vertebra, and the patient can be disconnected from the ventilator during the period of the test for 20-30 seconds.

d. Vestibulo-ocular reflex (VOR) (thermal test):

It is performed through putting 50 ml of cold water at a temperature of 0°C in the external auditory canal of the right and left ear alternately (for children: It is sufficient to put 10-20 ml). If no eye movements occur, this means that there is brain death.

The absence of eye squint towards the direction of the test indicates a break in the reflex arc due to damage to the reflex centers (the brain stem) or paralysis in the external eye muscles. Therefore, this test should not be performed for a patient receiving muscle relaxants.

The integrity of the tympanic membrane (eardrum) must be checked by an otoscope before starting the test, making sure that there is no mechanical obstruction in the auditory canal (cerumen/ earwax). In the event that the tympanic membrane is damaged, cold air can be used instead of cold water, and this test should not be performed when there is local damage to the ear.

Figure No. (5) Thermal Test

e. Excitability of the upper and lower respiratory tract:

(For example: by sucking pharyngeal and tracheal secretions):

This test is performed to stimulate the pharynx and the carina of trachea. Insert the catheter for sucking secretions from the pharynx and carina of trachea until it reaches the tracheal (Figure 6).

This test does not trigger any coughing or gagging reaction for the patient that has brain death.

Figure 6: The GAG Reflex Test

2.3.3 Observation Period (the intervals between the two clinical examinations):

After completing the first clinical examination, the second examination should be performed after the necessary observation period specified in the protocol is passed. The results of the two tests should be duly recorded in the brain death document and signed by the examining physicians.

The following table shows the time interval that is required between the first and second clinical examination according to different age groups:

Table of the observation period required between two clinical examinations according to the age groups

* Infants (7 days - 60 days)	48 hours
*Infants (> 60 days - 1 year)	24 hours
**Children (> years to adulthood)	12 hours
**Adults	6 hours

*Two electroencephalogram (EEG) tests may only be performed with a time interval between them equivalent to the observation period;

**One electroencephalogram (EEG) test may only be performed after completing the first clinical examination.

2.3.4 Confirmation tests:

If it is proven that all of the aforementioned brainstem reflexes are absent, the physician can proceed to performing the confirmation tests, which are either:

- Electroencephalogram (EEG)

This should show electro cerebral silence (ECS), and the recording must be made for at least 30 minutes according to the medically recognized principals, noting that if the patient has a hypothermia, his body temperature must be raised before doing the EEG.

- Cerebral angiography:

The lack of blood-cerebral flow when imaging the four cerebral arteries constitutes a confirmation test for diagnosing death in children and adults. Isotopic cerebral angiography is considered a confirmation test for death in children as it shows the lack of cerebral-arterial blood flow and the stop of carotid artery blood flow at the base of the skull even if it shows a part of venous sinuses inside the brain.

Indications for imaging Cerebral Arteriography:

The following conditions constitute reasons for conducting cerebral arteriography:

1. The absence of an EEG machine or the impossibility of imitating it due to technical problems, in which case a clinical examination and an apnea test should be performed before the arteriography;
2. Inability to exactly and precisely determine the cause of death;
3. The presence of metabolic disorders, shock, or hypothermia and inability to treat any of them despite providing the appropriate intensive treatment;
4. Difficulty in persuading the family of the brain-dead person of his/ her death using cerebral guides;

The lack of cerebral perfusion and cerebral blood flow constitutes evidence of irreversible brain damage.

Proving the lack of cerebral blood flow (CBF) using other means:

In all fields, the lack of cerebral blood flow can be proven using brain arteriography or Transcranial Doppler (TCD) and they all confirm the presence of irreversible brain damage.

2.4 Apnea test:

This test is performed as a last step after performing the two clinical examinations, as previously mentioned, and confirming the absence of brain stem reflexes. It is performed by two specialists only once after performing one of the other confirmation tests and ensuring their compatibility with the reasons of death through cerebral guides.

How to perform the test?

This test demonstrates the existence of apnea (absence of spontaneous respiration); therefore, the following precautions must be taken before performing this test:

General considerations:

a. The apnea test (AT) should be performed for a body with temperature of 36.5 °C or higher;
b. Avoid lack of oxygen that can further damage the brain;
c. Ensure that the partial pressure of carbon dioxide (PCO_2) has reached level of 8.1 - 6.7 kilopascals (50-60 mmHg) at the end of the period of separating the patient from the ventilator, as the aforementioned concentration constitutes a sufficient stimulus for the respiratory centers in the living brain stem;
d. If the patient is in a critical condition that does not allow performing the apnea test, the test can be replaced by the aforementioned cerebral perfusion tests.

Steps of performing the test:

a. Raising the Oxygen concentration for the patient at 100% for ten minutes. (The oxygen concentration is increased without changing the ventilation rate);

b. Separate the patient from the ventilator and provide him/ her with humidified high flow of oxygen at 6 L/ minute (-100% oxygen) using a catheter passing through the carina of trachea. (In children: It is sufficient to provide them with 1.5-2 L/ minute). Ensure that the catheter's size does not cause obstruction of the airway, and it is recommended to use a pulse oximeter during the test period;
c. The patient is separated from the ventilator for 10 minutes, during which the patient is observed to see any attempt to breathe, and an arterial blood sample is drawn to measure the partial pressure of carbon dioxide, which should be higher than 8.1 kPa (> 60 mm Hg) in adults and 7. 6 kPa (55 mmHg) in children or the existence of increase of 20 mmHg more than the main increase;

The apnea test is considered positive if there is no breathing during the period of separation of the patient from the ventilator.

3. <u>Diagnosis of death using cerebral criteria in children:</u>

For declaration of death in children, the same general steps followed in adults must be followed with some necessary adjustments according to age, which are as follows:

- Babies of 7 days - 2 months old: The observation period should be prolonged to 48 hours, and two electroencephalogram tests should be performed with time interval of 48 hours, and both of them show cerebral inactivity, i.e. electro cerebral silence (ECS);
- Babies of 2 months – 1 year-old: Prolonging the observation period to be 24 hours along with performing two electroencephalogram tests with time interval of 24 hours, and both of them show cerebral inactivity, i.e. electro cerebral silence, or one electroencephalogram test showing electro cerebral silence, along with studying the blood flow using computed tomography (CT) scan or using isotopes showing the lack of cerebral blood flow (CBF);
- Children over one year until adulthood:
  Follow the same protocol as adults, except for the observation period, which must be at least 12 hours.
- After adulthood: The same protocol as adults should be followed.