# **Encyclopedia of Health Legislation**

Book 4: Human Organ and Tissue Transplantation Legislation



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ISBN: 978-9948-786-46-7 Approval of Media Regulatory Office United Arab Emirates Print Permission: MC-03-01-5985078 02-May-2023

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Third Issue - February 2023

Book 4:

# Human Organ and Tissue Transplantation Legislation



# صاحب السمو الشيخ محمد بن زايد آل نهيان رئيس دولة الإمارات العربية المتحدة

رئيس دولة الإمارات العربية المتحدة HIS HIGHNESS SHEIKH MOHAMED BIN ZAYED AL NAHYAN PRESIDENT OF THE UNITED ARAB EMIRATES



# **المغفور له بإذن اللّٰه الشيخ زايد بن سلطان آل نهيان** تغمده الله بواسع رحمته SHEIKH ZAYED BIN SULTAN AL NAHYAN



# المغفور له بإذن الله الشيخ خليفة بن زايد آل نهيان تغمده الله بواسع رحمته SHEIKH KHALIFA BIN ZAYED AL NAHYAN



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The release of the third issue of the Encyclopedia of Health Legislation by the Department of Health - Abu Dhabi reflects the aspirations of the Government of Abu Dhabi to deliver the best services to customers and provide an organizational and legislative knowledge, and is the Department's first step towards legislative digitization in the health field to achieve its vision of "a healthier Abu Dhabi" and hence promote the wellbeing and happiness of community.

"Legislation Regulating the Transplantation of Human Organs and Tissues" in this fourth book of the Encyclopedia is released due to the special and sensitive nature of this sector on the health of people first, and then on the security and safety of the community. This necessitated the enactment of a set of laws to codify, regulate and set the controls, prohibitions and penalties necessary to combat some of the behaviors that may be related thereto, such as trafficking in human organs, at the level of the state and GCC countries.

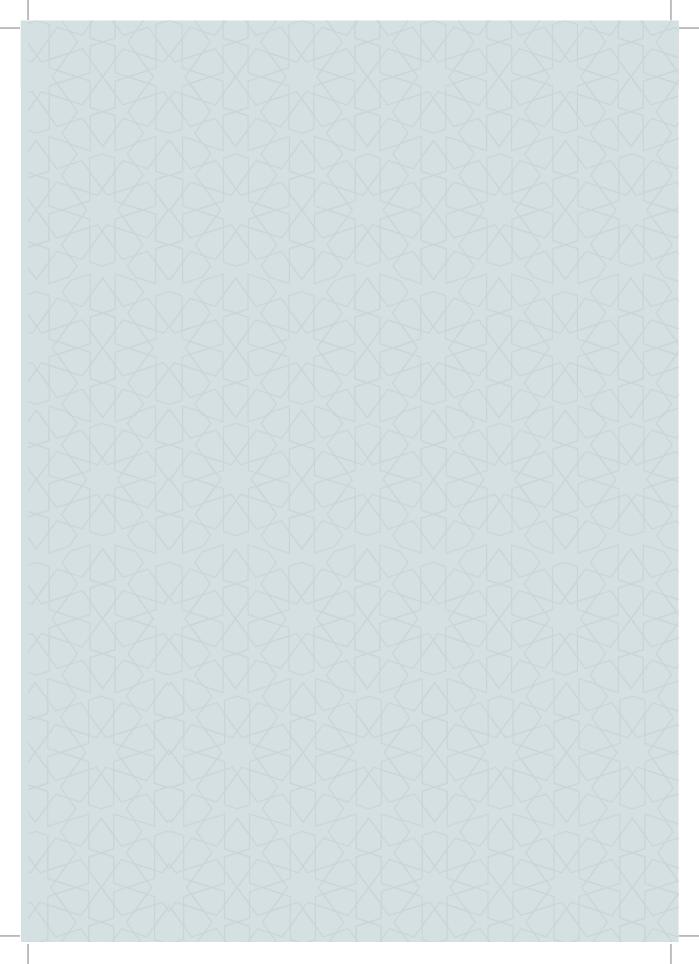
Legislation Regulating the Transplantation of Human Organs and Tissues includes the regulating laws and regulations, GCC Ministers of Health Council Resolution and the GCC Unified Guide to Organs Transplantation in the GCC Countries, in an effort by the Abu Dhabi government to govern this important sector locally and regionally in light of scientific progress and tremendous discoveries In medical sciences and their practices, and the unique technical revolution that the world is witnessing in this field.

DOH will seek to strengthen the body of human organ and tissue transplantation legislation with further contributions and initiatives, to maintain the sustainability of human and community protection, and support medical practices based on innovation, leadership and foreseeing the medical future of the Emirate and the UAE in this vital field.

Finally, we would like to express our profound gratitude for the guidance and trust of H.E. the Chairman of the Department of Health and for the follow-up, support and attention of H.E. the Undersecretary. We would also like to extend our thanks and appreciation to DOH partners, all the Encyclopedia team, and the officials of DOH organizational units for their efforts and active participation in completion of this book, looking forward to working together towards further development and modernization to strengthen the body of the health legislation in the Emirate of Abu Dhabi.

# Saqr Al Marzooqi

Manager, Legal Affairs Office Abu Dhabi - February 2023



# Decree-Law No. (5) of 2016 on the Regulation of Transplantation of Human Organs and Tissues\*

#### We, Khalifa bin Zayed Al Nahyan, President of the United Arab Emirates:

- Having regard to the Constitution;
- Federal Law No. (1) of 1972 on the Mandates of Ministries and Powers of the Ministers, as amended;
- Federal Law No. (7) of 1975 on the Practice of Human Medicine Profession,, as amended;
- Federal Law No. (3) of 1987 Promulgating the Penal Code, as amended;
- Federal Law No. (10) of 1992 on Evidence in Civil and Commercial Transactions, as amended;
- Federal Law No. (11) of 1992 Promulgating the Civil Procedure Code, as amended;
- Federal Law No. (35) of 1992 Promulgating the Criminal Procedure Code, as amended;
- Federal Law No. (15) of 1993 on the Regulation of Transplantation of Human Organs;
- Federal Law No. (28) of 2005 on Personal Status;
- Federal Law No. (9) of 2006 on Population Register System and ID Card, as amended;
- Federal Law No. (51) of 2006 on Combating Human Trafficking Crimes;
- Federal Law No. (10) of 2008 on Medical Liability;
- Federal Law No. (11) of 2008 concerning the Licensing of Fertilization Centres in the State;
- Federal Law No. (4) of 2013 on the Regulation of Notarial Profession;
- Federal Law No. (14) of 2014 on the Prevention of Communicable Diseases;
- Federal Law No. (4) of 2015 on Private Health Facilities;
- Federal Decree-Law No. (4) of 2016 on Medical Liability; and



<sup>\*</sup> This translation from Arabic to English is provided for your convenience only. In case of any discrepancy, the Arabic version prevails.

- Based on the proposal of the Minister of Health and Prevention, and the approval of the Cabinet;
- Promulgate the following Decree-Law:

# **Chapter One**

#### **General Provisions**

# Article (1) Definitions

In application of the provisions of this Decree-Law, the following words and expressions shall have the meanings ascribed to them, unless the context otherwise requires:

State	: The United Arab Emirates.
Ministry	: The Ministry of Health and Prevention.
Minister	: The Minister of Health and Prevention.
Competent Health Authority	: The Ministry or any local government entity in charge of health affairs.
Organ	: A collection of interconnected human tissues and cells taken from a living or deceased person, and involved in specific vital functions in the human body.
Tissue	: A mixture of human organic compounds, such as cells and fibres that do not form an Organ, and constitute altogether an anatomical entity consistent with the functioning of human Tissue, such as bone, muscle or nervous tissue.
Transfer (Organs and Tissues)	: A surgery in which an Organ or part thereof or a human Tissue is removed from a living or deceased person to be transplanted into a living person.

Death	: The total cessation of life, definitely and reliably,
	due to either the irreversible total cessation of
	respiratory and cardiovascular functions or the
	irreversible total cessation of brain functions,
	according to accurate medical standards issued
	by decision of the Minister and the physicians'
	judgment that such cessation is irreversible.

Donation : A legal act that indicates the consent of a person during his life or the legally authorized persons after his death to transfer from him an Organ, or part of it, or one or more human Tissues to another person during his life, or recommends that after his death, without compensation.

# Article (2) Scope of Application

Provisions of this Decree-Law shall apply to Organs and Tissues' Transfer and transplantation surgeries performed in the State, including the free zones.

Provisions of this Decree-Law shall not apply to the stem cells, blood cells and bone marrow transplantation surgeries.

# <u>Article (3)</u> Objectives of the Law

This Decree-Law aims to:

- 1. regulate and develop the Transfer, transplantation and storage of human Organs and Tissues.
- 2. prevent trafficking in human Organs and Tissues.
- 3. protect the rights of donors and recipients of human Organs and Tissues.
- 4. regulate human Organs and Tissues' Donation process.
- 5. prevent the exploitation of the patient or the donor's needs.

# Article (4)

#### Licenses

Transplantation of Organs and parts thereof and human Tissues shall be made only by specialised physicians licensed to do so, and inside health facilities licensed by the Competent Health Authority. The Implementing Regulations of this Decree-Law shall determine the licensing conditions and procedures.

# Article (5) Prohibitions

It shall be prohibited to:

- 1. sell and purchase Organs or parts thereof or human Tissues by any means whatsoever, or receive any consideration in return for them;
- 2. perform and participate in the Transfers and transplants of Organs or parts thereof or human Tissues in violation of the provisions hereof;
- 3. publicize, advertise, promote or mediate in unlicensed Transfers and transplants of Organs or parts thereof or human Tissues;
- 4. finance the Transfers and transplants of Organs or parts thereof or human Tissues where it is known that the Donation has been made against a consideration.

# Article (6)

#### Costs of Organ and Tissue Transfer and Transplant Surgeries

Health facilities and their employees are prohibited from receiving sums of money that exceed the financial compensation for the costs and services they have provided within the scope of their work when performing Transfers or transplants of Organs or parts thereof or human Tissues, as determined by the Competent Health Authority in this regard.

# Article (7)

#### Transfer and Transplant of Organs and Tissues Carrying Genetic Traits

Without prejudice to the provisions set forth in any other law, Transfer or transplantation of Organs or parts thereof or human Tissues that are carriers of genetic traits shall be prohibited.

# Article (8)

#### **Medical tests**

- 1. Physicians shall conduct the necessary medical and psychological tests prior to the Transfer or transplant surgeries of Organs or their parts or human Tissues, to ensure that:
  - a. the donor is in good health according to the conventional medical principles.
  - b. the removal will not endanger the life of the donor or cause him any harm, contrary to the conventional medical rules.
  - c. the psychological condition of the donor allows the removal surgery.
  - d. the transplantation of an Organ or part thereof or human Tissue is the best way to treat the recipient.
  - e. the Organ or part thereof or the human Tissue to be removed is free from infectious diseases that would threaten the recipient's life, according to conventional medical principles.
  - f. the Organ or part thereof or the human Tissue is compatible with the recipient's body.
- 2. All the results of the tests referred to in paragraph (1) above shall be noted in a medical report signed by those in charge of the Transfer or Transplant surgery.

# <u>Article (9)</u> Complications of Removal

The donor must be notified of the proven and potential side effects or complications resulting from the removal of the Organ or part thereof or the human Tissue, and any possible repercussions on his personal, family and professional life.

#### <u>Article (10)</u> Establishment of a National Centre

The Cabinet may establish a national centre to regulate the Transfer, transplantation and storage of Organs and Tissues, and shall determine its duties and functions, the entity with which it shall be affiliated, and its functioning system and procedures.

# <u>Article (11)</u>

#### **Committees for Study of Cases that Require Organ Transplant**

One or more medical committees shall be formed in the national centre referred to in Article 10 of this Decree-Law, and shall be composed of no less than three (3) members of specialised physicians, and be concerned with the study of cases that require human Organ or Tissue transplant and the issuance of recommendations it deems fit. The committee members shall not be owners of, or partners in the licensed health facility, in which the removal or transplant surgery will be performed.

# **Chapter Two**

#### **Transfer of Organs and Tissues from Living Persons**

# Article (12)

#### Conditions of Transfer from a Living Person

- 1. No Transfer of Organs or part thereof or human Tissues shall be performed among living persons except as a Donation and by a person of a full legal capacity.
- 2. Donation referred to in paragraph (1) above shall be documented in accordance with the form prepared for this purpose by the Competent Health Authority, accompanied by medical reports required for the Transfer of Organs or part thereof or human Tissues of the Donor.
- 3. Donation of Organs or parts thereof or human Tissues shall be restricted among:
- a. Relatives up to the fourth degree.
- b. Spouses who have been married for at least two (2) years.
- c. Relatives of either spouse in relation to the other spouse up to the fourth degree.
- d. Mutual transplantation of human Organs and Tissues taken from the relatives of the donor and the recipient up to the fourth degree.
- 4. The Implementing Regulations of this Decree-Law shall determine any other conditions required for the implementation of the provisions of this Article.

# Article (13) Conditions of Transfer of Bone Marrow

As an exception to Article 12 of this Decree-Law, It shall be permissible to obtain bone marrow extracted from a minor or a partly or wholly incompetent person, on condition that:

- 1. the purpose of extraction is the bone marrow transplant into any of the parents, children or siblings of the donor.
- 2. the written consent of the parent or guardian of the donor is obtained.
- 3. there is no better way to treat the recipient.
- 4. the bone marrow extraction does not cause any harm to the donor.

# Article (14)

#### **Retracting Consent to Donate**

The donor may retract his consent to donate before removal of the Organ or part thereof or the human Tissue, and may not retrieve the Organ that has been removed after being donated pursuant to the provisions of this Decree-Law.

# **Chapter Three**

#### **Transfer of Organs and Tissues from Deceased Persons**

#### Article (15)

#### **Conditions of Transfer after Death**

An Organ or part thereof or human Tissue may be transferred, on condition that:

- 1. transfer is made only after Death is established.
- 2. Death is established by a committee formed of three (3) specialist physicians, including a physician specialized in neurological diseases, provided that such committee does not comprise at the time of report preparation, the physician entrusted with the Organ and Tissue Transfer surgery, or the owner of the health facility where the surgery takes place, or any of the partners therein.

- 3. the donor has not explicitly expressed his refusal to donate his Organs and Tissues during his life.
- 4. the donor has expressed his wish to donate his Organs or Tissues according to the provisions of Article 16 of this Decree Law. In case of failure to do so, the approval provided for in Article 17 hereof must be obtained.
- 5. the Transfer is made in a manner that does not distort the body.

#### Article (16) Establishing Donation after Death

Anyone enjoying full capacity may express his wish to donate, after his Death, one of his Organs or parts thereof or Tissues, and may retract his wish to donate at any time unconditionally, provided that the same is stated in the identity card or any other document, as specified by the Implementing Regulations of this Decree-Law.

#### <u>Article (17)</u>

#### Conditions of Transfer from a Deceased Person who Did not express his Wish in this Respect

In order to remove an Organ or part thereof or a Tissue from the corpse of a deceased person who did not express in writing and in his life, his wish or refusal to donate, the approval of any of his relatives who are fully capacitated and present within the state at the time of his Death, shall be obtained, according to the following order:

- i. The father.
- ii. The eldest son.
- iii. The only son in the state.
- iv. The grandfather.
- v. The eldest full-brother, then the eldest paternal half-brother, in the absence of a full-brother.
- vi. The only brother in the State.
- vii. The agnate uncle brother of the father having both parents in common (full uncle) shall prevail over the paternal half-uncle.

viii. The husband or wife if the deceased person has no relatives as per the aforesaid order.

# Article (18)

#### Non-disclosure of the Identity of the Donor and the Recipient

The identity of the deceased donor or any of his family members or relatives shall not be disclosed to the recipient. Likewise, the identity of the recipient or any of his family members or relatives shall not be disclosed to any of the deceased donor's family members or relatives.

# **Chapter Four**

#### Penalties

# Article (19)

Application of penalties provided for herein shall not prejudice any severer penalty provided for in any other law.

#### Article (20)

Shall be sentenced to detention and a fine of no less than AED 30,000 (Dirham Thirty Thousand) and not more than AED 100,000 (Dirhams One Hundred Thousand), whoever sells or buys, or offers for sale or purchase, or mediates in the sale or purchase of a human Organ or part thereof or a human Tissue.

# Article (21)

Shall be sentenced to imprisonment for a minimum term of five (5) years and a maximum term of seven (7) years and a fine of no less than AED 500,000 (Dirhams Five Hundred Thousand) and not more than AED 3,000,000 (Dirhams Three Million), whoever traffics, or mediates with the intent of trafficking, in Organs or any part thereof or human Tissues.

The court shall order confiscation of the proceeds of the crime.

#### Article (22)

Shall be sentenced to imprisonment for a minimum term of ten (10) years and a fine of no less than AED 1,000,000 (Dirhams One Million) and not more than AED 10,000,000 (Dirhams Ten Million), whoever removes surreptitiously, fraudulently or by coercion an Organ or part thereof or a human Tissue from a living person.

The penalty shall be life imprisonment and a fine of no less than AED 20,000,000 (Dirhams Twenty Million), if the act results in the Death or total disability or incapacity of the donor.

#### Article (23)

Shall be sentenced to detention and a fine of no less than AED 1,000,000 (Dirhams One Million), whoever:

- removes an Organ or part thereof or a Human Tissue from a living person without taking into account the terms and conditions of Articles 12 and 13 of this Decree-Law. The penalty shall be life imprisonment and a fine of no less than AED 20,000,000 (Dirhams Twenty Million), if the act results in the Death or total disability of the donor.
- 2. removes an Organ or part thereof or a Human Tissue or more from the corpse of a deceased person without taking into account the terms and conditions of Articles 15 and 17 of this Decree-Law.

#### Article (24)

Shall be sentenced to detention for a minimum term of six (6) months and/ or a fine of no less than AED 500,000 (Dirhams Five Hundred Thousand) and not more than AED 1,000,000 (Dirhams One Million), any physician who performs a surgery of Transfer or transplantation of an Organ or part thereof or a human Tissue, while knowing that this surgery is the subject of commercial transaction.

#### Article (25)

Shall be sentenced to detention for a minimum term of one (1) year and/ or a fine of no less than AED 500,000 (Dirhams Five Hundred Thousand) and not more than AED 1,000,000 (Dirhams One Million), whoever transplants an Organ or part thereof or a human Tissue outside licensed health facilities.

# Article (26)

Shall be sentenced to detention for a minimum term of six (6) months and/ or a fine of no less than AED 20,000 (Dirhams Twenty Thousand) and not more than AED 50,000 (Dirhams Fifty Thousand), whoever violates the provisions of Article 18 of this Decree-Law.

# Article (27)

- 1. Shall be sentenced to detention for a minimum term of six (6) months and/or a maximum fine of AED 1,000,000 (Dirhams One Million), whoever violates any provision of Articles 5, 6, 7, 8 and 9 of this Decree-Law.
- The licensed health facility shall be punished in the case of violation of the person in charge thereof of the provisions of Articles 5, 6 and 7 of this Decree-Law - by a fine of no less than AED 1,000,000 (Dirhams One Million) and not more than AED 20,000,000 (Dirhams Twenty Million).

# Article (28)

In addition to the original penalties provided for herein, the court may order:

- 1. the suspension of practice of the Profession for a period not exceeding three (3) years.
- 2. the confiscation of money, instruments and equipment used in the offence.
- the closure of the facility where the offence was committed, or part thereof, for no less than two (2) months and not more than one (1) year. Such closure shall be permanent in case of recidivism.

# Article (29)

The commission of any offence under this Decree-Law by an Organised criminal group shall be deemed an aggravating circumstance.

# Article (30)

Shall be exempt from the penalties prescribed for the offences set out in Articles 20, 21, 22 and 23 of this Decree-Law, each offender who reports information about the offence to the judicial or administrative authorities, prior to its commission.

The court may exempt from punishment if the reporting was made after the commission of the offence and before the start of the investigation. The court may also commute the sentence if the offender facilitates to the competent authorities the arrest of any of the perpetrators of the offence during the investigation or trial.

#### Article (31)

The penalties provided for herein shall not prejudice the right of the Competent Health Authorities to make decisions and take disciplinary procedures against offenders.

# **Chapter Five**

#### **Final Provisions**

# Article (32) Judicial Officer Capacity

Employees designated by decision of the Minister of Justice, in agreement with the chairman of the Competent Health Authority, shall have the capacity of judicial officers to establish, within the limits of their jurisdiction, the violations of the provisions of this Decree-Law, its Implementing Regulations and decisions issued in its implementation.

#### Article (33) Implementing Regulations

The Cabinet shall issue the Implementing Regulations of this Decree-Law.

# Article (34)

#### **Adjustment of Position**

Health facilities existing at the date of entry into force of this Decree-Law shall adjust their positions in accordance with its provisions, within one (1) year of the date of its entry into force, and such period may be extended for a similar period by a Cabinet Resolution upon proposal of the Minister.

# Article (35)

#### **Repeal of Contrary Provisions**

- 1. Federal Law No. (15) of 1993 on the Regulation of Transplantation of Human Organs shall be abrogated.
- 2. Any provision contrary to, or in conflict with the provisions of this Decree-Law shall be repealed.

# <u>Article (36)</u>

#### Publication in the Official Gazette

This Decree-Law shall be published in the Official Gazette, and shall come into force six (6) months after the date of its publication.

# Khalifa bin Zayed Al Nahyan President of the United Arab Emirates

Promulgated by Us at the Presidential Palace in Abu Dhabi

On: 28/Shawwal/1437 H

2/August/2016 G



Cabinet Resolution No. (25) of 2020 concerning the Implementing Regulations of Federal Decree-Law No. (5) of 2016 on the Regulation of Transplantation of Human Organs and Tissues\*

#### The Cabinet:

- Having regard to the Constitution,
- Federal Law No. (1) of 1972 on the Mandates of Ministries and Powers of Ministers, as amended;
- Federal Decree-Law No. (5) of 2016 on the Regulation of Transplantation of Human Organs and Tissues, and
- Based on the proposal of the Minister of Health and Prevention, and the approval of the Cabinet,
- Resolves:

# Article (1)

#### Definitions

Definitions set forth in the referenced Federal Decree-Law No. (5) of 2016 shall apply to this Resolution. Otherwise, the following words and expressions shall have the meanings ascribed to them, unless the context otherwise requires:

Ministry	: The Ministry of Health and Prevention.
Decree-Law	: The Federal Decree-Law No. (5) of 2016 on the Regulation of Transplantation of Human Organs and Tissues.

# Article (2)

#### **Conditions and Procedures for Licensing Health Facilities**

1. 1. A health facility wishing to perform surgeries for transplantation of Organs and parts thereof and human Tissues shall obtain the relevant license from the Competent Health Authority prior to practicing any activity in this field.

<sup>\*</sup> This translation from Arabic to English is provided for your convenience only. In case of any discrepancy, the Arabic version prevails.

2. In order to obtain the license mentioned in paragraph (1) above, the facility shall have medical equipment, requirements, human resources and infrastructure required for carrying out such activity in proportion to the field it seeks to operate in, according to the requirements specified in the Annex hereto.

#### Article (3)

#### **Conditions and Procedures for Licensing Physicians**

- 1. A physician performing a surgery for the transplantation of Organs and parts thereof and Tissues shall have the relevant license from the competent authority prior to performing the surgery.
- 2. For a physician to obtain the said licence, the physician shall:
  - a. Have a competency recognized by the Health Authority in order to perform surgeries for the transplantation of Organs and parts thereof and Tissues based on his experience in such field or based on the receipt of a proper training thereon as per the category of the human Organs or Tissues that fall under his scope of work and practice.
  - b. Sign an acknowledgement stating his familiarity and compliance with the legislation applicable in the State regarding the field of human Organs and Tissues transplant.
  - c. Any other conditions or controls set by the Health Facility.

# Article (4)

#### Conditions for Renewal of the Licence of the Health Facility

For the renewal of the license of a health facility, the following is required:

- 1. The conditions stated in paragraph (2), Article 2 hereof shall be met.
- 2. A detailed scientific report shall be submitted annually to the Ministry clarifying the transplantation results in the health facility in line with the data specified by the Ministry, which shall include:
  - a. The medical condition of patients who had undergone human Organ or Tissue transplant surgeries.
  - b. The condition of the transplanted Organ.
  - c. The rate of complications resulting from the Transfer and

transplantation, compared to the international standards and procedures thereof.

3. Any other conditions set by the Health Authority; provided that they include the minimum number of surgeries performed by the health facility in accordance with the standard medical practices.

# <u>Article (5)</u> Reciprocal Transfer

A reciprocal Transfer shall require that:

- 1. there are two patients who need an Organ or Tissue transplantation and have no kinship up to the fourth lineage.
- 2. A donor of each patient' side is present; provided that he is a relative up to the fourth degree.
- 3. Each donor accepts to donate reciprocally to the other patient, with whom he has no kinship as mentioned above.
- 4. Physicians acknowledge that it is medically proper to perform the transplant surgery for the interest of both reciprocal patients.
- 5. Each donor submits an undertaking and declaration not to claim any damages between them, regardless of the results of the transplant surgery.

# Article (6)

#### **Conditions for Post-Death Donation Confirmation**

A person wishing to donate one of his Organs or parts thereof or Tissues after his Death shall confirm the same in his identity card data in line with the Identity Card regulations and procedures, via registration in the website specified by the Ministry, or by way of a written will signed by two witnesses having full legal capacity in the form set by the Ministry.

The said provision shall also apply in respect of any person who does not wish to donate one of his Organs or parts thereof or Tissues after his Death. This wish not to have the said procedures carried out shall be proved via the modes mentioned in the paragraph above.

In any case, the wish to donate an Organ, or the absence thereof, may be altered unconditionally in accordance with the procedures of this Article.

# Article (7)

#### **Register of Persons wishing to Donate**

A register shall be set in the Ministry including the names of those wishing to donate after their Death. Such register shall be set using the data recorded at the Federal Authority for Identity and Citizenship or via the website specified by the Ministry.

# Article (8)

#### Amendment of Licensing Requirements

Without prejudice to the Decree-Law, the Minister may amend the conditions laid down in the Annex hereto after coordination with the Health Authorities.

# <u>Article (9)</u>

#### **Issuance of Executive Decisions**

The Minister shall issue the decisions necessary to implement the provisions of this Resolution.

# Article (10)

#### Publication and Implementation of the Resolution

This Resolution shall be published in the Official Gazette and shall be effective as from the day following the date of its publication.

# Original signed by His Highness Mohammed bin Rashid Al Maktoum Prime Minister

Issued by us:

On: 7/Sha'ban/1441 H

31/March/2020 G

# Annex

#### То

# Cabinet Resolution No. (25) of 2020 Concerning the Implementing Regulations of Federal Decree-Law No. (5) of 2016 on the Regulation of Transplantation of Human Organs and Tissues

Conditions for Licensing Private Health Facilities performing Human Organ and Tissue Transplant Surgeries

#### I. Kidney Transplant

1. Technical Team:

The technical team shall consist of:

- a. Kidney transplant consultant: with at least one (1) year of experience at a recognized kidney transplant centre.
- b. Kidney disease consultant (nephrologist): with at least one (1) year of experience at a recognized kidney transplant centre.
- c. Nursing staff: nursing personnel must be highly experienced in caring for patients during and after kidney transplant surgery.
- d. Kidney transplant coordinator: He must have enough experience which qualifies him to carry out the previous obligations and may be a member of the aforementioned technical team members.
- e. Nutritionist.
- f. Social worker.
- 2. Technical Equipment:

The hospital shall have the following technical equipment:

a. The following technical departments:

Cardiology department, Gastro-Intestinal (GIT) department (endoscopy available), pneumology department (endoscopy available), radiology department, hematology department, pathology department, biochemical analysis laboratory, renal disease and blood purification unit (this unit must preferably contain mobile purification equipment) and an intensive care unit (ICU).

- b. At least two (2) operating rooms.
- c. At least two (2) recovery rooms shall be available for inpatients after the transplant.
- 3. Support Medical Departments:

The support medical departments of a hospital shall meet the following technical conditions:

- a. Laboratory: Special equipment shall be available to conduct all routine tests needed for the evaluation of the patients before and after the transplant. Equipment shall be available to carry out tissue analysis, cytotoxic antibody regulation and drug level regulation, including cyclosporine or its analogs.
- b. Medical Imaging (Radiology): regular X-rays, ultrasound imaging, radionuclide diagnosis and Computed Tomography (CT) scan.
- 4. Medication:

The following medications must always be available in the hospital:

- a. Immunosuppressants: Calcineurin, azathioprine and prednisolone inhibitors, antimetabolites and rapamycin-receptor inhibitor or their analogs.
- b. Drugs used to treat transplant rejection, such as: Methylprednisolone, anti-lymphocyte globulin (ALG), anti-thymocyte globulin (ATG) and monoclonal antibodies.
- c. Fluids used for organ ischemia, such as: Urecholine, University of Wisconsin solution or Histidine-Tryptophan-Ketoglutarate solution (HTK).
- d. Drugs used for treating bacterial, viral, parasitic and fungal infections.

#### II. Heart Transplant

1. Technical Team:

The technical team shall consist of:

a. Heart transplant consultants: they must have good experience in open-heart surgeries at an international accredited heart centre, and

must have performed a sufficient number of open-heart surgeries and have used the pump in at least 200 cases.

- b. Intensive care specialists: with experience in post open-heart surgery follow-up and preferably with experience in following up heart transplant cases.
- c. Consultant cardiologists: who are capable of conducting all kinds of heart exams and tests, using regular or advanced techniques, and who have experience in following up cases of patients before and after transplant and in taking the required samples from the heart.
- d. Nursing staff: nursing personnel must be highly experienced in caring for patients during and after heart transplant surgery.
- e. Organ transplant coordinator.
- f. Social worker.
- g. Nutritionist.
- 2. Technical Equipment:

The hospital shall have the following technical equipment:

a. Technical departments:

Gastro-Intestinal (GIT) department, radiology department, hematology department, pathology department, biochemical analysis laboratory, renal disease and blood purification unit and immunology department.

- b. At least (2) fully equipped rooms set for open-heart surgeries.
- c. Cardiac assist devices (CAD), such as: Intra Aortic Balloon Pump (IABP), Cardiopulmonary bypass (CPB) machine and other assist devices, with specialised technicians to operate them.
- d. A fully equipped Intensive Care Unit (ICU) for cases of open-heart surgery, where patients may be isolated, where necessary, and pacemaker may be implanted temporarily or permanently.
- e. Availability of the following specialists:
  - 1) Nephrologist with adequate experience in the follow-up of Organ transplant cases.

- 2) Immunologist with adequate experience in the follow-up of heart transplant cases.
- 3) Pulmonologist.
- 4) Respiratory physiotherapist.
- 5) Epidemiologist.
- 6) Medical staff to control epidemic diseases.
- 7) Pathologist with adequate experience in reading and analyzing samples taken from heart membranes and muscle.
- 8) Psychologist.
- 3. Support Medical Departments:

The support medical departments of a hospital shall meet the following technical conditions:

- a. Laboratory: Special equipment shall be available to conduct all routine tests needed for the evaluation of the patients before and after the transplant. Equipment shall be available to carry out tissue analysis, cytotoxic antibody regulation and drug level regulation, including cyclosporine or its analogs as well as the different immunological tests.
- b. Medical Imaging (Radiology): regular X-rays, ultrasound imaging, radionuclide diagnosis, Computed Tomography (CT) scan, and 2D Echocardiography.
- 4. Medication:

The following medications must always be available in the hospital:

- a. Immunosuppressants: Calcineurin, azathioprine and prednisolone inhibitors, antimetabolites and rapamycin-receptor inhibitor or their analogs.
- b. Drugs used to treat transplant rejection, such as: Methylprednisolone, anti-lymphocyte globulin (ALG), anti-thymocyte globulin (ATG) and monoclonal antibodies.
- c. Fluids used for organ ischemia, such as: Urecholine, University of Wisconsin solution or Histidine-Tryptophan-Ketoglutarate solution (HTK).

d. Drugs used for treating bacterial, viral, parasitic and fungal infections.

#### III. Lung Transplant

1. Technical Team:

The technical team shall consist of:

- a. Lung transplant consultants: They must have good experience in lung transplant at an international accredited surgery centre, and must have performed a sufficient number of lung transplant surgeries.
- b. Intensive care specialists: with experience in post lung surgery followup and preferably with experience in following up lung transplant cases.
- c. Pulmonologists (chest disease consultants): who are capable of conducting all kinds of lung exams and tests, using regular or advanced techniques, and who have experience in following up cases of patients before and after transplant and in taking the required samples from the lung.
- d. Nursing Staff: nursing personnel must be highly experienced in caring for patients during and after lung transplant surgeries.
- e. Organ transplant coordinator.
- f. Social worker.
- g. Nutritionist.
- 2. Technical Equipment:

The hospital shall have the following technical equipment:

a. Technical departments:

Gastro-Intestinal (GIT) department, radiology department, hematology department, pathology department, biochemical analysis laboratory, renal disease and blood purification unit, immunology department, cardiology department and heart surgery department.

- b. A fully equipped room set for lung surgeries.
- c. An intensive care unit (ICU), where patients may be isolated, when necessary.

- d. Availability of the following specialists:
  - 1) Nephrologist with adequate experience in the follow-up of Organ transplant cases.
  - 2) Immunologist.
  - 3) Cardiologist.
  - 4) Respiratory physiotherapist.
  - 5) Medical staff to control epidemic diseases inside the hospital.
  - 6) Pathologist with adequate experience in reading and analyzing samples taken from lungs tracheas and tissues.
  - 7) Psychologist to assess the patient's psychological condition before and after transplant surgery.
- 3. Support Medical Departments:

The support medical departments of a hospital shall meet the following technical conditions:

- a. Laboratory: Special equipment shall be available to conduct all routine tests needed for the evaluation of the patients' condition before and after the transplant. Equipment shall be available to carry out tissue analysis, cytotoxic antibody regulation and drug level regulation, including cyclosporine or its analogs as well as the different immunological tests.
- b. Medical imaging (Radiology): lung imaging devices that enable the performance of all regular and advanced studies and tests such as (lung computed tomography, radioisotope scintigraphy, ...etc.).
- 4. Medication:

The following medications must always be available in the hospital:

- a. Immunosuppressants: Calcineurin, azathioprine and prednisolone inhibitors, antimetabolites and rapamycin-receptor inhibitor or their analogs.
- b. Drugs used to treat transplant rejection, such as Methylprednisolone, anti-lymphocyte globulin (ALG), anti-thymocyte globulin (ATG) and monoclonal antibodies.

- c. Fluids used for organ ischemia, such as: Urecholine, University of Wisconsin solution or Histidine-Tryptophan-Ketoglutarate solution (HTK).
- d. Drugs used for treating bacterial, viral, parasitic and fungal infections.

#### IV. Liver Transplant

1. Technical Team:

The technical team shall consist of:

- a. Liver transplant and bile duct consultants: They must have at least one
   (1) year of experience at an international accredited liver transplant centre.
- b. Hepatologist (liver disease consultant): He must have at least one
   (1) year of experience at an international accredited liver transplant centre.
- c. Paediatric Gastroenterologist: He must have at least one (1) year of experience at an international accredited liver transplant centre.
- d. Consultant Anaesthetist: He must have at least six (6) months of experience at an international accredited liver transplant centre.
- e. Intensive care consultant.
- f. Nutritionist.
- g. Epidemiologist consultant.
- h. Liver transplant coordinator.
- i. Nursing staff: nursing personnel must be highly experienced in caring for patients during and after liver transplant surgery.
- 2. Technical Equipment:

The hospital shall have the following technical equipment:

a. Technical departments:

Cardiology department, endoscopy department, radiology department, hematology department, pathology department, biochemical analysis laboratory, renal disease and blood purification unit, Intensive care unit (ICU), immunology department, pneumology department, physiotherapy department and microbiology department (germs, parasites, viruses and fungi).

b. At least (2) fully equipped rooms set for liver transplant surgeries, including, in particular:

A thromboelastogram, a blood purification device, a fast pumping device, a venous blood pump, a laser device to stop bleeding or any device of same category and a blood warmer, with technicians to operate it.

3. Support Medical Departments:

The support medical departments of a hospital shall meet the following technical conditions:

- a. Laboratory: Special equipment shall be available to conduct all routine tests needed for the evaluation of the patients' condition before and after the transplant. Equipment shall be available to carry out tissue analysis, cytotoxic antibody regulation and drug level regulation, including cyclosporine or its analogs.
- b. Medical Imaging (radiology): regular X-rays, ultrasound imaging (with mobile devices), Doppler, radionuclide diagnosis, artery Computed Tomography (CT) scan and Percutaneous Cholangiography.
- c. Endoscopy department: It must contain all medical and diagnostic capabilities including Endoscopic Retrograde Cholangiopancreatography (ERCP).
- 4. Medication:

The following medications must always be available in the hospital:

- a. Immunosuppressants: Calcineurin, azathioprine and prednisolone inhibitors, antimetabolites and rapamycin-receptor inhibitor or their analogs.
- b. Drugs used to treat transplant rejection, such as: Methylprednisolone, anti-lymphocyte globulin (ALG), anti-thymocyte globulin (ATG) and monoclonal antibodies.
- c. Fluids used for organ ischemia, such as: Urecholine, University of Wisconsin solution or Histidine-Tryptophan-Ketoglutarate solution (HTK).

d. Drugs used for treating bacterial, viral, parasitic and fungal infections.

#### Fifth: Pancreas Transplant

1. Technical Team:

The technical team shall consist of:

- a. Pancreas transplant consultant: He must have at least one (1) year of experience at an international accredited pancreas transplant centre.
- b. Nephrologist He must have at least one (1) year of experience at an international accredited kidney transplant centre.
- c. Diabetologist: At least one consultant in endocrinology and metabolic diseases with at least one (1) year of experience at an international accredited complicated diabetes centre shall be available.
- d. Nursing staff: nursing personnel must be highly experienced in caring for patients during and after pancreas transplant surgery.
- e. Pancreas transplant coordinator: He must have enough experience to perform the coordination duties. He may be a member of the technical team.
- f. Nutritionist.
- g. Social worker.
- 2. Technical Equipment:

The hospital shall have the following technical equipment:

a. Technical departments:

Cardiology and cardiac catheterization department, Gastro-Intestinal (GIT) department (endoscopy available), pulmonary department (endoscopy available), radiology department, hematology department, tissue department, biochemical analysis laboratory, renal disease and blood purification unit (this unit must preferably contain mobile purification equipment) and an intensive care unit (ICU).

- b. Al least (2) operating rooms.
- c. At least two (2) recovery rooms shall be available for inpatients after the transplant.

3. Support Medical Departments:

The support medical departments of a hospital shall meet the following technical conditions:

- a. Laboratory: Special equipment shall be available to conduct all routine tests needed for the evaluation of the patients' condition before and after the transplant. Equipment shall be available to carry out tissue analysis, cytotoxic antibody regulation and drug level regulation, including cyclosporine or its analogs as well as various immunological tests.
- b. Medical Imaging (radiology): regular X-rays, ultrasound imaging, radionuclide diagnosis, computed tomography (CT) and interventional radiology.
- 4. Medication:

The following medications must always be available in the hospital:

- a. Immunosuppressants: Calcineurin, azathioprine and prednisolone inhibitors, antimetabolites and rapamycin-receptor inhibitor or their analogs.
- b. Drugs used to treat transplant rejection, such as: Methylprednisolone, anti-lymphocyte globulin (ALG), anti-thymocyte globulin (ATG) and monoclonal antibodies.
- c. Fluids used for organ ischemia, such as: Urecholine, University of Wisconsin solution or Histidine-Tryptophan-Ketoglutarate solution (HTK).
- d. Drugs used for treating bacterial, viral, parasitic and fungal infections.

#### Sixth: Corneal Transplant

1. Technical Team:

The technical team shall consist of:

a. Corneal transplant consultant: He must have at least one (1) year of experience in corneal transplant and external eye diseases at an international accredited corneal transplant centre, must have performed these surgeries in person during this period and submit a supporting certificate, or must have acquired at least five (5) years of experience in corneal transplant at an accredited hospital and submit a certificate from the hospital he worked for.

- b. Consultant Anaesthetist: with a previous experience in the field of ocular anesthesia.
- c. Microbiologist: A full-time microbiologist to work in the hospital, with a microbiology department (bacteria, parasites, viruses and fungi).
- d. Technician: A technician working in the eye bank having an experience in the field of corneal preservation and assessment of corneal validity for transplantation. The corneal transplant consultant may perform this duty.
- e. Corneal transplant coordinator: who must have adequate experience to coordinate the process of corneal preservation until transplantation phase.
- f. Nursing staff: nursing personnel must be highly experienced in caring for patients during corneal transplantation and thereafter.
- 2. Technical Equipment:

The hospital shall have the following technical equipment:

- a. Ophthalmology department: the department must be fully equipped and have the necessary medical equipment, in particular:
  - 1. Special biological microscopes (Slit Lamp).
  - 2. Funduscopes.
  - 3. Snellen charts.
  - 4. Corneal topography.
  - 5. Refractometer.
  - 6. Tonometers.
  - 7. Fully equipped operating rooms set for corneal transplantation procedures, such as: surgical microscopes, vitrectomy units, etc.
- b. The hospital outpatient clinics shall contain all equipment required to examine ophthalmic patients, who had or will have a corneal surgery, such as: special forceps, scalpels, eyelid retractors, etc.

#### GCC Unified Guide to

**Organ Transplant in the GCC Countries\*** 

## GCC Health Ministers' Council Resolution No. (3) dated 26/04/1427 H, Corresponding to 14/5/2006 G

The Health Ministers for GCC Countries, by virtue of the powers vested in them, resolve as follows:

- I. The GCC Unified Guide to Organ Transplant issued by the GCC Executive Board is adopted.
- II. All government and private hospitals and organ transplant centres shall comply with the procedures of this Guide as of the date of its issuance.
- III. Executive undersecretaries and employees of the Ministries of Health for GCC Countries shall implement this Resolution within their respective competence.

Minister of Health, UAE	Minister of Health, Bahrain
Minister of Health, KSA	Minister of Health, Oman
Minister of Health, Qatar	Minister of Health, Kuwait
Minister of Health, Yemen	

\* This translation from Arabic to English is provided for your convenience only. In case of any discrepancy, the Arabic version prevails.



#### Definition of Terms used in this Guide

Council	: The Gulf Cooperation Council.
Health Ministers' Council	: The Council of Health Ministers for the GCC Countries.
Coordination Centre	: The national centre with the supervision, follow- up and coordination of services provided to patients with terminal organ failure, and organ donation and transplantation.
Donor	: The person who donates an organ or part of an organ for its transplant in a patient with terminal organ failure.
Fully Competent Person	: A person who has attained at least 18 years of age.
Death	: Irreversible and complete cessation of heart, respiratory or brain functions.

### Introduction

I am pleased to present to you the "GCC Unified Guide to Organ Transplant", issued by my colleagues, members of the GCC Committee for Organ Transfer and Transplant, in their efforts to paint a picture of the development and progress witnessed by the GCC Countries in the field of organ transplant as well as the qualitative and quantitative expansion not only in transplant programs but also in the provision of care to organ failure patients. This Guide explains the technical and administrative procedures and every other matter related to the organ transplant program, including the scientific cause of death and the required conditions for diagnosis, how and who should explain the situation to the family of the deceased, the conditions and method of organ removal, the method of transfer and distribution to hospitals and, consequently, the organs received at the transplant centre, the conditions for opening an organ transplant centre whether in the public or the private sector, the method for monitoring the organ transplant results in different centres and many other procedures, which we believe have come at the right time, where the circulation of information and cooperation between GCC Countries on a scientific basis are necessary to guarantee safe performance and upgrade quality of performance.

#### **Best regards**



## GCC Unified Guide to Organ Transplant in the GCC Countries

A regulatory decision is a key reference in the field of organ transfer and transplant. Most of the GCC Countries initiated legislative instruments in this regard, varying in force between law and bylaws. All these regulations reflected the growing interest in laying down organ transplant procedures and conditions in the GCC Countries, and the dire need for a unified regulation of organ transfer and transplant in these states.

In response to the above approach, at its second meeting held in Muscat on 25-26/9/1994, the Organ Transplant Committee recommended working towards the unification of all the decisions and laws related to organ transfer and transplant in the GCC Countries as well as definition and diagnosis of Death. The GCC Health Ministers' Council approved the aforementioned recommendation in clause 6 of the Council's Decision No. 3 issued at the 20th session of the 38th conference (Kuwait 11/1/1995).

In application of the decision of GCC Health Ministers, the Organ Transplant Committee prepared the draft regulatory law (attached) entitled "Unified Draft Law Regulating Human Organ Transfer and Transplant in GCC Countries", which includes the principal rules governing organ transplant and the main controls for verification of Death.

The draft law was submitted at the Executive Committee's meeting held in June 2004 in Dubai. The committee approved the draft law and recommended that it be presented to the GCC Health Ministers' Council, which, in turn, approved the draft law at its meeting at the 31st session - 61st conference, held on 26/4/1427 H. corresponding to 24/5/2006 G, by virtue of Decision No. 3 concerning organ transplant, since it included all the legislations of the GCC Countries and reflected the key points in these legislations.

#### Article (1)

Whenever used herein, the following expressions shall have the following meanings:

Council: means the Gulf Cooperation Council.

**Health Ministers' Council:** means the council of Health Ministers of the GCC Countries.

#### Article (2)

Specialized physicians, authorized in this regard, may remove organs from the body of a living or deceased person and transplant them in the body of another person for treatment or life-saving purposes, in accordance with the conditions and procedures hereunder.

#### Article (3)

A Fully Competent Person may donate, whether during their lifetime or after their Death, any of their body organs to treat or save the life of a patient. Donation during the Donor's lifetime shall take place by virtue of a written declaration signed by the Donor. For donation after Death, the Donor may order such donation during their lifetime, provided that the consent of the Donor's family is obtained after the Donor's Death.

#### Article (4)

The removal of an organ from a living Donor's body shall be carried out after the Donor undergoes a full medical examination conducted by a specialized medical team and shall be advised of all established and potential outcomes resulting from the removal of the donated organ.

#### Article (5)

The Donor may, at any time prior to the removal of the organ, unconditionally retract his offer to donate. The Donor may not recover the removed organ after having donated it in accordance with this law.

#### Article (6)

An organ may not be transferred from the body of a living person, even with his consent, if the organ is essential for life or if the removal of this organ will lead to the Death of the Donor or render him unable to perform a certain function.

#### Article (7)

An organ may be transferred from a dead person after conclusive verification of Death by a committee of specialized physicians and after obtaining the written permission of the family of the deceased to donate his organs.

#### Article (8)

Trading in human organs by any means shall be prohibited, and physicians shall not perform any organ transfer surgery while knowing this, in line with the recommendations of the World Health Organization and the Declaration of Istanbul on Organ Trafficking and Transplant.

#### Article 9

Organ transfer and transplant surgeries shall be performed at the specialized medical centres licensed to this effect in the GCC Countries, in accordance with the conditions and procedures to be issued by decision of the Health Ministers' Council.

#### **Duties of the Coordination Centre for Organ Transplant**

Duties of the Coordination Centre for Organ Transplant are as follows:

- 1. Coordinating services provided by various health sectors to patients with terminal organ failure, overseeing organ transplant programs and following up the execution of the procedures stated herein for the optimum accomplishment of these programs.
- 2. Coordinating and following up all Death cases Annex 1, diagnosed at different hospitals of the concerned state, in order to remove organs from the deceased to be distributed among the organ transplant centres according to the procedures stated herein.
- 3. Paying close attention to aspects of health information and awareness.
- 4. Conducting training programs and scientific seminars for persons working in the field of organ transplant.
- 5. Issuing different scientific publications and exchanging information with international centres to create a common ground for communication in the field of organ transplant.
- 6. Conducting researches and studies on diseases leading to terminal organ failure in order to provide patients with better health services.
- 7. Developing specifications related to the establishment of organ transplant centres in health zones of the concerned states and regularly evaluating and assessing these centres as stated hereunder.

Collaborating with other Coordination Centres for organ donation - Annex
 2 in GCC Countries with regard to all the aforementioned duties.

#### General Procedures for Organ Transplant in the GCC Countries

The general procedures that all hospitals and organ transplant centres must follow include:

- 1. To notify all suspected Death cases to the Coordination Centres supervising organ transplant in the GCC Countries.
- 2. All hospitals must form internal committees to be responsible for Death cases and organ donations, as follows:
  - a. Notification and Follow-Up Committee: Consisting of a physician and an administrator and/or a coordinator, or their designates, in addition to a medical coordinator - who shall notify the suspected Death cases to the Coordination Centre for organ transplant, follow up the regular communication of information, send all the required blood samples to the laboratory to verify the suitability of the organs of the deceased for transplant and coordinate with organ transplant centres at the hospitals in this regard. The duty of this committee will be to follow up and report all matters related to the Death cases and submit its recommendations towards developing the program of donation after Death in its region to the Coordination Centre for organ transplant.
  - b. Convincing Committee: To be formed by the director of the hospital. This committee shall address the family and relatives of the deceased to obtain their consent to donate the deceased's organs. The committee may consist of counselors who have been given special training in this field.
  - c. To provide conclusive verification of Death through diagnosis according to the points contained in the Death Documentation Form by Brain Function Criteria Annex 3, and according to the procedures specified in this regard, while making sure, in the case of a deceased woman, that the woman was not pregnant, where if her pregnancy is proven, organ donation shall not be taken into consideration, unless the fetus was deceased. No member of the medical team assuming the preparation and execution of the organ transplant may participate in the diagnosis of the Death.
  - d. To obtain the consent of the legal heirs of the deceased to the donation of his organs, whether they are inside or outside the country,

in accordance with the consent form for organ donation under Annex 4. If the deceased or family cannot be identified, the approval of the competent official authorities must be obtained before removal of the organs.

- e. To coordinate with the Coordination Centre for organ transplant before the removal of any organ from the deceased so as to benefit from all the organs and distribute them according to the priorities guide.
- f. To remove the organs at the hospital where the Death has taken place and not transfer the case to another hospital unless upon occurrence of a force majeure. The hospital where the Death has taken place shall be responsible for issuing the final Death certificate.
- g. Where the Death case is established at a hospital and the family approves the organ donation, the organs shall be distributed and transplanted as stated in the procedures guide with respect to each organ.
- h. To verify the fulfillment of the following conditions upon transplanting organs from living persons:
  - That the living Donor is healthy and the donation will not cause harm to the health of the Donor or the recipient; no entire organ shall be transferred if the life of the Donor depends on that organ.
  - That the decision of donation is based on complete conviction and approval without submission to social or material pressure.
  - That the donation is supported by a written consent signed by the Donor, who may withdraw his offer to donate at any time prior to the surgery.
  - That the approved medical examination is carried out according to this Guide and that the Donor is notified of all the potential and established consequences resulting from the removal of the donated organ, with the registration of the Donor's notification thereof in writing in the Donor's clinical file.
- i. An organ transplant coordinator shall be assigned at each transplant centre to carry out the following tasks:
  - To act as a permanent contact with the Coordination Centre for organ transplant.

- To notify the names of suitable transplant candidates at the hospital to the Coordination Centre for organ transplant, to be placed on the national waiting list, and prepare the local waiting list relevant to each centre according to the approved priorities guide.
- To coordinate with the Coordination Centre for organ transplant upon the occurrence of a Death case in the supervision areas of the respective centre in order to offer the assistance needed depending on the case.
- To notify the Coordination Centre in case no suitable transplant candidates are available on the local waiting list. Furthermore, an organ transplant coordinator shall be assigned in every State hospital to gather, regularly update and send the required information related to the transplant candidates (whether candidates for kidney, heart, liver, lung transplant or any other kind of transplant) to the Coordination Centre for organ transplant according to the relevant forms. A representative shall be appointed on behalf of the coordinator in case of the latter's absence.
- j. Every hospital and transplant centre shall provide the Coordination Centre for organ transplant with a list of their patients with terminal organ failure. The Coordination Centre shall draw up national and local transplant lists for all types of organs according to the priorities guide and provide the organ transplant centres with these lists to act accordingly.
- k. Every transplant centre shall provide the Coordination Centre for organ transplant with reports and statistics related to the patients who have received an organ transplant whether from living relatives or brain-dead persons (every three months) in accordance with the follow-up forms.
- I. All kidney transplant centres shall assume their responsibilities towards the patients in the areas under their supervision according to the approved procedures.
- m. The transplant centres shall undergo evaluation every three (3) years. The evaluation shall be carried out by competent committees, each in its area of specialization, pursuant to the standards established by the Coordination Centre for organ transplant.

#### Procedures Followed by Kidney Transplant Centres to Perform their Obligations towards their Respective Intensive Care Units and Blood Purification (Blood Filtration) Units

- 1. The kidney transplant centres shall follow up and offer the required technical assistance to the blood purification (blood filtration) units in all the relevant hospitals, including:
  - To ensure that every centre acts as a consulting body in critical cases and surgical and non-surgical problems related to kidney transplant at blood purification (blood filtration) units.
  - To draw up lists of tissue analysis for all suitable candidates with terminal renal failure at these units.
  - To determine the suitable kidney transplant candidates at these units and provide the Coordination Centre for organ transplant with their names and test results as per the approved forms.
- 2. Every kidney transplant centre shall train all the employees at their respective intensive care units and provide them with technical supervision to raise their awareness towards detecting and immediately notifying Death cases to the Coordination Centre for organ transplant, which will collaborate with the kidney transplant centre in the diagnosis, as per the procedures related to Death cases and handling these cases and established by the Death committee.
- 3. Every kidney transplant centre shall receive information related to the Death cases via the Coordination Centre for organ transplant; coordination shall be established between the two centres with the intensive care unit. The centre shall carry out the duties and obligations assigned thereto up to the stage of organ removal.
- 4. Every kidney transplant centre shall contribute to clarifying the concept of Death and organ transplant at lectures and seminars, to the citizens and residents of the areas under their supervision.

#### **Conditions of Organ Transplant at Private Hospitals**

- I. A private hospital may perform an organ transplant from a living person pursuant to the controls stated herein.
- II. A private hospital may not benefit from cases of organ donation after Death occurring in other hospitals, whether private or government

hospitals. It may only benefit from the Death cases occurring at the hospital itself. The private hospital shall inform the Coordination Centre for organ transplant about any Death case that occurs at the hospital and may not remove any organ before coordinating with the Coordination Centre for organ transplant, which will participate in diagnosing the case through a public sector physician. The private hospital shall not receive any financial compensation for the organs donated by the relatives of the deceased to patients with terminal organ failure.

- III. The private hospital shall carry out all the procedures stated in the guide prepared by the GCC Committee for Organ Transfer and Transplant and shall be subject to the same penalties that apply to all other hospitals in case of violation.
- IV. Patients shall receive organs for transplantation according to the waiting lists, pursuant to the procedures prepared by the GCC Committee for Organ Transfer and Transplant. If the hospital does not have suitable transplant candidates, coordination shall take place with the Coordination Centre for organ transplant to give the organs to suitable candidates on the national waiting list according to the priorities guide. If the list does not include suitable transplant candidates, the suitable patient shall be located as stated in the priorities guide of each organ.

## **Kidney Transplant**

#### **Specifications for Establishing Kidney Transplant Centres**

The coordination centre for organ transplant has determined, through its competent committees, the specifications associated with the establishment of kidney transplant centres in GCC Countries. These specifications are:

#### 1. The technical team, consisting of:

#### 1.1 Kidney transplant consultant:

A consultant in the field of kidney transplant with at least one (1) year of experience at a recognized kidney transplant centre shall be available at the centre.

#### 1.2 Kidney disease consultant (nephrologist):

At least one nephrologist with at least one (1) year of experience at a recognized kidney transplant centre shall be available at the centre.

#### 1.3 Nursing Staff:

The persons in charge of the nursing staff, regardless of their gender, must have international expertise in giving care to patients during and after kidney transplant surgeries.

#### 1.4 Kidney transplant coordinator:

He must have enough experience which qualifies him to carry out the previous obligations and may be a member of the aforementioned technical team members.

#### 1.5 Nutritionist.

#### 1.6 Social Worker.

#### 2. Technical equipment:

2.1 The hospital where the kidney transplant centre will be established shall contain the following departments:

Cardiology department, GIS department (with endoscopy available), pneumology department (endoscopy available), radiology department, hematology department, pathology department, biochemical analysis laboratory, renal disease and blood purification unit (this unit must preferably contain mobile purification equipment), intensive care unit.

- 2.2 The hospital shall have at least two (2) operating rooms.
- 2.3 At least two (2) recovery rooms shall be available for inpatients after the transplant,

x or shall have the capacity to provide these services at another hospital.

#### 3. Support medical departments, including:

#### 3.1 Laboratory:

Special equipment shall be available to conduct all routine tests needed for the evaluation and assessment of the patients' condition before and after the transplant.

Equipment shall be available to carry out tissue analysis, cytotoxic antibody regulation and drug level regulation, including cyclosporine or its analogs.

#### 3.2 Radiology:

Regular X-ray imaging devices, ultrasound scan, radionuclide diagnosis, CT scan.

#### 4. Medication: The following drugs must be available at all times:

#### 4.1 Immunosuppressants:

Cyclosporine, azathioprine, prednisolone, mycophenolate mofetil and rapamune or their analogs.

#### 4.2 Drugs used to treat transplant rejection, such as:

Methylprednisolone, Anti-Lymphocyte Globulin (ALG) or Anti-Thymocyte Globulin (ATG) and monoclonal antibodies (OKT3).

#### 4.3 Fluids used for organ ischemia, such as:

Urecholine, University of Wisconsin solution or Histidine-Tryptophan-Ketoglutarate solution (HTK).

# 4.4 Drugs used for treating bacterial, viral, parasitic and fungal infections.

#### Conditions for Continuity of Kidney Transplant Centres:

- 1. The centre shall implement the required specification guides relevant to the establishment of new transplant centres.
- 2. The centre shall conduct at least 10 transplant operations every year.
- 3. The kidney transplant centre shall train the employees and workers at the intensive care units at the respective hospitals and provide technical and consultative supervision over the death cases occurring at the hospitals, in collaboration with the coordination centre for organ transplant, provided that the kidney transplant centre provides the coordination centre with permanent reports regarding these activities.
- 4. The transplant centre shall carry out all its assigned duties towards the citizens and residents, including raising awareness and holding lectures and seminars to explain all matters related to organ transplant and death. It shall also submit regular reports in this regard to the coordination centre for organ transplant.
- 5. The transplant centre shall submit a detailed scientific report every year on the results of the transplants performed at the centre to the coordination centre for organ transplant, including:
  - a. The condition of the patients that have undergone the kidney transplant surgery.
  - b. The condition of the transplanted kidneys.
  - c. Percentage of complications.
- 6. The transplant centres shall be evaluated every three years by the kidney transplant committee at the coordination centre for organ transplant. A permanent committee shall be formed from the kidney transplant committee. This committee shall have the right to visit any kidney transplant centre at any time and whenever necessary to examine the work progress at the centre.
- 7. The kidney transplant committee shall meet at the coordination centre for organ transplant every year to study all the reports submitted by its permanent committee as well as the reports submitted by the kidney transplant centres and that include the death rate, the percentage of loss of transplanted organs and the health problems resulting from the transplant. If the committee finds that any of these centres is not abiding by the procedures of the Guide or that the success rate of the transplant

surgeries carried out at the centre is not satisfactory, the permanent committee generating from the kidney transplant committee shall visit the said centre and study the reasons and obstacles hindering proper performance at the centre. The centre shall be given three months to improve its situation. Then, the kidney transplant committee shall meet again to evaluate the centre's performance and shall have the right to make a recommendation to the Medical Licenses Department at the Ministry of Health to shut down the centre, if the centre shows no improvement, provided that the committee's decision is taken by the two-third majority and in presence of at least 70% of its members.

8. These conditions shall apply to all transplant centres now existing or to be established later.

#### Procedures of Kidney Transplant from Deceased Donors

Suitable candidates shall undergo kidney transplant from deceased persons according to the following procedures:

- 1. It must be established that the patients suffer from terminal renal failure.
- 2. It must be established that the patients do not suffer from another eminent organ disease (including active tuberculosis, active peptic ulcer, cancer or severe or chronic active infections).
- 3. The result of all the tests conducted on the patient shall be normal (see Annex 5 with respect to nondiabetic patients suffering from terminal renal failure and Annex 6 with respect to diabetic patients).
- 4. The patient shall be of proper age and weight to undergo transplant.
- 5. It must be verified that the patients are able to abide by the post-transplant treatment.
- 6. The patients shall be HIV negative.
- 7. The result of the Hepatitis B virus test must be negative. If it is positive, a sample shall be taken from the liver to prove that it is normal.
- 8. Regarding patients with anti-glomerular basement membrane or deoxyribonucleic acid antibodies (DNA) or anti-neutrophil cytoplasmic antibodies (ANCA), these antibodies should become negative.
- 9. Regarding the specific procedures related to hepatitis virus infections, the following procedures shall be adopted:

- a. Patients with Hepatitis B core antibody (HBcAb) or patients with immunity to the Hepatitis B Virus (HBV) may undergo kidney transplant using kidneys extracted from deceased persons carrying the same antibody.
- b. Patients with Hepatitis C core antibody may undergo kidney transplant using kidneys extracted from deceased persons carrying the same antibody.

#### **Conditions of Kidney Donation from Living Donors**

- 1. Kidney donation from living relatives or non-relatives may occur as follows:
  - a. Donation from living relatives: The donors may be related by blood, by breastfeeding or by marriage (between the husband and wife and their relatives), provided that such relationship is established by means of the competent official authorities.
  - b. Donation from living non-relatives: Applied according to the conditions and controls of each country (for example: KSA - Annex 7: Controls and Conditions for Organ Donation from Living Non-Relatives).
- 2. Donation must be based on mutual consent and total conviction, free from pressure.
- 3. The donor must be in perfect physical and mental health -Annex 8.
- 4. The donor must not be under 18 or over 60 years of age.
- 5. The blood groups of the patient and the donor must be compatible.
- 6. The result of the tissue analysis test between the patient and the donor must be negative.
- 7. The Hepatitis B virus test must be negative.

#### Contraindications to Kidney Transplant in all cases

- 1. If the patient has incurable cancer.
- 2. If the patient has primary oxalosis (unless the patient undergoes double kidney and liver transplant).
- 3. If the patient is addicted to drugs or narcotics.
- 4. If the patient does not continue with the treatment or observe the medical instructions as stated.

- 5. If the patient suffers from another organ disease such as:
  - a. Liver cirrhosis
  - b. Liver fibrosis with advanced esophageal varices
  - c. Untreatable fourth-degree heart failure
  - d. terminal respiratory failure limiting the patient's daily performance
  - e. Untreatable widespread vascular disease
  - f. Active hepatitis.

#### **Kidney Transplant Priorities Guide**

The cases in which kidney transplants are conducted are determined as follows:

**First:** If the patient's life is in danger due to a problem related to the vascular access, he shall be given absolute priority and shall undergo kidney transplant as soon as a suitable kidney is available, provided that this condition is established by means of the respective kidney transplant centre, which will in turn formally notify the coordination centre for organ transplant in this regard.

**Second:** As for the remaining patients, they shall undergo kidney transplant according to the medical priority adopted based on the degree given to each case:

- Whenever the cytotoxic antibody percentage exceeds 50% by 10%, the patient is granted (one degree), and the degree will multiply whenever the increase percentage multiplies.
- If the patient is between 3 and 5 years old, he is given (3 degrees); if the patient is between 6 and 10 years old, he is given (2 degrees); if the patient is between 11 and 45 years old, he is given (1 degree).
- If the patient is treated by purification (filtration), he is given (0,1 degree) for each month he spends under treatment by purification.
- If the patient has already undergone a kidney transplant by donation from living relatives, he is given (2 degrees).
- If the patient's tissues are compatible with the donor's tissues, he is given (one degree) for each tissue compatibility.
- If the patient's blood group is compatible with the donor's blood group, he is given (3 degrees).

- If the patient's age is close to the donor's age, he is given (2 degrees).

#### After extraction, the kidneys shall be distributed as follows:

The first kidney shall be transplanted into the suitable patient given priority on the national list established by the coordination centre for organ transplant. The patient is brought in to the transplant centre where the extraction is taking place, unless the patient is being treated in another transplant centre, in which case the kidney will be sent to this centre.

The second kidney shall be transplanted into the suitable patient given priority on the local list of the transplant centre where the extraction is taking place, according to the priorities guide; if the technical conditions are available in a patient at the hospital that has notified the death case, the kidney shall be transplanted into this patient if possible.

The extracted kidneys shall be transplanted into the patients according to the waiting lists if the suitable patient is available. In case no suitable patient is available anywhere in the State, after consulting and obtaining the approval of the coordination centre for organ transplant, these kidneys may be transplanted into other patients, in which case priority shall be given to resident patients then visiting patients. Exchange or transfer of kidneys with sister States may take place in accordance with the agreements concluded between the coordination centre for organ transplant and similar institutions therein.

 The suitable candidate is the patient fulfilling the medical conditions and guide specifications.

## **Heart Transplant**

#### **Specifications for Establishing Heart Transplant Centres**

The coordination centre for organ transplant has determined, through its competent committees, the specifications associated with the establishment of heart transplant centres in GCC Countries. These specifications include the following:

#### 1. The technical team, consisting of:

#### 1.1 Heart transplant consultants:

A cardiovascular surgery team with adequate experience in open heart surgery shall be available at the centre. They shall have conducted a sufficient number of open heart surgeries and have used the pump in at least 200 cases. The members of this team must have had experience in an internationally accredited heart centre.

#### 1.2 Intensive care specialist:

An intensive care specialist with experience in post open heart surgery follow-up and preferably with experience in following up heart transplant cases shall be available at the centre.

#### 1.3 Cardiology consultants:

Cardiology consultants who are capable of conducting all kinds of heart exams and tests, using regular or advanced techniques, and who have experience in following up cases of patients before and after transplant and in taking the required samples from the heart, shall be available at the centre.

#### 1.4 Nursing body:

The persons working in this area must have adequate experience in giving care to patients during and after heart transplant surgeries.

#### 1.5 Organ transplant coordinator.

- 1.6 Social Worker.
- 1.7 Nutritionist.

#### 2. Technical Equipment:

2.1 The hospital where the heart transplant centre will be established shall contain the following departments: GIS department, radiology department, hematology department, division of pathology, biochemical analysis laboratory, renal disease and blood purification unit, immunology department.

#### 2.2 The hospital shall also contain:

- At least Two (2) operating rooms fully equipped for open heart surgery.
- Heart assist devices such as the Intra-aortic balloon pump (IABP), the cardiopulmonary bypass machine (artificial heart) and other assist devices, along with the required specialized technicians to operate these devices.
- An intensive care unit fully equipped for open heart surgeries, where the patients may be isolated, if necessary, and a pacemaker may be temporarily or permanently transplanted.

#### 2.3 The following specializations must be available at the hospital:

- An immunology specialist with experience in following up heart transplant cases.
- A pulmonologist.
- A physiotherapist concerned in providing patients with respiratory care.
- A specialist in epidemic diseases.
- A medical team to control epidemic diseases at the hospital.
- A pathology specialist with experience in reading and analyzing samples taken from the heart membranes and muscle.
- A psychiatrist

#### 3. Support medical departments, including:

#### 3.1 Laboratory:

- Special equipment shall be available to conduct all routine tests

needed for the evaluation of the patients before and after the transplant.

 Special equipment shall be available to carry out tissue analysis, cytotoxic antibody regulation and drug level regulation, including cyclosporine or its analogs, as well as the different immunological tests.

#### 3.2 Radiology:

- Regular X-ray devices, radionuclide diagnosis, CT scan, 2D echo.

#### 4. Medication: The following drugs shall always be available:

#### 4.1 Immunosuppressants:

- Cyclosporine, azathioprine, prednisolone, mycophenolate mofetil and rapamune or their analogs.

#### 4.2 Drugs used to treat transplant rejection, such as:

- Methylprednisolone, Anti-Lymphocyte Globulin (ALG) or Anti-Thymocyte Globulin (ATG) and monoclonal antibodies (OKT3)

#### 4.3 Fluids used for organ ischemia, such as:

- Urecholine, University of Wisconsin solution or Histidine-Tryptophan-Ketoglutarate solution (HTK).

#### 4.4 Drugs used for treating bacterial, viral, parasitic and fungal infections.

#### Cases of Heart Transplant

The patient must fulfill all or some of the following conditions in order to undergo a heart transplant:

**First:** He must have a terminal heart failure (the ejection fraction of the heart is less than 20%) and his heart is not responding to medical or surgical treatment.

**Second:** He must be classified in Class III (difficulty in breathing upon making a simple effort) or in Class IV (difficulty in breathing without any effort) according to the NYHA functional classification.

Third: He must have a non-extractable heart tumor.

**Fourth:** He cannot be separated from the cardiopulmonary bypass machine (artificial heart) after undergoing any surgical procedure.

Fifth: He is in danger of quick death after an occlusion of the coronary artery (myocardial infarction). See Guide of tests that patients with terminal heart failure must undergo prior to heart transplant.

#### **Contraindications to Heart Transplant**

#### First: Absolute Contraindications:

- If the patient has exceeded 55 years of age.
- If the patient has high pulmonary vascular resistance (more than 6 Wood units) in spite of undergoing intensive heart treatment using inotropic drugs and other.
- If the patient has cancer.
- If the arteries surrounding the body are infected.
- If an infection is spread in the body's blood vessels as a result of a collagen disease.
- If the patient suffers from an above-average renal failure as a result of heart failure.
- If the patient suffers from an above-average hepatic failure as a result of heart failure or if this failure is accompanied with a blood coagulation disorder.
- If the patient suffers from another organ disease in its final stage such as (terminal respiratory failure, amyloidosis...etc.).
- If the patient is psychologically unstable and may not continue with the treatment or observe the medical instructions as stated.
- If the patient has HIV.
- If the patient is addicted to narcotics including alcohol and drugs.

#### Second: Relative Contraindications \*

- the patient has diabetes, especially if it is type 1 diabetes, and needs treatment with insulin.
- If the patient has peptic ulcer.
- If the patient suffers from a pulmonary infarction as a result of pulmonary embolus during the pre-healing stage.

<sup>\*</sup> The suitable candidate is the patient who meets the medical conditions and Guide specifications

- If the patient is overly obese.
- If the patient has cachexia (physical wasting).
- If the patient's clinical indications reveal a former infection with the Cytomegalovirus, the Epstein – Barr virus, toxoplasmosis, sickle cell disease or thyroid gland disorder.
- If the patient has high and uncontrolled arterial blood pressure.
- If he has an active infection in any of the body systems.
- If the patient's clinical indications reveal a former case of tuberculosis or if the tuberculosis test turns out to be positive but without an active infection, the patient shall be placed under Isoniazid treatment for 12 months.

#### **Heart Transplant Priorities Guide**

# The coordination centre for organ transplant has determined, through its competent committees, the priorities by virtue of which heart transplants are performed, as follows:

- 1. If the patient is a resident at the hospital and placed under artificial respiration, if he is living on mechanical cardiac-support devices and needs to be provided with inotropic drugs at all times or if separating him from the cardiopulmonary bypass machine (artificial heart) is impossible.
- 2. If the patient is a resident at the hospital and needs to be provided with inotropic drugs at all times or else, he will need artificial respiration or mechanical cardiac-support devices.
- 3. If the patient is on the heart transplant waiting list without being a resident at any hospital.

#### After extraction, the heart shall be distributed as follows:

- a- Every heart transplant centre shall prepare a local waiting list to be sent to the coordination centre for organ transplant where a local waiting list will be formed according to the priorities guide (see the heart transplant priorities guide). The transplant centre may, after notifying the coordination centre for organ transplant, change the priority level of the patient if the case so requires.
- b- The hospitals shall notify the names of their patients who are in urgent need of heart transplant. These names shall be entered in an urgent waiting list at the coordination centre for organ transplant.

- c- The hearts shall be distributed to the patients stated on the urgent waiting list, regardless of the turn of the centre that will carry out the transplant, for first priority patients shall not follow the turn system in heart distribution and shall be given absolute priority whenever a heart is available for transplant, wherever they may be and at whatever centre in the Gulf states.
- d- If the urgent list does not contain a suitable candidate for the heart transplant, the heart shall be given to the transplant centre whose turn has come, if such centre has the suitable candidate. If said centre does not have a suitable candidate for the transplant, the heart shall be given to the centre that has a suitable candidate. Priority between the patients who do not have first priority shall be given according to blood group compatibility and the waiting period of the patient on the list.

## Lung Transplant

#### **Specifications for Establishing Lung Transplant Centres**

The coordination centre for organ transplant has determined, through its competent committees, the specifications associated with the establishment of lung transplant centres in the Kingdom. These specifications include the following:

#### 1. The technical team, consisting of:

#### 1.1 Lung Transplant Consultants:

A team of consultants in thoracic and vascular surgery shall be available at the centre. The members of this team shall have had experience in lung transplant at an internationally accredited surgery centre and shall have conducted a sufficient number of transplants.

#### 1.2 Intensive care specialist:

An intensive care specialist with sufficient experience in post lung surgery follow-up, and preferably with experience in following up lung transplant cases, shall be available at the centre.

#### 1.3 Chest disease consultants:

Chest disease consultants, who are capable of conducting all kinds of lung exams and tests, using regular or advanced techniques, and who have had experience in following up the condition of lung patients before and after the transplant and in taking the required samples from the lung, shall be available at the centre.

#### 1.4 Nursing Staff:

Nursing personal must have adequate experience in giving care to patients during and after lung transplant surgeries.

#### 1.5 Organ transplant coordinator.

1.6 Social worker.

#### 1.7 Nutritionist.

#### 2. Technical Equipment:

2.1 The hospital where the lung transplant centre will be established shall contain the following departments: GIS department, radiology department, hematology department, pathology department, biochemical analysis laboratory, renal disease and blood purification unit, immunology department, Cardiology department, heart surgery department.

#### 2.2 The hospital shall also contain:

- An operating room fully equipped for lung surgery.
- An intensive care unit, where patients may be isolated if necessary

#### 2.3 The following specializations must be available at the hospital:

- A renal disease specialist with experience in following up organ transplant cases.
- An immunology specialist.
- A cardiology specialist.
- A physiotherapist concerned in providing patients with respiratory care.
- A medical team to control epidemic diseases at the hospital.
- A specialist in pathology with experience in reading and analyzing samples taken from the trachea and lung tissue.
- A psychiatrist to evaluate the patient's psychiatric state before and after the transplant.

#### 3. Support medical departments, including:

#### 3.1 Laboratory:

- Special equipment shall be available to conduct all routine tests needed for the evaluation of the patients before and after the transplant.
- Equipment shall be available to carry out the following: tissue analysis, cytotoxic antibody regulation and drug level regulation, including cyclosporine or its analogs, as well as the different immunology tests.

#### 3.2 Radiology:

- Lung X-ray machines shall be available to conduct all kinds of regular and advanced tests (thoracic CT scan, scintiscan... etc.).

#### 4. Medication: The following drugs shall be available at all times:

#### 4.1 Immunosuppressants:

Cyclosporine, azathioprine, prednisolone, mycophenolate mofetil and rapamune or their analogs.

#### 4.2 Drugs used to treat transplant rejection, such as:

Methylprednisolone, Anti-Lymphocyte Globulin (ALG) or Anti-Thymocyte Globulin (ATG) and monoclonal antibodies (OKT3).

#### 4.3 Fluids used for organ ischemia, such as:

Urecholine, University of Wisconsin solution or Histidine-Tryptophan-Ketoglutarate solution (HTK).

## 4.4 Drugs used for treating bacterial, viral, parasitic and fungal infections.

#### **Cases of Lung Transplant**

The patient must fulfill all or some of the following conditions in order to undergo lung transplant, such as terminal respiratory failure resulting from:

First: Severe obstructive pulmonary disease of all kinds.

Second: Restrictive lung disease of all kinds.

**Third:** Severe primary pulmonary hypertension or progressive secondary pulmonary hypertension along with Eisenmenger disease.

Fourth: Suppurative lung disease.

See Annex 10 (Guide of tests that patients with terminal respiratory failure must undergo prior to lung transplant).

#### **Contraindications to Lung Transplant**

#### **First: Absolute Contraindications:**

- If the patient suffers from active non-pulmonary infection or active pulmonary infection in case of single lung transplant.
- If the patient has other organ diseases such as renal failure and hepatic failure.
- If the patient's coronary arteries are severely damaged or if he suffers from disorder in the function of the left heart or disorder in the function of the right heart (the ejection fraction of the heart is less than 25%), unless he will be undergoing a double heart and lung transplant.
- If the patient is psychologically unstable and may not continue with the treatment or observe the medical instructions as stated if the patient has a new incurable cancer.
- If there is a possibility that the patient may stay alive for a period varying between 18-24 months, his dynamic lung function is within the reasonable limits and he does not always need oxygen.
- \* The patient's age does not constitute an obstacle in lung transplant provided that his cardiac renal and hepatic functions are in good condition at the time of the transplant.

#### Second: Relative Contraindications:

- If the patient has been placed under artificial respiration for a long time; however, this is no longer a contraindication to lung transplant at many centres, especially if the patient wishes to undergo the transplant and his cardiac, renal and hepatic functions are within the reasonable limits.
- If the patient has received high doses of steroid orally or intravenously and over 15 mg of Prednisolone a day; today, it is possible to approve lung transplant for such patients even if it is not possible to take them off steroid treatment before the surgery, because the new techniques in esophagi surgery and fabrication will allow healing after surgery without risking the splitting of the esophagus.

<sup>\*</sup> The suitable candidate is the patient fulfilling the medical conditions and guide specifications and whose chest size is compatible with the chest of the deceased donor as per the approved criteria.

- If the patient has undergone chest surgeries in the past such as pleural biopsy or fixation; however, there is a tendency to conduct lung transplant (one side or double side consecutive) on these patients by cutting the anterior chest through the sternum.
- If the patient has been smoking up to the year preceding his acceptance on the lung transplant waiting list.

#### After extraction, the lung shall be distributed as follows:

- 1. Every lung transplant centre shall prepare a local waiting list to be sent to the coordination centre for organ transplant in order to be included in a national waiting list.
- 2. The lung transplant centres shall notify the names of their patients who are in urgent need for lung transplant. These names shall be stated on an urgent waiting list at the coordination centre for organ transplant.
- 3. The lungs shall be distributed to the patients stated on the urgent waiting list at the coordination centre for organ transplant, regardless of the turn of the centre that will carry out the transplant.
- 4. If the urgent list does not contain a suitable candidate for the lung transplant, the lung shall be given to the transplant centre whose turn has come, if such centre has the suitable candidate. If not, the lung shall be given to the centre that has a suitable candidate.

## **Liver Transplant**

#### **Specifications for Establishing Liver Transplant Centres**

The coordination centre for organ transplant has determined, through its competent committees, the specifications associated with the establishment of liver transplant centres in the GCC Countries. These specifications include the following:

#### 1. The technical team, consisting of:

#### 1.1 Liver transplant consultants:

- A consultant in the field of liver and biliary tract surgery shall be available at the centre. The consultant shall have had at least one year of experience at an internationally accredited liver transplant centre.
- A liver disease consultant with at least one year of experience at an internationally accredited liver transplant centre.
- A consultant Paediatric gastroenterologist with at least one year of experience
- A consultant Paediatric gastroenterologist with at least one year of experience at an internationally accredited liver transplant centre
- **1.2** An anesthesiologist with at least six months of experience at an internationally accredited liver transplant centre.
- 1.3 Intensive care consultant.
- 1.4 Nutritionist.
- 1.5 Epidemic disease consultant.
- 1.6 Liver transplant coordinator.

#### 1.7 Nursing body.

The persons working in this area, regardless of their gender, shall have adequate experience in giving care to patients during and after liver transplant surgeries.

#### 2. Technical Equipment:

2.1 The hospital where the liver transplant centre will be established shall contain the following divisions: Cardiology department, division of endoscopy, radiology department, hematology department, division of pathology, biochemical analysis laboratory, renal disease and blood purification unit, intensive care unit, immunology department, pneumology department, division of psychiatry, division of physiotherapy, microorganism division (bacteria, parasites, viruses, fungus).

# 2.2 The hospital shall also contain two operating rooms that are equipped with all the necessities required for liver transplant surgery, particularly the following devices:

Thromboelastogram, blood return device, perfusion pump, venovenous hemofiltration, blood stop or replacement laser device, blood warming device, along with the competent technicians to operate these devices.

### 3. Support medical departments, including:

# 3.1 Special equipment shall be available to conduct all routine tests needed for the evaluation and assessment of the patients' condition before and after the transplant.

- Special equipment shall be available to carry out the following: tissue analysis, cytotoxic antibody regulation and drug level regulation, including cyclosporine or its analogs

### 3.2 Radiology:

The hospital or centre shall contain the following: Regular X-ray imaging devices, ultrasound scan (Doppler), radionuclide angiogram, CT scan, cardiac tomography, percutaneous cholecystostomy.

### 3.3 Endoscopy:

This division shall contain all curative and diagnostic capabilities including pancreascopy and endoscopic retrograde cholecystostomy.

### 4. Medication: The following drugs must be available at all times:

### 4.1 Immunosuppressants:

Cyclosporine, azathioprine, prednisolone, mycophenolate mofetil and rapamune or their analogs.

#### 4.2 Drugs used to treat transplant rejection, such as:

Methylprednisolone, Anti-Lymphocyte Globulin (ALG) or Anti-Thymocyte Globulin (ATG) and monoclonal antibodies (OKT3).

#### 4.3 Fluids used for organ ischemia, such as:

Urecholine, University of Wisconsin solution or Histidine-Tryptophan-Ketoglutarate solution (HTK).

# 4.4 Drugs used for treating bacterial, viral, parasitic and fungal infections.

#### Cases of Liver Transplant

The patient must fulfill all or some of the following conditions in order to undergo liver transplant:

#### First: Acute (sudden) liver failure resulting from:

- 1. Hepatitis A, B, C, D and CMV or the Epstein Barr virus. etc.
- 2. Drugs that are toxic for the liver (halothane, disulfiram, acetaminophen... etc.)
- 3. Metabolic liver diseases
- 4. Wilson's disease
- 5. Rey's disease
- 6. Severe hepatic trauma
- 7. Other diseases

#### Second: Chronic liver diseases in advanced stages, including:

- 1. Primary biliary cirrhosis
- 2. Primary sclerosing cholangitis
- 3. Biliary tract obstruction
- 4. Autoimmune hepatitis of unknown etiology
- 5. Chronic alcoholic cirrhosis
- 6. Chronic toxic hepatitis resulting from various toxins

- 7. Chronic viral hepatitis
- 8. Vascular diseases of the liver (Budd-Chiari Syndrome) or (veno-occlusive disease)

#### Third: Hereditary metabolic liver diseases, including:

- 1. Alpha 1-Antitrypsin
- 2. Wilson's disease
- 3. Crigler-Najjar Syndrome
- 4. Glycogen storage disease
- 5. Protein C deficiency disease
- 6. Oxalosis

#### Fourth: Local hepatic tumors, such as:

- 1. Hepatocellular Carcinoma
- 2. Other liver cancers
- 3. Transitional liver cell tumor (carcinoid...)

See Annex 11 (Guide of tests that patients with chronic liver failure must undergo prior to liver transplant).

### **Contraindications to Liver Transplant**

#### First: Absolute Contraindications:

- If the patient has an active infection outside the biliary system.
- If the patient has any kind of cancer other than liver cancer.
- If the patient is HIV positive.
- If the patient has terminal heart or lung failure.
- If the patient is addicted to alcohol or drugs.

#### **Liver Transplant Priorities Guide**

The coordination centre for organ transplant has determined the priorities by virtue of which liver transplants are conducted, as follows:

- If the patient is at the intensive care unit and placed under artificial respiration (4th degree), which shall have top priority; the patient's degree shall be reevaluated weekly.
- If the patient is at the intensive care unit but not placed under artificial respiration (3rd degree).
- If the patient is an inpatient at the hospital (2nd degree).
- If the patient is at home (1st degree).
- If there is a temporary reason prohibiting the patient from undergoing liver transplant (0 degree), provided that his condition is reevaluated after the reason disappears.

#### After extraction, the liver shall be distributed as follows:

- 1. Every liver transplant centre shall prepare a local waiting list to be sent to the coordination centre for organ transplant where a national waiting list will be formed according to the priorities guide (see the liver transplant priorities guide).
- 2. The liver transplant centres shall notify the names of their patients who are in urgent need for liver transplant. These names shall be entered in an urgent waiting list at the coordination centre for organ transplant.
- 3. The lungs shall be distributed to the patients in need according to the priorities system and based on their waiting period on the waiting list as well as their blood group. The liver transplant centre shall be given one hour to reply regarding its readiness for the notified liver transplant.

#### **Conditions of Liver Donation from Living Persons**

- 1. The living donor must be physically healthy and psychologically stable.
- 2. The donor shall not be under 18 years or over 45 years of age.
- 3. The blood group of the donor and the recipient shall be compatible.
- 4. The hepatic functions must be normal, and the Hepatitis B core antibodies (HBcAb) as well as the Hepatitis C antibodies must be negative.
- 5. The donor shall not be addicted to drugs, medications that may be harmful to the liver or alcohol.

### **Corneal Transplant**

Specifications for Establishing Corneal Transplant Centres

The coordination centre for organ transplant has determined, through its competent committees, the specifications associated with the establishment of corneal transplant centres. These specifications include the following:

### 1. The technical team, consisting of:

### 1.1 Corneal transplant consultants:

A consultant in the field of corneal transplant shall be available at the centre. The consultant shall have had at least one year of experience at an internationally accredited corneal transplant centre, provided that he has conducted the surgeries himself during this period with a certificate confirming the same, or he has an experience of at least five years in corneal transplant at an internationally accredited hospital, provided that he submits a certificate of expertise issued by said hospital.

- 1.2 An anesthesiologist with previous experience in the field of anesthesia for eye surgery shall be available at the centre.
- 1.3 A full-time microorganism specialist at the hospital with a microorganism division shall be available.
- 1.4 A technician who works at an eye bank with experience in the field of storing the cornea and evaluating the quality and viability of the cornea for transplant shall be available; a corneal transplant consultant may carry out these tasks.
- 1.5 A corneal transplant coordinator with adequate experience to qualify him to coordinate corneal transplant and storage until it is time for the transplant.

### 1.6 Nursing Body:

The persons working in this area, regardless of their gender, shall have adequate experience in giving care to patients during and after corneal transplant surgeries.

<sup>\*</sup> One qualified person may assume the tasks of both the coordinator and the eye bank technician at the same time.

### 2. Technical Equipment:

#### 2.1 Ophthalmology Department

It must be well equipped and shall especially contain the following:

- Specific microscopes (split lamp)
- Ophthalmoscope to examine the fundus
- Visual acuity chart
- Corneal topography
- Refractometer
- Tonometer
- The external clinics at the hospital shall contain all the equipment needed to examine eye patients who have undergone or will undergo corneal transplant such as special (forceps, blades, eyelid speculums... etc.
- 2.2 The hospital where the corneal transplant centre will be established shall contain fully-equipped operating rooms for such fragile operations such as (operating microscopes, the vitrectomy unit... etc.).

#### **Corneal Transplant Priorities Guide**

The corneas shall be distributed according to the priorities guide determined by the corneal transplant committee at the coordination centre for organ transplant, as follows\*

**First priority:** Patient with corneal puncture or patient with disease or damage to the anterior part of the eye, requiring urgent rectification.

**Second priority:** One-eyed patient (one seeing eye) suffering from loss of vision in this eye as a result of a corneal injury.

**Third priority:** The cornea shall be transplanted into patients not fulfilling any of the previous priorities according to the order of their names on the local waiting list.

First-priority patients shall have absolute priority upon the availability of any cornea for transplant. This cornea shall be transplanted into the patient classified under this priority in the area where the cornea has been extracted. If no patient classified under this priority is available, the cornea shall be transplanted into a patient of this same priority in any other area in the concerned State.

<sup>\*</sup> See Annex 12 (Guide to the Tests that Corneal Transplant Candidates must undergo).

<sup>\*</sup> Priority between patients having the same priority level shall be given according to their conditions.

If no patient classified under the first priority is available in any Gulf State, the cornea shall be transplanted into any of the patients on the local waiting list according to priority. If no patient is available in the same area where the cornea has been extracted, it will be transferred to another State to be transplanted according to the priorities guide.

#### Standards of Viability of Deceased Donors' Organs for Transplant

#### First: Common general standards\*\*

The organs of a deceased person will be considered as (unviable) for transplant if any of the following conditions exists:

- 1. If the organ is damaged as a result of the primary injury causing the death or due to undergoing a state of shock for more than 30 minutes, except in cases of corneal transplant (see standards of corneal transplant).
- 2. If the deceased has confirmed or suspected cancer, excluding primary brain tumors that have been confirmed through analysis of the samples extracted therefrom and excluding skin cancer (basal cell carcinoma).
- 3. If the deceased is afflicted with a disease of unknown origin.
- 4. If the deceased is afflicted with an active and widespread bacterial or viral infection.
- 5. If the deceased is HIV positive.
- 6. If the deceased has Hepatitis B or C or is afflicted with Human T-lymphotropic virus (HTLV)\*\*\*
- 7. If the deceased is afflicted with a neurological disease such as Rey's disease, slow virus diseases such as Creutzfeldt-Jakob Disease, progressive multifocal leukoencephalopathy (PML), rabies or Kawasaki diseases (KD).
- 8. If the deceased is addicted to drugs.

## Second: Specific standards relevant to kidney transplant from deceased persons:

The coordination centre for organ transplant shall be consulted in cases of Extended Criteria Donors (ECD):

<sup>\*\*</sup> Note: The hospital where the death case has taken place shall coordinate with the coordination center for organ transplant and transplant centre to which the intensive care unit belongs to find out whether or not the deceased person's organs are viable for transplant.

<sup>\*\*\*</sup> Donation of a kidney from the deceased person may be approved if the latter has the Hepatitis B or C antibody, to be transplanted into patients with Hepatitis B immunity or afflicted with Hepatitis C or into patients carrying the same antibody provided that they are not afflicted with an active hepatitis. Decision shall be made for each case separately.

- 1. In case the creatinine level in the deceased person remains higher than 2.5 mg/dl in spite of giving him the needed liquids; the coordination centre for organ transplant must be consulted before taking any decision regarding the non-viability of the deceased person's organs for donation.
- 2. In case of advanced chronic renal failure and/or acute and chronic arterial hypertension in the deceased person. Regarding patients with mild diabetes or with non-active Systemic Lupus Erythematous (SLE), their organs may be viable for donation. The coordination centre for organ transplant must be consulted in this regard in order to make the appropriate decision.
- 3. If the deceased is under 2 years or over 50 years of age or when the age is unknown, the decision shall be taken based on their physiological condition, clinical history and the creatinine level in the blood. In all cases, the coordination centre for organ transplant must be consulted.

#### Third: Specific standards relevant to heart transplant:

The heart of the deceased will be considered as (viable) for transplant except in the following cases:

- 1. If any of the aforementioned common general standards is applicable.
- If the deceased is over 40 years old in the case of male donors or 50 years old in the case of female donors; the coordination centre for organ transplant must be consulted in all cases\*.
- 3. If the heart's condition is not normal according to the clinical test, the cardiac enzyme tests, the electrocardiography, the chest X-ray and the ultrasound.
- 4. If the deceased has an acute chest contusion causing damage to the heart.
- 5. If the cold ischemic time (CIT) exceeds 5 hours.

#### Fourth: Specific standards relevant to lung transplant:

The lungs of the deceased will be considered as (viable) for transplant except in the following cases:

1. If any of the aforementioned common standards is applicable.

<sup>\*</sup> The heart may be considered as viable for transplant in the contradicting cases provided that its function including the condition of the coronary arteries is examined and proven to be normal.

- 2. If the deceased is over 50 years old in the case of male donors or 55 years old in the case of female donors; the coordination centre for organ transplant must be consulted in all cases.
- 3. If the medical history of the deceased reveals that he has chronic respiratory failure or that he is addicted to smoking, if he has previously undergone a chest surgery, knowing that conducting surgery on one side will not prevent from benefiting from the other side, if he suffers from a bronchial disorder or if he suffers from repeated respiratory infection.
- 4. If the deceased has a chest contusion causing damage to the lungs, if he has inhaled toxic gases or if he has inhaled gastric secretions.
- 5. If the lungs' condition is not normal according to the clinical test, the blood gas test after placing the patient under oxygen tension (10%) for five minutes with positive pressure at the end of the respiratory circulation of an average of 5 cmH20, as well as the chest X-ray.
- 6. If the broncho-tracheal mucus secretions of the deceased are purulent and the coloring and transplant analyses reveal that they contain diseaseinducing bacteria.
- 7. If the size of the deceased person's chest is not compatible with the chest of the patient who will undergo the lung transplant.

### Fifth: Specific standards relevant to liver transplant\*:

The liver of the deceased will be considered as (viable) for transplant except in the following cases:

- 1. If any of the aforementioned common general standards is applicable.
- 2. If the deceased is over 50 years old.
- 3. If the liver functions of the deceased are not normal.
- 4. If the deceased is addicted to alcohol, drugs or both.

#### Sixth: Specific standards relevant to corneal transplant:

The corneas of the deceased will be considered as (viable) for transplant except in the following cases:

<sup>\*</sup> The coordination centre for organ transplant must be consulted in all cases.

- 1. If any of the aforementioned common standards is applicable.
- 2. If the eye has any internal disease such as malignant tumors, active conjunctivitis or any disease in the cornea or iris, or if the eye has previously undergone a surgical procedure, which may have a negative effect on the cornea.
- 3. If he has rubella.
- 4. If the period between the stoppage of the heart of the deceased and the extraction of the cornea exceeds 12 hours.

#### **Procedures of Intensive Care for the Deceased**

In order to provide intensive care to the deceased and acquire viable organs for transplant, the coordination centre for organ transplant believes that the following procedures must be followed:

- Keep the systolic arterial pressure above 100 mmHg in adults by giving the patient the necessary liquids as required, while keeping the central venous pressure around 12 cmH20, and by using vasoconstrictors as required. Dopamine, with or without other vasoconstrictors, is considered the best medicinal choice for optimum results.
- 2. Keep a urine output of 80 100 ml/hour with good balance between liquid intake and total urine output.
- 3. Keep the blood gases within the normal limits, where the partial pressure of oxygen shall be around 100 mmHg and the partial pressure of carbon dioxide shall be around 35 mmHg.
- 4. Keep the acid-base balance and the ions in the patient within the normal limits.
- 5. Since acute diabetes insipidus is common in deceased people, the adequate drugs, such as vasopressin, must be used when necessary, where the urine output shall be between 1.5 3 ml/kg/hour.
- 6. Pay full attention to prevent infection.
- 7. Keep the body temperature of the deceased within the normal limits by using warming or cooling means.
- 8. If the deceased has a slow heartbeat (less than 50 beats per minute), isoproterenol may be used as required.

- 9. Hormone treatment (insulin, thyroxine or cortisol) may be used as required under coordination with the organ transplant staff and the coordination centre for organ transplant.
- 10. Keep the eyes of the deceased closed and moisturized using the proper medical drops.
- x See Annex 13 (Care of the Deceased Diagram)
- x These procedures are carried out by the intensive care physician or the attending physician who shall decide on a treatment to achieve the objectives anticipated from the intensive care provided to the brain dead in collaboration with a kidney disease consultant and the organ transplant centre.

### Annexes

### Annex 1

# Resolution of the Islamic Fiqh Academy Council in Saudi Arabia

Praise be to the Lord of all worlds. Prayers and peace be upon our Prophet, Muhammad, his family and all of his companions

#### Resolution No. (5) d3/86/07 concerning Resuscitation Equipment

The Islamic Fiqh Academy Council, at its third conference in Amman, capital of the Hashemite Kingdom of Jordan, from 11 to 16 October 1986 G, corresponding to 8 to 13 Safar 1407 H,

Having discussed all the aspects raised on the subject of (resuscitation equipment) and heard the extensive explanation of the competent physicians,

Resolves that:

A person is legally considered to have died, and all the legally prescribed provisions for death follow if one of the following two signs becomes apparent:

1- If all his brain functions are permanently disrupted, and the specialist doctors have ruled that this disruption is irreversible, and his brain is decomposing.

In this case, it is permissible to remove resuscitation equipment from the person, even if some organs, such as the heart, are still working functioning mechanically by means of the attached devices.

Allah knows best.

### Text of the Council of Senior Scholars' Resolution No. 99 dated 6/11/1402 H

The Council has unanimously decided that an organ or part thereof may be transferred from a living Muslim or Dhimmi person to another, if necessary, and if it is decided that there is no danger in removing such organ or part thereof and that the transplant is likely to succeed. The Council has also decided, by virtue of the majority, as follows:

- 1. An organ or part thereof may be transferred from a deceased person to a Muslim, if necessary, and if it is decided that removing the organ from the donor will not cause trouble and that the transplant into the recipient will be likely to succeed.
- 2. A living person may donate an organ or part thereof to a Muslim who is in need of such organ.

### **Council of Senior Scholars**

### First Exam

### إستمارة تشخيص وتوثيق الوفاة باستخدام المعايير الدماغية Death Documentation Form by Brain Function Criteria

Name : .....

فصيلة الدم:...... Blood Group: الجنسية: Mationality: العمر: Blood Group العمر: Mationality

تاريخ الدخول: \_\_\_\_\_ Date of Admission: \_\_\_\_\_\_ المستشفى:\_\_\_\_\_

الفحص الأول First Exam	إستشاري أول	إستشاري ثاني
الفحص الأول First Exam	Consultant A	Consultant B
I. <u>PRECONDITIONS</u> الشروط الأولية		
It is absolutely certain that irremediable brain damage has occurred due to:		
2. More than six hours have passed since the initial insult.		
3. Coma with no spontaneous respiration.		
II. <u>EXCLUSIONS</u> أسباب ينبغي استبعادها       1. Hypothermia (core temperature < 34°C)		
2. Sedation (blood test or hospital record should indicate absence of significant levels of sedative drugs or muscle relax-ants).		
3. Untreated cardiovascular shock.		
4. Significant metabolic or endocrine causes of coma.		
III. CLINICAL ASSESSMENT التقييم السريري للجهاز العصبي		
1. Lack of response to stimulation (Spinal reflexes excepted).		
2 . Absence of brain stem reflexes:		
a. Pupils to light		
b. Corneal		
c. Oculocephalic		
d. Oculovestibular (50 ml of ice-cold water at 0°C in adults, 20 ml in children)		
e. Gag		
f. Cough		

### Encyclopedia of Health Legislation

First Exam	التاريخ / Date	الوقت / Time	الاسم / Name	التوقيع / Signature
Consultant A				
Consultant B				

Confirmatory Test: One of the following tests should be done after the above mentioned criteria are fulfilled: فحوصات تاکیدیة

EEG	Flat [ ]	Date	Signature
Absence of Brain circulation evidenced by either: - cerebral angiogram [] - radionuclide angiography [] - Transcranial doppler	No Flow [ ]	Date:	Signature
Note: Recommended time interval between first and second examinations in various age groups			
<ul> <li>* Adults minimum of 6hours</li> <li>** Infants (above 60 days - 1 year) 24 hours</li> <li>* Children (above one year) 12 hours</li> <li>** Neonate (7 days - 60 days)</li> <li>48 hours</li> </ul>			
* Two separated by the mentioned time interval			

### Annex 3 Second Exam

### إستمارة تشخيص وتوثيق الوفاة باستخدام المعايير الدماغية Death Documentation Form by Brain Function Criteria

Name :		الدسم:
Age: الجنس: Sex : العمر: National الجنس	Iity: الجنسية: E	فصيلة الدم:Blood Group:
المستشفى:Hospital :	Date of Admission:	تاريخ الدخول:

الفحص الثاني SECOND EXAM	إستشاري أول Consultant A	إستشاري ثاني Consultant B
I. <u>PRECONDITIONS</u> الشروط الأولية		
1. It is absolutely certain that irremediable brain damage has occurred		
due to:		
2. Appropriate time have passed between the first and second		
examination.		
3. Coma with no spontaneous respiration.		
II. <u>EXCLUSIONS</u> أسباب ينبغي استبعادها		
1. Hypothermia (core temperature < 34°C)		
2. Sedation (blood test or hospital record should indicate absence		
of significant levels of sedative drugs or muscle relaxants).		
3. Untreated cardiovascular shock.		
4. Significant metabolic or endocrine causes of coma.		
التقييم السريري للجهاز العصبي III. CLINICAL ASSESSMENT		
1. Lack of response to stimulation (Spinal reflexes excepted).		
2. Absence of brain stem reflexes:		
a. Pupils to light		
b. Corneal		
c. Oculocephalic		
d. Oculovestibular (50 ml of ice-cold water at 0°C in adults,		
20 ml in children)		
e. Gag		
f. Cough		

**IV. APNEA TEST** (Body temperature  $\ge 36.5^{\circ}$ C) Performed as per Saudi Protocol and is compatible with death by brain function criteria.

	التاريخ Date	الوقت Time	الاسم Name	التوقيع Signature
Consultant A				
Consultant B				
Hospital Director or Deputy				
ختم المستشفى Seal of the Hospital				ختم المستشفى

### موافقة التبرع بالأعضاء Consent For Organ Donation

I. Mr./Mrs.			أوافق أنا:
	ا ضغوط	يتع بكامل قواي العقلية وبدون أي	والموقع أدناه، والمتم
Father/mother/wi	fe/husband/brother/cousin/unc	le	
		زوجة/شقيق/عم/ابن عم	والد/والدة/زوج/
	حسب القرائن الدماغية	ء قريبي الذي قرر الأطباء وفاته	على التبرع بأعضا
Give the consent t	o donate the organs of the decea		
Mr./Mrs.	-		وإسمه:
In	hospital		في مستشفى:
To any suitable pa	tient(s) as deemed necessary.	فواني المرضى إبتغاء الأجر	وذلك لزراعتها لإ
		بحانه وتعالى. والله على ما أقوله	
□ I give the right t	to hospital		🗌 ﻠﯩﯩﺘﺸﻔﻰ:
	e-mentioned deceased relative		
			دماغياً أعلاه
□ I would like my	above-mentioned	ان قريبي المذكور	🗌 أرغب بنقل جثم
deceased relative t	to be transferred to:		أعلا <i>ه</i> إلى:
	er:		
	d No.:		
	/ / Place:		
Relationship to th	e deceased:		صلة القرابة: •••••
Address.			العنوان:
	ַل: الجوال:	ماتف المنز	هاتف العمل:
Work Tel. #:	Home Tel. #:	Mobile #:	
Signature:	Home Tel. #:		توقيع:
Witnesses:			الشهود:
Name:			الإسم:
Signature:	ID Card #:	رقم الهوية:	التوقيع:
Name:			الإسم:
Signature:	ID Card #:	رقم الهوية:	التوقيع:
Coordinator:			إسم المنسق:
Assistant Coordin	ator:	) بحضور:	تم توقيع هذا الإذن

# Guide to tests that non-diabetic patients with Terminal kidney failure must undergo prior to kidney transplant (x)

- 1. Conduct a complete blood count with comprehensive biochemical tests as well as a sedimentation rate and glucose tests.
- 2. Analyze a mid-stream urine sample and an end-stream urine sample to detect any bacterial and parasitic infections.
- 3. Analyze a morning mid-stream urine sample to detect any tuberculosis bacteria.
- 4. Conduct Hepatitis B and C tests, hepatic function tests, Prothrombin Time tests and Partial Thromboplastin Time tests.
- 5. Conduct an electrocardiography, a chest X-ray and tuberculosis skin tests.
- 6. Conduct tests for the cytomegalovirus, HIV, malaria, Schistosomiasis, sickle cell anemia.
- 7. Conduct a kidneys, ureters and bladder X-ray (KUB) using tincture via retrograde method.
- 8. Conduct blood group, tissue and cytotoxic antibody analyses.

### Guide To Tests That Diabetic Patients With Terminal Kidney Failure Must Undergo Prior To Kidney Transplant

- 1. Conduct all the tests stated under Annex 3.
- 2. Conduct an echocardiography.
- 3. Conduct a cardiac stress test.
- 4. Conduct a coronary angiogram.
- 5. Test the blood vessels in the neck and pelvis using ultrasound scan (Doppler).

### Controls and Conditions for Organ Donation from Living Non-Relatives in KSA

# Donation of organs (kidney, part of a liver) from living persons is divided into two main parts:

- Indirect donation (without compensation to an unspecified recipient): The identities of the donor and the recipient are known to the institutions overseeing the donation, including the transplant centre and the Saudi Centre for Organ Transplantation as well as the Ministry of Health that pay the compensation to the donor. However, the donor evaluation committee authorizing the process will only be aware of the identity of the donor with respect to this type of donation.
- 2. Direct donation (to a specified person): The identity of the donor is known to the recipient so is the identity of the recipient to the donor. Regarding this type of donation, the approval of donors shall be restricted to individuals of the same nationality.
- 3. Donor donating his kidney in return for financial compensation (placing his kidney for sale): This is not acceptable.
- 4. The person or patient offering to buy a kidney: This is also not acceptable.
- 5. Regulatory mechanism of kidney donation from living persons:
  - 1. The transplant shall only take place at a recognized government transplant hospital authorized by the Saudi Centre for Organ Transplantation to operate as a kidney transplant centre.
  - 2. The donor shall report to the transplant centre which will refer him to the transplant evaluation committee following the preliminary medical examination of the donor to verify his viability for donation.
  - 3. Evaluation shall be carried out by means of the donor evaluation committee: the donor by grant or non-relative donor shall appear in person before the donor evaluation committee.

### Formation of the committee

Committees shall be formed from the employees of government transplant hospitals at different regions of KSA.

#### Members of the committee

- a. The director of the transplant hospital or his representative.
- b. Two consultant physicians who are not competent in the field of kidney or liver transplant.
- c. A social worker.
- d. A religious expert.
- e. A psychiatry consultant.
- 4. The psychiatry consultant shall conduct a psychiatric evaluation to identify the psychological state of the donor without compensation to an unspecified person and his awareness regarding the donation. The psychological evaluation shall be verified before the evaluation committee by virtue of the signature of the psychiatry consultant.
- 5. The donor shall be interviewed by the committee at least two times with a two -week interval.
- 6. The donor shall have the right to retract the donation at any moment prior to the transplant surgery and may not claim to recover the donated organ after removal.
- 7. Minutes of the donors' evaluation shall be kept at every meeting of the donor evaluation committee; the minutes shall be confidential.
- In the case of donation to a specified person (direct donation), the evaluation committee shall ensure that the donor is of the same nationality as the recipient to avoid the temptation of money and exclude any suspicion of trading.
- 9. The decisions of approving or declining the donor's kidney donation shall be verified by virtue of a specific form to be signed by the members of the committee including the chairman of the committee with respect to that case.
- 10. The committee's approval shall be sent to the Saudi Centre for Organ Transplantation.
- 11. The Saudi Centre for Organ Transplantation shall coordinate with the heads of the transplant programs at the transplant centres in order to carry out the transplant following the evaluation of the donor and conduct

accurate medical tests to verify that there are no medical contraindications to prevent the donation and that no harm may befall the donor after the donation process.

- 12. After the donor is approved by the transplant centre and passes the medical and psychiatric evaluation, the transplant shall then be approved by the Saudi Centre for Organ Transplantation to be notified to the transplant centre. No donation from non-relatives may take place without the written approval of the Saudi Centre for Organ Transplantation
- 13. After completing the transfer of the donated organ, the transplant centre shall submit a detailed medical report to the Saudi Centre for Organ Transplantation.
- 14. The Saudi Centre for Organ Transplantation shall submit a report to the Minister of Health stating the completion of the transplant.
- 15. The Saudi Centre for Organ Transplantation shall submit a request to the Minister of Health to claim the compensation specified in the Council of Ministers' resolution for payment to the donor.
- 16. The compensation shall be paid according to a form prepared by the Saudi Centre for Organ Transplantation.
- 17. A request shall be submitted to His Majesty to award King Abdulaziz Medal - Third Class to the donor (only for Saudi Nationals).
- 18. The Saudi Arabian Airlines will be requested to issue a fee reduction card (only for Saudi nationals).

### Guide to tests that living kidney donors must undergo

- 1. Conduct routine blood tests.
- 2. Conduct complete kidney function tests.
- 3. Analyze urine and establish a microbial culture.
- 4. Regulate protein level and creatinine level in a 24-hour urine collection.
- 5. Detect the possibility of having schistosome eggs in the urine.
- 6. Conduct an intravenous pyelogram to visualize the renal pelvis.
- 7. Conduct renovascular imaging.
- 8. Conduct complete liver function tests.
- 9. Conduct Hepatitis B and C tests.
- 10. Conduct HIV tests.
- 11. Conduct the cytomegalovirus test.
- 12. Conduct syphilis tests.
- 13. Conduct malaria, brucella and schistosoma tests.
- 14. Conduct the sickle cell anemia test.
- 15. Conduct stool analysis and detect schistosome eggs and other parasites.
- 16. Conduct a chest X-ray, an electrocardiography and a tuberculosis skin test.
- 17. Conduct an abdominal echography.
- 18. Conduct blood group and tissue analyses and verify compatibility between the cells of the donor and the recipient.

### Guide To Tests That Patients With Terminal Heart Failure Must Undergo Prior To Heart Transplant

- 1. Conduct a complete blood count with comprehensive biochemical tests as well as a sedimentation rate and glucose tests.
- 2. Conduct complete kidney function tests.
- 3. Conduct complete liver function tests.
- 4. Conduct tests for blood coagulation factors.
- 5. Regulate complete protein and the albumin/globulin ratio and regulate the immunoglobulins in the blood.
- 6. Analyze and cultivate a midstream urine sample.
- 7. Cultivate nasal, pharyngeal, armpit and perineal swabs.
- 8. Conduct stool analysis to detect parasites.
- 9. Conduct tests to detect mycoplasma, Q fever, legionella, human metapneumovirus (hMPV), varicella zoster virus (VZV), parainfluenza virus, toxoplasmosis, cytomegalovirus, HIV and syphilis.
- 10. Conduct Hepatitis B and C tests.
- 11. Conduct a tuberculosis skin test and sputum culture.
- 12. Conduct blood group and tissue analyses and regulate cytotoxic antibodies.
- 13. Conduct complete tests for lung functions and blood gases, a scintiscan and a chest X-ray.
- 14. Conduct an abdominal echography.
- 15. Conduct a complete electrocardiography, an echocardiography, a cardiac catherization and a coronary angiogram and take pericardium samples.
- 16. Seek the opinion of a respiratory disorder consultant.
- 17. Seek the opinion of an epidemic disease consultant.

### Guide To Tests That Patients With Terminal Respiratory Failure Must Undergo Prior To Lung Transplant

- 1. Conduct a complete blood count with comprehensive biochemical tests as well as a sedimentation rate and glucose tests.
- 2. Conduct complete kidney function tests.
- 3. Conduct complete liver function tests.
- 4. Conduct tests for blood coagulation factors.
- 5. Regulate complete protein and the albumin/globulin ratio and regulate the immunoglobulins in the blood.
- 6. Conduct blood group and tissue analyses and regulate cytotoxic antibodies.
- 7. Conduct Hepatitis B and C tests.
- 8. Conduct a complete 12-lead electrocardiogram, an echocardiography, a Doppler test to evaluate the pulmonary tension, a cardiac catherization and a coronary angiogram for all patients over 40 years old or who have indications of injury to the coronary arteries.
- 9. Conduct a kidney and liver ultrasound.
- 10. Conduct tests to detect mycoplasma, Q fever, legionella, human metapneumovirus (hMPV), varicella zoster virus (VZV), parainfluenza virus, toxoplasmosis, cytomegalovirus, HIV and Syphilis.
- 11. Conduct a tuberculosis skin test and sputum culture (bronchial secretions) including cultures to detect Aspergillus fumigates.
- 12. Analyze and cultivate a midstream urine sample.
- 13. Cultivate nasal and pharyngeal swabs.

Transmission of (3) sputum samples for transplantation to search for tuberculosis bacteria in patients previously infected with tuberculosis or if the cutaneous tuberculosis test is positive.

14. Conduct complete tests for lung functions and blood gases, a chest X-ray (from the front, back and side), a scintiscan for the lung ventilation and a CT scan.

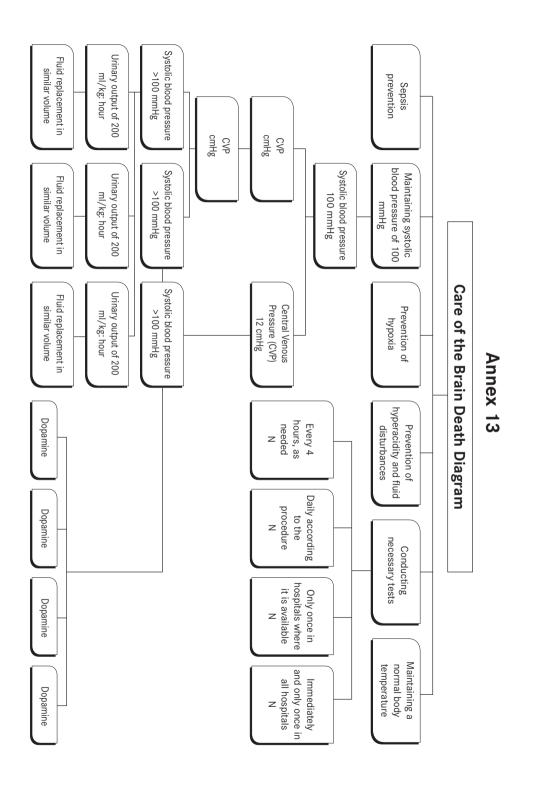
- 15. Conduct a stress test by asking the patient to walk for six minutes, while monitoring him with an oximeter, under the observance of an ENT specialist and a gynecologist for women, and assessing the patient's psychological and nutritional condition.
- 16. Conduct a general medical examination with a dentist, an ENT specialist and a gynecologist, in the case of women, and evaluate the psychological and nutritional condition of the patient.
- 17. Keep 10 cm of the patient's blood for when it is needed to test tissue compatibility between the cells of the donor and the recipient.

### Guide To Tests That Patients With Terminal Liver Failure Must Undergo Prior To Liver Transplant

- 1. Conduct the tests stated in Annex 5 excluding Item 7.
- 2. Regulate the iron in the blood, the Total Iron Binding Capacity (TIBC), the ferritin, the complete protein and the albumin.
- 3. Conduct complete liver function tests.
- 4. Conduct complete tests to detect hepatitis.
- 5. Conduct complete lung function tests and blood gas tests.
- 6. Conduct tests to detect the Epstein Barr virus, HIV, the Cytomegalovirus, syphilis, sickle cell anemia, malaria and Schistosomiasis.
- 7. Detect ttuberculosis bacteria in urine and sputum.
- 8. Detect parasites in the stool and cultivate it.
- Conduct an upper gastrointestinal endoscopy, an abdominal CT scan for all patients without exception and a lower gastrointestinal test if the patient is over 45 years old.
- 10. Conduct an ear, nose and throat examination, an eye exam and a teeth inspection.
- 11. Conduct a genital examination in the case of married female patients and a cervical pap smear if the female patient is over 45 years old.
- 12. Examine and evaluate the psychological condition of the patient to see whether he will respond to the treatment and follow the medical instructions.
- 13. Take the all necessary and possible vaccinations in the case of children patients and detect varicella antibodies.

### Guide To Tests That Corneal Transplant Candidates Must Undergo

- 1. Conduct a total eye exam with evaluation of visual acuity to verify that the visual acuity deficit results from a corneal disease.
- 2. Conduct a bacterial, viral, parasitic and fungal evaluation with regard to the corneal puncture especially if there is doubt of an infection.
- 3. Conduct all routine blood tests.
- 4. Conduct all biochemical blood tests.
- 5. Conduct a chest X-ray and an electrocardiogram.



#### **Encyclopedia of Health Legislation**



## Conclusion

With God's blessings, the third issue of the Encyclopedia of Health Legislation of the Department of Health - Abu Dhabi has been released to be launched in 2023.

On behalf of myself and all the members of the team working on the Health Legislation Encyclopedia project, I would like to extend my thanks for the precious trust placed by His Excellency the Chairman of the Department of Health - Abu Dhabi, and for the interest and follow-up of His Excellency the Undersecretary of the Department, by providing all means of support and motivation throughout the stages of work until the release of the third issue of the Encyclopedia.

I also pay tribute to the outstanding efforts and hard work made by my fellow team members for the release of this Encyclopedia in its current issue.

To conclude, we look forward to working together with our partners towards further initiatives that achieve the Department's promising vision that "the Emirate of Abu Dhabi be a place where everyone is at his healthiest" by providing a distinguished and sustainable healthcare and services that achieve the well-being and happiness of the community.

Saqr Al Marzooqi

Manager, Legal Affairs Office Abu Dhabi - February 2023



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