DIRECTORY OF THE REGULATIONS OF ORGAN TRANSPLANTATION IN THE KINGDOM of SAUDI ARABIA

2nd Edition
2014
Ministerial Resolution

No. 154219 Dated 06/05/1434

The Minister of Health,
President of Saudi Health Council,

According to his prerogative has resolved the following:

First: Endorsement of the updated Directory of the Regulations of Organ Transplantation in the Kingdom of Saudi Arabia.

Second: All Public and private hospitals should apply these regulations.

Third: The General secretariat of council should implement this resolution.

Dr. Abdullah bin Abdulaziz Alrabiah
Minister of Health
President of Saudi Health Council
Ministerial Resolution

No. 1081/1/29 Dated 18/6/1414

The Minister of Health, according to his prerogative has resolved the following.

First: Endorsement of the Directory of the Regulations of Transplantation laid down by the Saudi Center for Organ Transplantation.

Second: Approval of the criteria laid down by the Saudi Center for Organ Transplantation for the establishment of organ transplant centers in different areas of the Kingdom.

Third: Private Medical Institutions which intend to establish organ transplantation centers should forward an application to the Commission for licensing of Practice of Medicine, Ministry of Health along with the necessary documents.

Fourth: All public and private hospitals and organ transplant centers in the Kingdom should apply these regulations from the date of issue of this resolution mentioned above.

Fifth: The deputy Minister for Executive Affairs, the Director General of Medical Licenses and the Director of the Saudi Center for Organ Transplantation should put into practice this resolution in their respective fields of duty.

Faisal Alhegelan
Minister of Health
Members of Supreme National Committee for Development of Organ Transplantation (2010)

1. Dr. Faissal A.M. Shaheen, Director General, Saudi Center for Organ Transplantation
2. Dr. Abdulmajeed Abdulkareem, National Guard Hospital
3. Dr. Haidar Al Shurafa, Armed Forces Services
4. Dr. Ali Al Harbi, Security Forces Hospital
5. Dr. Mohammed Al Subayel, King Faisal Specialist Hospital & Research Center
6. Dr. Faisal Bin Abdullah Al Saif, King Saud University
7. Dr. Adnan Alfi, King Abdulaziz Hospital & Oncology Center, Jeddah

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3. Dr. Haidar Al Shurafa, Representative of Medical Military Services
4. Dr. Sulaiman Mohaya, Representative of Medical Affairs in Security Forces Hospitals
5. Dr. Mohammed Al Subayel, Representative of Medical Affairs in King Faisal Specialist Hospitals
6. Dr. Faisal Bin Abdullah Al Saif, Representative of King Saud University
7. Dr. Adnan Alfi, Representative of Ministry of Health
8. Dr. Mohammed Al-Saghier, Representative of Medical Affairs in Medical Cities
9. Dr. Hamad Bin Saad Al-Fraikh, Representative of Medical Affairs Specialist Hospitals
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Dr. Abdul Rahman Al Swailem
(1985-2000)

Previous Directors of National Kidney Foundation

Dr. Saleh Aswad
(1985-1989)

Dr. Abdulatif Aldress
(1990-1993)
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Directory of the Regulations of Organ Transplantation in the Kingdom of Saudi Arabia
The National Committee for Death Declaration by using Neurologic Criteria (2009)

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Consultant Physician and Nephrologist
General Director
Saudi Center for Organ Transplantation

Dr. Mohammad Zuhair Al-Qawi, MD
Chairman
Senior Consultant Neurologist
King Faisal Specialist Hospital and Research Center, Riyadh

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Directory of the Regulations of Organ Transplantation in the Kingdom of Saudi Arabia
The National Committee for Brain Death Declaration (1992)

Dr. Abdulatif Aldress, MD  
Chairman  
Consultant Transplant Surgeon  
Director, National Kidney Foundation, Riyadh

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| Dr. Mohammad Zuhair Al-Qawi, MD | Consultant Neurologist  
King Faisal Specialist Hospital and Research Center, Riyadh |
| Dr. Mohammed Al-Bar, MD       | Consultant Islamic Medicine  
King Abdul Aziz University, Jeddah |
The National Committees for Organ Donation and Transplantation

1. Kidney Transplantation Committee:
   Includes representatives of the kidney transplant programs in all hospitals licensed to perform and active in the practice of kidney transplantation.

2. Heart Transplantation Committee:
   Includes representatives of the heart transplant programs in all hospitals licensed to perform and active in the practice of heart transplantation.

3. Liver Transplantation Committee:
   Includes representatives of the liver transplant programs in all hospitals licensed to perform and active in the practice of liver transplantation.

4. Pancreas Transplantation Committee:
   Includes representatives of the pancreas transplant programs in all hospitals licensed to perform and active in the practice of pancreas transplantation.

5. Lung Transplantation Committee:
   Includes representatives of the lung transplant programs in all hospitals licensed to perform and active in the practice of lung transplantation.

6. Bone Transplantation Committee:
   Includes representatives of the bone transplant programs in all hospitals licensed to perform and active in the practice of bone transplantation.

7. Corneal Transplantation Committee:
   Includes representatives of the corneal transplant programs in all hospitals licensed to perform and active in the practice of corneal transplantation.

8. The ethics committee of the Organ Transplant Committee includes representatives from the different Organ Transplantation Centers and donor hospitals and legal affairs and medical ethics specialists.

9. The Committee of intensive care unit includes representatives from all donor hospitals.

10. The Committee of Activation and promotion of organ donation includes representatives of all donor hospitals and transplant hospitals and universities.

11. The National Committee for the diagnosis of brain death includes representatives of consultants in neurological diseases and intensive care of all hospitals and medical ethics specialists.
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Introduction

I am pleased to introduce this endeavor, the updated directory of the regulations of organ transplantation in the Kingdom of Saudi Arabia brought out by my colleagues who are members of the supreme national committee for development of organ transplantation program. This directory reflects the progress achieved in the field of organ transplantation in Saudi Arabia both in quality and quantity. They also reflect the good care being extended to patients with various end stage organ failure.

The regulations in this directory outline the technical and administrative aspects concerning: organ donation and transplantation, scientific definition of brain death and pre-conditions required for its diagnosis, who is going to explain the brain death concept to the family, conditions and methods of organ recovery, transferring of retrieved organs, distribution of hospitals to the transplant centers, distribution of the retrieved organs, criteria to be met with for opening new transplant center, both government and private, and post transplant follow-up of the patients in different centers.

Our thanks and appreciation to all my colleagues who contributed to the creation of the directory, which is a continuation of the first edition of the directory issued in 1414 H. Many aspects of policies and procedures and most importantly, the new regulations of Saudi Center for Organ Transplantation (SCOT) and its relationship with the donating hospitals, intensive care units and regional coordination offices have been updated. Special thanks are extended to my colleagues in SCOT for their excellent performance in bringing out this directory.

Best wishes

Dr. Faissal A.M. Shaheen
Director General
Saudi Center for Organ Transplantation

Dr. Yagob Al Mazrou
Secretary General
Saudi Health Council
Regulations for Organ Donation and Transplantation in the Kingdom of Saudi Arabia

Regulations are essential to the process of organ donation and transplantation and therefore, the Higher National Committee for the Development of Organ Donation and Transplantation in the Kingdom of Saudi Arabia (KSA), which was formed according to the Ministerial resolution 14853/84 dated 30/2/1431, reviewed the regulations and passed them as follows:

Item 1: The following terms are defined as follows:

Council: The Council for the Health Services
Center: The Saudi Center for Organ Transplantation (SCOT)
Directory: The Directory for Organ Donation and Transplantation in the KSA.

Item 2: Only authorized specialized physicians can perform organ transplantation from the living or deceased human donors to a human recipient with intention for cure and rescue according to the regulations included in this document.

Item 3: Any rightful person can donate or place a directive for donation of one of his body organs to rescue or treat a patient with end-stage organ failure. A statement should be signed by the donor as a will for donation. Nevertheless, only those who attain 18 years of age can donate to their relatives.

Item 4: Fully known medical investigations as advised by the specialist in the field should be performed before approving the organ donation from living donors. Full discussion of the risks and possible outcomes should be conducted with the donor before donation.

Item 5: Donors have the right to withdraw their consent for donation any time before the operation without penalties. No donor can claim his organ after transplantation is completed.

Item 6: It is prohibited for living donors to donate vital organs, donation of which could result in the death of the donor or complete disabling of vital functions.

Item 7: Organ donation can be from the persons only after full documentation of death by a committee of specialized physicians and in the absence of a directive by the donor objecting to donation during his life.

Item 8: Organ donations, as in item 7, can be performed if brain stem death is documented by the available means of technology.
Item 9: Commercial transplantation is prohibited in any manner.

Item 10: Transplantation is performed only in centers authorized by the Ministry of Health in the GCC Countries.

Item 11: Penalties will be levied in case of any violation of the above regulations according to system of the medical practice, after intensive investigation by the SCOT and the concerned authorities.
A Brief Historical Overview of Organ Donation and Transplantation Programs in the Kingdom of Saudi Arabia

- Initiative of His Royal Highness Prince Salman bin Abdul Aziz - governor of Riyadh region - may God protect him, to issue a decision of the Council of Senior Scholars No. 99 dated 06/11/1402 that permits the transfer of organs from one human being to another, whether he is alive or dead (Appendix 1). It also followed by the decision of the Council of Islamic Jurisprudence about the definition of death and permission to switch off the ventilator from brain dead (Appendix 2).

- Initiative of His Royal Highness Prince Salman bin Abdul Aziz (Governor of Riyadh region) to establish a center supervising and coordinating organ transplantation and donation from brain dead 1404H as well as regulating the treatment of patients with kidney failure with issuing of the Royal Decree No. 7/1561/M on 15/5/1404H for establishment of the National Kidney foundation (Appendix 3).

- Initiative of His Royal Highness Prince Salman bin Abdul Aziz to raise the level of care for organ failure patients, to include all members and expand the activities of the National Kidney foundation till issuing of the Royal Decree No. 80 dated 20/06/1413H change the name of the National Kidney foundation to the Saudi Center for Organ Transplantation thereby expanding its activities to include all Organ Transplantation fields (Appendix 4).

- Initiative of His Royal Highness Prince Salman bin Abdul Aziz, to create a new headquarters for Saudi Center for Organ Transplantation thereafter laying the foundation stone for the new headquarters 1418H.

- The opening of the new headquarters of the Saudi Center for Organ Transplantation and Prince Salman kidney Center by His Royal Highness Prince Salman bin Abdul Aziz, Honorary President of the Saudi Center for Organ Transplantation, 9 Shaaban 1421, corresponding to November 5, 2000.

- Initiative of His Royal Highness Prince Salman bin Abdul Aziz, to establish a charity for the care of patients with kidney failure in 1418H.

- Initiative and support of His Royal Highness Prince Salman bin Abdul Aziz, the requirement of the organ donation and transplantation program in the Kingdom of Saudi Arabia has been raised and the approval of the Council of Ministers No. 195, dated 01/08/1423 had been issued to support the organ donation and transplantation.

- Initiative and support of His Royal Highness Prince Salman bin Abdul Aziz, Honorary President of the Saudi Center for Organ Transplantation to support the needs of dialysis patients by giving them a paid vacation day on dialysis day through Saudi Center for Organ Transplantation.
- Decision of the Council of Health Ministers of the Gulf Cooperation Council (GCC) No. 3 for the organ transplantation congress (61) On 26/04/1427, corresponding to 24/05/2006 stated:

1. Adoption of the Saudi Center for Organ Transplantation as a referral center for the Gulf Cooperation Council (GCC) countries.

2. Adoption of a uniform law on regulation of organ sharing among Gulf Cooperation Council countries as a guidelines.

- The decision of the Council of Ministers No. 270, date 08/09/1429 stating the attachment of Saudi Center for Organ Transplantation with Council of health services directly and allocate a special budget for the end organ failure program and organ transplantation program separated from the budget of the Ministry of Health with the provision of administrative and medical and technical resources required for the center Saudi for Organ Transplantation.

- The decision of the Council of Ministers No. 38 dated 01/26/1434, defining the duties of the Saudi Center for Organ Transplantation within the new organization.

See the overview on organ donation and transplantation program in the Kingdom of Saudi Arabia (Appendix 5).
Responsibilities of the Saudi Center for Organ Transplantation

1. Setting up a national registry for end-stage organ failure patients, organ transplant recipients and organ donors with their follow-up and outcome, and setting up the necessary procedures.

2. Receiving and following-up of brain death cases in intensive care units, coordinating the removal of organs after getting the necessary approvals and distributing the organs to the organ transplant centers in the various health institutions in the Kingdom.

3. Coordinating with the concerned authorities to send medical teams to the various areas in the Kingdom and abroad, to remove the organs from the person mentioned in paragraph 2 of this clause and transplant it to a patient.

4. Cooperating and coordinating with the health authorities in the field of organ transplantation, both inside the Kingdom and abroad.

5. Preparing and updating the necessary procedures for organ transplantation from living donors in accordance with Sharia law restrictions.

6. Preparing and updating the policies and procedures (measures, descriptions, conditions and restrictions) related to organ transplantation in the Kingdom.

7. Monitoring and following-up on the application of organ transplantation programs, carrying out regular appraisals of the establishments and following-up with the specialized bodies.

8. Preparing administrative and financial roles for the personnel of the center, the researchers and those collaborating with it.

9. Holding symposia and conferences and educational and training programs, in the field of organ failure, organ donation and transplantation, on regional and international levels and holding orientation programs.

10. Offering awareness and educational health programs, in the field of organ failure and organ donation and transplantation in the community.

11. Publishing a scientific journal specializing in organ transplantation on the subjects of organ failure, organ donation and transplantation.

12. Taking part in scientific research related to organ transplantation and organ failure, in the Kingdom and abroad.

13. Cooperating with charities to support organ failure patients.
Organizational Structure of SCOT

Saudi Health Council

The Higher Committee for Developing Organ Transplantation Program

Director General of SCOT

Scientific Committees

Planning and Development Dept.

Journal and Research Dept.

Director Office

Public Relation and Media Department

Legal Counsel

Information Technology Dept.

Administrative and Financial Affairs Dept.

Technical Affairs Dept.

Regional Coordination Offices

Operation and Maintenance

Information Services Dept.

National Registry for Organ Transplant Dept.

Supportive Services Dept.

Administrative Communication Dept.

Human Resources Dept.

Financial Affairs Dept.

Medical Supply Dept.

Social Services Dept.

Administrative Coord. Dept.

Medical Coord. Dept.
1. General Procedures for Organ Donation and Transplantation in the Kingdom of Saudi Arabia

1. General procedures that must be followed by all hospitals and transplant centers:

- Reporting of all possible brain death cases.
  All hospitals are responsible for establishing internal committees, which will be fully responsible for handling cases with brain death and organ transplantation.

1.1 Role of intensive care and emergency units:

Identification of potential brain dead patients and early notification of suspected cases to the Saudi Center for Organ Transplantation (SCOT) must be regarded as one of the main responsibilities of the intensive care units. Also, regular communication between the coordinator at the hospital and coordination office at the SCOT is part of their daily routine and is important for subsequent evaluation of their performance.

It is incumbent on the director of the donor hospital to ensure that proper supervision of the management and follow-up of the cases of the donors and implementation of this order are undertaken.

Staff in the emergency room (ER) should be educated about the concepts of brain death and organ donation program. When a potential donor is brought to the ER, attempts to resuscitate must be made without losing hope, and there should be coordination with the ICU for further care.

Staff in the intensive care units in the hospitals should show interest in the training courses organized by the SCOT on a regular basis. The courses are meant to train the staff on concepts of diagnosis of brain death, care of the deceased as well as procedures for organ donation.

1.2 Coordinators in donor hospitals: all hospitals shall form internal committees consisted of medical and administrative coordinators who would be responsible for handling all cases of brain death and organ donation as follows:

1.2.1 Notification and follow-up: coordinators in hospitals should report suspected brain death cases to the SCOT continue to send information on a regular basis and all necessary samples to the laboratory. They should also coordinate with regional coordination offices (RCO) and the SCOT in order to follow all the special procedures related to brain death and contacting the family members regarding donation.
1.2.2 Approaching family of the deceased and convince them to consent for donation in coordination with the SCOT and the RCO; special training is necessary to accomplish this mission.

See appendix 6: organ transplant centers, and appendix 7: hospitals distribution to transplant centers.

1.3 The role of RCO in organ donation:

1.3.1 Goal: Organ promotion through intensive care units and emergency departments in the various regions of the Kingdom.

1.3.2 The affiliation of the RCOs and their mechanism of action:

- The RCOs belong fully to the SCOT in all administrative, financial, and organizational aspects.

- The SCOT specifies the locations of RCOs and their affiliated donor hospitals.

1.3.3 The missions:

1.3.3.1 Communication with intensive care units in hospitals regarding organ donors through daily communication and regular visits to overcome the difficulties encountered in the program.

1.3.3.2 Early identification of cases of brain death and follow-up of the diagnostic procedures and medical care.

1.3.3.3 Interview with the family of deceased donor for organ donation and end the administrative procedures after the removal of organs.

1.3.3.4 Assistance in raising awareness of those working in the medical field as well as the general public about the importance of organ donation and spreading knowledge through seminars, lectures and workshops in hospitals in coordination with the SCOT.

1.3.3.5 To report periodically on the activities of the office to the SCOT.

1.3.4 Requirements for the establishment and operation of the RCOs:

1.3.4.1 Customize a convenient place for the Coordinating office (at the donor hospital or a separate building).

1.3.4.2 Provision of office equipment and means of communication (Direct dial phone - Fax - Internet) and a computer with a printer and accessories.
1.3.4.3 Providing a portable electroencephalogram (EEG) machine.

1.3.4.4 Staff in coordinating offices: They should at least consist of the following personnel:

1.3.4.4.1 Doctor trained to deal with cases of brain death and care of the donor.

1.3.4.4.2 Administrative coordinator trained to deal with organ donation and procedures.

1.3.4.4.3 Nurse or technician trained to perform EEG and draw blood samples and support medical and administrative staff.

1.3.4.4.4 Secretary fluent in Arabic, English and can operate a computer and its applications.

1.3.4.4.5 Suitable means of transportation for the medical and administrative teams other tasks related to the RCO.

1.3.5 Role of medical coordination in the RCO:

1.3.5.1 Ensure that the intensive care units in hospitals identify cases of brain death through routine visits to those units.

1.3.5.2 When a suspected case of brain death is identified in any donor hospital in his district, he will be responsible for:

1.3.5.2.1 Reporting to the SCOT the status of the cases and coordination with medical and administrative coordinator at the respective hospital.

1.3.5.2.2 Coordination with the ICU doctor in charge to follow the national protocol diagnosing death using neurological criteria within the earliest possible time and to overcome the difficulties that can be encountered.

1.3.5.2.3 Coordination with the ICU doctor in charge of the case to maintain the organ donor and overcome the difficulties and other relevant requirements.

1.3.5.2.4 Coordination with the treating physician in the hospital inform and explain to the relatives the status of the deceased.

1.3.5.2.5 Coordination with the SCOT and the donor hospital once the approval for organ donation is obtained in order to determine the place and time of the harvesting procedure and provide assistance.
with special technical materials needed to preserve and transport the retrieved organs.

1.3.5.2.6 Coordination with the SCOT and donor hospitals in his area to organize training workshops to disseminate awareness among medical workers and the public about the importance of organ donation and transplantation.

1.3.5.2.7 Submission of periodic reports (at least every 3 months) to the SCOT, including the statistics and obstacles and proposed solutions to improve performance and results.

1.3.6 Role of administrative coordinator in regional coordination:

The administrative coordinator must have obtained at least a high school certificate and be familiar with the legal and medical aspects of the meaning of death and the importance of organ donation and transplantation. He should have the ability to communicate with the family of the deceased and to establish new relationships with different operators and relevant departments in hospitals, administrative and governmental bodies in his area.

1.3.6.1 Work along with the medical coordinator in overcoming any obstacles that may hinder the diagnosis of death due to administrative aspects.

1.3.6.2 Careful interview with the family of the deceased to introduce the idea of organ donation for their approval on it, and to ensure continuity of communication with them even after organ donation.

1.3.6.3 Overcome the administrative difficulties that might hinder organ donation procedures before, during and after the removal of organs in coordination with the SCOT (such as a death certificate, operating rooms, and delivery of the corpse to his family, etc.).

1.3.6.4 Inform the SCOT about the personnel involved in the success of the case and their roles in it, and follow-up with material and moral incentives for them.

1.3.6.5 Work along with members of the RCO in spreading awareness about the importance of organ donation through seminars and training courses.

1.3.6.6 Continuity of communication and support for families after completion of organ donation

1.3.6.7 Work together with the medical coordinator for the submission of the periodic reports to the SCOT about the activities of the RCO and collaboration with SCOT research activities.

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1.4 General Conditions of cases of organ donation after death:

1.4.1 Verification of brain death unequivocally and that diagnosis is in accordance with the brain death national protocol (Appendix 8) and with the forms described for the diagnosis (Appendix 9). Also, in case of pregnancy of the deceased the donation process will be continued only if the fetus is proven dead. Participation of any member of the transplant team in the diagnosis of the brain death is prohibited.

1.4.2 Obtaining the approval of the legal next of kin of the deceased donor to donate organs, whether they are inside or outside the country, according to the consent form in Appendix 10. If the deceased person is un-identified and family cannot be located, approval of the competent official authorities should be obtained before the removal of organs.

1.4.3 Coordination with the SCOT prior to the removal of any organ of the deceased until the distribution is decided based on priority criteria.

1.4.4 Recovery of organs should be completed in the donor hospital and not to transfer the case to another hospital unless there are compelling reasons.

1.4.5 Organs are distributed and transplanted as described in the procedures manual for each organ.

1.5 General Conditions for transplantation from living donors:

1.5.1 Donor should be at least 18 years of age.

1.5.2 The donor should be genetically related, breastfed or related by law and authenticated officially. The exception is transplantation of renewable organs such as bone marrow or donation from genetically unrelated donor, Donation from non-relatives is accepted to discourage organ trading and with specific controls to guarantee the rights of patients and donors (see Appendix no. 11).

1.5.3 Donation from the living should not result in any harm to the health of the donor or the recipient, and not to recover any organ that is indispensable for the life of the donor.

1.5.4 The donation should not include any social or material coercion.

1.5.5 The donation should be supported with a written consent and authenticated by the donor. The donor may withdraw the consent for donation at any time before the procedure.

1.5.6 Living donors should have undergo detailed medical examination, and the donor shall be informed of all possible outcomes or consequences of organ donation. All data of the donor including the consent should be entered in his or her in medical records.
1.6 Other duties of organ transplant centers include the following:

1.6.1 Appoint a transplant coordinator in transplant centers to engage in the following tasks:

1.6.1.1 Continuously coordinate with the SCOT.

1.6.1.2 Report the names of patients suitable for transplantation in the hospital to the SCOT to prepare the local waiting list for his center according to priorities.

1.6.1.3 Coordination with the SCOT on all brain death cases in the affiliated hospitals to his center and offer the appropriate support.

1.6.1.4 Report to the SCOT in case of absence of suitable recipient for transplantation in his local list. Each hospital of the Kingdom should assign Coordinator for Organ Transplantation to gather the required information and constantly update and sent to the SCOT through assigned forms for end-stage organ failure patients, whether kidney, heart, liver, lungs or other, and also to appoint his deputy to work in his absence.

1.6.2 Each donor hospital and transplant center should provide the SCOT with the list of their end stage organ failure patients; the SCOT in turn develops national and local lists for transplantation of all organs according to directory of regulations.

1.6.3 Each transplant center has to provide the SCOT with reports and statistics on recipients of organ transplants periodically in the assigned forms.

1.6.4 All transplant centers should fulfill their responsibilities towards end stage organ failure patients affiliated with them.

1.6.5 Transplant centers are evaluated every three years by the competent committees in their respective areas of specialization, according to the standards laid down by the SCOT.

1.6.6 There are certain benefits granted to organ donors, whether living or deceased, after donating to patients with end stage organ failure (Appendix 12).

1.7 Other sources of organ donation after cardio-circulatory death (DCD):

1.7.1 An important source of donor organs is that from patients who are dead after DCD and this is based on the experience and the published results from Western countries (United States, Spain, the Netherlands, France, etc.).

1.7.2 DCD requires expertise regarding details pertaining to declaration of death, maintenance of the deceased, and organ recovery (Appendix 13).
2. Sequence of Procedures for Organ Donation after Death

2.1 Procedures to be applied when there is a possible deceased heart beating donors:

Possible deceased heart beating donors are individuals who suffer from irreversible total damage of the brain including brain-stem as a result of road accidents, cerebral hemorrhage, cerebral anoxia, or primary brain tumors. When such a patient is in coma and the cause of coma has been firmly established, the patient has no spontaneous respiration and is totally supported by a ventilator, and the event causing brain-death occurred at least six hours previously. The following protocol should be instituted:

2.1.1 The First Step/Donor Detection

Identification and recognition of a possible organ donor is initially done in the intensive care unit by the ICU physician, attending physician, neuro-physician, neurosurgeon, or anesthesiologist, (rarely done in emergency room or surgical units).

2.1.2 The Second Step/Notification

2.1.2.1 Once a physician suspects and identifies a possible death of a patient by brain function criteria, he should immediately notify the SCOT.

2.1.2.2 Notification could be done by direct telephone call to 011 445 1100 or (Toll free 800 124 5500) or by fax at 011 445 3934, through an ICU nurse, or hospital/regional coordinators.

2.1.2.3 The SCOT nurses should screen the active ICUs daily inquiring about possible death by brain function criteria; a good professional relationship should be developed between the coordinators and the medical staff in the different ICUs in the kingdom.

2.1.2.4 Once the case is reported, full medical data should be filled by the SCOT coordinators including personal data, cause of death by brain function criteria in addition to medical and social history.

2.1.2.5 Data should be subjected to medical and administrative discussion by the SCOT team in a meeting on a daily basis, in which organ viability or fitness for donation is subjected to continuous evaluation.

2.1.2.6 The SCOT is also responsible to obtain the address and the contact telephone numbers of the family of the possible donor.
2.1.2.7 The case should be followed-up by medical coordinators in the SCOT to monitor and manage any abnormality in laboratory values; e.g. electrolyte imbalances.

2.1.2.8 Further investigations should be requested by the medical coordinators as indicated such as serology and different cultures.

2.1.2.9 Proper and good donor maintenance cannot be overemphasized.

2.1.3 The Third Step/Documentation of Death

2.1.3.1 Documentation of death should be carried out by two physicians trained in the diagnosis of death by brain function.

2.1.3.2 Steps of diagnosis should be followed according to the rules and regulations issued by the Council for Health Services and death by brain function criteria committee in the SCOT (see Appendix 8).

2.1.3.3 None of the members of the organ transplant team can be involved in the process of documentation of death.

2.1.3.4 A deceased pregnant donor should be excluded from organ donation unless the fetus is dead.

2.1.4 The Fourth Step/Family Approach (1)

2.1.4.1 Once the documentation of death by brain function criteria is completed, the ICU physician or attending physician should inform the family about the patient’s condition.

2.1.4.2 The message should be clear to them that their patient has sustained an irreversible brain damage explaining that following full investigations and medical check-up, the patient is dead by brain function criteria.

2.1.4.3 No hope can be given to the family about their deceased patient and no weak or misleading statements can be used; e.g. (seriously ill or deep coma).

2.1.5 The Fifth Step/Sending Information

2.1.5.1 Once the documentation form of death by brain function criteria is completed, the ICU staff are required to send a copy of documentation form by fax to the SCOT.

2.1.5.2 In addition, all the necessary documents of the potential donor should be filled and fully checked and reviewed daily by the SCOT medical coordinators.
2.1.6 The Sixth Step/Family Approach (2)

2.1.6.1 Once the file of the potential deceased donor is checked by the SCOT medical coordinator and found that he/she is fit for organ donation, the administrative coordinator should start his communications with the next of kin.

2.1.6.2 In collaboration with the RCO or a hospital coordinator, a meeting with the next of kin should be arranged in proper time and place to discuss the possibility of organ donation.

2.1.6.3 The coordinator involved in convincing the family to donate should be aware of the social and medical background of the donor.

2.1.6.4 Only written consent is accepted and signed by the 1st degree relatives with two witnesses.

2.1.6.5 If the potential donor is non-Saudi, the family should be contacted by telephone after some period from receiving the news of death of their close deceased relative.

2.1.6.6 If they agreed for organ donation they should sign the consent form for organ donation.

2.1.6.7 Authorization maybe given to a relative living in the Kingdom of Saudi Arabia to sign the consent on behalf of the family of the deceased.

2.1.6.8 Consents should always be confirmed in writing and the original consent should be attached to the medical hospital charts (Appendix 10).

2.1.6.9 In case of unknown identity of the deceased organ donor, the consent for organ donation should be obtained from the official authorities (Governor of Region).

2.1.7 The Seventh Step/Organ procurement and Distribution

2.1.7.1 Organ donating hospitals and transplant centers should not proceed with procurement of organs without coordination and permission from the SCOT, which is totally responsible for organ distribution according to priority criteria and national waiting list.

2.1.7.2 Once the consent is obtained, file of the donor should be re-evaluated by the medical coordinators, and then organs are offered to the transplant centers and full information should be communicated to them.
2.1.7.3 A definite answer of acceptance or rejection of the transplant centers to the offered organs within a reasonable time (e.g. 2 hours) should be documented by the SCOT.

2.1.7.4 The Distribution offer plan of organs should include:

- **2.1.7.4.1** Kidneys are distributed to transplant centers according to their affiliated donor hospital and Zonal distribution.

- **2.1.7.4.2** Livers are distributed by rotation to accredited centers according to the rules and regulations set by the SCOT and the national liver transplant committee.

- **2.1.7.4.3** Hearts are distributed to the accredited centers according to priority criteria. If no suitable recipient for whole heart transplant is available, the allograft will be recovered to be a source for valves.

- **2.1.7.4.4** Lungs are distributed to the accredited transplant centers, according to the wait list.

- **2.1.7.4.5** Pancreases are distributed according to priority criteria to the accredited transplant centers.

- **2.1.7.4.6** Corneas are distributed according to the affiliated transplant centers and zonal distribution.

- **2.1.7.4.7** Bone tissue is distributed to the accredited transplant centers.

**2.1.8 The Eighth Step /Arrangement for Organ Recovery**

- **2.1.8.1** Once the organ allocation plan is set, time for organ recovery should be fixed by the SCOT medical and administrative coordinators.

- **2.1.8.2** Transportation of the harvesting team should be planned carefully by the SCOT administrative coordinator according to the location of the donor hospital and number and types of recovered organs.

- **2.1.8.3** The availability and readiness of the operating room in the donating hospitals for organ recovery should be arranged by the SCOT medical coordinator through the help of the medical coordinator of the donating hospital and the RCO.

- **2.1.8.4** The harvesting procedure is detailed in appendix 14.

- **2.1.8.5** A coordinator from the SCOT (medical, administrative or technician) should be present in the donating hospitals during organ recovery procedure with the recovery team.
2.1.8.6 The SCOT coordinator double checks the accuracy of the medical and administrative data in the donor SCOT files and that they match with those of the patient’s hospital chart.

2.1.8.7 The SCOT coordinator should ensure the smoothness of the flow of the organ recovery procedure and solve any obstacle related to it.

2.1.8.8 In case of failure to recover any organ. The SCOT coordinator should ensure the issuance of a related report to the event by the harvesting team.

2.1.8.9 The SCOT coordinator should ensure the delivery of the recovered organs to the transplant centers according to the pre-set distribution plan.

2.1.8.10 The SCOT coordinator should ensure the maximum utilization of the allocated organs.

2.1.8.11 The SCOT has the right to modify any steps in the process of organ recovery such as:

2.1.8.11.1 Timing of transportation and harvesting procedure.

2.1.8.11.2 Priority of organ distribution according to any changes in the condition of the donors that dictate the urgency of recovery and the priority waiting list.

2.1.8.12 The SCOT coordinator, the donating hospital, the RCO for organ donation, and recovery team should consider the social issues and respect the family wishes to expedite the surgical procedures for organ recovery (e.g. early burial of the corpse).

2.1.9 The Ninth Step

2.1.9.1 The SCOT staff should follow the process of recording the data on the transplants and after organ recovery; recipient’s and donor’s data should be recorded in the national data base.

2.1.10 The Tenth Step/Post Donation Care:

2.1.10.1 The SCOT administrative coordinators should follow up the process of burial or transportation of the corpse to the native country for expatriates, and all the necessary administrative paper work for the funerals.

2.1.10.2 The SCOT administrative coordinators should support the donor families.
The Council of Health Services will bear the cost of sending the body of the deceased donor to his homeland accompanied by one chaperone.

2.1.11 The Eleventh Step/Certification of Death:

2.1.11.1 The legal death certificate should be issued after the discontinuation of the mechanical ventilator support and the cessation of heart beating.

2.1.11.2 Death certificate should be issued by the hospital where the recovery of organs is performed and should be signed by either the attending physician, intensive care physician or the anesthesiologist who has supervised the recovery operation.

2.2 Procedures to be applied when there’s a possible deceased non heart beating donors.

2.2.1 This type of donation has not been applied on a wide range in the Kingdom of Saudi Arabia at time of issue of this directory, (you can refer to the international procedures in Appendix 13).
3. Strategies and Roles for Optimizing Organ Donation

3.1 Nursing care:

Management of the brain dead organ donor remains a major challenge to the nursing staff, both prior to surgery (in ICU) and intra-operatively. In the process of organ donation there are many things the nursing staff has to perform. The major activities include identification of potential brain death donor’s referral evaluation, recovery and maintenance.

Also, the nursing staff in the ICU may assume more roles at any time during the care of the patient and support the family together with the administrative coordinators and social workers.

3.2 Factors for a successful approach of the donor family:

These factors are very important for any transplant coordinator to know before approaching the potential donor family.

3.2.1 If family is having trouble accepting death, give them time.

3.2.2 Offering psychological support to the family is very important. The purpose of asking is not necessarily to get a donation but to extend care to the family and offering the option.

3.2.3 The person who approaches the family must be well trained.

3.2.4 An interview guidelines must be known before.

3.2.5 The ICU doctor or the neurologist must inform the family everything about brain death and irreversibility of the brain damage.

3.2.6 The presence of a signed donor card.

3.2.7 It is important to inform the family about all FATWAS and purport of the Senior Ulama commission concerning their approval to organ donation.

3.3 Strategies for optimizing organ donation:

Increasing the number of brain death donors can be achieved with the following:

3.3.1 Early detection of all possible donors to SCOT.

3.3.2 Early diagnosis according to the national protocol.

3.3.3 Continuous contact with the donor family to inform them about the latest development in donor’s condition.
3.3.4 Obtain the consent for organ donation from the next-of-kin.

3.3.5 Obtain help from religious affairs in the hospital to convince families to consent for donation of their deceased relative.

3.3.6 Increase the awareness of the public about the importance of organ donation and transplantation.

3.3.7 Encourage signing donor cards to help the donor families to make decisions about organ donation.
4. The Procedures Followed by Transplant Centers and their Duties towards their Affiliated Hospitals

The various organ transplant centers should determine the mechanism of distribution for hospitals and their relationship with the affiliated donor hospitals in the context of the national committees.

4.1 Kidney transplant centers:

4.1.1 The kidney transplant centers provide follow-up and technical assistance to all hemodialysis and peritoneal dialysis centers in all affiliated hospitals. This includes the following:

4.1.1.1 It constitutes a referral center for difficult cases, surgical or non-surgical, concerning renal transplantation.

4.1.1.2 It performs tissue typing on all end-stage renal disease patients fit for transplantation.

4.1.1.3 It decides on the fitness of patients for transplantation and sends their names and results of investigations to the SCOT in special assigned forms.

4.1.2 The kidney transplant centers provide the necessary technical assistance to affiliated ICUs to detect all cases of brain death and report them immediately to the SCOT to maximize benefits of these cases.

4.1.3 Each kidney transplant center shall receive information on cases of brain death by the SCOT to facilitate coordination between them and the ICU and carry out the duties entrusted to them all the way to the recovery of organs.

4.1.4 Each kidney transplant center should participate in increasing the awareness of the public about organ donation and transplantation in the region affiliated to it.

4.2 Liver transplant centers:

4.2.1 The liver transplant centers provide the necessary technical assistance to affiliated ICUs to detect all cases of brain death and report them immediately to the SCOT to maximize benefits of these cases.

4.2.2 Each liver transplant center shall receive information on cases of brain death by the SCOT to facilitate coordination between them and the ICU and carry out the duties entrusted to them all the way to the recovery of organs.
4.2.3 Each liver transplant center should participate in increasing the awareness of
the public about organ donation and transplantation in the region affiliated to
it.

4.3 Heart transplant centers:

4.3.1 The heart transplant centers provide the necessary technical assistance to
affiliated ICUs to detect all cases of brain death and report them
immediately to the SCOT to maximize benefits of these cases.

4.3.2 Each heart transplant center shall receive information on cases of brain death
by the SCOT to facilitate coordination between them and the ICU and carry
out the duties entrusted to them all the way to the recovery of organs.

4.3.3 Each heart transplant center should participate in increasing the awareness of
the public about organ donation and transplantation in the region affiliated to
it.

4.4 Lung transplant centers:

4.4.1 The lung transplant centers provide the necessary technical assistance to
affiliated ICUs to detect all cases of brain death and report them
immediately to the SCOT to maximize benefits of these cases.

4.4.2 Each lung transplant center shall receive information on cases of brain death
by the SCOT to facilitate coordination between them and the ICU and carry
out the duties entrusted to them all the way to the recovery of organs.

4.4.3 Each lung transplant center should participate in increasing the awareness of
the public about organ donation and transplantation in the region affiliated to
it.

4.5 Pancreas transplant centers:

4.5.1 The pancreas transplant centers provide the necessary technical assistance to
affiliated ICUs to detect all cases of brain death and report them
immediately to the SCOT to maximize benefits of these cases.

4.5.2 Each pancreas transplant center shall receive information on cases of brain
death by the SCOT to facilitate coordination between them and the ICU and
carry out the duties entrusted to them all the way to the recovery of organs.

4.5.3 Each pancreas transplant center should participate in increasing the
awareness of the public about organ donation and transplantation in the
region affiliated to it.

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4.6 Cornea transplant centers:

4.6.1 The corneal transplant centers provide the necessary technical assistance to affiliated ICUs to detect all cases of brain death and report them immediately to the SCOT to maximize benefits of these cases.

4.6.2 Each corneal transplant center shall receive information on cases of brain death by the SCOT to facilitate coordination between them and the ICU and carry out the duties entrusted to them all the way to the recovery of organs.

4.6.3 Each corneal transplant center should participate in increasing the awareness of the public about organ donation and transplantation in the region affiliated to it.

4.7 Bone transplant centers:

4.7.1 The bone transplant centers provide the necessary technical assistance to affiliated ICUs to detect all cases of brain death and report them immediately to the SCOT to maximize benefits of these cases.

4.7.2 Each bone transplant center shall receive information on cases of brain death by the SCOT to facilitate coordination between them and the ICU and carry out the duties entrusted to them all the way to the recovery of organs.

4.7.3 Each bone transplant center should participate in increasing the awareness of the public about organ donation and transplantation in the region affiliated to it.
5. Regulations of Organ Transplantation in Private Hospitals

5.1 Private hospitals could perform transplantation from living related donors on the condition that the relationship is proved by an official institution specialized in this field and on condition that the documentation of this proof is kept in the file of each patient concerned. If any case is discovered not fulfilling this condition the proposal for closure of the transplant center in their hospital will be submitted to the licensing authority for medical practice in the Ministry of Health.

5.2 Private hospitals cannot benefit from brain-death cases from other private or government hospitals. They have the right only to benefit from their own brain-death cases on the condition that the SCOT is informed about the brain-death and its documentation is shared by one doctor from a government hospital through co-ordination with the SCOT. Private hospitals have no right to take any monetary compensation for the organs used for transplantation.

5.3 All rules and regulations issued by the SCOT are applicable to private hospitals as for any other government hospital and same penalties apply in case of non-compliance.

5.4 Organs should be transplanted according to the waiting lists in compliance with the regulations laid down by the national transplant committees in Saudi Arabia. If the private hospital does not have any patient fit for transplantation it should co-ordinate with the SCOT for transplantation of the organ according to priority in the national waiting list. If this waiting list also has no patient fit for transplantation, another suitable patient could be transplanted according to the priority level related to each organ.
6. Kidney Donation and Transplantation

6.1 Criteria for establishment of a kidney transplant center

The SCOT through its specialized committees has laid down certain criteria for establishment of kidney transplant centers in Saudi Arabia. They include:

6.1.1 Working staff:

6.1.1.1 Consultant kidney transplant surgeon.

One consultant kidney transplant surgeon with at least one year’s experience from a recognized kidney transplant center.

6.1.1.2 Consultant nephrologists.

At least one nephrologist with a minimum of one year’s experience from a recognized kidney transplant center.

6.1.1.3 Nursing staff.

They must be highly experienced in caring for the patients during and after kidney transplantation.

6.1.1.4 A transplant coordinator.

This individual must have adequate experience in order to perform the previously mentioned duties. The coordinator can also be appointed from the above-mentioned staff.

6.1.1.5 A dietitian.

6.1.1.6 A social worker.

6.1.2 Technical facilities required:

6.1.2.1 The hospital in which a kidney transplant center will be established must have the following departments:

Cardiology, gastroenterology (with endoscopy), chest (with endoscopy), radiology, hematology, pathology laboratory, biochemistry laboratory, nephrology with hemodialysis unit (preferably containing portable dialysis machines), and ICU.

6.1.2.2 At least two operating rooms must be available.
6.1.2.3 There should be at least two rooms for management of post-transplant patients.

6.1.3 Support services:

6.1.3.1 Laboratory.

All routine investigations necessary for the patients either before or after the transplantation must be available. Facilities to perform tissue typing, cytotoxic antibodies, and blood levels of drugs including cyclosporine or similar drugs should be available.

6.1.3.2 Radiology.

Conventional X-ray, ultrasound, radioisotope scanning, and computerized axial tomography must be available in the hospital.

6.1.4 Drugs:

The following drugs must be continuously available in the center:

6.1.4.1 Immunosuppressive drugs.

- Cyclosporine,  
  TACROLIMUS (FK 506)

- Azathioprine,  
  MYCOPHENOLATE MOFETIL (MMF)

- Prednisolone,

- Sirolimus,  
  (RAPAMYCIN)

- Other similar drugs.

6.1.4.2 Drugs for treating rejection episodes such as methylprednisolone, and anti-lymphocyte or anti-thymocyte globulin, anti-thymus globulin and monoclonal antibodies.

6.1.4.3 Solution for perfusing the organs such as Eurocollins solution or Wisconsin University solution or HTK solution.

6.1.4.4 Drugs for treating bacterial, viral, fungal, or parasitic infections.
6.2 Criteria for continuity of kidney transplant centers

6.2.1 Application of the criteria relevant for the establishment of new transplant centers, as mentioned previously.

6.2.2 The number of kidney transplants performed in the center should be not less than 10 per year.

6.2.3 The center must contribute to the training activities to the staff and help in the management of brain-dead cases in the ICUs attached to it in collaboration with the SCOT and report to it about these activities.

6.2.4 The transplant center should satisfy its entire obligations towards the citizens and expatriates by conducting meetings concerning all aspects of organ transplantation and brain death and must submit regular reports about these activities to the SCOT.

6.2.5 A detailed scientific annual report about the results of transplantation performed in each center must be forwarded to the SCOT. It should include the following points:

   6.2.5.1 The condition of the transplanted patients.

   6.2.5.2 The state of transplanted kidneys.

   6.2.5.3 The rate of complications.

6.2.6 All transplantation centers will be evaluated every three years by the national kidney transplant subcommittee attached to the SCOT. An ad-hoc committee should be appointed by the national committee and has the right to visit any kidney transplant center whenever it is judged necessary to examine the pace of work in the respective center.

6.2.7 The Kidney Transplant Committee should meet annually to review all the reports from different transplant centers, including mortality rate, incidence of organ rejection, and complications of transplantation, as well as the reports submitted by the ad-hoc committee. If it appears that one of these centers is not applying these regulations and/or the success rate of transplants performed is not satisfactory, the ad-hoc committee shall visit the center in order to explore the reasons and obstacles preventing this center from carrying out its functions properly. The center will be given three months to improve its performance, following which the kidney transplant committee will re-evaluate the center with the right to close center if no improvement occurs. A two-thirds majority is needed for the decision of the committee with at least 70% of its members present.

6.2.8 These criteria apply to all kidney transplant centers currently existing as well as to the centers, which will be opened in future.
6.3 Criteria for deceased kidney transplantation

Patients are included in the local and national waiting lists for kidney transplantation according to the following criteria:

6.3.1 Patients should have end-stage renal disease (ESRD).

6.3.2 The patients should not have any other significant organ disease (e.g., active tuberculosis, active peptic ulcer, malignancy, or active acute or chronic infection).

6.3.3 The results of all investigations done on this patient must be within normal limits (see appendix 15 for the non-diabetic ESRD patients and appendix 16 for diabetic patients).

6.3.4 The patient must be between 3 and 70 years old and age and body weight should be matched between donor and recipient for transplantation.

6.3.5 The patient must be psychologically stable and compliant to therapy.

6.3.6 The patient must be human immuno-deficiency virus (HIV) negative.

6.3.7 The patient must be hepatitis B negative. If he/she is hepatitis B positive, liver biopsy must be normal.

6.3.8 Patients who are positive for anti-glomerular basement membrane antibodies, anti-DNA antibodies, or antineutrophil cytoplasmic autoantibodies must turn negative before they are put on the waiting list.

6.3.9 Under special circumstances concerning hepatitis serology, the following is to be noted:

6.3.9.1 Hepatitis B Antigen (HBsAg) positive patients and hepatitis B immune patients can be transplanted with kidneys from HBsAg positive deceased donors.

6.3.9.2 Hepatitis C positive carriers can be transplanted with hepatitis C positive deceased kidneys.
6.4 Criteria for living kidney transplantation

6.4.1 The donor should be blood-related or must be the breast feeding mother or her children or relatives-in-law. This must be confirmed by official specialized institutions. Also, emotionally related and non-directed non-commercial donation can be accepted.

6.4.2 Paired kidney donation can be carried in the following situations:

6.4.2.1 If a family has candidate recipient for kidney transplantation and none of his family members is an appropriate donor (un-matching blood groups).

6.4.2.2 Another family has a similar situation, but some of the candidate donors match with the candidate recipients in the first family and vice versa; then in the appropriate medical setting, the donors and recipients can be exchanged in these families as follows:

6.4.2.2.1 A clear consent and agreement should be signed by both families of donors and recipients. There should be no request of compensation in case of graft failure in any of the patients.

6.4.2.2.2 All cases to be registered at the SCOT.

6.4.3 General rules for living donation:

6.4.3.1 The act of donation must be without any coercion and the donor must be fully convinced.

6.4.3.2 The donor should be completely healthy both physically and psychologically (appendix 17).

6.4.3.3 The donor age must be at least 18 years and not more than 60 years.

6.4.3.4 The donor’s blood group should be compatible with that of the recipient.

6.4.3.5 The cross-match should be negative.

6.4.3.6 The donor must be HBsAg, HCV antibodies, and HIV negative.

6.4.4 Contraindications for kidney transplantation:

6.4.4.1 Patients with incurable malignant disease

6.4.4.2 Patients with primary oxalosis (except if the patients will undergo a combined kidney and liver transplant).
6.4.4.3 Patients addicted to narcotics and other similar drugs.

6.4.4.4 Non-compliant patients.

6.4.4.5 Patients with organic diseases such as:

6.4.4.5.1 Liver Cirrhosis.

6.4.4.5.2 Periportal fibrosis with advanced esophageal varices.

6.4.4.5.3 End-stage heart failure, Class IV not responding to treatment.

6.4.4.5.4 End-stage respiratory failure, which restricts the patient’s daily activities.

6.4.4.5.5 Progressive vascular disease.

6.4.4.5.6 Chronic active hepatitis.
6.5 Priority criteria for kidney transplantation

The kidney transplant committee has laid down priority criteria for kidney transplantation as follows:

6.5.1 If the patient has life threatening vascular access problems, he has absolute priority for transplantation wherever he is, and as soon as a suitable kidney is available on the condition that the decision is made by the kidney transplant center to which the patient is wait-listed after officially informing the SCOT by the transplant center.

6.5.2 For patients who do not have vascular access problems, the priority level is based on the points given as follows:

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.5.2.1 Cytotoxic antibodies</td>
<td>1 for each 10% more than 50%</td>
</tr>
<tr>
<td>6.5.2.2 Age: 3 to 5 years</td>
<td>3 points</td>
</tr>
<tr>
<td>6 to 10 years</td>
<td>2 points</td>
</tr>
<tr>
<td>11 to 45 years</td>
<td>1 point</td>
</tr>
<tr>
<td>6.5.2.3 Period on dialysis</td>
<td>0.1 point per each month on dialysis</td>
</tr>
<tr>
<td>6.5.2.4 Previously failed LRD Tx.</td>
<td>2 points</td>
</tr>
<tr>
<td>6.5.2.5 Human leukocyte antigen (HLA) match</td>
<td>1 per each antigen match</td>
</tr>
<tr>
<td>6.5.2.6 Identical blood group</td>
<td>3 points</td>
</tr>
<tr>
<td>6.5.2.7 Identical age-group</td>
<td>2 points</td>
</tr>
</tbody>
</table>

6.5.3 Distribution of the recovered kidneys will be as follows:

6.5.3.1 The first kidney will be transplanted to a suitable patient in the national waiting list and according to priority. The patient should be brought to the transplant center that has recovered the kidneys, except for patients wait-listed in another organ transplant center. In such cases, the kidney will be sent to that center for transplantation.

6.5.3.2 The second kidney will be transplanted to a patient from the local waiting list according to the priority that is set by the transplant center. If possible and according to priority levels, the kidney in the kidney transplant center should be transplanted to a patient from the donor hospital as possible.

6.5.3.3 The kidney should be transplanted to patients whenever a suitable patient is available. If there is no suitable national patients anywhere, and after obtaining consent, the kidney may be transplanted to a non-
national patient with priority for residents followed by visitors. Moreover, kidneys could be exchanged with other countries according to an agreement established between the SCOT and similar institutions in other countries.

6.5.3.4 Pediatric patients should be allocated 20% of the standard donated kidney allografts.

6.5.3.5 Some extended criteria donated kidneys can be used for certain recipient groups after their consent.

*Appropriate patient is the one who has fulfilled the criteria for priority and medical conditions.
7. **Heart Transplantation**

7.1 **Criteria for establishment of a heart transplant center**

The SCOT through specialized transplant committee has laid down certain criteria for establishment of heart transplant centers in the Kingdom of Saudi Arabia. They include:

7.1.1 **Working staff:**

7.1.1.1 *Consultant cardiac transplant surgeons.*

There should be a team of cardiovascular surgeons with good experience in performing open heart surgeries, who should have performed an adequate number of pump cases per year (more than 200) and who are fully certified and experienced from one of the recognized heart centers internationally.

7.1.1.2 *ICU specialists.*

An ICU specialist should have adequate experience in follow-up of patients after open heart surgery and preferably having adequate experience in follow-up of cardiac transplant recipients.

7.1.1.3 *Consultants in cardiology.*

They should have adequate experience in dealing with pre-and post-heart transplant patients as well as in performing all relevant cardiac investigations including endomyocardial biopsy.

7.1.1.4 *Nursing staff.*

They must be highly experienced in caring for the patients during and after heart transplantation.

7.1.1.5 *A transplant coordinator.*

7.1.1.6 *A social worker.*

7.1.1.7 *A dietitian.*

7.1.2 **Technical facilities required:**

The hospital in which the heart transplant center will be established should include:

7.1.2.1 Departments of Gastroenterology, Radiology, Hematology, Pathology
laboratory, Biochemical laboratory, Nephrology with hemodialysis unit, and Immunology.

7.1.2.2 At least two fully equipped open-heart surgical theaters equipped with circulatory support systems, e.g., intra-aortic balloon pump, by-pass support systems, or mechanical assist devices with the availability of technicians necessary to handle them. A fully equipped ICU should be available for management of patients after open-heart surgery with facilities to isolate patients as well as installation of pacemakers, both temporary and permanent.

7.1.2.3 The following specialists should be available in the hospital:

7.1.2.3.1 Fully certified nephrologists experienced in the follow-up of organ transplant recipients.

7.1.2.3.2 Immunologists experienced in follow-up of heart transplantation.

7.1.2.3.3 Certified pulmonologist.

7.1.2.3.4 Certified respiratory therapists.

7.1.2.3.5 Certified infectious disease specialist.

7.1.2.3.6 Team for infection control.

7.1.2.3.7 Certified pathologists with experience in interpreting myocardial biopsies.

7.1.2.3.8 Certified psychiatrist.

7.1.3 Support Services:

7.1.3.1 Laboratory.

All routine investigations for the patients either before or after the transplantation must be available in the center.

Facilities to do tissue typing, cytotoxic antibodies, and blood levels of drugs including cyclosporine and similar drugs must be available in addition to other immunological tests.

7.1.3.2 Radiology.

Conventional X-ray, ultrasound, radioisotope scanning, and computerized axial tomography must be available in the hospital. There should be availability of bimodal echocardiography.
7.1.3.3 Drugs.

The following drugs must be continuously available in the center:

7.1.3.3.1 Immunosuppressive drugs:

- Cyclosporine, TACROLIMUS (FK 506)

- Azathioprine, MYCOPHENOLATE MOFETIL (MMF)

- Prednisolone,

- Sirolimus, (RAPAMYCIN)

- Other similar drugs.

7.1.3.3.2 Drugs for treating rejection episodes such as methylprednisolone, anti-lymphocyte or anti-thymocyte globulin and monoclonal antibodies.

7.1.3.3.3 Solutions for perfusing the organs like Eurocollins solution or Wisconsin University Solution, and HTK solution.

7.1.3.3.4 Drugs for treating bacterial, fungal, viral, or parasitic infections.
7.2 Indications for heart transplantation

The SCOT through its transplant committee has laid down indications for heart transplantation in the Kingdom as follows:

7.2.1 All patients who have end-stage cardiac disease unresponsive to adequately supervised medical or surgical treatment (left ventricular ejection fraction less than 20%).

7.2.2 Patients categorized in New York Heart Association (NYHA) functional class III-IV.

7.2.3 Patients having unresectable cardiac tumors.

7.2.4 Patients who fail to come off cardio-pulmonary bypass after any surgical procedure.

7.2.5 Patients who are at risk of death from acute myocardial infarction.

*(Appendix 18: investigations to be done on a potential recipient for cardiac transplantation)

7.3 Contra-indications for heart transplantation

7.3.1 Absolute contraindications:

7.3.1.1 High pulmonary vascular resistance of more than 4 wood units despite intensive cardiac management.

7.3.1.2 Malignancy.

7.3.1.3 Collagen vascular disease.

7.3.1.4 Renal failure above and beyond the expected pre-renal failure.

7.3.1.5 Hepatic failure, which exceeds that explained by cardiac failure, or when accompanied by significant coagulopathy.

7.3.1.6 Other irreversible organ diseases such as emphysema, intractable systemic illness, or amyloidosis.

7.3.1.7 Infection with HIV.

7.3.1.8 History of substance abuse (alcohol or other drugs).

7.3.2 Relative contraindications*

7.3.2.1 Age more than 60 years.
7.3.2.2 Presence of peripheral arterial diseases

7.3.2.3 Diabetes mellitus, especially type I.

7.3.2.4 Peptic ulcer disease.

7.3.2.5 Unresolved pulmonary infarction.

7.3.2.6 Marked obesity.

7.3.2.7 Cachectic patients.

7.3.2.8 History of CMV, EBV, toxoplasmosis, sickle cell disease, or thyroid dysfunction.

7.3.2.9 Uncontrolled hypertension.

7.3.2.10 Presence of active systemic infection.

7.3.2.11 Patients where are emotionally unstable and may not cope with the demands and burdens of strict compliance with medications and follow-up requirements.

*Patients with positive PPD or clinical evidence of tuberculosis are to be treated prophylactically with INH for 12 months.

7.4 Priority criteria for heart transplantation

7.4.1 The transplant committee of the SCOT have laid down priority criteria for heart transplantation as follows:

7.4.1.1 Patients admitted in ICU on ventilator or on mechanical cardiac support and cannot be weaned off inotropic drugs.

7.4.1.2 Patients cannot be weaned from cardiopulmonary bypass (artificial heart-lung pump)

7.4.1.3 Patients with high PRA or cross match positive for at least 2 times.

7.4.1.4 Patients in the general or cardiology ward who require inotropic drugs, with no requirement for ventilation or mechanical cardiac support.

7.4.1.5 Patients who are on the waiting list and are waiting at home.

7.4.2 Distribution of hearts

Each harvested heart is distributed as follows:

7.4.2.1 Each heart transplant center should establish a local waiting list. A national
waiting list should be made according to priority criteria. The heart transplant center should change the patient’s priority level between the previously mentioned categories according to the patient’s condition, after informing the SCOT.

7.4.2.2 All transplant centers should inform the SCOT about patients who need urgent heart transplantation so that they can be included in a special urgent waiting list.

7.4.2.3 Patients in the urgent waiting list have the absolute priority wherever they are, because patients with priority I do not follow the rota system.

7.4.2.4 If there is no suitable patient on the urgent waiting list, the heart will be transplanted in the heart transplant center according to the rota. If the center does not have a suitable patient, the heart will be given to the center which has a suitable patient, in which case the selection of the patient will be according to blood group and the date on which the patient was registered on the local waiting list.
8. Lung Transplantation

8.1 Criteria for establishment of a lung transplant center

The transplant committee at the SCOT has laid down certain criteria for establishment of lung transplant centers in Saudi Arabia. They include:

8.1.1 Working staff:

8.1.1.1 Consultant lung transplant surgeons.

There should be a team of chest and vascular surgeons with good experience in performing lung transplantation acquired from a recognized international center and they should have performed a sufficient number of these transplantations themselves.

8.1.1.2 ICU specialists.

There should be an ICU specialist with experience in follow-up of patients after lung surgery, preferably having experience in the follow-up of lung transplant recipients.

8.1.1.3 Consultants in chest medicine.

There should be a team of consultants in chest medicine who are capable of performing all respiratory investigations by conventional or advanced methods including lung biopsies and who have experience in the evaluation of patients before and after transplantation.

8.1.1.4 Nursing staff.

They must be highly experienced in taking care of patients during and after lung transplantation.

8.1.1.5 A transplant coordinator.

8.1.1.6 A social worker.

8.1.1.7 A dietitian.

8.1.2 Technical facilities required

The hospital in which the lung transplantation center will be established should have the following departments:

8.1.2.1 Gastroenterology, radiology, hematology, pathology, biochemical laboratory, nephrology with hemodialysis unit, immunology, Cardiology.
and Cardiac surgery.

8.1.2.2 One fully equipped lung Transplantation Theater.

- ICU with isolation possibilities.

8.1.2.3 The following specialists should be available in the hospital:

8.1.2.3.1 A nephrologist experienced in follow-up of organ transplantation.

8.1.2.3.2 An immunologist.

8.1.2.3.3 A cardiologist.

8.1.2.3.4 A physiotherapist.

8.1.2.3.5 A team for infection control.

8.1.2.3.6 A pathologist with experience in interpreting lung biopsies.

8.1.2.3.7 A psychiatrist to evaluate patients before and after transplantation.

8.1.3 Support services

8.1.3.1 Laboratory

8.1.3.1.1 All routine investigations for the patients either before or after transplantation must be available.

8.1.3.1.2 Tissue typing and cytotoxic antibodies and measurement of drug levels including cyclosporine or similar drugs should be available in addition to other immunological tests.

8.1.3.2 Radiology

8.1.3.2.1 X-ray facilities for conventional and advanced lung investigations (e.g., CT scan, radioisotope scanning...etc.).

8.1.4 Drugs

The following drugs must be permanently available in the center:

8.1.4.1 Immunosuppressive drugs:

- Calcineurin inhibitors,

- Azathioprine,
- Prednisolone,
- Anti metabolite,
- Sirolimus, and
- Other similar drugs.

8.1.4.2 Drugs for treating rejection episodes such as methylprednisolone, anti-lymphocyte or anti-thymocyte globulin, and monoclonal antibodies.

8.1.4.3 Solution for perfusing the organs such as Eurocollins solution, Wisconsin University solution or HT solution.

8.1.4.4 Drugs for treating bacterial, viral, fungal, and parasitic infections.
8.2 Indications for lung transplantation

8.2.1 The SCOT through transplant committee has laid down the indications for lung transplant, which are end-stage respiratory failure resulting from:

8.2.1.1 Severe obstructive lung disease of any cause.

8.2.1.2 Restrictive lung disease.

8.2.1.3 Primary pulmonary hypertension or secondary pulmonary hypertension with Eisenmenger syndrome.

8.2.1.4 Suppurative lung disease.

(Appendix 19 for investigations to be done on a potential recipient for lung transplantation).

8.2.2 Contraindications for lung transplantation

8.2.2.1 Absolute contraindications:

8.2.2.1.1 Active extra-pulmonary infection or active pulmonary infection when single lung transplantation is contemplated.

8.2.2.1.2 Associated systemic disease such as renal failure or liver failure.

8.2.2.1.3 Significant coronary artery disease or dysfunction of left or right ventricles (with ejection fraction <25%) unless the patient is considered for a combined heart-lung transplantation.

8.2.2.1.4 Significant psychological problems, which could preclude compliance with follow-up and treatment.

8.2.2.1.5 History and evidence of incurable malignant disease.

8.2.2.1.6 Patients who have a life expectancy of 18 to 24 months with their respiratory disease, who are not yet oxygen dependent, and whose dynamic pulmonary function is still within acceptable limits.

*Age is not a contraindication provided acceptable cardiac, hepatic, and renal functions are present.

8.2.2.2 Relative contraindications

8.2.2.2.1 Patients on prolonged mechanical ventilator support, though many centers do not consider this a contraindication anymore, especially if the patient is well motivated and has acceptable cardiac, hepatic,
and renal functions.

8.2.2.2 If the patients are receiving high-dose systemic steroids (>15 mg of prednisolone per day). There is a new trend to accept such patients for lung transplantation even if they are not weanable from pre-operative steroids, as newer techniques of bronchoplasty procedures have led to acceptable bronchial anastomotic healing, thereby avoiding risk of bronchial dehiscence.

8.2.2.3 Patients who have had thoracotomy with pleurectomy or pleurodesis, though there is a new trend to accept such patients for lung transplantations such as single lung transplant or bilateral sequential lung transplants using anterior sterno-thoracotomy.

8.2.2.4 Patients should wait for at least one year after discontinuation of smoking to be listed for transplantation.

8.2.3 **Distribution of lungs**

Lungs will be distributed as follows:

8.2.3.1 Each lung transplant center should establish a local waiting list and send it to the SCOT, which will add the names to the national waiting list.

8.2.3.2 Lung transplant centers should report the names of patients in need of urgent lung transplantation so that they will be included in a special urgent waiting list.

8.2.3.3 The patients on the urgent waiting list have absolute priority for lung transplant wherever they are.

8.2.3.4 If there is no patient on the urgent waiting list, the lung is distributed to the transplant centers according to rota.

*Suitable patient is the patient who fulfills medical fitness and priority criteria and has a compatible chest size match with the donor.
9. Liver Transplantation

9.1 Criteria for establishment of a liver transplant center

The SCOT through its specialized committees has laid down certain criteria for establishment of liver transplant centers in Saudi Arabia. They include:

9.1.1 Working staff:

9.1.1.1 Consultants in liver transplantation:

9.1.1.1.1 Surgeons.

At least one consultant transplant surgeon experienced in hepatobiliary surgery with a minimum of one year’s experience from a recognized liver transplant center internationally.

9.1.1.1.2 Hepatologists.

At least one consultant hepatologist with a minimum of one year’s experience from a recognized liver transplant center internationally.

9.1.1.1.3 Pediatric gastroenterologists.

At least one consultant pediatric gastroenterologist with a minimum of one year’s experience from a recognized liver transplant center internationally.

9.1.1.2 Anesthesia consultant.

At least one consultant anesthesiologist with a minimum of 6 months experience from a recognized liver transplant center.

9.1.1.3 An ICU consultant.

9.1.1.4 A dietitian.

9.1.1.5 An infectious disease consultant.

9.1.1.6 A transplant coordinator.

9.1.1.7 Nursing staff.

They should be well trained with experience in taking care of patients during and after liver transplantation.
9.1.2 Technical equipment:

9.1.2.1 The hospital in which the liver transplant center will be established should have the following departments:

Cardiology, Endoscopy, Radiology, Hematology and blood bank, Pathology, Biochemistry laboratory, Nephrology with hemodialysis unit, ICU facility, Immunology, Chest diseases, Psychiatry, Physiotherapy, Microbiology laboratory.

9.1.2.2 The hospital should contain two operating rooms containing all the necessary equipment for liver transplantation and especially:

Thromboelastogram, Cell saver machine, Rapid infusion system, Veneenous by-pass machine, Infra-red coagulator or equivalent, Blood warmer, Technicians needed to operate these machines should be available.

9.1.3 Support Services:

9.1.3.1 Laboratory.

9.1.3.1.1 Routine laboratory services, including pre- and post-transplant work-up.

9.1.3.1.2 HLA typing, cytotoxic antibodies, drug levels of cyclosporine and similar drugs.

9.1.3.2 Radiology.

9.1.3.2.1 The following tests should be available in the hospital or the center:

Conventional X-ray facility, ultrasound with the availability of a portable machine, Doppler ultrasonography, isotope scan, angiography, CT scan, and percutaneous transhepatic cholangiography.

9.1.3.3 Endoscopy department.

9.1.3.3.1 This department should have all diagnostic and therapeutic facilities, including Endoscopic Retrograde Cholangio Pancreateography (ERCP).

9.1.4 Drugs.

The following drugs should be permanently available in the center:
9.1.4.1 Immunosuppressive drugs.

- Cyclosporine,
  TACROLIMUS (FK 506)

- Azathioprine,
  MYCOPHENOLATE MOFETIL (MMF)

- Prednisolone,

- Sirolimus,
  (RAPAMYCIN)

- Other similar drugs.

9.1.4.2 Drugs used to treat acute rejection episodes such as methylprednisolone, anti-lymphocyte globulin or anti-thymocyte globulin, and monoclonal antibodies.

9.1.4.3 Perfusion fluid such as Eurocollins solution or Wisconsin University solution and HTK solution.

9.1.4.4 Drugs to treat bacterial, viral, fungal, or parasitic infections.
9.2 Indications and contra-indications for liver transplantation

9.2.1 Indication for liver transplantation

The SCOT, through its scientific committee has established situations in which a liver transplant could be performed.

9.2.1.1 Fulminant hepatic failure resulting from:

9.2.1.1.1 Viral hepatitis.
    A, B, C, D, EBV, CMV.

9.2.1.1.2 Drug-induced liver disease (Halothane, Disulfiram, Acetaminophen, Others).

9.2.1.1.3 Metabolic liver disease.

9.2.1.1.4 Wilson’s disease.

9.2.1.1.5 Reye’s syndrome.

9.2.1.1.6 Massive hepatic trauma.

9.2.1.1.7 Others.

9.2.1.2 Advanced chronic liver diseases such as:

9.2.1.2.1 Primary biliary cirrhosis.

9.2.1.2.2 Primary sclerosing choloangitis.

9.2.1.2.3 Biliary atresia.

9.2.1.2.4 Idiopathic autoimmune hepatitis.

9.2.1.2.5 Chronic alcoholic cirrhosis.

9.2.1.2.6 Chronic toxic hepatitis.

9.2.1.2.7 Chronic viral hepatitis.

9.2.1.2.8 Vascular disease, e.g. Budd-Chiari syndrome, Veno-occlusive diseases.

9.2.1.3 Inherited metabolic disorders such as:

9.2.1.3.1 α-1 antitrypsin deficiency.
9.2.1.3.2 Wilsons disease.
9.2.1.3.3 Crigler-Najjar syndrome.
9.2.1.3.4 Glycogen storage.
9.2.1.3.5 Protein C deficiency.
9.2.1.3.6 Oxalosis.

9.2.1.4 Localized liver tumors such as:
9.2.1.4.1 Primary hepatocellular carcinoma.
9.2.1.4.2 Other liver tumors.
9.2.1.4.3 Isolated hepatic metastatic disease, e.g., Carcinoid.

(Appendix 20: Investigations for evaluation of chronic liver disease for liver transplantation)

9.2.2 Contraindications for liver transplantation

9.2.2.1 Absolute contraindications:
9.2.2.1.1 Active extra-hepatobiliary infections.
9.2.2.1.2 Extra-hepatic malignancy.
9.2.2.1.3 AIDS.
9.2.2.1.4 End-stage cardiac or pulmonary failure.
9.2.2.1.5 Narcotics or alcohol addiction.

9.2.2.2 Relative contraindications
9.2.2.2.1 Age of patients less than 4 weeks and more than 65 years.
9.2.2.2.2 Active hepatitis B infection.
9.2.2.2.3 Extensive abdominal surgery.
9.2.2.2.4 Hepatocellular carcinoma more than 5 cm in size or multifocal carcinoma more than 3 cm in size.
9.2.2.2.5 Cholangiocarcinoma.
9.3 Priority criteria for liver transplantation

9.3.1 The SCOT through its specialized committee has laid down priority criteria for liver transplantation as follows:

9.3.1.1 An ICU patient who is intubated and on mechanical ventilation (status 4). This patient has absolute priority and the status should be evaluated weekly.

9.3.1.2 ICU patient, not on ventilator (status 3).

9.3.1.3 Hospitalized (status 2).

9.3.1.4 At home (status 1).

9.3.1.5 If the patient has a relative contra-indication (status 0), his condition should be re-evaluated after the relative contra-indication resolves.

9.3.2 Distribution of liver allografts

The liver allografts are distributed as follows:

9.3.2.1 Each liver transplant center establishes a local waiting list and sends it to the SCOT, which in turn establishes a national waiting list according to the priority criteria mentioned above.

9.3.2.2 Liver transplant centers should report the names of patients requiring urgent liver transplantation to the SCOT so that they are enlisted on a special urgent waiting list.

9.3.2.3 The liver is distributed according to priority, period on the waiting list, and blood group according to the preset conditions. The center to which the liver is to be allocated has to reply to the SCOT within two hours its decision to accept the allograft or decline. In case of acceptance, the liver transplant center has the task of performing the retrieval of the liver.
9.4 Criteria for living liver donation

9.4.1 The donor should be sound physically and stable psychologically.

9.4.2 Donor age should be not less than 18 years and not more than 45 years.

9.4.3 Donor and recipient should be blood group (ABO) compatible.

9.4.4 Liver function should be normal and the donor should be negative for HBs Ag and HCV Ab.

9.4.5 The donor should not be addicted to narcotics or alcohol and should not be taking drugs that are toxic to the liver.
10. Pancreas Transplantation

10.1 The specifications for the establishment of pancreas transplantation centers.

The SCOT through its specialized committees has defined the specifications for establishment of pancreas transplant centers in the Kingdom of Saudi Arabia, as follows:

10.1.1 Technical staff:

10.1.1.1 A consultant pancreas transplant surgeon.

There must be a consultant in the field of pancreas transplantation, with at least one year experience in an internationally recognized center for pancreas transplantation.

10.1.1.2 A nephrology consultant.

There must be least one nephrology consultant with at least one year experience from a recognized kidney transplant center.

10.1.1.3 A diabetologist.

There must be at least one diabetologist consultant with at least one year experience in an international recognized center for treating complicated diabetic cases.

10.1.1.4 Nursing staff.

There must be nursing staff well experienced in taking care of patients during and after pancreas transplantation.

10.1.1.5 Pancreas transplant coordinator.

Must be of sufficient experience that qualifies him to do the coordination for pancreas transplantation and can be one member of the technical staff referred to above.

10.1.1.6 A dietitian.

10.1.1.7 A social worker.

10.1.2 Technical equipment:

10.1.2.1 The hospital in which the pancreas transplant center will be established must have the following departments:
Cardiology, Endoscopy, Radiology, Hematology and blood bank, Pathology, Biochemistry laboratory, Nephrology with hemodialysis unit, ICU facility, Immunology, Chest diseases, Psychiatry, Physiotherapy, Microbiology laboratory.

10.1.2.2 The hospital must have (at least) two rooms for surgical operations.

10.1.2.3 The hospital must provide two rooms (at least) to post transplant inpatients.

10.1.3 Supportive medical department:

10.1.3.1 Laboratory.

10.1.3.1.1 All devices required for routine investigations that are necessary to evaluate patients before and after transplantation should be available, including bacterial, viral and fungal infections.

10.1.3.1.2 Devices for tissue typing and measurement of cytotoxic antibodies and levels of different drugs including cyclosporine and similar drugs should be available.

10.1.3.2 Radiology.

10.1.3.2.1 All regular x-ray, ultrasound imaging, radioisotope scanning, computerized tomography and interventional radiology should be available.

10.1.4 Drugs:

The following drugs should be continuously available.

10.1.4.1 Immunosuppressive drugs:

Calcineurin inhibitors, azathioprine, prednisolone, anti-metabolites, rapamycin receptors inhibitors and similar drugs.

10.1.4.2 Drugs used to treat episodes of rejection, such as methylprednisolone, anti-lymphocyte globulin (ALG), anti-thymocyte globulin (ATG) and monoclonal antibodies.

10.1.4.3 Organ perfusion fluids such as University of Wisconsin solution or the HTK solution.

10.1.4.4 Drugs used to treat bacterial, viral parasitic and fungal infections.
10.2 Indications and contra-indications for pancreas transplantation.

10.2.1 Indication for pancreas transplantation

The SCOT, through its scientific committee has established situations in which a pancreas transplant could be performed.

10.2.1.1 The age of the patent should be less than 50 years.

10.2.1.2 Patients should have type I diabetes and confirmed by measuring the blood level of c peptide.

10.2.1.3 The body mass index (BMI) should be less than 30.

10.2.1.4 Difficulty in controlling the blood glucose level after ensuring the patient’s compliance to treatment and continuous intensive insulin therapy or insulin pump.

10.2.1.5 The patient is clear from other prominent organic disease (including active tuberculosis, active peptic ulcer, cancer, acute or chronic active infections).

10.2.1.6 The patient is psychologically stable and totally compliant to treatment.

10.2.1.7 HIV antibodies test should be negative.

10.2.2 Contraindications to pancreas transplantations:

10.2.2.1 Presence of untreatable heart, respiratory or hepatic failure.

10.2.2.2 Active infections or tumors.

10.2.2.3 Standard BMI more than 30.

10.2.2.4 The patient is an active smoker.

10.2.2.5 Presence of active gastric ulcer.

10.2.2.6 Presence of HIV

10.2.2.7 Presence of mismatch with the donor tissue.

10.2.2.8 Presence of untreatable diffuse vascular disease.

10.2.2.9 Inadequate psychological evaluation of the patient for any reason.

(Appendix 21: Investigations to be done on a potential recipient for pancreas transplantation).

Directory of the Regulations of Organ Transplantation in the Kingdom of Saudi Arabia
11. Bone Transplantation

11.1 Specifications for the establishment of bone bank.

11.1.1 Technical staff:

11.1.1.1 Consultant in orthopedics.

There must be a consultant in orthopedic surgery, with at least five years experience in the field of orthopedic surgery and not less than two years in bone transplantation and experience of not less than two years in an administrative position, and is still involved in the practice of orthopedic surgery.

11.1.1.2 Bone bank coordinator.

Must have obtained a university degree in nursing or equivalent health specialty, preferably with experience in the field of surgical procedures, especially orthopedics operations for at least five years, and has obtained a formal training in a specialized institution on the procurement of human bones as well as its storing, processing and disinfection, and has obtained a formal training in disinfection procedures and the processes that need to be handled in a sterile manner, and be familiar with the rules and international standards in the field of transplantation of bones and human tissue, preferably those who had training in the field of data processing and information saving.

11.1.1.3 Bone bank technician.

Must have obtained a university degree in nursing or equivalent health specialty, preferably with experience in the field of surgical procedures that deal with human tissue, and also preferably with experience in the field of human organ tissue transplantation and has experience (or formal training) in the procurement of human bones as well as its storing, processing and disinfection.

The number of workers in the bone bank would depend on its size and the work load expected in it.

11.1.2 Technical equipment and facilities required in the bone bank:**

The bone bank should be created in a specific manner for storing and processing of human bones, and each section should be equipped with the following:
11.1.2.1 The bone bank is divided into two zones:

11.1.2.1.1 A non-clean zone:

It is the zone that contains the customized freezers to save human bones according to international standards, and also contain staff offices and places for keeping donor records and other documents needed to run the bone bank.

11.1.2.1.2 A clean zone.

This is an isolated sterilized zone in which bone samples are processed in a completely sterile manner, this area contains a room for bone processing in a completely sterile manner, including the packaging of the processed bone and taking samples to ensure the absence of any bacteria that can be transferred to bone recipients. The zone also contains a clean room to label necessary information on each patch. The sterile zone has a room to store materials needed in the bone bank.

**The specific devices in the bone bank differ in each stage of bone processing.

11.1.3 Supportive medical departments:

The hospital in which bone bank will be established must contain other necessary departments for the bone bank or outsourcing such services.

11.1.4 Laboratory department:

As the bone bank needs to use the services provided by this department for the different samples from bone donors and harvested bones, including blood samples or surgical swabs or samples of harvested bone or any other samples to be tested in the laboratory department.

11.1.5 Radiology department:

Imaging for every bone harvested from the bone donors by X-ray to make sure the harvested bone is free from disease.

11.1.6 Disinfection department:

The bone bank benefits from the services of the disinfection department by sending equipment and surgical instruments used in harvesting procedure and in bone processing in order to be cleaned, packaged and disinfected.

11.1.7 Gamma ray disinfection department:
Processed bones are sterilized using gamma ray disinfection, according to international standards for the disinfection of human tissue. Thus the produced bone grafts are totally disinfected by gamma rays.

11.1.8 A source to supply dry ice when it is needed by the bone bank:

This source may be a third-party dry ice manufactures according to the needs of bone bank, and this dry ice is indispensable in the bone bank.

11.2 Surgical operations which require bone transplantation the so-called bone patching process:

The type and shape of the skeletons patch needed depends on the type of surgical procedure; there are surgical procedures that need an integral part of a specific bone (such as the top of the femur, the bottom of the femur, upper leg bone, the top of the forearm, and others), there are surgical procedures that need various forms of bone, which may be in the form of crushed bone, certain shapes and sizes of bone pieces. The type of process determines the shape of the bone needed.

11.3 Surgical indications for bone transplantation:

11.3.1 Restoration of the joints: the restoration of the top of the femur and pelvis joints.

11.3.2 The removal of bone tumor: the top of the femur, the bottom of the femur, part of the pelvic bone, and the upper bone forearm.

11.3.3 Fix and repair operations for congenital hip dislocation in children, using parts of bone that were previously prepared from the pelvic region.

11.3.4 Fixing spine deviation, where crushed bone is needed in such operations.

11.3.5 Operations related to knee ligaments such as the repair of cruciate ligament.

This is in addition to other orthopedic surgical operations that require different forms of bone.
12. Corneal Transplantation

12.1 Criteria for establishment of a corneal transplant center

The SCOT through its specialized committees has laid down the criteria for establishment of corneal transplant centers in the Kingdom. They are as follows:

12.1.1 Working Staff:

12.1.1.1 Consultant corneal transplant surgeons: There should one consultant in corneal transplantation with good experience in performing corneal transplants and treating external eye diseases for at least one year from a recognized international corneal transplant center on the condition that he has done a large number of the operations himself with a certificate confirming that experience. Alternatively, he should have a certificate of experience of at least five years in corneal transplantation from a recognized center.

12.1.1.2 One consultant anesthesiologist with experience in anesthesia for eye surgery.

12.1.1.3 A full-time microbiologist.

12.1.1.4 An eye-bank technician with experience in preservation of corneas and evaluation of suitability of corneas for transplantation. Alternatively, the consultant corneal transplant surgeon could accept responsibility for performing this duty.

12.1.1.5 A corneal transplant coordinator with experience in coordination of corneal transplantation and preservation of corneas until the time of transplant.*

12.1.1.6 Nursing Staff: They must be highly experienced in taking care of patients during and after corneal transplantation.

*One qualified person can perform the duties of eye-bank technician and coordinator.

12.1.2 Technical facilities required:

12.1.2.1 Ophthalmology department fully equipped with:

12.1.2.1.1 Biomicroscope (slit lamp)

12.1.2.1.2 Ophthalmoscopes
12.1.2.1.3 Visual acuity charts

12.1.2.1.4 Refractometer

12.1.2.1.5 Retinoscopes

12.1.2.1.6 Tonometers

12.1.2.1.7 Outpatient clinic that is fully equipped for examination of patients who have already undergone corneal transplantation as well as evaluating those who are potential candidates (should have special forceps, plates, specula, etc.).

12.1.2.2 The hospital should have fully equipped operating rooms (a surgical microscope, vitrectomy equipment, etc.,) for performing major eye operations.

12.2 Priority criteria for corneal transplantation

Corneas will be distributed according to priority criteria laid down by the corneal transplant committee as follows:

12.2.1 Priority 1: Patients with corneal perforation or who have a disease or a lesion in the anterior part of the eye needing urgent reparation.

12.2.2 Priority 2: Patients with only one functioning eye with loss of vision due to a corneal lesion.

12.2.3 Priority 3: Patients who are not included in any of the previous categories and who will be transplanted according to the duration on the waiting list.

12.2.4 Patients having priority 1 have the absolute priority at any time a cornea is available and a cornea is transplanted to such patients who are in the same region from where the cornea was harvested. If there is no patient with this priority level in the same region, the cornea can be transported to other regions according to the priority criteria.

12.2.5 If there is no patient with priority at any place in the kingdom, the cornea can be transported to any other GCC country to be transplanted according to its priority level.

*(Appendix 22: Investigations to be done for a potential recipient of corneal transplantation)

*If there is more than one patient under a particular category, patient selection will be based on his/her age.
13. General Standards for Organ Validity from Deceased Donors

13.1 General standards*

The organs of the deceased donor are considered valid for transplantation except in the following cases:

13.1.1 Damage as a result of the initial injury causing death or shock lasting for more than 30 minutes, except cases of tissue transplantation.

13.1.2 Cancer in the deceased donor (documented or suspected), except in primary brain tumors confirmed by pathology and skin cancer (basal cell carcinoma).

13.1.3 Idiopathic illness.

13.1.4 Active and disseminated infection.

13.1.5 Active infection with HIV.

13.1.6 Active infection with hepatitis B or C viruses or HTLV virus.**

13.1.7 Neurological diseases such as Reye’s syndrome or slow virus diseases such as Creutzfeldt-Jacob disease, progressive multi-focal encephalopathy, rabies, or Kawasaki disease.

13.1.8 Addiction to drugs.

13.2 Special criteria for kidney transplant from deceased.

The SCOT should be consulted in the following cases with extended criteria donors:

13.2.1 Presence of a higher level of creatinine (2.5 mg/dL) in the deceased donors, adequate fluid replacement.

*Note: The donor hospital should coordinate with the SCOT and also with the RCO.

**The kidney from a deceased donor can be accepted for transplantation if he/she has hepatitis B antigen (HbsAg) +ve and transplanted to patients with immunity against hepatitis B or C or carrying the antigen itself provided that they do not have active hepatitis and the decision is made on a case by case basis in consultation with the SCOT.

13.2.2 Presence of advanced chronic kidney disease and/or chronic arterial hypertension in the deceased donor in addition to donors affected by mild
diabetes or inactive systemic lupus erythematosis disease.

13.2.3 If the age of the deceased donor below (2) or more than (50) years, or when the patient’s age is unknown.

13.3 Special criteria for heart transplantation.

The heart of the deceased donor is considered valid for transplantation except in the following cases:

13.3.1 If the donor has one of the problems mentioned under the general criteria.

13.3.2 If the age of deceased donor is above 40 years for males, or above (50) years for females and should consult with the SCOT in all cases.*

13.3.3 If the condition of the heart was not normal, based on clinical examination, cardiac enzymes, electrical cardiac activity, chest X-ray and ultrasound examination.

13.3.4 If the deceased donor had a previous severe chest trauma that caused damage to the heart.

13.3.5 If the period of cold ischemia exceeds five hours.

*The heart could be considered fit for transplantation if investigations confirmed its normal condition.

13.4 Special criteria for the lung transplantation.

Lungs of deceased donor is considered valid for transplantation, except in the following cases:

13.4.1 If the donor has one of the problems mentioned under general criteria.

13.4.2 If the donor age exceeds 60 years. The SCOT should be consulted in all cases.

13.4.3 If the past medical history of the donor reveals evidence of chronic respiratory disease, or he was a smoker over 20 pack-years, or if he has had thoracic surgery knowing that a unilateral thoracic surgery does not affect the stability of the other lung, or if he has had bronchial disease or recurrent respiratory infections.

13.4.4 If the donor has had trauma that caused injury to the lungs, exposure to toxic gases or fumes or aspiration of gastric contents.

13.4.5 If the lungs were abnormal by clinical evaluation, X-ray chest and blood gases examination performed after putting the patient on FiO₂ of 100% with PEEP of 5 cm water for 5 minutes show PaO₂ <300 mm Hg.
13.4.6 If the donor has purulent thracheobronchial secretions and Gram’s stain and possibly culture reveals pathologic organism.

13.4.7 If there is size incompatibility between donor and recipient.

13.5 **Special criteria for liver transplantation.**

13.5.1 The liver of the deceased donor is considered valid for transplantation, except in the following cases:

13.5.1.1 If the donor has one of the problems mentioned under general criteria.

13.5.1.2 If his age exceeds 50 years.

13.5.1.3 If his liver function tests are abnormal.

13.5.1.4 If there is alcohol and/or drug addiction.

13.5.2 Indications for split liver transplantation.

13.5.2.1 Age less than 45 years old.

13.5.2.2 The level of serum sodium less than 160 mmol/L.

13.5.2.3 ALT ratio of less than 3 times the normal value.

13.5.2.4 AST ratio of less than 3 times the normal value.

13.5.2.5 GGT ratio is less than twice the normal value.

13.5.2.6 If there is no macroscopic liver trauma.

13.5.2.7 Stable hemodynamic condition of the donor.

13.5.2.8 Low to moderate administered dose of inotrops.

13.5.2.9 Donor stay in intensive care less than 7 days.

*The SCOT should be consulted in all cases.

13.6 **Special criteria for the pancreatic transplantation.**

The pancreas of deceased donor is considered valid for transplantation except in the following cases:

13.6.1 The donor exceeds the age of 45 years.

13.6.2 History of diabetes or alcohol addiction.
13.6.3 Serum glucose >11 mmol/L (200 mg/dL).

13.6.4 The body mass index (BMI) more than 30.

13.6.5 History of previous trauma or surgery of the pancreas.

13.6.6 Active inflammation of the pancreas either (acute or chronic) and lipase serum level over 300 IU/L.

13.6.7 Prolonged hypotension or hypoxemia with end organ damage.

13.6.8 The donor is on high doses of inotropic drugs.

13.7 **Special criteria for bone transplantation.**

The bones of the deceased donor is considered valid for transplantation except in the following cases:

13.7.1 The presence of an infectious disease that may be passed from one patient to another, such as: HIV, and hepatitis B, hepatitis C, and others.

13.7.2 Presence of certain diseases of the nervous system, especially brain diseases such as Alzheimer’s, Parkinson’s and others.

13.7.3 Presence of certain types of diseases of the joints and bones.

13.7.4 Presence of some types of cancer diseases.

13.7.5 Direct damage of the donated bone.

13.7.6 If the period between the cardiac arrest of the deceased donor and retrieval of bone was more than (12) hours.

13.8 **Special criteria for corneal transplantation.**

The cornea from deceased donor is considered valid for transplantation except in the following cases:

13.8.1 If the donor has one of the problems mentioned under general criteria.

13.8.2 If there is any disease of the eye such as a tumor, active conjunctivitis, any disease involving the corneas or iris, or if a previous surgical procedure has been performed on the eye which has damaged the cornea.

13.8.3 If he has congenital rubeola.

13.8.4 If the time between donor cardiac arrest and corneal harvesting exceeds 12 hours.
14. Procedures of Deceased Donor Maintenance

The SCOT recommend the following measures in order to achieve the goals of maintenance of the deceased donor maintenance and obtain viable organs for transplantation.*

14.1 To keep systolic arterial blood pressure >100 mm Hg for adults by administrating the appropriate fluid according to need while keeping the central venous pressure around 12 mmH2O and by using vasoconstrictors according to needs considering dopamine the vasoconstrictor of choice to be used with best outcome.

14.2 To keep urine output between 80-100 mL/hr with proper balance between fluid input and total urine output.

14.3 To keep arterial blood gas (ABG) values within normal range (PO2 100 mm Hg – PCO2 35 mm Hg).

14.4 To keep normal balances of acid base and electrolytes of the deceased donors.

14.5 Since polyuria is common in deceased donors, the use of medications such as vasopressin would be appropriate to keep total urine output between 1.5 – 3 mL/kg/hr.

14.6 Prophylaxis against infection.

14.7 To keep temperature of deceased donor within normal range by using either warming or cooling measures.

14.8 If bradycarida of deceased donors develops (less than 50 beats/min), isopretnol could be used if needed.

14.9 Hormonal therapy (insulin – thyroxin – cortisol) may be used according to the need and after coordination with the SCOT and organ transplant teams.

14.10 To keep the eyes of the deceased donor closed and to use appropriate medical eye drops systematically.

Appendix 23: Diagram of maintenance of the deceased donor.

*This protocol should be applied by the treating physicians or ICU doctors to achieve the goals of brain-death maintenance in cooperation with the nephrologists in the hospital and organ transplant center.
Appendices
Appendix 1

Fatwa of Senior Ulama Commission Concerning Organ Donation and Transplantation


The board unanimously resolved the permissibility to remove an organ, or a part thereof from a Moslem or Thimmi living person and graft it onto himself, should the need arise, should there be no harm in the removal and should the transplantation seem likely successful.

The board also resolved, by majority, the following:

a. The permissibility to remove an organ or part thereof from a dead person for the benefit of a Moslem, should the need arise and should the removal cause no dissatisfaction and should the transplantation seem likely successful.

b. The permissibility for the living person to donate one of his organs or a part thereof for the benefit of a Moslem in need thereof.

Senior Ulama Commission
Appendix 2

Resolution of the Council of Islamic Jurisprudence on Resuscitation Apparatus
Amman, 1407 H (1986 G) No.86-07-3D (5)

The Council of Islamic Jurisprudence academy in its third session held in Amman 13-02-1407 H (16-10-1986 G) discussed the supportive means in intensive care units and after comprehensive explanation from consultant doctors decided the following:

The person is considered legally dead, and all the Shariah principles of death apply if one of the following conditions is confirmed:

a. Complete cessation of the heart and respiration, and the doctors have ruled that the cessation is irreversible.

b. Complete cessation of all functions of the brain and the consultant doctors have ruled that the cessation is irreversible, and the brain has started to degenerate.

In this condition there is permissibility to discontinue the supportive means from the patient even if some of his organs, like heart, still work artificially.
Appendix 3

The Establishment of National Kidney Foundation

Kingdom of Saudi Arabia  
Secretary General of Saudi Cabinet  
No. 1561/7  
19/5/1404 H

Subject: Approval for Establishment of National Kidney Foundation

Dear His Excellency, the Minister of Health:

According to your letters no. 74/11 dated 10/3/1404, and 1442/11 dated 7/3/1404 H that carried the proposal of establishing a National Kidney Center and denoted the study of experts in this field including members of the Ministry of Health and King Faissal Specialist Hospital, which concluded in favor of this project and that the supervising committee of the center should be presided by the minister of health and includes representatives of the National Guard Hospital, Ministry of Defense Hospital, Higher Education Hospitals, Ministry of Health and King Faissal Sp. Hospital. The committee’s domain should be to lay the goals, rules and regulations for the kidney center and the allocated budget should be five million Saudi riyals from the budget of the Ministry of Health and this letter carried our approval for the project.

Prime Minister
Appendix 4

Approval to Rename National Kidney Foundation as Saudi Center for Organ Transplantation

Resolution (80) 20/6/1413 H

In correspondence to the letter of the Minister of Health 1058/K/23 dated 9/10/1412 H raised to the cabinet secretary 7/6/35/R on 19/1/1413H and according to the previous resolution 19/5/1404 to establish the National Kidney Foundation and due to the developments in the field of organ transplantation and expansion of the duties of the National Kidney Foundation as shown by the escalating statistics related to organ failure patients and services related to include heart and liver transplantation, the cabinet approves the request of changing the name of National Kidney Foundation to become the Saudi Center for Organ Transplantation.

Prime Minister
Appendix 5

Progress of Organ Donation and Transplantation Program in the Kingdom of Saudi Arabia

A: From the National Kidney Foundation to the Saudi Center for Organ Transplantation:

Based on the letter of the Head of the Council of Ministers No. 7/1561/M dated on 19/05/1404 H the approval of establishment of the National Kidney Foundation under the supervision of a committee of all health sectors in the Kingdom, is considered to be the beginning of a new era in the care of end stage renal disease patients. Also regulations were laid down on renal transplantation from living related donors and to start a program of organ donation from deceased donors.

The establishment of the National Kidney Foundation has a positive impact on the acceleration of the establishment of many dialysis centers in the Kingdom and later upgrading the NKF to Saudi Center for Organ Transplantation (SCOT) (the Council of Ministers decision no. 80 dated on 1413).

Through these years many goals have been achieved in the field of organ donation and transplantation program based on the unlimited support of the government of the KSA and the direct follow-up and supervision of His Royal Highness Prince Salman bin Abdul Aziz, President Emeritus, of the SCOT as well as the contribution of all government agencies, NGOs and the volunteer donors.

B: Establishment of a new headquarters for the Saudi Center for Organ Transplantation:

The efforts towards the establishment of the new headquarters for the SCOT and the attached charity dialysis center, was under the supervision of HRH Prince Salman bin Abdul Aziz (may Allah protect him), who laid the foundation stone for the new headquarters on 18/08/1418 H with the contribution and support of the Royal Highnesses the princes and philanthropists, government agencies, and NGOs.

C: Council of Ministers Resolution no. 195 dated 08/01/1423 H

Given the importance of the program of organ donation and transplantation and the need to achieve the goals of the SCOT, came the initiative of Prince Salman bin Abdul Aziz - again to confirm his primary role and effective support in the progress of the SCOT this caused a major impact with the decision of the Council of Ministers no. 195 on the date of 01/08/1423 H agreeing to support the program of organ donation and transplantation.
D: Decision of the Council of Health Ministers of the Gulf Cooperation Council (GCC) no. 3 in 1427H:

Due to the great success of the program of organ donation and transplantation in the Kingdom of Saudi Arabia, the Council of Health Ministers of the Gulf Cooperation Council (GCC) in the Conference (61) on 24/04/1427 H corresponding to 24/05/2006 has laid the decision (3) which included:

1. Adoption of the SCOT as a reference center for the Gulf Cooperation Council (GCC) in the field of organ donation and transplantation.

2. Adoption of a uniform law and policy and procedure for organization and transfer of organs between Gulf Cooperation Council Countries as a guidance process.


By an initiative and support of His Royal Highness Prince Salman bin Abdul Aziz, President Emeritus, of the SCOT towards supporting the needs of dialysis patients who work in private sectors for a paid leave on their dialysis day (based on medical report from the treating unit). The SCOT has submitted a request to the Council of Ministers, who approved the decision No. 107 dated 8/4/1429 for granting patients working in private sector a paid leave on their dialysis days (like those in the governmental sector) from the Human Resources development fund.

F: Decision of the Council of Ministers no. 270 dated 09/18/1429 H

Which the SCOT under the auspices of the Council of Health Services and the allocation of an independent budget for the program of organ donation and transplantation.

**Improvement of services for the care of patients with organ failure**

The most notable successes were in the progress and the practice of organ donation and transplantation in the Kingdom, which grew and evolved explicitly during the past 25 years, and evidenced by the increasing numbers of transplanted organs such as the kidneys, hearts, livers, lungs and pancreas, where the number of the transplanted kidneys has exceeded 6,000 kidney transplants as of the end of 2012. Moreover, the liver transplant program in the KSA, which began in 1990, has achieved more than 750 liver transplants by the end of 2012, of which 40% were from living donors and 60% from decease donors.

Over the same period, 160 whole hearts have been transplanted in addition to more than 500 hearts which were utilized as sources for valve replacement.
Concerning the cornea transplantation program in the Kingdom of Saudi Arabia, more than 500 corneas have been transplanted from deceased donors till the end of 2012.

**International developments in the regulation of organ donation and transplantation**

The World Health Organization (WHO) had issued, at the seventh meeting session, which was held in Switzerland in May 2004, a resolution on the transplantation of human organs and tissues. It confirmed the need for establishment of national centers in each country to oversee and supervise the process of organ, tissue and cells donation and transplantation, taking into account the ethical issues to ensure the rights of the donor and recipients, and to protect the poor people from transplant tourism and organ trafficking. The organization stressed the need to take advantage of all sources of organ donation from living and deceased donors in each country.

Additionally, The International Transplantation Society (TTS) has issued an ethical statement for the care of living organ donors in its meeting held in Vancouver, Canada, in May 2006, which stated that a transplant center that performs live organ transplantation must implement procedural safeguards to enhance donor rights, safety and autonomous decision-making to proceed with live organ donation.

Followed by the Istanbul Declaration to the WHO and TTS in May 2008 which emphasizes that organ trafficking and transplant tourism should be prohibited because they violate the principles of equity, justice and respect for human dignity. The Declaration asserts that because transplant commercialism targets impoverished and otherwise vulnerable donors, it leads inexorably to inequity and injustice and should also be prohibited.

The declaration provides ethical guidelines for practice in organ donation and transplantation.

**G: Council of Ministers issued a decision no. 38 dated 01/26/1434 H:**

1. Has agreed upon the regulation and organization of the SCOT as stated.
2. The SCOT has to prepare a comprehensive system for organ donation and transplantation.
Appendix 6

Organ Transplant Centers in the Kingdom of Saudi Arabia

Renal transplant centers:
1. King Faisal Specialist Hospital and Research Center, Riyadh
2. Prince Sultan Medical Military City, Riyadh
3. King Abdul Aziz Medical City National Guard, Riyadh
4. King Faisal Specialist Hospital and Research Center, Jeddah
5. King Fahd Specialist Hospital, Dammam
6. King Fahd Hospital, Jeddah
7. King Fahd Military Hospital, Jeddah
8. King Abdul Aziz Medical City National Guard, Jeddah
9. King Abdul Aziz Hospital and Oncology Center, Jeddah
10. Al Hada Armed Forces Hospital, Taif
11. North West Armed Forces Hospital, Tabuk
12. Armed Forces Hospital, Southern Region, Khamis Mushayt
13. Saad Specialist Hospital, Alkhobar
14. Dr. Suleiman Fakheeh Hospital, Jeddah
15. New National Hospital, Jeddah
16. King Fahd Medical Military Complex, Dhahran

Inactive/previous renal transplant centers:
1. King Saud Medical City was active from 1987-1993
2. King Fahad Hospital, Madinah from 1990-2006
3. King Fahd Medical Military Complex, Dhahran from 1990-2010
4. King Abdul Aziz Hospital and Oncology Center, Jeddah from 1992-2008

Pancreas transplant centers
1. King Faisal Specialist Hospital and Research Center, Riyadh
2. King Fahd Specialist Hospital, Dammam

Bone transplant centers
1. King Faisal Specialist Hospital and Research Center, Riyadh

Heart transplant centers
1. King Faisal Specialist Hospital and Research Center, Riyadh
2. Prince Sultan Medical Military City, Riyadh

Inactive/previous heart transplant center:
1. King Fahd Hospital, Jeddah was a heart transplant center in the period from 1989 to 1993

Directory of the Regulations of Organ Transplantation in the Kingdom of Saudi Arabia
Lung transplant centers:
1. King Faisal Specialist Hospital and Research Center, Riyadh
2. King Faisal Specialist Hospital and Research Center, Jeddah

Inactive/previous lung transplant center:
1. King Fahd Hospital, Jeddah performed lung transplantation in 1991 to 1992
2. King Faisal Specialist Hospital and Research Center, Jeddah performed lung transplantation in 2001 to 2006

Liver transplant centers:
1. King Faisal Specialist Hospital and Research Center, Riyadh
2. King Abdul Aziz Medical City, National Guard, Riyadh
3. King Fahd Specialist Hospital, Dammam
4. Prince Sultan Medical Military City, Riyadh (for pediatrics only)

Inactive/previous liver transplant center:
1. King Fahd Hospital, Jeddah performed liver transplantation in year 1994

Corneal transplant centers:
1. King Khalid Eye Specialist Hospital, Riyadh
2. King Abdul Aziz University Hospital, Riyadh
3. King Abdul Aziz Medical City, National Guard, Riyadh
4. Armed Forces Hospital, Southern Region, Khamis Mushayt
5. Jeddah Eye Hospital
6. Ohud Hospital, Madina
7. Almaghrabi Hospital, Jeddah
8. King Abdul Aziz Medical City National Guard, Jeddah
9. Royal Commission in Jubail and Yanbu Heath Center, Jubail
10. Assir Central Hospital
11. Almanea Hospital, Alkhobar
## Appendix 7

### Hospital Distribution on Transplant Centers

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<tr>
<th>Transplant Center</th>
<th>Hospital Name</th>
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<tr>
<td>Prince Sultan Military Medical City, Riyadh</td>
<td>Prince Sultan Military Medical City, Riyadh</td>
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<td>King Saud Medical City**</td>
<td>King Saud Medical City**</td>
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<td>Prince Salman Hospital, Riyadh</td>
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<td>Hayat National Hospital, Riyadh</td>
<td>Hayat National Hospital, Riyadh (previously Al Mowasat)</td>
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KFMMC-Dhahran is not active since mid 2009.
Patients for transplant will be for KFSH–Dammam

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Diagnosis of Brain Death by Brain Function Criteria

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FOREWORD

Documentation of death by brain function criteria is a well established diagnosis in the field of medicine today and deceased organ transplantation is now considered the best available established technique for the treatment of end stage failure of most essential organs (kidneys, liver, heart, lungs and pancreas).

In the Kingdom of Saudi Arabia, the true era of deceased kidney transplantation started in 1986 after the establishment of the National Kidney Foundation (NKF). Since its inception, the deceased kidney transplantation program has depended on the close cooperation of colleagues handling cases of deceased donors.

The NKF was promoted to the Saudi Center for Organ Transplantation (SCOT) in 1993, ever since the practice of deceased organ transplantation has increased progressively. We acknowledge the previous work on the protocol of (diagnosis of brain death and policy on cadaveric organ procurement in KSA). The members of the committee provided support to SCOT over the years, in training intensive care units staff and the application of the protocol at the national level. The revision of the protocol by the current committee is intended to comply with the updated international protocols. The modification includes better explanation on the form used for the diagnosis of deaths by brain function criteria. The committee have revised the protocol and satisfied with most of it, however they updated some of the confirmatory test and some inclusion criteria such as level of hypothermia during the diagnosis and apnea test.

The SCOT is grateful to all members of the National Committee for Death Documentation by Brain Function Criteria who contributed so much energy and thought to initiate and maintain of this protocol which is fundamental for the practice of deceased organ donation and transplantation in the Kingdom of Saudi Arabia.

Dr. Faissal A.M. Shaheen
General Director
Saudi Center for Organ Transplantation
1.0 Introduction

The advent of effective artificial cardiopulmonary support has created new concepts about the diagnosis of death in the last few decades. Previously, cessations of heart and lung functions were the only signs for diagnosing death whether the initial event occurred in the brain, the heart, and the lungs or elsewhere in the body. Since the cardiac and pulmonary functions can be recovered by modern resuscitation techniques and sufficiently maintained artificially, even when the brain is irreversibly damaged, the need emerged to establish other criteria to define death (impossibility to return to life). Hence the concept of brain-death and the need for definitive neurological criteria that must be used to assess whether the brain functions have ceased irreversibly.

The concept of brain death was first reported in 1959 by a group of French physicians. Later during the same year, Mollaret and Goulon called this condition Coma depasse, which means a state beyond coma. In 1968, the Ad-Hoc Committee of Harvard Medical School was appointed to examine the definition of “brain death” and the Harvard Criteria were adopted in the USA. In 1971, a major conceptual advance occurred when two Minneapolis neurosurgeons, Mohandas and Chou, made the challenging suggestion that patients with known irreparable intra-cranial lesions, irreversible damage to the brain-stem represented the point of no return. Thus, evolved the concept of brain-stem death. The criteria were laid down for the diagnosis and became known as the Minnesota Criteria. This stimulated much later work particularly in the UK. The UK code in 1976 and the addendum to the original report in 1979 described diagnosis of brainstem death and emphasized the need for observing strict pre-conditions and necessary exclusions without which the diagnosis by Brain Function Criteria cannot be considered.

In the USA, further important developments took place in 1981, thirteen years after the Harvard Criteria was adopted. A large panel of physicians from various specialties presented the report on The Diagnosis of Death to the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. They recommended uniform criteria for the diagnosis of brain death and defined brain death as irreversible cessation of all functions of the entire brain, including the brain-stem. Accordingly, the irreversibility of brain damage is recognized when evaluation discloses all of the following:

a. An established cause of coma sufficient to account for the loss of brain function.

b. Exclusion of the possibility of recovery of any brain function.

c. The persistent cessation of all brain functions during an appropriate period of observation and/or a trial of therapy. This may take 6-24 hours depending on the availability of different confirmatory tests such as EEG, evoked potentials and four vessel cerebral angiography. For patients suspected to have conditions such as drug intoxication, metabolic derangements and hypothermia, a longer period of observation and persistence of cessation of brain functions despite correction of these abnormalities are needed in order to declare them brain-
dead. Infants and children before puberty also need longer observation periods.

The concept of brain death is very specific. It does not apply to patients existing in a persistent vegetative state or to other severe degrees of brain damage from causes such as metabolic derangements, drug intoxication, etc. (Figure 1).

![Figure 1. Lateral view of the human brain showing areas affected in persistent vegetative state, brain-stem death and total brain death.](image)

### 2.0 The Concept of Death by Brain Function Criteria

As cardiac arrest was sufficient in the past to declare death because no treatment existed for it, and it represented the point of “no return” to life. Advances in resuscitation made cardiac arrest in some circumstances reversible and thereby insufficient to define the point of “no return”. This necessitated the search for more robust criteria to define the point of “no return”. The concept of death based on viability of the brain, conveniently termed death by brain function criteria, is now a recognized entity in medicine. The diagnosis is made by clinical examination and supplemented by objective investigations. The determination of death by brain function criteria commonly referred to as diagnosis of death by brain function criteria can be made in every hospital with a well-functioning ICU and must be done as a part of the general management of any patient fulfilling the criteria of death by brain function criteria, irrespective of the issue of organ donation. Organ donation programs
became a secondary issue in this concept as the organs that remain functioning may save someone else’s life while the alternative will be to bury them under earth. The question nowadays is not whether the diagnosis of death by brain function criteria is accepted, but is regarding further management of the brain-dead patients, i.e., whether to continue connection to life supporting equipments or not and for how long and how and when to procure donated organs.

1.1 Who is Responsible for the Diagnosis of Death by Brain Function Criteria?

A neurologist, a neuro-surgeon, an internist, an ICU physician, an anesthesiologist, a pediatrician or a consultant physician who received training in evaluation of death documentation by brain function criteria can perform the examination. Physicians or surgeons who are involved in the transplantation operation should not be involved in the establishment of documentation of death.

1.2 Who is responsible for the care of patients with Death by Brain Function Criteria?

The following professionals are responsible for the care of the potential organ donor: an ICU physician, an anesthesiologist, an internist, a neurosurgeon or a neurophysician in cooperation with a nephrologists and treating physicians.

1.3 The Potential Deceased Donor

1.3.1 Initial recognition of a potential deceased donor

A potential deceased donor is usually a patient in coma, due to any of the following conditions and requiring ventilatory support:

a. Head trauma  
b. Cerebrovascular hemorrhage  
c. Cerebral anoxia  
d. Primary brain tumor

3.0 Death by Brain Function Criteria: Medical Aspects

3.1 Definition

Death by brain function criteria is a legal definition of death based on the irreversible cessation of all functions of the entire brain including the brain-stem due to total necrosis of the cerebral neurons following loss of blood flow and oxygenation.

3.2 Medical Criteria for the Diagnosis of Death by Brain Function Criteria

The diagnosis of death by brain function criteria needs to be rigorous to determine whether the condition is irreversible. The question of death by brain function criteria” should not be entertained unless there is a positive history or
diagnosis of a condition that usually leads to total brain injury such as severe head trauma or prolonged cardiac arrest etc. At least six hours should have passed after the initial event before such consideration is raised. The patient is usually deeply comatose and makes no respiratory efforts (See Appendix I – Glasgow Coma Scale). It is important to distinguish between brain death and states that may mimic brain death, such as narcotic or barbiturate overdose, hypothermia or severe metabolic disturbance such as hypoglycemia.

Testing in suspected death by brain function criteria is done only after the above preconditions and exclusions are exhausted. It is based on detailed clinical exams that must show complete absence of brain functions of both cortex and brainstem. Clinical exam should be performed by two trained physicians and repeated after an interval appropriate to the patient’s age. Confirmatory tests may include isoelectric (flat-line) EEGs done according to standardize criteria. The patient should have a normal temperature and be free of drugs that can suppress brain activity. Alternatively cerebral blood flow scan or angiogram that shows complete absence of intracranial blood flow can be used.

3.2.1 Preconditions for the Diagnosis of Death by Brain Function Criteria

Before proceeding to make the diagnosis of death by brain function criteria on a patient, the following conditions should be present.

a. Patient is in coma and the cause of coma has been firmly established.
b. Patient has no spontaneous respiration and is supported by a ventilator.
c. The event causing brain damage occurred at least six hours previously and the cause of irreversible brain damage has been clearly determined (i.e., head trauma, brain hemorrhage, etc).
d. Patient is not in cardiovascular shock.
e. Obvious metabolic and endocrinal derangements have been corrected.
f. No response to any kind of stimuli.
g. Complete areflexia. However, simple spinal cord reflexes may be present.

3.2.2 Exclusions

a. Patient should not be hypothermic. The core temperature must be above 34°C before testing for death. If the temperature is below this, the patient must be warmed-up.
b. Patient is not receiving any sedatives, muscle relaxants, anticonvulsants, hypnotics, narcotics or anti-depressants. Blood test or hospital record should indicate absence of significant levels of sedative drugs or muscle...
relaxant, or receiving sedation in the preceding 5 days.

Toxicology screen must be done especially in cases of road traffic accidents, drug overdoses and unexplained causes of coma, and in other cases, as deemed necessary. If indicated, and facilities are not available for estimating the blood levels, an interval of five days should lapse before testing for death.

c. Patients with metabolic and endocrine causes of coma should be excluded.

d. Patient should not have any sign of cerebral activity like decerebrate or decorticate posture and seizure activities (see Appendix II – Clinical Triggers of the Diagnosis of Death by Brain Function Criteria).

3.3 How to Diagnose Death by Brain Function Criteria?

Once the patient is found to have the necessary preconditions and exclusions, one should proceed with the clinical examination as per the recommendation in the death documentation form by brain function criteria (See Appendix III – Death Documentation Form by Brain Function Criteria). The findings are to be recorded in the prescribed form and signed by the physicians conducting the examination. They must also be available also after the stipulated observation interval, to carry-out the second examination and sign the death documentation form.

3.3.1 Initial clinical examination

a. Confirm that the patient is in coma.

b. Evaluate the patient for the presence of any seizure activity and any decerebrate or decorticate movements.

None should be found in a death by brain function criteria patient. Presence of spinal myoclonus and/or spinal reflexes alone does not indicate brain viability and does not exclude death by brain function criteria.

c. Test for absence of motor response to painful stimulation.
For example, absence of grimacing upon applying pressure over the frontal sinus (Figure 3*).

Figure 3. Testing for motor response to painful stimulus
3.3.2 Tests for Brain-Stem Reflexes

After the initial evaluation described above, tests are done to demonstrate the absence of brain-stem reflexes. These tests have to be done in the following order: (If anyone of these reflexes is preserved, there is no need to proceed further).

a. Pupillary response to light

Shine a bright beam of light from a suitable source, e.g., a pen flashlight, on to the open eyes (Figure 4). In a death by brain function criteria patient, no response, neither direct nor consensual, is seen to the stimulus in either eye.

Both eyes must be tested. Make sure that mydriatic or meiotic eye drops or drugs have not been used in the recent past prior to carrying out the test.

![Figure 4. Testing for pupillary response to light](image)

b. Corneal reflex

Touch the cornea with a wisp of cotton wool (Figure 5). If the brain stem is dead, no blinking response is noted on either side. The test should be performed on both sides.

In a patient with suspected death by brain function criteria, much firmer pressure is justified while doing this test. The use of a cotton swab is more suitable.

![Figure 5. Testing for corneal reflex](image)
c. Oculo-cephalic reflex (Doll’s head eye phenomenon)

Stand at the head-end of the patient’s bed. Hold the head of the patient in the neutral position firmly with both hands. Move the head briskly, first to one side and then to the other. Observe the eye movements during these maneuvers -by retracting the eyelids with the thumbs. A positive reflex is elicited in a comatose patient when the eyes move in an opposite direction to the head movement as if to keep the fixation axis straight ahead (Figure 6). If the reflex is elicited, the brain-stem is alive and there is no need to proceed with further testing. In a patient with non-functioning brain-stem, the head and eyes will move together.

The test should be avoided in cases of recent trauma with suspicion of cervical fracture. The ventilator may be disconnected for 20-30 seconds while performing this test.

![Figure 6. Positive oculo-cephalic reflex. Notice the position of the eyes in relation to the direction of head movements. I. Head and eyes in neutral position. IIa & IIIa. Deviation of eyes to opposite sides when the head is moved to the left and right respectively. IIb & IIIb. Eyes in neutral position, after the realignment.](image)

d. Vestibulo-ocular reflex (Caloric test)

Instill about 50 mL of ice-cold water or saline into each auditory meatus, in turn (Figure. 7). In children, a smaller volume (10-20 mL) may be used. Normally, eye movements will be observed within 20-30 seconds. No eye movements are seen in case of death by brain function criteria.

Absence of eye deviation towards the tested ear indicates a disrupted reflex arc by damage to the reflex centers (brain-stem) or paralysis of extra-ocular muscles. Therefore, do not perform this test if muscle relaxants have been administered.

Otoscopic examination must have confirmed the integrity of the tympanic membrane. Make sure that there is no mechanical obstacle in the auditory canal, such as wax. If the tympanic membrane is not intact, elicit the reflex
using cold air instead of cold water. Testing should be done in both ears. The test may be contraindicated in patients with local trauma.

![Caloric Test](image)

**Figure 7. Caloric test**

c. Upper and lower airways stimulation (e.g., pharyngeal and endotracheal suction).

This test is carried out with the intention to achieve pharyngeal and carinal stimulation. Pass a suction catheter down into the pharynx and the trachea up to the carina (Figure 8). In a death by brain function criteria patient; this will not produce either gagging or coughing.

![Testing for Gag Reflex](image)

**Figure 8. Testing for gag reflex.**

### 3.3.3 Observation Period (Interval between examinations)

After completion of the first examination, a second examination should be conducted after the stipulated time interval. The findings are to be recorded in the death by brain function criteria documentation form (See Appendix III – Death Documentation Form by Brain Function Criteria) and signed by the consultants conducting the examination. The recommended time intervals between the first and second examinations are given in Table 1.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Recommended Time Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonate (7 days – 60 days)</td>
<td>48 hours</td>
</tr>
<tr>
<td>Infants (above 60 days – 1 year)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Children (above 1 year)</td>
<td>12 hours</td>
</tr>
<tr>
<td>Adults</td>
<td>6 hours</td>
</tr>
</tbody>
</table>

*Two EEGs separated by the stipulated time interval

** One EEG only, at the time of first examination

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Confirmatory tests

If all the above-described brain-stem reflexes are found to be lost, then proceed to do one of the following confirmatory tests.

a. Electroencephalogram (EEG)

EEG should show electro cerebral silence recording is to be done for at least 30 minutes and must conform to the criteria given in EEG guidelines (See Appendix IV – EEG Guidelines). If the patient has hypothermia, he/she must be warmed-up before conducting EEG examination.

b. Cerebral angiography

Demonstration of absence of intracranial arterial circulation by four-vessel angiography is a confirmatory test of brain death for adults and children. In children, a cerebral radionuclide angiogram (CRAG) also confirms cerebral death by demonstrating the lack of visualization of the cerebral circulation. A technically satisfactory CRAG that demonstrates arrest of carotid circulation at the base of the skull and absence of intracranial arterial circulation can be considered confirmatory of brain death, even though there may be some visualization of the intracranial venous sinuses.

The indications for angiography are:

a. EEG is either not available or cannot be interpreted due to technical problems. In this case, the clinical examination and apnea test are done by the examiners before the angiography.

b. The cause of death cannot be determined with absolute certainty.

c. Metabolic derangement, shock or hypothermia cannot be corrected of intensive therapy.

d. Difficulty in convincing the relatives about the brain-death of their patient.

In all these cases, demonstration of absence of cerebral blood flow by angiography or radionuclide study or transcranial Doppler study proves that the brain is irreversibly damaged.

3.4 Apnea Test

Apnea test should be performed as the last test after two clinical examinations with the mandatory observation period in between, have confirmed the absence of brain stem functions and the result of EEG or one of the other confirmatory tests is compatible with brain death. This test is done once with both examiners observing and need not be repeated.
3.4.1 Testing for Apnea

The apnea test demonstrates the failure of spontaneous respiration. The following precautions should be observed before proceeding with the test.

3.4.2 General considerations

Apnea test should be done with body temperature of \( \geq 36.5^\circ C \).

- Avoid hypoxia which could damage the brain further.

  Ensure that PaCO2 builds up to a critical level of 8.1 kPa (60 mm Hg) or 20 mm Hg over the baseline by the end of disconnection period. This is a sufficient stimulus to the respiratory center in a functioning brain-stem.

- If the patient is unable to tolerate the apnea test, it can be substituted by brain circulation confirmatory test.

3.4.3 Procedure for the apnea test

- Pre-oxygenate with 100% \( O_2 \) for 10 minutes. Increase the inspired fraction of oxygen (FI02) without changing the ventilation rate.

- Disconnect the patient from ventilator and supply a continuous flow of humidified 100% \( O_2 \) at the rate of 6 liters/min through an intra-tracheal catheter placed at the carina. In children, a flow of 1.5-2 liters/min can be used. Make sure that the catheter is thin enough as not to block the airway. Pulse oximeter is recommended to be used throughout the apnea testing.

- Maintain disconnection for 10 minutes while observing the patient to see if there is any attempt to breathe. Draw blood for ABG to check the final PaCO2 and record this value. The PaCO2 must be above 8.1 kPa (60 mmHg) in adults and 7.6 kPa (55 mmHg) in children or 20 mmHg over the baseline.

Apnea test is considered positive when no respiratory movements have occurred during the disconnection period (see Appendix V – Fact Sheet for the Approach to Diagnosis of Death Breath by Brain Function Criteria).

3.5 Documentation of Death by Brain Function Criteria

After the death by brain function criteria documentation form (See Appendix III – Death Documentation Form by Brain Function Criteria) is duly completed with the findings of all the tests and examinations specified therein and with the necessary signatures, it must be countersigned by the Chief of Staff of the hospital, who should ensure that all the stipulated criteria have been met. Documentation of death by brain function criteria must be done only at this stage.
Once death is confirmed, the treating physician should communicate the situation to the family, without offering the option of organ donation. (See Policy on Deceased Organ Procurement in Saudi Arabia, SCOT Publication).

4.0 Death Certification by Brain Function Criteria in Children

In pediatric cases, one has to follow the same general guidelines, but with some necessary modifications described below, according to age.

a. In infants aged seven days to two months, the observation period has to be extended to 48 hours, during which two EEGs are taken separated by an interval of 48 hours, both showing electro cerebral silence, i.e., two recordings showing no cerebral activity, one at the beginning of the observation period and another at the end (Table 1 – Recommended Time Interval between First and Second examination in various age groups).

b. In infants from two months to one year, an observation period of 24 hours is necessary. The confirmation should be done by two EEGs separated by 24 hours showing electro-cerebral silence in both, or one EEG with electro cerebral silence and one cerebral radionuclide angiography (dynamic isotope brain scan) showing no arterial blood flow to the brain.

c. For children over one year of age, the protocol is not different from that for adults except that the observation period should not be less than 12 hours.

d. After puberty, protocol for the adult is to be followed.
### APPENDIX I

Glasgow Coma Scale

<table>
<thead>
<tr>
<th>EYES</th>
<th>Open</th>
<th>Spontaneously 4</th>
<th>To verbal stimuli 3</th>
<th>To pain 2</th>
<th>No response 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>BEST MOTOR RESPONSE</td>
<td>To verbal command</td>
<td>Obeys 6</td>
<td>Localizes pain 5</td>
<td>Semi-purposeful 4</td>
<td>Decorticates 3</td>
</tr>
<tr>
<td>BEST VERBAL RESPONSE</td>
<td>To painful stimulus</td>
<td>Oriented and converses 5</td>
<td>Disoriented and converses 4</td>
<td>Inappropriate words 3</td>
<td>Incomprehensible sounds 2</td>
</tr>
<tr>
<td>TOTAL</td>
<td>3-15</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX II

Clinical Triggers of the Diagnosis of Death by Death by Brain function Criteria

Refer all severe brain damage regardless of age or diagnosis to Saudi Center for Organ Transplantation (SCOT).

Clinical signs to Refer a Possible Organ Donor:

- Any ventilator dependent, unresponsive patient with a possibility to progress to irreversible Brain Damage after more than 6 hours have passed since the initial insult.

   AND

- Clinical findings consistent with GCS ≤5

   OR

- Absence of 2 or more brain stem reflexes
  - *no pupillary response
  - *no corneals
  - *no ice water calorics
  - *no doll’s eyes
  - *no gag/cough
  - *not triggering the ventilator
  - *no motor response

   OR

- Family mentions or asks about organ and tissue donation.

PUPIL GAUGE (mm)

| 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

Pupils
No Response to bright light. Size: midposition (4 mm) to dilated (9 mm).

Ocular Movement
No oculocephalic reflex. No deviation of eyes to irrigation in each ear with 50 ml of cold water (allow 1 minute after injection and ≥5 minutes between testing on each side).

Facial Motor Response and Sensation
No jaw reflex. No grimacing to deep pressure on nail bed, supraorbital ridge, or temporomandibular joint. No corneal reflex to touch with swab.

Pharyngeal and Tracheal Reflexes
No response after stimulation of the posterior pharynx with tongue blade. No cough response or bradyarrythmia to bronchial suctioning.
### APPENDIX III

**Death Documentation Form by Brain Function Criteria**

<table>
<thead>
<tr>
<th>Name:</th>
<th>Age:</th>
<th>Sex:</th>
<th>Nationality:</th>
<th>BLOOD GROUP</th>
<th>Date of Admission:</th>
</tr>
</thead>
</table>

#### FIRST EXAM

**PRECONDITIONS:**

1. 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.

**EXCLUSIONS:**

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).


4. Significant metabolic or endocrine causes of coma.

**CLINICAL ASSESSMENT:**

1. Lack of response to stimulation (Spinal reflexes excepted).

2. Absence of brain stem reflexes:
   
   - Pupils to light
   - Corneal
   - Oculocephalic
   - Oculovestibular (50 ml. of ice-cold water at 0°C in adults, 20 ml. in children)
   - Gag
   - Cough

**Consultant A**

<table>
<thead>
<tr>
<th>FIRST EXAM</th>
<th>Date/التاريخ</th>
<th>Time/الوقت</th>
<th>Name/الاسم</th>
<th>Signature/توقيع</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Consultant B**

<table>
<thead>
<tr>
<th>CONFIRMATORY TEST</th>
<th>EEG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flat [ ] Date:</td>
<td>No Flow [ ] Date:</td>
</tr>
</tbody>
</table>

**Note:** Recommended time interval between first and second examinations in various age groups:

- Adults: minimum of 6 hours
- **Infants:** (above 60 days – 1 year) 24 hours
- Children (above one year) 12 hours
- **Neonate:** (7 days – 60 days) 48 hours
- One EEG at end of first exam
- Two separated by the mentioned time interval

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Name: ____________________________
Age: ________ Sex: __________
Nationality: __________ BLOOD GROUP: __________
Hospital: ____________________________ Date of Admission: ________________

I. PRECONDITIONS:
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. EXCLUSIONS:
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).
4. Significant metabolic or endocrine causes of coma.

III. CLINICAL ASSESSMENT:
التقييم السريري للجهاز العصبي:
1. Absence 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 ≥36.5°C) Performed as per Saudi Protocol and is compatible with death by brain function criteria.

Date/التاريخ: ____________________________ Time/الوقت: ____________________________
Name/الإسم: __________________________________ Signature/التوقيع: ____________________________
Consultant A
Consultant B
Hospital Director or Deputy

Seal of the Hospital

Note: After completion of the Death Documentation form, please fax to Saudi Center for Organ Transplantation P.O. Box 27049, Riyadh 11417. K.S.A. Tel: 01 4451100 – Toll Free Phone: 8001245500, Fax: 01 4453934

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APPENDIX IV

EEG Guidelines*

1. A minimum of eight scalp electrodes and ear lobe references covering the major brain areas shall be used; ground electrode should not be used in ICU or if electrical monitoring equipment is in-use.

2. Disk electrodes will be applied; inter-electrode impedances will be kept under 10,000 ohms and over 100 ohms; the inter-electrode distance should be at least 10 cm.

3. Each electrode will be tested by touching it separately to create an artifact potential on the record.

4. Gain sensitivity will be increased by changing sensitivity from 7.5 V/mm to 2 V/mm during most of the recording with inclusion of appropriate calibration.

5. Filters should provide a wide window i.e., time constant 0.3 sec-land high frequency > 70 Hz.

6. EEG should be tested for reactivity to loud noise and pitch.

7. Recording will be done for at least 30 minutes.

8. A pair of electrodes will be applied on the dorsum of the right hand at a distance of 6-7 cm; electrocardiographic monitor will be applied.

9. Electromyographic artifacts can be seen sometimes in a patient with electrocerebral silence. If these obscure the recording, neuromuscular blocking agents like pancuronium or succinylcholine may be used, but during the recording only.

10. Recording should be made only by a qualified EEG technologist. A repeat EEG should be obtained if there is doubt about electrocerebral silence.

*Modified from:


APPENDIX V

Fact Sheet for the Approach to the Diagnosis of Death by Brain Function Criteria

I. Preamble

Death by brain function criteria is a legal definition of death based on the irreversible cessation of all functions of the entire brain including the brain-stem due to total necrosis of the cerebral neurons following loss of blood flow and oxygenation. Before any supportive means are discontinued, the family members must be counseled. This should be documented in the patient's chart.

II. Criteria for establishing Death by Brain Function Criteria

All spaces provided should be initialed by two consultants (A & B) certifying the results of their assessment of the patient's condition.

1. Preconditions
   - The etiological diagnosis for death by brain function criteria should be entered.

   Exclusions
   - Any signs of cerebral activity (like decerebrate or decorticate posturing or seizure activities).
   - Hypothermic patient should be warmed up to near normal body temperature.
   - Blood should be screened for the presence of barbiturates, opiates, benzodiazepines, synthetic narcotics, hypnotics and alcohol if the patient had been hospitalized for 5 days or more.

   It should first be established that the patient is normothermic, is not under the influence of barbiturates or other sedative drugs, and is not suffering from remediable, toxic or metabolic brain disorders. In addition, it should be established that the patient is not in cardiovascular shock. death by brain function criteria will then be said to have occurred when the following criteria are found on two successive examinations, separated by an interval of 6 hours, and performed by two consultant physicians, experienced in the diagnosis of death by brain function criteria.

2. Clinical assessment
   - Total lack of response to any stimuli: painful, auditory or visual.
   - The absence of brain stem reflexes, pupil to light, corneal, oculocephalic, oculovestibular, gag and cough.
   - Maximal vestibular stimulation should be used by injecting 50 mL of ice-cold water (temperature near 0°C) as close to the eardrum as possible in both ears.
3. When the above are fulfilled then

One isoelectric electroencephalogram (EEG) of thirty minutes duration or by cerebral angiography.

(The presence of spinal reflexes does not rule out death by brain function criteria).

*See special requirements for children.

If 1, 2 and 3 are fulfilled then do:

**Apnea Test**
Absence of spontaneous respiration or movement. This is tested by ventilating with pure oxygen or an oxygen 95% and carbon dioxide 5% mixture for ten (10) minutes. At the end of this time, the PaCO\(_2\) should be within the normal range. The respirator should then be disconnected from the patient for ten (10) minutes, while the patient is supplied by continuous flow of 100% Oxygen through an intratracheal catheter reaching the carina and delivering continuous flow at 6 liters/min (1.5-2 liters/min in children) and establishing that the Pa CO\(_2\) has risen above 8.1 kPa (60 mmHg) in adults and 7.6 kPa (55 mmHg) in children.

**III. Death Documentation Form by Brain Function Criteria**

a. To document the above criteria, this form entitled “Death Documentation by Brain Function Criteria” must be completed and signed by the two consultant physicians conducting the tests. It must be countersigned by the Hospital Director or the Deputy Hospital Director, or they may appoint a Saudi senior staff physician to do so before any supportive means are discontinued. All names must be written clearly in Arabic and English and the completed form placed in the patient’s chart.

b. This form does not replace the legal death certificate.

*Special requirements for death documentation by brain function criteria in children

- Infants 7 days to 2 months: two flat EEGs separated by 48 hours of observation.

- Infants 2 months to one year: two flat EEGs Separated by 24 hours of observation.

Children from 1 year to puberty: observation period of 12 hours, one flat EEG.
APPENDIX VI

PURPORT OF THE SENIOR ULAMA COMMISSION’S

The board unanimously resolved the permissibility to remove an organ, or a part thereof from a Moslem or Thimmi living person and graft it onto himself, should the need arise, should there be no harm in the removal and should the transplantation seem likely successful.

The board also resolved, by majority, the following:

a. The permissibility to remove an organ or part thereof from a dead person for the benefit of a Moslem, should the need arise and should the removal cause no dissatisfaction and should the transplantation seem likely successful.

b. The permissibility for the living person to donate one of his organs or a part thereof for the benefit of a Moslem in need thereof.
APPENDIX VII

"RESOLUTION OF THE COUNCIL OF ISLAMIC JURISPRUDENCE ON RESUSCITATION APPARATUS"

Amman, 1407 H (1986 G) No.86-07-3D (5)

The Council of Islamic Jurisprudence academy in its third session held in Amman 13-02-1407 H (16-10-1986 G) discussed the supportive means in intensive care units and after comprehensive explanation from consultant doctors decided the following:

The person is considered legally dead, and all the Shariah principles of death apply if one of the following conditions is confirmed.

a. Complete cessation of the heart and respiration, and the doctors have ruled that the cessation is irreversible.

b. Complete cessation of all functions of the brain and the consultant doctors have ruled that the cessation is irreversible, and the brain has started to degenerate.

In this condition there is permissibility to discontinue the supportive means from the patient even if some of his organs, like heart, still work artificially.
Important Memo

His Excellency the Director of the National Guard Health Affairs
His Excellency the Executive Administrator of the General Organization
King Faisal Specialist Hospital and Research Center
Deputy Minister of Higher Education
His Excellency Deputy Minister for Executive Affairs
His Excellency Director General of Medical Services of the Armed Forces
Director General of Security Forces Hospital Program

Due to the importance of supporting the national program for organ donation and transplantation and the large increase in the number of patients on waiting lists for transplantation and the resulting health and social burden on the patients and financial burden on different health sectors, I appeal to the staff in all hospitals and especially those in the intensive care units, emergency departments, neurology and neurosurgical departments, and all relevant departments to cooperate with the Saudi Center for Organ Transplantation of the administration of each hospital to fulfill the following:

1. **Early Notification** of cases of brain death to Saudi Center for Organ Transplantation and considering that as the core tasks of intensive care physicians and other relevant departments.

2. **Support** for organ donation in the hospital and put the appropriate plan with the Saudi Center for Organ Transplantation for optimizing cases of organ donation after death and overcome the obstacles faced by.

3. **Facilitate continuous communication** of medical and administrator coordinators inside the hospitals with intensive care units and emergency departments and relevant departments with respect to the organ donation and transplantation program.

**DR. ABDULLAH BIN ABDELAZIZ AL RABEEAH**

Minister of Health
Chairman of the Health Services Council

Directory of the Regulations of Organ Transplantation in the Kingdom of Saudi Arabia
APPENDIX IX

OFFICIAL STATEMENT OF THE NATIONAL COMMITTEE FOR THE DIAGNOSIS OF DEATH BY NEUROLOGICAL CRITERIA AND VENTILATOR SYSTEM

STATEMENT

The members of National Committee for diagnosis of death by Neurological Criteria held a meeting in Saudi Center for Organ Transplantation (SCOT) on Sunday 31/01/2010 (23/11/1431H) to discuss what has been published recently in the media about the reluctance of some medical doctors on the “fatwa” on removing the ventilator machine from brain dead case where some consider it as killing a person.

Accordingly the following steps were done by the committee:

- Review of these articles and international global scientific publications emerging on the subject.
- Review of the medical ethics of diagnosis of death by neurological criteria.
- Review the legal opinion “Fatwa” issued within the Kingdom of Saudi Arabia (Senior Ulama Commission) or abroad, especially the resolution of the Council of Islamic Jurisprudence on Resuscitation Apparatus.

Hence, we have decided unanimously the following:

1. The diagnosis of death by the time was, and continues to be a medical decision made by the experienced professionals.
2. The concept of brain death based on evidence has not undergone any recent disputing developments both in the definition or diagnosis using the Saudi protocol. Moreover, the protocol used within the Kingdom of Saudi Arabia is one of the most demanding protocols in the world.
3. According to the diagnosis of brain death by neurological criteria using the strict scientific protocol, the deceased person reaches the point of no return and no chance that he will regain his life.
4. It is permissible to remove the respirator from the persons diagnosed dead by the neurological criteria according to the scientific protocol applied in all the health institutions in the Kingdom and supervised by the committees of ethics and medical expertise.

The National Committee for The Diagnosis of Death By Neurological Criteria

Dr. Mohammad Zuheir Alkawi
Chairman,
Senior Consultant Neurologist
King Faisal Specialist Hospital & Research Center, Riyadh

Dr. Mohammed Al-Bar
Consultant, Islamic Medicine
King Abdul Aziz University - Jeddah

Dr. Nabil Biary
Consultant, Neurologist
Riyadh Military Hospital

Dr. Abdullah Turki
Consultant Pediatric Intensivist,
Director, Pediatric Critical Care Unit
King Faisal Specialist Hospital & Research Center, Riyadh

Dr. Mohammad Ibrahim Almajeed
Consultant Anesthesiologist,
King Khalid University Hospital – Riyadh

Dr. Awad Addasi
Consultant Intensivist,
Riyadh Military Hospital

Dr. Yasser Mandourah
Consultant Intensivist,
Head, Saudi Society of Critical Care
Head, Intensive Care Unit
Riyadh Military Hospital

Dr. Amin M. Yousef
Consultant Intensivist,
Deputy Head, Saudi Society of Critical Care
Head, Intensive Care Unit
King Saud Medical Complex, Riyadh

This statement is approved by the Saudi Society of Critical Care (SCCS):

Directory of the Regulations of Organ Transplantation in the Kingdom of Saudi Arabia
Bibliography


Directory of the Regulations of Organ Transplantation in the Kingdom of Saudi Arabia

ACKNOWLEDGEMENT OF PREVIOUS COMMITTEE (1992)

We would have been unable to bring out this document without the support of Dr. Abdul Rahman Al-Swailem, Deputy Minister for Executive Affairs, Ministry of Health and the co-operation of King Faisal Specialist Hospital and Research Center, Riyadh, represented by Dr. Osman Al-Furayh, Head of Kidney Transplant Unit. We would like also to acknowledge the efforts of Dr. T. Timothy Paul and Dr. Abdul Ghayoum Mohd. Saleh in compiling this document, Mr. M.A. Taher for typing and formatting the final manuscript and all other colleagues at the National Kidney Foundation for their valuable assistance and support.

Brain-Death Committee
National Kidney Foundation
Riyadh, Kingdom of Saudi Arabia

ACKNOWLEDGEMENT OF CURRENT COMMITTEE (2009)

We would like to acknowledge the SCOT secretarial help of Michael V. Abeleda, R.N, Johny E. Cillo, R.N, M.A. Taher, and Jaffer Adam in the preparation of the manuscript and all other colleagues at SCOT for their valuable assistance and support.

National Committee for Death Documentation
Saudi Center for Organ Transplantation
Riyadh, Kingdom of Saudi Arabia
**Death Documentation Form by Brain Function Criteria**

<table>
<thead>
<tr>
<th>Name:</th>
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<tr>
<td>Age:</td>
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<tr>
<td>Sex:</td>
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<td>Hospital:</td>
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<td>Date of Admission:</td>
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</table>

**FIRST EXAM**

<table>
<thead>
<tr>
<th>Name</th>
<th>Consultant A</th>
<th>Consultant B</th>
</tr>
</thead>
</table>

**I. PRECONDITIONS:**

1. It is absolutely certain that irredeemable brain damage has occurred due to ________
2. More than six hours have passed since the initial insult.
3. Coma with no spontaneous respiration.

**II. EXCLUSIONS:**

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).
4. Significant metabolic or endocrine causes of coma.

**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

<table>
<thead>
<tr>
<th>FIRST EXAM</th>
<th>Date/التاريخ</th>
<th>Time/الوقت</th>
<th>Name/الاسم</th>
<th>Signature/توقيع</th>
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<tbody>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consultant B</td>
<td></td>
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</tbody>
</table>

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

- EEG: Flat [ ]
- Absence of Brain circulation evidenced by either:
  - cerebral angiogram [ ]
  - radionuclide angiography [ ]
  - Transcranial doppler [ ]

<table>
<thead>
<tr>
<th>EEG</th>
<th>Flat [ ]</th>
<th>Date:</th>
<th>Signature</th>
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<tbody>
<tr>
<td>No Flow [ ]</td>
<td>Date:</td>
<td>Signature</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** Recommended time interval between first and second examinations in various age groups:

- Adults: minimum of 6 hours
- Children (above one year): 12 hours
- Infants (above 60 days): 24 hours
- Neonate (7 days – 60 days): 48 hours
- One EEG at end of first exam

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### Death Documentation Form by Brain Function Criteria

#### Preconditions:

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.

#### Exclusions:

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).


4. Significant metabolic or endocrine causes of coma.

#### Clinical Assessment:

1. 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

#### Apnea Test

(Body temperature ≥36.5°C) Performed as per Saudi Protocol and is compatible with death by brain function criteria.

### Consultations

<table>
<thead>
<tr>
<th>First Consultation</th>
<th>Second Consultation</th>
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<tbody>
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<td>Consultant A</td>
<td>Consultant B</td>
</tr>
</tbody>
</table>

### Completion

- **Date/التاريخ**: ____________________
- **Time/الوقت**: ____________________
- **Name/الاسم**: ____________________
- **Signature/توقيع**: ____________________

**Seal of the Hospital**

---

*Note: After completion of the Death Documentation form, please fax to Saudi Center for Organ Transplantation P.O. Box 27049, Riyadh 11417. K.S.A. Tel: 01 4451100 – Toll Free Phone: 8001245500, Fax: 01 4453934*
Appendix 10
Directory of Regulations of Organ Transplantation in the Kingdom of Saudi Arabia

Consent of Organ Donation

<table>
<thead>
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<th>Hospital File No.</th>
<th>SCOT File No.</th>
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Brain Death Information

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<th>Name:</th>
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The Person Authorized to Agree For Organ Donation

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<th>Relationship</th>
<th>Name</th>
<th>Remarks:</th>
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Address & Contacts No.

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<th>Telephone No.</th>
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</table>

I agree to donate the organs of my relative (who was confirmed brain dead by neurological criteria) to any suitable patients as deemed necessary.

I wish to transfer the body to: ________________________________

Remarks:

Signature: ________________________

The Witness: ________________________

<table>
<thead>
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<th>Identification No.</th>
<th>Relationship</th>
<th>Name</th>
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</table>

For Official Use

Signature: ________________________

Name: ________________________

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Appendix 11

Regulations and Procedures for Organ Donation from the Living Genetically Unrelated Donors

These regulations and procedures for organ donation from living genetically unrelated donors were developed after extensive review and discussion by the National Committee for Renal transplantation and after discussions involving experts in the field of biomedical ethics, Islamic medical ethics and transplantation ethics, representing all health care sectors in the Kingdom of Saudi Arabia, as well experts from abroad.

This Directory of Regulations is based on the best ethics of practice of live organ transplantation and taking special care of the physical and psychological well-being of the donor, it also outlines the responsibility of the transplant team performing live donation to ensure informed consent, donor autonomy and donor selection based on international consensus as set out by:

- The Vancouver forum of the care of the live organ donor, May 2006.
- The transplantation Society, Kuwait Meeting, December 2006.

The aims of these regulations and procedures are:

1. To prevent the practice of commercial transplantation
2. To protect the poorest and vulnerable groups from “transplant tourism”.
3. To extend the use of living organ donation in order to meet end stage organ failure patient needs, after applying a strict ethical and safety risks evaluation.
4. These regulations and procedures apply to all national and legal residents in Saudi Arabia, upon voluntary decision with informed consent in an autonomous manner (minors are not accepted as live donors).
5. Prior to organ donation (either directed or non-directed), the live donor must receive a complete medical and psychological evaluation, to be informed of the venture, results and consequences of the process.
6. The medical and psychological assessment and the decision to donate will be undertaken by health care professionals not involved in the care of the recipient.
The Procedures to be followed in Live Unrelated Organ Donation

1. Donors may present to the organ transplant centers authorized by the Saudi Center for Organ Transplantation (SCOT), (Index 1).

2. The transplantation team in the transplant center should make sure that primary screening and clinical evaluation of the prospective donor including laboratory investigations was performed. After passing the initial screening, the donor will be referred to the evaluation committee in the transplant center, (Index 2, 3).

3. An interview of the donor by the evaluation committee will be performed and documented on a pre-prepared form. A consent to donate should be signed by the donor, (Index 4, 5).

4. The interview document and the consent of the donor will be sent to the SCOT.

5. The SCOT will coordinate and ensure with the transplant team in the transplant center that complete the thorough medical evaluation of the donor has been done to ensure the safety and fitness of the donor for organ donation according to the Saudi Regulations for Organ Transplantation.

6. After satisfying the medical and psychological evaluation, the donor’s medical report will need to be approved by the SCOT. If satisfied, permission will then be granted by the SCOT to perform the operation.

7. Following this, the procedure will vary according to whether the donation is directed or non-directed.

   a. Directed donation: the potential recipient will be assessed for his suitability for transplantation and the donor’s suitability to donate him/her (including blood group compatibility and cross-matching (not necessary in liver transplantation).

   b. Non-directed donation: the transplant center will select the most suitable recipient from the waiting of the transplant center and its affiliated hospitals (according to the Saudi Regulations). The priority of patients on the waiting list is determined according to the preset scoring system.

8. This procedure will apply to all nationals as well as legal residents of at least one year, and to inform the embassies of their respective countries before the approval is given by the SCOT for donation.

9. No transplant operation will be performed without the written approval of the SCOT.

10. The written approval of the SCOT on the organ donation will be received at the transplant center before the performance of the transplant operation.

11. The SCOT will be informed by the transplant center upon completion of the transplant operation. A medical report will be submitted to the SCOT about the

Directory of the Regulations of Organ Transplantation in the Kingdom of Saudi Arabia
condition of both the donor and the recipient (index 6 and 7).

12. The SCOT will undertake the following:
   A) It will guarantee the follow up of the donor for life in the transplant center, evaluates and treats any complication that might arise due to the organ donation
   B) It will coordinate the issue of re-imbursement for the donor for absence from work due to surgery, in compliance with the decision of the council of ministers no. 235 dated 16/9/1427 H.
   C) It will coordinate the issuance of the King Abdul Aziz Medal of third degree to the donors
   D) It will ensure that the donors will be granted discount when traveling on Saudi Airlines.

13. The SCOT will issue periodic reports about the progress of the project to be submitted to the Minister of Health.

14. Any reported misconduct to the SCOT by any transplant center regarding the evaluation or management of the donors will be subjected to investigation and disciplinary action to ensure the application of the WHO recommendations related donor care.

15. The evaluation of the whole program activity including regulations, procedures, and outcome will be undertaken after completion of one year of the commencement of this related living un-related donor program.
Appendix 12

Benefits offered to Organ Failure Patients and Organ Donor

8.2 Benefits for organ failure patients.

1.1 The Royal Order No (70/3158/T) dated 30/3/1416 H based upon the proposal of the Council of Civil Services to grant employees with organ Failure leave with full paid salary for their dialysis days (based on the Medical Report issued by the treating Medical Center).

1.2 Approval of HRH the 2nd Deputy Prime Minister and Member of Defence and Aviation and Inspector General, as well as the Council of Ministers Resolution No (130) dated 09/04/1417H to consider the military patient with renal failure as medically unfit for military service and shall be treated in accordance with Article (15) of the military recruitment system and be paid (70%) of the last salary earned before retirement or on the basis of length of service, whichever is greater, and provided that the Higher Medical Committee does not recommend for those who are in advanced stage of renal failure and has exhausted (90) days of dialysis leave. Kidney donors will continue their work and be considered fit for military service and in case of deterioration of their health, they shall retire and will be paid (70%) of their last salary.

1.3 Saudi Arabian Airlines decision number PD /6/128, dated 11/14/1411 H granting renal failure patients (240) kilogram for free (drugs and solvents) on domestic and international flights that start from the Kingdom only.

1.4 Approval of the Ministry of Social Affairs to grant annual financial support to poor renal failure patients, an amount of (5000) Saudi Riyals.

1.5 Issuing identity card for patients with kidney failure and other organ failure to help them and facilitate their movements.

1.6 Approval of HRH the Second Deputy Prime Minister and Minister of Defense and Aviation and Inspector General to grant patients who got transplanted organs discounted tickets on Saudi Arabian Airlines of (25%) on domestic flights, three tickets annually, for a period of two years, renewable for a third year only.

8.2 Benefits for organ donors.

1.1 Royal Order No.(1489/), dated 07/05/1410 H granting The King Abdul Aziz Medal of the third degree for organ donors of heart, liver, kidneys and bone marrow.

1.2 The Royal Order No (195) of Date 01/08/1422 H based on the recommendations of the committee formed at the Ministry of Health to study
cases of renal failure and the length of waiting lists for kidney transplants within the Kingdom, recommended to increase the incentive given to relatives of deceased donors to (50,000) Fifty Riyals, which was approved by the Council of Ministers resolution No. (61) dated 09/06/1414 H.

1.3 Card authorizing discount on Saudi Arabian Airlines tickets by 50% for donors of kidney or part of the liver, and their relatives.

1.4 Issuing a card (ID) for organ donors to help them and facilitate their travel and other movements.
Appendix 13

General Regulations for Organ Donation after Cardiac/circulatory Arrest

1. Donation after cardiac death (DCD) has been accepted by the SCOT as an ethically and medically acceptable option for organ donation.

2. The decision to withdraw mechanical ventilation and hemodynamic support should be made prior to, and independent of, any discussion of organ and tissue donation.

3. The SCOT, transplant centers, and donor hospitals should develop written protocols to address systems and mechanisms for the type of organ recovery based on Islamic Fatwas, ethical and legal regulations.

4. The decision to donate organs requires the informed consent from the next of kin and the same procedures and regulations practiced after brain death or living donation should be followed.

5. Classification and practice of DCD:

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Type of DCD</th>
<th>Location practiced</th>
</tr>
</thead>
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<tr>
<td>I</td>
<td>Dead on arrival</td>
<td>Uncontrolled</td>
<td>ED in a transplant center</td>
</tr>
<tr>
<td>II</td>
<td>Unsuccessful resuscitation</td>
<td>Uncontrolled</td>
<td>ED in a transplant center</td>
</tr>
<tr>
<td>III</td>
<td>Anticipated cardiac arrest</td>
<td>Controlled</td>
<td>ICU and ED</td>
</tr>
<tr>
<td>IV</td>
<td>Cardiac arrest in a brain dead donor</td>
<td>Controlled</td>
<td>ICU and ED</td>
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<tr>
<td>V</td>
<td>Unexpected arrest in ICU patient</td>
<td>Uncontrolled</td>
<td>ICU in transplant center</td>
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</tbody>
</table>

ICU: Intensive Care Unit, ED: Emergency Department

6. The critical pathways for DCD and DBD are to be adopted as per the recommendations of the World Health organization and the Transplantation Society (TTS), published in Transplant International 2011;24:373-378.
Appendix 14

Harvesting Procedure and Guidelines

Steps in multiple organ recovery recommended by the SCOT.

1. The heart and great vessels are exposed through an extended sternotomy incision and examined by inspection and palpation (this is done by the cardiac surgeons). The liver is inspected and palpated. Then, mobilization of the liver begins and attention is turned to the distal aorta. The entire right colon and small bowel mesentery are mobilized by dividing the retroperitoneal attachments and the intestines are swept up (attention directed towards great vessels, hepatoduodenal ligament and peritoneum).

2. Then the liver surgeons perform a midline incision from the suprasternal notch to the symphysis pubis – a midline sternal splitting is performed. Afterwards, they complete the dissection and catheterize the aorta in the lower abdomen for later perfusion with cold fluid.

3. Cardiac surgeons will then dissect the heart and the donor is heparinized. The aorta is ligated distally and cannulated for cold perfusion. If there is a thoracic team, both teams coordinate the cardiopulmonary arrest and the supraceliac aorta is clamped, then the veno caval decompression is performed.

4. Liver team will perfuse the already catheterized aorta in the lower abdomen synchronized with clamping of the aorta. Ligation is done by cardiac and hepatic teams at the same time together with perfusion.

5. The heart and lung are removed first.

6. Liver and pancreas recovery are then completed.

7. Kidney procurement is then performed.

8. Samples to be collected by the harvesting team:

   Collect blood, lymph, spleen and urine samples for 3 prospective recipient hospitals.

   8.1 Blood:

      Blood Cultures’ × 1 set (Aerobic and Anaerobic samples).

      5 Red top (10 ml volume clotted blood sample) specimens.
8.2 **Urine:**

1 Urine sample (60-80 mLs) in a sterile container for each transplant centers.

8.3 **Lymph nodes:**

Collect 15-20 lymph nodes for each hospital and store then in a sterile container with RPIM 1640 solution. Do not use saline as a storage medium.

8.4 **Spleen:**

The entire spleen should be taken if possible and divided into 3 segments (one segment for each recipient hospital).

Store in a sterile container with RPIM 1640 solution.

8.5 **Other samples:**

8.5.1 Sputum sample

8.5.2 Wound Swab when applicable.

All specimens should be stored in sterile containers, with tight fitting lids and labeled with the donor name, date and time when specimen was obtained.

9. **Packing and storing and grafts:**

9.1 The grafts must be packed and stored using only sterile equipment and strict aseptic technique.

9.2 The grafts should be stored in cold sterile fluids in plastic bags and not placed directly on ice. A hard plastic containers should be used to store the grafts for extra protection.

10. **Documentation:**

Record the following details and forward to the recipient hospital.

10.1 **Donor details:**

Name, age, sex, nationality, date of admission, diagnosis, date and time of brain death should be recorded. A copy of the completed brain death form and the death certificate should be sent to each prospective hospital.

10.2 **Vital signs:**

10.2.1 **Blood pressure readings:** Immediately pre-op, lowest recording and
duration, and highest record and duration.

10.2.1 **Blood pressure readings:** Immediately pre-op, lowest recording and duration, and highest record and duration.

10.2.2 **Central venous pressure readings:** Highest and lowest readings.

10.2.3 **Temperature:** Highest and lowest recordings and method of measurement (oral, axilla, or rectal).

10.2.4 **Fluid Balance:** Input and output for the last 24 hours, lowest output and duration, and weight and height.

10.3 **Blood values** including:

Blood group, latest biochemistry results, and any relevant microbiology results.

10.4 **Medications:** List the dose and frequency of any vasopressors used.

10.5 **Operation details:**

- Harvesting date.
- Harvesting surgeon and hospital.
- Indicate the harvested organ.
- Aorta clamp time.
- Perfusion start time.
- Type of perfusion.
- Type of perfusion fluid used and the volume.
- Description of perfusion flow.
- List number of arteries, veins with or without patch for the organ.
- Recipient hospitals for each organ.
- Include any other details/comments, which may be useful to the recipient hospital.
Appendix 15

Investigations to be done for ESRD before Kidney Transplantation* (non-diabetic patient)

1. CBC, ESR, complete biochemistry, blood glucose.
2. Mid-stream and terminal-stream urine analysis for bacterial and parasitic infection.
3. Early morning mid-stream urine for AFB.
4. Hepatitis screen, liver function tests, PT, PTT.
5. ECG, chest X-ray, tuberculin skin test.
6. CMV, HIV, malaria, bilharzia, and sickle cell screen.
7. Abdominal ultrasound, micturating urethrogram.
8. Blood group, HLA type, cytotoxic antibodies.
Appendix 16

Investigations to be done for ESRD Patients before Kidney Transplantation (diabetic patients)

1. All investigations mentioned in appendix 15
2. Echocardiogram
3. Stress test
4. Coronary angiography
5. Doppler study of pelvic and neck vessels
Appendix 17

Investigations to be done for Living Kidney Donors

1. All routine blood tests
2. Complete renal function tests
3. Urine analysis and culture and sensitivity
4. 24-Hour urine protein and creatinine concentration
5. Urine for schistosomal ova
6. IVP
7. Renal angiogram
8. Liver function tests
9. Hepatitis screen
10. HIV antibody screening
11. CMV antibody screening
12. VDRL
13. Malaria screen, brucella titer, schistosoma titer
14. Sickle cell screen
15. Stool analysis for bilharzia ova and other parasites
16. ECG, chest X-ray, and tuberculin skin test
17. Abdominal ultrasound
18. Blood group, HLA typing, crossmatching
Appendix 18

Investigations to be done in a Potential Recipient for Cardiac Transplantation

1. CBC, complete biochemistry, ESR, blood glucose.
2. Complete renal function tests.
3. Complete liver function tests.
4. Coagulation factor tests.
5. Serum protein electrophoresis and immunoglobulin assay.
6. Urine analysis and urine culture.
7. Swabs from nose, throat, axilla, and perineum.
8. Stool culture and examination for parasites.
9. Mycoplasma, Q-fever, legionella, respiratory syncitial virus, varicella zoster, para-influenza, toxoplasma, CMV and HIV antibodies and syphilis serology.
11. Tuberculin skin test and sputum culture.
13. Pulmonary function tests, arterial blood gases, chest X-ray and perfusion ventilation scan of lung.
15. 12-lead ECG, bi-dimensional echocardiography, cardiac catheterization, coronary angiogram and endomyocardial biopsy.
17. Pulmonologist consultation.
18. Infectious diseases consultation.
Appendix 19

Investigations to be done in a Potential Recipient for Lung Transplantation

1. CBC, complete biochemistry, ESR, blood glucose.
2. Complete renal function tests.
3. Complete liver function tests.
4. Coagulation factor tests.
5. Serum protein electrophoresis and immunoglobulin assay.
8. 12-lead ECG, bi-dimensional echocardiogram and Doppler ultrasound to estimate the pulmonary artery and right and left carotid artery pressures, and coronary angiogram, if suggested by symptoms, or if the patient is over 40 years of age.
10. Mycoplasma, Q-fever, legionella, respiratory sincytial virus, varicella zoster, para-influenza, toxoplasma, CMV and HIV antibodies and syphilis serology.
11. Tuberculin skin test and sputum culture for organisms including aspergillus.*
12. Urinalysis and urine culture.
14. Pulmonary function tests, arterial blood gases, X-ray chest, perfusion-ventilation lung scan and CT scan of the chest.
15. Six minutes walk, with oxygen if needed, and under observation by oxymetry.
16. To perform a medical check-up including dental consultation, ENT consultation, gynecological assessment for females, psychological analysis and nutritional assessment.
17. To keep 10 mL of patients blood to perform cross-matching when needed.

*Three sputum samples should be sent for mycobacterial culture in patients with old tuberculosis or positive tuberculin skin test.
Appendix 20

Investigations to be done in a Potential Recipient for Liver Transplantation

1. All investigations in appendix 15 except micturating urethrogram.

2. Serum iron, total iron binding capacity, total protein and albumin.

3. Complete liver function tests.

4. Hepatitis screen.

5. Arterial blood gases and pH and lung function tests.

6. EBV antibody titer, HIV antibody, CMV antibody titer, VDRL, sickle screen, schistosoma titer.

7. Sputum and early morning urine for AFB.

8. Stool for ova, parasite and culture.

9. Gastroscopy, colonoscopy (if patient is >45 yrs), CT scan abdomen.

10. ENT, ophthalmology and dental examination.

11. PAP smear (females above 45 yrs), gynecological examination (for married women).

12. Psychological evaluation.

13. Varicella titre and immunization profile (for children).
Appendix 21

Investigations to be Done in a Potential Recipient for Pancreas Transplantation

*All investigations related to kidney transplantation in appendix 15 and 16.
Appendix 22

Investigations to be done in a Potential Recipient for Corneal Transplantation

1. Complete eye examination with evaluation of visual acuity to ensure that the loss of vision is caused by a corneal disease.

2. Bacterial, viral, parasitic and fungal studies for perforating corneal lesions, especially if it is suspected to be associated with infection.

3. Complete routine blood investigations.


5. Chest x-ray and ECG.
Goals of Deceased Donor Maintenance

- Prevent hypoxia
- Prevent infection
- Maintain systolic BP >100 mm Hg
- Prevent acidosis & electrolyte disturbances
- Carry out investigations
- Maintain normal temperature

Systolic BP <100 mm Hg

- CVP <12 cm H₂O
  - Volume expansion (fluids, albumin, etc.) till CVP = 12 cm H₂O

- CVP ≥12 cm H₂O
  - HBs Ag, HIV, Blood culture, Blood group, and Rh.

SBP >100 mm Hg

- Urinary output < 50 mL/hr in two consecutive hours
  - Furosemide

SBP <100 mm Hg

- Urinary output 1.5 to 3 mL/kg/hr
  - Volume by volume replacement

- Diabetes insipidus
  - Fluids & pitressin as needed

Vasopressors

- Dopamine
- Dopamine + Epinephrine
- Dopamine + Dobutamine
- Vasopressin + Epinephrine

- Once only (obligatory)
  - HBs Ag, HIV, Blood culture, Blood group, and Rh.

- Once only (if available)
  - Titers for HCV, CMV, EBV, HTLV, HSV, VDRL, Brucella and Toxoplasma.

- Daily (as needed)
  - CBC, LFT, PT, PTT, Blood glucose, Chest X-ray, Blood culture, Urine analysis, Urine culture, Wound culture

- Four hourly (as needed)
  - Urea, Creatinine, Electrolytes, ABG.