المركـــز الســـعودي لزراعـــة الأعضـــاء
Saudi Center for Organ Transplantation

3rd Edition
2024

Directory of Organ Donation and Transplantation Procedures

in the Kingdom of Saudi Arabia

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رؤيـــة VISION 2030
المملكة العربية السعودية
KINGDOM OF SAUDI ARABIA

المركـــز الســـعودي لزراعـــة الأعضـــاء

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In The Name of Allah
The Most Gracious
The Most Merciful

Introduction

The Saudi Center for Organ Transplantation is pleased to present this comprehensive guide to the regulations governing organ donation and transplantation within the Kingdom of Saudi Arabia. This scientific and instructional work is the result of the collaborative efforts of distinguished colleagues from the scientific committees of organ transplantation programs and the Supreme Medical Committee. They have adhered to the highest international standards in the field of organ donation and transplantation, ensuring full alignment with Islamic principles, ethical guidelines, and relevant official orders and decrees, including Royal Decree No. (M/70) dated April 1, 2021, and Ministerial Resolution No. (4-29425) dated September 28, 2021, which clarifies the relevant executive bylaw (refer to Appendix A).

This guide represents the updated version of the first edition, originally published in 1414H, and has been developed to reflect regulatory changes and scientific advancements in the field of organ donation and transplantation. It features substantial updates to policies and procedures, notably the new regulatory frameworks governing the relationship between the Saudi Center for Organ Transplantation, donor hospitals, regional coordination offices, and transplantation programs.

The guide stands as a testament to the significant progress achieved in the field of organ transplantation in the Kingdom, highlighting the quality and efficiency of care provided to patients suffering from end-stage organ failure. It systematically addresses the various aspects of organ donation and transplantation processes, including procedures for living and deceased donors, tissue compatibility testing, the establishment of the national platform “Athar” for tracking donations and transplantations, standards for program accreditation and compliance assurance, as well as related legal and administrative aspects.

We extend our sincere thanks and appreciation to the members of the Supreme Committee and to all participants involved in the preparation and updating of this guide for their scientific and professional efforts, which have contributed to producing such a comprehensive reference.
We are confident that this guide will serve as an important reference for healthcare practitioners, healthcare institutions, and decision makers in the field of organ donation and transplantation, thereby enhancing development efforts, contributing to saving lives, and achieving excellence both locally and globally.

Acknowledgment

The Saudi Center for Organ Transplantation extends its sincere thanks and deep appreciation to the Supreme Committee, chaired by His Excellency Dr. Talal Algoufi, Director General, for their continuous support and valuable contributions, which have had a significant impact on the development of this guide.

We also express our profound gratitude to all colleagues from the relevant departments and entities who contributed their expertise and sincere efforts to the preparation of this work.

Their constructive collaboration and professional commitment played a fundamental role in producing this guide in a manner that reflects the level of advancement achieved by the Kingdom of Saudi Arabia in the field of organ donation and transplantation.

We pray that Allah blesses everyone›s efforts, accepts this work sincerely for His sake, and makes it a source of benefit in serving patients and supporting the Center’s humanitarian mission.

Members of the Higher Medical Committee

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التاريخ: ١٤٤٢/٨/١٩هـ

بعون الله تعالى

نحن سلمان بن عبدالعزيز آل سعود

ملك المملكة العربية السعودية

بناءً على المادة (السبعين) من النظام الأساسي للحكم، الصادر بالأمر الملكي رقم (أ/٩٠) بتاريخ ١٤١٢/٨/٢٧هـ.

وبناءً على المادة (العشرين) من نظام مجلس الوزراء، الصادر بالأمر الملكي رقم (أ/١٣) بتاريخ ١٤١٤/٣/٣هـ.

وبناءً على المادة (الثامنة عشرة) من نظام مجلس الشورى، الصادر بالأمر الملكي رقم (أ/٩١) بتاريخ ١٤١٢/٨/٢٧هـ.

وبعد الاطلاع على قراري مجلس الشورى رقم (٥٤/٢١٥) بتاريخ ١٤٤١/١/١٧هـ، ورقم (٤/٢٤) بتاريخ ١٤٤٢/٤/١٥هـ.

وبعد الاطلاع على قرار مجلس الوزراء رقم (٤٦٨) بتاريخ ١٤٤٢/٨/١٧هـ.

رسمنا بما هو آت:

أولاً : الموافقة على نظام التبرع بالأعضاء البشرية، بالصيغة المرافقة.

ثانياً : على سمو نائب رئيس مجلس الوزراء والوزراء ورؤساء الأجهزة المعنية المستقلة - كل فيما يخصُّه - تنفيذ مرسومنا هذا.

سلمان بن عبدالعزيز آل سعود

نظام التبرع بالأعضاء البشرية ولائحته التنفيذية

المادة الرابعة عشرة:

تُكوَّن بقرار من الرئيس -بناءً على اقتراح المدير العام- لجنة طبية عليا من جميع القطاعات الصحية لا تقل درجة العضو فيها عن طبيب استشاري، تتولى إعداد دليل متكامل يتضمن جميع الشروط والضوابط الصحية والمعايير المعتمدة دوليًا لزراعة الأعضاء البشرية، وتحديثه من وقت إلى آخر، بما لا يتعارض مع أحكام الشريعة الإسلامية والنظام واللائحة. ويُعمل بهذا الدليل بعد اعتماده من الرئيس.

قرار وزاري

إن وزير الصحة رئيس المجلس الصحي السعودي

بناءً على الصلاحيات المخولة له

وبناءً على المادة الرابعة عشرة من نظام التبرع بالأعضاء البشرية الصادر بالمرسوم الملكي رقم(م/٧٠) بتاريخ ١٤٤٢/٨/١٩هـ والتي نصت على: "تكون بقرار من الرئيس – بناءً على اقتراح المدير العام – لجنة طبية عليا من جميع القطاعات الصحية لا تقل درجة العضو فيها عن طبيب استشاري، تتولى إعداد دليل متكامل يتضمن جميع الشروط والضوابط الصحية والمعايير المعتمدة دولياً لزراعة الأعضاء البشرية، وتحديثه من وقت إلى آخر، بما لا يتعارض مع أحكام الشريعة الإسلامية واللائحة، ويعمل بهذا الدليل بعد اعتماده من الرئيس"، وبعد الاطلاع على خطاب مدير عام المركز السعودي لزراعة الأعضاء رقم ٣٥٠١-٤٣-٠٠١١٤٢ وتاريخ ١٤٤٣/١٠/١٤ هـ المتضمن مقترح تشكيل اللجنة المشار إليها أعلاه والمشتمل على الترشيحات الواردة من القطاعات الصحية.

وبناءً على ما تقتضيه المصلحة العامة.

يقرر ما يلي:

أولاً: تشكيل اللجنة الطبية العليا لإعداد الدليل المتكامل لزراعة الأعضاء البشرية على النحو التالي:

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٣- د. حمد بن محمد الباهلي	مدينة الأمير سلطان الطبية العسكرية	عضواً
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٧- د.عبد الله بن محمد العريني	جامعة الملك سعود	عضواً
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ثانياً: تتولى اللجنة إعداد دليل متكامل يتضمن جميع الشروط والضوابط الصحية والمعايير المعتمدة دولياً لزراعة الأعضاء البشرية.

ثالثاً: يعامل أعضاء اللجنة من النواحي المالية حسب تنظيم ولوائح المركز السعودي لزراعة الاعضاء.

رابعاً: يسري هذا القرار اعتباراً من تاريخ صدوره ويبلغ لمن يلزم لإنفاذه.

خامساً: أصل القرار للمركز السعودي لزراعة الأعضاء وصورة لأعضاء اللجنة.

والله الموفق

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قرار

إن وزير الصحة رئيس المجلس الصحي السعودي

بناءً على الصلاحيات المخولة له نظاماً، واستناداً على المادة الرابعة عشرة من نظام التبرع بالأعضاء البشرية الصادر بالمرسوم الملكي رقم (م/٧٠) وتاريخ ١٤٤٢/٠٨/١٩هـ ولائحته التنفيذية، وبعد الاطلاع على قرارنا رقم ١٤-٣٦٨٩٨ وتاريخ ١٤٤٥/٠٥/٠٧هـ والمتضمن استمرار العمل بدليل زراعة الأعضاء في المملكة المحدث الصادر بقرارنا رقم ١/١٥٤٢١٩ وتاريخ ١٤٣٤/٠٥/٠٦هـ.

يُقرر ما يلي:

أولاً: اعتماد دليل إجراءات التبرع وزراعة الأعضاء في المملكة العربية السعودية بالصيغة المرفقة بهذا القرار.

ثانياً: يلغي هذا الدليل الادلة والتعاميم السابقة الصادرة في موضوعه بقرارنا رقم ١٤-٣٦٨٩٨ وتاريخ ١٤٤٥/٠٥/٠٧هـ، وقرارنا رقم ١/١٥٤٢١٩ وتاريخ ١٤٣٤/٠٥/٠٦هـ.

ثالثاً: يسري الدليل على كافة المنشآت الصحية العامة والخاصة.

رابعاً: على المركز السعودي لزراعة الأعضاء تنفيذه ومتابعة العمل بموجبه.

والله الموفق.

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Directory Overview

CHAPTER 01

Chapter 1 Directory Overview

The Directory at the Glance

The organ donation and transplantation process is a complex, multifaceted system that requires coordination among numerous stakeholders, including donor hospitals, transplant programs, regulatory bodies, and healthcare professionals. This directory and procedures aims to establish standardized procedures, guidelines, and best practices that govern the entire organ donation process, ensuring operational efficiency, safety, and ethical management of organ transplantation. This chapter serves as a comprehensive introduction to the directory, outlining its purpose, structure, and practical guidance on how to read the document effectively.

Purpose of the Directory

The significance of the directory extends beyond its immediate role as a resource; it has been meticulously developed to foster substantial improvements in patient outcomes and overall health. The easy-to-follow procedures in the directory enhance the efficiency of implementing the regulations of organ transplantation, leading to better outcomes for recipients. It also reinforces ethical compliance, promoting transparency and fairness in organ allocation. Additionally, the directory helps healthcare facilities maintain legal adherence to the national regulations of organ donation and transplantation.

The primary purpose of the directory is to provide a centralized resource for all stakeholders involved in the organ donation and transplantation process. It serves several key functions:

- **Governance:** The directory serves as a translation of the human organ donation regulation and executive bylaw, ensuring that all stakeholders can easily understand and implement the national regulations of organ donation and transplantation.
- **Standardization:** The directory provides clear and consistent procedures to govern the donation and transplantation processes to minimize variability in practices across different healthcare facilities, promoting uniformity and quality in organ donation and transplantation.
- **Guidance:** The directory offers detailed guidelines on all aspects of the organ donation and transplantation processes, from donor identification and evaluation to surgical recovery and post-transplant care. This guidance is essential for ensuring compliance with regulations and best practices.
- **Education:** The directory acts as an educational tool for healthcare professionals, offering insights into the ethical, legal, and clinical considerations associated with organ donation and transplantation.
- **Compliance and Quality Improvement:** The directory helps stakeholders uphold compliance with national regulations and reinforces quality improvements across all stages of organ donation and transplantation, ensuring continuous improvement and accountability in these processes.

Structure of the Directory

The directory is organized into four (4) chapters, each addressing specific aspects of the organ donation and transplantation process. The structure includes:

Chapter 1: Directory Overview

The Directory Overview chapter serves as a critical introduction to the framework of organ donation and transplantation practices. It highlights that the directory is more than just a compilation of regulations and procedures; it is a living document designed to enhance the understanding and implementation of the human organ donation framework. Also, the chapter provides insights on how to navigate the directory effectively.

Chapter 2: Organ Donation

The Organ Donation chapter details the foundational elements of the organ donation process, focusing on both deceased and living donors. It begins by addressing the regulations that govern organ donation from deceased donors and outlining also the criteria for living organ donation. The chapter provides a comprehensive view of procedures, requirements, and ethical considerations that define organ donation. It includes three sections:

- **Section 2A: Organ Donation from Deceased Donors**
    - General regulations on donations from deceased donors
    - Regulations for donor hospitals
    - Procedure for organ donation after brain death (DBD)
    - Procedure for management of deceased donors
    - Procedure for donor validity
    - Procedure for organ allocation
    - Procedure for organ and tissue procurement
    - Donation after cardiac death (DCD)
- **Section 2B: Organ Donation from Living Donors**
- **Section 2C: Histocompatibility Testing**

Chapter 3: The unified Organ Donation and Transplantation Platform (Athar)

The unified Platform (Athar) chapter presents an exploration of how the system is designed to streamline and enhance the organ donation and transplantation process in Saudi Arabia. Athar serves as a centralized platform that integrates various stakeholders, including donor hospitals, transplant programs, and dialysis centers, facilitating real-time data management to improve the efficiency of organ donation and transplantation efforts. The chapter also discusses important governance topics, including data sharing and scientific collaboration, digital integration and real-time access, and the downtime procedure of Athar.

Chapter 4: Accreditation and Compliance

The final chapter, Accreditation and Compliance, examines the standards that govern the accreditation of donor hospitals and transplant programs. The chapter provides a comprehensive overview of the accreditation process, including eligibility criteria, the scope of accreditation, and the roles of accreditation assessment teams. A key focus of this chapter will be the procedure of how to maintain compliance with accreditation standards and regulations, as well as, the consequences in case of violating the regulations. The chapter includes:

- **Section 4A: Accreditation of Donor Hospitals**
- **Section 4B: Accreditation of Transplant Hospitals**
- **Section 4C: Compliance of Donor and Transplant Hospitals**
- **Section 4D: Implications of Violating Organ Donation Regulation**

Appendices

The appendices of the directory provide essential resources that complement the guidelines and procedures outlined throughout the document. They feature the national protocol for diagnosis of death by neurological criteria (DNC), along with detailed guidelines on assessing the risk of cancer transmission. Additionally, the appendices include SCOT forms intended for use by donor hospitals and transplant programs, particularly during downtime. They also encompass the standards for donor hospitals, which serve as helpful guides for donor hospitals to ease the implementation of the organ donation process.

Organ Donation

CHAPTER 02

Chapter 2 Organ Donation

Introduction

Organ donation, whether from deceased or living donors, plays a critical role in providing vital organs to patients in need. In Saudi Arabia, organ donation is governed by a comprehensive set of legal, ethical, and procedural frameworks designed to ensure that donations are conducted in an impartial, respectful, and medically sound manner, in accordance with Islamic principles and ethical standards. The process of organ donation, particularly from deceased individuals, requires careful coordination between the families of potential donors, potential recipients, and healthcare facilities.

For deceased organ donation, there is a set of regulations and procedures to ensure adherence to ethical practices and international standards, including the detection of possible donors, donor assessment, donor management, organ evaluation, and organ allocation to guarantee impartial and effective transplant outcomes. In this, hospitals that participate in the donation process must be equipped with the necessary structures and meet specific criteria to ensure they can diagnose and manage brain-dead patients in a manner that upholds the highest standards of medical care.

Living donation is another crucial aspect of the SCOT donation framework. Living donors undergo rigorous medical and psychosocial evaluations to ensure that they are healthy and fully prepared for the donation process. The ethical considerations surrounding living donations are significant, as donors must be protected from coercion or undue pressure. SCOT rules aim to prevent unethical practices and ensure that donations, whether related, unrelated, or paired exchange, are conducted within SCOT-licensed facilities.

The Regional Coordination Offices (RCO) work under SCOT to promote organ donation and manage all operational aspects of donor hospitals assigned by SCOT. Their responsibilities include daily communication with the Organ Donation Units (ODU) in hospitals, identifying and tracking potential donor cases, coordinating with donor families, and handling necessary procedures post-organ recovery. Additionally, RCOs play a key role in educating healthcare professionals and the public on organ donation through seminars and workshops, reporting their activities regularly to SCOT.

This chapter provides a comprehensive view of procedures, requirements, and ethical considerations that define organ donation in Saudi Arabia. The chapter includes:

- **Section 2A: Organ Donation from Deceased Donors**
    - General regulations on donations from deceased donors
    - Regulations for donor hospitals
    - Procedure for organ donation after brain death (DBD)
    - Procedure for management of deceased donors
    - Procedure for donor validity
    - Procedure for organ allocation
    - Procedure for organ and tissue procurement
    - Donation after cardiac death (DCD)
- **Section 2B: Organ Donation from Living Donors**
- **Section 2C: Histocompatibility Testing**

Section 2A Organ Donation from Deceased Donors

The regulations and procedures, for organ donation from deceased donors, are established in alignment with the best ethical practices as outlined in the human organ donation regulation and executive bylaw. These regulations and procedures were developed following an extensive review by relevant specialized committees at SCOT, in collaboration with national experts in organ transplantation and related medical fields. Further, the regulations are informed by international policies, including the European Directorate for the Quality of Medicines and HealthCare (EDQM), Organ Procurement and Transplantation Network (OPTN), Health Resources and Services Administration (HRSA), and Transplant Procurement Management (TPM) – Donation and Transplantation Institute (DTI) Foundation. The primary goal of these regulations is to enhance the efficiency and effectiveness of the deceased donation process, thereby improving transplant recipient outcomes.

This section includes regulations and procedures on the following:

2.1 General regulations on donations from deceased donors
2.2 Regulations for donor hospitals
2.3 Procedure for organ donation after brain death (DBD)
2.4 Procedure for management of deceased donors
2.5 Procedure for donor validity
2.6 Procedure for organ allocation
2.7 Procedure for organ and tissue procurement
2.8 Donation after cardiac death (DCD)

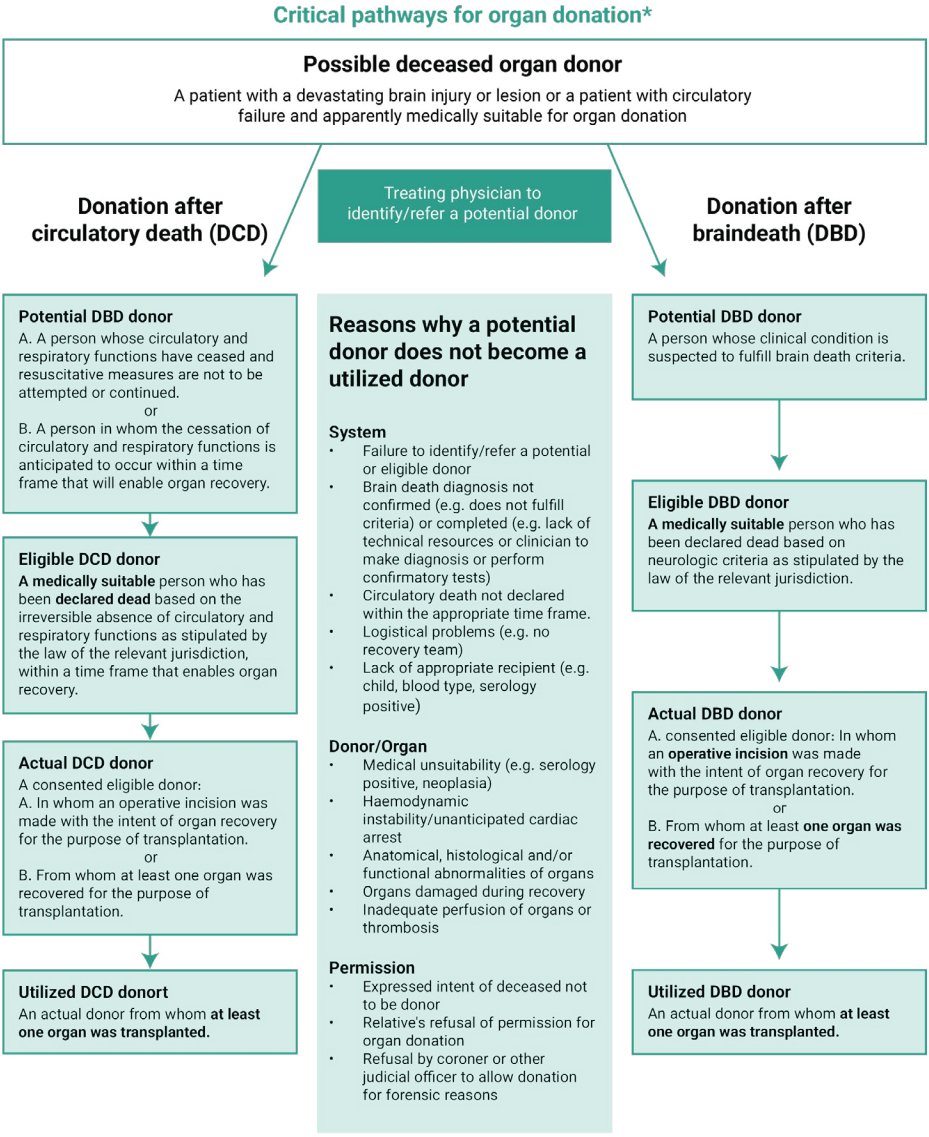


Figure 2.1 The World Health Organization Critical Pathways for Organ Donation.

Adopted from Domínguez-Gil B, et al. The critical pathway for deceased donation: re¬portable uniformity in the approach to deceased donation. Transpl Int 2011, 24(4), 373–8. Copyright © 2011 European Society for Organ Transplantation.

2.1 General Regulations on Donations from Deceased Donors

2.1.1 The critical pathways for donation after Death by Neurological Criteria (DNC) and donation after cardiac death (DCD) are to be adopted as per the recommendations of the World Health Organization and the Transplantation Society (see Figure 2.1).

2.1.2 SCOT encourages early identification of DNC patients, aggressive donor management (ADM), and organ protective therapy to maintain the organ viability of possible deceased donors.

2.1.3 SCOT retains the ultimate responsibility of determining the validity of the organ from the deceased donor that is intended for transplantation.

2.1.4 SCOT is solely responsible for matching donated organs with candidates needing transplants using the organ allocation framework.

2.1.5 SCOT ensures equity in the allocation of organs, without discrimination. All patients with comparable clinical profiles on the waiting list should have an equal probability of receiving organs from deceased donors, with respect to the allocation attributes.

2.1.6 Tissue donation after death has been accepted ethically and medically, including cornea, bone, heart for valves (HFV), vessels, musculoskeletal (MSK) tendons, and skin.

2.1.7 SCOT has accepted donation after cardiac death (DCD) as an ethically and medically acceptable option for organ donation (refer to section 2.8).

2.1.8 The decision to donate organs or tissue after DNC or DCD requires informed consent from the next of kin.

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

2.1.10 Any misconduct related to organ donation will be subject to investigation and disciplinary action, in accordance with the human organ donation regulations and executive bylaws.

2.2 Regulations for Donor Hospitals

2.2.1 Health facilities that meet the following Minimum Criteria are recognized as donor hospitals:

2.2.1.1 Intensivist and/or anesthesiologist and/or emergency physician,

2.2.1.2 Neurologist and/or neurosurgeon, or access to neurological/neurosurgical consultation,

2.2.1.3 Availability of or access to diagnostic tools for death confirmation by neurological criteria, such as CT angiography, perfusion scan, electroencephalogram, transcranial Doppler ultrasound…etc.

2.2.2 Relevant committees in SCOT will review (i.e. virtually or physically) the availability of the minimum criteria for donor hospitals annually. An updated list of donor hospitals will be published annually through official channels, with frequent updates as needed when changes occur.

2.2.3 Donor hospitals are required to:

2.2.3.1 Comply with human organ donation regulations and executive bylaws. Misconduct in applying regulations is subject to investigation and disciplinary action as per the bylaw.

2.2.3.2 Adhere to approved practices for deceased donor identification, reporting, diagnosis, and management, as specified by SCOT (Form 1: Donor Hospital Census).

2.2.3.3 Establish a set of key performance indicators (KPIs) to monitor their performance in organ donation processes (see Table 2.1).

2.2.3.4 Establish an organ donation unit (ODU), which is a functional unit responsible for reporting and handling patients with possible death by neurological criteria (DNC).

2.2.3.5 Establish a set of policies and procedures that regulate deceased organ donation processes. Policies shall address the following areas:

2.2.3.5.1 The roles of ODU members, the training required by staff on death by neurological criteria, and the process of referring patients to the ODU.

2.2.3.5.2 The process of establishing active (i.e. daily ICU rounds by the ODU team) and passive (i.e. 24/7 referral to ODU) detection of possible donors.

2.2.3.5.3 Following the national protocol for diagnosis of death by neurological criteria, while avoiding unnecessary delays.

2.2.3.5.4 The process of initiating donor management protocol, donor assessment, and communication with SCOT once a possible organ donor is identified.

2.2.3.5.5 The process for obtaining and documenting family consent, including necessary tests for donor evaluation (e.g. cardiac catheterization, bronchoscopy, radiology, etc.).

2.2.3.5.6 The process of preparing the operating room for organ procurement once SCOT allocates organs.

2.2.3.5.7 The process of conducting regular audits to identify missed opportunities and implement a quality improvement plan with a clear reporting system.

2.2.4 Organ Donation Unit (ODU)

ODU is an in-hospital team dedicated to coordinating all aspects of deceased organ donation within the hospital and its community. Although it is not mandatory to have a physical unit (i.e. structured stand-alone unit), the unit should be available functionally to oversee and manage the provision of deceased organ donation services.

ORGAN DONATION UNIT (ODU)

The establishment of ODU is a globally recognized standard practice, gearing up healthcare systems to ensure the consistent, ethical, and efficient management of organ donation and transplantation processes worldwide.

2.2.4.1 **The Composition of ODU**

2.2.4.1.1 **ODU leader**: an intensive care, emergency, anesthesia, or neurology physician is assigned to lead the ODU and oversees the entire organ donation process based on the level of the hospital (see Table 2.2), preferably someone who has experience in diagnosing and dealing with brain deaths.

2.2.4.1.2 **ODU coordinator**: a coordinator(s) is assigned to coordinate ODU activities with involved stakeholders and manage the operational aspects of organ donation. The coordinator might be a physician, nurse, or technician.

2.2.4.1.3 **ODU members**: a multidisciplinary team responsible for carrying out the organ donation process from identifying possible donors to ensuring the successful procurement and preservation of organs. In the team, a social/psychological specialist is assigned as a member to deal with the relatives of the brain-dead donor and obtain approval for organ donation. Also, depending on the resources available, the team could be strengthened by adding an administrative or religious scholar. It is recommended that the composition of the ODU depends on the level and number of ICU beds in the donor hospital.

2.2.4.2 **The Requirements of ODU**

2.2.4.2.1 Job descriptions outlining the role and required knowledge, skills, and experience of the ODU leader, coordinator, and members shall be established.

2.2.4.2.2 ODU team members shall dedicate at least 10 hours to organ donation functions and activities weekly.

2.2.4.2.3 Every ODU member needs to have appropriate training in deceased donation and communication skills.

Table 2.1 Key Performance Indicators (KPIs) for Donor Hospitals

1.Organ Donation Process Procedures	Type of Indicator: Structure
Definition	All the main steps of the donation process are covered by protocols/policies and procedures (Donor identification, Death declaration, Donor evaluation, Donor maintenance, Family approach, organ procurement procedure, Communication with the Saudi Centre for Organ Transplantation (SCOT), post donation care), which ensure the proper and standardised performance of each step of the donation process.
Formula	Existence of protocols and procedures for all relevant steps of the donation process (Yes /100 % or No / 0%)
Explanation	• To ensure that deceased donations align with national and international best practices, hospitals should establish clear protocols and procedures that standardize each step in the donation process. • Relevant steps: 1. Donor identification 2. Death declaration 3. Donor evaluation 4. Donor maintenance 5. Family approach 6. Organ procurement procedure 7. Communication with the Saudi Centre for Organ Transplantation (SCOT) • Existence of protocols/policies and procedures: Each protocol/policy and procedure must include the following information: - Who performs the procedure - When - How • The protocol is considered current if it has been developed or updated within the last 3 years. • The protocol should be available to all the people involved in the organ donation process.
Target	100%/Yes
Data source	Hospital's Registry of protocols/policies and procedures.
Reporting frequency	Data will be collected biannually.

2. Donation team full-time availability	Type of Indicator: Structure
Definition	Organ donation is an unplanned activity involving unstable potential donors who require urgent care. The detection and management of these donors by the Donation Team (DT) are essential throughout the entire process, from detection to recovery, to prevent losing a donor. The availability of the DT is determined based on the hospital level, ensuring appropriate coverage to manage potential donors effectively.
Formula	Donation Team Availability (%) = (Actual Hours Dedicated by ODU Team per Week / Target Hours per Week)
Explanation	Due to the unpredictable nature of new donors being accepted to the hospital, the donation team m Due to the unpredictable nature of new donors being accepted to the hospital, the donation team must ensure that functional coverage is available 24/7. This coverage does not necessarily require team members to be physically present in the hospital, but it does mean they must be able to oversee the process and ensure it is completed on time. Based on the hospital's activity volume, as estimated by the number of ICU beds, the team must allocate sufficient time to this program. The number of resources can be higher but should never be below the minimum requirements.
Target	Target 100% availability based on donor hospital level.
Data source	Documentation about the schedule of the DT in the hospital. Documentation from the Human Resources Department, for example, contracts, personnel file, etc.
Reporting frequency	Data will be collected biannually.

3. Donation team members with Critical Care background	Type of Indicator: Structure

Definition	Donation after Brain Death (DBD) is inherently linked to intensive care units (ICUs) because potential donors are typically ICU patients. The identification of brain death must be performed by ICU physicians, and maintaining and evaluating donors requires expertise in managing critically ill patients. Additionally, ICU personnel are experienced in communicating with families of critically ill patients and delivering difficult news.
Formula	(Number of physicians and nurses/technicians of the ODU with Critical Care background / Number of physicians and nurses in the ODU team) x 100
Explanation	• Critical care healthcare professionals are the ones handling patients with conditions progressing to brain death. • **Critical Care background**: experience of at least three years of full-time equivalent work in ICU or Emergency Department or Anaesthesiology. • **Donation Team Member**: each component of the team in charge of donation at hospital level. For a person to be considered as Donation Team Member some kind of official recognition by the hospital (administrative document) is necessary. • **NOTE:** The presence of other members of the donation team with no Critical Care background, such as social workers or psychologists, must also be encouraged, as they are very useful in certain aspects of the donation process.
Target	50%
Data source	Documentation from the Human Resources Department, for example, contracts, personnel file, etc.
Reporting frequency	Data will be collected biannually.

4. Identification of all possible donors in the ICU	Type of Indicator: Process

Definition

Identification of possible organ donors in the ICU is a critical step of the donation process. The monitoring of referred brain deaths may underestimate the real number of possible DBD donors. Having more reliable data depends on monitoring all comatose patients with acute cerebral lesion who are admitted to the ICU. This system may easily help to identify the subgroup of dying patients who meet the brain-death criteria.

Formula

(Number of comatose patients with devastating brain lesion admitted to the ICU who are referred to the Donation Team/ Number of comatose patients with devastating brain lesion admitted to the ICU) x 100

Explanation

- **Comatose patients**: GCS ≤ 5 on admission to the hospital or during ICU management, reasonably not caused by sedation.

- **Devastating brain lesion**: Any cerebral lesion with a bad prognosis potentially causing (or being a cofactor of or complication) brain death. This includes: (or being a cofactor of or complication) brain death. This includes:
  - An acute cerebral lesion including Brain trauma, Ischaemic or hemorrhagic Cerebrovascular accidents, anoxic brain damage, brain edema, cerebral neoplasm, or CNS infections.
  - Subacute or chronic disorders with an acute complication such as brain tumours when spontaneous or postoperative intracranial hypertension, hemorrhage and cerebral edema occur.

- **Patients referred**: Patients with devastating cerebral lesion admitted to the ICU who are reported to the Donation Team as soon as they meet the clinical criteria (GCS ≤ 5). Any local trigger or warning system can be used. Referred patients are documented in a registry, in which clinical data and the time of triggering are reported, maintained by the Donation Team.

Target

100%

Data source

Donation team referral registry and results from an internal audit of ICU clinical charts (review)

Reporting frequency

Data will be collected monthly.

5. Time to completing brain death declaration	Type of Indicator: Process

Definition	The time between the 1st brain death exam and the complete declaration of death by neurological criteria according to Saudi national protocol.
Formula	Time to Completing Brain Death Declaration (hours)=Time of Complete Declaration-Time of 1st Brain Death Exam
Explanation	• Delays in the process of completing the declaration of death by neurological criteria (brain death) lead to the loss of donors due to multiorgan failure or cardiac arrest. This indicator contemplates logistical challenges that could extend the time for brain death declaration up to double its intended time. Efforts should be made to minimize this time to its minimum. • **Time of Complete Declaration**: The time when the complete declaration of death by neurological criteria is made according to the Saudi national protocol. • **Time of 1st Brain Death Exam**: The time when the first brain death neurological exam is conducted.
Target	Varies according to the age group of the donor as follows: o Adult: less than 24 hours (Ideally <12 hours), o Pediatric age >1 year old and young adult: 48 hours (Ideally <24 hours), o Neonate (>2 months to <1 year): 72 hours.
Data source	SCOT's registry from completion of 1st neurological exam and completion of 2nd neurological exam time and date.
Reporting frequency	Data will be collected monthly

6. Time of Breaking bad news	Type of Indicator: Process

Definition	The time of the family to be informed about the death of their relative from the time of death declaration by neurological criteria.
Formula	Breaking bad news (hours)= Time of Breaking the Bad News-Time of Death Declaration by Neurological Criteria
Explanation	• Delays in the deceased donation process can lead to unnecessary loss of donors due to cardiac arrest or multi-organ failure. It is essential to communicate openly with donor families about the suspicion and final confirmation of death by neurological criteria (brain death). Clear and timely communication with families prepares them for the brain death diagnosis and can help avoid delays, increasing acceptance. This indicator tracks possible delays from the moment brain death is declared to when the family is informed. Any unavoidable communication delays should be properly documented in the patient's medical records. • **Time of Breaking the Bad News**: The time when the family is informed about the death of their relative. • **Time of Death Declaration by Neurological Criteria**: The time when the death is officially declared based on neurological criteria.
Target	< 12 hours
Data source	SCOT's registry from 2nd exam and breaking the bad news time and date.
Reporting frequency	Data will be collected monthly.

7. Unexpected cardiac arrest	Type of Indicator: Outcome
Definition	Brain death is associated with various pathophysiological changes that require proper handling by experienced ICU personnel. Otherwise, cardiac arrest may occur and the donor is lost. This is a measure of a cause of donor's loss that can be rectified.
Formula	(Number of potential DBD donors who suffered an unanticipated cardiac arrest/ Total number of potential DBD donors) x100
Explanation	• **Potential DBD donors**: in whom diagnostic procedures for brain-death diagnosis have been initiated. • **Unanticipated cardiac arrest:** cardiac arrest that occurs from the moment at which brain death is suspected or afterwards, and that is not attributable to multi-organ failure/sepsis.
Target	3%
Data source	Internal audit of ICU clinical charts (review) and National Registry in SCOT.
Reporting frequency	Data will be collected monthly.

Table 2.2 The composition of ODU According to the Level and Number of ICU beds

	Acute Care Hospitals	Minimum Team
Level 3 Donor Hospital	> 25 ICU beds	1 FTE ODU leader and 1 FTE ODU coordinator
Level 2 Donor Hospital	10 - 25 ICU beds	0.25 FTE ODU leader and 1 FTE ODU coordinator
Level 1 Donor Hospital	< 10 ICU beds	1 FTE ODU coordinator and has an agreement for referral to a level 3 donor hospital

ICU: Intensive Care Unit; FTE: Full-time Equivalent

2.2.4.3 **The Role of ODU**

2.2.4.3.1 The ODU should guarantee 24 hours a day, 7 days a week coverage of clinical duties, either on-site or on-demand, according to the hospital's activity level.

2.2.4.3.2 The ODU should report issues regarding organ donation directly to the medical director, not the department director they are assigned to.

2.2.4.3.3 Externally, the ODU should actively communicate with the SCOT team regarding the deceased organ donation process to facilitate the follow-up of new patients. In addition to submitting the required performance data and the hospital monthly census to SCOT (Form 2: Hospital Monthly Census).

2.2.4.3.4 Internally, the ODU should actively communicate with the medical director, ICU team, and quality department regarding the deceased organ donation process.

2.2.4.3.5 The ODU shall assume dedicated clinical and non-clinical duties (see Figure 2.2)

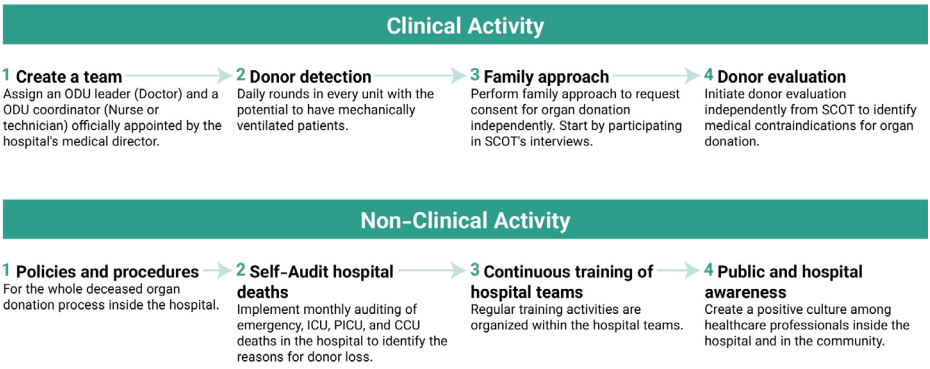


Figure 2.2 Clinical and Non-clinical Activities of Organ Donation Unit (ODU)

2.3 Procedures of DBD – The Critical Pathway

The critical pathway (see Figure 2.3) for organ donation after brain death (DBD) is a comprehensive framework designed to streamline the organ donation process, ensuring clarity and uniformity in the identification, referral, and management of potential donors. This pathway, which was developed by the World Health Organization (WHO), serves as a clinical tool applicable across various countries, regions, and hospitals to assess the potential of deceased organ donation, evaluate performance in the donation process, and identify areas for improvement.

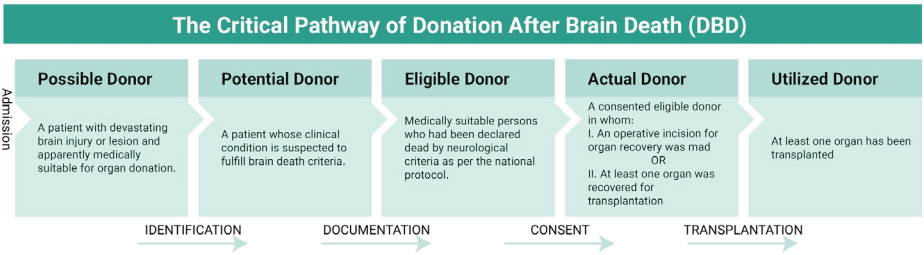


Figure 2.3 The Critical Pathway of Donation After Brain Death (DBD)

2.3.1 Possible Deceased Organ Donor

The donation process begins with the identification of a possible deceased organ donor, which includes patients with devastating brain injuries who are apparently medically suitable for organ donation (see Figure 2.4). These patients are typically in intensive care units (ICU) receiving mechanical ventilation but may also be found in other settings where decisions regarding the continuation of life-sustaining therapies are being considered. Early identification and timely referral of these potential donors to SCOT are crucial steps in the donation process. This ensures that medical suitability can be assessed, family approaches can be carefully prepared, and logistical aspects can be efficiently managed. For possible deceased organ donors, the following procedure shall be followed:

2.3.1.1 Identify the possible organ donor. This can be done by the ICU physician, emergency physician, neurologist, neurosurgeon, anesthesiologist, or attending physician.

2.3.1.2 Ensure that all admitted patients are screened according to the specified criteria for possible deceased organ donors (see Figure 2.5).

Screening Criteria for Brain Death	
01	Clear evidence of devastating brain insult
02	Mechanically ventilated
03	Glasgow Coma Scale (GCS) of ≤ 5
04	Fixed dialted pupils

Figure 2.4 The Screening Criteria for Identifying Possible Deceased Donors

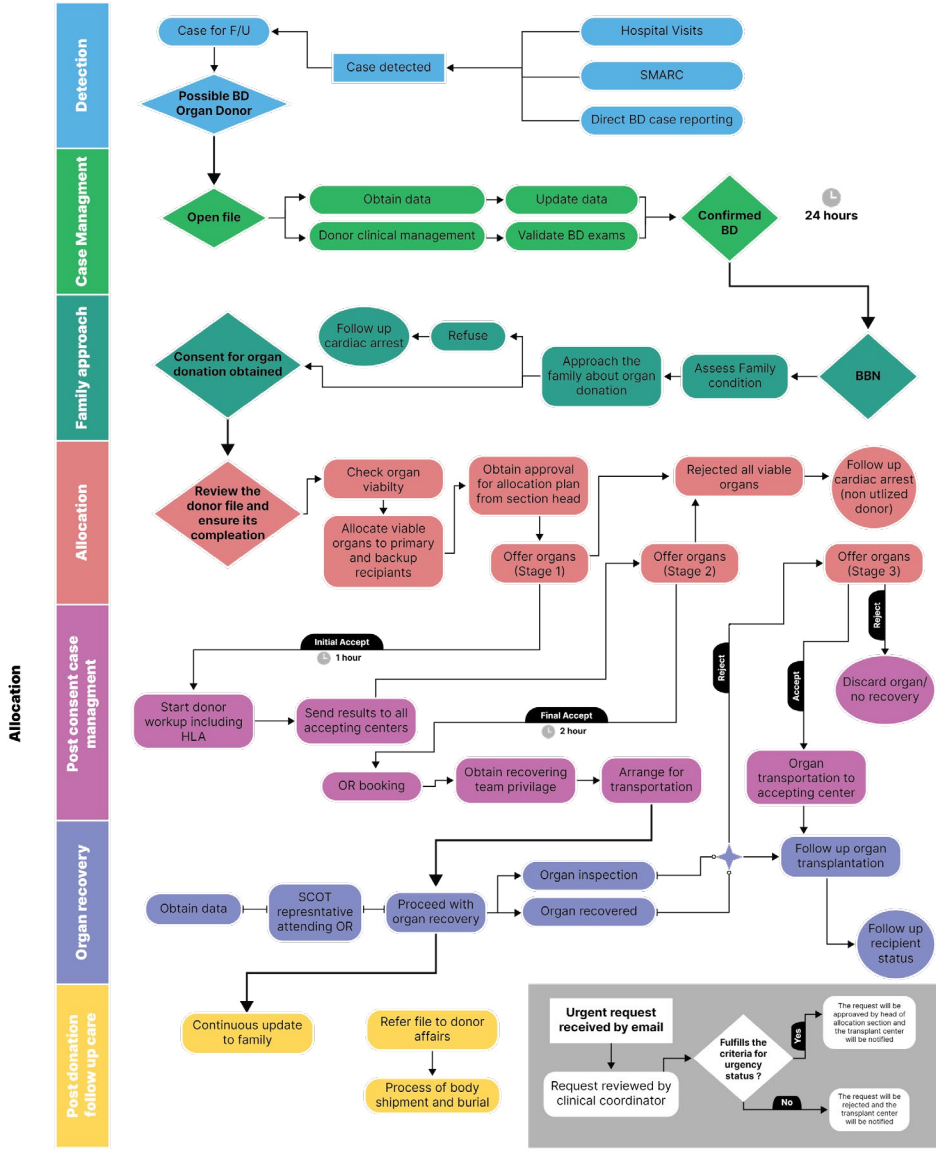


Figure 2.5 Workflow of Handling Possible Deceased Organ Donors

2.3.1.3 Refer to the ICD-10 codes for diseases associated with potentially devastating cerebral lesions that may lead to brain death (see Table 2.3).

Table 2.3 ICD-10 codes of diseases associated with potentially devastating cerebral lesions related to brain death

Group of cerebral lesions	ICD-10 code*
Trauma	S02 Fracture of skull and facial bones
	S06.1 Traumatic cerebral edema
	S06.2 Diffuse brain injury
	S06.3 Focal brain injury
	S06.4 Extradural hemorrhage
	S06.7 Intracranial hemorrhage with prolonged coma
	S06.8 Other intracranial injuries
	S06.9 Intracranial injury unspecified
Cerebrovascular accidents	I60 Subarachnoid hemorrhage
	I61 Intracranial hemorrhage
	I62 Other non-traumatic intracranial hemorrhage
	I63 Cerebral infarction
	I64 Stroke not specified as stroke or infarction
	I65 Occlusion and stenosis of precerebral arteries
	I66 Occlusion and stenosis of cerebral arteries
Cerebral damage	G93.1 Anoxic brain damage
	G93.5 Compression of brain
	G93.6 Cerebral edema
Cerebral neo¬plasm	C71 Malignant neoplasm of the brain
	D33 Benign neoplasm of the brain
CNS infections	G00, G01, G02, G03 Meningitis

Adopted from: European Committee on Organ Transplantation. Guide to the quality and safety of organs for transplantation. 8th Edition. European Directorate for the Quality of Medicines and Healthcare (EDQM) 2022.

2.3.1.4 Once a possible donor is identified, notify SCOT immediately via 1969, The unified organ donation and transplantation platform (Athar), or other approved communication channels.

WHEN TO REPORT?
Report any patient who meets the screening criteria to SCOT promptly prior to initiating the national protocol for death declaration by neurological criteria. Early reporting ensures timely coordination and evaluation.

2.3.1.5 Submit the possible donor's demographic, personal, medical, and social information through the The unified organ donation and transplantation platform (Athar) as outlined in Chapter 3. Information is subject to medical and administrative review by SCOT to evaluate organ viability for donation.

2.3.1.6 Manage the possible organ donor as full code status (i.e., do not designate as DNR) upon notification (refer to Chapter 2, Section 2A, Sub-section 2.4).

2.3.1.7 If there is suspicion of any contraindications to organ donation, conduct a thorough evaluation and consult SCOT before excluding the possible donor (see Table 2.8).

2.3.1.8 Perform daily evaluations and document brain stem reflexes to monitor the brain death process. If a change is detected, the following shall be considered:

2.3.1.8.1 Reassess all brain stem reflexes and other signs of brain activity.

2.3.1.8.2 Perform additional diagnostic tests as necessary to confirm brain death diagnosis.

2.3.1.8.3 Investigate reversible conditions that might explain the observed change.

2.3.1.8.4 Notify the clinical team and involve them in addressing the situation.

2.3.1.8.5 Pause the brain death determination process if the change is inconsistent with brain death until further investigation and testing are completed.

2.3.1.8.6 Adjust the medical management plan if the change indicates a non-terminal condition or improvement.

2.3.1.9 Keep the family informed about the clinical status of the possible donor, ensuring clear and consistent communication throughout the critical pathway phases.

2.3.1.10 Exclude deceased pregnant donors from organ donation unless the fetus is dead or has been delivered.

2.3.1.11 Take all necessary and exhaustive measures to establish the identity of an unknown deceased donor using all available resources and channels, including contacting relevant authorities.

2.3.1.12 Measure key performance indicators (KPIs) to ensure the proper identification of possible deceased donors and monitor compliance at each step of the process (see Table 2.1, KPI 3).

2.3.1.13 Ensure that all required data of possible donors is reported accurately and promptly through the The unified organ donation and transplantation platform (Athar). (refer to Chapter 3)

2.3.2 POTENTIAL DECEASED ORGAN DONOR

A potential DBD donor is a patient whose clinical condition is suspected to fulfill brain death criteria. This stage involves a thorough evaluation of the patient's medical history and current health status to confirm the likelihood of brain death. The multidisciplinary medical team must work together to ensure that all clinical signs point towards brain death, and that all necessary preliminary tests and evaluations are conducted. This stage sets the foundation for the subsequent phases by confirming the medical viability of the patient as a potential donor. For potential donors, the following procedure shall be followed:

2.3.2.1 Follow the national protocol for diagnosing, declaring, and documenting death by neurological criteria (DNC) (refer to Appendix B). Any deviations must be discussed with SCOT and justified.

2.3.2.2 Consider the following unique circumstances during the documentation of the DNC:

2.3.2.2.1 If unable to test one or more brainstem reflexes, document the reason in the form and continue testing other reflexes.

2.3.2.2.2 If a confirmatory test does not support the diagnosis of DNC, repeat it in 48 hours or as per the test interpreter's recommendations.

2.3.2.2.3 If the apnea test cannot be conducted or fails due to clinical reasons, document this in the form. A blood flow study is required in such cases.

2.3.2.3 The donor hospital's management team will handle the patient, with SCOT overseeing and recommending further actions or investigations as indicated and deemed necessary (refer to Chapter 2, Section 2A, Sub-section 2.4).

2.3.1.4 Once the documentation form of death by neurological function criteria the death is completed (Form 3: Death Documentation Form by Neurological Criteria), the ICU staff or ODU is required to submit it to SCOT for review to ensure proper application of the national DNC protocol.

2.3.1.5 All forms must be filled out completely and legibly. Any missing information will invalidate the form, requiring it to be returned for completion.

2.3.1.6 Measure key performance indicators (KPIs) to monitor compliance at each step of the process (see Table 2.1, KPIs 4 and 5).

WHEN TO REPORT?
Donor hospitals should report the potential tissue donor to SCOT promptly within 6 hours of death declaration.

2.3.1.7 Ensure that all required data of potential donors is reported accurately and promptly through The unified organ donation and transplantation platform (Athar). (refer to Chapter 3)

2.3.1 ELIGIBLE DECEASED ORGAN DONOR

An eligible DBD donor is a medically suitable individual declared dead by neurological criteria according to the national protocol. This stage ensures all legal and medical requirements for brain death by neurological criteria are met, with rigorous adherence to standards to confirm the accuracy of the declaration. Only after this confirmation can the donor be considered eligible for organ donation. For eligible deceased organ donors, the following four interconnected procedures shall be followed:

- Breaking Bad News Procedure
- Family Approach Procedure
- Obtaining the Consent Procedure
- Post Consent Procedure

2.3.1.1 BREAKING BAD NEWS PROCEDURE

Breaking bad news is rarely easy, but it is a crucial aspect of patient-centered care in the ICU. By preparing well, using a structured communication approach (e.g. SPIKES; Setting up, Perception, Invitation, Knowledge, Emotions/Empathy, and Strategy/Summary), and demonstrating empathy and support, ICU staff can guide families through these challenging conversations with dignity and understanding. **The following steps should be followed when breaking the bad news of the DNC to the family:**

2.3.1.1.1 Once death by neurological criteria is documented, the ICU physician or attending physician must immediately inform the next of kin and maintain continuous communication with the family.

IMPORTANT NOTE

After breaking the bad news (i.e., before approaching the family about the possibility of donation), the clinical team and donation coordinator must maintain effective communication with the family to provide emotional support, address their concerns, offer clear explanations about the patient's condition, and build trust.

2.3.1.1.2 Deliver bad news gradually, using a stepwise disclosure approach to allow the family to process the information received comfortably while easing the emotional impact and distress.

2.3.1.1.3 Clearly explain that the patient has sustained irreversible brain damage and, after full medical examination and investigation, is confirmed dead by neurological function criteria.

2.3.1.1.4 Avoid giving the family false hope and avoid using vague or misleading terms such as "seriously ill" or "deep coma."

2.3.1.1.5 Do not discuss organ donation with the family at this time.

2.3.1.1.6 Ensure that a qualified interpreter is present for non-Arabic-speaking families to help them understand the diagnosis clearly.

2.3.1.1.7 Measure key performance indicators (KPIs) to monitor the timely breaking of bad news (see Table 2.1, KPI 6).

2.3.3.2 FAMILY APPROACH PROCEDURE

Approaching the family of a deceased donor to discuss organ donation is of great importance in modern healthcare. At this stage, the treating physician and ICU staff play a key role in increasing organ donation approvals through effective communication and providing the family with sufficient information to clearly understand the condition. This humanitarian step of organ donation requires cooperation between the medical team, the organ donation coordinator, and the deceased's family to ensure that this decision is based on solid medical and ethical principles. **The following steps should be followed when approaching the family for organ donation (see Figure 2.6):**

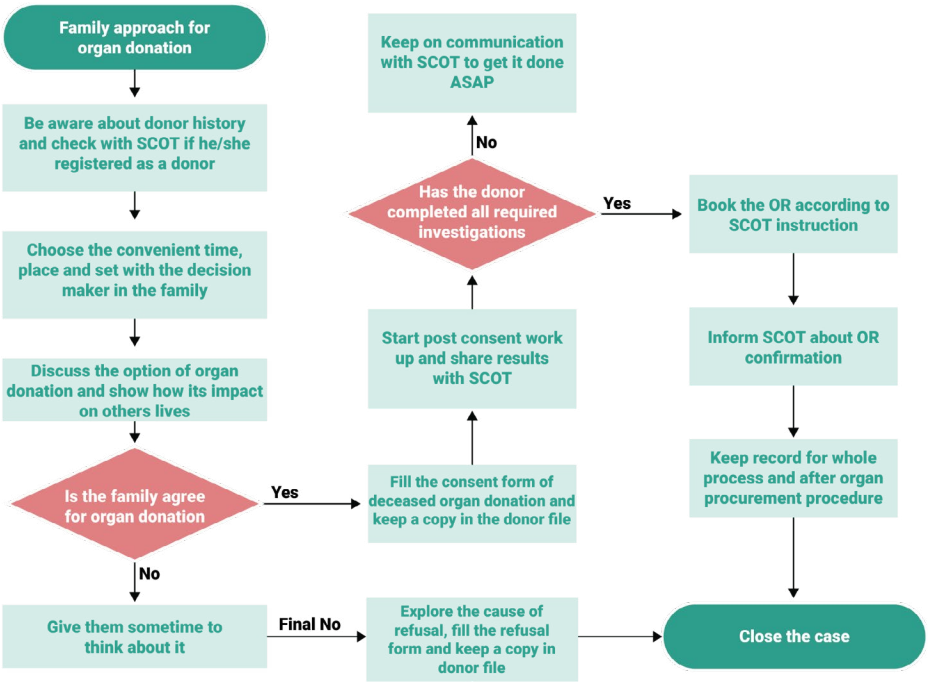


Figure 2.6 Workflow of Family Approach for Organ Donation

2.3.3.2.1 **Verification of Will Existence**

- SCOT will verify if the deceased patient had a documented will to donate organs through official channels. The will must be written and documented via officially approved channels in Saudi Arabia, and SCOT has the right to inquire and accept it. However, the testator has the right to withdraw the will at any time through approved channels without restrictions.

- If a will exists, SCOT has the right to proceed with the will but is obliged to inform the family, if present. Also, if the desire to donate is expressed through digital channels (e.g. **Tawakkalna** services), SCOT proceeds with obtaining written consent from the first of kin or legal relatives (Form 4: Deceased Organ and Tissue Donation Consent).

2.3.3.2.2 **Prior to Family Approach**

- Review the donor's medical and social history, including whether they were registered as a donor (e.g. Tawakkalna services), to support the family's decision-making process.

- The donation coordinator must communicate with the family to assess their understanding after informing them of the brain death diagnosis.

    - If physical communication is not possible, they can be contacted via video or phone conference within 12 hours of receiving the death notice.

    - If the family lives outside Saudi Arabia, a relative in the Kingdom may be authorized to sign the donation consent, which must be documented through official SCOT channels.

- Arrange a meeting with the multidisciplinary team and the family decision-maker, in coordination with SCOT, at an appropriate time and place to discuss the donation option.

- Provide an interpreter for non-Arabic-speaking families to ensure clear communication about the organ donation process.

2.3.3.2.3 **During Family Approach**

- Ensure the family fully understands the brain death diagnosis, as they may not be ready to discuss organ donation until they grasp the clinical reality.
- Present organ donation as a humanitarian act that can significantly impact the lives of patients with organ failure who have no other options, which often resonates with families.
- Avoid engaging in discussions that could lead to controversy, and be mindful of religious and cultural sensitivities.

2.3.3.2.4 **After Family Approach**

- Give the family sufficient time to consider the option of organ donation. This may take a few hours or longer, depending on the family's emotional readiness and the patient's circumstances.
- Document the family's final decision, whether in favor of or against organ donation, in the donor's medical file (Form 4: Deceased Organ and Tissue Donation Consent) (Form 5: Reasons of Organ Donation Refusal).
- Maintain effective communication with the family throughout the donation process if the family approves organ donation.

2.3.3.3 **OBTAINING THE CONSENT PROCEDURE**

The consent process for organ donation is a critical and sensitive step that requires careful navigation and compassionate communication. It involves engaging with the family of the eligible donor, ensuring they fully understand the implications of their decision while providing them with the emotional support they need during this challenging time. **The following steps shall be followed during obtaining informed consent for organ donation:**

2.3.3.3.1 The donation coordinator shall prepare the consent document.

2.3.3.3.2 Acknowledge the family's desire to invite someone to the signing consent step.

2.3.3.3.3 Facilitate the introduction and review the key points discussed during the family approach step to confirm understanding.

2.3.3.3.4 The donation coordinator shall ensure that the family's privacy and emotional state are protected

2.3.3.3.5 Ensure the family understands the consent document by clearly explaining each section (Form 4: Deceased Organ and Tissue Donation Consent).

2.3.3.3.6 Donations from deceased individuals are considered altruistic gifts, and no financial compensation is required.

2.3.3.3.7 Provide the family with the opportunity to sign the consent form, while maintaining confidentiality.

2.3.3.3.8 Accurately document the date and time of the consent, the names of the family members who consented, and any discussions held regarding the decision.

2.3.3.3.9 Maintain open lines of communication and be prepared to mediate any differing opinions or tensions that arise during the signing process.

2.3.3.4 **POST CONSENT PROCEDURES:**

After the family consents to organ donation, it is crucial to ensure continuous communication and coordination between the medical team, the organ donation coordinator, and the family. This process involves documenting the consent, providing ongoing emotional support to the family, and keeping them informed about the donation procedure and timeline. **The following steps shall be followed after obtaining informed consent for organ donation:**

2.3.3.4.1 Maintain continuous and clear communication with SCOT throughout the critical pathway steps, especially after obtaining consent for organ donation.

2.3.3.4.2 Ensure that all required data of eligible donors is reported accurately and promptly through The unified organ donation and transplantation platform (Athar). (refer to Chapter 3)

2.3.3.4.3 Proceed with any necessary procedures or investigations without needing further consent from the next of kin, as the signed organ donation consent form is sufficient.

2.3.3.4.4 Collaborate with SCOT by conducting further investigations and work-up as requested in order to assist SCOT's evaluation of the organs' viability (see Table 2.4).

Table 2.4 Routine Donor Workup for Each Organ/Tissue Intended for Transplantation

Organ/Tissue	Routine Work-up
Lung	Challenge test, chest x-ray, CT chest windows, bronchoscopy, TB PCR from tracheal aspirate, pneumonia panel, and COVID test.
Heart	Cardiac catheterization, Echo, and ECG.
Liver	Liver Function tests, bilirubin, GGT, albumin, coagulation profile, and US/CT abdomen.
Kidney	Kidney Function tests, electrolytes, total intake/output, and US/CT abdomen.
Pancreases	Amylase, lipase, HbA1c, and US/CT abdomen.
Intestinal	Amylase, lipase, and abdominal girth.
Cornea	Serology, including Hepatitis C antibodies

CT: Computed Tomography; ECG: Electrocardiogram; Echo: Echocardiogram; GGT: Gamma-Glutamyl Transferase; HbA1c: Hemoglobin A1c; PCR: Polymerase Chain Reaction; TB: Tuberculosis; US: Ultrasound.

2.3.3.4.5 SCOT will allocate viable organs to recipients, providing all relevant donor data to their transplant programs.

2.3.3.4.6 Upon initial acceptance of an organ, transplant programs may request additional investigations.

2.3.3.4.7 SCOT or the transplant programs coordinator will collect and send required samples (e.g., blood, cultures) to the affiliated transplant programs lab (or another initially accepting transplant programs), including HLA matching, which must be completed within 8 hours of receiving the samples.

2.3.3.4.8 Conduct all post-consent donor workups with urgency to avoid delays that could compromise the organ viability, as the family also expects the process to be reasonably quick.

2.3.3.4.9 Once all viable organs are allocated and accepted, SCOT will handle the recovery procedure preparation by (refer to Chapter 2, Section 2A, Sub-section 2.7):

- Scheduling the time for organ recovery.
- Organizing the transportation of the recovery team(s) based on the donor hospital's location and organ types.
- Coordinating with the donor hospital to ensure the operating room readiness.
- Double-checking medical and administrative data for accuracy between the SCOT files and the donor hospital records.

2.3.3.4.10 Organ recovery must occur at the donor hospital unless SCOT approves transferring the patient due to compelling reasons. In this case, the family MUST be informed and agree to transfer the patient.

2.3.3.4.11 SCOT has the right to modify transportation times, the recovery process, organ distribution priority, or any recovery step if deemed necessary.

2.3.4 ACTUAL DECEASED ORGAN DONOR

Eligible donors become actual DBD donors when an operative incision is made with the intent of organ procurement or when at least one organ is retrieved for transplantation. The emphasis here is on the operational aspects of organ retrieval, ensuring that the organs are recovered in a manner that maximizes their viability for transplantation while maintaining the dignity and respect of the donor. **For actual deceased organ donors, the following procedure shall be followed:**

2.3.4.1 SCOT coordinates logistics for the organ procurement process. However, the transplant programs will bear any damages resulting from delays or violations by the procurement team.

2.3.4.2 SCOT decides on what team should undertake the organ procurement process in case of logistics difficulties, based on the recipient's medical condition, and provides the donor hospital with the details and the privileges of the assigned organ procurement team.

2.3.4.3 SCOT ensures the organ procurement team arrives at the donor hospital at least 1 hour before the scheduled OR time.

2.3.4.4 The procurement team(s) shall adhere to evidence-based practices and ethical standards throughout the organ recovery procedure (refer to Chapter 2, Section 2A, Sub-section 2.7).

2.3.4.5 The processes of documenting the recovery procedure and issuing the legal death certificate shall follow SCOT regulations.

2.3.4.6 The processes of packaging, labeling, and transporting the recovered organs, following the recovery procedure, shall follow SCOT regulations.

2.3.4.7 Ensure that all required data of actual donors is reported accurately and promptly through The unified organ donation and transplantation platform (Athar). (refer to Chapter 3)

2.3.4.8 The Ministry of Health will bear the cost of repatriating the deceased donor to their homeland, accompanied by one chaperone, as per resolution no. 386-7 Dated 07/05/1420H.

2.3.4.9 The employer shall bear the costs of all administrative funeral paperwork, whether the burial is inside or outside the Kingdom, in accordance with Article Forty of the Labor Law. SCOT's role is limited to issuing a letter to health affairs to cover the transportation costs of the body.

2.3.5 UTILIZED DECEASED ORGAN DONOR

A utilized DBD donor is an actual donor from whom at least one organ has been successfully transplanted. This final phase encompasses the transplantation of the donor's organs into recipients, completing the donation process. The success of this phase is measured by the transplantation outcomes and the positive impact on the recipients' health and lives. It highlights the ultimate goal of the critical pathway; to save and improve lives through successful organ transplantation. At this phase, the transplant programs shall submit all required data as defined by SCOT (refer to Chapter 3).

2.4 Deceased Donor Management

Significant brain injury causes the onset of a systemic inflammatory response syndrome (SIRS) prior to the occurrence of DNC. The DNC causes a variety of further inflammatory, hemodynamic, and endocrine effects, which may lead to significant organ injury prior to organ recovery. To maintain the viability and quality of organs of potential deceased donors, early identification of DNC patients and aggressive donor management (ADM) are recommended. ADM protocols involve the prompt use of fluid resuscitation, vasopressors, and hormone therapy to stabilize cardiovascular function, correct metabolic and endocrine abnormalities, and prevent hypothermia to preserve organ viability for transplantation. ICU plays a pivotal role in stabilizing potential donors, managing their physiological parameters, and optimizing organ function until procurement. Outlined here, are the fundamental principles and procedures for effective donor management in the ICU, including possible and potential donors.

IMPORTANT NOTE

While the goal and approach of deceased donor management and end-of-life care may differ, deceased donor management extends the principles of end-of-life care, respecting the patient's wishes and ensuring ethical stewardship of the donation process.

2.4.1 POSSIBLE DONOR MANAGEMENT

For proper management of a possible donor, it is essential to consider the inclusion and exclusion criteria mentioned in the DNC protocol. The following procedure outlines the key actions required to manage a possible donor effectively, ensuring that physiological parameters are properly managed:

2.4.1.1 Confirm devastating brain insult using an appropriate imaging modality.

2.4.1.2 Discontinue sedatives and muscle relaxants before proceeding with the neurological evaluation of the potential donor.

2.4.1.3 Maintain normothermia using appropriate warming measures to prevent hypothermia and keep the patient's body temperature around 36°C.

2.4.1.4 Stabilize cardiovascular function by maintaining the mean arterial pressure (MAP) above 60 mmHg before beginning any neurological assessment.

2.4.1.5 Address metabolic and endocrine derangement, such as hypernatremia and acidosis, by treating underlying coma causes as necessary before evaluating the possible donor (see Table 2.5).

Table 2.5 Metabolic Derangements That May Confound DNC Evaluation

	Laboratory Result	Value*
Metabolic	Ammonia	>75 µmol/L
	Blood urea nitrogen	>75 mg/dL
	Calcium (or ionized calcium)	<7 mg/dL or >11 mg/dL (or <1 mmol/L or >1.3 mmol/L)
	Glucose	<70 mg/dL or >300 mg/dL
	Magnesium	<1.5 mg/dL or >4 mg/dL
	Potassium	<3 mmol/L or >6 mmol/L
	Sodium	<130 mmol/L or >160 mmol/L
Acid-Base	pH	<7.3 or >7.5
Endocrine	Total T4	<3 mg/dL or >30 mg/dL
	Free T4	≤0.4 ng/dL or >5 ng/dL

Adopted from American Academy of Neurology, Brain Death Guideline (2023)

* The presence of any of these levels/values may confound the accurate evaluation of DNC.

2.4.2 POTENTIAL DONOR MANAGEMENT

Managing potential organ donors is a highly specialized process that involves maintaining the physiological stability of a brain-dead individual to ensure the viability of organs for transplantation. Managing these physiological parameters should be guided by protocols designed to optimize organ function and improve transplant outcomes. Herein are the most important considerations to be taken in managing the common physiological derangements associated with brain death:

2.4.2.1 Monitoring of Key Parameters

Monitoring of key parameters in potential donors is essential to ensure proper management. The following are key parameters and investigations that must be done for all potential donors (see Table 2.6):

- Renal function test
- Liver function test
- Coagulation profile
- Blood grouping
- Complete septic workup
- Serum electrolytes
- Complete blood count
- Arterial blood gasses
- Daily Chest X-Ray
- Inflammatory markers (CRP, Procalcitonin)
- Serological testing for HIV, HSV antibody, HBV surface antigen, core antibody, surface antibody, HCV antibody, and IgM and IgG for cytomegalovirus are necessary.

Table 2.6 Monitoring Parameters in Critical Care and Target Ranges in Adults		
Basic Parameters	**Target Range (Adults)**	**Monitoring Frequency**
Central Body Temperature	36°C to 37°C	Continuously
Invasive Mean Arterial Pressure (MAP)	60–75 mmHg	Continuously
Heart Rate	70–100/min	Continuously
Urine Output	0.5 to 1.5 mL/kg/h	Hourly
Central Venous Pressure (CVP)	6–12 mmHg	Continuously
Peripheral Arterial Oxygen Saturation (SpO2)	> 95%	Continuously
Arterial Blood Gas, pH	7.35–7.45	Every 2 to 4 hours or as needed
Sodium (Na)	135–145 mmol/L	Every 2 to 4 hours or as needed
Potassium (K)	3.5–4.5 mmol/L	Every 2 to 4 hours or as needed
Blood Glucose	< 180 mg/dL (8.3 mmol/L)	Every 2 to 4 hours or as needed
Plasma Biochemistry, Urine Sediment, C-Reactive Protein	N/A	Every 12 hours or as needed
Calcium Level	Normal range	Every 2 to 4 hours or as needed
Hemoglobin	≥ 7 g/dL (≥ 4.4–5.6 mmol/L)	Every 6 hours or as needed
Platelets	> 50 G/L	Every 12 hours or as needed
Prothrombin Time/ Partial Thromboplastin Time	Within acceptable range to avoid bleeding	Every 12 hours or as needed
Magnesium Level	Normal range	Every 12–24 hours

Adopted from: European Committee on Organ Transplantation. Guide to the quality and safety of organs for transplantation. 8th Edition. European Directorate for the Quality of Medicines and Healthcare (EDQM) 2022.

2.4.2.2 Managing Electrolyte Disturbances

Electrolyte imbalances can mimic brain death symptoms, and they must be corrected before brain death assessment to avoid misdiagnosis and ensure accurate evaluation (see Table 2.7).

Table 2.7 Managing Electrolyte Disturbances in Potential Donors

Sodium (Na+)	• Hyponatremia: fluid restriction and saline infusion. • Hypernatremia: gradual fluid replacement. • Acceptable Levels for DNC Diagnosis: 135–159 mmol/L.
Potassium (K+)	• Hypokalemia: potassium replacement • Hyperkalemia: insulin, medications, or dialysis. • Acceptable Levels for DNC Diagnosis: 3.5–5.0 mEq/L.
Calcium (Ca2+)	• Hypocalcemia: calcium supplementation • Hypercalcemia: hydration and diuretics. • Acceptable Levels for DNC Diagnosis: 8.5–10.5 mg/dL (or 2.1–2.6 mmol/L).
Magnesium (Mg2+)	• Hypomagnesemia: magnesium replacement. • Hypermagnesemia: stopping magnesium intake and promoting excretion. • Acceptable Levels for DNC Diagnosis: 1.8–2.5 mg/dL (or 0.75–1.05 mmol/L).

2.4.2.3 Eye Care

Critically ill patients often experience compromised ocular function, predisposing them to various ocular complications. To mitigate these complications, the following are recommended:

- Close the eyelid adequately for patients unable to maintain it independently. Utilize mechanical taping methods to ensure complete eye coverage.
- Implement routine eye cleaning protocols to eliminate debris, secretions, dried ointments, and residual ocular medications.
- Administer moisturizing eye drops at regular intervals, typically four to six times daily, to maintain adequate ocular hydration and prevent corneal dryness.

2.4.2.4 **Endotracheal Tube (ETT), and Oral Care**

Effective care of EET in mechanically ventilated (MV) patients is crucial for ensuring donors' safety in the ICU. Failure to provide proper care can lead to significant complications, such as ventilator-associated pneumonia. To mitigate these complications, the following are recommended:

- Perform chest physiotherapy and endotracheal tube suctioning at least every 4 hours, unless contraindicated. Additionally, administer mouthwash every 6 hours to maintain oral hygiene.
- Monitor arterial blood gas (ABG) levels regularly to assess ventilation status. Perform ABG every 12 and 8 hours for patients on low and high MV settings, respectively.
- Administer inhaled bronchodilators, such as Salbutamol Nebulizer, every 6 hours, unless contraindicated, to optimize airway function and alleviate bronchospasm.

2.4.2.5 **Maintaining Normothermia**

Maintaining the donor's body temperature within the optimal range is crucial for organ preservation. To maintain normothermia between 35.5°C and 37°C in potential donors, the following measures are recommended:

- Reduce passive heat loss by covering the donor with materials such as metal foil or utilizing electric blankets and hot-air blowers to maintain body temperature.
- Use heat-infusion solutions/fluids warmed in water baths or specialized infusion heaters before administration.
- Minimize exposure to cold environments to further prevent heat loss.

2.4.2.6 **Blood Pressure, Fluids and Vasopressors**

To stabilize the circulatory system and maintain organ perfusion, large volumes of fluid replacement may be required. The selection of intravenous fluids and the rate of administration must consider any prior treatments for cerebral edema or cardiac complications, as well as the presence of uncontrolled diabetes insipidus (DI). Fluid and vasopressor management can be optimized to improve patient outcomes. The target is to maintain 60–75 mmHg mean arterial pressure (MAP) for adults, with a diuresis rate of 0.5–1.5 mL/kg/h. Achieving this requires careful management through the following procedure (see Figure 2.7):

2.4.2.6.1 Assess the hemodynamic status, including fluid balance and blood pressure.

2.4.2.6.2 Discontinue any medications with hypotensive effects to avoid further complications.

2.4.2.6.3 Administer fluid resuscitation with crystalloids or colloids to correct intravascular volume deficits, aiming for a central venous pressure (CVP) of 4-12 mmHg for adults (lower in lung donors: 4-8 mmHg).

2.4.2.6.4 Monitor hemodynamics continuously for signs of fluid overload and avoid hyperchloremic acidosis by opting for balanced salt solutions if large volumes of crystalloids are used, especially in multi-organ donors.

2.4.2.6.5 Initiate vasopressor therapy if fluid replacement alone is insufficient to maintain the target MAP. Consider the following when vasopressor therapy is needed:

- Norepinephrine is the first-choice vasopressor. If doses exceed 0.2 µg/kg/min, evaluate for potential complications.
- If dysfunction is detected by echocardiography, add dobutamine to improve cardiac output.
- Consider vasopressin when a high dose of other vasopressors is needed.
- Low-dose dopamine (< 4 µg/kg/min) can reduce the need for dialysis and protect kidney grafts, while high-dose dopamine (> 10 µg/kg/min) should be avoided due to risks of renal vasoconstriction and systemic complications.

2.4.2.6.6 For persistent hypotension, use echocardiography and minimally invasive cardiac output measurements, as needed, to monitor the patient's hemodynamic status.

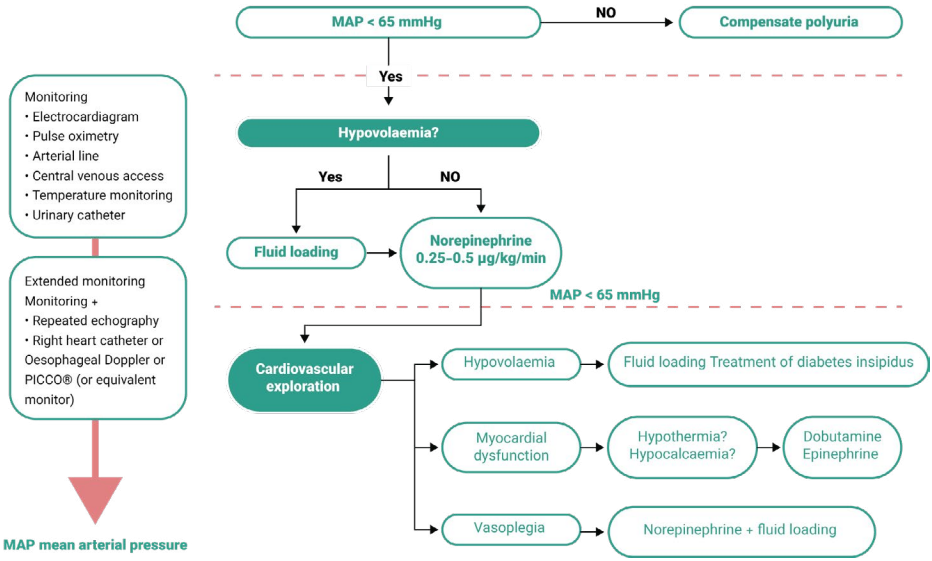


Figure 2.7 Hemodynamic Objectives and Care in Managing Potential Donors After Brain Death.
Adopted from: European Committee on Organ Transplantation. Guide to the quality and safety of organs for transplantation. 8th Edition. European Directorate for the Quality of Medicines and Healthcare (EDQM) 2022.

2.4.2.7 Ventilation and Lung Protective Therapy

Apply lung-protective strategy as needed. The strategy should be applied by the treating physicians or ICU physician to achieve maintenance goals in cooperation with organ-specific specialties (e.g. cardiology, nephrology, infectious disease, hepatology…etc.) in the hospital and organ transplant programs. The lung-protective strategy includes:

2.4.2.7.1 Mechanical ventilation: lowest possible FiO2, tidal volume 6-8 mL/kg, plateau pressure < 30 cm H2O, PEEP 8-10 cm H2O (note: high PEEP prevents lung edema and atelectasis).

2.4.2.7.2 Recruitment maneuvers: once per hour and after every disconnection from the ventilator (e.g. apnea test). It is suggested to use controlled ventilation (i.e. plateau pressure 35 mmHg), with PEEP of 18-20 cm H2O for 1 minute, and decreased 2 cm H2O each minute. After that, increased 50% of tidal volumes for 10 breaths.

2.4.2.7.3 Bronchoscopy: with bilateral bronchoalveolar lavage, immediately after DNC.

2.4.2.7.4 Close monitoring of hemodynamics: with PiCCO or equivalent monitor, EVLW < 10 mL/kg (administering diuretics, if necessary), CVP < 8 mmHg

2.4.2.7.5 Methylprednisolone: 15 mg/kg every 24 hours.

2.4.2.7.6 Positioning: Semi-lateral decubitus position in lung donors with PaO2/FiO2 <300 mmHg.

2.4.2.7.7 Suctioning: Closed circuit for tracheal suction to avoid loss of pressurization caused by tube disconnection and decrease the risk of atelectasis.

2.4.2.7.8 Avoid any decrease in oxygenation: appropriate ventilation should be ensured during the stay at the ICU, during any transfer within the hospital, and during surgery in the operating theatre at procurement with a target PaO2/FiO2 > 300 mmHg (> 40.0 kPa).

2.4.2.8 **Central Diabetes Insipidus (DI)**

Central DI results from the loss of anti-diuretic hormone (ADH) production due to hypothalamic-pituitary axis failure. DI is characterized by excessive urine output, low urine specific gravity, and the development of hypernatremia, often accompanied by hypokalemia. If left untreated, DI can lead to rapid fluid loss and severe electrolyte imbalances, particularly hypernatremia. Prompt treatment of DI is crucial and includes the following steps:

2.4.2.8.1 Use desmopressin (1-4 µg IV bolus) as the first-line treatment. Alternatively, vasopressin (0.8-1 IU/h IV infusion) can be used.

2.4.2.8.2 Restore fluid balance if diuresis decreases significantly, indicating possible anuria.

2.4.2.8.3 Repeated, titrated doses of desmopressin may be needed if DI symptoms recur.

2.4.2.8.4 For persistent polyuria, blood sugar levels should be checked to rule out osmotic diuresis, and if necessary, corrected before further desmopressin administration. (see Figure 2.8)

2.4.2.8.5 To treat hypernatremia with hypovolemia:

- Administer water via a nasogastric tube and restore intravascular volume with isotonic sodium chloride.
- Correct water deficits with 5% glucose solution combined with insulin, while closely monitoring blood glucose levels.

2.4.2.8.6 To treat hypernatremia without fluid depletion:

- Avoid electrolyte-free solutions alone to prevent overhydration.
- Administer furosemide and replace the urine output hourly with a 5% glucose solution. Hemodialysis or hemoperfusion may be considered as alternatives if necessary.

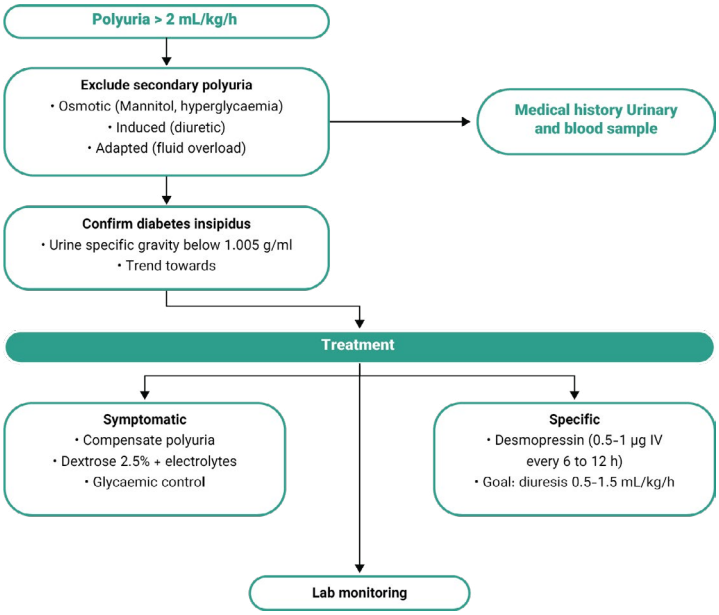


Figure 2.8 Management of Polyuria in the Potential Donor After Brain Death.
Adopted from: European Committee on Organ Transplantation. Guide to the quality and safety of organs for transplantation. 8th Edition. European Directorate for the Quality of Medicines and Healthcare (EDQM) 2022.

2.4.2.9 **Metabolic and Respiratory Acidosis**

The correction of acidosis plays a critical role in managing potential donor, as acidosis can mimic brain death, potentially leading to misdiagnosis if not properly addressed. Also, maintaining acid-base balance is essential for preserving organ viability and function in potential donors. Hence, blood gas analysis becomes mandatory in this process, as it allows for the assessment of pH, bicarbonate, and CO2 levels. To treat acidosis, the following are recommended:

2.4.2.9.1 Metabolic acidosis (low pH due to acid accumulation or bicarbonate loss) can depress CNS, which may mimic brain death. Management involves identifying the cause and treating it with bicarbonate, fluids, or dialysis.

2.4.2.9.2 Respiratory acidosis (low pH due to CO2 buildup from inadequate ventilation) can cause hypercapnia, depressing the CNS and potentially masking apnea tests. Management involves addressing the underlying cause and may require mechanical ventilation adjustments.

2.5 Organ Validity from Deceased Donors

A comprehensive assessment of organ validity from deceased donors is essential to ensure the safety, efficacy, and ethical integrity of organ transplantation. SCOT retains the ultimate responsibility of determining whether a deceased donor's organs are suitable for transplantation. This process aims to maximize transplant success by ensuring organ viability, reducing the risk of graft failure, and enhancing recipient safety. In evaluating donor suitability, the following four (4) critical components must be addressed in a multi-step evaluation process:

DETERMINING OF CONTRAINDICATIONS (GENERAL AND ORGAN/TISSUE-SPECIFIC)

The first step in determining organ validity involves assessing for both general and organ/tissue-specific absolute contraindications. When an absolute contraindication is identified, this disqualifies the organ from being suitable for donation. Additionally, organ/tissue-specific criteria help identify conditions that require further evaluation or consultation.

ASSESSMENT OF ORGAN ACCEPTANCE CRITERIA

Organ acceptance criteria are essential for determining whether an organ is fit for transplantation. This involves evaluating the organ's viability, considering antigen mismatches, and applying organ-specific requirements. The goal is to ensure that only high-quality organs are selected, maximizing the likelihood of successful transplantation and minimizing the risk to recipients.

SCREENING FOR TRANSMISSIBLE DISEASE

Screening for infectious diseases is crucial, as donor-derived infections (DDIs) can lead to significant morbidity and mortality in recipients. A thorough evaluation of the donor's epidemiological, clinical, and laboratory data helps identify active or latent infections that may pose a risk. This screening allows for the implementation of preventive measures and ensures that the risk of transmission is minimized.

SCREENING FOR CANCER TRANSMISSION RISK

Screening for cancer is another critical component of the donor assessment process, as the transmission of cancerous cells through transplantation is associated with high risks. The presence of solid tumors or hematological malignancies in the donor can lead to severe complications in recipients. A detailed evaluation of the donor's medical history and cancer status is essential to avoid unnecessary rejection of viable organs, while still protecting the recipient from potential risks.

2.5.1 DETERMINING OF CONTRAINDICATIONS (GENERAL AND ORGAN/TISSUE-SPECIFIC)

2.5.1.1 GENERAL CONTRAINDICATIONS FOR ORGAN DONATION

2.5.1.1.1 Damage that resulted in the initial injury causing death or shock lasting for more than 30 minutes except in cases of tissue transplantation.

2.5.1.1.2 Active and disseminated infection, such as active infections with tuberculosis, HIV, candidemia, Parasites, and Active fungal, parasitic, or viral, meningitis or encephalitis.

2.5.1.1.3 Documented or suspected cancer in the deceased donor such as leukemia, Hodgkin's disease, lymphoma, multiple myeloma, or history of melanoma.

2.5.1.1.4 Idiopathic illness.

2.5.1.1.5 Certain neurological diseases (e.g. Reye's syndrome, Creutzfeldt-Jacob disease), or slow virus diseases (e.g. progressive multi-focal encephalopathy or Kawasaki disease).

2.5.1.1.6 No clear cause of DNC despite sufficient investigations e.g. undiagnosed Meningoencephalitis.

2.5.1.2 ORGAN/TISSUE SPECIFIC CONTRAINDICATIONS FOR DONATION

In addition to general contraindications, organ and tissue-specific criteria must be considered to determine donation validity. These include absolute contraindications—conditions that disqualify organs or tissues from being valid for transplantation—and specific considerations, which may require further evaluation or reporting to SCOT (see Table 2.8).

Table 2.8 Specific Criteria for Organ/Tissue Validity from Deceased Donors

	Absolute Contraindication	Specific Consideration
Heart	• Age above 65 years • History of CABG • History of coronary stent/intervention • Current or past medical history of MI • Severe vessel diagnosis (e.g., >50% vessel occlusion or 2+ vessel disease as per cardiac catheterization) • Acute myocarditis or endocarditis, or both • Heart failure due to cardiomyopathy • Internal defibrillator or pacemaker • Moderate to severe valve or 2-valve disease as per the echo, cardiac cath, or previous valve repair. • Severe global hypokinesis • Myxoma • Congenital defects (surgically corrected or not)	Report the following to SCOT for further consideration: • Age >45 years (cardiac catheterization needed) • Significant history of cardiovascular disease • Abnormal cardiac investigations • Previous severe chest trauma causing heart damage
Lung	• Age above 65 years. • Diagnosed with COPD. • Asthma (on daily prescription, or if the asthma is the cause of death). • Pulmonary fibrosis. • Previous lobectomy. • Multiple blebs documented on CAT scan. • Pneumonia in CT, X-ray, bronchoscopy, or cultures. • Bilateral severe pulmonary contusions in CT scan	Report the following to SCOT for further considerations (marginal lung donor)β: • Bronchial disease. • Recurrent respiratory infections. • History of smoking (>20 pack-years). • Terminal PaO2/FiO2 < 250 mmHg
Kidney	• Age above 50 years with type 1 diabetes for >20 years. • Autosomal Dominant/Recessive Polycystic Kidney Disease (ADPKD/ARPKD). • Glomerulosclerosis ≥20% by kidney biopsy. • Advanced chronic kidney disease	Report the following to SCOT for further consideration: • High creatinine (>2.5 mg/dL) despite adequate fluid replacement. • Positive hepatitis B surface antigen (HBsAg). • Age >60 with acceptable GFR (≥45 ml/min/1.73 m2) and no heavy proteinuria (≤ 300mg /day).

	Absolute Contraindication	Specific Consideration
Liver	• Cirrhosis. • Terminal total bilirubin ≥4 mg/dL. • Portal hypertension. • Fulminant hepatic failure. • Micro-steatosis ≥50% or fibrosis ≥ stage II	Report the following to SCOT for further consideration: • HCV-positive donors. • Age >60 years. • Terminal AST/ALT >700 U/L The liver can be considered for **splitting** if the following criteria are met: • Age less than 45 years. • Sodium <160 mmol/L. • AST 3 times less than the normal value. • ALT less than 3 times less than the normal value. • GGT 2 times less than the normal value. • No macroscopic liver trauma. • Stable hemodynamics with 1 only inotrope • ICU stay <7 days
Pancreas	• Age above 50 years. • History of diabetes or alcohol addiction. • Serum glucose >11 mmol/L (200 mg/dL). • BMI >30 kg/m². • Significant increase in amylase level. • Prolonged hypotension or hypoxemia with end-organ damage. • The donor is on high doses of inotropic drugs. • Active acute/chronic pancreatic inflammation, with lipase serum level >300 IU/L. • Previous trauma or surgery of pancreas or macroscopic appearance (i.e. at recovery) showing edematous, hemorrhage, capsular tears, or peripancreatic hematoma	No specific considerations
Intestine and Multi-Visceral	• Age above 50 years. • Abnormal liver function tests. • Sodium >165 mmol/L. • BMI >28 kg/m². • Unexplained diarrhea. • Ascites discovered by abdominal ultrasound or CT. • Tumors discovered by abdominal ultrasound or CT	Report the following to SCOT for further consideration: • CPR longer than 10 minutes. • ICU stay longer than 2 weeks. • High dose of vasopressors

	Absolute Contraindication	Specific Consideration
Bone Tissue	• Diseases of the nervous system (e.g., Alzheimer's, Parkinson's). • Direct bone damage. • Time between cardiac arrest and bone retrieval >12 hours	Certain types of cancer, joint diseases, and bone diseases may be accepted for donation after risk assessment.
Corneal Tissue	• Intrinsic eye diseases, including: • Eye tumors, such as retinoblastoma, malignant tumors of the anterior segment as primary of metastatic origin, and melanoma. • Previous surgeries on the cornea • Damaged corneas with scar or ectatic diseases. • Active infectious or inflammatory diseases of the anterior segment • Rubeola, Rubella, Rabies, Human T-Lymphotropic retrovirus type 1 and type 2. • Time between cardiac arrest and corneal recovery >24 hours	• Aplastic anemia and agranulocytosis are not contraindications. • Solid tumors elsewhere in the body may be accepted for donation after risk assessment.

β Marginal lungs might still be viable for transplantation, but they often require careful evaluation and might be reserved for patients who are in urgent need or who have fewer options.

ALT: Alanine Aminotransferase; AST: Aspartate Aminotransferase; BMI: Body Mass Index; CABG: Coronary Artery Bypass Graft; CAT: Computed Axial Tomography; CPR: Cardiopulmonary Resuscitation; CT: Computed Tomography; GFR: Glomerular Filtration Rate; GGT: Gamma-Glutamyl Transferase; HCV: Hepatitis C Virus; ICU: Intensive Care Unit; MI: Myocardial Infarction.

2.5.2 ASSESSMENT OF ORGAN ACCEPTANCE CRITERIA

Determining the acceptance criteria plays a crucial role in maximizing the success of transplants while minimizing risks to recipients. The criteria are designed based on minimum acceptance criteria, organ-specific requirements, and antigen mismatches. This procedure promotes recipient safety and enhances shared decision-making between transplant programs and recipients:

2.5.2.1 **Establish Minimum Acceptance Criteria**

2.5.2.1.1 Transplant programs shall define the minimum acceptance criteria which are the minimum standards that organs from deceased donors should meet to be offered by SCOT to transplant programs.

2.5.2.1.2 Transplant programs shall report the minimum acceptance criteria for the intended transplant program to SCOT. Also, notify SCOT of any future changes to the criteria.

2.5.2.2 **Define Organ-Specific Acceptance Criteria**

2.5.2.2.1 **Heart Transplants:**

- The allocation of a donated heart is based on identical blood groups, except for highly sensitized patients (with cPRA > 80%) and pediatric patients under 2 years old, where the heart can be offered to compatible recipients.

2.5.2.2.2 **Liver Transplants:**

- Determine and report acceptable deceased donor weight for each liver candidate.
- Specify additional acceptance criteria, such as minimal requirements or willingness to accept organs from donors with different blood types.

2.5.2.2.3 **Kidney Transplants:**

- The kidney minimum acceptance criteria do not apply to highly sensitized candidates (defined as cPRA ≥95%) or imported zero antigen mismatch (0-ABDRDQ) offers.
- Require written informed consent from candidates for kidneys with a Kidney Donor Profile Index (KDPI) score above 85%.
- Specify the willingness of the transplant candidate to accept both kidneys (dual/en-bloc) from a single deceased donor and communicate this to SCOT.

2.5.2.3 **Set Maximum Mismatched Antigens Criteria**

2.5.2.3.1 Specify the maximum number of mismatched antigens that will be accepted, as well as any unacceptable antigens for its candidates.

2.5.2.3.2 Upon specifying these criteria, SCOT will only offer organs from deceased donors with mismatched antigens equal to or less than the maximum specified.

2.5.2.4 **Report Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)**

2.5.2.4.1 Define unacceptable antigens to prevent their transplantation (refer to Chapter 2, Section 2C, Sub-section 2.14).

2.5.2.4.2 Establish additional criteria for unacceptable antigens.

2.5.2.5 **Infectious Disease Acceptance**

2.5.2.5.1 Specify whether a candidate is willing to accept an organ from a donor with certain infectious diseases.

2.5.2.5.2 Refer to the appropriate screening table (see Table 2.9) for infectious disease acceptance criteria to facilitate shared decision-making with the recipient.

Table 2.9 Donor Infectious Disease Screening Options

If the donor tests positive for:	Candidates may choose not to receive offers on the following match runs
Cytomegalovirus (CMV)	Intestine
Hepatitis B Core Antibody (HBcAb) or Hepatitis B NAT	Heart, Lung, Kidney, Liver, Pancreas, Intestine, Heart-Lung, Kidney-Pancreas
Hepatitis C (HCV) Antibody or Hepatitis C NAT	Heart, Lung, Kidney, Liver, Pancreas, Intestine, Heart-Lung, Kidney-Pancreas

2.5.3 SCREENING FOR TRANSMISSIBLE DISEASE

Donor-derived infections (DDIs) are defined as any infection present in the donor that is transmitted to one or more recipients via grafts. Although DDIs are rare, they are associated with significant morbidity and mortality. Bacterial, viral, fungal, and parasitic infections have been proven to be transmissible via organ transplantation. Hence, the identification of active or latent infections in donors allows for a better assessment of risk, establishes preventive measures, minimizes negative consequences, and improves recipient survival (see Table 2.10). DDIs are often characterized as; expected (i.e. known to be infected with a pathogen that can be detected and treated) or unexpected (i.e. transmission of pathogens from donor to recipient when donor infection is previously unknown, undetected, or incompletely treated).

2.5.3.1 **Absolute infectious contraindication for organ donation**

2.5.3.1.1 Donors with pan-resistant organisms.

2.5.3.1.2 Donors with known active TB infection.

2.5.3.1.3 Donors with active and disseminated candidemia.

2.5.3.1.4 Donors with documented candida auris.

2.5.3.1.5 Donors with documented systemic or central nervous system cryptococcosis.

2.5.3.1.6 Donors with documented active and disseminated aspergillus infection.

2.5.3.1.7 Donors with active invasive yeast infections (SCOT should be notified in case of unrecognized yeast infection in the donor at the time of transplant).

2.5.3.1.8 Donors with active infection with Trypanosoma Cruzi (Chagas), Leishmania, Strongyloides, malaria (plasmodium sp.), or parasitic meningitis.

2.5.3.2 **Specific considerations for infections**

1.5.1.1.1 Evaluate potential deceased donors with non-traumatic CNS events carefully. Ensure the report sent to SCOT and the transplant programs includes detailed brain imaging, CSF analysis results, and information on antimicrobial therapy.

1.5.1.1.2 Infectious disease consultation and repeated cultures to document pathogen clearance are recommended if they don't delay the recovery process.

1.5.1.1.3 Pending culture results should not delay the recovery procedure. However, SCOT must be notified of any outstanding investigations, and the donor's medical file should remain open until all culture results are finalized.

1.5.1.1.4 Organs from donors with CNS infections caused by Neisseria meningitidis, Streptococcus pneumoniae, Haemophilus influenzae, or Escherichia coli may be used if the donor received at least 24-48 hours of targeted therapy.

1.5.1.1.5 Donors with bacteremia should receive appropriate antibiotics for a minimum of 48 hours, with a full susceptibility report available to the transplant programs.

1.5.1.1.6 Infected donors with Brucella (Brucellosis) must undergo at least 24-48 hours of targeted antimicrobial treatment before donation.

1.5.1.1.7 It is preferable to exclude donors with vancomycin-intermediate Staphylococcus Aureus (VISA) and vancomycin-resistant Staphylococcus Aureus (VRSA) infections from donation.

1.5.1.1.8 Positive Candida results from donor respiratory tract cultures must be reported to SCOT and shared with the transplant programs (s).

1.5.1.1.9 Donation should be avoided from donors who have traveled to Zika-endemic areas in the 28 days before donation (refer to Weqayah for updated information).

1.5.1.1.10 Donation should be avoided from donors who have traveled to Ebola virus disease (EVD) areas in the 21 days before donation (refer to Weqayah for updated information).

1.5.1.1.11 Donors suspected of having emerging viral infections, such as West Nile virus, rabies, or lymphocytic choriomeningitis virus, should be excluded from organ donation.

1.5.1.1.12 Serologic testing for Schistosomiasis is recommended for donors from endemic areas.

Table 2.10 Summary of the Required Tests for Deceased Donors, Timing, and Risk of Infection		
Test	**Timing/place of testing**	**Risk on organ recipients**
HIV serology	Upon SCOT notification (To be done at the local hospital)	Unacceptable high risk
CMV/EBV serology	If a donor is accepted for donation.	Calculated risk
Herpes virus	Optional (To be done at the transplant programs)	Calculated risk
Respiratory viruses (for lung & small bowel)	To be done at the transplant programs if indicated	High risk
MERS-CoV and SARS-CoV2	To be done at the transplant programs if indicates	High risk
Emerging viruses	Done at the reference laboratory	Unacceptable high risk
HBV	Upon SCOT notification. (To be done at the local hospital)	Calculated risk
HCV	Upon SCOT notification	Calculated risk
Mycobacterium TB	Upon recovering lung transplant AFB stain, culture, and MTB PCR	Calculated risk
Brucellosis	At the recovery,	Low risk
Parasitic infections	Optional based on the transplant programs local guidance	Risk is dependent on the type of parasitic infection and type of transplant
MDR bacteria	At the time of SCOT notification Respiratory, blood cultures. To be done at the local hospital Screening for MDR pathogens with nasal/skin and rectal swabs. To be done at the transplant programs Upon an offer from SCOT Cultures from blood, respiratory samples, and surgical cultures To be done at recovery	High risk Risk is dependent on the pathogen, susceptibility report, site of infection, and options for therapy
Fungal infections	Screening is not recommended. If positive cultures from any site of the body. (To be reported to SCOT)	Calculated risk
CNS events/ infection	At presentation: Patients admitted with a CNS event that is not explained by risk factors or trauma have To be investigated for potential CNS infection at the local hospital	Risk is dependent on the pathogen and the available treatment options and treatment for the donors

AFB: Acid-Fast Bacilli; CNS: Central Nervous System; CMV: Cytomegalovirus; EBV: Epstein-Barr Virus; HCV: Hepatitis C Virus; HIV: Human Immunodeficiency Virus; MDR: Multidrug-Resistant; MERS-CoV: Middle East Respiratory Syndrome Coronavirus; MTB: Mycobacterium Tuberculosis; PCR: Polymerase Chain Reaction; SARS-CoV-2: Severe Acute Respiratory Syndrome Coronavirus 2.

2.5.4 SCREENING FOR CANCER TRANSMISSION RISK

The potential transmission of cancer from deceased donors poses significant risks to organ transplant recipients. Various types of cancers have been documented to be transmissible via organ transplantation. Therefore, identifying donors with active or latent cancerous conditions is crucial for assessing risk, mitigating adverse outcomes, and enhancing recipient survival rates. Notwithstanding, it's important to note that the decision not to accept organs from cancer patients should be carefully evaluated to avoid indiscriminate rejection of potentially life-saving donations. The following recommendations are important to be taken into account for various types of cancer.

2.5.4.1 Procedure for Assessing Donor Malignancy

Prior to Recovery

- Perform a comprehensive physical examination of the donor.
- Evaluate clinical and family history to identify potential contraindications for organ donation.
- Conduct standard laboratory tests for all possible donors to detect specific diseases, such as hematological malignancies, that may contraindicate organ donation.
- Review radiological studies performed during the donor's hospitalization for signs of malignancy.
- For donors with a history of cancer, perform CT scans of the thorax, abdomen, and pelvis to assess for tumor recurrence.
- At the time of donation, ensure that a chest radiograph is taken, and additional imaging (e.g., ultrasound, CT scans) may be ordered if deemed necessary.

IMPORTANT NOTE

Routine screening for tumor markers is not recommended to avoid false positives, leading to unnecessary rejection of donors. However, in donors with a known of malignancies history, appropriate tumor markers should be tested to evaluate the current status.

IMPORTANT NOTE

The organ donation process should not be excluded due to a non-specific radiological finding. Clarification should be sought in a reasonable timeframe, and the results must be shared with the accepting transplant programs if the organ donation process continues.

During Recovery

- During organ recovery, any suspicious lesion, mass, or lymphadenopathy should be immediately examined histologically, preferably by a pathologist experienced in the organ where the abnormality was detected. If malignancy is suspected, notify the transplant programs immediately.

After Recovery (pre-transplantation)

- In cases where a donor malignancy, primary tumor, or metastasis is identified shortly after organ recovery (but before transplantation), alert all transplant programs immediately. If the organ has already been transplanted, inform SCOT and the transplant programs without delay.

2.5.4.2 **Determinants in Assessing Donor Malignancy**

2.5.4.2.1 Exclude organ donation for donors with newly diagnosed tumors, except for specific active malignancies with acceptable risk (see Table 2.11).

2.5.4.2.2 A remission period of 5 to 10 years is required for donors with historically treated malignancies, depending on the tumor type and stage, before considering them for organ donation, although some exceptions exist.

2.5.4.2.3 Exclude organs from donors with metastatic malignancies unless the tumor was diagnosed more than 5 years ago, initially staged at pN1, fully treated, and has had a recurrence-free follow-up, indicating a presumed cure.

2.5.4.2.4 Consider all solid organ tumors (e.g. breast cancer, colorectal cancer, lung cancer, ovarian cancer…etc) as potential contraindications for donation and/or entail a significant risk of transmission despite the treatment and recurrence (refer to Appendix C).

2.5.4.2.5 Leukemia, lymphoma, and plasmacytoma diagnosed during donor recovery are classified as an unacceptable risk for organ donation. Other hematopoietic malignancies as Monoclonal gammopathies of undetermined significance (MGUS), Myeloproliferative neoplasms (MPN), require careful consideration, in consultation with an experienced hemato-oncologist.

2.5.4.2.6 Assess CNS tumors based on the WHO histological grade and the interventions performed (e.g., surgery, chemotherapy, radiotherapy) and exclude brain tumors higher than WHO Grade I from donation, as higher-grade tumors (WHO Grade III or IV) and more interventions increase the risk of transmission (see Figure 2.9).

Table 2.11 Actions for Detection/Assessment of Malignancy in Possible Organ Donors

When	How	What to do
Before donor assessment	Malignancy diagnosed from the patient's medical history.	If donor organs are accepted despite a history of malignancy; detailed histological reports, with staging and imaging studies as well as all information and actual diagnostic findings, should be documented on the donor information form. **Transplant programs may decide to accept the organs:** • Oncologist advice can be sought. • Informed consent should be obtained pre-transplantation. • Follow-up to assess possible transmission should be undertaken. • Possible transmission should be reported to SCOT.
During donor assessment, recovery, and before Transplantation	Malignancy found incidentally during clinical donor assessment or surgical inspection.	• Urgent histological assessment should be performed immediately for preliminary diagnosis; subsequent work-up should be done for definitive diagnosis. • All recipient programs should be alerted immediately • Oncologist advice can be sought • informed consent should be obtained pre-transplantation • Follow-up to assess possible transmission should be undertaken. • Possible transmission should be reported SCOT.
After transplantation of at least one organ	Misinterpreting a frozen section as benign, but the final diagnosis is malignant. Malignancy incidentally found during pre-transplant preparation of the organ in the recipient center (other organs already transplanted). Donor autopsy results (available after transplantation) indicated malignancy.	• Immediately alert SCOT and SCOT will alert all transplant programs, especially in cases where metastases are detected.

Diffuse astrocytic and oligodendroglial tumours	I	II	III	IV
Diffuse astrocytoma, IDH-mutant		•		
Anaplastic astrocytoma, IDH-mutant			•	
Glioblastoma, IDH-wildtype				•
Glioblastoma, IDH-mutant				•
Diffuse midline glioma, H3K27 M-mutant				•
Oligodendroglioma, IDH-mutant and 1p/19q-codeleted		•		
Anaplastic oligodendroglioma, IDH-mutant and 1p/19q-codeleted			•	

Other astrocytic tumours	I	II	III	IV
Pilocytic astrocytoma	•			
Subependymal giant cell astrocytoma	•			
Pleomorphic xanthoastrocytoma		•		
Anaplastic pleomorphic xanthoastrocytoma			•	

Ependymal tumours	I	II	III	IV
Subependymoma	•			
Myxopapillary ependymoma	•			
Ependymoma		•		
Ependymoma, *RELA* fusion-positive		•	•	
Anaplastic ependymoma			•	

Other gliomas	I	II	III	IV
Angiocentric glioma	•			
Chordoid glioma of third ventricle		•		

Choroid plexus tumours	I	II	III	IV
Choroid plexus papilloma	•			
Atypical choroid plexus papilloma		•		
Choroid plexus carcinoma			•	

Pineal tumours	I	II	III	IV
Pineocytoma	•			
Pineal parenchymal tumour of intermediate differentiation		•	•	
Pineoblastoma				•
Papillary tumour of the pineal region		•	•	

Meningiomas	I	II	III	IV
Meningioma	•			
Atypical meningioma		•		
Anaplastic (malignant) meningioma			•	

Embryonal tumours	I	II	III	IV
Medulloblastoma (all subtypes)				•
Embryonal tumour with multi-layered rosettes, C19MC-altered				•
Medulloepithelioma				•
CNS embryonal tumour, not otherwise specified				•
Atypical teratoid/rhabdoid tumour				•
CNS embryonal tumour with rhabdoid features				•

Neuronal and mixed neuronal-glial tumours	I	II	III	IV
Dysembryoplastic neuroepithelial tumour	•			
Gangliocytoma	•			
Ganglioglioma	•			
Anaplastic ganglioglioma			•	
Dysplastic gangliocytoma of cerebellum (Lhermitte–Duclos)	•			
Desmoplastic infantile astrocytoma and ganglioglioma	•			
Papillary glioneuronal tumour	•			
Rosette-forming glioneuronal tumour	•			
Central neurocytoma		•		
Extraventricular neurocytoma		•		
Cerebellar liponeurocytoma		•		

Tumours of the cranial and paraspinal nerves	I	II	III	IV
Schwannoma	•			
Neurofibroma	•			
Perineurioma	•			
Malignant peripheral nerve sheath tumour (MPNST)		•	•	•

Mesenchymal, non-meningothelial tumours	I	II	III	IV
Solitary fibrous tumour/haemangiopericytoma	•	•	•	
Haemangioblastoma	•			

Tumours of the sellar region	I	II	III	IV
Craniopharyngioma	•			
Granular cell tumour	•			
Pituicytoma	•			
Spindle cell oncocytoma	•			

Figure 2.9 Grading of Selected Central Nervous System Tumors (WHO 2016 Classification (EDQM 2022))

Adapted from: Louis DN, Perry A, Reifenberger G et al. The 2016 WHO Classification of Tumors of the Central Nervous System: a summary. Acta Neuropathologica 2016; 131(6): 803-20.

2.6 Organ Allocation Framework

2.6.1 GENERAL GUIDELINES IN ORGANS ALLOCATION

2.6.1.1 Organ allocation is the process of determining how organs are distributed. Allocation includes the system of policies and guidelines that ensure that organs are distributed in an equitable, ethical, and medically sound manner.

2.6.1.2 The responsibility of organ allocation relies solely on SCOT using the organ allocation framework that is designed to ensure fairness, optimize transplantation outcomes, and maximize the benefits for candidates in need.

2.6.1.3 SCOT exercises extreme caution in limiting the access to allocation documentation to authorized personnel involved in the organ allocation process to maintain confidentiality and impartiality of sensitive information.

2.6.1.4 All patients with comparable clinical profiles on the waiting list have an equal probability of receiving organs from deceased donors without discrimination, with respect to the allocation types and attributes.

2.6.1.5 If a transplant programs encounters a conflict with SCOT policy on organ allocation, they can raise the issue through the official channels of SCOT or e-mail: opex@scot.gov.sa, and SCOT will investigate accordingly.

2.6.1.6 SCOT reviews the allocation criteria periodically to ensure its effectiveness and relevance. The latest released allocation policy can always be accessible and available under the policies and procedures section on the SCOT website (www.scot.gov.sa).

2.6.1.7 Allocation decisions made by transplant programs regarding organ offers must be recorded in The unified organ donation and transplantation platform (Athar).

2.6.1.8 SCOT mandates that transplant programs maintain accurate and timely data submissions to ensure fair and equitable organ allocation.

2.6.1.9 SCOT mandates that transplant programs update their waitlists weekly and notify SCOT immediately of any significant updates or changes in patient status to ensure timely and accurate information (refer to Chapter 3).

2.6.2 TYPES AND ATTRIBUTES IN ORGAN ALLOCATION

SCOT's organ allocation system is structured to ensure the fair and efficient distribution of organs through four distinct allocation types: Standard, Exceptional, Rescue, and Organ Offer from countries outside KSA.

2.6.2.1 **Standard Allocation**: offers for each organ are made based on the match list" Recipient oriented Allocation", prioritizing the first recipient as the "primary offer." If this offer is declined, SCOT will proceed to the next recipient on the list, referred to as the "backup offer".

2.6.2.1.1 **Primary Offer**: The offer made to the first recipient on the matching list. The transplant programs has the option to accept this offer and proceed with the transplantation for the designated recipient. SCOT strongly urges programs to make their decision within 60 minutes for logistical reasons.

2.6.2.1.2 **Secondary Offer (Backup)**: When the primary offer is made, the second recipient on the match list will generally receive a backup or secondary offer. This offer is intended to save time in the allocation process. Transplant programs are also urged to decide on the secondary offer within a 60-minute time limit. Transplant programs must treat backup offers the same as actual organ offers.

2.6.2.1.3 Standard organ allocation is based on the attributes of medical urgency, compatibility, waiting time, and organ utilization.

- **Medical Urgency:** organ allocation considers the level of medical urgency of candidates, ensuring that those with the most critical medical conditions are prioritized for transplantation; the principle of "sickest first" is always emphasized, considering that allocation criteria based on medical urgency are different for each organ.
- **Compatibility:** certain compatibility tests shall be performed in each organ allocation process. The compatibility in blood group, HLA and size matching might be done based on the type of the transplanted organ, to maximize the likelihood of successful transplantation and minimize the potential for organ rejection (see Table 2.12).

Table 2.12 Matching Eligibility Based on Blood Group Compatibility

Donor blood group	The recipient blood group can be:
O	O, A, B, AB
A	A, AB
B	B, AB
AB	AB

- **Waiting time:** SCOT emphasizes the consideration of waiting time in organ allocation within the same medical urgency, ensuring that candidates who have been waiting for a longer duration are given priority to receive a suitable organ.

- **Organ utilization:** To maximize organ utilization, factors such as the organ's suitability for transplantation, the likelihood of a successful outcome, the proximity of candidates to the donor, and logistical issues, and others, must be considered during organ allocation. In the absence of urgency, the allocation process considers the distance and transportation feasibility between the donor and potential recipients to ensure efficient utilization of available organs (i.e. shorter cold ischemia time).

2.6.2.2 **Exceptional Allocation:** This applies to unique or urgent cases requiring a deviation from standard allocation attributes. Such cases are evaluated individually by the organ-specific transplantation sub-committee assigned by the SCOT's national committee, which will convene as needed when an exceptional case arises prior to the allocation process.

2.6.2.3 **Rescue Allocation:** This is initiated when the standard allocation method is unsuccessful due to an unstable recipient/donor, long cold ischemic time, or other causes that could lead to losing the organ. In such instances, SCOT assumes sole responsibility to ensure the organ is utilized effectively.

2.6.2.3.1 If no suitable recipients are available within Saudi Arabia, the SCOT coordinator shall reach out to the approved organ sharing program (e.g., the Gulf Countries Organ Sharing Program) to explore potential recipients and to ensure organ utilization.

2.6.2.4 **Allocation of organs offered from Outside KSA:** when an organ is offered from outside KSA, it will be allocated according to the standard allocation methods.

2.6.3 ORGAN ALLOCATION AND OFFERING PROCEDURE (see Figure 2.10)

2.6.3.1 SCOT commences the allocation process, within 1 hour of obtaining organ donation consent.

2.6.3.2 SCOT coordinator requests post-consent donor workup from donor hospitals for the considered organ (see Tables 2.4 and 2.13).

Table 2.13 Routine Donor Workup (for all donors)

Blood culture	Surveillance MRSA: Groin, Axilla, Nasal
Urine culture	Liver enzyme
Throat culture	Electrolyte
CBC and Blood type	Blood gases
Serology*	HLA (Only to be done after the consent is obtained)

* Refer to Table 2.9 for details of types of serology.

CBC: Complete Blood Count; HLA: Human Leukocyte Antigen; MRSA: Methicillin-Resistant Staphylococcus Aureus.

2.6.3.3 The SCOT coordinator shall promptly review the case details, ensure data completion, and diligently assess the viability of the organs based on the established criteria for each organ.

2.6.3.4 The SCOT coordinator shall allocate the viable organ based on the allocation attributes outlined in the organ-specific allocation policy (available under the policies and procedures section on the SCOT website www.scot.gov.sa).

2.6.3.5 The organ allocation offer shall be made to both the primary recipient and backup recipients simultaneously. The final allocation plan must receive approval from the head of the Waiting List Management and Organ Allocation section at SCOT.

2.6.3.6 The SCOT coordinator shall promptly contact the coordinator at the transplant programs to make the organ offer and provide all relevant donor information.

2.6.3.7 The transplant programs has a maximum of 1 hour to accept the offer, which is considered an initial acceptance. During this time, the transplant programs may request further investigations (Form 6: Organ and Tissue Acceptance and Rejection).

2.6.3.8 The SCOT coordinator is responsible for ensuring that all necessary workups are completed and submitted to the accepting transplant programs promptly.

2.6.3.9 Upon receiving all necessary or requested data about the donor and HLA results, the transplant programs must provide a final acceptance or rejection within 1 hour from the time the last investigation result is shared, and the decision should be documented promptly.

2.6.3.10 Failure to respond within 1 hour will result in the programs being excluded from the organ allocation and will be treated as a refusal.

2.6.3.11 If the organ is accepted, the transplant programs shall not proceed with the recovery process until SCOT provides confirmation. SCOT retains the authority to determine when organ recovery should begin, taking into account logistics and the medical conditions of both the donor and recipient to ensure the best possible organ utilization.

2.6.3.12 The primary transplant programs may reject the organ during the recovery process based on a macroscopic examination. In case of rejection, the transplant programs must provide a valid reason for the rejection (Form 6: Organ and Tissue Acceptance and Rejection). Thereafter, The SCOT coordinator shall communicate the rejection reason to the backup transplant programs (s).

2.6.3.13 If the organ is not accepted by any transplant programs due to unsuitability for transplantation, the discard report must be filled by the transplant programs (Form 7: Deceased Organ Discard Report).

2.6.3.14 If the organ is transplanted, the transplant programs shall complete the Post Organ Transplantation Form within 24 hours of the transplantation date.

2.6.3.15 The SCOT coordinator, responsible for allocation, shall document the entire allocation process as relevant.

2.6.3.16 The organ allocation process is considered concluded once the organs have been successfully transplanted to the recipient.

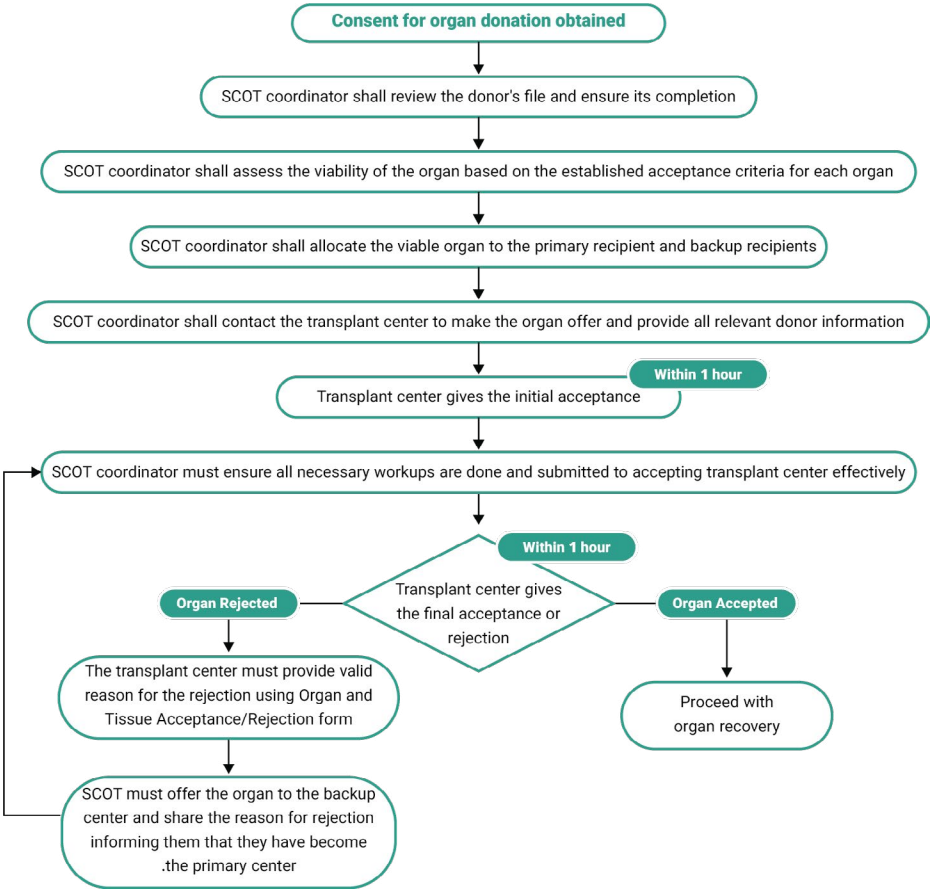


Figure 2.10 General Standard Organ Allocation and Offering Workflow

2.6.4 ORGAN REALLOCATION PROCEDURE

The reallocation procedure is intended to ensure the fair and efficient distribution of available organs to patients on the transplant waiting list. This process focuses on maximizing the utility of donated organs and addressing the medical urgency of recipients. The procedure of organ reallocation considers the following:

2.6.4.1 If a donor's initial test for infectious diseases was negative or pending, but later turns positive, SCOT will stop the allocation based on the initial match, re-execute the match according to the infectious disease screening options, and reallocate the organ accordingly.

2.6.4.2 SCOT will reallocate the accepted organ to the backup recipient if the intended recipient is no longer able to receive the organ after recovery (i.e. prior to shipping the organ). However, if the organ has already been shipped to the accepting transplant programs but the intended recipient is no longer able to receive the organ, the organ will be allocated to the next eligible patient at that programs only if there is a risk of losing the organ. Otherwise, the organ shall be sent to the program where the backup recipient is located.

2.6.4.3 SCOT will always maintain open communication and discussion with the transplant programs affected by the reallocation decision.

2.6.4.4 Every reallocation case is subject to investigation by SCOT to ensure allocation fairness. Identified misconducts are subject to disciplinary action following the bylaw.

2.7 Organ Procurement Procedure

Organ procurement is a vital aspect of the transplant process, encompassing the pre-procurement, procurement, and post-procurement phases (see Figure 2.11). Successful transplantation depends on a thorough donor evaluation, careful surgical removal of organs in optimal condition, and proper assessment of the donated organs. The procurement procedure, which involves the surgical recovery of organs, must follow the latest evidence-based practices, despite of the organ type being procured or whether multiple organs are being recovered. Following procurement, it is essential to follow strict procedures for packaging, labeling, and transporting the recovered organs to maintain their viability. Thereafter, following organ verification guidelines by the transplant programs is necessary to verify procured organs/tissues. The following guidelines must be strictly adhered to throughout organ procurement and verification procedures:

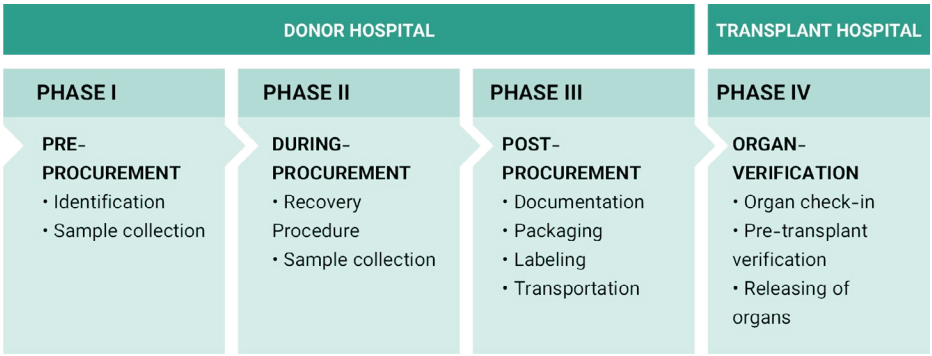


Figure 2.11 Organ/tissue Procurement and Verification Procedures

PHASE I: PRE-PROCUREMENT

2.7.1 Donor and Organ Identification

Before any organ recovery process, the recovery hospital needs to verify specific details to ensure accuracy, along with the corresponding verification sources. This identification is performed by both the on-site recovering surgeon and the SCOT coordinator or ODU representative (see Table 2.14).

Table 2.14 Pre-procurement Identification Requirements

Verification Elements	Verification Source	Verification Responsibility (by both of the following individuals)
Donor Identification	Donor identification band, or Patient medical record	• On-site recovering surgeon • SCOT coordinator/ODU
Organ Identification	Patient medical record	• On-site recovering surgeon • SCOT coordinator/ODU
Donor Blood Type and Subtype	Patient medical record	• On-site recovering surgeon • SCOT coordinator/ODU

2.7.2 Pre-procurement Sample Collection

It is essential to collect various biological samples from the deceased donor to ensure transplant compatibility. Specimens outlined in Table 2.15 are typically obtained prior to commencing the procurement procedure and collected by the procurement team, along with the required quantities for each. Specimens shall be stored in sterile containers, with tight-fitting lids, and labeled with the name of the donor, and the date and time of obtaining the specimen.

Table 2.15 Samples to be collected by the procurement team from the diseased donor*

Sample Type	Required Quantities
Blood	- ACD-A tube, (for HLA typing) at least 7 tubes** - SST II tube, at least 2 tubes - EDTA tube, at least 3 tubes - CAT tube, at least 3 tubes - Aerobic and Anaerobic blood culture – 1 each
Urine	- 1 urine sample (60-80 ml) in a sterile container for each transplant programs.
Sputum	- 1 sputum sample.

* The quantity of specimens is intended for 3 prospective transplant programs.

** For direct HLA crossmatch purposes.

PHASE II: PROCUREMENT PROCEDURE

2.7.3 Guidelines for Procurement Procedure

Organ procurement is a vital procedure, involving the careful recovery of organs from a deceased donor. This procedure must be meticulously planned to ensure the utmost adherence to evidence-based practices and ethical standards. The procedure requires coordination among the procurement team(s) to ensure the success of the organ recovery while respecting the donor's contribution to life-saving transplants. Also, it requires support and assistance from the donor hospital (see Table 2.16). The following guidelines are of great importance throughout the surgical recovery procedure:

2.7.3.1 Ensure that all team members involved in the procurement procedure are competent in their respective roles. The structure of the organ procurement team is recommended to include:

- Lead surgeon(s), fully trained in organ procurement aspects
- Assistant surgeon
- OR nurse(s), fully trained in organ procurement aspects
- Organ perfusionist, responsible for organ perfusion machine
- Transplant coordinator

2.7.3.2 Ensure that all involved surgical teams and coordinators communicate and collaborate effectively. A preoperative briefing should outline each team's role, order of operations, and timeframes.

2.7.3.3 Organ procurement teams should pursue a sequential approach for recovering organs from deceased donors with multiple donation organs, recovering the heart and lung first, followed by the liver and pancreas, and then the kidney. The cornea and other tissues can be recovered after organ retrieval.

2.7.3.4 All critical donor information, including donor identity, consent, blood type, and medical history are to be confirmed once again immediately prior to the surgical intervention.

2.7.3.5 In the event of donor clinical deterioration, the organ procurement team must promptly initiate rapid organ recovery procedures.

2.7.3.6 Surgeons should follow standardized surgical techniques tailored to the specific organ being recovered, ensuring alignment with best practices and evidence-based guidelines to minimize damage to the organ and surrounding tissues.

2.7.3.7 Organ procurement teams should prioritize minimizing ischemic time by efficiently coordinating the procedure, ensuring that organ perfusion begins promptly following organ isolation.

2.7.3.8 Inside the operating room and during the organ procurement procedure, the transplant programs team may reject an organ based on inspection before the cross-clamp or at the back table after the cross-clamp. In this case, notify SCOT immediately, providing the reason for rejection.

2.7.3.9 In case of failure to recover any organ due to medical (e.g. sudden cardiac arrest) or logistical (e.g. unnecessary delay) reasons, the event shall be documented by the involved parties (e.g. recovery team or the donor hospital) and shared with SCOT.

2.7.3.10 Adherence to strict sterile protocols is mandatory during organ recovery procedures to maintain the viability of the recovered organ for transplantation.

2.7.3.11 The recovery team shall maintain all legal and ethical standards regarding organ donation and recovery, including the dignity and privacy of the donor during the organ recovery procedure, and protect the donor against humiliation or deformity according to the standard surgical technique.

2.7.3.12 SCOT, the donor hospital, the RCO, and the procurement team must consider social issues and respect the family's wishes to expedite recovery, such as accommodating early burial requests.

2.7.3.13 SCOT maintains the right to attend the operating room, if deemed necessary, to ensure compliance with SCOT regulations.

Table 2.16 Responsibilities of Donor Hospitals Throughout Organ Recovery Procedures

Stage	Responsibilities
Before Recovery	• Ensure a safe transfer of the donor to the operating room. • Provide a fully equipped operating room for the recovery procedure, including appropriate anesthetic equipment and drugs to support the donor. • Provide an anesthetist to assist with DBD donors during the recovery process. • Offer the surgical team necessary access and support throughout the organ recovery procedure.
During Recovery	• Keep operating room staff present during the recovery to assist both the scrub nurse and anesthetist. • Ensure that the operating room staff are qualified and familiar with the surgical equipment, instruments, and procedures involved. • Facilitate training opportunities for all members of the team. • SCOT will verify the privileges of the surgeons participating in the organ recovery; the donor hospital does not need to verify these privileges.
After Recovery	• Ensure that all relevant surgical recovery data is accurately and completely documented. • Ensure that the donor's body is securely closed and respectfully prepared for transfer to the morgue of the donor hospital. • Assist with the safe and timely transport of recovered organs to the transplant programs, as needed.

2.7.4 Sample Collection During Procurement

It is essential to collect various biological samples from the deceased donor to ensure transplant compatibility. Specimens outlined in Table 2.17 are typically obtained during the procurement procedure and collected by the procurement team, along with the required quantities for each. Specimens shall be stored in sterile containers, with tight-fitting lids, and labeled with the name of the donor, and the date and time of obtaining the specimen.

Table 2.17 Samples to be collected by the procurement team from the diseased donor*

Sample Type	Required Quantities
Lymph Nodes	15-20 lymph nodes in a sterile container with RPMI 1640 solution for each transplant programs (don't use normal saline as a medium)**.
Spleen	The entirety of the spleen should be taken, if possible, and divided into 3 segments (one for each transplant programs). Store in a sterile container with RPMI 1640 solution (don't use normal saline as a medium)**.
Wound Swab	1 swab sample from each wound, when applicable.

* The quantity of specimens is intended for 3 prospective transplant programs.

** For direct HLA crossmatch purposes.

PHASE III: POST-PROCUREMENT

2.7.5 Documentation of Organ Procurement

2.7.5.1 Document the procurement procedures in the donor's medical record at the donor hospital.

2.7.5.2 Require the surgeon(s) in the procurement team to prepare an operative report detailing the recovered organs, including organ anatomy and characteristics (Forms 8-12: Deceased Recovery Report). This report must be shared with SCOT through the official communication channel.

2.7.5.3 Ensure the attending physician completes the death certificate and medical report within 24 hours to allow the donor's family to proceed with burial arrangements.

2.7.5.4 The legal death certificate should be issued after mechanical ventilation is discontinued and the heart ceases beating.

2.7.5.4.1 The death certificate should be issued by the hospital where the recovery of organs is performed and should be signed by the anesthesiologist who has supervised the recovery operation.

2.7.5.4.2 The death certificate should be issued by the hospital if the permanent circulatory arrest occurs in the ICU and should be signed by either the attending physician or the intensive care physician.

2.7.5.5 Send a copy of the completed DNC form and the death certificate to each prospective transplant programs.

2.7.5.6 Ensure that the following details are recorded and disseminated to all recipient hospitals:

2.7.5.6.1 The demographic variables of the donor, including name, age, sex, weight, height, nationality, date of admission, and diagnosis.

2.7.5.6.2 Vital sign readings, including blood pressure (i.e. immediately preoperative, lowest reading and duration, and highest reading and duration), central venous pressure (i.e. highest and lowest readings), and temperature (i.e. highest and lowest readings, and method of measurement.

2.7.5.6.3 The list of medications, including type, dose, and frequency of vasopressors, if used.

2.7.5.6.4 Organ procurement procedure date and time.

2.7.5.6.5 Type of recovered organ(s).

2.7.5.6.6 Skin incision time.

2.7.5.6.7 Aorta clamp time.

2.7.5.6.8 Perfusion start time, type, flow, and volume of perfusion fluid used.

2.7.5.6.9 Organ perfusion machine parameters, if used.

2.7.6 Packaging of Recovered Organs, Tissues, and Vessels

2.7.6.1 Assign the packaging process responsibility to the organ procurement team, including the transplant surgeon, transplant coordinator, and operating room nurse.

2.7.6.2 Standardize the packaging process for recovered organs, tissues, and vessels in a sterile environment, with adherence to universal precautions.

2.7.6.3 Utilize internal and external containers to transfer recovered organs, tissues, and vessels internally or externally, ensuring proper handling during transportation.

2.7.6.4 Complete the internal packaging process by securing recovered organs and vessels with triple sterile, separated, and firmly tied bags; the first bag contains the organ and preserving solution (i.e. no ice in the bag), the second bag contains a cold sterile solution (i.e. normal saline, sterile water, or Ringer's lactate), and the third bag contains nothing.

2.7.6.5 Complete the external packaging process by placing the internal containers into a dedicated, insulated, secured, and temperature-controlled organ transport box or container, that includes sufficient ice or refrigeration to protect the organs during transportation.

2.7.6.6 Ensure that vessels are packed separately from the organs during packaging processes.

2.7.7 Labeling of Recovered Organs, Tissues, and Vessels

2.7.7.1 Assign the labeling process to the organ procurement team, including the transplant surgeon, transplant coordinator, and operating room nurse.

2.7.7.2 Standardize the labeling process using internal and external labeling to ensure the identification and traceability of the recovered organs, tissues, and vessels.

2.7.7.3 Complete the internal labeling process by attaching a water-proof label containing the package's contents, the donor identification number, and the donor blood type and subtype to the outermost layer of the triple sterile bags.

2.7.7.4 Complete the external labeling process by attaching a water-proof label onto the outer surface of the organ transport box, ensuring all necessary information is included:

2.7.7.4.1 SCOT case number

2.7.7.4.2 The donor identification number

2.7.7.4.3 Date and time of organ recovery

2.7.7.4.4 Type of recovered organ(s).

2.7.7.4.5 Aorta clamp time.

2.7.7.4.6 The type and volume of used perfusion fluid

2.7.7.4.7 Blood group type and subtype

2.7.7.4.8 Type of serology testing results and any infectious diseases.

2.7.7.4.9 The sender's name and telephone number

2.7.7.4.10 The receiving person's name and telephone number

2.7.7.4.11 Date and time of transportation

2.7.8 Transporting of Recovered Organs, Tissues, and Vessels

2.7.8.1 Transport the organ in either an organ transport box or a transportable perfusion system that must have an external label.

2.7.8.2 If the organ is transported using a perfusion machine, the recovery team must communicate the machine parameters to the SCOT nursing coordinator prior to transport.

2.7.8.3 Transport the recovered organ to the transplant programs by ambulance, medevac, commercial flight, or a combination of these methods.

2.7.8.4 Evaluate the organ transport boxes for adequacy, intactness, security, and cleanliness prior to organ transportation to ensure that boxes are capable of maintaining preservation temperature, and suitable for organ transportation.

2.7.8.5 Fill the organ transport box with 2/3 crushed ice before using the transport box, adjusting the amount based on the size of the organs being transported.

2.7.8.6 Expedite the transport time of the organ(s) to transplant programs (s) to minimize cold ischemia time efficiently. The transportation team is accountable for unjustified delay or mishandling of the transported organ.

2.7.8.7 Take surgical swab cultures from the organ transport box regularly (i.e., once a month) to ensure a sterile environment inside.

2.7.8.8 Remove all labels from the previous donor before reusing the organ transport box.

PHASE IV: ORGAN-VERIFICATION (by the transplant programs)

Organ verification plays a crucial role in the transplantation process, acting as a safeguard to maintain the accuracy of organ transplants, and ensuring that the correct organ is matched to the appropriate recipient. This phase includes organ check-in, pre-transplant verification, and release back of unacceptable organs.

2.7.9 Organ Check-In

2.7.9.1 Complete the organ check-in process upon the arrival of any organ that recovered outside the transplant programs.

2.7.9.2 Confirm the donor ID, organ type, and laterality (if applicable) using the external organ label before opening the external transport container.

2.7.9.3 Notify SCOT immediately if there is any discrepancy between the information on the label and the expected information.

2.7.9.4 Document the entire check-in process in the donor medical record at the transplant programs.

2.7.10 Pre-Transplant Verification

2.7.10.1 Perform pre-transplant verification before receiving the intended organ in the operating room by confirming the expected donor ID, organ type, laterality (if applicable), donor blood type and subtype (if used for allocation), recipient unique identifier, recipient blood type, and compatibility (or intended incompatibility) between the donor and recipient.

2.7.10.2 Perform pre-transplant verification immediately upon receiving the intended organ in the operating room, ensuring it occurs before the anastomosis of the first organ and while the intended recipient is present.

2.7.10.3 Perform surgical "Time-Out" immediately before commencing the transplant surgery to confirm the donor's identity, medical record number, and ABO blood type.

2.7.10.4 Document the completion of the pre-transplant verification according to the transplant programs internal protocol.

2.7.11 Transplanting or Releasing Organs

2.7.11.1 Upon receiving the intended organ, the transplant programs shall make the final decision regarding its transplantation, ensuring that the organ is transplanted into the originally intended recipient (refer to Chapter 2, Section 2A, Sub-section 2.6).

2.7.11.2 If the organ is transplanted, the transplant programs shall complete the organ transplantation form promptly, ensuring it is finalized within 24 hours of the transplantation date (Forms 13-19: Post Organ Transplantation).

2.7.11.3 If the organ is not transplanted and is released back, the transplant programs shall provide a detailed explanation to SCOT regarding the refusal to accept the organ for that candidate, using the appropriate form. SCOT will be responsible for reallocating the released organ to other candidates based on organ-specific allocation policies.

2.7.11.4 If the released organ is not accepted by any transplant programs, the transplant programs shall complete the organ disposal form and submit it to SCOT through the official channels (Form 7: Deceased Organ Discard Report).

2.8 Donation After Cardiac Death (DCD)

Unlike donation after brain death (DBD), DCD refers to the process of organ donation that occurs after a patient's heart has irreversibly stopped beating, leading to circulatory death. This type of donation allows for the possibility of organ recovery in patients who experience cardiac death under controlled circumstances. DCD protocols require careful coordination to ensure ethical and legal standards are met while optimizing the viability of organs for transplantation. The DCD process involves unique medical, logistical, and ethical considerations, including strict criteria for death declaration, rapid organ viability measures, and sensitive communication with families throughout.

SCOT is committed to advancing organ donation in the Kingdom by actively developing and formalizing protocols for DCD. Although **not yet implemented**, DCD protocols are a strategic priority, with SCOT focused on establishing rigorous standards that align with best practices globally and the recommendations of the World Health Organization and the Transplantation Society (see Figure 2.1). This initiative represents a significant step forward in expanding organ donation pathways, meeting urgent transplant needs, and enhancing the ethical and operational frameworks of donation in the Kingdom.

GENERAL REGULATIONS FOR ORGAN DONATION AFTER CARDIAC/CIRCULATORY ARREST

2.8.1 The critical pathway for DCD is to be adopted as per the recommendations of the World Health Organization and the Transplantation Society (see Figure 2.1).

2.8.2 SCOT has accepted DCD as an ethically and medically acceptable option for organ donation.

2.8.3 DCD requires expertise regarding details pertaining to the declaration of death, maintenance of the deceased donor, and organ recovery.

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

2.8.5 The DCD decision requires informed consent from the next of kin and the same procedures and regulations practiced after DNC or living donation should be followed.

2.8.6 The classification of DCD along with the location of practice is summarized in Table 2.18.

Table 2.18 Modified Maastricht classification of DCD and the location where mainly practiced

Category	Description	Type of DCD	Location practiced
I	Dead on arrival	Uncontrolled	ED in a transplant programs
II	Unsuccessful resuscitation	Uncontrolled	ED in a transplant programs
III	Anticipated cardiac arrest	Controlled	ICU and ED
IV	Cardiac arrest in a brain-dead donor	Controlled	ICU and ED
V	Unexpected arrest in ICU patient	Uncontrolled	ICU in a transplant programs

ICU: Intensive Care Unit, ED: Emergency Department

2.9 End of Life Care

Integrating Organ/Tissue Donation in End-of-Life Care in the ICU

There has been a growing recognition that effective palliative care in the ICU must encompass the opportunity for organ and/or tissue donation after death. This integration is essential because end-of-life care (EOLC) and organ/tissue donation are intricately linked; the decisions made during this critical time can significantly impact the availability of organs and tissues for transplantation.

Definition

End-of-Life Care is " an approach to a terminally ill patient that shifts the focus of care to symptom control, comfort, dignity, quality of life, and quality of dying rather than treatments aimed at cure or prolongation of life. "

According to the World Health Organization (WHO), palliative care is "an approach that improves the quality of life of patients (adults and children) and their families who are facing problems associated with life-threatening illness. It prevents and relieves suffering through the early identification, correct assessment and treatment of pain and other problems, whether physical, psychosocial or spiritual."

The relationship between healthcare providers and patients during end-of-life care is particularly significant. Healthcare providers play a pivotal role in guiding patients and their families through the complexities of end-of-life decisions.

End-of-life care in the ICU is often associated with decisions such as withholding cardiopulmonary resuscitation (CPR) or implementing do-not-resuscitate (DNR) orders, withholding life support (WHLS), and withdrawing life support (WDLS). These decisions are made following thorough discussions and mutual agreement between the treating medical team and the patient's family.

Effective communication, empathy, and active listening are critical components of this relationship, as they help create an environment where patients and families feel valued and understood.

Healthcare providers who frequently care for dying patients, including those specializing in palliative care, should be well-versed in the criteria and considerations related to organ and tissue donation.

By understanding these factors, they can incorporate donation practices into their approach to patient care, ensuring that families are informed of all available options.

SCOT emphasizes that trust is fundamental to the organ and tissue donation process. Establishing trust with patients and their families is essential for fostering open and honest conversations, which can lead to positive outcomes in both patient care and organ donation decisions.

Several factors influence patients' and families' choices regarding organ donation, including the quality of care and their willingness to consent. Trust must be actively cultivated to ensure

compassionate care throughout their time in the ICU, regardless of whether donation is part of the treatment.

Healthcare providers should approach end-of-life discussions with sensitivity, recognizing the emotional challenges faced by patients and families. By creating a supportive environment, providers can help families navigate their feelings and consider organ donation as a meaningful option.

Demonstrating genuine compassion and respect for patients' wishes enhances the quality of care and strengthens relationships between providers and families. This supportive atmosphere encourages discussions about donation, allowing families to find comfort in the idea that their loved one's gift can save lives and provide hope to others. Ultimately, honoring the donor's legacy through organ donation can bring a sense of purpose and meaning to families during a profoundly difficult time.

Regulations for Healthcare Providers on End-of-Life Care and Organ and Tissue Donation

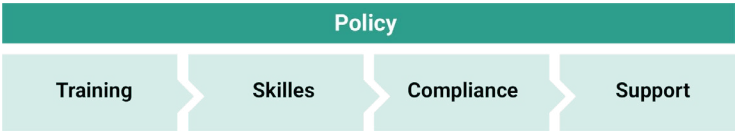
2.9.1 Healthcare facilities must establish and implement policies that integrate organ and tissue donation into end-of-life care (EOLC), outlining the roles and responsibilities of healthcare providers and ensuring alignment with national regulations, ethical guidelines, and timely, compassionate discussions with families about donation opportunities.

2.9.2 All ICU and palliative care staff must be trained in organ and tissue donation criteria, communication skills, and ethical considerations. Healthcare facilities must ensure regular competency assessments in these areas. (reffer to Chapter 2: Organ Donation).

2.9.3 Healthcare providers must engage families in clear, empathetic, and honest discussions about end-of-life care and donation options. Written documentation of these discussions should be maintained to ensure transparency.

2.9.4 Healthcare providers must prioritize building trust with patients and families, ensuring that all interactions are conducted with respect, integrity, and without undue pressure regarding donation decisions.

2.9.5 Healthcare facilities must establish mechanisms for auditing and reviewing end-of-life care and donation practices to ensure alignment with national and regulatory standards.



2.9.6 Healthcare providers must respect the rights, wishes, and emotional needs of patients and their families during end-of-life care, offering ongoing emotional and spiritual support, clear communication, counseling resources, and the option of organ donation as a meaningful legacy.

2.9.7 Post-Donation Support: Ensure families receive comprehensive follow-up care, including grief counseling, resources to address emotional or logistical concerns, and information on the impact of the donated organs.

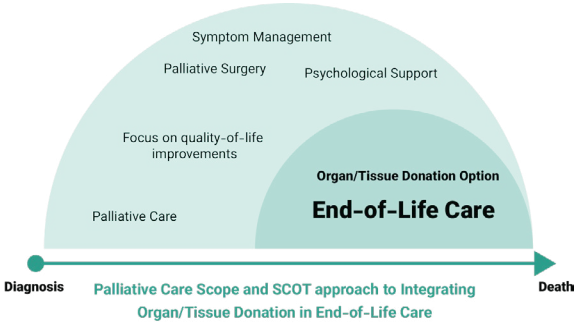
A Compassionate Legacy

Integrating organ and tissue donation into end-of-life care within the ICU represents a profound opportunity to honor the lives of patients while offering hope to those in need. As healthcare providers navigate the complexities of this critical time, the emphasis on trust, compassion, and effective communication becomes paramount. By fostering an environment where families feel valued and understood, providers can guide them through difficult decisions, ensuring that discussions about donation are approached with sensitivity and respect.

The legacy of a donor extends far beyond the act of donation itself; it embodies a lasting impact on the lives of recipients and their families. By recognizing the emotional and spiritual significance of organ donation, healthcare providers can help families find comfort in the knowledge that their loved one's gift can save lives and provide hope to others.

As we strive to improve end-of-life care practices, it is essential to adhere to established regulations and ethical guidelines that uphold the dignity of both patients and their families. Training healthcare staff in the nuances of organ donation and fostering a culture of empathy will not only enhance the quality of care but also empower families to make informed decisions during a profoundly challenging time.

The integration of organ and tissue donation into end-of-life care is not merely a procedural obligation; it is an opportunity to create a compassionate legacy that honors the wishes of the deceased while offering solace and hope to those left behind, and transforming the end-of-life experience into one that is filled with meaning, purpose, and the enduring power of life.



Palliative Care Scope and SCOT approach to Integrating Organ/Tissue Donation in End-of-Life Care

Section 2B: Organ Donation from Living Donors

Organ donation from living donors is governed by comprehensive regulations and procedures that prioritize the ethical practices and psychological and physical well-being of donors. These regulations were established through an extensive review by relevant committees at the SCOT in collaboration with national experts in biomedical and transplantation ethics. Furthermore, they align with international consensus, as outlined by:

- **World Health Organization: WHA 57.18 Human Organ and Tissue Transplantation, May 2004.**
- **International Forum on the Care of the Live Kidney Donor. Amsterdam, April 2004.**
- **The Vancouver Forum of the Care of the Live Organ Donor, May 2006.**
- **The Transplantation Society, Kuwait Meeting, December 2006.**
- **Istanbul Declaration on Prohibiting Transplant Trafficking and Tourism, May 2008.**

The primary aims of these regulations include preventing commercial transplantation practices, protecting vulnerable groups from transplant tourism, and providing the opportunity to save or enhance the lives of individuals suffering from end-stage organ failure through rigorous ethical and safety evaluations. Organ donation from living donors encompasses the voluntary act of donating an organ or a portion thereof—such as a kidney or a part of the liver—to someone in need of a transplant. This process includes three types of donations: related to the recipient up to the fourth degree, by affinity, or **related** with breastfeeding (provided that breastfeeding relation is certified by the official authorities); **unrelated** with the recipient; and **pair exchange** between families according to SCOT regulations. The donor, before recovery of his/her organ, may cancel the donation without any restriction or condition. Misconducts regarding the application of these regulations are subject to investigation and disciplinary action as outlined in the human organ donation regulation and executive bylaw.

IMPORTANT NOTE

The regulations of living donation are intended to be applied to all citizens and residents in Saudi Arabia, upon voluntary and autonomous decision to donate.

IMPORTANT NOTE

The Living donation should be based on free will, self-satisfaction, and confidence, with no pressure or coercion, and with a written informed consent

IMPORTANT NOTE

To strengthen the living donation protection process, transplant programs are required to appoint an independent living donor advocate (ILDA), who is an experienced licensed healthcare provider with adequate knowledge and skills to advocate for the rights of living donors. The ILDA works independently of the transplant team to ensure that he/she is not influenced by the transplant team's opinions or biases and to advocate for the rights of living donors.

This section includes regulations and procedures on the following:

2.10 Regulations for Inclusion and Exclusions for Living Donation
2.11 Regulations for Medical and Psychosocial Evaluation of Living Donors
2.12 Regulations for Unrelated Living Donations
2.13 Regulations for Kidney / Liver Paired Donation (K/LPD)

2.10 Inclusion and Exclusion Criteria of Living Donation

The inclusion and exclusion criteria for living organ donation are designed to ensure the safety and well-being of both the donor and the recipient. These criteria provide a clear framework for assessing potential donors, ensuring that only those who meet strict medical, psychological, and ethical standards are eligible for donation. While the inclusion criteria determine a donor's suitability, the exclusion criteria help to identify factors that may pose risks to the donor or reduce the likelihood of a successful transplant. Table 2.19 summarizes the inclusion and exclusion criteria for living donation generally, with specific criteria for living kidney and liver donations.

Table 2.19 Inclusion and Exclusion Criteria of Living Donation*

ALL ORGAN LIVING DONATION	
Inclusion Criteria	**Exclusion Criteria****
• Donor age: more than 18 years (Gregorian) • Mentally capable of making an informed decision • Medically fit to donate • Holds a valid identification (i.e., ID) • Compatible blood groups (ABO) with the recipient	• Organ essential for donor's life, or • Organ may result in death, disability, or hinder the donor's ability to do daily activities, or • Donor incapable or incompetent (guardian/ trustee approval not accepted), or • Active malignancy or incompletely treated malignancy, or • High suspicion of coercion or illegal financial exchange, or • Acute active symptomatic infection, or • Positive HBsAg, HCV antibodies, or HIV, or • Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including evidence of suicidality.
LIVING KIDNEY DONATION	
Inclusion Criteria	**Exclusion Criteria****
• Donor age: 18-60 years (Gregorian) • Normal kidney function • Negative crossmatch	• Diabetes, or • Uncontrollable hypertension, or • History of hypertension with evidence of end-organ damage.
LIVING LIVER DONATION	
Inclusion Criteria	**Exclusion Criteria****
• Donor age: 18-45 years (Gregorian) • Normal liver function • No addiction to narcotics or alcohol • No use of liver-toxic drugs	• HCV RNA positive, or • HBsAg positive, or • Prior living liver donor, or • Expected donor remnant volume <30% of native liver volume.

* To qualify a donor for living organ donation, all inclusion criteria must be met. Conversely, the presence of any exclusion criteria disqualifies the donor from proceeding with the living donation.

** Transplant programs may exclude donors with any condition that, in the medical judgment, causes the donor to be unsuitable for donation or the team considerably thinks that the transplantation will not be successful in the recipient.

2.11 Medical and Psychosocial Evaluation of Living Donors

2.11.1 Living Donor Psychosocial Evaluation Requirements

2.11.1.1 Psychosocial evaluation requirements apply to living kidney, liver, and lung living donors.

2.11.1.2 The living donor's psychosocial evaluation should be performed in the transplant programs by a psychiatrist and psychologist/ or a qualified licensed social worker prior to organ recovery to ensure the absence of any reason that may influence the validity of the donation consent.

2.11.1.3 The psychosocial evaluation and the decision to donate will be undertaken by healthcare professionals who are not involved in the care of the recipient.

2.11.1.4 Living donors should be informed of the results of the psychological evaluation, the venture, and the consequences of the donation process.

2.11.1.5 Documentation of the psychosocial evaluation should be maintained in the medical record of the living donor. The documentation includes the following components: (Form 20: Living Related Organ Donor Evaluation; Form 21: Living Unrelated Organ Donor Evaluation)

2.11.1.5.1 Evaluation for psychosocial and mental issues that may complicate the living donor's recovery and could be identified as risks for poor psychosocial outcomes.

2.11.1.5.2 Evaluation of psychiatric conditions and illnesses that require treatment before donation, including depression and any evidence of suicidality.

2.11.1.5.3 Evaluation of social history, including occupation, employment status, health insurance status, and the need for social support.

2.11.1.5.4 Evaluation of the living donor's history of smoking, alcohol, and drug use, including past or present substance abuse disorder.

2.11.1.5.5 Evaluation of factors that warrant educational or therapeutic intervention before the final donation decision.

2.11.1.5.6 Evaluation of the living donor's understanding of the short and long-term medical and psychosocial risks associated with the donation for the donor and recipient.

2.11.1.5.7 Evaluation of whether the donation decision is free of inducement, coercion, and other undue pressure by exploring the reasons for donating and the nature of the relationship, if any, to the transplant candidate (Form 22: Living Related Donor Consent; Form 23: Living Unrelated Donor Consent).

2.11.2 Living Donor Medical Evaluation Requirements

2.11.2.1 Living donor medical evaluation requirements apply to living kidney, liver, and lung donors.

2.11.2.2 The living donor's medical evaluation should be performed in the transplant programs by a physician or surgeon experienced in living donation.

2.11.2.3 The medical evaluation and the decision to donate will be undertaken by healthcare professionals who are not involved in the care of the recipient.

2.11.2.4 Living donors should be informed of the results of the medical evaluation, the venture, and the consequences of the donation process.

2.11.2.5 Documentation of the medical evaluation should be maintained in the medical record of the living donor. The documentation includes the components in (see Table 2.20):

Table 2.20 Living Donor Medical Evaluation Requirements

Evaluation Component	Evaluation includes but is not limited to:
General Donor and Family History	History of infections
	Allergies
	History of significant medical conditions such as hypertension, diabetes, lung disease, heart disease, gastrointestinal disease, autoimmune disease, neurologic disease, genitourinary disease, hematologic disorders, bleeding or clotting disorders, and cancer including melanoma
	Active or previous use of medications that are known to cause nephrotoxicity or hepatotoxicity, including the chronic use of pain medications
Complete Physical Exam	Including vital signs, height, weight, body mass index (BMI), and examination of all major organ systems
General Laboratory Tests	CBC, PT or INR, PTT, blood type and subtype, metabolic testing (electrolytes, urea, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin), and HCG quantitative pregnancy test for premenopausal women
General Imaging Tests	Chest X-ray and electrocardiogram (ECG)
Screening for Transmissible Diseases	CMV (Cytomegalovirus) and EBV (Epstein Barr Virus) antibody
	Syphilis testing
	As close to the organ recovery date as feasible, but within 28 days prior, ensure completing the following viral screening tests; HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination; Hepatitis B surface antigen (HBsAg); Hepatitis B core antibody (anti-HBc); Hepatitis C antibody (anti-HCV); and HCV ribonucleic acid (RNA) by nucleic acid test (NAT)
	For tuberculosis (TB), the transplant programs should determine if the living donor is at TB risk. If the risk is suspected, testing should include screening for latent infection using either intradermal PPD or Interferon Gamma Release Assay (IGRA)
Screening for Cancer	Including cervical, breast, prostate, lung, and colon cancers

2.11.3 Specific Requirements for the Medical Evaluation of Living Kidney Donors

2.11.3.1 Evaluation of family history should include kidney diseases, diabetes, hypertension, and kidney cancer.

2.11.3.2 Transplant programs should follow a written protocol for polycystic kidney disease or other inherited renal disease as indicated by family history

2.11.3.3 Physical Examination should include measuring blood pressure at least on two different occasions, 24 hours apart, or overnight.

2.11.3.4 Metabolic testing should include fasting blood glucose, fasting lipid profile, and glucose tolerance test or glycosylated hemoglobin in individuals with diabetes risk.

2.11.3.5 Kidney-specific laboratory tests should include urinalysis or urine microscopy, Schistosomiasis testing, urine for Schistosomal ova, malaria screen, brucella titer, Schistosoma titer, stool analysis for bilharzia ova and other parasites, urine culture if clinically indicated, urinary protein and albumin excretion.

2.11.3.6 Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection.

2.11.3.7 Patients with a history of nephrolithiasis or nephrolithiasis (>3 mm) identified on radiographic imaging should have a 24-hour urine stone panel measuring Calcium, Oxalate, Uric acid, Citric acid, Creatinine, and Sodium.

2.11.3.8 Anatomic assessment should be completed to determine whether the kidneys are of equal size, kidneys have masses, cysts, or stones, kidneys have anatomical defects, and which kidney is more anatomically suited for transplant.

2.11.4 Specific Requirements for the Medical Evaluation of Living Liver Donors

2.11.4.1 Evaluation of family history should include liver diseases and bleeding or clotting disorders.

2.11.4.2 Transplant programs should develop and follow written protocols for the following:

2.11.4.2.1 Hypercoagulable state evaluation.
2.11.4.2.2 Testing for genetic diseases.
2.11.4.2.3 Screening for autoimmune diseases.
2.11.4.2.4 Pre-donation liver biopsy.

2.11.4.3 Liver-specific laboratory tests should include hepatic function panel, iron, iron-binding capacity, ferritin, ceruloplasmin in a donor with a family history of Wilson's disease, and alpha-1-antitrypsin level (note: those with a low alpha-1-antitrypsin level should have a phenotype).

2.11.4.4 Anatomic assessment should be completed to evaluate projected graft volume, donor's remnant volume, vascular anatomy, and presence of steatosis. Also, a radiological assessment should be completed to determine whether the liver is anatomically suitable for transplantation and to assess the safety of resection for the donor.

2.12 Regulations for Unrelated Living Donations

2.12.1 Types of Living Genetically Unrelated Donors

2.12.1.1 **Indirect donation** (by donation to an unspecified person):

2.12.1.1.1 The identity of the organ donor or part of it and the recipient is known to SCOT and the transplant programs that supervises the donation.

2.12.1.1.2 The donor evaluation committee should know the identity of the donor and it includes the citizen and the legal resident in Saudi Arabia.

2.12.1.1.3 The donor should be unaware of the recipient's identity, who is selected based on medical priority in coordination between SCOT and transplant programs.

2.12.1.2 **Direct donation** (by donation to a specific person):

2.12.1.2.1 The identity of the person who donates an organ or part of it is known to the patient, as well as the identity of the patient to the donor.

2.12.1.2.2 Acceptance for donors of this category is restricted to individuals of the same nationality, which includes citizens and residents legally in Saudi Arabia.

2.12.1.2.3 Non-Saudi donor is required to be a regular resident in the Kingdom for at least one year.

2.12.2 Regulations for Living Unrelated Donor Evaluation Committee

2.12.2.1 The director of the transplant hospital should form a "Donor Evaluation Committee" consisting of five experienced members;

2.12.2.1.1 The director of the transplant hospital or his representative (committee chairman).

2.12.2.1.2 Two consultant physicians who are not involved in kidney or liver transplantation.

2.12.2.1.3 A psychiatrist consultant.

2.12.2.1.4 A social worker or religious affairs specialist.

2.12.2.2 Committee members should have no relationship or involvement with the organ transplantation department in the transplant hospital.

2.12.2.3 The decision to accept the organ donor requires the majority approval of the committee members.

2.12.2.4 The committee should conduct at least two personal interviews, with a minimum of 2 weeks interval, with the person wishing to donate an organ or part of it (Form 21: Living Unrelated Organ Donor Evaluation). In limited exceptional circumstances, the committee may:

2.12.2.4.1 Conduct the two interviews in less than 2 weeks if the health condition of the recipient is critical and requires an urgent transplant.

2.12.2.4.2 Conduct the second interview through video conference if the donor resides outside the city and it is difficult to attend in person, with the presence of the majority of members.

2.12.2.5 The committee is responsible for ensuring that the donor is mentally healthy, aware of the potential consequences of donation, and has no social or material pressures to donate.

2.12.2.6 The committee is responsible for ensuring that the donor and recipient are of the same nationality, in case of direct donation, to avoid the temptation and suspicion of organ trading.

2.12.2.7 The committee is responsible for ensuring that the donor is not under pressure to donate, has the right to withdraw the donation at any moment before organ recovery without any condition or restriction, and has no right to claim the organ after donation.

2.12.2.8 The evaluation result, whether by acceptance or rejection, is shared with SCOT along with a copy of the living donation consent (i.e. original consent is kept in the donor's medical record).

2.12.3 The Living Unrelated Organ Donation Procedure

2.12.3.1 Living donors seeking to donate organs should present themselves to an organ transplant program accredited by SCOT.

2.12.3.2 Living donors who offer to donate an organ or part of it thereof in exchange for monetary compensation (i.e. selling organs) and individuals or patients seeking to purchase an organ or part of it thereof in exchange for monetary remuneration (i.e. buying organs) are promptly disqualified from consideration and rejected with documenting their data in the violent record in SCOT (Black List).

2.12.3.3 The transplantation team in the transplant programs should ensure that the prospective donor undergoes primary screening, clinical evaluation, and laboratory investigations. Upon passing this initial screening, the donor is referred to the transplant programs evaluation committee (Form 24: Living Unrelated Organ Donor Referral).

2.12.3.4 The evaluation committee interviews the donor and documents it using a prepared form (Form 21: Living Unrelated Organ Donor Evaluation) and obtains consent from the donor if the interview reveals no contraindication for donation (Form 23: Living Unrelated Donor Consent).

2.12.3.5 The transplant programs should complete the medical and psychological evaluation.

2.12.3.6 Following the comprehensive evaluation, the interview document, the consent of the donor, and the results of the medical and psychological evaluation are to be submitted to SCOT for approval. **At this stage, seeking written approval from SCOT prior to operation is a must**. If approved, SCOT grants permission to proceed with the donation surgical operation.

2.12.3.7 The procedure, then, depends on whether the donation is directed or non-directed:

2.12.3.7.1 **Directed donation:** the potential recipient's suitability for transplantation is assessed along with the donor's suitability to donate.

2.12.3.7.2 **Non-directed donation:** the transplant programs selects the most suitable recipient based on the waiting list.

2.12.3.8 The transplant programs should promptly complete the organ transplantation form within 24 hours of the transplantation date (Form 15: Post Liver Transplantation) (Form 16: Post Kidney Transplantation).

2.12.3.9 Upon completion of the transplantation, SCOT will undertake the following:

2.12.3.9.1 Ensure that the transplant programs provides lifelong follow-up care for the donor at any healthcare facility, while evaluating and managing any complications arising from the organ donation procedure.

2.12.3.9.2 Coordinate the issuance of reimbursement for the donor to cover the cost of absence from work due to surgery, in compliance with the decision of the Council of Ministers no. 235 dated 16/9/1427 H.C.

2.12.3.9.3 Coordinate the issuance of the King Abdul Aziz Medal of the third degree to the donor.

2.12.3.9.4 Ensure granting the donor a discount when traveling on Saudia Airlines.

2.13 Regulations for Kidney/Liver Paired Donation (K/LPD)

2.13.1 K/LPD General Requirements:

2.13.1.1 If a family has a kidney / Liver transplant candidate but no suitable donors within their family (i.e. blood group mismatch), while another family faces a similar situation with a candidate donor matches with the candidate recipients in the first family, then a mutual exchange of donors and recipients between these families can occur in a medically appropriate setting.

2.13.1.2 Consent and agreement should be signed by the families or households of donors and recipients, with no party claiming compensation in case of graft failure in any of the patients.

2.13.1.3 All K/LPD cases should be registered at SCOT.

2.13.2 Specific Requirements for K/LPD Candidates

2.13.2.1 In K/LPD exchanges, a paired candidate will not be eligible for a K/LPD match test until the paired candidate's transplant programs obtains written consent from the paired candidate to share health record information with all other transplant programs in the K/LPD exchange.

2.13.2.2 In K/LPD exchanges, the transplant programs should document in the candidate's medical record that they have informed the paired candidate of all relevant aspects of the K/LPD program, including:

2.13.2.2.1 The K/LPD program's matching requirements.

2.13.2.2.2 The inability of K/LPD donors and candidates to choose their match.

2.13.2.2.3 The ability of K/LPD donors and candidates to decline a match.

2.13.2.2.4 The ability of K/LPD candidates to withdraw from participation in the K/LPD program at any time, for any reason.

2.13.2.2.5 The K/LPD program's rules for when members are allowed to facilitate meetings between matched donors and recipients.

2.13.2.2.6 The possibility that even if the candidate's paired donor donates, the paired candidate might not be transplanted.

2.13.3 Specific Requirements for K/LPD Donors

2.13.3.1 In K/LPD exchanges, a paired donor will not be eligible for a K/LPD match test until the paired donor's transplant programs obtains written consent from the paired donor to share health record information with all other transplant programs in the K/LPD exchange.

2.13.3.2 In K/LPD exchanges, the paired donor's transplant programs is responsible to obtain and document informed consent from the paired donor. Also, if a different transplant programs performs organ recovery, the recovery hospital should obtain and document informed consent.

2.13.3.3 In K/LPD exchanges, the transplant programs should document in the donor's medical record that they have informed the paired donor of all relevant aspects of the K/LPD program, including:

2.13.3.3.1 The K/LPD program's matching requirements.

2.13.3.3.2 The inability of K/LPD donors and candidates to choose their match.

2.13.3.3.3 The ability of K/LPD donors and candidates to decline a match.

2.13.3.3.4 The ability of K/LPD candidates to withdraw from participation in the K/LPD program at any time before the operation, for any reason.

2.13.3.3.5 The possibility of helping more than one candidate receive a transplant.

2.13.3.3.6 The possibility that the paired donor may have to wait to find a match.

2.13.3.3.7 The possibility that the paired donor might have to wait longer to donate after a match has been identified because of logistical issues.

2.13.3.3.8 The possibility that the paired candidate might not receive a transplant because of an unexpected issue found during or after surgery with the matched donor.

2.13.3.3.9 The K/LPD program addresses failed exchanges but the remedy does not include giving the paired candidate additional priority in the deceased donor waiting list.

2.13.3.3.10 The possibility that the matched candidate's insurance might not cover travel costs if the paired donor travels to the matched recipient's transplant programs.

2.13.3.3.11 The possibility of the paired donor's name appearing on the matched candidate's insurance estimation of benefits.

2.13.3.3.12 The possibility that the paired donor's paired recipient and the paired donor's matched recipient might not have equal outcomes.

2.13.3.3.13 That the donor's kidney could be lost in transport, and other potentially negative consequences related to shipping a kidney.

2.13.3.3.14 The paired donor may require additional testing, including multiple blood draws for cross-matching.

2.13.3.3.15 The K/LPD program's rules for when members are allowed to facilitate meetings between matched donors and recipients.

2.13.3.4 In K/LPD exchanges involving non-directed donors (NDD), the transplant programs should document in the NDD's medical record that they have informed the NDD of all relevant aspects of the K/LPD program, including the option of donating to a candidate waiting for a deceased donor kidney according to SCOT national waiting list.

2.13.4 Specific Requirements for Bridge Donors

2.13.4.1 In K/LPD exchanges, before a bridge donor is entered into a K/LPD match, the bridge donor's transplant programs should document in the donor's medical record that they have informed the bridge donor of all relevant aspects of the K/LPD program, including:

2.13.4.1.1 The bridge donor might require additional medical evaluation at a future time.

2.13.4.1.2 The bridge donor might need to provide blood for cross-matching multiple times.

2.13.4.1.3 Explanation of how the K/LPD program decides if a chain ends with a bridge donor.

2.13.4.1.4 An estimate of the waiting time for the bridge donor before undergoing surgery to donate their kidney.

2.13.4.2 The bridge donor can revise their willingness to be a bridge donor based on the provided information regarding the estimated waiting time. In this, the bridge donor's transplant programs should record this duration in the donor's medical file.

2.13.4.3 The bridge donor's transplant programs should maintain documentation in the donor's medical record that the donor has verbally consented to remain a bridge donor each time the donor is identified as a bridge donor in an accepted K/LPD exchange.

2.13.5 Saudi National Kidney Paired Exchange Program (SNPKEP)

2.13.5.1 SCOT has developed SNPKEP to enhance the compatibility of living kidney donors by sharing donor lists across transplant programs in different health sectors throughout the Kingdom. SCOT's role is to provide The unified platform for managing the unified kidney transplant list, supervise the matching of living donors, and establish policies and procedures for the SNPKEP program in cooperation with relevant scientific committees.

2.13.5.2 Transplant programs that meet the program's requirements can apply to participate in SNPKEP, via opex@scot.gov.sa, if they meet the eligibility criteria.
The enrollment criteria include:

2.13.5.2.1 The kidney transplant program in the transplant programs must be accredited by SCOT.

2.13.5.2.2 The kidney paired donors list at each transplant programs must meet a minimum number of couples (i.e. donors and recipients), as specified by SCOT.

2.13.5.2.3 Participating programs must adhere to all SNPKEP policies and procedures.

2.13.5.2.4 The transplant programs adheres to other enrollment criteria established and updated by SCOT.

Section 2C: Histocompatibility Testing

Histocompatibility testing is an essential component of both deceased and living transplant programs. Histocompatibility testing aims to ensure the compatibility between donors and recipients to minimize the risk of rejection. For accurate and reliable results, laboratories within transplant programs must adhere to strict standards and practices. This section outlines the necessary requirements for laboratories involved in pre-and post-transplant investigations, emphasizing the importance of HLA typing, cross-matching, and other immunological tests.

2.14 HLA Typing Procedure and Requirements

2.14.1 Laboratory Capability and Management

2.14.1.1 The laboratory in the transplant programs should be able to perform all laboratory investigations required pre-and-post transplantation, including HLA, anti-HLA antibody testing, tissue typing, cross-match, and other immunological tests.

2.14.1.2 The laboratory in the transplant programs should be managed by a qualified director, with a sufficient number of qualified laboratory staff members and technical supervisors.

2.14.2 Samples Collection and Handling

2.14.2.1 For deceased donors, blood, lymph nodes, and spleen samples are to be collected by the recovery team and submitted to HLA laboratories (see Tables 2.14 and 2.15).

2.14.2.2 The laboratory in the transplant programs is to preferably preserve enough specimens from the deceased donor to perform subsequent testing for at least five years after the transplant.

2.14.3 HLA Typing Procedure

2.14.3.1 A transplant program may specify the maximum number of mismatched antigens it will accept, as well as any unacceptable antigens for its candidates. In this case, SCOT will only offer organs from deceased donors with mismatched antigens equal to or less than the maximum specified.

2.14.3.2 Perform HLA typing using molecular methods and determine the results accurately before reporting them to the transplant programs within the agreed-upon turn-around time. HLA typing will be performed according to the following:

2.14.3.2.1 **Deceased Donor:** the laboratory should perform molecular typing of HLA A, B, Bw4, Bw6, Cw, DR, DR51, DR52, DR53, DQA1, DQB1, DPA1, and DPB1 antigens for kidney, kidney-pancreas, pancreas, pancreas islet, small bowel, heart, heart-lung, or lung deceased donors. The results are to be reported with the serological equivalent prior to organ offers.

2.14.3.2.2 **HLA Typing for Patients:** the laboratory should perform molecular typing of HLA A, B, Cw, Bw4, Bw6, DR, DQ, and DP for kidney, kidney-pancreas, pancreas, pancreas islet, or small bowel patients. The results are to be reported to the transplant programs before registration on the waiting list.

2.14.3.3 Screen potential patients for the presence of anti-HLA antibodies using at least one solid phase immunoassay (e.g. Luminex or Flow cytometry).

2.14.3.4 When listing a candidate for a pancreas following a kidney transplant, the transplant programs may enter the antigens of the patient's previous deceased or living kidney donor. This ensures that previous sensitization is considered in the matching process.

2.14.4 Crossmatching Requirements

2.14.4.1 Perform and report the results of the virtual crossmatch to the transplant hospital before the transplant. A final physical crossmatch for the selected patient can be performed either retrospectively or prospectively based on laboratory and transplantation programs agreement

2.14.4.2 Perform the physical crossmatch with potential donor T and B-lymphocytes to identify anti-HLA class I and II antibodies using sensitive techniques such as AHG- CDC or flowcytometry, according to the terms specified in the agreement between the laboratory and transplant programs.

2.14.5 Results Review and Reporting

2.14.5.1 Review the HLA typing and virtual cross-matching reports of all deceased donors prior to the release of physical reports.

2.14.5.2 Maintain laboratory records of performing, reviewing, and verifying the histocompatibility data, in a manner that permits tracking and timely accessibility, for at least three years or the period required by the institution or local regulations, whichever is longer.

2.14.5.3 The HLA report should include antigen values and split equivalences. The list of antigen values and split equivalences should be reviewed and updated by the histocompatibility laboratory annually.

2.14.6 SCOT Notification

2.14.6.1 The laboratory should report HLA typing results to SCOT through The unified organ donation and transplantation platform (Athar). HLA typing results that are entered manually must be verified for the accurate entry of the information.

2.14.6.2 SCOT and the host who performs the initial HLA typing should be notified in case of a discrepancy in one or more loci in the donor's or recipient's HLA typing. Following this, SCOT will notify all accepting transplant programs of this discrepancy as soon as possible.

2.15 Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)

2.15.1 CPRA should be calculated by the laboratory performing the anti-HLA antibody screening and identification.

2.15.2 Transplant programs can prevent the transplantation of antigens that are not acceptable by using criteria that define unacceptable antigens or based on laboratory detection of HLA-specific antibodies. Consideration of prior donor antigens exposure involved in pregnancies, prior blood transfusion, or transplantation can be also included as unacceptable antigens.

CPRA

CPRA estimates the likelihood that a patient will have an immune response to a potential donor's organs due to pre-existing antibodies. CPRA is expressed as a percentage and its values will be rounded to the nearest one-hundredth percentage.

2.15.3 Transplant programs may establish criteria for additional unacceptable antigens, such as multiple unexpected positive crossmatches.

2.15.4 CPRA values are determined based on HLA antigen/allele group and haplotype frequencies for different racial and ethnic groups, proportional to their representation in the national deceased donor population.

The Unified Organ Donation and Transplantation Platform (Athar)

CHAPTER 03

Chapter 3 The Unified Organ Donation and Transplantation Platform (Athar)

SCOT is committed to maintaining transparency, equity, and efficiency throughout the organ donation and transplantation processes. The unified organ donation and transplantation platform (أثر Athar) plays an important role by connecting donor hospitals, transplant programs, and dialysis units, streamlining processes from donor referrals to post-transplant care (i.e. after-care). Ultimately, integrating Athar with governmental platforms and electronic health record (EHR) systems will allow SCOT to monitor donor and recipient journeys, identify areas of noncompliance, and drive continuous improvements in organ donation and transplantation policies (see Figure 3.1).

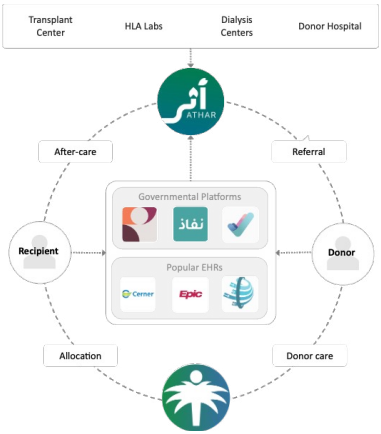


Figure 3.1 Athar Integration and Management

This chapter outlines the procedures governing Athar to ensure ethical data use and compliance with data security and confidentiality protocols, while adhering to the Executive Bylaw of Human Organ Donation Regulation and the National Data Management and Personal Data Protection Standards set by the National Data Management Office (NDMO).

DATA SECURITY AND CONFIDENTIALITY PROTOCOLS

o Athar users must adhere to strict measures set to protect sensitive data of donors and recipients, in line with national data protection laws.

o Access controls must restrict sensitive data on Athar to authorized personnel only.

o Staff involved in donation and transplantation must be trained on data protocols and ethical handling of health information

The chapter includes:

- **Data Management Procedure for Donor Hospitals**
- **Data Management Procedure for Transplant Programs**
- **Data Management Procedure for Dialysis Centers**
- **Data Governance and Platform Management**
  - Data Sharing and Scientific Collaboration
  - Digital Integration and Real-Time Access
  - The unified Platform Downtime Procedure
- **Platform User Access Management**

3.1 Data Management Procedure for Donor Hospitals

The unified organ donation and transplantation platform (Athar) plays an important role in streamlining the data submission process, particularly from donor hospitals. Athar enables donor hospitals to efficiently manage and submit accurate, real-time data for potential donors, ensuring continuous updates and swift communication with SCOT. Athar can significantly improve the coordination and timeliness of organ donation procedures, from initial donor notification to outcome documentation. **The data management procedure includes the following:**

3.1.1 INITIAL DATA SUBMISSION

3.1.1.1 Donor hospitals shall submit detailed and accurate data for each possible deceased donor through Athar platform. This submission includes, but is not limited to demographics, clinical examination results, investigation results, current medications, medical and social history, in addition to other information as necessary.

3.1.1.2 The initial notification of a possible donor shall be made as soon as the patient meets the criteria for a potential donor (refer to Chapter 2, Section 2A, Sub-section 2.3).

3.1.1 ONGOING DATA SUBMISSION

3.1.1.1 Donor hospitals, particularly ICUs, shall provide timely, continuous, and accurate data updates in Athar platform for any case that is accepted as a possible donor by SCOT.

3.1.1.2 Donor hospitals shall update Athar in real-time with any detected significant changes in the donor's condition, including changes in hemodynamic status, ventilatory status, urine output, laboratory results, or interventions/ treatments.

3.1.1.3 Donor hospitals shall enter investigation results into Athar and **upload scanned copies** of reports, including confirmatory exams for death by neurological criteria, brain death confirmatory imaging, blood type, cultures, serologies, and other relevant reports, as applicable.

IMPORTANT NOTE
All The uploaded scanned copies shall clearly display the donor's identification information.

3.1.1.4 Donor hospitals shall cooperate with SCOT, upon requesting supplementary data for a potential donor, through providing the data via Athar as soon as the information is available.

3.1.3 OUTCOMES DATA SUBMISSION

3.1.3.1 Donor hospitals shall document the outcome of each potential donor case in Athar, including progression to actual donation, family decline of donation, medical unsuitability for donation, and any other outcome that precludes donation.

3.2 Data Management Procedure for Transplant Programs

The unified organ donation and transplantation platform (Athar) is important in improving the operational efficiency and transparency of transplant programs. It enables transplant programs to maintain accurate and updated waiting lists of transplant candidates and facilitates the timely submission of transplant-related data. Further, Athar supports the management of living donation processes by enabling transplant programs to report data on all living donors and recipients, and their follow-up monitoring, thereby improving the effectiveness of the overall donation and transplantation data management. **The data management procedure includes the following:**

3.2.1 REGISTRATION AND WAITLIST MANAGEMENT

3.2.1.1 Only SCOT-accredited transplant programs can register candidates for organ transplants on the waitlist through Athar.

3.2.1.2 Transplant programs shall submit detailed and accurate candidate data into Athar, including pre- and post-transplant information and surgical details (refer to Chapter 2, Section 2A, Sub-section 2.7).

3.2.1.3 Transplant programs shall enter required candidate data into Athar, following the specified organ allocation criteria and timelines (see Table 3.1).

- **Initial registration:** this occurs when a candidate is officially listed on the national waitlist after confirming their eligibility for a transplant (Forms 25-27: Organ Failure Registry).
- **Ongoing updates:** this occurs regularly to update candidate data on the national waitlist when a change or an event affects a transplant candidate's waitlist status, including activating, inactivating, reactivating, and removal of candidates to ensure that the waitlist accurately reflects the most current and medically relevant information

Table 3.1 Notification timelines and waitlist management of transplant candidates

Action	Notification Timeline	Description
Initial Registration	At the time of listing	Complete required data fields and submit it to the registry upon transplant candidate evaluation and decision to list (Forms 25-27: Organ Failure Registry).
Removal From the Waitlist	As changes occur	Update for candidate removal from the waitlist in detail.
Regular Follow-ups	Every 6 months	Routine updates on transplant candidate health, even if no significant changes have occurred (Forms 28-31: Post-transplantation Follow-up).
Waitlist Transplant Candidate Inactivation/ Reactivation	Within 24 hours	Update status when a transplant candidate is inactivated or becomes active again.

3.2.1.4 Transplant programs shall remove or inactivate transplant candidates from the waitlist upon transplantation, death, or other qualifying reasons (see Table 3.2).

3.2.1.5 In the event of immediate and permanent non-function of a transplanted organ, SCOT permits the reinstatement of wait time through Athar to ensure that recipients are re-registered on the waiting list fairly and promptly.

3.2.1.6 Transplant programs shall maintain open communication with transplant candidates to ensure they are promptly and adequately informed about their status on the waiting list.

3.2.1.7 Transplant programs shall send a written notification to the transplant candidate, within 10 business days, in the following cases:

- Registration on the waiting list
- Completion of evaluation without registration
- Removal from the list for reasons other than transplant or death

Table 3.2 Reasons for removal or inactivating transplant candidates from the waitlist

Reason for Removal/ Inactivation	Description
Improved Health	The patient's health improves to the point where a transplant is no longer necessary.
Worsened Health	The patient's condition deteriorates, making them too ill to undergo or survive the transplant.
Non-Compliance	The patient does not follow medical advice, misses crucial appointments, or fails to take necessary medications.
Death	The patient passes away before a transplant can occur.
Received Transplant	The patient receives the needed organ. From the programs, or elsewhere.
Declined Transplant	The patient decides against undergoing the transplant when an organ becomes available.

Reason for Removal/ Inactivation	Description
Substance Abuse	Active substance abuse, including alcohol, drugs, or tobacco, can lead to inactivation or removal from the list.
Inability to reach the candidate	Failure to update contact information, leading to an inability to reach the patient when an organ becomes available.
Legal Issues	Legal problems or incarceration can affect a patient's eligibility or ability to undergo a transplant.

3.2.1 REPORTING OF LIVING DONORS

3.2.1.1 Transplant programs shall submit detailed data on all living donors and recipients through Athar, including but not limited to medical history, transplant surgical details, transplantation outcomes, and follow-up care.

- **Surgical details** include procedure types, techniques, encountered complications, and recovery information.
- **Post-transplant outcomes** include short-term and long-term transplant candidate survival, graft survival rates, and any complications or rejections.

3.2.1.2 Transplant programs shall complete any additional information related to living donation that may influence transplantation practices as required by SCOT through Athar.

3.2.1.3 Transplant programs shall conduct one-year post-procedure follow-ups for donors, and thereafter maintain lifelong follow-up to ensure continuous care and support, thus ensuring ongoing donor well-being. All follow-up data shall be reported through Athar.

- For living kidney donors, the follow-up data includes but is not limited to health status, readmissions, kidney complications, dialysis status, hypertension, and diabetes, in addition to essential laboratory data. (Form 32: Post Kidney Nephrectomy Follow-up)
- For living liver donors, the follow-up data includes but is not limited to health status, readmissions, liver complications, and essential laboratory data. (Form 33: Post Liver Hepatectomy Follow-up)

3.3 Data Management Procedure for Dialysis Centers

The unified organ donation and transplantation platform (Athar) is important in improving data management in dialysis centers and ensuring accurate and timely documentation of End Stage Renal Disease (ESRD) patient information. Dialysis centers are responsible for registering patients, updating data, and reporting significant events to ensure that patient records for hemodialysis and peritoneal dialysis are properly managed, updated, and accessible to SCOT. **The data management procedure includes the following**:

3.3.1 INITIAL DATA SUBMISSION

3.2.1.4 Dialysis centers shall provide timely and updated data on End Stage Renal Disease (ESRD) patients, on hemodialysis and peritoneal dialysis, to SCOT using the Athar platform.

3.2.1.5 Initial registration of ESRD patients in Athar shall occur within 14 days of the patient starting chronic dialysis treatment.

3.2.1.6 Any significant events, such as patient death or transfer to another dialysis facility shall be documented in Athar within 14 days of the event.

3.3.2 ONGOING DATA SUBMISSION

3.3.2.1 Dialysis centers shall designate a data coordinator responsible for ensuring the accuracy and timeliness of data submitted to Athar.

3.3.2.2 The designated data coordinator shall perform a monthly review of all patient data in Athar to ensure its accuracy and completeness.

3.3.2.3 Dialysis centers shall respond to data queries from SCOT within 5 business days, providing clarification or additional information as requested.

3.3.2.4 Dialysis centers shall participate in an annual data quality assessment conducted by SCOT. This assessment may include:

- Random audits of patient records
- Comparison of Athar data with center-specific records
- Evaluation of data completeness and timeliness

3.3.2.5 Dialysis centers shall complete an annual survey issued by SCOT, which may include questions about center demographics, staffing, equipment, quality improvement initiatives, and challenges.

3.4 Data Governance and Platform Management

The data governance framework ensures the security and efficient management of The unified organ donation and transplantation platform (Athar). It includes guidelines for data sharing and scientific collaboration, ensuring that researchers and institutions can access data responsibly. Also, it outlines the integration process, enabling governmental institutions to connect with Athar via a secure Application Programming Interface (API), and includes procedures for managing platform downtime to ensure continuous, reliable access to donation and transplantation data. The data governance framework supports operational efficiency as well as data security.

3.4.1 DATA SHARING AND SCIENTIFIC COLLABORATION

3.4.1.1 Transplant programs and research institutions seeking access to SCOT's national donation and transplantation data shall submit a formal research proposal to the Research Review Committee (RRC) at SCOT for review, evaluation, and approval.

3.4.1.2 The research proposal shall specify at minimum research objectives, methodology, data required, intended use of the data, ethical considerations, and data security measures.

3.4.1.3 The approval of research proposals by the RRC depends on the scientific merit, potential benefits, ethical considerations, and the alignment of the proposal with SCOT's research priorities

3.4.1.4 Researchers shall sign a data use agreement that outlines the terms and conditions of data access upon approval of the research proposal by the PRC. The agreement includes:

- Scope of data usage
- Data security protocols
- Publication guidelines
- Confidentiality requirements
- Conflict of interest

3.4.2 DIGITAL INTEGRATION AND REAL-TIME ACCESS

3.4.2.1 SCOT enables governmental institutions to integrate their systems with Athar through its Application Programming Interface (API).

3.4.2.2 Governmental institutions seeking API integration with Athar shall submit a formal request to SCOT, outlining the purpose of integration and specific data elements required.

3.4.2.3 If the request is aligned with SCOT's strategic objectives and security considerations, the request will be approved, and the requesting institute will be asked to:

- Sign an API usage agreement,
- Designate a technical point of contact for the integration process,
- Bear the API integration cost, including development, implementation, and maintenance.

3.4.2.4 Institutions with API access shall implement and maintain security measures that meet SCOT's standards, and SCOT reserves the right to conduct periodic compliance audits to ensure adherence to these security standards and the API usage agreement.

3.4.3 The unified PLATFORM DOWNTIME PROCEDURE

3.4.3.1 The downtime procedure shall be followed by all relevant organ donation and transplantation stakeholders during planned (i.e. scheduled maintenance/updates where Athar will be temporarily unavailable) and unplanned (unexpected system outages that cause Athar to be inaccessible) downtime of Athar to ensure continuity of data management and operations.

3.4.3.2 SCOT will notify donor hospitals, transplant programs, and dialysis centers at least 72 hours in advance of scheduled maintenance or planned downtime.

3.4.3.3 Upon an unplanned outage, SCOT will issue immediate communication via official communication channels, including an estimated time to recovery, with a regular follow-up status update.

3.4.3.4 During planned and unplanned downtime, donor hospitals, transplant programs, and dialysis centers are required to **follow the following procedure**:

- Switch to paper-based forms (refer to Appendix D) for all data submissions and documentation related to donation and transplantation processes.
- Record all relevant patient, donor, and transplant details accurately and legibly on the forms.
- Safeguard all collected forms securely in designated locations until Athar is back online.
- Notify staff responsible for data entry to input all paper-based records into Athar once the platform is restored.
- Communicate urgent matters (e.g., organ matching, donor updates) with SCOT via official communication channels.
- SCOT will issue a notification when Athar is back online, detailing the steps for transitioning from paper-based to digital operations.
- Enter all paper-based forms completed during downtime into Athar within 24 hours of system restoration.
- Verify the accuracy of information transferred from paper to Athar through a designated data coordinator.
- Conduct a reconciliation process to ensure all downtime data has been correctly transferred to the digital system.
- Audit paper-based forms and data entries post-restoration to ensure compliance with downtime procedures, as reserved by SCOT.

3.5 Platform User Access Management

3.5.1 ACCESS MANAGEMENT

Healthcare facilities are responsible for requesting and managing their staff's access to Athar. All users must be registered healthcare professionals actively working in national healthcare facilities. Access is granted on a time-limited basis and requires periodic renewal to maintain system security. SCOT manages all system access and serves as the primary administrator for the platform. Organizations must submit access requests through official channels, providing standard healthcare information system (HIS) registration requirements for each user.

3.5.2 User Roles and Permissions

Platform users may hold multiple roles within the system when appropriate for their clinical responsibilities. Each role carries specific permissions aligned with the user's organizational responsibilities and professional scope of practice (see Table 3.3).

Table 3.3 User Roles and Basic Access Levels in Athar

Role	Organization Type	Primary Functions
ICU Physician/Nurse	Donor Hospital	Donor referral
Organ Donation Unit Staff	Donor Hospital	Case Management and donation process oversight
Transplant Coordinator	Transplant programs	Waitlist management and organ offers
Transplant Surgeon	Transplant programs	Surgical documentation and organ acceptance
SCOT Coordinator	SCOT	System oversight and allocation management
Dialysis Coordinator	Dialysis Center	Dialysis patient registration and monitoring

3.5.3 Access Termination

Access to Athar terminates automatically at the end of the defined access period unless renewed. Organizations must promptly notify SCOT when users leave their roles or no longer require system access. SCOT maintains the right to modify or terminate access as needed to ensure system security and appropriate use.

3.5.4 Technical Support

Users can access technical support through multiple channels:

- Email support at; athar@scot.gov.sa
- Emergency support line at 1969 for urgent cases
- In-person support by request

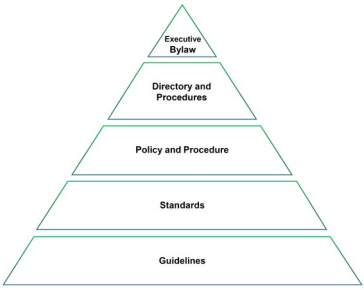
Accreditation and Compliance

CHAPTER 04

Chapter 4 Accreditation and Compliance

Introduction

The importance of accreditation cannot be overstated, as it directly impacts the quality, safety, and effectiveness of organ donation and transplantation services. Accreditation provides a structured framework to ensure the quality, safety, and effectiveness of healthcare services, particularly in the context of organ donation and transplantation. In such high-stakes medical practices, the need for standardized processes, adherence to clinical guidelines, and strict compliance with ethical and regulatory frameworks is critical.



SCOT recognizes the importance of maintaining a robust accreditation system for donor hospitals and transplant programs to ensure consistency in the quality of the services provided. This uniformity enhances safety and strengthens public confidence in the organ donation and transplantation system. Furthermore, standardization helps streamline operations, reduce variability in practices, and enhance overall system efficiency. The components of accreditation, as outlined by SCOT, encompass a wide range of criteria, from infrastructure and staffing to clinical procedures and care pathways. Compliance with these standards requires organizational commitment and a systematic approach to quality improvement, training, and performance evaluation.

Accreditation is not a one-time achievement; rather, it is a continuous process that requires ongoing compliance with established standards. Setting clear ongoing compliance requirements aims to create a transparent and accountable system where patient care is the highest priority. SCOT emphasizes the importance of continuous compliance with accreditation standards to ensure that donor hospitals and transplant programs consistently meet the evolving quality standards and adhere to national laws and regulations.

This chapter provides a comprehensive view of procedures, requirements, and ethical considerations that define SCOT accreditation and maintenance processes for donor hospitals and transplant programs in Saudi Arabia. The chapter includes:

- **Section 4A: Accreditation of Donor Hospitals**
- **Section 4B: Accreditation of Transplant Hospitals**
- **Section 4C: Compliance of Donor and Transplant Hospitals**
- **Section 4D: Implications of Violating Organ Donation Regulation**

Section 4A: Accreditation Of Donor Hospitals

The accreditation program for donor hospitals is an essential component of the SCOT regulatory framework, aimed at ensuring the safety and ethical conduct of organ donation processes in Saudi Arabia. SCOT's accreditation process evaluates healthcare facilities on their ability to identify, manage, and report potential organ donors in compliance with national regulations. Accredited organ donor hospitals (ODH) must demonstrate readiness in terms of the availability of medical expertise and diagnostic tools for death confirmation by neurological criteria.

IMPORTANT NOTE

The organ donation standards outlined in Appendix E serve as essential guidance to assist donor hospitals in aligning their practices with SCOT regulations and policies. These standards provide a valuable framework that donor hospitals can utilize to ensure full compliance with national requirements and uphold the highest standards in organ donation processes.

4.1 Accreditation Cycle in Donor Hospitals

The accreditation cycle for donor hospitals is a structured and continuous process established by SCOT to ensure that hospitals meet and maintain the necessary requirements for organ donation. This cycle involves a series of sequential steps designed to evaluate, recognize, and monitor hospitals that qualify for donor hospital accreditation. **The following is the procedure for accrediting donor hospitals:**

4.1.1 Review of Operating Hospitals

SCOT obtains an updated list of all hospitals licensed and operating in the Kingdom of Saudi Arabia from the relevant health authorities and governing bodies.

4.1.2 Evaluation Against Minimum Criteria

SCOT reviews the list of hospitals to verify their compliance with the minimum criteria for donor hospital accreditation. This review is conducted through desk review, virtually, or an on-site assessment visit. Hospitals that meet the following minimum criteria are recognized/accredited as donor hospitals:

IMPORTANT NOTE

Accreditation of donor hospitals is **legally mandatory**. Once a hospital meets the minimum criteria for a donor hospital, it is automatically accredited.

4.1.2.1 Availability of an intensivist and/or anesthesiologist and/or emergency physician

4.1.2.2 Availability of a neurologist and/or neurosurgeon, or access to neurological/ neurosurgical consultation

4.1.2.3 Availability of or access to diagnostic tools for death confirmation by neurological criteria, such as CT angiography, perfusion scan, electroencephalogram, transcranial Doppler ultrasound…etc.

4.1.3 Access to The unified Organ Donation Platform

Hospitals meeting the minimum criteria are granted electronic access to The unified organ donation and transplantation platform (Athar). Donor hospitals are required to use the platform to complete their data and demonstrate ongoing compliance with the minimum criteria.

4.1.4 Official Recognition and Publication

Once a hospital is verified to meet all minimum criteria, it is officially recognized/ accredited as an organ donor hospital (ODH). SCOT publishes an updated list of accredited ODH annually through official channels, including the official website of SCOT. This list is also updated as needed when changes occur.

4.1.5 Compliance with Organ Donation Regulations

Accredited donor hospitals must adhere to all organ donation regulations and executive bylaws (refer to Chapter 4, Section 4D). Any misconduct or failure to apply these regulations is subject to investigation, and disciplinary actions may follow. The following are required to be established in accredited ODH:

4.1.5.1 **Establishment of an Organ Donation Unit (ODU):** Accredited ODHs are required to establish a functional ODU (refer to Chapter 2, Section 2A, Sub-section 2.2). This unit is responsible for ensuring the timely identification, reporting, and handling of possible donors who have died by neurological criteria (DNC). Although it is not mandatory to have a physical unit (i.e. structured stand-alone unit), the unit should be available functionally to oversee and manage the provision of deceased organ donation services.

ORGAN DONATION UNIT (ODU)

The establishment of ODU is a globally recognized standard practice, gearing up healthcare systems to ensure the consistent, ethical, and efficient management of organ donation and transplantation processes worldwide.

4.1.5.2 **Development of Policies and Procedures**: ODH must establish a set of policies and procedures that regulate the deceased organ donation process. These policies ensure that all steps in the donation process are consistent, ethical, and in line with national standards.

4.1.5.3 **Monitoring and Continuous Improvement**: Accredited ODHs are expected to continuously monitor and improve their organ donation processes. This is achieved through the use of established key performance indicators (KPIs) that track compliance with regulations and overall performance in the donation process (see Table 2.1, Chapter 2).

4.1.6 Annual Reassessment of Accreditation Status

SCOT reviews the accreditation status of donor hospitals annually to verify their continued compliance with the minimum criteria. Hospitals that no longer meet the criteria are removed from the accredited list, while new hospitals that meet the criteria are added.

Section 4B: Accreditation of Transplant Programs

The accreditation program for transplant programs is a component of the SCOT regulatory framework designed to ensure the quality of care and ethical conduct of transplant processes provided by transplant programs in the Kingdom of Saudi Arabia. SCOT offers a rigorous accreditation process to evaluate healthcare facilities' compliance with a predefined set of transplantation-related standards for a wide range of organs and tissues. In Saudi Arabia, healthcare facilities are not allowed to perform organ recovery or offer transplant services without a valid accreditation from SCOT. The accreditation program includes standards related to the structure, process, and outcomes of transplant programs, addressing aspects such as the structure of the transplant program, workforce safety, technical and support services, patient-centric care delivery, and performance management.

This section includes regulations and procedures on the following:

4.2 Accreditation Eligibility Criteria

4.3 Accreditation Scope and Cycle

4.4 Accreditation Assessment Team

4.5 Accreditation Policies

- Accreditation Certificate Use
- Appeal Against Accreditation Decision
- Accreditation Cancellation, withdrawal, and Renewal
- Accreditation Suspension and Revocation
- Accreditation impartiality

4.2 Accreditation Eligibility Criteria

Healthcare facilities can seek transplantation accreditation if they meet specific eligibility criteria before applying for accreditation. These criteria are designed to ensure that the facility is capable of providing safe, ethical, and high-quality transplantation services. Healthcare facilities intending to obtain transplantation accreditation must meet the following eligibility criteria:

- Licensed by relevant authorities to operate in the kingdom.
- Operating for at least 12 months as a hospital.
- Accredited by the Saudi Central Board for Accreditation of Healthcare Organizations (CBAHI).
- Paid the fee associated with the accreditation process.
- Considered strategically needed by SCOT, based on factors such as waiting lists, geographical location, and the number of existing accredited programs.

Once SCOT accepts a transplant accreditation application, the applicant facility must assume the following general duties:

- Submit the required documents to SCOT for the accreditation process, while ensuring data accuracy.
- Cooperate fully with SCOT and the assessment team during on-site visits.
- Provide the necessary resources to support the SCOT assessment team in accomplishing their tasks.
- Demonstrate satisfactory compliance with all Foundational Criteria (FC) outlined in SCOT accreditation standards for the specific intended organ or tissue transplantation program.

4.3 Accreditation Scope and Cycle

4.3.1 ACCREDITATION SCOPE

The scope of SCOT transplantation accreditation includes the following transplant programs; **kidney, liver, heart, lung, pancreas, intestine, and cornea**, as well as tissue banks. Healthcare facilities seeking accreditation for other transplantation programs are subject to an independent assessment by SCOT following national regulations and the best available international evidence.

For each transplantation program, SCOT defined a number of standards related to the program structure, workforce safety, technical and support services, patient-centric care, and performance management. Each standard consists of a set of measurable criteria. Of these, SCOT has defined a number of foundational criteria (FC) that need to be fulfilled at the initial phase of the accreditation process.

4.3.2 ACCREDITATION CYCLE

SCOT is committed to a transparent and impartial accreditation process that adheres to pre-established. Although healthcare facilities need to comply with all accreditation standards related to their intended organ/tissue transplantation program, the accreditation processes are sequential and designed to support continuous improvement, allowing healthcare facilities to address any identified gaps while progressing through each stage of the process (see Figures 4.1, 4.2).

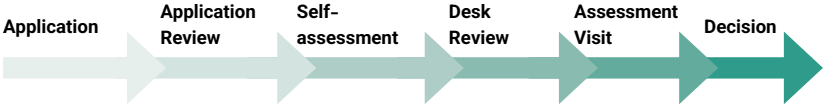


Figure 4.1 The Stages of Accreditation Cycle in Transplant programs

4.3.1.1 Accreditation Application

Facilities capable of and willingly seeking transplantation accreditations are required initially to complete the application request located on the SCOT website (www.SCOT.gov.sa).

IMPORTANT NOTE

Facilities can be interested in obtaining accreditation for multiple organs, but SCOT handles the request of each transplant program separately to ensure compliance with the intended accreditation criteria.

4.3.2.2 Application Review

The accreditation application will be reviewed, by the concerned department at SCOT, to ensure that the healthcare facility meets the eligibility criteria (refer to Chapter 4, Section 4B, Sub-section 4.2).

4.3.2.3 Accreditation Self-assessment

Healthcare facilities need to assess their compliance with the foundational criteria (FC) that are relevant and applicable to the intended organ/tissue transplantation program. The results of the self-assessment along with documented evidence that supports their compliance need to be submitted to SCOT for review purposes.

4.3.2.4 Desk Review

Concerned departments at SCOT will carefully review the self-assessment results and the supporting documents to verify that the healthcare facility assessed accurately its compliance with the foundational criteria (FC) and provided sufficient evidence to support it.

4.3.2.5 Assessment Visit

Following the desk review, an on-site assessment visit to the applicant facility will be conducted to assess the full compliance with the foundational criteria (FC) in real-time. During the visit, assessors will evaluate how the healthcare facility operates using various assessment activities, such as reviewing documents, interviewing staff members, observing patient care processes, and reviewing staff qualifications.

4.3.2.6 Accreditation Decision

The results of the on-site assessment visit will be used to determine the degree to which the healthcare facility complies with foundational criteria (FC). The compliance status is thereafter presented to the accreditation and compliance committee (ACC) that is responsible for recommending a decision to grant or not to grant a transplantation service accreditation. The ACC's recommendation is not based on a mathematical calculation of the compliance rate with FC, but rather; based on risk assessment associated with nonconformance. Next, the ACC's recommendation is reviewed by the general director of SCOT who has the ultimate responsibility of reviewing recommendations and approving one of the following final accreditation decisions:

ACCREDITED: is a decision granted when the healthcare facility demonstrates a satisfactory level of compliance with foundational criteria (FC), with no remarkable observation that carries an immediate threat to the safety of the transplant patients. When the decision is taken to accredit a healthcare facility, accreditation will be valid for three (3) years from the date of the assessment visit. Thereafter, the facility shall comply with all post-accreditation requirements as per SCOT policy.

NON-ACCREDITED: is a decision granted when the healthcare facility demonstrates a non-satisfactory level of compliance with foundational criteria (FC) or a remarkable observation that carries an immediate threat to the safety of the transplant patients has been detected. In this case, the facility will receive a written report detailing the areas of concern, with a window to complete and re-submit the required corrections and evidence. Thereafter, the ACC reviews additional evidence and makes the final recommendation. However, if the additional evidence does not satisfy accreditation requirements, the healthcare facility will not be able to submit further evidence and may submit a new transplantation accreditation application within the duration specified by SCOT. However, these facilities are allowed to appeal against the decision following the SCOT accreditation appeal process.

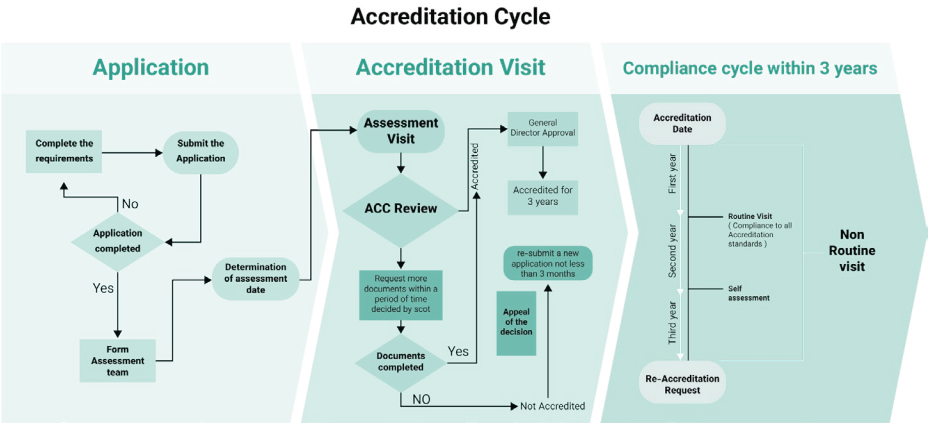


Figure 4.2 SCOT Accreditation Pathway for Transplantation Programs

4.4 Accreditation Assessment Team

SCOT assessors are experienced transplantation professionals who are selected meticulously based on specific selection criteria, including their profession, specialization, skills, and areas of expertise, and trained on all relevant transplantation standards and assessment competencies. Assessors in SCOT have education, experience, skills, and attitudes that qualify them to assess compliance with the transplantation services standards fairly and objectively.

The on-site assessment team comprises a number of Certified Transplantation Assessors (CTA) specialized in the relevant organ/tissue that is planned to be assessed. One of the assessors will be assigned as a lead assessor who serves as a liaison coordinator between SCOT and the healthcare facility. The assessment team is formed impartially based on specialty, seniority, and conflict of interest status. The list of the assessment team members along with their biographies will be shared with the scheduled facility to verify the lack of conflict of interest with any assessor.

4.5 Accreditation Policies

The SCOT accreditation process is guided by a comprehensive set of policies designed to ensure a transparent, consistent, and fair evaluation framework. These policies govern the various aspects of accreditation, providing clear guidelines for maintaining the highest standards of quality and integrity throughout the accreditation process. Understanding and strict adherence to these policies is crucial for all involved stakeholders to ensure the reliability of the accreditation assessment process. These policies include:

- Policy on accreditation certificate use
- Policy on appeal against accreditation decision
- Policy on accreditation cancellation, withdrawal, and renewal
- Policy on accreditation suspension and revocation
- Policy on accreditation impartiality

4.5.1 ACCREDITATION CERTIFICATE USE

The SCOT accreditation certificate is a mark of distinction and a symbol of quality and trust that is awarded to and signifies healthcare facilities that meet SCOT transplantation accreditation standards. The accreditation certificate serves as a public declaration of the facility's dedication to excellence in caring for transplant patients. The accreditation certificate is a protected intellectual property, and its integrity must be maintained all the time. Once a healthcare facility earns accreditation, the way it handles and displays the accreditation certificate is crucial. The following rules must be followed in this matter:

4.5.1.1 The accreditation certificate may be used solely by facilities that have received SCOT accreditation. Non-accredited facilities may not use the accreditation certificate in any manner.

4.5.1.2 The accreditation certificate may be used by accredited facilities in their public announcements and advertising materials electronically or paper-based.

4.5.1.3 The accreditation certificate may only be applied to materials, documents, and marketing collateral related to the accredited healthcare facility's transplantation services.

4.5.1.4 The accreditation certificate shall not be used to endorse products, services, or activities not related to the transplantation program that has been assessed and accredited by SCOT.

4.5.1.5 Accredited transplantation programs can print out additional copies of the accreditation certificate if the printed copies are made with high quality, without distortion, and while maintaining the same size as the original accreditation certificate.

4.5.1.6 The validity of the SCOT accreditation certificate is three years. The use of the accreditation certificate shall be stopped immediately in case of accreditation suspension, revocation, or expiry. Noncompliance with this rule that exceeds 14 working days shall result in referring the issue to the concerned committees at SCOT and may result in notifying relevant regulatory authorities.

4.5.1.7 The following instances are violation examples for the SCOT accreditation certificate use policy:

- Using the accreditation certificate by a non-accredited healthcare facility.
- Using the accreditation certificate of a specific organ/tissue to endorse another organ/tissue.
- Using the accreditation certificate after expiry or in case of accreditation suspension or revocation.
- Using the accreditation certificate in training activities without obtaining explicit authorization from SCOT.

4.5.2 APPEAL AGAINST ACCREDITATION DECISION

4.5.2.1 Healthcare facilities that have been granted a "non-accredited" decision, suspension decision, or revocation decision are allowed to appeal against the decision.

4.5.2.2 Appeal requests need to be supported by evidence indicating a breach for one or more of the following four appeal grounds:

4.5.2.2.1 **Procedural Errors:** refers to accreditation procedural errors committed by SCOT or SCOT's assessors during the accreditation process. For example, not notifying the programs of the assessment visit, or not following the SCOT assessment process or timeframes.

4.5.2.2.2 **Conflict of Interest:** refers to allegations of bias or conflict of interest among the assessors associated with unfair assessment or prejudice. For example, having a personal or professional relationship between one of the assessors and a competing hospital.

4.5.2.2.3 **Failure to Consider Relevant Evidence:** refers to not considering, overlooking, or misunderstanding relevant factors or evidence during the assessment. For example, an assessor did not or refused to review a specific document or evidence submitted during the visit.

4.5.2.2.4 **Accreditation Status Impact:** refers to an occasion where the outcome of the appeal against a specific number of criteria, if it comes true, will result in changing the accreditation status. For example, appealing against incorrect scores could result in reaching accreditation criteria if it comes in favor of the appealer.

4.5.2.3 Appeal Procedure:

4.5.2.3.1 The healthcare facility submits a notice of appeal with supporting evidence to SCOT via the approved communication channels.

4.5.2.3.2 The Accreditation section in SCOT reviews the appeal request for completeness and presents it to the Appeal Review Committee (ARC).

4.5.2.3.3 The ARC evaluates the appeal request and submits evidence thoroughly. As necessary, the ARC may request additional evidence or request conducting a focused assessment (virtual or on-site) visit.

4.5.2.3.4 The ARC submits a recommendation to the SCOT general director for a final decision.

4.5.2.3.5 SCOT provides the healthcare facility with the appeal decision despite the appeal results/outcomes

4.5.2.3.6 If the decision is unchanged, the facility may reapply for accreditation within a duration specified by SCOT

4.5.3 ACCREDITATION CANCELLATION, WITHDRAWAL, AND RENEWAL

The renewal and cancellation of transplantation accreditation for healthcare facilities are integral parts of the SCOT accreditation process. Accredited healthcare facilities are required to maintain compliance with SCOT standards and undergo reaccreditation typically every three years. The following are the procedural steps of accreditation renewal and accreditation cancellation:

4.5.3.1 Procedural Steps for Accreditation Renewal

4.5.3.1.1 The accreditation section at SCOT will notify accredited transplant programs, 3 months in advance of their reaccreditation due date.

4.5.3.1.2 The reaccreditation process will follow the same steps as the initial accreditation, including a compliance assessment for all applicable standards in the SCOT manual for the intended organ/ tissue transplantation program and the fee payment.

4.5.3.1.3 Based on the assessment, a decision will be made, and the accreditation status will either be renewed or updated accordingly.

4.5.3.2 **Procedural Steps for Accreditation Cancellation**

4.5.3.2.1 Accredited transplant programs that choose not to renew their accreditation must inform SCOT of their decision before the accreditation expires.

4.5.3.2.2 If "non-renewal" is requested, the facility's accreditation will expire at the end of the current accreditation period.

4.5.3.2.3 SCOT will confirm the cancellation of accreditation upon receiving the facility's request or after the accreditation period without renewal.

4.5.3.2.4 Upon accreditation cancellation, the accredited transplant program must adhere to the SCOT "accreditation certification use" policy.

4.5.3.3 **Procedural Steps for Accreditation Withdrawal by the Healthcare Facility**

4.5.3.3.1 The healthcare facility intending to withdraw from accreditation must notify SCOT of its decision at least 30 days before the desired withdrawal date.

4.5.3.3.2 SCOT will review the facility's request, confirm receipt, and issue an acknowledgment detailing the withdrawal process and the effective date of accreditation termination.

4.5.3.3.3 The healthcare facility must comply with SCOT's "accreditation certification use" policy, including the immediate cessation of accreditation-related promotions and removal of SCOT certification logos from all marketing materials.

4.5.3.3.4 SCOT will update the accreditation list to reflect the withdrawal.

4.5.3.3.5 Any future accreditation reapplication by the facility will be considered as a new application and must follow the full initial accreditation process.

4.5.4 ACCREDITATION SUSPENSION AND REVOCATION

Accredited transplant programs must comply with SCOT's accreditation standards and policies. Failure to do so may result in suspension or revocation of accreditation. SCOT will ensure a transparent, fair, and consistent implementation of the suspension and revocation processes, providing facilities with clear communication, justification, and timeline. The following are the guidelines and procedural steps of accreditation suspension and revocation:

4.5.4.1 Guidelines for Accreditation Suspension and Revocation

4.5.4.1.1 Suspension or revocation of accreditation may be initiated in response to non-compliance with accreditation standards, legal or regulatory violations, ethical breaches, failure to submit required documentation, false or misleading information, or unjustified safety events.

4.5.4.1.2 Suspension and revocation are independent decisions; SCOT may choose to suspend a transplant program, suspend it and then later revoke it, or directly revoke the program without a prior suspension, depending on the severity, impact, risk, and repetition of the non-compliance.

4.5.4.1.3 Suspended facilities will be notified of the violation and allowed to rectify issues through a corrective action plan (CAP). However, the revoked facilities may reapply for a new accreditation cycle within a period specified by SCOT.

4.5.4.2 Procedural Steps for Accreditation Suspension and Revocation

4.5.4.2.1 SCOT notifies the healthcare facility of the non-compliance issues using suspension/revocation notice if a ground for suspension or revocation is identified.

4.5.4.2.2 The healthcare facility responds to the notification by providing evidence or explanation within a timeframe specified by SCOT.

4.5.4.2.3 The submitted evidence and explanation will be reviewed to recommend a decision, which might be withdrawal of the suspension/revocation notice, suspension, or revocation based on the violation circumstances.

4.5.4.2.4 The healthcare facility will be formally notified of the suspension/revocation decision once the decision is confirmed, reviewed, and approved.

4.5.4.2.5 During the suspension/revocation, the facility may not represent itself as accredited by SCOT following the accreditation certification use policy.

4.5.4.2.6 In case of suspension, the facility will submit a CAP addressing the issues. SCOT will review the CAP to decide whether to restore accreditation, request more actions, or proceed with revocation.

4.5.4.2.7 In case of revocation, the facility may reapply for accreditation, within a period specified by SCOT, after addressing the reasons for revocation.

4.5.4.2.8 The healthcare facility has the right to appeal against the suspension/revocation decision.

4.5.5 ACCREDITATION IMPARTIALITY

SCOT is committed to maintaining impartiality throughout its accreditation process. This ensures that all healthcare facilities are treated fairly and equally, without bias or discrimination. SCOT's impartiality framework is designed to uphold the integrity, transparency, and fairness of the accreditation system. The following measures are taken by SCOT to ensure accreditation impartiality:

4.5.5.1 All healthcare facilities have equal access to transplantation standards and processes.

4.5.5.2 Accreditation visits are scheduled impartially, regardless of the healthcare facility's size or location.

4.5.5.3 Accreditation recommendations are made by the ACC, which includes diverse independent stakeholders.

4.5.5.4 Assessors are selected based on qualifications and undergo thorough training and competencies.

4.5.5.5 Assessors disclose any conflicts of interest, sign relevant agreements, and adhere to impartiality measures.

4.5.5.6 Healthcare facilities are allowed to report conflicts and request a replacement for assessors if necessary.

4.5.5.7 Mechanisms are in place to detect and mitigate bias, conflicts of interest, or partiality during the accreditation process.

Section 4C: Compliance Of Donor And Transplant Hospitals

Maintaining accreditation is as important as obtaining it, as it ensures that donor hospitals and transplant programs continue to meet evolving standards in medical science and transplant patient care. SCOT emphasizes that accreditation is not a one-time event but a continuous commitment to excellence, requiring regular assessments, updates, and improvements. Compliance audits are designed to continuously evaluate the adherence of healthcare facilities to the organ donation regulation and its executive bylaw, the directory and procedures of organ donation and transplantation, and SCOT policies, standards, and guidelines. Continuous compliance reinforces ethical integrity, ensuring that all organ donation and transplantation aspects follow ethical and legal standards. This section provides a structured framework for compliance audits to ensure the safety and effectiveness of organ donation and transplantation processes (see Figure 4.3).

This section includes regulations and procedures on the following:

4.6 COMPLIANCE OF ORGAN DONOR HOSPITALS

- 4.6.1 Routine Compliance Audit
  - Performance review
  - Compliance review
- 4.6.2 Non-routine Compliance Audit
- 4.6.3 Administrative Data Submission
  - Self-assessment submission
  - Safety event reporting
  - Major change notification

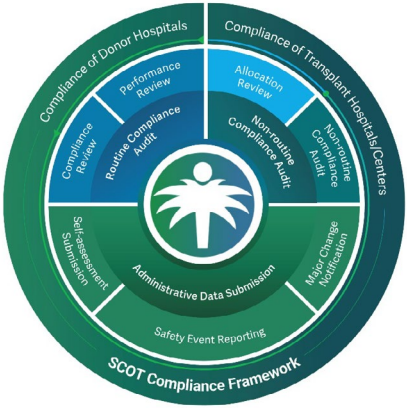


Figure 4.3 SCOT Accreditation Compliance Framework

4.6 COMPLIANCE OF TRANSPLANT programs

- 4.6.1 Routine Compliance Audit
  - Performance review
  - Compliance review
- 4.6.2 Non-routine Compliance Audit
  - Allocation process review
  - Other non-routine compliance audit
- 4.6.3 Administrative Data Submission
  - Self-assessment submission
  - Safety event reporting
  - Major change notification

4.7 Compliance of Organ Donor Hospitals

Organ donor hospitals (ODH) shall adhere to SCOT's regulations and critical pathways, while SCOT regularly assesses their compliance to ensure the effectiveness of the donation process within the legal framework, protecting both donors and recipients. By continuously assessing ODH compliance, SCOT maintains high donation standards and supports the success and sustainability of the organ donation process in Saudi Arabia. Once a healthcare facility meets the minimum criteria of donor hospitals and is accredited by SCOT as a donor hospital, the following compliance procedures will be pursued:

4.7.1 ROUTINE COMPLIANCE AUDIT

Routine Compliance Audit is an annual external audit conducted by SCOT, either physically or virtually, to ensure donor hospitals meet established standards and comply with regulatory requirements. The audit consists of two main components:

Performance Review: To evaluate the effectiveness of donation processes within the hospital. It includes examining how potential donors are reported and managed and reviewing the outcomes of related Key Performance Indicators (KPIs).

Compliance Review: To assess the hospital's adherence to SCOT's criteria, policies, and requirements for donor hospitals. It involves an evaluation of possible, potential, and actual brain death cases, including data validation, report verification, policy review, staff interviews, and donor medical record assessments. The routine

compliance audit follows the following procedure (see Figure 4.4):

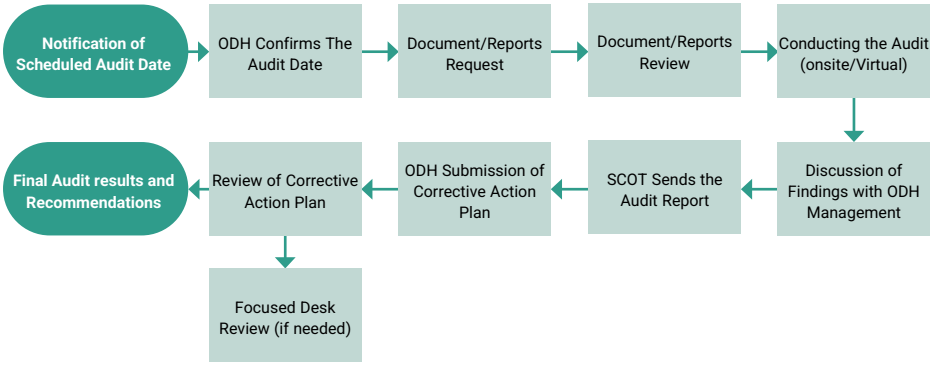


Figure 4.4 The Procedure of Routine Compliance Audit in Organ Donor Hospitals

4.7.1.1 SCOT notifies the ODH of the scheduled audit at least 30 days in advance, outlining the purpose, objectives, and audit date.

4.7.1.2 ODH confirms the audit date and ensures key personnel, documents, and system access are available.

4.7.1.3 Prior to the audit, SCOT requests and reviews relevant documentation and information, such as brain death reports, donation-related policies, and other necessary materials.

4.7.1.4 During the audit, SCOT conducts an interview with relevant staff, reviews health records, and performs data validation to ensure compliance with SCOT standards and regulations. In addition, SCOT may provide staff education on organ donation processes, as necessary, to improve compliance.

4.7.1.5 At the end of the audit, SCOT discusses the findings with hospital management and relevant staff, as needed, to present initial findings, highlight concerns, and outline the next step.

4.7.1.6 After the audit, SCOT sends a formal audit report to the ODH, requesting a corrective action plan for noncompliance identified.

4.7.1.7 ODH is expected to submit the corrective action plan along with additional/supportive documents within 30 days starting from the date of receiving the audit report.

4.7.1.8 SCOT reviews the submitted documents and corrective action plan, followed by sending the ODH a final report that summarizes the audit results and recommendations.

4.7.1.9 On some occasions, SCOT may opt to conduct a focused desk review if significant noncompliance is found or to verify corrective actions have been implemented.

4.7.2 NON-ROUTINE COMPLIANCE AUDIT

This is a non-routine external audit conducted by SCOT to evaluate the donation processes. The audit is unplanned and usually performed through a desk review. However, SCOT may conduct the audit through onsite or virtual visits, as necessary, depending on the nature of the event or the review. Such an audit aims to ensure adherence to SCOT's regulatory standards and identify potential areas for improvement. The non-routine audit is triggered by one of the following:

- Follow-up to a routine audit where noncompliance was identified, or
- In response to a safety event or reported noncompliance, or
- In response to a gap identified in the routine performance review, or
- Whenever SCOT deems it necessary.

The non-routine compliance audit follows the following procedure:

4.7.2.1 SCOT initiates a non-routine audit when necessary, defining the objectives of the audit and the documents/records needed for review.

4.7.2.2 SCOT formally notifies the ODH of the audit, specifying the reason for the audit, scope, and required documents/records, if needed.

4.7.2.3 The ODH is required to submit the requested documents/records (e.g. brain death cases, donor health records), within one week.

4.7.2.4 SCOT conducts a thorough desk review of the submitted documents/records to evaluate compliance with donation regulations and standards.

4.7.2.5 SCOT issues a formal audit report outlining performance gaps, if any, once the audit is completed.

4.7.2.6 The ODH reviews the audit findings and submits corrective actions within 30 days, addressing all identified issues, rectification actions, and timeframe.

4.7.2.7 SCOT evaluates the proposed corrective actions, determines their adequacy, and communicates with the ODH if adjustments or further amendments are required.

4.7.2.8 Once all corrective actions are satisfactorily implemented and verified, SCOT issues a letter confirming the resolution of the audit.

4.7.2.9 If the audit reveals significant risks, high noncompliance, or unresolved issues, the findings will be escalated to the SCOT's violation committee for further review, investigation, and possible penalties.

4.7.3 ADMINISTRATIVE DATA SUBMISSION

ODHs recognized/accredited by SCOT as donor hospitals are required to maintain compliance with accreditation requirements by accurately and promptly reporting administrative data. This includes completing an annual self-assessment, immediately reporting any safety events or violations, and timely notifying SCOT of significant changes that could impact compliance with donation standards. SCOT typically reviews the submitted data through a desk review but may also conduct onsite or virtual audits if needed, based on the completeness, accuracy, and timeliness of the data provided.

4.7.3.1 ANNUAL SELF-ASSESSMENT

4.7.3.1.1 ODH, represented typically by the donation team, is required to conduct a self-assessment annually to assess their compliance with regulatory requirements and donor hospital standards, and identify areas for improvement (refer to Appendix E).

4.7.3.1.2 The self-assessment results shall be reported to SCOT in order to maintain accreditation. Unjustified delay or failure in submitting the completed self-assessment may impact the accreditation status of the donor hospital.

4.7.3.1.3 Once the self-assessment is submitted, SCOT will evaluate the results through a desk review to monitor the compliance of the donor hospital with SCOT standards. An additional non-routine compliance audit (i.e. on-site or virtual) might be conducted by SCOT when deemed necessary.

4.7.1.1 SAFETY EVENTS REPORTING

4.7.1.1.1 ODH must immediately report any identified or suspected safety events related to donations at any stage of the process. Submission can be through The unified organ donation and transplantation platform (Athar), SCOT's incident reporting system, or via email at opex@scot.gov.sa.

IMPORTANT NOTE
SCOT encourages donor hospitals, families, and health professionals to raise complaints related to the quality of donation services.

4.7.1.1.2 SCOT may request additional information or documents to facilitate a thorough desk review of the reported incident and ensure all relevant details are considered during the investigation. An additional non-routine compliance audit (i.e. on-site or virtual) might be conducted by SCOT when deemed necessary.

4.7.1.1.3 Upon completion of the desk review, a written report detailing the findings, gaps, and recommendations will be sent to the ODH, and a corrective action plan will be requested for the identified areas of noncompliance, if any.

4.7.3.3 MAJOR CHANGES REPORTING

4.7.3.3.1 ODH must report any major changes that may affect compliance with donation standards or the quality and integrity of the donation process to SCOT promptly via SCOT's incident reporting system, or email at opex@scot.gov.sa. This may include but is not limited to:

- **Governance**: changes in hospital ownership or leadership (e.g. CEO, CMO) that may affect the management of organ donation processes.
- **Operation**: changes that may impact ODH operations, such as an expired hospital license or closure of the hospital by health authorities.
- **Scope of Service**: changes in the ODH scope of service, such as introducing or removing services relevant to organ donation.
- **Quality**: change in the ODH's national or international accreditation status, such as suspension or revocation of hospital accreditation.
- **Structural**: major construction, renovation, or relocation that disrupts donation activities or the hospital's operational capacity.

4.7.3.3.2 SCOT may request additional information or documents to facilitate a thorough desk review of the reported major change. A non-routine compliance audit (i.e. on-site or virtual) to verify the impact of the change might be conducted by SCOT when deemed necessary.

4.7.3.3.3 Upon completion of the desk review, SCOT will either acknowledge the reported change without requiring further action or request corrective measures to address any identified risks.

4.8 Compliance of Transplant Hospitals

The accreditation process of transplant hospitals is designed to ensure ongoing compliance rather than relying on one-time evaluation. Accredited transplant hospitals are required to demonstrate continuous adherence to SCOT's regulations, policies, and standards of their accredited organ transplant programs throughout the entire accreditation period. This approach ensures high-quality care and operational excellence, fostering the long-term success and sustainability of transplant services in Saudi Arabia. For transplant hospitals to maintain accreditation status, the following compliance procedures will be pursued:

4.8.1 ROUTINE COMPLIANCE AUDIT

This is an externally scheduled audit visit conducted by SCOT for all accredited transplant hospitals. The audit will be conducted physically (i.e. on-site assessment visit) after one year of granting the transplantation accreditation decision. A team of Certified Transplantation Assessors (CTA) will carry out the audit using a variety of assessment tools and activities. This audit consists of two main components:

Performance Review: to assess the effectiveness of transplant processes by evaluating the results of all transplant-related Key Performance Indicators (KPIs). Key metrics include waitlist activity, offer acceptance rates, the census of transplant recipients, mortality rates, and post-transplant outcomes, such as graft and patient survival rates. In addition to the results of KPIs, the performance review includes an evaluation of the functional activities. Each transplant program must remain functionally active by performing a minimum number of transplants. In SCOT, functional inactivity is defined as (see Table 4.1):

Table 4.1 Definition of Functional Inactivity in Transplant programs

Organ	When the programs is considered inactive
Kidney, Liver, or Heart	Failure to perform at least 1 transplant in 3 consecutive months
Lung	Failure to perform at least 1 transplant in 6 consecutive months
Pancreas	Failure to perform at least 2 transplants in 12 consecutive months
Intestine	Failure to perform at least 2 transplants in 12 consecutive months

Compliance Review: to assess the compliance of transplant hospitals with SCOT standards. It includes a comprehensive assessment of health records, document reviews, personnel records, direct observations, and interviews. Each transplant domain (such as kidney, liver, heart, lung, pancreas, intestine, and cornea) includes multiple standards, with each standard containing a number of measurable criteria. During the initial phase of accreditation, only foundational criteria (FC) are evaluated;

however, at this stage, all applicable standards of the accredited transplant program are assessed. SCOT assessors will assign a score to each applicable criterion using a three-level scoring method: completely achieved, partially achieved, or not achieved. If a criterion does not apply to the healthcare facility, it will be marked as Not Applicable. The duration of the on-site assessment visit of transplantation accreditation is typically set as one day or longer if deemed necessary. The exact date of the assessment visit is specified following the annual accreditation plan at SCOT and shared with the healthcare facility ahead of time.

The routine compliance audit follows the following procedure:

4.8.1.1 SCOT notifies the accredited transplant hospital of the scheduled audit visit at least 30 days in advance, outlining the purpose, objectives, and the onsite assessment visit date, along with the assessors' list.

4.8.1.2 The transplant hospital confirms the onsite assessment visit date and ensures that key personnel, necessary documents, and system access are available.

4.8.1.3 Before the visit date, SCOT assessors review all relevant documents, findings from the initial accreditation visit, and key performance indicators data related to the accredited hospital.

4.8.1.4 During the onsite visit, SCOT assessors conduct interviews with relevant staff, review health records, review documents, review personal records, and perform an observational round to ensure compliance with all applicable standards.

4.8.1.5 At the end of the visit, SCOT assessors discuss the major findings with hospital management and relevant transplant staff, as needed.

4.8.1.6 SCOT compiles reports from the assessment team, calculates compliance scores, and presents the results to the Accreditation and Compliance Committee (ACC) for review and decision.

4.8.1.7 To maintain transplantation accreditation status, the transplant hospital must achieve a specific compliance level defined by SCOT.

4.8.1.8 The ACC's recommendation on whether to maintain, suspend, or revoke accreditation of a transplant program will be communicated to the healthcare facility.

- If the decision is to maintain accreditation, the accredited transplant program may still be required to submit a corrective action plan for the remaining areas of noncompliance.
- If the decision is to suspend or revoke accreditation, the transplant program may not represent itself as accredited by SCOT.

4.8.1.9 The healthcare facility will receive formal notification of the decision once it has been confirmed, reviewed, and approved. Noting that the healthcare facility has the right to appeal against the suspension/revocation decision.

4.8.2 NON-ROUTINE COMPLIANCE AUDIT

This is a non-routine external audit conducted by SCOT to evaluate the transplantation processes. The audit is unplanned and usually performed through a desk review. However, SCOT may conduct the non-routine audit through onsite or virtual visits, as necessary, depending on the nature of the review. Such an audit aims to ensure adherence to SCOT's regulations, accreditation standards, and policies. The non-routine audit for transplant hospitals may be conducted at any time during the accreditation cycle and is triggered by one of the following:

- In response to discrepancies, complaints, or non-compliance with the SCOT allocation process, or
- In response to a safety event or reported noncompliance, or
- In response to a complaint against an accredited transplant program, or
- In response to a gap identified in the routine performance review, or
- Whenever SCOT deems it necessary.

4.8.2.1 **ALLOCATION COMPLIANCE AUDIT**: This audit is an evaluation process conducted by SCOT to ensure that transplant hospitals adhere to established policies and regulations regarding the allocation of organs. This audit assesses the fairness, transparency, and effectiveness of the organ allocation process, verifying that it aligns with ethical guidelines and legal requirements. During this audit, SCOT reviews the recipient listing

procedures, patient files, and the organ acceptance and transplant recipients information and outcome, **this audit follows the following procedure:**

4.8.2.1.1 SCOT uses The unified organ donation and transplantation platform (Athar) to select organ allocation cases for review. The review is retrospective, including organs that were allocated during the past two months.

4.8.2.1.2 The review includes verifying organ acceptance and rejection, ensuring that accepted organs were allocated according to the match run sequence, and comparing documented acceptance with transplant recipient records, following the SCOT allocation policy.

4.8.2.1.3 SCOT may request additional documents from the transplant programs for a thorough desk review. On a case-by-case basis, SCOT may conduct the allocation review via onsite or virtual visits.

4.8.2.1.4 Based on the review findings, SCOT will notify the transplant programs of the allocation compliance audit findings and respond according to the following:

- If no violations are found, SCOT will close the review with no further action.
- If the violation is unintended and minor, SCOT will request a corrective action plan to prevent future reoccurrence of the event.
- If the violation is intended, repeated, or serious, SCOT will defer the case to the relevant committee to determine appropriate actions or penalties.

4.8.2.2 **For other NON-ROUTINE COMPLIANCE AUDIT, the audit follows the following procedure:**

4.8.2.2.1 SCOT initiates non-routine audit compliance when necessary, defining the objectives of the audit and the documents/records needed for review.

4.8.2.2.2 SCOT formally notifies the transplant hospital of the audit, specifying the reason and scope of the audit.

4.8.2.2.3 SCOT may request additional documents from the transplant programs for a thorough desk review. On a case-by-case basis, SCOT may conduct the review via onsite or virtual visits.

4.8.2.2.4 In case of requesting documents from the transplant hospital, the requested documents/ records shall be submitted to SCOT within one week.

4.8.2.2.5 SCOT conducts a thorough desk review of the submitted documents/records to evaluate compliance with transplantation regulations, policies, and standards.

4.8.2.2.6 The audit results will be presented to the ACC for review and decision:

- If no noncompliance is found, the ACC will close the review with no further action.
- If noncompliance is detected, the ACC may request a corrective action plan, suspend, or revoke the transplant program, depending on the analysis and audit findings.
- If a major violation is detected, the ACC will defer the case to the relevant committee to determine appropriate actions or penalties.

4.8.2.2.7 If a corrective action plan is needed, the transplant hospital needs to submit corrective actions within 30 days, addressing identified issues, rectification actions, and timeframe.

4.8.2.2.8 SCOT evaluates the proposed corrective actions, determines their adequacy, and communicates with the transplant hospital if adjustments or further amendments are required.

4.8.2.2.9 Once all corrective actions are satisfactorily implemented and verified, SCOT issues a letter confirming the resolution of the audit.

4.8.3 ADMINISTRATIVE DATA SUBMISSION

Transplant hospitals are required to maintain compliance with accreditation requirements by accurately and promptly reporting administrative data. This includes completing a self-assessment, immediately reporting any safety events or violations, and timely notifying SCOT of significant changes that could impact compliance with donation standards. SCOT typically reviews the submitted data through a desk review but may also conduct onsite or virtual audits if needed, based on the completeness, accuracy, and timeliness of the data provided.

4.8.3.1 **SELF-ASSESSMENT**

4.8.3.1.1 The transplant hospital is required to conduct a self-assessment one year after the routine compliance audit to assess their compliance with relevant accreditation standards and identify areas for improvement (refer to Appendix E).

4.8.3.1.2 The self-assessment results shall be reported to SCOT in order to maintain accreditation. Unjustified delay or failure in submitting the completed self-assessment may impact the accreditation status of the transplant hospital.

4.8.3.1.3 Once the self-assessment is submitted, SCOT will evaluate the results through a desk review to monitor the compliance of the transplant hospital with SCOT accreditation standards. An additional non-routine compliance audit (i.e. on-site or virtual) might be conducted by SCOT following the submission of the self-assessment when deemed necessary.

4.8.1.1 **SAFETY EVENTS REPORTING**

4.8.1.1.1 Transplant hospitals must immediately report any identified or suspected safety events related to any stage of the transplantation process. Submission can be through The unified organ donation and transplantation platform (Athar), SCOT's incident reporting system, or via email at opex@scot.gov.sa.

4.8.1.1.2 The preliminary notification shall be followed by a detailed report within 72 hours of the event. The detailed report shall include a description of the safety event, the affected individuals, the actions taken, and the measures implemented to prevent future occurrences.

IMPORTANT NOTE
SCOT encourages transplant hospitals, health professionals, patients, and families to raise complaints related to the quality of transplantation services.

4.8.1.1.3 SCOT may request additional information or documents to facilitate a thorough desk review of the reported incident and ensure all relevant details are considered during the investigation. An additional non-routine compliance audit (i.e. on-site or virtual) might be conducted by SCOT when deemed necessary.

4.8.1.1.4 Upon completion of the desk review, a written report detailing the findings, gaps, and recommendations will be sent to the transplant hospital, and a corrective action plan will be requested for the identified areas of noncompliance, if any.

4.8.1.1.5 If a major violation or noncompliance is detected, the safety report will be referred to the ACC to determine appropriate actions and decide accordingly.

4.8.3.3 MAJOR CHANGES REPORTING

4.8.3.3.1 Transplant hospitals must report any major changes that may affect compliance with transplantation standards or the quality and integrity of the transplantation process to SCOT promptly via SCOT's incident reporting system, or email at opex@scot.gov.sa. This may include but is not limited to:

- **Governance:** changes in hospital ownership or leadership (e.g. CEO, CMO) that may affect the management of organ transplantation processes.
- **Operation:** changes that may impact the transplant hospital operations, such as an expired hospital license or closure of the hospital by health authorities.
- **Scope of Service:** changes in the transplant hospital scope of service, such as introducing or removing services relevant to organ transplantation services.
- **Quality:** change in the transplant hospital's national or international accreditation status, such as suspension or revocation of hospital accreditation.
- **Structural:** major construction, renovation, or relocation that disrupts transplantation activities or the hospital's operational capacity.

4.8.3.3.2 SCOT may request additional information or documents to facilitate a thorough desk review of the reported major change. A non-routine compliance audit (i.e. on-site or virtual) to verify the impact of the change might be conducted by SCOT when deemed necessary.

4.8.3.3.3 Upon completion of the desk review, SCOT will either acknowledge the reported change without requiring further action or request corrective measures to address any identified risks.

4.8.3.3.4 As needed, the change notification report will be referred to the ACC to determine appropriate actions and decide accordingly.

Section 4D: Implications of Violating Organ Donation Regulation

"VIOLATION OF THE EXECUTIVE BYLAW OF HUMAN ORGAN DONATION REGULATION"

In the Kingdom of Saudi Arabia, the governance of organ donation and transplantation is meticulously outlined in the Executive Bylaw of Human Organ Donation Regulation, a pivotal legislative document enacted under Royal Decree No. (M/70) on 19/08/1442H. Along with its associated approved regulations numbered 29425-4 and dated 21/02/1443H. These regulations represent a cornerstone in the kingdom's commitment to upholding the ethical principles and procedural standards integral to the organ donation and transplantation processes. Further, it establishes prohibitions against unethical practices and violations to promote transparency, accountability, and patient safety. Such violations undermine the principles of fairness and medical ethics and also pose risks to the safety, well-being, and trust of donors and recipients alike. This chapter aims to raise awareness about the importance of adherence to organ transplantation regulations, highlight the consequences of violations, and promote a culture of ethical conduct within the relevant healthcare facilities.

4.9 Measures to Prevent Regulation Violations

In pursuit of fostering a regulated environment for organ donation and transplantation, SCOT has implemented a set of strategic preventative measures aimed at preventing violations, ensuring compliance with regulations, and upholding the integrity of organ donation and transplantation practices. These measures include:

4.9.1 SCOT collaborates with healthcare facilities, regulatory authorities, and law enforcement agencies to strengthen oversight and enforcement mechanisms.

4.9.2 SCOT has developed various awareness campaigns aimed at healthcare professionals, donors, and the general public to raise understanding and awareness about organ donation regulations and ethical considerations.

4.9.3 SCOT implements a centralized organ donation and transplantation platform (Athar) to record, monitor, track, and analyze all aspects of organ donation and transplantation from various healthcare facilities.

4.9.4 SCOT requires healthcare facilities to report organ donation and transplantation activities in real-time, allowing for immediate oversight and intervention in case of violations.

4.9.5 SCOT has established a set of performance indicators to monitor and track trends and patterns of donation and transplantation activities to assess compliance with regulations and mitigate the risk of potential violations.

4.9.6 SCOT holds the ultimate responsibility of implementing organ allocation policy following predefined evidence-based criteria that consider multifaceted factors.

4.9.7 SCOT has established transplantation accreditation standards outlining best practices and regulations in terms of organ/tissue donation and transplantation to help healthcare providers understand their responsibilities and adhere to standards.

4.9.8 Mandating adherence to SCOT accreditation standards for all healthcare facilities that offer transplantation services to ensure compliance with organ transplantation regulations and best practices.

4.10 Tools and Methods to Detect Violations

Ensuring adherence to organ donation and transplantation regulations is vital to maintaining the integrity of the process and protecting donors and recipients. In this, SCOT has established a multifaceted approach to detect and address potential violations. These methods include;

4.10.1 Developing predictive statistical models based on the trends and patterns of historical data to forecast potential future violations in organ donation and transplantation practices, enabling proactive intervention and prevention.

4.10.2 Analyzing submitted data retrospectively for patterns and trends indicative of potential suspicious activities or violations to enable timely intervention and investigation.

4.10.3 Forming a specialized committee (i.e. Violations Review Committee) that comprises a team of experts in organ donation and transplantation processes, healthcare professionals, legal experts, and regulatory specialists to conduct a comprehensive review of healthcare facilities' adherence to regulations.

4.10.4 Conducting random audits (i.e. on-site or virtually) of healthcare facilities' records and practices to verify compliance with regulations and identify any violations or discrepancies.

4.10.5 Reviewing (i.e. on-site or virtually) medical records and documentation of organ/tissue donors and recipients, such as consent forms and recovery records to detect possible violations and ensure compliance with regulations.

4.10.6 Selecting a random sample of accredited transplant healthcare facilities for unannounced inspections to verify adherence to regulations and detect non-compliance.

4.10.7 Empowering patients, healthcare professionals, and the public to report suspected violations of organ donation regulations anonymously through SCOT's official communication channels, while guaranteeing confidentiality for reporters to encourage reporting of violations without fear of retaliation.

4.10.8 Utilizing behavioral analysis techniques to detect unethical behavior among healthcare professionals or facilities involved in organ transplantation.

4.11 Procedure for Addressing Violations

4.11.1 **Initial Detection:** detection of a potential violation may occur through various channels, including internal review, external reports, or regular audits.

4.11.2 **Preliminary Review:** upon detection, a preliminary review will be initiated using the available data to assess the validity, size, and impact of the suspected violation by the concerned department in SCOT.

4.11.3 **Committee Review:** if the preliminary review confirms the presence of a possible violation, the case is presented for further evaluation and comprehensive review by the violations review committee.

4.11.4 **Gathering Additional Data:** the violations review committee is authorized to gather additional evidence, interview pertinent parties, or conduct an onsite or virtual visit to the implicated healthcare facility to complete the investigation and ascertain the veracity of the violation.

4.11.5 **Committee Decision:** following the investigation, the violations review committee will conclusively determine a formal decision outlining the findings of the investigation as:

4.11.5.1 No violation found: the committee will close the case and complete the required documentation of investigation results and outcomes as per SCOT policies.

4.11.5.2 Violation confirmed: the committee will assess the impact of the violation and determine the appropriate course of action or penalties based on the nature of the violation and following the provisions outlined in the Executive Bylaw of Human Organ Donation Regulation (see Table 4.2).

4.11.6 **Decision Notification:** the decision, along with its full details, is sent to the legal affairs department in SCOT to review the decision and refer it to the concerned legal authorities if needed. Relevant authorities and courts are notified about the violation depending on the type of violation and the breached article. Also, once penalties are determined, SCOT notifies the healthcare facility implicated in the violation of the findings and associated penalties. In this:

4.11.6.1 The Public Prosecution has the jurisdiction to investigate prosecute for committing the violations stated in Article 21 before the penal court.

4.11.6.2 Following Article 22 of the regulation, the violation review committee at SCOT reviews cases that are not explicitly stated in Article 21. Any person who violates any provision of the regulation or the Bylaw shall be punished with a fine not exceeding three hundred thousand Saudi Riyals.

4.11.7 **Decision Appeal:** the impacted facility is allowed to appeal against the decision according to the following:

4.11.7.1 **In case the violation is related to Article 21:** The facility has the right to appeal before the Appellate Court within 30 days from the date of receiving the decision.

4.11.7.2 **In case the violation is related to Article 22:** The facility has the right to appeal before the administrative court according to the procedural law before the Board of Grievance within 60 days from the date of receiving the decision.

4.11.8 **Implementation of Penalties:**

4.11.8.1 The criminal court has the jurisdiction to consider claims arising from the application of Article 21 and impose the stipulated penalties.

4.11.8.2 Upon confirmation of the violation of Article 22 and exhaustion of the facility's appeal process, SCOT implements the prescribed penalties (see Table 4.2).

4.11.9 **Monitoring and Follow-Up:** SCOT monitors the compliance of the violated facility with the imposed penalties and conducts follow-up inspections or audits as necessary to ensure ongoing adherence to regulations.

4.11.10 **Reporting and Transparency:** SCOT maintains transparency throughout the process by documenting all stages and outcomes of the investigation, including findings, penalties imposed, and actions taken.

Table 4.2 Penalties Associated with Violating or Attempting to Violate the Executive Bylaw of Human Organ Donation Regulation.

PENALTIES

Article Twenty-one

1. Without prejudice to any other severer punishment stated in another Regulation, violators committing any of the following acts shall be punished as follows:

A. Violators of **Articles (Eight) and (Ten)** of the Regulation shall be punished by a fine not exceeding five hundred thousand Saudi Riyal.
B. Violators of **Article (Twelve)** of the Regulation shall be punished by imprisonment for a period not exceeding two years and a fine not exceeding one million Saudi Riyal or any of the two punishments.
C. Violators of **Article (Thirteen)** of the Regulation shall be punished by a fine not exceeding one million Saudi Riyal.

2. Anyone who attempts to commit any of the violations stated in items (1/A, 1/B, and 1/C) of this Article shall be punished by half of the maximum specified punishment at a maximum.

3. The Public Prosecution shall have the jurisdiction to investigate prosecute for committing the violations stated in this Article before the penal court.

4. The criminal court shall have the jurisdiction for considering claims arising from the application of this Article and impose the stipulated penalties.

5. The criminal court, while convicting of committing the violations stated in items (1/B and 1/C) of this Article- shall issue a judgment to forfeit the financial or in-kind consideration used in the committed violation.

6. The criminal court may double the stated penalty stated in this Article if the violation is repeated.

Article Twenty-two

1. Whatever is not explicitly stated in Article (Twenty-one) of the Regulation, and without prejudice to any severer punishment stipulated in any other Regulation, any person who violates any provision of the Regulation or the Bylaw, shall be punished with a fine not exceeding three hundred thousand Saudi Riyals.

2. A committee (or more) shall be formed to consider violations and impose the prescribed penalties stated in item (1) of this Article, provided the number of its members shall not be less than (Three) including one legal or Sharia counselor and one expert in the organ donation and transplantation field. The resolutions of the committee shall be issued by the majority.

3. A person who is punished with the penalty stipulated in item (1) of this Article has the right to appeal before the administrative court according to the Procedural Law before the Board of Grievance.

Article Twenty-three

A sentence or resolution issued to apply any of the stated punishments in item (1) of Article (Twenty-one) and item (1) of Article (Twenty-two) of the Regulation may include one or more of the following punishments:

1. Suspension of any of the medical team members who participated in the organ recovery or transplantation from practicing the profession temporarily or permanently.

2. Suspension of the health institution's license to practice organ procurement or transplantation for a period not exceeding one year.

3. Closure of the health institution where such violation is committed for a period not less than two months and not more than one year while considering the permanent closure in case of repeating the violation.

4. The court judgment shall be published in one or more newspapers in the place of the violator's residence at his/her own cost or any suitable method according to the type and severity of the violation act, provided the publication shall be after issuing the final court judgment or resolution.

Article Eight
Organ donation is prohibited in the following cases:

1. If the donated human organ is essential for the life of the donor, or if the donation may cause death or disability of full organ function or prevent him/her from practicing his/her daily affairs.

2. If the medical team commissioned with the organ procurement and transplantation considerably thinks that the transplantation will not be successful in the recipient.

3. If the living person is incapable or incompetent, the approval of his/her guardian or trustee shall not be valid.

4. If the person has expressed by way of will not to donate any of his/her organs after death.

5. If the intended human organ is an organ that produces reproductive cells that carry all or part of genetic traits.

Article Ten
It is necessary to consider the dignity of the donor during organ recovery and protect him/her against humiliation or deformity. Also, it is not permissible to disclose any information related to the donor's body whether alive or dead except in the legally permitted cases or according to an order from a judicial authority.

Article Twelve

1. Without prejudice to the provisions of Article (Twenty) of the Regulation, the donor or his/her heirs or his/her relatives are prohibited to request any financial or in-kind consideration of any type whatsoever or to receive a consideration from the recipient, his/her relatives, or from the health institutions for the approval of himself/herself or his/her heirs or relatives.

2. The recipient, his/her relatives, or any other person, may not give any financial or in kind consideration of any type to the donor, his/her heirs, or relatives for obtaining his/her approval or the approval of his/her heirs or relatives.

3. The prohibition stated in items (1) and (2) of this Article shall apply to all mediators in claiming or receiving any financial or in-kind consideration of any type.

Article Thirteen
Health institutions are prohibited to do any of the following:

1. Disposal of any of the recovered organ for any purpose other than the purpose specified for donation with the exception that it is not possible to transplant the organ in the recipient, or if it is not possible to obtain another approval from the donor or the one whose approval is required according to Article (Three) of the Regulation to dispose of the organ. In all cases, it is mandatory to coordinate with the Center before organ disposal.

2. Failure to or delay in inform(ing) the Center of death as detailed in the Bylaw if it is taken place in the health institution.

3. Transplantation of an organ recovered in the execution of a judicial sentence.

4. Receiving any financial or in-kind consideration of any type whatsoever for organ donation. The financial consideration shall not include the cost or services provided by the health institutions for the organ recovery and transplantation.

5. Paying or giving any financial or in-kind consideration of any type to the donor, his/her heirs, or relatives for organ donation or mediation.

The Bylaw

13.1 If it is not possible to transplant the donated organ, the transplant programs shall fill up the form of unused organ stated in the Directory and notify the Center before disposing of the organ.

13.2 The licensed health institution as a donor hospital shall comply with the following:

13.2.1 Follow the critical pathway of the possible deceased donor as stated in the Directory.

13.2.2 Notify the Center of all possible deceased donors within no more than 24 hours from the initial insult that may lead to death according to the procedures stated in the Directory.

13.2.3 Notify the Center of all death cases for tissue donation promptly within 6 hours from the death declaration according to procedures stated in the Directory.

13.2.4 Send a monthly mortality report of death cases from at different departments according to the form stated in the Directory.

APPENDIX A Endorsement of the Directory
APPENDIX B National Protocol for Diagnosis of Death by Neurological Criteria (DNC)
APPENDIX C Risk of Transmission of Cancer
APPENDIX D SCOT Forms
APPENDIX E Donor Hospital Standards
APPENDIX F Directory Abbreviations

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APPENDIX A
ENDORSEMENT OF THE DIRECTORY

Ministerial Resolution Endorsement of the Directory

MINISTERIAL RESOLUTION	
No.:.....Date 24\1\1444 H – 22\8\2022	
Members of the higher medical committee	
Name	**Institution**
Talal Turki Algoufi *Chairman of Higher Medical Committee*	*Saudi Center for Organ Transplant (SCOT)*
Members	
Mohammad Zuhair Alqawi	*King Abdulaziz Science and Technology City*
Hamad Mohammad Albahili	*Prince sultan medical military city*
Mohammad Saad Alqahtani	*King Fahad Specialist Hospital Dammam*
Jihad Abdulhameed Alburaiki	*King Faisal Specialist Hospital and Research Center Riyadh*
Saad Ali Alghamdi	*King Faisal Specialist Hospital and Research Center Riyadh*
Abdullah Mohammad Aloraini	*King Saud University Riyadh*
Mohammad Abdulfattah Almotlaq	*King Khaled Eye Specialist Hospital*
Faisal Dahsh Aldahsh	*Security Force Hospital Riyadh*
Ahmed Nagi Albolashi	*King Saud Medical City Riyadh*
Abdulrahman Rabee Althiabi	*King Abdulaziz Medical City National Guard Riyadh*

Kingdom of Saudi Arabia
General Secretariat of the Council of Minister

Resolution #: (468)
Date: 17/08/1442H
30/03/2021G

Resolution of the Council of Ministers

The Council of Ministers,
After reviewing the transaction received from the Royal Order No. 22218 dated 22/04/1442H, including a telegram from the Minister of Health, the president of the Saudi Health Council No. 2104481 dated 10/08/1437H regarding the proposed Human Organ Donation Regulation;
After reviewing the above stated proposal;
After reviewing the recommendation of the General Board of the Council of Ministers No. (4833) dated 19/07/1442H;

Resolves as follows:

First: Approval of the Human Organ Donation Regulation according to the enclosed document.

Second: The Saudi Center of Organ Transplantation – shall coordinate when necessary-with the concerned authority in the Health Endowment Fund, regarding the needs of licensed health institutions in the field of human organ transplantation.

Prime Minister (Signed)

Ref. No.: M/70
Date: 19/08/1442H
01/04/2021G

By the will of Almighty Allah,
We, King Salman Bin Abdulaziz Al Saud
King of the Kingdom of Saudi Arabia
Based on Article (Seventy) of the Governance Constitution, issued by the Royal Decree No. (A/90) on 27/08/1412H);
Based on Article (Twenty) of the Council of Ministers Regulation issued by the Royal Decree No. (A/13) on 03/03/1414H)
Based on Article (Eighteen) of the Shura Council Regulation issued by the Royal Decree No. (A/91) on 27/08/1412H)
After reviewing the two resolutions of the Shura Council No. (215/54) on 17/01/1441H and No. (24/04) on 15/04/1442H
After reviewing the Resolution of the Council of Ministers No. (468) on 17/08/1442H

Order the Following

First: Approve the Human Organ Donation Resolution according to the enclosed document.

Second: His Highness the Vice President of the Council of Ministers, the Council of Ministers and principals of the concerned institutions- each in his field – should enforce this regulation.

Salman Bin Abdulaziz Al Saud (Signed)

Ministerial Resolution

No. 29425-4 Dated 28/09/2021

The Minister of Health,
President of Saudi Health Council,

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

First: Approval of the Executive Bylaw of Human Organ Donation Regulation according to the enclosed document.

Second: This Bylaw should be published in the Official Gazette and should come into effect as of the date of publication.

Third: This resolution should supersedes whatever may contradict with its provisions.

Fourth: The resolution should be endorsed to all concerned parties to enforce its application.

Tawfiq bin Farhan AlRebea (Signed)
Minister of Health
President of Saudi Health Council

The decision of the council of the minister defining the duties of SCOT
No. 38, Date 26/01/1434

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 on 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 programs 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 transplant, 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.

APPENDIX B
National Protocol for Diagnosis of Death by Neurological Criteria

In the past, cardiac arrest was enough to declare death because it meant a point of "no return" to life. However, advances in resuscitation have made it possible to reverse cardiac arrest in some cases, so it is no longer enough to define the point of "no return".
This led to the search for more reliable criteria to define the point of "no return". The concept of death based on the viability of the brain, termed death by neurological criteria (DNC), is now a recognized entity in medicine.

Brain death is a legal definition of death based on the irreversible cessation of all functions of the entire brain, including the brainstem, due to the total necrosis of the cerebral neurons following the loss of blood flow and oxygenation. The concept is very specific and does not apply to patients existing in a persistent vegetative state or to other severe degrees of brain damage (see Figure 1) The criteria for diagnosing brain death are outlined in (see Table 1).

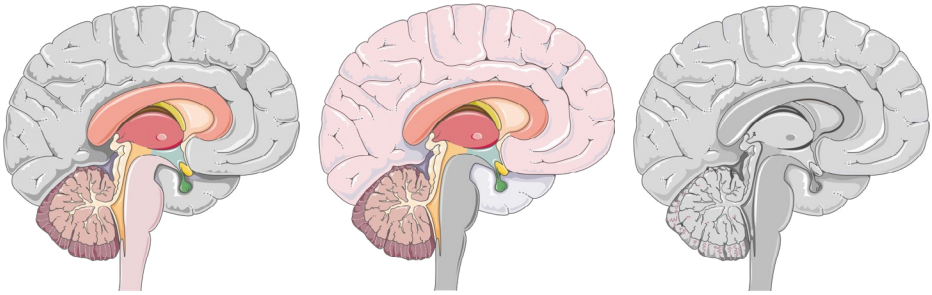

Figure 1: Lateral view of the human brain showing areas affected in a persistent vegetative state, brainstem death, and total DNC.

Table 1: Criteria for Irreversible Brain Damage and Brain Death

Cause	Established cause of irreversible brain injury sufficient to account for complete loss of brain function
Exclusion of Reversible Causes	All reversible causes with the possibility of recovery of any brain function have been excluded
Therapeutic Trials	All possible medical and surgical trials have been conducted to reverse the brain-destructive pathology
Cessation of Brain Function	All brain functions have persistently ceased for an appropriate observation period (6-24 hours, depending on etiology)
Special Considerations	Longer observation periods are needed for patients with drug intoxication, metabolic derangements, hypothermia, and for infants and children before puberty

2.1 The Diagnosis of Death by Neurological Criteria (DNC)

The determination of death by neurological criteria can be made in every hospital with a well-functioning ICU and must be done as part of the general management of any patient fulfilling the criteria of death by neurological criteria, irrespective of the issue of organ donation.

In fact, organ donation 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. Neurologists, neurosurgeons, internists, intensivists, anesthesiologists, pediatricians, or physicians who have training or experience in evaluating death by neurological criteria can perform the examination. In cooperation with sub-specialty physicians, the ICU team is responsible for the care of brain-dead patients after the diagnosis of death by neurological criteria if they are possible organ donors.

A possible deceased donor is usually a patient in a coma due to any of the following conditions (head trauma, cerebral anoxia, cerebrovascular hemorrhage, or primary brain tumor) and requiring ventilatory support.

2.2 Medical Criteria for the Diagnosis of Death by Neurological Criteria

DNC is based on the permanent and irreversible cessation of all functions of the whole brain, manifested by irreversible loss of consciousness and all brainstem reflexes, including the ability to breathe independently.

The diagnosis of death by neurological criteria needs to be rigorous to determine whether the condition is irreversible. The question of death by neurological 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. It is based on detailed clinical exams that must show a complete absence of brain functions of both cortex and brainstem. It is important to distinguish between DNC and states that may mimic DNC, such as narcotic or barbiturate overdose, hypothermia, or severe metabolic disturbance such as hypoglycemia or any other confounders to the diagnosis.

Performing clinical examination in suspected DNC is done only after all possible confounders are excluded by reliable investigations. The patient must exhibit no cerebral function, including absence of decerebrate posturing, decorticate posturing, and seizure activity.

2.2.1 Preconditions for the Diagnosis of Death by Neurological Criteria

Before proceeding to make the diagnosis of death by neurological criteria on a patient (see Table 2):

Table 2: Preconditions for Brain Death Diagnosis

Criteria	Description
Coma Status	The patient is in a deep coma, and the cause of the coma has been firmly established.
Respiration	The patient has no spontaneous respiration efforts and is supported by a mechanical ventilator.
Timing & Cause of Brain Damage	The event causing brain damage occurred at least six hours previously, and the cause of irreversible brain damage (e.g., herniation, massive head trauma, massive brain hemorrhage, etc.) has been clearly determined.
Cardiovascular Stability	The patient is not in cardiovascular shock.
Metabolic & Endocrinal Status	Obvious metabolic and endocrinal derangements have been corrected.
Response to Stimuli	No response to any kind of stimuli.
Reflexes	Complete areflexia (simple spinal cord reflexes may be present).

2.2.2 Exclusions for the Diagnosis of Death by Neurological Criteria

2.2.2.1 Temperature Requirement

a) The patient must not be hypothermic.
b) The core temperature must be above 36°C before conducting brain death testing.
c) If the patient's temperature is below this threshold, they must be warmed up before proceeding.

2.2.2.2 Absence of Sedative and Depressant Drugs

a) The patient must not be receiving sedatives, muscle relaxants, anticonvulsants, hypnotics, narcotics, or antidepressants (see Appendix B.1).
b) Blood tests or hospital records should confirm no significant levels of these drugs.
c) If the patient received sedation in the past five days, this must be considered before testing.
d) If a drug is identified, wait at least five half-lives before starting the brain death examination.

2.2.2.3 Toxicology Screening

a) A toxicology screen is required in cases of:

1. Road traffic accidents
2. Drug overdoses
3. Unexplained coma
4. Other cases where necessary

b) If toxicology testing is needed but unavailable, a waiting period of five days is recommended before testing for death.

2.2.2.4 Exclusion of Metabolic and Endocrine Causes

Several metabolic and endocrine conditions can mimic brain death and must be carefully evaluated before confirming brain death diagnosis (see Table 3).

Table 3: Exclusion of Metabolic and Endocrine Causes

Category		Abnormal Range	
Diabetic Conditions	Glucose	< 70 mg/dL	> 300 mg/dL
Metabolic Disorders	Ammonia	—	> 75 µmol/L
	Blood Urea Nitrogen (BUN)	—	> 75 mg/dL
	Uremic Encephalopathy	—	—
	Hepatic Encephalopathy	—	—
Electrolyte Disturbances	Total Calcium	< 1.75 mmol/L	> 2.75 mmol/L
	Magnesium	< 1.5 mg/dL	> 4 mg/dL
	Potassium	< 3 mmol/L	> 6 mmol/L
	Sodium	< 130 mmol/L	> 160 mmol/L
Endocrine Disorders	Total T4	< 3 mg/dL	> 30 mg/dL
	Free T4	≤ 0.4 ng/dL	> 5 ng/dL
	Myxedema Coma	—	—
	Panhypopituitarism	—	—

Several conditions can mimic brain death and should be carefully ruled out, including uremic encephalopathy in kidney failure, hepatic encephalopathy in liver failure, myxedema coma in severe hypothyroidism, and panhypopituitarism, which can lead to metabolic coma.

2.3 Diagnosing Death by Neurological Criteria

Once exclusions and preconditions are rolled out, clinical examination as per the recommendation in the death documentation form by neurological criteria can be pursued.

Clinical exams should be performed by two trained physicians and repeated after an interval appropriate to the patient's age. The findings are to be recorded in the prescribed form (see Form 3) and signed by the physicians conducting the examination. They must also be available after the stipulated observation interval, to carry out the second examination and sign the death documentation form.

In diagnosing death by neurological criteria, the following four examinations/tests are sequential and interdependent (see Table 4)

Table 4: Neurological Criteria for Brain Death: Summary of Diagnostic Protocol

Step		Key Details
Pre	**Exclusion/Inclusion** (see Ensure no reversible conditions mimic brain death (see 2.2.1)	Confirm severe brain injury and exclude hypothermia (<36°C), intoxication, metabolic disturbances, shock, or neuromuscular/CNS depressant effects before proceeding.
Step 1	**First Clinical Examination** Initial assessment confirming absence of neurological function (see 2.3.1)	GCS 3/15, absence of seizures, motor responses, and brainstem reflexes. Ensure patient is hemodynamically stable.
Step 2	**Confirmatory Tests** Provide objective evidence supporting clinical diagnosis (see 2.3.3)	EEG, CTA, or alternative methods (radionuclide scan, transcranial Doppler) depending on the patient context.
Step 3	**Second Clinical Examination** Reinforce initial diagnosis after an observation period (see 2.3.4)	Repeat first clinical exam; timing varies by age (6-24 hours). Confirms no change in neurological function.
Step 4	**Apnea Test** Confirm absence of spontaneous respiration (see 2.3.4)	Pre-oxygenation, ventilator disconnection, observe for respiratory effort, measure $PaCO_2$; confirms loss of brainstem function. Abort if patient becomes unstable.
Step 5	**Final Documentation & Communication** Document findings and communicate diagnosis to family (see 2.3.6)	Complete Form 3, treating physician informs family, ensuring clarity and compassion. Maintain separation from organ donation discussions.

2.3.1 First Clinical Examination (see Form 3)

1. Confirm that the patient is in a coma, with a GCS of 3/15.
2. Evaluate the patient for the presence of any signs of convulsive or nonconvulsive seizure activities and any decerebrate or decorticate movements, none should be found in death by neurological criteria patient. (Note: The presence of spinal myoclonus and/or spinal reflexes alone does not indicate brain viability and does not exclude death by neurological criteria.)
3. Test for the absence of motor response to central painful stimulation. For example, the absence of grimacing upon applying pressure over the supraorbital notch (see Figure 2:b).

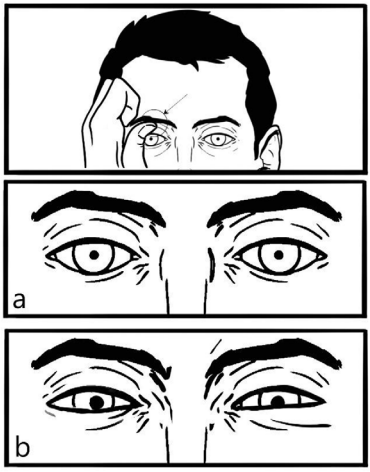

Figure 2: Testing Motor Response to Painful Stimulus.
a. No Response. b. Grimacing Response

2.3.2 Tests for Brainstem Reflexes

After the initial clinical examination, tests are performed to demonstrate the absence of brainstem reflexes. The tests have to be performed in the following order, and if any of these reflexes are preserved, there is no need to proceed further:

a) Pupillary response to light

Shine a bright light (e.g., pen flashlight) into open eyes. In brain death, no direct or indirect response occurs in either eye—both must be tested. Ensure no recent use of mydriatic/miotic drops, drugs, or eye trauma/surgery that may affect results (See Figure 3).

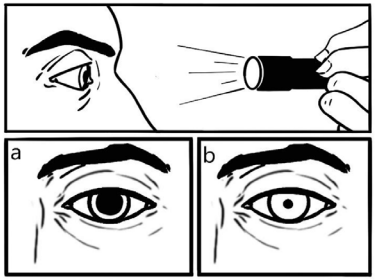

Figure 3: Pupillary Light Reflex Test
a. No Response. b. Response.

b) **Corneal reflex**

1. 1. Touch the cornea (i.e., over the limbus, which is the area between cornea and sclera) with a wisp of cotton wool.
2. 2. If the brainstem 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 neurological criteria, much firmer pressure is justified while doing this test. The use of a cotton swab is more suitable.

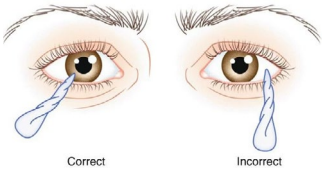

Figure 4: Corneal Reflex Test

(Note: This test can be affected in cases of Bell's palsy as the afferent facial nerve will be paralyzed.)

c) **Oculo-cephalic reflex** (Doll's Eye Test)

Stand at the head-end of the patient's bed. Hold the head of the patient in a neutral position firmly with both hands. Move the head briskly, first to one side and then to the other while retracting the eyelids with the thumbs. Observe the eye movements during these maneuvers. In a patient with a non-functioning brainstem, the head and eyes will move together (see Figure 5:a). A positive reflex is elicited in a comatose patient when the eyes move in an opposite direction to the head movement (see Figure 5:b). If the reflex is elicited, the brainstem is alive, and there is no need to proceed with further testing.

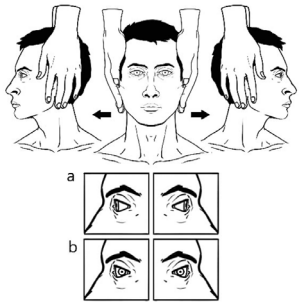

Figure 5: Oculo-cephalic Reflex Test.
a. Eyes in a neutral position, after the realignment.
b. Deviation of eyes to opposite sides when the head is moved to the left and right respectively.

Note: If the oculo-cephalic reflex can't be tested due to recent trauma with confirmed or suspected cervical fracture, but the vestibulo-ocular reflex is performed and shows no extraocular movements (see 2.3.2.d), the oculo-cephalic reflex isn't necessary. The ventilator may be disconnected for 20–30 seconds during this test.

d) **Vestibulo-ocular reflex** (Cold Caloric Test)

1. Prepare the Ear Canal:
Perform an otoscopic exam to confirm the tympanic membrane is intact. Ensure no obstructions (e.g., wax).
If the membrane is perforated, use cold air instead of water.
2. Administer Cold Water/Saline:
Adults: Instill 50 mL of ice-cold water or saline into each ear. Children: Use 10–20 mL instead.
3. Observe Eye Movements:
No eye deviation suggests brainstem damage or extraocular muscle paralysis, supporting brain death. (see Figure 6:a) Normally, eyes should move toward the irrigated ear within 20–30 seconds. (see Figure 6:b)

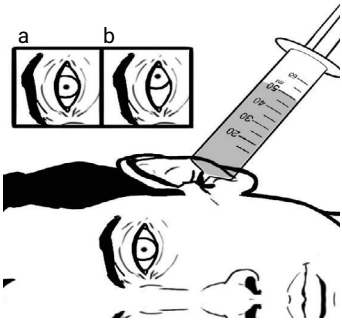

Figure 6: Vestibulo-ocular reflex
a. No Response. b. Response

e) **Upper and lower airway stimulation**
(e.g., pharyngeal/tracheal suction)

Test the gag reflex by stimulating the posterior pharyngeal wall with a suction catheter, observing for palate elevation, pharyngeal contractions, head movement, or facial changes. To test the cough reflex, pass the catheter into the endotracheal tube, move it side to side while suctioning to the carina, and check for a cough response. In brain death, neither test elicits a response. Both reflexes must be absent and confirmed by two physicians for brain death determination.

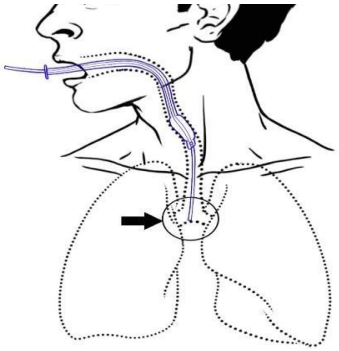
Figure 7: Testing for Gag Reflex

2.3.2.1 Observation Period:

After completion of the first examination, a second examination should be conducted after the stipulated time interval (see Table 5).

Table 5: Recommended time interval between first and second examination as per age groups.

Age Group	Interval
Neonate (37 weeks' gestation–30 days)	24 hours
Infants, children, and young adults (31 days–18 years)	12 hours
Adults older than 18 years	6 hours

2.3.3 Confirmatory tests

If all the above-described brainstem reflexes are completed to the fullest extent possible and found to be lost, then proceed to do one of the following confirmatory tests: electroencephalogram (EEG) or cerebral angiography. An alternative to cerebral angiography, a radionuclide study, or a transcranial Doppler study may be used to confirm the absence of cerebral blood flow and therefore irreversible brain damage. Confirmatory testing may be used to promote understanding of the clinical determination to families who express resistance or uncertainty.

a) Electroencephalogram (EEG)

To confirm DNC by neurological criteria, EEG shall show electrocerebral silence recording for at least 30 minutes. Note that a hypothermic patient must be warmed up before conducting an EEG examination. EEG must conform to the following Guidelines for death declaration by neurological criteria (see Table 6).

Table 6: EEG Protocol for Brain Death Determination

Step	Description
Electrode Placement	Use at least eight scalp electrodes with ear lobe references covering major brain areas. Avoid ground electrodes in the ICU or when electrical monitoring is in use.
Electrode Application & Impedance	Use disk electrodes, ensuring inter-electrode impedance is between 100–10,000 ohms. Maintain an inter-electrode distance of at least 10 cm.
Electrode Testing	Each electrode should be tested individually by touching it to generate an artifact potential.
Gain Sensitivity Adjustment	Increase sensitivity from 7.5 µV/mm to 2 µV/mm for most of the recording, ensuring appropriate calibration.
Filter Settings	Use a wide frequency window: time constant of 0.3 sec and high-frequency cutoff above 70 Hz.
Reactivity Testing	Evaluate EEG reactivity by exposing the patient to loud noises and pitch variations.
Recording Duration	Maintain EEG recording for a minimum of 30 minutes.
Peripheral Electrode Placement	Place a pair of electrodes on the dorsum of the right hand (6–7 cm apart) and apply an electrocardiographic monitor.
Handling Artifacts	Electromyography artifacts may appear even in electrocerebral silence. If they obscure recordings, neuromuscular blockade may be used.
Technologist & Repeat Testing	Recording must be performed by a qualified EEG technologist. A repeat EEG is required if electrocerebral silence is uncertain.

b)Cerebral angiography

Cerebral circulation tests can be conducted after a conclusive first clinical exam or as a replacement for the apnea test (see 2.3.4) in the chance it cannot be done. to confirm the absence of intracranial blood flow and reinforce the diagnosis of brain death (see Table 7).

The indications for angiography are:

1. EEG is unavailable or uninterpretable – Clinical exam and apnea test must be completed before angiography.
2. Persistent metabolic instability – When metabolic disorders, shock, or hypothermia cannot be corrected.
3. Difficulty in family acceptance – When additional objective evidence is needed to support brain death determination.

Table 7: Confirmatory Testing for Brain Death: Cerebral Circulation Assessment

Test	Purpose	Criteria for Confirmation	Notes
Four-Vessel Angiography	Confirms absence of intracranial arterial circulation in adults and children.	No blood flow in intracranial arteries.	Gold standard for confirming brain death.
Cerebral Radionuclide Angiogram (CRAG)	Confirms cerebral death in children by assessing cerebral circulation.	Absence of carotid circulation at the skull base, no intracranial arterial circulation (intracranial venous sinuses may still be visible).	Considered valid even if venous sinuses are seen.
Radionuclide Angiography	Alternative method to document absent brain circulation.	No cerebral blood flow detected.	Useful when angiography is not feasible.
Transcranial Doppler Ultrasound	Evaluates cerebral blood flow using ultrasound.	No cerebral perfusion detected.	Non-invasive, but interpretation requires expertise.

2.3.4 Apnea Test for Brain Death Confirmation

The apnea test is the final assessment in brain death determination, performed after the second clinical examination with the required observation period (see Table 8). It confirms the absence of spontaneous respiration, indicating complete brainstem failure.

Table 8: Apnea Test Procedure for Brain Death Confirmation

Pre-Requisites and Key Precautions	
Single Attempt Only: The test is performed once, with both examiners observing the patient's exposed chest. **Vital Signs Requirement:** Patient's temperature must be ≥ 36.0°C. and Systolic BP ≥ 100 mmhg.	**Exclusion Criteria:** Not applicable for patients with high cervical cord injury or neuromuscular disorders (e.g., Guillain-Barré Syndrome, Myasthenia Gravis). **Prevent Hypoxia:** Oxygenation must be maintained to avoid further brain injury.
1.Pre-Oxygenation	
1. Draw a **baseline ABG** sample at the start of the test	2. Administer **100% O_2 for 10 minutes**, Increase FiO_2 without changing ventilation rate to ensure adequate oxygen saturation.
2. Ventilator Disconnection & Oxygenation	**2.1 Alternative Oxygenation Methods**
Disconnect the ventilator and provide continuous humidified 100% O_2 via an intra-tracheal catheter placed at the carina. *Flow rate: 6 L/min (adults), 1.5-2 L/min (children). Ensure catheter is thin enough to avoid airway obstruction.	Use CPAP/PEEP via ventilator (no backup breaths) or a self-inflating resuscitation bag with a functioning PEEP valve
3. Monitoring	**3.1 Abort & Alternative Test (If needed)**
1. Continuously monitor oxygen saturation using a pulse oximeter 2. Prevent hypoxia and ensure stability throughout the test.	1. Oxygen saturation is <85% for >30 s 2. SBP < 90mmHg despite adequate pressor Support Use brain circulation confirmation test
4. Observation Period	
1. Maintain ventilator disconnection for **10 minutes** while observing for any respiratory movements	2. Any spontaneous respiration indicates brainstem activity.
5. Blood Gas Analysis (ABG)	
1. Draw an ABG sample at the end of the test	2. Ensure $PaCO_2$ reaches ≥8.1 kPa (60 mmHg) **or increases 20 mmHg above baseline**.
Test Interpretation	Positive Apnea Test: No respiratory movements or spontaneous breathing observed. Confirms Brain Death.

2.4 Documentation of Death by Neurological Criteria

Form 3: Death Documentation Form by Neurological Criteria must be completed in real-time as each examination and test is conducted, not filled out retrospectively. The form consists of two pages: the first records the first clinical examination and confirmatory test, while the second documents the repeat clinical examination and apnea test. Each section must be signed immediately by the examining physicians and countersigned by the Chief of Staff, ensuring compliance with all required criteria.

The treating physician must then inform the family of the patient's death without discussing organ donation (refer to Chapter 2, Section 2A, Sub-section 2.3). To maintain impartiality, physicians or surgeons involved in transplantation must not participate in the determination or documentation of death.

Appendix B:1: Common Neuroactive Drugs and Their Half-Lives1

Drug	Age Group	Half-Life*
IV Sedatives		
Dexmedetomidine	Infant (≤ 28 days)	3.2 hours
	Pediatric (< 2 years)	2.3 hours
	Pediatric (2 - 11 years)	1.6 hours
	Adult	~3 hours
Etomidate	All age groups	2.6 - 3.5 hours
Ketamine	All age groups	~2.5 hours
Midazolam	Infant (≤ 28 days)	4 - 12 hours
	Pediatric	2.9 - 4.5 hours
	Adult	~3 hours
Propofol	All age groups	Initial: 40 minutes
		Terminal: 4 - 7 hours
IV Narcotics		
Fentanyl	Infant (≤ 28 days)	5.5 ± 1.2 hours
	Pediatric	2.4 hours
	Adult	2 - 4 hours
Hydromorphone	Infant (≤ 28 days)	2.3 hours
	Pediatric	
	Adult	

Drug	Age Group	Half-Life*
Morphine	Infant (≤ 28 days)	6.5 ± 2.8 hours
	Pediatric	2 ± 1.8 hours
	Adult	2 hours
Remifentanil	≤ 2 months	5.4 minutes
	> 2 months - < 2 years	3.4 minutes
	2 - 6 years	3.6 minutes
	7- 12 years	5.3 minutes
	13 - < 16 years	3.7 minutes
	16 - 18 years	5.7 minutes
	> 18 years	10–20 minutes
Antiepileptic Medications		
Clonazepam	Infant ≤ 28d	22 - 81 hours
	Pediatric	28.7 hours
	Adult	17 - 56 hours
Diazepam	All age groups	Parent: 33–45 hours
		Active metabolite: 87 hours
Levetiracetam	Infant ≤ 28d	8.9 hours
	Pediatric	<4 years: 5.3 ± 1.3 hours
		4–12 years: 6 ± 1.1 hours
	Adult	6–8 hours
Lorazepam	Infant ≤ 28d	40.2 ± 16.5 hours
	Pediatric	5 months to < 3 years: 15.8 hours
		3 to < 13 years: 16.9 hours
		13 to < 18 years: 17.8 hours
	Adult	~14 hours
Pentobarbital	Infant ≤28d	26 ± 16 hours
	Pediatric	
	Adult	22 hours

Phenobarbital	Infant ≤28d	< 10 days: 114.2 ± 43 hours
		11 - 30 days: 73.19 ± 24.17 hours
	Pediatric	2 - 3 months: 62.9 ± 5.2 hours
		4 - 12 months: 63.2 ± 4.2 hours
		1 - 5 years: 68.5 ± 3.2 hours
	Adult	~79 hours
Phenytoin	Infant ≤ 28d	0 - 2 days: 80 hours
		3 - 14 days: 15 hours
		15 - 150 days: 6 hours
	Pediatric	10 - 12 hours
	Adult	
Valproic acid	Infant ≤ 28d	First week of life: 40–45 hours
		< 10 days: 10 - 67 hours
	Pediatric	> 2 months: 7 - 13 hours
		2 - 14 years: 9 hours
	Adult	9–19 hours
Neuromuscular blockers		
Atracurium	Infant ≤ 28d	Infants: 20 minutes Children: 17 minutes
	Pediatric	
	Adult	20 minutes
Cisatracurium	All age groups	22 - 29 minutes
Pancuronium	All age groups	89 - 140 min
Rocuronium	Infant ≤28d	3 - 12 months: 1.3 ± 0.5 hours 1 to < 3 year: 1.1 ± 0.7 hours 3 to < 8 years: 0.8 ± 0.3 hours
	Pediatric	
	Adult	1.4 - 2.4 hours
Succinylcholine	All age groups	< 1 minute
Vecuronium	Infant ≤ 28d	Infants: 65 minutes Children: 41 minutes
	Pediatric	
	Adult	65–75 minutes

1. American Academy of Neurology. 2023.

*The time required to withhold medications before a brain death assessment depends on both the drug and patient-specific factors, such as hypothermia, organ dysfunction, obesity, and concurrent therapies. While 3 to 5 half-lives generally allow for adequate clearance, some drugs with active metabolites or enterohepatic recirculation may persist longer. Whenever feasible, drug levels should be checked to ensure they are in a low to mild therapeutic range before neurological evaluation.

APPENDIX C
Guidelines for Assessing the Risk of Cancer Transmission from Deceased Donors

The potential transmission of cancer from deceased donors poses significant risks to organ transplant recipients, leading to substantial morbidity and mortality. Various types of cancers, including solid tumors and hematological malignancies, have been documented to be transmissible through organ transplantation. Therefore, identifying donors with active or latent cancerous conditions is crucial for assessing risk, mitigating adverse outcomes, and enhancing recipient survival rates.

3.1 Assessing Transmission Risks in Solid Organ Tumors

3.1.1 Appendicular tumor

3.1.1.1 The presence of or diagnosing appendiceal tumors during organ recovery is a contraindication to donation.

3.1.1.2 Organs from donors with non-neuroendocrine appendiceal tumors may be used if fully treated and recurrence-free for >5 years, with a cure probability.

3.1.1.3 If the appendiceal neuroendocrine tumor is in donor history (e.g. differentiated carcinoid tumor < 2 cm (pT1) without lymph node or distant metastases), it is assumed to be a low transmission risk after adequate excision and disease-free survival of > 5 years.

3.1.2 Breast cancer

3.1.2.1 Newly diagnosed invasive breast cancer during donor recovery is an unacceptable risk for organ donation.

3.1.2.2 If breast cancer is identified in the donor history:

- Organs from invasive breast cancer donors might be accepted in selected cases after full treatment, complete remission, and stringent follow-up for >5 years, depending on the initial stage and E/P and HER2/neu receptor expression, always bearing in mind the risk of transmission due to possible late metastases.
- Breast cancer stage 1A cured surgically, with a cancer-free period >5 years considered as low to intermediate risk of transmission.
- High nuclear grade DCIS is considered low to intermediate risk for transmission.
- Other invasive breast cancer stages are considered high risk for transmission despite the treatment and recurrence-free survival.

3.1.3 Carcinoma in situ, pancreatic, and biliary intra-epithelial neoplasia

3.1.3.1 Most of the in-situ carcinomas (e.g. uterine cervix, colon, vocal cord, non-melanoma skin), together with pancreatic intra-epithelial neoplasia (PanIN) or biliary intra-epithelial neoplasia (BilIN) in the absence of invasive cancer, may be considered as low risk.

3.1.3.2 Transplantation of a pancreas with PanIN or a liver with BilIN is not recommended.

3.1.3.3 Non-muscle-invasive urinary bladder cancers, in situ urothelial cancer (pTis), and intra-epithelial papillary urothelial carcinoma (pTa/G1-2) are considered low risk for non-renal transplants. However, renal transplants from these donors should be considered as a higher risk for transmission.

3.1.3.4 High-grade in-situ breast cancer, in-situ lung cancer, and in-situ melanoma/lentigo maligna are considered low to intermediate risk for transmission.

3.1.4 Choriocarcinoma

3.1.4.1 Choriocarcinoma diagnosed during donor recovery is an unacceptable risk for organ donation in any stage of the disease.

3.1.4.2 Choriocarcinoma identified in the donor history is associated with a high or unacceptable risk for transmission, depending on the recurrence-free period.

3.1.5 Colorectal cancer

3.1.5.1 Colorectal cancer diagnosed during donor recovery is an unacceptable risk for organ donation unless in donors with pT1 tumors who also should be accepted with the utmost caution and high-risk assumption.

3.1.5.2 The presence of pT1/pT2 colorectal carcinoma (infiltration of submucosa/muscularis propria) in the donor history without lymph node or distant metastases is assumed to have a low transmission risk after adequate treatment and disease-free survival of > 5 years.

3.1.6 Gastrointestinal stromal tumor (GIST)

3.1.6.1 In GIST diagnosed during donor recovery, small GIST (< 2 cm) of the stomach or duodenum may be acceptable for donation with a low-to-intermediate risk of transmission, while GIST from other primary sites, of larger size or high mitotic count, are associated with high risk of transmission.

3.1.6.2 When GIST is identified in the donor history, small GIST (< 2 cm) of the stomach or duodenum and mitotic count < 5 % may be acceptable for donation with a low-to-intermediate risk of transmission, depending on therapy, follow-up time, and recurrence-free survival, while GIST from other sites or higher mitotic count is associated with a higher risk of transmission.

3.1.7 Lung cancer

3.1.7.1 Newly diagnosed lung cancer donor during recovery is an unacceptable risk for organ donation.

3.1.7.2 Treated Lung cancer in the donor history is considered to be associated with a high transmission risk. The risk may decrease after curative therapy, with longer recurrence-free time, and with increasing probability of cure.

3.1.8 Malignant melanoma

3.1.8.1 Malignant melanoma in the donor history should be considered to be associated with a high risk of transmission, while in-situ melanoma and lentigo maligna are considered low-to-intermediate risk for transmission.

3.1.9 Non-melanoma skin cancer

3.1.9.1 Basal cell and squamous cell carcinoma of the skin are considered with a low transmission whether diagnosed during recovery or in donor history. In contrast, Kaposi sarcoma, Merkel cell carcinoma, and skin sarcoma are considered an unacceptable risk.

3.1.10 Neuroendocrine tumors

3.1.10.1 High-grade neuroendocrine carcinomas diagnosed during donor recovery or treated in the donor history are an unacceptable risk for organ donation. However, in the case of critically ill recipients, neuro-endocrine tumors might be acceptable after a careful individualized risk-benefit analysis.

3.1.10.2 Donors with a previous history (> 5 years) of neuroendocrine tumors (i.e. carcinoid tumors, PCCs, and PGLs) should be still considered at high risk for transmission even when no disease recurrence or progression is detected.

3.1.11 Esophageal, gastric, pancreatic, liver, and biliary cancers

3.1.11.1 Esophageal, gastric, pancreatic, liver, and biliary cancers diagnosed during donor recovery are classified as unacceptable risk.

3.1.11.2 Treated esophageal, gastric, pancreatic, liver, and biliary cancers in the donor history are classified to be associated with a high transmission risk. Risk may decrease for early stages after curative therapy, with recurrence-free time > 5 years and with increasing probability of cure.

3.1.12 Ovarian cancer

3.1.12.1 Ovarian cancer diagnosed during donor recovery is considered an unacceptable risk for organ donation.

3.1.12.2 Treated ovarian cancer in the donor history is considered high-risk for organ donation. Depending on the initial stage, grade, therapy, and time of recurrence-free survival (> 5 years), the risk category might decrease individually.

3.1.13 Prostate cancer

3.1.13.1 In prostate cancer diagnosed during donor recovery, if the Gleason score is available, then a low-grade small intra-prostatic tumor (Gleason score ≤ 6) is considered low-risk, intra prostatic tumor (Gleason score 7) is considered a low-to-intermediate risk, and intra-prostatic (pT2) tumor (Gleason score > 7) is considered high-risk. While extra-prostatic tumor extension should be excluded from the donation process as an unacceptable risk.

3.1.13.2 When prostate cancer is identified in the donor history, the acceptable time interval for complete remission is strongly correlated with the stage and Gleason score as the following:

- Donors with a history of curatively treated prostate cancer ≤ pT2 (tumor confined to the prostate) and Gleason 3 + 3, as well as donors with very small prostate cancers and Gleason 3 + 3 under 'active surveillance', can be accepted for organ donation as low-risk.
- Prostate cancer ≤ pT2 (confined to the prostate) and Gleason grade < 7 after curative treatment and cancer-free period > 5 years are considered low-risk.
- Higher stages (i.e. grades) and/or shorter cancer-free periods require an individual risk assessment. A history of extra-prostatic tumor extension poses a high risk for transmission.
- In these cases of past prostate cancer, current PSA values should be obtained to compare to former ones in order to assess the likelihood of dissemination.

3.1.14 Thyroid cancer

3.1.14.1 In thyroid cancer diagnosed during donor recovery, consider:

- Solitary papillary thyroid carcinoma < 0.5 cm is considered minimal risk and 0.5–2 cm is considered low to intermediate risk.
- Minimally invasive follicular carcinoma < 1 cm is considered minimal risk and 1–2 cm is considered low to intermediate risk.
- Newly diagnosed medullary and anaplastic thyroid cancers are an unacceptable risk for organ donation.

3.1.14.2 When thyroid cancer is identified in the donor history to be treated, small, and differentiated (papillary and follicular), the risk will be acceptable. However, anaplastic thyroid cancer should be excluded from organ donation.

3.1.15 Urothelial cancer

3.1.15.1 Urothelial cancer diagnosed during donor recovery should be assessed carefully based on risk-benefit analysis due to limited literature.

3.1.15.2 When urothelial cancer is identified in the donor history, consider:

- Kidney transplantation will be associated with increased risk.
- After a disease-free interval of > 5 years, the transmission risk of invasive urothelial cancer will depend on the probability of cure and has to be assessed individually before accepting donation.
- The non-muscle-invasive urothelial cancers, in-situ urothelial cancer (pTis), and intra-epithelial papillary urothelial carcinoma (pTa/G1-2) are considered minimal risk for non-renal transplants and high-risk for renal transplants.

3.1.16 Uterus or uterine cervix cancer

3.1.16.1 The presence of invasive uterine or cervical cancers diagnosed during donor recovery is considered an unacceptable risk for organ donation.

3.1.16.2 The uterus or uterine cervix cancer in the donor history, after a disease-free interval > 5 years, the transmission risk will depend on the probability of cure and has to be assessed individually before accepting the possible donor.

3.1.16.3 Cervical carcinoma in situ (CINIII) is associated with minimal transmission risk.

3.2 Assessing Transmission Risks in Hematopoietic Malignancies

3.2.1 Leukemia, lymphoma, and plasmacytoma

3.2.1.1 Leukemia, lymphoma, and plasmacytoma diagnosed during donor recovery are classified as an unacceptable risk for organ donation.

3.2.1.2 Active (acute or chronic) leukemia, lymphoma, and plasmacytoma in the donor history are an unacceptable risk for organ donation.

3.2.1.3 Treated acute leukemia and lymphoma after a definite disease-free interval of > 10 years may be considered for donation with a high risk for transmission.

3.2.2 Monoclonal gammopathies of undetermined significance (MGUS)

3.2.2.1 MGUS identified in the donor history with appropriate follow-up, no progression to multiple myeloma or related disorders, and a definite disease-free interval of 5-10 years may be considered for organ donation and may be assumed to pose a low risk for transmission.

3.2.3 Myeloproliferative neoplasms (MPN)

3.2.3.1 MPN diagnosed during donor recovery or identified in the donor history should be assessed carefully and individually with the highest caution for the risk of transmission, in consultation with an experienced haemato-oncologist.

3.2.3.2 The results of CBC (i.e. with differential) and liver enzymes (i.e. including LDH) might help in assessing the actual situation of the pre-diagnosed MPN. Also, bone marrow biopsy can help to rule out blasts at the time of donation.

3.2.3.3 Patients with spleno-/hepatomegaly need particular attention, in consultation with an experienced hematologist.

3.2.3.4 Pre-diagnosed MPN might be associated with a reasonable acceptable risk for selected recipients, especially in cases of confirmed MPN without the need for treatment or the diagnosis has been confirmed years ago and good therapy results were obtained. However, Primary myelofibrosis (PMF) seems to be associated with a higher risk for transmission due to a higher proportion of circulating blasts.

Form 1:
Donor Hospital Census

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Donor Hospital Census

Hospital Name:	
Hospital Director Name:	
Region:	

Hospital Affiliation

- ☐ Ministry of Health
- ☐ Military Hospitals
- ☐ University Hospitals
- ☐ Private Hospitals
- ☐ National Guard Hospitals
- ☐ Security Forces Hospital
- ☐ Royal Court Hospitals

Department

☐ ICU	No. of Beds	Contact details
☐ MICU	No. of Beds	Contact details
☐ NICU	No. of Beds	Contact details
☐ CCU	No. of Beds	Contact details
☐ PICU	No. of Beds	Contact details
☐ Others:	No. of Beds	Contact details
	No. of Beds	Contact details
	No. of Beds	Contact details

Total ICU Beds (all)		
H-DMC* Name Contact Details:		Contact details
H-DAC** Name Contact Details:		Contact details
ICU Head Doctor Contact Details:		Contact details
ICU Head Nurse		Contact details

* H-DMC- Hospital – Donor Medical Coordinator
** H-DAC- Hospital – Donor Administrative Coordinator

Availability of:

Neurologist	☐ Yes ☐ No	Portable EEG	☐ Yes ☐ No
Neurosurgery	☐ Yes ☐ No	EEG Technician	☐ Yes ☐ No
Other ancillary test	☐ Yes: Specify ☐ No		

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FORM-OSC-008

Form 2:
Hospital Monthly Census

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Hospital Monthly Census

Hospital Name: Date: Month of

Filled by: Name Position Contact details

1. Hospital Records

1a.) What is the total number of patients admitted in your ICU by the end of the month:

1b.) How many ventilated, comatose patient were admitted (please indicate the number):

1c.) What are the causes for admission of Ventilated/Comatose patients?

- ☐ Brain Anoxia
- ☐ Cerebrovascular/Stroke
- ☐ Head trauma
- ☐ CNS tumor
- ☐ CNS Infections
- ☐ Others: Please specify / Please specify / Please specify

1d.) How many patients are considered to be a Possible Deceased Organ Donor* as defined in CRITICAL PATHWAY for ORGAN DONATION:

1e.) What is the total number of patient mortality by the end of this month:

* (A patient with a devastating brain injury or lesion or a patient with circulatory failure and apparently medically suitable for organ donation)

2. Brain Death Diagnosis

2a.) How many Possible brain death cases have you reported to SCOT by the end of the month:

2b.) How many patients; Brain death exam (1st exam) has been performed:

2c.) How many patients had been diagnosed Brain Death; Fully Documented or Declared Brain Death based on National Protocol (1st exam, EEG(any ancillary test), 2nd exam with APNEA done):

3. Family Approach (Breaking Bad News to Family)

3a.) How many cases have you delivered the message of brain death declaration to the family:

4. Education and BD activities

4a.) Do you conduct a scientific meeting medical your hospital for:

☐ Medical Staff ☐ Internal Dept. ☐ Others: Specify

☐ Yes, How many times? ☐ No

4b.) Do you conduct a social and religious meeting for public inside your hospital/institution:

☐ Yes, ☐ No

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FORM-OSC-008

Form 3 (page 1):
Death Documentation Form by Neurological Criteria

Kingdom of Saudi Arabia
Saudi Health Council

المجلس الصحي السعودي
SAUDI HEALTH COUNCIL

المملكة العربية السعودية
المجلس الصحي السعودي

FIRST EXAM

استمارة تشخيص وتوثيق الوفاة باستخدام المعايير الدماغية

Death Documentation Form by Neurological Criteria (Page 1)

MRN: _____ رقم الملف الطبي: **Name:** _____ الاسم:

Age: _____ العمر: **Sex:** ___ الجنس: **Nationality:** _____ الجنسية: **Blood Group:** _____ فصيلة الدم:

Hospital Name: _____ المستشفى: **Date of Admission:** _____ تاريخ الدخول:

	FIRST EXAM الفحص الأول	الطبيب الأول Physician 1	الطبيب الثاني Physician 2
I.	**PRECONDITIONS:** الشروط الأولية *(Are the following fulfilled?)*	Check if applicable	Check if applicable
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.	☐	☐
II.	**EXCLUSIONS:** أسباب ينبغي استبعادها *(Are the following excluded?)*		
4.	Hypothermia (core temperature < 36°C)	☐	☐
5.	Sedation (blood test or hospital record should indicate absence of significant levels of sedative drugs or muscle relaxants or ≥ 5 half-lives from last dose administered).	☐	☐
6.	Untreated cardiovascular shock.	☐	☐
7.	Significant metabolic or endocrine causes of coma.	☐	☐
III.	**CLINICAL ASSESSMENT:** التقييم السريري للجهاز العصبي *(Are the following fulfilled?)*		
8.	Absence of response to stimulation (Spinal reflexes excepted).	☐	☐
9.	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	☐	☐

FIRST EXAM	Date التاريخ	Time الوقت	Name الاسم	Signature التوقيع
الطبيب الأول Physician 1				
الطبيب الثاني Physician 2				

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

EEG	**Electrocerebral Silence (ECS)** ☐		Date: _____	Signature: _____
Absence of brain circulation evidence by either:				
Cerebral Angiogram	☐	**NO FLOW** ☐	Date: _____	Signature: _____
Radionuclide Angiography	☐			
Transcranial Doppler	☐			

Note: Recommended time interval between first and second examinations in various age groups	
Adults (Older than 18 years): minimum of 6 hours[1]	[1]One EEG at the end of first exam
Infants, Children, and Young Adults (31 days – 18 years): 12 hours[2]	[2]Two separated by the mentioned time interval
Neonate (37 weeks gestation – 30 days): 24 hours[2]	

Form 3 (page 2):
Death Documentation Form by Neurological Criteria

Kingdom of Saudi Arabia
Saudi Health Council

المجلس الصحي السعودي
SAUDI HEALTH COUNCIL

المملكة العربية السعودية
المجلس الصحي السعودي

SECOND EXAM

استمارة تشخيص وتوثيق الوفاة باستخدام المعايير الدماغية
Death Documentation Form by Neurological Criteria (Page 2)

MRN: _____ رقم الملف الطبي: **Name:** _____ الاسم:

Age: _____ العمر: **Sex:** _____ الجنس: **Nationality:** _____ الجنسية: **Blood Group:** _____ فصيلة الدم:

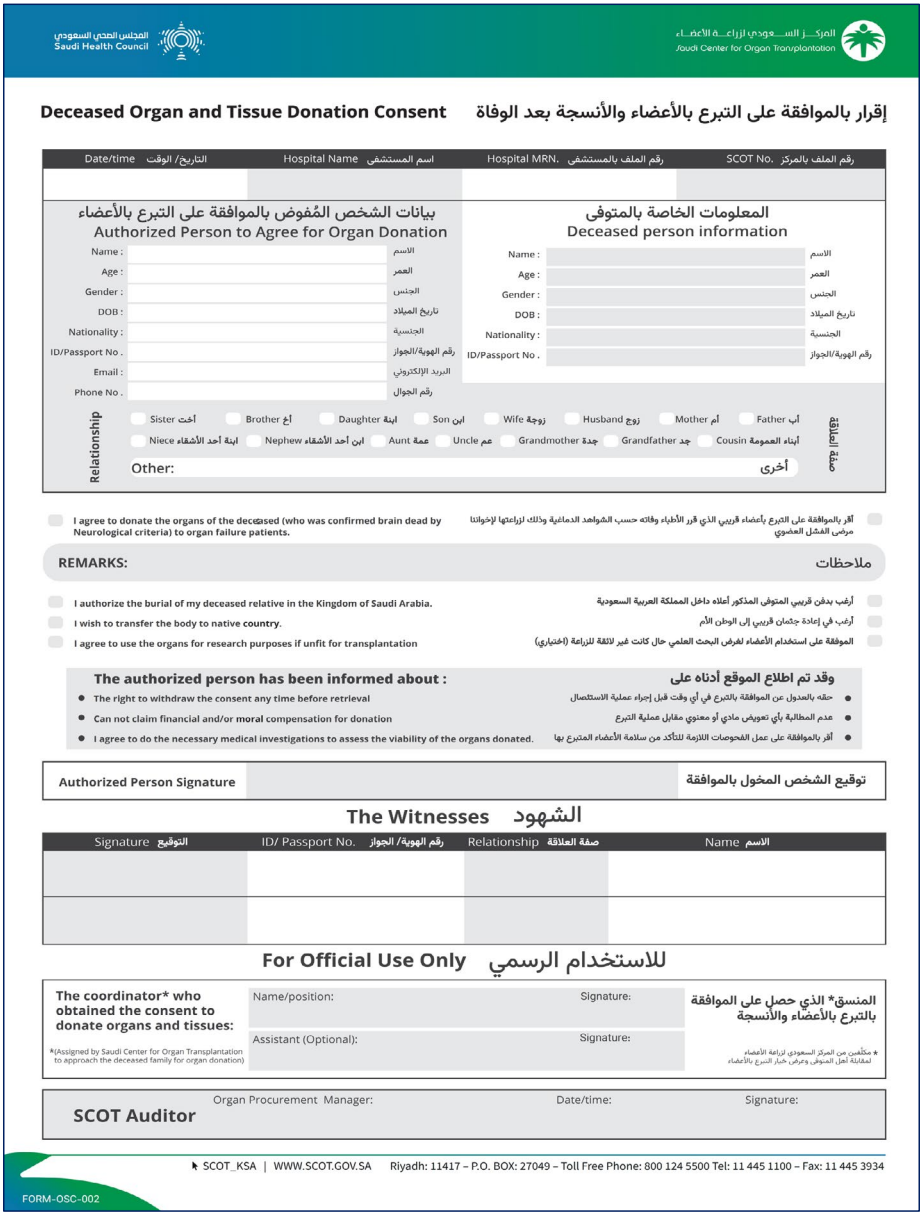
Hospital Name: _____ المستشفى: **Date of Admission:** _____ تاريخ الدخول:

	SECOND EXAM الفحص الثاني	الطبيب الأول Physician 1	الطبيب الثاني Physician 2
I.	**PRECONDITIONS:** الشروط الأولية *(Are the following fulfilled?)*	Check if applicable	Check if applicable
1.	It is absolutely certain that irremediable brain damage has occurred due to:_____	☐	☐
2.	More than six house have passed since the initial insult.	☐	☐
3.	Coma with no spontaneous respiration.	☐	☐
II.	**EXCLUSIONS:** أسباب ينبغي استبعادها *(Are the following excluded?)*		
4.	Hypothermia (core temperature < 36°C)	☐	☐
5.	Sedation (blood test or hospital record should indicate absence of significant levels of sedative drugs or muscle relaxants or ≥ 5 half-lives from last dose administered).	☐	☐
6.	Untreated cardiovascular shock.	☐	☐
7.	Significant metabolic or endocrine causes of coma.	☐	☐
III.	**CLINICAL ASSESSMENT:** التقييم السريري للجهاز العصبي *(Are the following fulfilled?)*		
8.	Absence of response to stimulation (Spinal reflexes excepted).	☐	☐
9.	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 اختبار انقطاع النفس	**Apnea Test is performed after the last two clinical examination and a confirmatory test (EEG or another confirmatory test) has been done.** ▪ **A positive apnea** test is considered when no respiratory movements have occurred during disconnection period Provided that sufficient stimulus to the respiratory center is done ($PaCO_2$ must be above 60 mmHg in adult and 55 mmHg in children OR 20 mmHg over the baseline.		
	IV. APNEA TEST: (should be done with body temp ≥ 36°C) Performed as per Saudi Protocol and is compatible with death by brain function criteria.	**YES** ☐	
		Pre-PCO_2	Post-PCO_2

SECOND EXAM	Date التاريخ	Time الوقت	Name الاسم	Signature التوقيع
الطبيب الأول Physician 1				
الطبيب الثاني Physician 2				

Form 4:
Deceased Organ and Tissue Donation Consent



المجلس الصحي السعودي
Saudi Health Council

المركز السعودي لزراعة الأعضاء
/Saudi Center for Organ Tran/plantation

Deceased Organ and Tissue Donation Consent إقرار بالموافقة على التبرع بالأعضاء والأنسجة بعد الوفاة

رقم الملف بالمركز SCOT No.	رقم الملف بالمستشفى Hospital MRN.	اسم المستشفى Hospital Name	التاريخ/ الوقت Date/time

المعلومات الخاصة بالمتوفى
Deceased person information

Name :		الاسم
Age :		العمر
Gender :		الجنس
DOB :		تاريخ الميلاد
Nationality :		الجنسية
ID/Passport No .		رقم الهوية/الجواز

بيانات الشخص المُفوض بالموافقة على التبرع بالأعضاء
Authorized Person to Agree for Organ Donation

Name :		الاسم
Age :		العمر
Gender :		الجنس
DOB :		تاريخ الميلاد
Nationality :		الجنسية
ID/Passport No .		رقم الهوية/الجواز
Email :		البريد الإلكتروني
Phone No .		رقم الجوال

Relationship صفة العلاقة

☐ Father أب ☐ Mother أم ☐ Husband زوج ☐ Wife زوجة ☐ Son ابن ☐ Daughter ابنة ☐ Brother أخ ☐ Sister أخت

☐ Cousin أبناء العمومة ☐ Grandfather جد ☐ Grandmother جدة ☐ Uncle عم ☐ Aunt عمة ☐ Nephew ابن أحد الأشقاء ☐ Niece ابنة أحد الأشقاء

Other: أخرى

☐ I agree to donate the organs of the deceased (who was confirmed brain dead by Neurological criteria) to organ failure patients.

☐ أقر بالموافقة على التبرع بأعضاء قريبي الذي قرر الأطباء وفاته حسب الشواهد الدماغية وذلك لزراعتها لإخواننا مرضى الفشل العضوي

REMARKS: ملاحظات

☐ I authorize the burial of my deceased relative in the Kingdom of Saudi Arabia.

☐ أرغب بدفن قريبي المتوفى المذكور أعلاه داخل المملكة العربية السعودية

☐ I wish to transfer the body to native country.

☐ أرغب في إعادة جثمان قريبي إلى الوطن الأم

☐ I agree to use the organs for research purposes if unfit for transplantation

☐ الموافقة على استخدام الأعضاء لغرض البحث العلمي حال كانت غير لائقة للزراعة (اختياري)

The authorized person has been informed about : وقد تم اطلاع الموقع أدناه على

- The right to withdraw the consent any time before retrieval — حقه بالعدول عن الموافقة بالتبرع في أي وقت قبل إجراء عملية الاستئصال
- Can not claim financial and/or moral compensation for donation — عدم المطالبة بأي تعويض مادي أو معنوي مقابل عملية التبرع
- I agree to do the necessary medical investigations to assess the viability of the organs donated. — أقر بالموافقة على عمل الفحوصات اللازمة للتأكد من سلامة الأعضاء المتبرع بها

Authorized Person Signature	توقيع الشخص المخول بالموافقة

The Witnesses الشهود

Name الاسم	Relationship صفة العلاقة	ID/ Passport No. رقم الهوية/ الجواز	Signature التوقيع

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The coordinator* who obtained the consent to donate organs and tissues:	Name/position:	Signature:	المنسق* الذي حصل على الموافقة بالتبرع بالأعضاء والأنسجة
*(Assigned by Saudi Center for Organ Transplantation to approach the deceased family for organ donation)	Assistant (Optional):	Signature:	* مكلّفين من المركز السعودي لزراعة الأعضاء لمقابلة أهل المتوفى وعرض خيار التبرع بالأعضاء

Organ Procurement Manager:	Date/time:	Signature:
SCOT Auditor		

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FORM-OSC-002

Form 5:
Reasons of Organ Donation Refusal Form

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

FAMILY APPROACH

Reasons of Organ Donation Refusal

Donor Demographics

Name:		SCOT Case No.	#
Hospital:		Date/Time:	
MRN:	#	Approach Attempts:	#

Interview

Interviewer	Medium	Interviewee
1. 2. Attendant: Name, Position & Signature	☐ Online video interview ☐ Direct interview	☐ 1st degree (Mother /Father, Wife/Husband, Brother/Sister, Son/Daughter) ☐ 2nd degree (Grandfather /Grandmother) ☐ 3rd degree (Niece/Nephew, Aunt/Uncle) ☐ 4th degree (Cousin) ☐ Others (Friend, Co-worker, Sponsor, Neighbor)

☐ Approached ☐ Not approached

Reasons of Refusal

Medical	☐ Not satisfied with healthcare: Late transfer ☐ Not satisfied with healthcare: Poor management ☐ Not satisfied with healthcare: Not covered by insurance ☐ Not satisfied with healthcare: Perception of BD resulting as complication of a previous medical/surgical intervention
Cultural	☐ Does not believe brain death is death. ☐ Knowing /Not knowing what the deceased believed about organ donation during their life. ☐ Family conflict. ☐ Fear of social backlash/Stigma ☐ Feeling that patient had suffered enough.
Religious	☐ Conflicting religious opinion ☐ Strong believe in a miracle ☐ Loss of the Integrity.
Other	☐ Avoidance ☐ Police case ☐ Assertive Refusal ☐ Unknown Other (Specify):

* Please select one reason that is most reflecting to family's opinion

Auditor Name/SCOT Representative: Date/time: Signature:

Comments:

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FORM-OSC-001

Form 6:
Organ and Tissue Acceptance and Rejection Form

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Organ and Tissue Acceptance/ Rejection

Donor Demographics

Name:		SCOT Case No.:	#
Hospital:		Coordinator:	
Offer Date/Time:	#		

Organ:

☐ Kidney	☐ Liver	☐ Heart	☐ Lungs
☐ Pancreas	☐ Small Bowel	☐ Corneas	☐ Bones

☐ Accepted	☐ Rejected
	Kindly indicate the reason:
Date/Time:	Date/Time:

The transplant center shall complete the organ transplantation form promptly after the organ transplantation within 24 hours of the transplantation date

Information Provider

Transplant Center:			
Consultant:		Signature:	
Transplant Coordinator:		Signature:	
		Date/time:	

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FORM-OSC-007

Form 7:
Deceased Organ Discard Report

المركـــز الســـعودي لزراعـــة الأعضـــاء
Saudi Center for Organ Transplantation

Deceased Organ Discard Report

Donor Demographics

Hospital:			
Name:		SCOT Case No.:	#
Age:	#	Date/Time:	
Nationality:		Blood Group:	

Discarded Organ:

☐ Kidney ☐ Liver ☐ Heart ☐ Lungs
☐ Pancreas ☐ Small Bowel ☐ Corneas ☐ Bones

*Use a different form if you would like to report more than one organ for disposal

Transplant Center:	
Received date & time:	

Reason of Disposal

Reason organ harvested not used for transplantation

☐ Result of Perfusion Pump
☐ Long Cold Ischemia Time
☐ Vascular damage
☐ Ureteral damage
☐ Inadequate urine output
☐ Positive CMV
☐ Positive HIV
☐ Positive hepatitis
☐ Warm ischemic time too long
☐ Organ trauma
☐ Organ not as described
☐ Biopsy findings
☐ Recipient determined to be unsuitable for transplant in Operating room
☐ Poor organ function
☐ Infection
☐ Diseased organ
☐ Anatomical abnormalities
☐ No recipient located - listed exhausted
☐ Other, specify:

Disposal Method: ☐ Pathology ☐ Research

Information Provider

Coordinator Name:		Signature:	
Position:		Date/time:	
Transplant Center:			

In accordance with Articles 9 and 10 of the Human Organ Donation Regulation and Executive Bylaw, all medical examination and scientific research conducted on donated organs must adhere to Islamic principles and be done only with the informed consent of the donor. The dignity and confidentiality of the organ donor, whether living or deceased, shall be respected at all times during organ recovery and transplantation procedures. Any disclosure of medical information related to the donor's body is prohibited except when legally required or ordered by a judicial authority. All parties involved in organ donation, procurement, and transplantation procedures must uphold these principles outlined in Articles 9 and 10.

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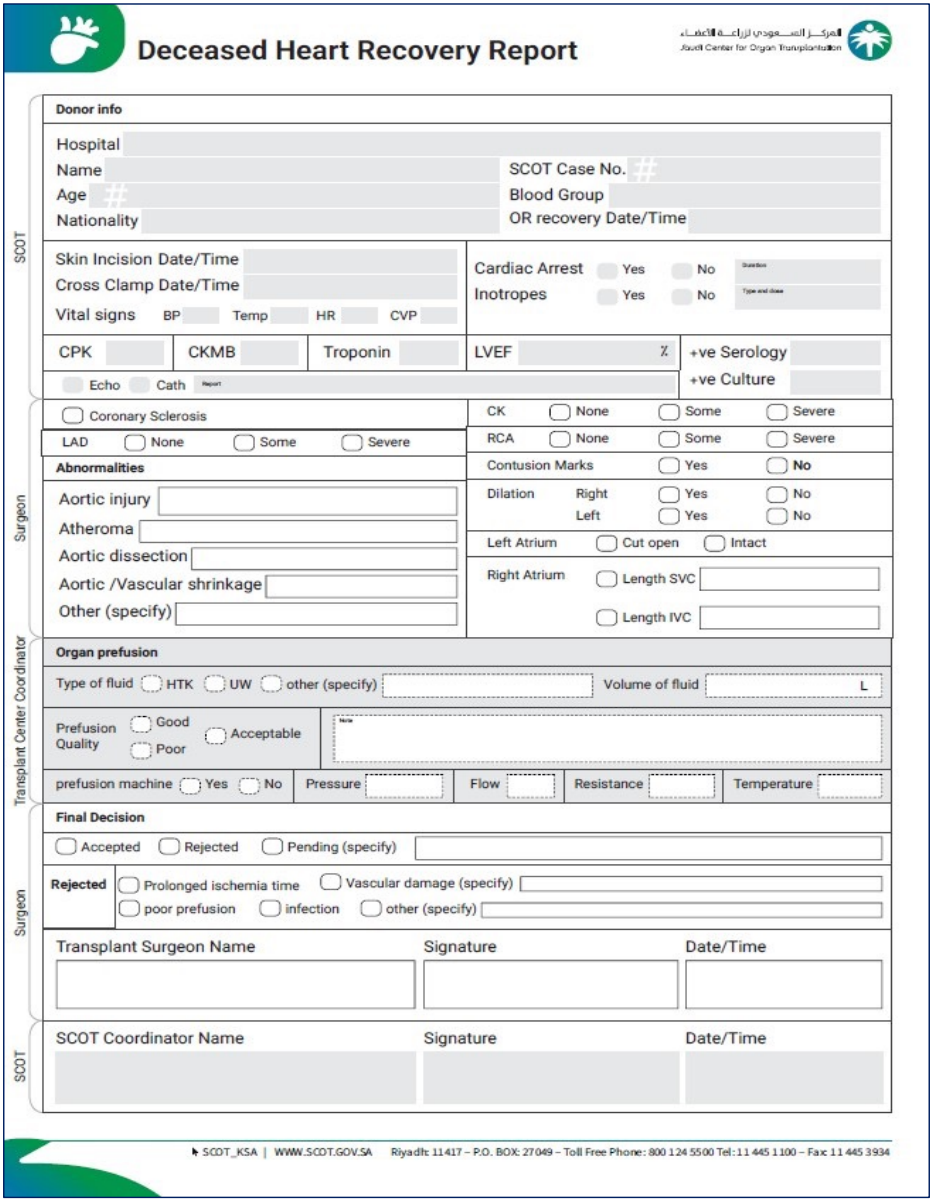
FORM-OSC-009

Form 8:
Deceased Heart Recovery Report



Deceased Heart Recovery Report

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

SCOT

Donor info

Hospital
Name — SCOT Case No. #
Age # — Blood Group
Nationality — OR recovery Date/Time

Skin Incision Date/Time
Cross Clamp Date/Time
Vital signs BP Temp HR CVP

Cardiac Arrest ◯ Yes ◯ No
Inotropes ◯ Yes ◯ No

CPK | CKMB | Troponin | LVEF % | +ve Serology
◯ Echo ◯ Cath | +ve Culture

Surgeon

◯ Coronary Sclerosis

LAD ◯ None ◯ Some ◯ Severe

CK ◯ None ◯ Some ◯ Severe
RCA ◯ None ◯ Some ◯ Severe
Contusion Marks ◯ Yes ◯ No
Dilation Right ◯ Yes ◯ No
Left ◯ Yes ◯ No
Left Atrium ◯ Cut open ◯ Intact
Right Atrium ◯ Length SVC
◯ Length IVC

Abnormalities

Aortic injury
Atheroma
Aortic dissection
Aortic /Vascular shrinkage
Other (specify)

Transplant Center Coordinator

Organ prefusion

Type of fluid ◯ HTK ◯ UW ◯ other (specify) — Volume of fluid L

Prefusion Quality ◯ Good ◯ Poor ◯ Acceptable

prefusion machine ◯ Yes ◯ No | Pressure | Flow | Resistance | Temperature

Surgeon

Final Decision

◯ Accepted ◯ Rejected ◯ Pending (specify)

Rejected ◯ Prolonged ischemia time ◯ Vascular damage (specify)
◯ poor prefusion ◯ infection ◯ other (specify)

Transplant Surgeon Name | Signature | Date/Time

SCOT

SCOT Coordinator Name | Signature | Date/Time

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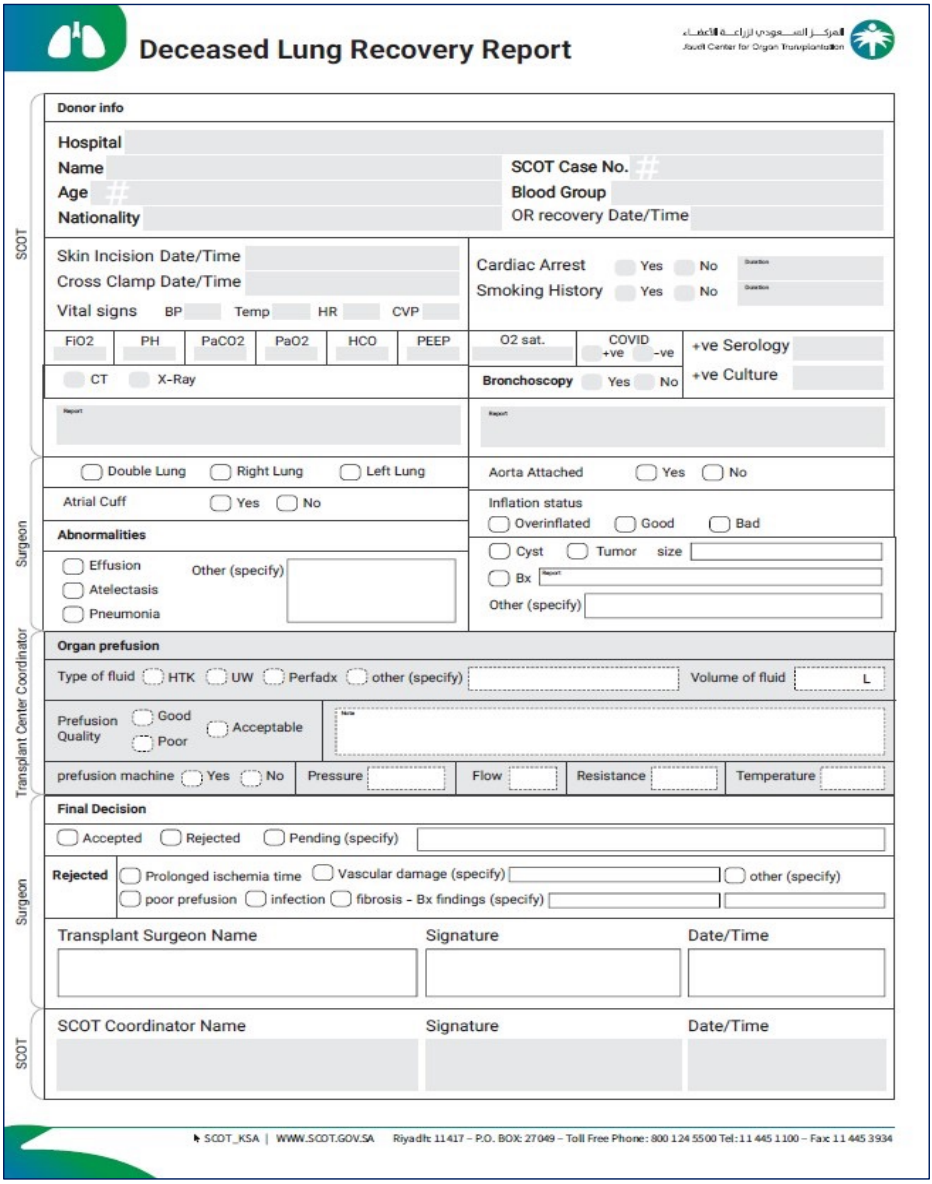
Form 9:
Deceased Lung Recovery Report



Deceased Lung Recovery Report

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

SCOT

Donor info

Hospital
Name
Age #
Nationality
SCOT Case No. #
Blood Group
OR recovery Date/Time

Skin Incision Date/Time
Cross Clamp Date/Time
Vital signs BP Temp HR CVP

Cardiac Arrest Yes No
Smoking History Yes No

FiO2	PH	PaCO2	PaO2	HCO	PEEP	O2 sat.	COVID +ve -ve	+ve Serology
								+ve Culture

CT X-Ray

Bronchoscopy Yes No

Report

Report

Surgeon

Double Lung Right Lung Left Lung

Aorta Attached Yes No

Atrial Cuff Yes No

Inflation status
Overinflated Good Bad

Abnormalities

Effusion
Atelectasis
Pneumonia
Other (specify)

Cyst Tumor size
Bx Report
Other (specify)

Transplant Center Coordinator

Organ prefusion

Type of fluid HTK UW Perfadx other (specify) Volume of fluid L

Prefusion Quality Good Poor Acceptable

Note

prefusion machine Yes No Pressure Flow Resistance Temperature

Surgeon

Final Decision

Accepted Rejected Pending (specify)

Rejected
Prolonged ischemia time Vascular damage (specify) other (specify)
poor prefusion infection fibrosis - Bx findings (specify)

Transplant Surgeon Name	Signature	Date/Time

SCOT

SCOT Coordinator Name	Signature	Date/Time

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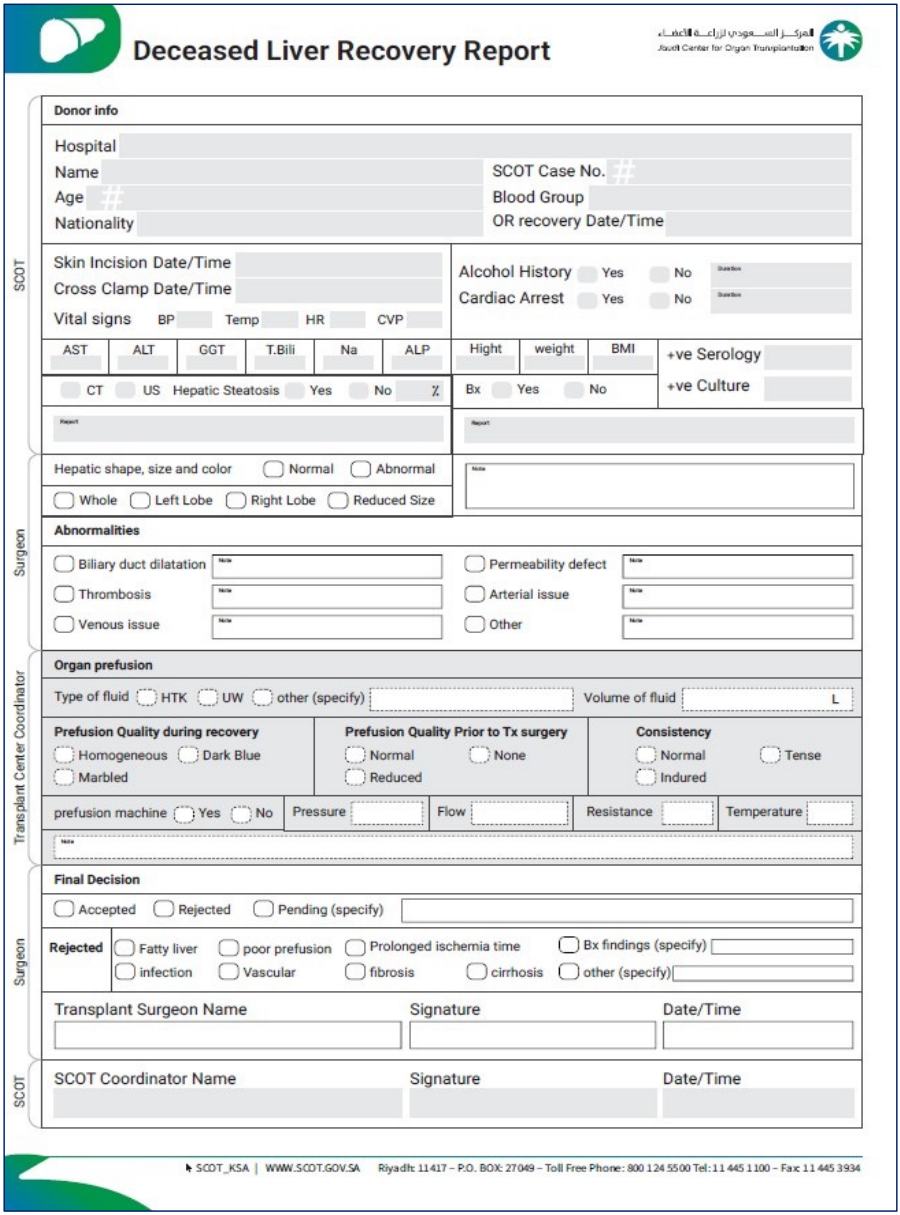
Form 10:
Deceased Liver Recovery Report



Deceased Liver Recovery Report

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

SCOT

Donor info

Hospital
Name
Age #
Nationality
SCOT Case No. #
Blood Group
OR recovery Date/Time

Skin Incision Date/Time
Cross Clamp Date/Time
Vital signs BP Temp HR CVP

Alcohol History Yes No
Cardiac Arrest Yes No

AST	ALT	GGT	T.Bili	Na	ALP	Hight	weight	BMI

+ve Serology
+ve Culture

CT US Hepatic Steatosis Yes No %
Bx Yes No

Surgeon

Hepatic shape, size and color Normal Abnormal
Whole Left Lobe Right Lobe Reduced Size

Abnormalities

Biliary duct dilatation
Thrombosis
Venous issue
Permeability defect
Arterial issue
Other

Transplant Center Coordinator

Organ prefusion

Type of fluid HTK UW other (specify)
Volume of fluid L

Prefusion Quality during recovery
Homogeneous Dark Blue
Marbled

Prefusion Quality Prior to Tx surgery
Normal None
Reduced

Consistency
Normal Tense
Indured

prefusion machine Yes No
Pressure
Flow
Resistance
Temperature

Surgeon

Final Decision

Accepted Rejected Pending (specify)

Rejected
Fatty liver poor prefusion Prolonged ischemia time Bx findings (specify)
infection Vascular fibrosis cirrhosis other (specify)

Transplant Surgeon Name	Signature	Date/Time

SCOT

SCOT Coordinator Name	Signature	Date/Time

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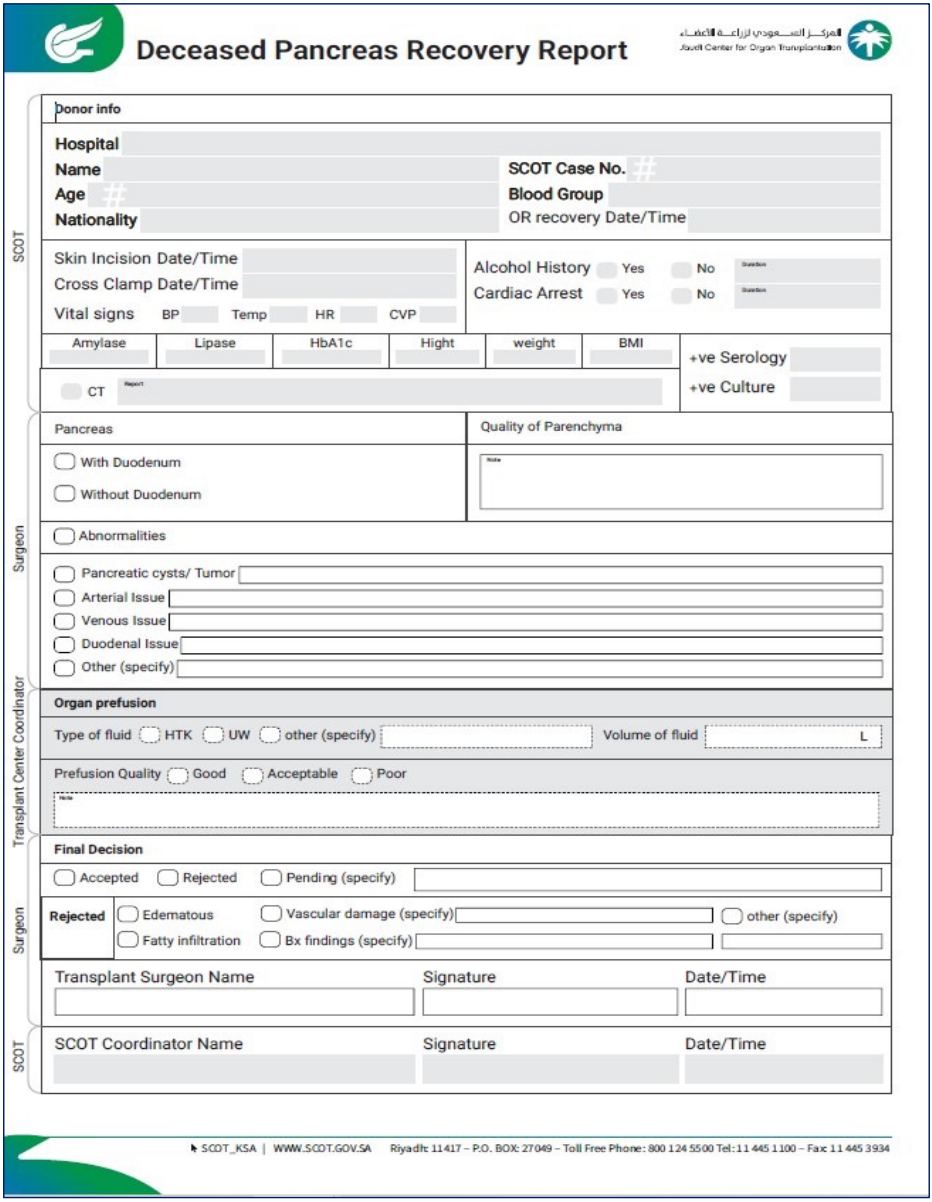
Form 11:
Deceased Pancreas Recovery Report



Deceased Pancreas Recovery Report

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

SCOT

Donor info

Hospital

Name | **SCOT Case No.** #

Age # | **Blood Group**

Nationality | OR recovery Date/Time

Skin Incision Date/Time

Cross Clamp Date/Time

Vital signs BP Temp HR CVP

Alcohol History ○ Yes ○ No

Cardiac Arrest ○ Yes ○ No

Amylase	Lipase	HbA1c	Hight	weight	BMI

+ve Serology

+ve Culture

○ CT Report

Surgeon

Pancreas

○ With Duodenum

○ Without Duodenum

Quality of Parenchyma

Note

○ Abnormalities

○ Pancreatic cysts/ Tumor

○ Arterial Issue

○ Venous Issue

○ Duodenal Issue

○ Other (specify)

Transplant Center Coordinator

Organ prefusion

Type of fluid ○ HTK ○ UW ○ other (specify) | Volume of fluid L

Prefusion Quality ○ Good ○ Acceptable ○ Poor

Note

Surgeon

Final Decision

○ Accepted ○ Rejected ○ Pending (specify)

Rejected

○ Edematous ○ Vascular damage (specify) ○ other (specify)

○ Fatty infiltration ○ Bx findings (specify)

Transplant Surgeon Name	Signature	Date/Time

SCOT

SCOT Coordinator Name	Signature	Date/Time

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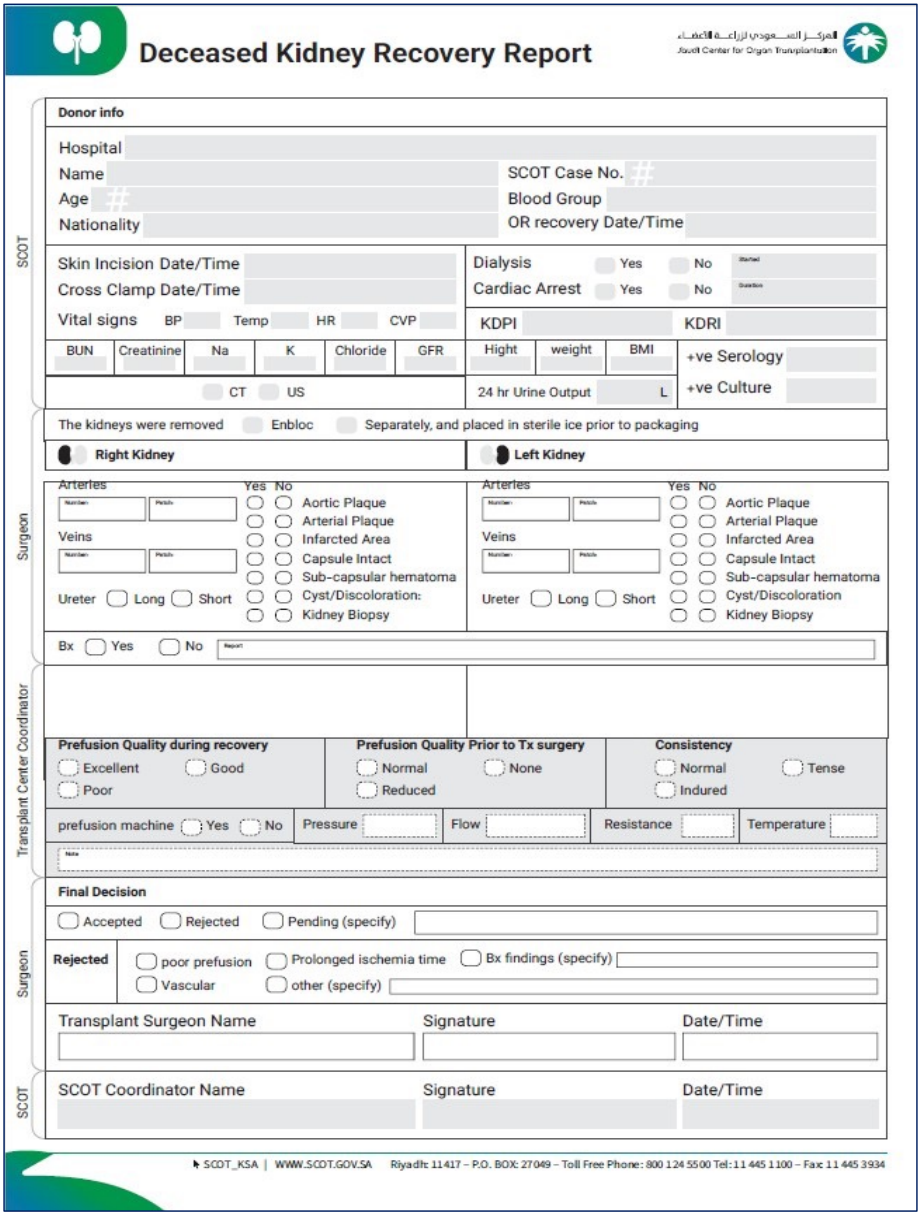
Form 12:
Deceased Kidney Recovery Report



Deceased Kidney Recovery Report

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

SCOT

Donor info

Hospital
Name
Age #
Nationality

SCOT Case No. #
Blood Group
OR recovery Date/Time

Skin Incision Date/Time
Cross Clamp Date/Time
Vital signs BP Temp HR CVP

Dialysis Yes No
Cardiac Arrest Yes No

KDPI KDRI

BUN	Creatinine	Na	K	Chloride	GFR	Hight	weight	BMI

+ve Serology
+ve Culture

CT US
24 hr Urine Output L

Surgeon

The kidneys were removed Enbloc Separately, and placed in sterile ice prior to packaging

Right Kidney

Arteries	Yes	No	
	◯	◯	Aortic Plaque
	◯	◯	Arterial Plaque
Veins	◯	◯	Infarcted Area
	◯	◯	Capsule Intact
	◯	◯	Sub-capsular hematoma
Ureter ◯ Long ◯ Short	◯	◯	Cyst/Discoloration:
	◯	◯	Kidney Biopsy

Left Kidney

Arteries	Yes	No	
	◯	◯	Aortic Plaque
	◯	◯	Arterial Plaque
Veins	◯	◯	Infarcted Area
	◯	◯	Capsule Intact
	◯	◯	Sub-capsular hematoma
Ureter ◯ Long ◯ Short	◯	◯	Cyst/Discoloration
	◯	◯	Kidney Biopsy

Bx ◯ Yes ◯ No Report

Transplant Center Coordinator

Prefusion Quality during recovery
◯ Excellent ◯ Good
◯ Poor

Prefusion Quality Prior to Tx surgery
◯ Normal ◯ None
◯ Reduced

Consistency
◯ Normal ◯ Tense
◯ Indured

prefusion machine ◯ Yes ◯ No | Pressure | Flow | Resistance | Temperature

Note

Surgeon

Final Decision

◯ Accepted ◯ Rejected ◯ Pending (specify)

Rejected
◯ poor prefusion ◯ Prolonged ischemia time ◯ Bx findings (specify)
◯ Vascular ◯ other (specify)

Transplant Surgeon Name	Signature	Date/Time

SCOT

SCOT Coordinator Name	Signature	Date/Time

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Form 13:
Post Heart Transplantation

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Post Heart Transplantation

Recipient Information

Hospital Code	Recipient MRN	SCOT MRN

Name: Given: | Father: | Grandfather: | Surname:

Date of Birth: | Age: Years

Sex: Male Female | Nationality:

Body Weight: | Saudi ID/Iqama No.

Address: P.O. Box: | City: | Tel/Mobile: #

Marital Status: Single Married Widow Divorced | Heart Status List: (Eg. 1A)

Hospital Admission Date: | Original Heart Disease:

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

Date of Transplantation: | Place of Transplantation:

In case of graft loss: How many re-transplant has been performed to the patient?

Type of Transplant: Heart Heart & Lung | Cold Ischemia: Hrs. Mins.

Remarks:

Deceased Donor Information

Hospital Code	Donor MRN	SCOT MRN

Name: Given: | Father: | Grandfather: | Surname:

Sex: Male Female | Age: Years | BMI:

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

Nationality:

Donor Hospital:

Address: P.O. Box: | City: | Tel/Mobile: #

Remarks:

The transplant center shall complete the organ transplantation form promptly after the organ transplantation within 24 hours of the transplantation date

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Form 14:
Post Lung Transplantation

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Post Lung Transplantation

Recipient Information

Hospital Code	Recipient MRN	SCOT MRN

Given: Father: Grandfather: Surname:

Name:

Date of Birth: **Age:** Years

Sex: Male Female **Saudi ID/Iqama No.** **Nationality:**

Address: P.O. Box: **City:** **Tel/Mobile:** #

Marital Status: Single Married Widow Divorced

Hospital Admission Date: **Original Lung Disease:**

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

Date of Transplantation: **Body Weight:**

In case of graft loss: How many re-transplant has been performed to the patient?

Type of Transplant: Lung Heart & Lung **Place of Transplantation:** Hrs. Mins.

Total Lung Tx. Single Bilateral **Cold Ischemia:**

Remarks:

Deceased Donor Information

Hospital Code	Donor MRN	SCOT MRN

Given: Father: Grandfather: Surname:

Name:

Sex: Male Female **Age:** Years **BMI:**

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

Nationality:

Donor Hospital:

Address: P.O. Box: **City:** **Tel/Mobile:** #

Remarks:

The transplant center shall complete the organ transplantation form promptly after the organ transplantation within 24 hours of the transplantation date

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Form 15:
Post Liver Transplantation

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Post Liver Transplantation

Recipient Information

Hospital Code	Patient No.	SCOT No.

Given: Father: Grandfather: Surname:

Name:

Date of Birth: **Age:** Years

Sex: Male Female **Body Weight:** **Nationality:**

Address: P.O. Box: **City:** **Tel/Mobile:** #

Marital Status: Single Married Widow Divorced **Original Liver Disease:**

Hospital Admission Date:

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

Date of Transplantation: **Place of Transplantation:**

Type of Transplant: Living Related Living Unrelated Cadaver

Cold Ischemia: Hrs. Mins.

Remarks:

Donor Information

Hospital Code	Donor MRN	SCOT MRN

Given: Father: Grandfather: Surname:

Name:

Sex: Male Female **Age:** Years **Weight:** Kg

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

Type of Donor: Living Related Living Unrelated Deceased Pair Exchange

Relation to Recipient: Directed Non-Directed **Nationality:**

Donor Hospital:

Address: P.O. Box: **City:** **Tel/Mobile:** #

Remarks:

The transplant center shall complete the organ transplantation form promptly after the organ transplantation within 24 hours of the transplantation date

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Form 16:
Post Kidney Transplantation

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Post Kidney Transplantation

Recipient Information

Hospital Code	Recipient MRN	SCOT MRN

Given: Father: Grandfather: Surname:

Name:

Date of Birth: **Age:** Years

Sex: Male Female **Nationality:**

Address: P.O. Box: **City:** **Tel/Mobile:** #

Marital Status: Single Married Widow Divorced **Date of First Dialysis:**

Hospital Admission Date: **Original Renal Disease:**

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

Date of Transplantation: **Place of Transplantation:**

Type of Transplant: Living Related Living Unrelated Deceased Pair Exchange

Cold Ischemia:

Remarks:

Donor Information

Hospital Code	Donor MRN	SCOT MRN

Given: Father: Grandfather: Surname:

Name:

Sex: Male Female **Age:** Years **Weight:** Kg **Creat. Cl.** ml/min

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

Type of Donor: Living Related Living Unrelated Cadaver

Relation to Recipient: Directed Non-Directed **Nationality:**

Donor Hospital:

Address: P.O. Box: **City:** **Tel/Mobile:** #

Remarks:

The transplant center shall complete the organ transplantation form promptly after the organ transplantation within 24 hours of the transplantation date

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Form 17:
Post Pancreas Transplantation

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Post Pancreas Transplantation

Recipient Information

Hospital Code	Recipient MRN	SCOT MRN

Given: Father: Grandfather: Surname:

Name:

Date of Birth: **Age:** Years

Sex: Male Female **Saudi ID/Iqama No.:** **Nationality:**

Address: P.O. Box: **City:** **Tel/Mobile:** #

Marital Status: Single Married Widow Divorced **Original Pancreas Disease:**

Hospital Admission Date: **Body Weight:**

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

Date of Transplantation: **Place of Transplantation:**

In case of graft loss: How many re-transplant has been performed to the patient?

Type of Transplant: PTA SPK **Cold Ischemia:** Hrs. Mins.

Other, Specify:

Remarks:

Deceased Donor Information

Hospital Code	Donor MRN	SCOT MRN

Given: Father: Grandfather: Surname:

Name:

Sex: Male Female **Age:** Years **BMI:**

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

Nationality:

Donor Hospital:

Address: P.O. Box: **City:** **Tel/Mobile:** #

Remarks:

The transplant center shall complete the organ transplantation form promptly after the organ transplantation within 24 hours of the transplantation date

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Form 18:
Post Intestinal Transplantation

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Post Intestinal Transplantation

Recipient Information

Hospital Code	Recipient MRN	SCOT MRN

Given: Father: Grandfather: Surname:

Name:

Date of Birth: **Age:** Years

Sex: Male Female **Saudi ID/Iqama No.:** **Nationality:**

Address: P.O. Box: **City:** **Tel/Mobile:** #

Marital Status: Single Married Widow Divorced **Original Intestinal Disease:**

Hospital Admission Date: **Body Weight:**

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

Date of Transplantation: **Place of Transplantation:**

In case of graft loss: How many re-transplant has been performed to the patient?

Type of Transplant: Alone **Cold Ischemia:** Hrs. Mins.

Other MVT: Specify

Remarks:

Deceased Donor Information

Hospital Code	Donor MRN	SCOT MRN

Given: Father: Grandfather: Surname:

Name:

Sex: Male Female **Age:** Years **BMI:**

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

Nationality:

Donor Hospital:

Address: P.O. Box: **City:** **Tel/Mobile:** #

Remarks:

The transplant center shall complete the organ transplantation form promptly after the organ transplantation within 24 hours of the transplantation date

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Form 19:
Bone Marrow Transplantation Form

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Bone Marrow Transplantation

Recipient Information

Hospital Code	Recipient MRN	SCOT MRN.

Name: Given: | Father: | Grandfather: | Surname:

Date of Birth: | Age: Years

Sex: Male Female

Country: Where transplant was done: | City: | Tel/Mobile: #

Hospital : | Original Disease/ Indication:

Date of Transplantation: | Nationality: Saudi / Non-Saudi

Specify:

Remarks:

Living Donor Information

Hospital Code	Donor MRN	SCOT MRN

Name: Given: | Father: | Grandfather: | Surname:

Sex: Male Female | Age: Years | Nationality: Saudi / Non-Saudi

Specify:

Donor's Hospital: Where stem cells were collected:

Address: P.O. Box: | City: | Tel/Mobile: #

Remarks:

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Form 20:
Living Related Organ Donor Evaluation Form

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

استمارة تقييم متبرع حي قريب (بعضو أو جزء منه)

اسم المركز الزارع	التاريخ

المتبرع	
العمر	لا يقل العمر عن 18 عام
الجنس	ذكر ☐ أنثى ☐
الجنسية	
هوية رقم	بطاقة أحوال مدنية – إقامة (مرفق صورتها)

يرغب بالتبرع بالهبة ودون ضغوط أو إجبار بـ

☐ إحدى كليتي	☐ جزء من الكبد

لصالح مريض قريب

الاسم	
العمر	
الجنسية	
الجنس	ذكر ☐ أنثى ☐
هوية رقم	
صلة القرابة	

وقد أُفهم المذكور مايلي :

- ☐ أنه يحق له التراجع عن التبرع في أي وقت قبل إجراء العملية
- ☐ لأنه لا يحق له المطالبة المالية بإعادة العضو المتبرع به بعد إتمام عملية التبرع مع علمه التام بجميع النتائج المؤكدة والمحتملة المترتبة على إجراء عملية التبرع
- ☐ أنه لا يحق له المطالبة بأي تعويضات مادية أو معنوية مقابل التبرع من المريض المتبرع له أو المستشفى الزارع في أي وقت من الأوقات مع علمي بالملاحقة القانونية في حال حدوث ذلك
- ☐ ضرورة الإلتزام بالمتابعة الدورية لحالتي الصحية بعد عملية التبرع حسب النظام المعمول به في قسم زراعة الأعضاء

بعد تقييم المتبرع من الناحية النفسية والإجتماعية وتقييم إدراكه لعملية التبرع و محاذيرها واختلاطاتها

- ☐ لامانع من إستكمال إجراءات التبرع من قبل قسم زراعة الأعضاء في المستشفى
- ☐ رفض طلب التبرع

للأسباب التالية :

الإعتماد

	الاسم	التوقيع
منسق الزراعة		
الأخصائي الاجتماعي/ النفسي		
رئيس برنامج الزراعة		

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Form 21:
Living Unrelated Organ Donor Evaluation Form

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

استمارة تقييم متبرع غير قريب (بعضو أو جزء منه)

اسم المركز الزارع	رقم الملف الطبي	التاريخ

اسم الراغب في التبرع

العمر *لا يقل العمر عن 18 عام

الجنس ذكر أنثى

الجنسية

هوية رقم بطاقة أحول مدنية – إقامة (مرفق صورتها)

أرغب بالتبرع بالهبة ودون ضغوط أو إجبار بـ

☐ إحدى كليتي ☐ جزء من الكبد

☐ لصالح مريض محدد ☐ لصالح مريض غير محدد

الاسم

العمر رقم الملف الطبي

الجنسية

الجنس ذكر أنثى

هوية رقم يسمح فقط مابين أفراد الجنسية الواحدة (مرفق صورتها)

وقد أُفهم المذكور بما يلي:

- ☐ يحق له التراجع عن التبرع في أي وقت قبل إجراء العملية
- ☐ لا يحق له المطالبة بإعادة العضو المتبرع به بعد إتمام عملية التبرع مع علمه التام بجميع النتائج المؤكدة والمحتملة المترتبة على إجراء عملية التبرع
- ☐ لا يحق له المطالبة بأي تعويضات مادية أو معنوية مقابل التبرع من المريض المتبرع له أو المستشفى الزارع في أي وقت
- ☐ ضرورة الإلتزام بالمتابعة الدورية لحالته الصحية بعد عملية التبرع حسب النظام المعمول به في قسم زراعة الأعضاء

أعضاء اللجنة	تاريخ المقابلة الأولى: الاسم/ التوقيع	تاريخ المقابلة الثانية: الاسم/ التوقيع
الطبيب الاستشاري		
الطبيب الاستشاري		
استشاري الأمراض النفسية		
أخصائي اجتماعي		
مدير المستشفى أو من ينوب عنه		

وترى اللجنة بعد فحصه النفسي والإجتماعي وتقييم إدراكه لعملية التبرع و محاذيرها واختلاطاتها بأنه

☐ لامانع من إستكمال الإجراءات التبرع من قبل قسم زراعة الأعضاء في مستشفاها

☐ رفض طلب التبرع

للأسباب التالية:

ترفع الإستمارة الى المركز السعودي لزراعة الأعضاء لإستكمال اللازم مع إحتفاظ اللجنة بصورة منها

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Form 22:
Living Related Donor Consent Form (Arabic)

إقرار بالتبرع (بعضو أو جزء منه) أثناء الحياة للأقارب

أقر أنا	
العمر	لا يقل المتبرع عن 18 عام
الجنس	ذكر ☐ أنثى ☐
الجنسية	
هوية رقم	بطاقة أحوال مدنية ☐ إقامة بعرض صورتها ☐

الموقع أدناه والمتمتع بكامل قواي العقلية بأني أرغب في التبرع بـ

☐ إحدى كليتي	☐ جزء من الكبد

لصالح مريض قريب	
الاسم	
العمر	
الجنسية	
الجنس	ذكر ☐ أنثى ☐
هوية رقم	
صلة القرابة	

وذلك دون ضغوط أو إجبار وأنه :

- ☐ يحق لي التراجع عن التبرع في أي وقت قبل إجراء العملية
- ☐ لا يحق لي المطالبة لمالية بإعادة العضو المتبرع به بعد إتمام عملية التبرع مع علمي التام بجميع النتائج المؤكدة والمحتملة المترتبة على إجراء عملية التبرع
- ☐ لا يحق لي المطالبة بأي تعويضات مادية أو معنوية مقابل التبرع من المريض المتبرع له أو المستشفى الزارع في أي وقت من الأوقات مع علمي بالملاحظة القانونية في حال حدوث ذلك
- ☐ من الضروري الإلتزام بالمتابعة الدورية لحالتي الصحية بعد عملية التبرع حسب النظام المعمول به في قسم زراعة الأعضاء

التوقيع

شاهدين

الاسم	الجنسية	رقم الهوية	التوقيع

- مرفق صورة من بطاقتي الهوية للشاهدين
- إرسال صورة من الإقرار إلى المركز السعودي لزراعة الأعضاء

Form 22:
Living Related Donor Consent Form (English)

المركـــز الســـعودي لزراعـــة الأعضـــاء
Saudi Center for Organ Transplantation

Declaration of Donation
(of an organ or part of it) During Life for **Relatives**

I Declare

Age		Must be at least 18 years of age
Sex	☐ Male	☐ Female
Nationality		
Identification		National ID Card – Residence (a copy of which is attached)

The undersigned below, being of sound mind, hereby expresses the desire to donate:

☐ **One of My Kidneys**	☐ **Part of My Liver**

For the benefit of a relative who is a patient

Name		
Age		
Nationality		
Sex	☐ Male	☐ Female
Identification		
Relationship		

And that this is done without any pressure or coercion and that

- ☐ I have the right to withdraw from the donation at any time before the procedure is performed.
- ☐ I do not have the right to any financial claim to have the donated organ returned after the completion of the donation process, fully aware of all the definite and potential outcomes associated with undergoing the donation procedure.
- ☐ I do not have the right to claim any material or moral compensation in exchange for the donation from the recipient patient or the transplant hospital at any time, with my full knowledge of the legal consequences in the event of such a claim.
- ☐ It is essential to commit to the regular follow-up of my health status after the donation procedure, in accordance with the protocol established in the organ transplant department.

Signature

Witnesses

Name	Nationality	ID	Signature

* Photos of the witnesses' ID cards.
* Send a photo of the declaration to the Saudi Center for Organ Transplantation.

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Form 23:
Living Unrelated Donor Consent Form (Arabic)

إقرار بالتبرع (بعضو أو جزء منه) أثناء الحياة لغير الأقارب

أقر أنا	
العمر	لا يقل العمر عن 18 عام
الجنس	ذكر / أنثى
الجنسية	
هوية رقم	بطاقة أحوال مدنية / إقامة وموقع صورتها

الموقع أدناه والمتمتع بكامل قواي العقلية بأني أرغب في التبرع بـ

☐ إحدى كليتي	☐ جزء من الكبد

☐ لصالح مريض غير قريب	☐ لصالح مريض غير محدد

الاسم	
العمر	
الجنسية	
الجنس	ذكر / أنثى
هوية رقم	

وذلك دون ضغوط أو إجبار وأنه :

- ☐ يحق لي التراجع عن التبرع في أي وقت قبل إجراء العملية
- ☐ لا يحق لي المطالبة المالية بإعادة العضو المتبرع به بعد إتمام عملية التبرع مع علمي التام بجميع النتائج المؤكدة والمحتملة المترتبة على إجراء عملية التبرع
- ☐ لا يحق لي المطالبة بأي تعويضات مادية أو معنوية مقابل التبرع من المريض المتبرع له أو المستشفى الزارع في أي وقت من الأوقات مع علمي بالملاحقة القانونية في حال حدوث ذلك
- ☐ من الضروري الإلتزام بالمتابعة الدورية لحالتي الصحية بعد عملية التبرع حسب النظام المعمول به في قسم زراعة الأعضاء

التوقيع

شاهدين

الاسم	الجنسية	رقم الهوية	التوقيع

- مرفق صورة من بطاقتي الهوية للشاهدين
- إرسال صورة من الإقرار إلى المركز السعودي لزراعة الأعضاء

Form 23:
Living Unrelated Donor Consent Form (English)

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Declaration of Donation
(of an organ or part of it) During Life for **Non Relatives**

I Declare	
Age	Must be at least 18 years of age
Sex	☐ Male ☐ Female
Nationality	
Identification	National ID Card – Residence (a copy of which is attached)

The undersigned below, being of sound mind, hereby expresses the desire to donate:

☐ **One of My Kidneys**	☐ **Part of My Liver**

☐ For the benifit of a **Specified** patient	☐ For the benifit of a **Unspecified** patient

Name	
Age	
Nationality	
Sex	☐ Male ☐ Female
Identification	
Relationship	

And that this is done without any pressure or coercion and that

- ☐ I have the right to withdraw from the donation at any time before the procedure is performed.
- ☐ I do not have the right to any financial claim to have the donated organ returned after the completion of the donation process, fully aware of all the definite and potential outcomes associated with undergoing the donation procedure.
- ☐ I do not have the right to claim any material or moral compensation in exchange for the donation from the recipient patient or the transplant hospital at any time, with my full knowledge of the legal consequences in the event of such a claim.
- ☐ It is essential to commit to the regular follow-up of my health status after the donation procedure, in accordance with the protocol established in the organ transplant department.

Signature

Witnesses

Name	Nationality	ID	Signature

* Photos of the witnesses' ID cards.
* Send a photo of the declaration to the Saudi Center for Organ Transplantation.

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Form 24:
Living Unrelated Organ Donor Referral Form

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

نموذج إحالة متبرع حي غير قريب (بعضو أو جزء منه) إلى لجنة تقييم المتبرعين

اسم المركز الزارع	التاريخ

تقدم إلينا المكرم/ ة

العمر	لا يقل العمر عن 18 عام	
الجنس	ذكر ☐ أنثى ☐	
الجنسية		
هوية رقم	بطاقة أحوال مدنية – إقامة (مرفق صورتها)	

أبدى رغبته بالتبرع بالهبة

☐ إحدى كليتي	☐ جزء من الكبد

☐ لصالح مريض محدد	☐ لصالح مريض غير محدد
الاسم	
العمر	
الجنسية	
الجنس	ذكر ☐ أنثى ☐
هوية رقم	

حيث أن المذكور بكامل أهليته وقد أستوفى الشروط الأولية للتبرع (بعضو أو جزء منه) عليه نأمل من سعادتكم تقييم المذكور أعلاه من قبل اللجنة الفنية الخاصة بتقييم الأشخاص المتبرعين وتعبئة الإستمارة الخاصة بذلك نظاماً

جهة الإحالة

☐ قسم زراعة الكلى	☐ قسم زراعة الكبد

منسق الزراعة	رئيس القسم
الاسم	الاسم
التوقيع	التوقيع

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Form 25 (page 1):
End Stage Renal Failure Patient on Renal Replacement Therapy

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

End Stage Renal Failure Patient on Renal Replacement Therapy

1. Patient Information

(This Section to be filled only once for every new chronic patient)

Hospital Code	Patient MRN	SCOT MRN

Name: Given: | Father: | Grandfather: | Surname:

Date of Birth: | Age: Years | Saudi ID/ Iqama No.

Sex: Male Female | Occupation: | Nationality:

Address: P.O. Box: | Tel/Mobile: #

Marital Status: Single Married Widow Divorced | Original Disease:

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

2. Dialysis Follow up

Did the patient start dialysis? Yes No | Date: | Hospital Name:

When did the patient start dialysis in your hospital? | Date:

Dialysis type: Hemo. Peritoneal | Vascular access adequate: Yes No

Body weight: | Date:

3. Laboratory Results For Dialysis Patients

(To be entered once every 12 months)

Note: Indicate your lab measuring unit International Old.

HEMATOLOGY

Date:

WBC (Cells/mm³)	Hb (g/dl)	Plts (Cells/mm³)

BLOOD CHEMISTRY

Date:

Urea (mg/dl)	Creatinine (mg/dl)
BF:	BF:
AF:	AF:

*(BF: Before Dialysis, AF: After Dialysis.)

BIOCHEMISTRY

Date:

Alb (g/dl)	Glu (mg/dl)	AST (IU/l)	ALT (IU/l)

*(To be entered entered each time it changes)

HEPATITIS SEROLOGY

Date:

HBsAg	HBsAb	HBcAb	HCVAb	HBV (Vaccine)	HIV
				Yes / No	

PRA (Panel Reactive Antibodies)

Date:

Available: Yes, Valu / No

TISSUE TYPING

A		BW		DPQ	
B		CW		DPW	
DR		DRW		DW	
AW		DRQ			

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Form 25 (page 2):
End Stage Renal Failure Patient on Renal Replacement Therapy

المركـــز الســـعودي لزراعـــة الأعضـــاء
Saudi Center for Organ Transplantation

End Stage Renal Failure Patient on Renal Replacement Therapy

Hospital Code	Patient MRN	SCOT MRN

4. Entry on Waiting List
(To be filled each time it changes)

Number of previous transplants?

1 2 3 4

Ready for transplant?
- Yes
- No
  - Under Workup
  - Temporarily
  - Permanent
  - Reason:

Urgent transplant is needed?
- Yes
- No
  - Reason:

5. Patient Departure
(To be filled when patient leave the dialysis unit)

Date of Leave:

Type of Leave:
- Permanent
- Temporary

6. Death
(To be filled upon the death of the patient)

Date:

Cause of Death:
- IHD
- Pericardial Effusion
- CVA
- PE
- Hyperkalemia
- Infection
- Malignancy
- Liver Cirrhosis
- Other:

7. Transplantation
(To be filled in case the patient gets a renal transplant)

Date of Transplant:

Place of Transplant:

Follow-up Hospital:

Pre-emptive Transplant: Yes No

Transplantation Donor Information

Donating Hospital Name:

Donor Hospital MRN.

Donor Name:

Sex: Male Female

Age:

Nationality:

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

HLA Match:
A: 0 1 2
B: 0 1
DR: 0 1 2

Address: P.O. Box

City:

Country

Tel. No.

Donor Type: Living Donor, Relationship: 1 2 3 4 5
Deceased Donor

Transplant Recipient Follow-up Status
(To be filled in every clinic visit or change in status)

Active
- A. S. Creatinine — Date:
- B. Immunosuppressive drugs — Total daily dose
  1. Cyclosporine
  2. Azathioprine
  3. Mycophenolate (MMF)
  4. Tacrolimus (FK-506)

Died (Please fill death box 6)

Discharged (Please fill departure box 5)

Return to Dialysis — Reason: — Date:

Name of Doctor:

Position:

Signature:

Date:

Form 26 (page 1):
Advance Liver Failure Patient Registry

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Advanced Liver Failure Patient Registry

(This form to be filled at least every 3 months or whenever clinical status changes)

1. Patient Identification

(This Section to be filled only once for every new patient)

Date of filling this form:

Hospital Code	Patient MRN	SCOT MRN

Given: Father: Grandfather: Surname:

Name:

Date of Birth: **Age:** Years **Saudi ID/ Iqama No.**

Sex: Male Female **Occupation:** **Nationality:**

Address: P.O. Box: **Tel/Mobile:** #

Marital Status: Single Married Widow Divorced **Original Disease:**

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

2. Cause of Liver Failure

Fulminant Hepatic Failure

- Viral hepatitis (A, B, C, D, EBV, CMV)
- Drug-induced liver disease (Halothane, Disulfiram, Acetaminophen etc ...)
- Metabolic liver disease
- Wilson's disease
- Reye's syndrome
- Massive hepatic trauma
- Others

Congenital Metabolic Disorder

- α-1 antitrypsin deficiency
- Wilson's disease hyperlipoproteinemia
- Crigler-Najjar syndrome
- Glycogen storage disease
- Protein C deficiency
- Oxalosis
- Others

Advanced Chronic Liver Disease

- Primary biliary cirrhosis
- Primary sclerosing cholangitis
- Biliary atresia
- Idiopathic autoimmune hepatitis
- Chronic alcoholic cirrhosis
- Chronic viral hepatitis
- Vascular disease (Eg. Budd-Chiari syndrome, Veno-occlusive disease
- Others

Liver Tumor

- Primary hepatocellular carcinoma
- Other liver tumors
- Isolated hepatic metastatic disease (Eg. Carcinoid)
- Others

3. Patient Status

(This section to be filled every time status changed)

ICU on ventilator not on ventilator In hospital At home
Temporary contra-indications for transplantation

Child-Pugh Class Class A Class B Class C

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Form 26 (page 2):
Advance Liver Failure Patient Registry

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Advanced Liver Failure Patient Registry

(This form to be filled at least every 3 months or whenever clinical status changes)

4. Laboratory Results

Date:

WBC	Hb	Plts.	PT	PTT	INR	Alb	AST	ALT	Bilirubin	Alk Phos.	GGT

HEPATITIS SEROLOGY

Date:

HBsAg	HBsAb	HBcAb	HCVAb	HBV (Vaccine)	HIV	Others
				☐ Yes ☐ No		

5. Death

(To be filled upon the death of the patient)

Date:

Cause of Death:

6. Transplantation

(To be filled in case the patient has a liver transplant)

Date of Tx.:

Type of Transplantation:

Place of Transplantation:

Follow-up Hospital:

Transplantation Donor Information

Donating Hospital Name:

Donor Hospital MRN.

Donor Name:

Sex: ☐ Male ☐ Female **Age:** **Nationality:**

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

Address: P.O. Box **City:**

Country **Tel. No.**

Donor Type: ☐ Living Donor, Relationship: ☐ Related ☐ Unrelated ☐ Deceased Donor

Transplant Recipient Follow-up Status

(To be filled in every clinic visit or change in status)

☐ **Active** Date:

AST	ALT	GGT	INR

B. Immunosuppressive drugs	Total daily dose	
1. Cyclosporine		
2. Mycophenolate (MMF)		
3. Tacrolimus (FK-506)		
4. Others		

☐ **Died** (Please fill death box 5)

Name of Doctor: **Position:**

Signature: **Date:**

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Form 27 (page 1):
Advance Heart Failure Patient Registry

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Advanced Heart Failure Patient Registry

(This form to be filled at least every 3 months or whenever clinical status changes)

1. Patient Identification

(This Section to be filled only once for every new patient)

Date of filling this form:

Hospital Code	Patient MRN	SCOT MRN

Given: Father: Grandfather: Surname:

Name:

Date of Birth: **Age:** Years **Saudi ID/ Iqama No.**

Sex: Male Female **Occupation:** **Nationality:**

Address: P.O. Box: **Tel/Mobile:** #

Marital Status: Single Married Widow Divorced **Original Disease:**

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

2. Cause of Heart Failure

- **End stage cardiac failure unresponsive to any acceptable medical or surgical treatment (L. V. = EF < 20%)**
- **Class III or IV according NYHA classification**
- **Unresectable cardiac tumors**
- **Failure to come off cardiac pulmonary bypass**
- **Patient is dying from acute myocardial infection**

3. Patient Status

(This section to be filled every time status changed)

Status I
- [1]Patients who are supported with temporary mechanical circulatory support such as veno-arterial extracorporeal membrane oxygenation (VA ECMO), temporary left or right ventricular assist devices or total artificial heart.
- [2]Patients with durable left, right or biventricular assist device malfunction or complication, such as device thrombosis, hemolysis or life-threatening arrhythmias; excluding driveline infection.

Status II
- [1]Patients who are inotropes dependent. (Status 2A)
- [2]Patients with high PRA (> 80%) (Status 2B)

Status III
- [1]Patients with durable left, right or biventricular assist devices who do not meet priority 1 criteria.
- [2]Patients admitted to hospital with decompensation who do not meet criteria for other priority listing.
- [3]Patients who are listed for multiple organ transplantation.

Status IV
- [1]All other listed patients who are out of hospital.

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Form 27 (page 2):
Advance Heart Failure Patient Registry

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Advanced Heart Failure Patient Registry

(This form to be filled at least every 3 months or whenever clinical status changes)

Hospital Code	Patient MRN	SCOT MRN

4. Investigations

Date:

Echocardiography:	
Cardiac Angiography:	
Others:	

5. Death

(To be filled upon the death of the patient)

Date:

Cause of Death:

6. Transplantation

(To be filled in case the patient has a liver transplant)

Date of Tx.:

Type of Transplantation:	
Place of Transplantation:	
Follow-up Hospital:	

Transplantation Donor Information

Donating Hospital Name:

Donor Hospital File No.

Donor Name:

Sex: Male Female Age: Nationality:

Blood Group: A+ A- B+ B- AB+ AB- O+ O-

Address: P.O. Box City:

Country Tel. No.

Transplant Recipient Follow-up Status

(To be filled in every clinic visit or change in status)

Active Date:

A. Immunosuppressive drugs	Total daily dose	
1. Cyclosporine		
2. Mycophenolate (MMF)		
3. Tacrolimus (FK 506)		
4. Others		

Died (Please fill death box 5)

Name of Doctor: Position:

Signature: Date:

Form 28:
Post Kidney Transplantation Follow-up (Recipient Form)

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Post Kidney Transplantation Follow-up

(Recipient)

Name of Transplant Center	Recipient MRN

Kidney Recipient Demographics

Recipient Name:			
Date of Birth:		Age:	
Original Disease:		Sex:	
Nationality:		National ID:	#

Transplantation Details

Date of Transplant:

Part of Kidney: ☐ Left ☐ Right

Type of Transplant: ☐ Living Related ☐ Living Unrelated ☐ Deceased

- ☐ Direct ☐ Indirect
- ☐ PKED

Note: Date should be linked to donor information

Post-Transplantation Status

Recipient Status:

- ☐ Alive with functioning graft
- ☐ Alive with failed graft
- ☐ Dead with functioning graft
- ☐ Dead with failed graft

Non-functioning graft: ☐ Yes Date: ☐ No

Graft loss: ☐ Yes ☐ No

Date:
Cause:

Death: ☐ Inside Hospital ☐ Outside

Date:
Cause:

Lost Follow-up Reasons: ☐ Routine ☐ Emergency ☐ Other:

Latest Lab Values (Required)

Either of the following:

- 30 days after the discharge from transplant center for transplantation and annual anniversary of the transplant date until the recipient's death or graft failure
- 14 days from notification of the recipient's death or graft failure

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FORM-OSC-012

Form 29:
Post Liver Transplantation Follow-up (Recipient Form)

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Post Liver Transplantation Follow-up

(Recipient)

Name of Transplant Center	Recipient MRN

Liver Recipient Demographics

Recipient Name:			
Date of Birth:		Age:	
Original Disease:		Sex:	
Nationality:		National ID:	#

Transplantation Details

Date of Transplant:

Part of Liver: ☐ Left lobe ☐ Right lobe ☐ Left Lateral Segment

Type of Transplant: ☐ Domino

☐ Deceased
- ☐ Whole
- ☐ Split

☐ Living
- ☐ Direct
- ☐ Indirect

Note: Date should be linked to donor information

Post-Transplantation Status

Recipient Status:
- ☐ Alive with functioning graft
- ☐ Alive with failed graft
- ☐ Dead with functioning graft
- ☐ Dead with failed graft

Non-functioning graft: ☐ Yes Date: ☐ No

Graft loss: ☐ Yes ☐ No
Date:
Cause:

Death: ☐ Inside Hospital ☐ Outside
Date:
Cause:

Lost Follow-up Reasons: ☐ Routine ☐ Emergency ☐ Other:

Latest Lab Values (Required)

AST	ALT	GGT	INR

Either of the following:
- 30 days after the discharge from transplant center for transplantation and annual anniversary of the transplant date until the recipient's death or graft failure
- 14 days from notification of the recipient's death or graft failure

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FORM-OSC-014

Form 30:
Post Heart Transplantation Follow-up (Recipient Form)

المركـز السـعودي لزراعـة الأعضـاء
Saudi Center for Organ Transplantation

Post Heart Transplantation Follow-up

Name of Transplant Center	Recipient MRN

Heart Recipient Demographics

Recipient Name:
Date of Birth: Age:
Original Disease: Sex:
Nationality: National ID: #

Transplantation Details

Date of Transplant:

Post-Transplantation Status

Recipient Status:
- Alive with functioning graft
- Dead with functioning graft

Graft loss:
- Yes
- No

Date:
Cause:

Death:
- Inside Hospital
- Outside

Date:
Cause:

Deceased Donor Information

Name of Donor Hospital	Hospital MRN	Donor MRN

Donor Name:
Date of Birth:
Cause of Death:
Age:
Sex:
Nationality:
National ID:
Remarks on Co-morbidities:

Lost Follow-up Reasons: Routine Emergency Other:

Latest Lab Values (Required)

Troponin T cTnT	Troponin I cTnI	Creatine Kinase CK	Myoglobin	BNP	LDH	Ejection Fraction

Either of the following:
- 30 days after the discharge from transplant center for transplantation and annual anniversary of the transplant date until the recipient's death or graft failure
- 14 days from notification of the recipient's death or graft failure

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FORM-OSC-010

Form 31:
Post Lung Transplantation Follow-up (Recipient Form)

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Post Lung Transplantation Follow-up

Name of Transplant Center	Recipient MRN

Lung Recipient Demographics

Recipient Name:
Date of Birth: Age:
Original Disease: Sex:
Nationality: National ID: #

Transplantation Details

Date of Transplant:
Part of Lung: Bilateral Lung
Left Lung: LUL LLL
Right lobe: RUL RML RLL

Deceased Donor Information

Name of Donor Hospital	Hospital MRN	Donor MRN

Donor Name:
Date of Birth:
Cause of Death:
Age:
Sex:
Nationality:
National ID:
Remarks on Co-morbidities:

Post-Transplantation Status

Recipient Status:
- Alive with functioning graft
- Death with functioning graft

Graft loss:
Yes No
Date:
Cause:

Death: Inside Hospital Outside
Date:
Cause:

Lost Follow-up Reasons: Routine Emergency Other:

Latest Lab Values (Required)
Lung Function Test

FVC	FEV1	FEV1/FVC	TLC	DLCO	Peak Flow	SpO2

Either of the following:
- 30 days after the discharge from transplant center for transplantation and annual anniversary of the transplant date until the recipient's death or graft failure
- 14 days from notification of the recipient's death or graft failure

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FORM-OSC-015

Form 32:
Post Kidney Nephrectomy Follow-up (Donor Form)

المركز السعودي لزراعة الأعضاء
Saudi Center for Organ Transplantation

Post Kidney Nephrectomy Follow-up

(Donor)

Name of Transplant Center	Donor MRN

Kidney Donor Demographics

Donor Name:
Date of Birth: Age:
Nationality: Sex:
Remarks National ID: #
Co-morbidities:

Date of Nephrectomy:
Which Kidney: ☐ Left ☐ Right
Recipient: ☐ Related ☐ Unrelated
Relationship:
☐ Direct ☐ Indirect
☐ PKED

Note: Date should be linked to donor information

Post-Nephrectomy Status

Donor Status:

☐ Alive
Date of last follow-up
☐ At home
☐ In hospital
☐ Lost follow up

☐ Died
☐ Inside Hospital
☐ Outside
Date:
Cause:

Remarks:
Complication Post Nephrectomy:
Medical:
Surgical:

Latest Lab Values (Required)

30 days after discharge from transplant center for transplantation then after 1-year anniversary of the donation date

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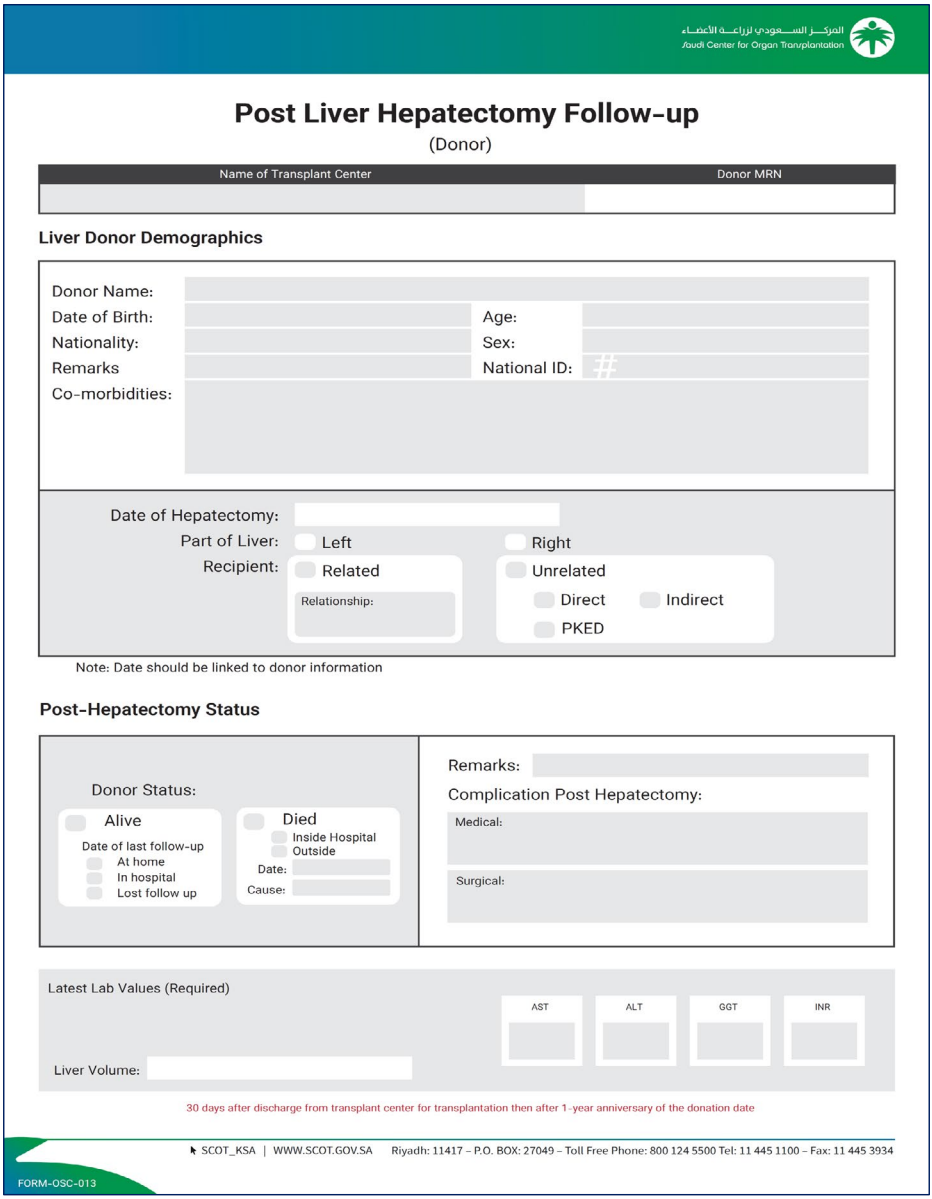
FORM-OSC-011

Form 33:
Post Liver Hepatectomy Follow-up (Donor Form)



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Saudi Center for Organ Transplantation

Post Liver Hepatectomy Follow-up

(Donor)

Name of Transplant Center	Donor MRN

Liver Donor Demographics

Donor Name:
Date of Birth: Age:
Nationality: Sex:
Remarks National ID: #
Co-morbidities:

Date of Hepatectomy:
Part of Liver: ☐ Left ☐ Right
Recipient: ☐ Related — Relationship: ☐ Unrelated — ☐ Direct ☐ Indirect ☐ PKED

Note: Date should be linked to donor information

Post-Hepatectomy Status

Donor Status:

☐ Alive
Date of last follow-up
☐ At home
☐ In hospital
☐ Lost follow up

☐ Died
☐ Inside Hospital
☐ Outside
Date:
Cause:

Remarks:
Complication Post Hepatectomy:
Medical:
Surgical:

Latest Lab Values (Required)

AST	ALT	GGT	INR

Liver Volume:

30 days after discharge from transplant center for transplantation then after 1-year anniversary of the donation date

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FORM-OSC-013

APPENDIX E
Donor Hospital Standards

1. The hospital establishes an organ donation unit (ODU) to effectively oversee and manage the provision of organ donation services.

1.1 The hospital appoints an emergency physician, intensivist, neurologist, or anesthesiologist to lead the ODU functions.

1.2 The ODU team is composed of at least a physician, nurse, and social worker or psychologist, with clear job descriptions to describe their role in organ donation.

1.3 The ODU operates under a reporting structure where it directly reports to the hospital's medical director.

1.4 The ODU oversees the timely completion of death declaration, securing donation consent, recovery of organs, and coordinating care post-donation procedures.

1.5 The ODU maintains two-way communication with the critical care team to identify potential brain death patients.

1.6 The ODU reports the list of possible donors, performance indicators, and other required information to SCOT promptly.

1.7 The hospital evaluates the effectiveness of the ODU functions through a set of performance measures.

2. The hospital appoints a qualified coordinator to assume the internal and external coordination and communication related to the donation processes.

2.1 The organ donation coordinator is a healthcare provider, with a valid license from the SCFHS.

2.2 There is a job description outlining the required knowledge, skills, and experience of the organ donation coordinator.

2.3 The organ donation coordinator facilitates the coordination process between the families of potential donors, medical teams, and relevant departments.

2.4 The organ donation coordinator assists the medical team in discussing donation possibilities with families of deceased patients and securing donation consent.

2.5 The hospital appoints an individual to assume coordination responsibilities in case of the absence of the organ donation coordinator.

3. The hospital conducts internal and external awareness campaigns to the staff members and community to raise awareness about organ donation benefits and processes.

3.1 The hospital conducts internal awareness campaigns about organ donation to keep the staff members engaged in the donation process.

3.2 The hospital provides the community with understandable information and educational materials regarding organ donation to raise public awareness.

3.3 The hospital participates in national-wide activities and events related to organ donation and transplantation.

4. The hospital establishes effective communication processes with the Saudi Center for Organ Transplantation (SCOT) regarding the donation process.

4.1 The hospital participates in the national transplant hub to register patients with end-stage organ failure.

4.2 The hospital communicates the names of possible donors with SCOT instantly, with a constant update upon changes.

5. The hospital develops policies and procedures to guide the internal and external notification of a possible brain death donor.

5.1 The hospital develops a screening procedure or protocol to assist healthcare providers in critical areas in the identification of possible organ donors.

5.2 The hospital establishes an internal notification procedure to notify ODU and the organ donation coordinator when a possible organ donor is identified.

5.3 The hospital establishes an external notification procedure to notify SCOT or the Saudi Medical Appointments and Referral Center (SMARC) when a possible organ donor is identified.

6. The hospital establishes policies and procedures to guide the diagnosis, confirmation, and documentation of brain death in accordance with the national protocol for death diagnosis using neurological criteria.

6.1 The hospital implements the national protocol for diagnosing, confirming, and documenting brain death.

6.2 The hospital prohibits the participation of the transplant team members in the process of brain death confirmation.

6.3 The hospital is equipped with the diagnostic tools that are required for death confirmation by neurological criteria, including electroencephalogram, computed tomography angiography, and transcranial Doppler ultrasound.

6.4 The documentation of brain death is completed by two physicians trained in the diagnosis of death by neurological criteria.

6.5 The hospital has a process to submit the death declaration form to SCOT for confirmed brain death cases by neurological criteria.

7. The hospital establishes a system or protocol for organ and tissue validity from deceased donors in accordance with SCOT directory and policies.

7.1 The hospital completes the medical evaluation of potential deceased donors to determine their suitability to undergo the donation process.

7.2 The hospital defines the accepted criteria and physiological measures to maintain the viability of organs and tissues intended for transplantation based on medical criteria and SCOT criteria.

7.3 The hospital defines the contraindications of organ and tissue validity, including age, malignancies, disseminated infection, idiopathic illnesses, neurological diseases, and chronic diseases based on medical criteria and SCOT criteria.

7.4 The hospital defines the required laboratory testing and imaging studies for validating organs and tissues for transplantation.

7.5 The hospital ensures that the donation process in deceased pregnant women is pursued only if the fetus is proven dead or has been delivered.

7.6 The hospital collaborates with SCOT team when additional physical and laboratory tests are deemed necessary to maintain the organ viability for donation in the possible donors.

8. The hospital develops policies and procedures to identify and manage possible transmissible diseases from deceased donors.

8.1 The hospital defines the required laboratory testing for each type of organ and tissue donation to detect diseases that may contraindicate donation.

8.2 The hospital defines the required serology testing of deceased donors, including Cytomegalovirus, Epstein–Barr virus, HIV, Hepatitis B, Hepatitis C, Toxoplasma, and other serology tests as indicated.

8.3 The hospital defines the required microbiology testing of deceased donors, including Blood culture.

8.4 The hospital defines the types of transmissible bacterial, fungal, and viral infections that contradict the donation process, absolutely or relatively.

8.5 The hospital prepares and uses an approved antibiogram to guide appropriate antibiotic selection for treating infections.

8.6 The hospital reports all positive microbiology and serology test results to SCOT instantly.

9. The hospital develops policies and procedures to identify and prevent the risk of transmitting cancer from deceased donors to the potential recipient(s).

9.1 The hospital defines the process to detect possible malignancies during donor assessment.

9.2 The hospital includes and documents malignancy history and screening in the medical evaluation of potential deceased donors prior to donation procedures.

9.3 Malignancy screening includes examination donor's skin for suspicious lesions, potential malignancies, and scars from previous surgical procedures.

9.4 The hospital defines the types of malignancies that absolutely or relatively contradict the donation process, considering the level of transmission risk.

10. The hospital develops processes to approach the family of an illegible deceased brain death donor for possible donation.

10.1 The hospital has a process to ensure that the notification of family about brain death is clear, understandable, and documented.

10.2 The hospital prohibits approaching the family before receiving a confirmation from SCOT regarding the eligibility of the deceased donor for donation.

10.3 The hospital designates a private room or space to confidentially discuss the possibility of organ donation with the next of kin of the deceased donor.

10.4 The hospital provides the family with the necessary information about the donation procedure to help them make an informed decision.

10.5 The hospital has a process to obtain donation consent from the legal next of kin of the deceased donor, whether they are inside or outside the country.

10.6 The hospital documents the family›s acceptance decision regarding the donation in the patient›s medical record using the “deceased organ and tissue donation consent form”, while documenting the refusal decision on the “reason of organ donation refusal form”.

10.7 The hospital obtains approval from the official authorities prior to the recovery of organs if the deceased person is unidentified and the family cannot be located.

11. The hospital develops policies and procedures to guide the process of organ recovery following national regulations.

11.1 The hospital establishes a process to transfer the donor to the operating room for organ recovery once the readiness of the operating room is confirmed.

11.2 The hospital implements processes and measures to avoid unnecessary delays in the surgical procedure for organ recovery.

11.3 The hospital develops a guideline to ensure successful organ recovery, along with a procedure to follow in any instances of organ recovery failure.

12. The hospital develops policies and procedures to issue and document the death certificate.

12.1 The hospital documents the death declaration by neurological criteria after the discontinuation of the mechanical ventilator support and the cessation of a heart beating.

12.2 The death certificate is signed by the anesthesiologist who supervised the organ recovery procedure in the operating room.

12.3 The death certificate is signed by the most responsible physician, intensive care physician, or emergency physician when heart cessation occurs in critical areas.

13. The hospital monitors a set of performance indicators to measure and improve the effectiveness of donation services.

13.1 The hospital monitors the availability and the amount of time dedicated to donation activities by the donation team.

13.2 The hospital monitors the percentage of comatose patients with devastating brain injuries who are referred to SCOT or SMARC.

13.3 The hospital monitors the percentage of potential organ donors who were declared dead by neurological criteria after the initial brain death exam.

13.4 The hospital monitors the timeliness of death declaration by neurological criteria after the initial brain death exam for potential organ donors.

13.5 The hospital monitors the percentage of families that are informed about the death of their relatives within 12 hours of death declaration by neurological criteria.

13.6 The hospital reviews the results of the performance indicators monthly to evaluate the effectiveness of the service and continually improve performance.

APPENDIX F
Directory Abbreviations

Abbreviation	Full Name
ABG	Arterial Blood Gas
ACC	Accreditation and Compliance Committee
ADM	Aggressive Donor Management
ALP	Alkaline Phosphatase
ALT	Alanine Aminotransferase
API	Application Programming Interface
BMI	Body Mass Index
CABG	Coronary Artery Bypass Graft
CBC	Complete Blood Count
CMV	Cytomegalovirus
COPD	Chronic Obstructive Pulmonary Disease
CPRA	Calculated Panel Reactive Antibody
CRAG	Cerebral Radionuclide Angiogram
CSF	Cerebrospinal Fluid
CVP	Central Venous Pressure
DBD	Donation after Brain Death
DCD	Donation after Cardiac Death
DAA	Direct-Acting Antiviral Agents
DDI	Donor-Derived Infection
DI	Diabetes Insipidus
DNC	Death by neurological criteria
DNR	Do Not Resuscitate
EBV	Epstein–Barr Virus
EDQM	European Directorate for the Quality of Medicines and Healthcare
EEG	Electroencephalogram
ESRD	End-Stage Renal Disease
EVLW	Extravascular Lung Water
FC	Foundational Criteria
GCC	Gulf Cooperation Council
GGT	Gamma-Glutamyl Transferase
GIST	Gastrointestinal Stromal Tumor
HBsAg	Hepatitis B Surface Antigen
HRSA	Health Resources and Services Administration
HTLV	Human T-cell Lymphotropic Virus
HFV	Heart for Valves
ID	Identification
ICU	Intensive Care Unit

Abbreviation	Full Name
IGRA	Interferon Gamma Release Assay
INR	International Normalized Ratio
KPD	Kidney Paired Donation
KDPI	Kidney Donor Profile Index
KPI	Key Performance Indicator
MAP	Mean Arterial Pressure
MDR	Multidrug-Resistant
MGUS	Monoclonal Gammopathies of Undetermined Significance
MERS	Middle East Respiratory Syndrome
MI	Myocardial Infarction
MRN	Medical Record Number
MRSA	Methicillin-Resistant Staphylococcus Aureus
NDD	Non-Directed Donors
NDMO	National Data Management Office
NAT	Nucleic Acid Test
ODU	Organ Donation Unit
OPTN	Organ Procurement and Transplantation Network

Abbreviation	Full Name
PEEP	Positive End-Expiratory Pressure
PPD	Purified Protein Derivative
PMF	Primary Myelofibrosis
RCO	Regional Coordination Offices
SARS	Severe Acute Respiratory Syndrome
SCOT	Saudi Center for Organ Transplantation
SIRS	Systemic Inflammatory Response Syndrome
TCD	Transcranial Doppler
TB	Tuberculosis
VISA	Vancomycin-Intermediate Staphylococcus Aureus
VRSA	Vancomycin-Resistant Staphylococcus Aureus
VRE	Vancomycin-Resistant Enterococcus
VZV	Varicella-Zoster Virus

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