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Saudi Center for Organ Transplantation

Heart Allocation Policy

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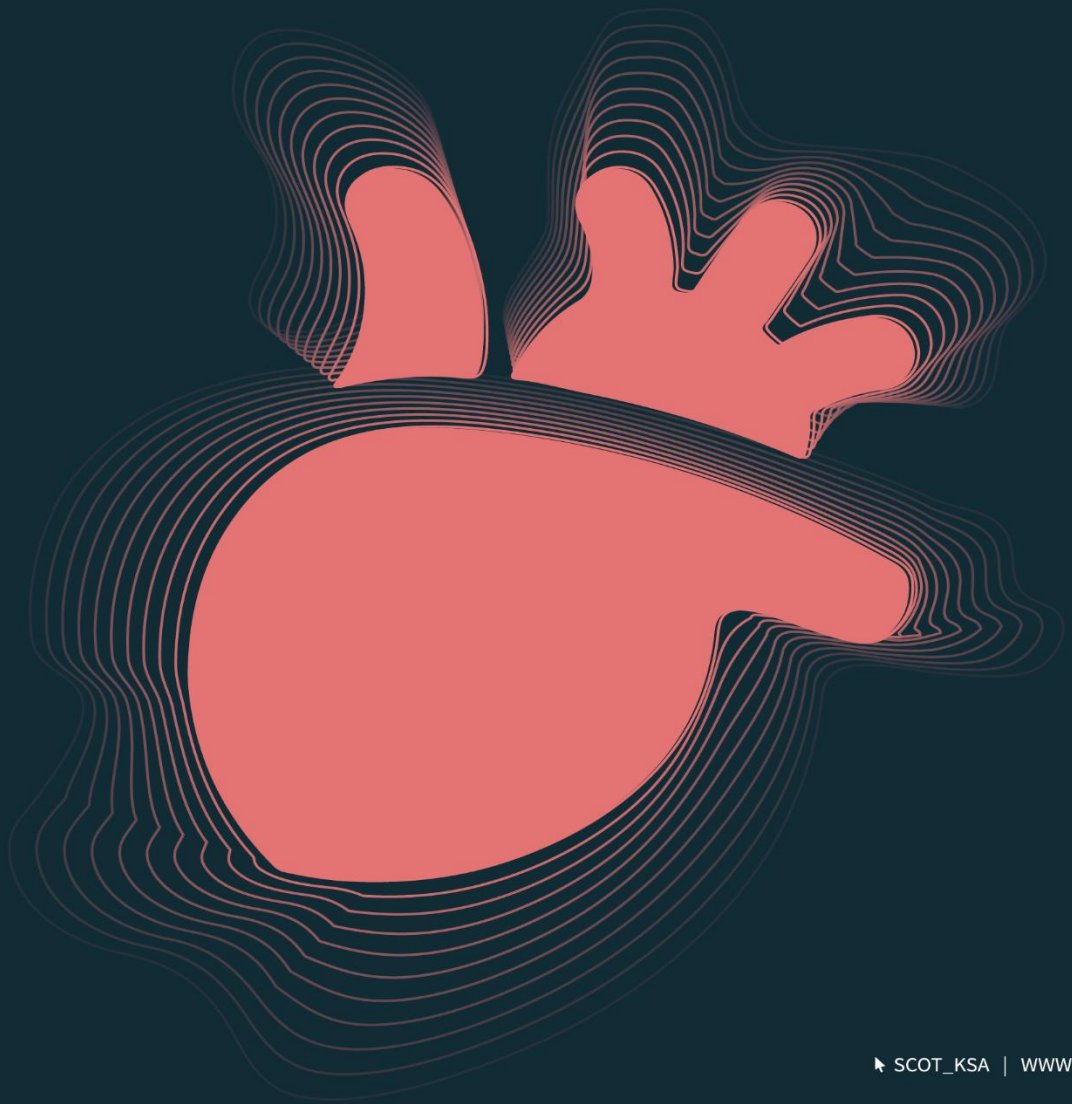

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Heart Allocation Policy

1. PURPOSE

The purpose of this policy is to ensure equitable and efficient allocation of hearts to maximize transplant outcomes and benefit patients in need.

2. RELATED DOCUMENTS

2.1 General Organ Allocation policy

2.2 Combined Organ Allocation policy

2.3 Data sharing and privacy policy

2.4 Deceased donor Management Policy

2.5 Post Consent Donor Management policy

2.6 Disposal of Discarded Human Organ/Tissue policy

3. DEFINITION

3.1 **Allocation:** the process used to match donated organs with candidates needing transplants.

3.2 **Recipient**: The patient to whom the donated human organ had been transplanted in his/her body.

3.3 **Deceased Donor:** An individual from whom at least one organ is recovered for the purpose of transplantation after declaration of death.

3.4 **Donor's Hospital:** The hospital where the deceased donor is admitted.

3.5 **SCOT coordinator**: Healthcare professionals appointed by SCOT waiting list management and organ allocation section: physicians and nursing staff.

3.6 **HLA**: Human Leukocyte Antigen

3.7 **PRA**: Panel-Reactive Antibody

3.8 **CPRA (Calculated Panel-Reactive Antibody):** A formula used to determine what proportion of deceased donors a potential candidate may be immunologically incompatible with and unable to accept organs from.

3.9 **MFI:** Mean Fluorescence Intensity

3.10 **MCS:** Mechanical circulatory support

3.11 **Berlin Heart:** A Paracorporeal pulsatile durable ventricular assist device (form of mechanical circulatory support).

3.12 **Pacemaker:** A small device implanted in the chest to help control the heartbeat.

3.13 **IABP (Intra-Aortic balloon pump):** A catheter-based mechanical circulatory support device used to temporarily support the function of the heart and improve blood flow to the coronary arteries.

3.14 **VAD (Ventricular assist device):** A mechanical pump that is used to support the function of a failing heart. It is typically used in patients with advanced heart failure. There are basically two major types of VADs that include temporary VADs that are generally catheter-based and require a patient to remain in the hospital during support and are utilized to recover native heart function or be used as a bridge to heart transplantation for patients with short, anticipated wait times. Durable VADs are surgically implanted and permit long term support (months to years) in the outpatient setting following hospital

discharge and used for those patients awaiting heart transplantation or as a long-term therapy for those who are not eligible for transplantation as destination therapy.

3.15 **VA-ECMO (Veno-Arterial Extracorporeal Membrane Oxygenation):** A type of temporary mechanical life support that provides both cardiac and respiratory support to patients whose heart and lungs are severely failing.

3.16 **Impella**: The Impella is a type of catheter-based temporary VAD that provides temporary mechanical circulatory support for patients with severe heart failure or during high-risk cardiac procedures.

3.17 **CentriMag:** The CentriMag is a type of extracorporeal (outside the body) temporary VAD that requires surgical implantation and is used for temporary circulatory support in patients with severe heart failure or following cardiac surgeries.

3.18 **Heart transplantation sub-committee:** It is a committee that branches from the national heart transplantation committee and consists of 2 to 3 members from the national committee assigned for the allocation of exceptional cases.

3.19 **Exceptional Cases:** Unique or urgent cases requiring a deviation from the standard allocation attributes.

3.20 **Cardiogenic Shock:** A state of end-organ hypoperfusion due to primary cardiac dysfunction, defined by:

3.20.1 Hypotension: SBP < 90 mmHg for ≥ 30 min or requiring vasoactive support to maintain SBP ≥ 90 mmHg

3.20.2 Evidence of hypoperfusion: oliguria (< 30 mL/h), altered mental status, cold/clammy extremities, rising lactate, acidosis, or low mixed venous O_2 saturation

3.20.3 Hemodynamics (if available): cardiac index ≤ 2.2 L/min/m^2 with PCWP ≥ 15 mmHg or CVP ≥ 10 mmHg.

4. POLICY

4.1 The responsibility of Heart Allocation relies solely on SCOT waiting list management and organ allocation section.

4.2 SCOT Organ Allocation Framework is designed to ensure fairness, optimize transplantation outcomes, and maximize the benefits for candidates in need.

4.3 SCOT policy mandates that organ allocation considers the attributes of medical urgency, compatibility, waiting time, and organ utilization.

4.4 **Medical Urgency:** SCOT policy requires that organ allocation considers the level of medical urgency of candidates, ensuring that those with the most critical medical conditions are prioritized for transplantation.

4.4.1 Allocation of heart from deceased donors follows four (4) priorities in which one (1) is the highest priority and four (4) is the lowest priority.

4.4.2 **Priority 1:**

4.4.2.1 1A) shall be assigned as follows:

4.4.2.1.1 (1A.1): Patients at imminent risk of dying due to cardiogenic shock with irreversible cause and need urgent heart transplant within 4 weeks.

4.4.2.1.2 (1A.2): Patients supported with durable MCS and **life-threatening complications** (Recurrent or intractable pump thrombosis or device malfunction with hemodynamic compromise).

4.4.2.1.3 (1A.3): Highest priority shall be assigned to patients supported with VA-ECMO followed by Bi-VAD and/or TAH.

4.4.2.2 1B) shall be assigned to:

4.4.2.2.1 Patients supported with Impella, or temporary single ventricle centrimag or Single ventricle Berlin Heart

4.4.2.2.2 Patients supported with durable MCS and serious complications, such as device hemolysis or systemic device-related infection.

4.4.2.2.3 Patients with complex congenital heart disease who are inotropes dependent and not VAD candidates.

4.4.2.2.4 Pediatric patients with single VAD Berlin Heart.

4.4.2.3 1S) shall be assigned to highly sensitized patients with high CPRA (> 80%), (in 2 measurements at least 1 month apart, considering only MFI > 5000 in those who can undergo virtual crossmatch testing)**.**

4.4.3 **Priority 2**:

4.4.3.1 2A) shall be assigned to:

4.4.3.1.1 patients who have a relatively high medical urgency, this includes **adult patients dependent on inotropes**, **defined as:** Presence of advanced heart failure requiring continuous intravenous inotropic therapy to maintain adequate systemic perfusion and prevent end-organ dysfunction, where Attempts to wean off inotropes result in recurrent hypotension, low output, or worsening renal/hepatic function or end-organ hypoperfusion.

4.4.3.1.2 Pediatric patients stable with LVAD (HM3) BUT spent more than 2 years on the waiting list

4.4.3.1.3 Pediatric patients with restrictive cardiomyopathy (RCM) due to high risk of death or development of Pulmonary Hypertension

4.4.3.2 2B) shall be assigned to:

4.4.3.2.1 Adult patients with hypertrophic or restrictive cardiomyopathy who are not VAD candidates, (with pulmonary vascular resistance index > 6 WU/m2).

4.4.3.2.2 Patients who are listed for heart-lung transplantation.

4.4.4 **Priority 3 shall be assigned** in the following priority sequence:

4.4.4.1 Patients that are admitted to hospital with decompensation, and do not meet any other criteria.

4.4.4.2 Patients that are listed for combined organ transplantation, and do not meet any other criteria.

4.4.4.3 Patients with durable MCS do not meet any other criteria.

4.4.4.4 Pediatric patients with HM3 stable.

4.4.5 **Priority 4 shall be assigned to:**

4.4.5.1 All other listed patients, who do not meet any other criteria.

4.5 **Compatibility:**

4.5.1 **Allocation of Heart by Blood Type**: the allocation process of donated heart is based on identical blood group, except in highly sensitized patients (Patients with high CPRA > 80%) and pediatric patients less than 2 years old a heart can be offered to compatible recipient.

4.5.2 **HLA matching:** is not currently used in the allocation of heart transplant donors due to shortage of donor organs and ischemic time. However, HLA mismatch might have a negative impact on the transplant outcome compared to more matching between donor and recipient.

4.5.3 **The calculated panel reactive antibodies (CPRA):** which directly estimates the proportion of donor candidates that is HLA incompatible is used in the allocation process. Donor specific antibodies (DSA) should be avoided as much as possible, otherwise desensitization might be necessary to mitigate the negative impact of DSA on the transplant outcome.

4.6 **Waiting Time:**

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

4.6.2 It Is the sole responsibility of transplant centers to continuously update and submit their waiting list data to SCOT.

4.6.3 Transplantation centers must update their waitlists on a weekly basis, and centers are required to notify SCOT immediately of any significant updates or changes in patient status to ensure timely and accurate information.

4.6.4 SCOT maintains authority over managing waiting lists, emphasizing the importance of accurate and timely data submissions to ensure fair organ allocation.

4.6.5 Transplant centers are required to submit their waiting lists including all requested information as specified by SCOT based on the organ type.

4.7 **Organ Utilization:**

4.7.1 To maximize organ utilization, factors such as the heart's suitability for transplantation, the likelihood of a successful outcome, the proximity of candidates to the donor and logistical issues must be taken into consideration during heart allocation.

4.7.2 In the absence of urgency, the allocation process shall account for the distance and transportation feasibility between the donor and potential recipients to ensure efficient utilization of available heart (i.e. shorter cold ischemia time).

4.8 Exceptional cases will be evaluated individually by the heart transplantation sub-committee, which will convene as needed when an exceptional case arises prior to the allocation process.

4.9 Once the heart is allocated, SCOT will not permit any changes to the heart allocation. However, SCOT retains the authority to withdraw the offer if the allocation is found to be in violation of the rules established in this policy.

4.10 SCOT coordinator in charge shall ensure that all correspondence, including emails, letters, and other forms of communication are documented promptly and accurately with the dates & times.

4.11 If the initial allocation process for the heart was unsuccessful for any reason, SCOT takes full responsibility for ensuring that the organ is utilized effectively following SCOT's General Organ Allocation Policy.

4.12 All documentation shall be handled in accordance with applicable privacy and data protection laws and regulations.

4.13 Access to allocation documentation shall be limited to authorized personnel involved in the organ allocation process, maintaining confidentiality, and protecting sensitive information.

4.14 The allocation policy shall be reviewed periodically to ensure its effectiveness, relevance, and alignment with SCOT regulatory requirements. Any necessary revisions or updates shall be made in a timely manner.

5. PROCEDURE

5.1 SCOT commences the allocation process, within 1 hour after obtaining consent for organ donation.

5.2 SCOT coordinator shall request post consent donor workup from donor hospitals for the heart. (Refer to Table 1: Routine Donor Workup)

5.3 SCOT coordinator shall promptly review the case details, ensure data completion and diligently assess the viability of the heart based on the established criteria. Table 2: Heart Acceptance Criteria

5.4 Following the viability assessment, SCOT coordinator shall allocate the heart according to the allocation attributes outlined in this policy.

5.5 SCOT coordinator shall allocate the heart to 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

5.6 SCOT coordinator shall promptly contact the coordinator at the patient's transplant center to make the heart offer and provide all relevant donor information.

5.7 The transplant center has a maximum of 1 hour to initially accept the offer, during this period, the transplant center may request further investigations.

5.8 SCOT coordinator shall ensure that all necessary workups are done and submitted to the accepting transplant center effectively.

5.9 Any new data obtained during the workup process shall be promptly submitted to the initially accepting center.

5.10 Once the transplant center receives all necessary/requested data about the donor, they must provide a final acceptance or rejection within 1 hour using (Organ and Tissue Acceptance/Rejection form)

5.11 Failure to respond within 1 hour will exclude the center from the allocation of that heart and will be considered as refusal.

5.12 In case of rejection, the transplant center must provide a valid reason for the rejection using. (Organ and Tissue Acceptance/Rejection form)

5.13 The reason for rejection by the initially accepting center must be shared with the backup centers, informing the next backup center that they have become the primary center for the heart.

5.14 During heart recovery, the primary transplant center may reject the heart based on macroscopic examination.

5.14.1 The primary transplant center must complete the Organ and Tissue Acceptance/Rejection form and send it to SCOT. SCOT coordinator shall inform the backup transplant center of the rejection and the reason behind it.

5.15 If the heart is not accepted by any transplant center due to unsuitability for transplantation, the transplant center coordinator must fill the Deceased Organ Discard Report according to SCOT's (Disposal of Discarded Human Organ/Tissue Policy).

5.16 If the heart is transplanted, the transplant center shall complete the Post Organ Transplantation Form within 24 hours of the transplantation date.

5.17 SCOT coordinator responsible for allocation shall document the entire allocation process using Organ Allocation Form.

5.18 The heart allocation process is considered concluded once the heart has been successfully transplanted to the recipient.

6. RESPONSIBILITY

6.1 The responsibility of implementing and ensuring compliance with the developed Policy and Procedure lies with Donor Affairs & Organ Allocation Department.

7. SYNOPSIS OF CHANGE

New

8. APPENDICES

8.1 Table 1: Routine donor workup

8.2 Table 2: Heart Acceptance Criteria

8.3 Organ and Tissue Acceptance/Rejection form

8.4 Organ Allocation Form

8.5 Post Organ Transplantation Form

8.6 Deceased Organ Discard report

9. REFERENCES

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9.3 SCOT, "Directory of the Regulations of Organ Transplantation in the Kingdom of Saudi Arabia." 2023. [Online]. Available: www.SCOT.gov.sa

9.4 Cardiac Transplantation: Eligibility and Listing Criteria in Canada: https://doi.org/10.1016/j.cjca.2019.12.025

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APPENDIXES

10. Heart Transplantation Scientific Committee
Dr. Osama Almqbel (Chairman): Consultant of Cardiology, Echocardiography, Advanced Heart Failure & Transplant and Cardio-Oncology - King Saud University Medical City, Riyadh
Dr. Abeer Bakhsh (Vice-Chairman): Consultant of Cardiology and Transplantation – Prince Sultan Military Medical City, Riyadh
Dr. Feras Khalel: Heart Transplant Consultant Surgeon King Faisal Specialist Hospital & Research Center (KFSHRC) Riyadh
Dr. Ahmed AlMustafa: Consultant, Advanced Heart Failure & Transplant Cardiology – King Faisal Specialist Hospital & Research Centre, Riyadh
Dr. Abdullah Al-ghamdi: Cardiac Surgery & Cardiothoracic Transplantation – King Abdulaziz Medical City and National Guard Hospital, Riyadh
Dr. Nedim Selimovich: Consultant of Cardiology and Transplantation – King Abdulaziz medical City and National Guard Hospital, Riyadh
Dr. Adam Mohammed: Consultant of Cardiology and Transplantation – Prince Sultan Military Medical City, Riyadh

Table 1: Routine Donor Workup:

A. Routine workups to all donors that should be done during case follow up							
Routine Workups	▪ Blood culture ▪ Urine culture ▪ Throat culture ▪ Serology	▪ Blood type ▪ Liver enzyme ▪ Electrolyte ▪ CBC	▪ Blood gases ▪ HLA **(Only to be done after the consent obtained)** ▪ Surveillance MRSA : Groin, Axilla, Nasal				
B. Routine workups to all donors by organ/tissue							
Organs	**Lung**	**Heart**	**Liver**	**Kidney**	**Pancreases**	**Intestinal**	**Cornea**
Routine Workups	▪ Challenge test ▪ Chest x-ray ▪ CT lung windows ▪ Bronchoscopy ▪ TB PCR from tracheal aspirate ▪ Pneumonia panel ▪ Covid test	▪ Cardiac Cath ▪ Echo ▪ ECG	▪ Liver function tests with bilirubin ▪ Coagulate profile ▪ GGT ▪ Albumin ▪ US/ CT abdomen	▪ kidney function tests ▪ electrolytes ▪ US/CT Abdomen ▪ Total intake/output	▪ Amylase ▪ Lipase ▪ HbA1c ▪ US/ CT Abdomen	▪ Abd girth ▪ Amylase ▪ Lipase	▪ Serology specially, HBc antibodies.

Table 2: Heart Acceptance Criteria:

Heart Acceptance Criteria
The Heart of the deceased's donor is considered valid for donation except in the following cases: ▪ Greater than 65 years old ▪ History of coronary artery bypass graft (CABG) ▪ History of coronary stent/intervention ▪ Current or past medical history of myocardial infarction (MI) ▪ Severe vessel diagnosis as supported by cardiac catheterization (that is more than 50 percent occlusion or 2+ vessel disease) ▪ Acute myocarditis or endocarditis, or both ▪ Heart failure due to cardiomyopathy ▪ Internal defibrillator or pacemaker ▪ Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair. ▪ Serial echo results show severe global hypokinesis. ▪ Cardiac Tumor **Discuss with transplant centers or request more investigation in the following cases:** ▪ If age above 45 years and/or significant history of cardiovascular disease and/or abnormal cardiac investigations. ▪ If the deceased donor had a previous severe chest trauma that caused damage to the heart. ▪ Complex Congenital Heart Defects (surgically corrected or not)

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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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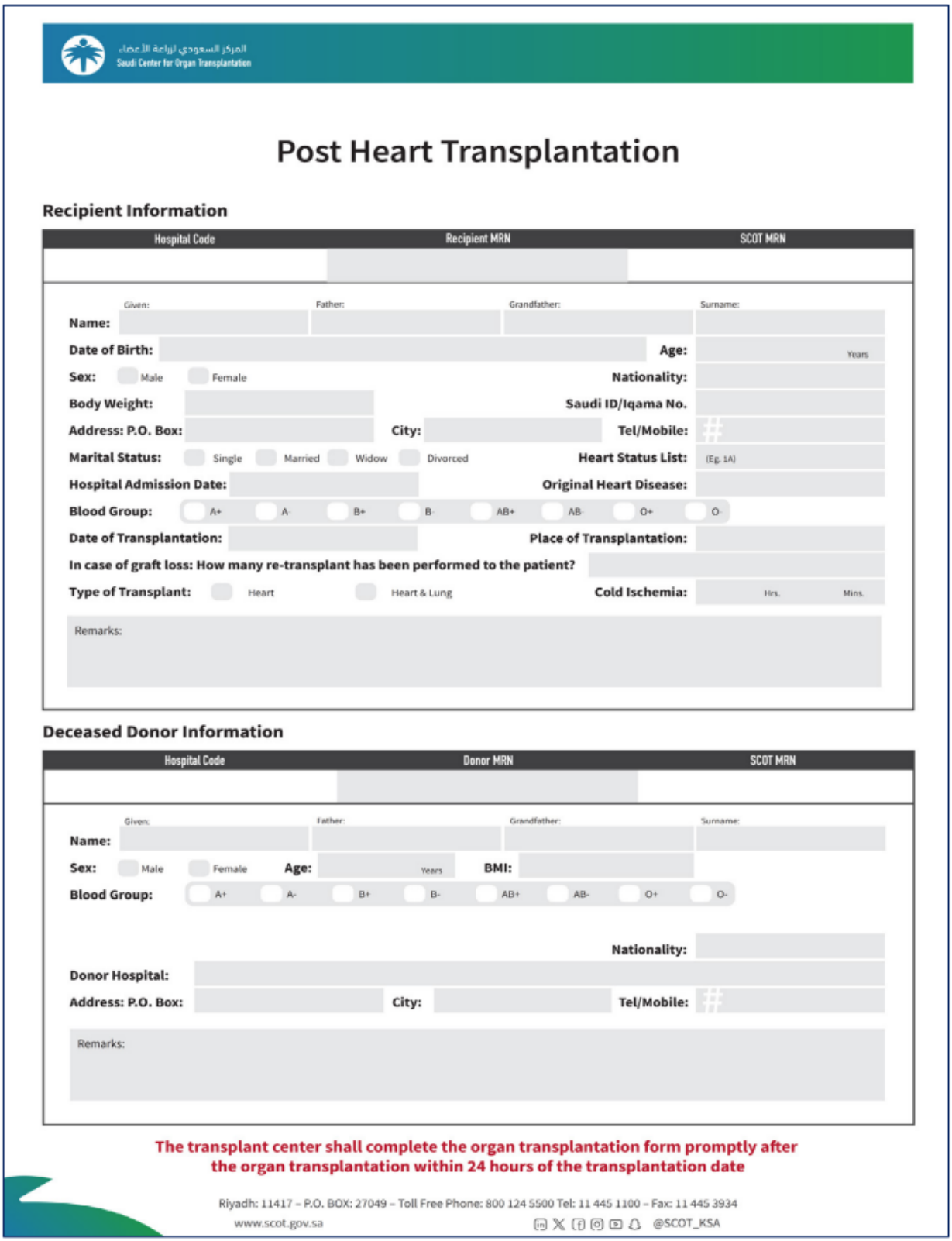
FORM-OSC-009



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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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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**

Date/Time:

☐ **Rejected**

Kindly indicate the reason:

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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