



Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

ASSESSMENT TOOL FOR LICENSING A KIDNEY TRANSPLANT FACILITY

Name of Hospital : _____

Address of the Hospital : _____
: _____

I. GENERAL INFORMATION

Owner : _____
Chief of Hospital/CEO/Medical Director : _____

Hospital Category : Secondary Care []
Tertiary Care []

Ownership : Government []
Private []

Hospital License Number : _____
Validity : From _____ To _____

II. ADMINISTRATIVE SERVICE

1. Organization/Program Setup and Goals

Efficient and effective governance ensure a planned and coordinated service delivery system appropriate to the needs of patients, families and service providers.

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1.1 An organizational chart and structure, [] Yes [] No Remarks
showing the scope of authority, function and responsibilities of the various personnel and the lines of communication among them, is placed in a location readily seen by the public.

1.2 A Hospital Organ Donation Program is [] Yes [] No Remarks
created to oversee organ donation activities and process in the hospital.

2. Medical Records

Medical records contain patient information that is uniquely identifiable, accurately recorded, current, confidential and accessible when required.

- 2.1 Medical diagnoses, procedures and/or operations performed on patients are recorded using ICD – 10. Yes No Remarks
- 2.2 A donor/recipient registry is properly recorded and filed using prescribed form by the Philippine Organ Donation Program. Yes No Remarks
- 2.3 Patient Charts are properly and completely filled up and contain up-to-date information on the following: Yes No Remarks

Content of Patient Chart	(/) if Available
Identification Data	
Consent	
Chief Complaint	
History of Present Illness	
Physical Examination	
Diagnosis	
Attending Physician	
Clinical Laboratory Reports	
Imaging Reports	
Doctor's Order Sheet	
Consultation/Referral Notes	
Progress Notes	
Medication/Treatment	
Nursing Record	
Operating Room Record	
Anesthesia Record	

- 2.4 Confidentiality of patient information is maintained at all times. Yes No Remarks

3. Auditory and Visual Privacy

Remarks

Adequate privacy for counseling donors/recipient is provided such that sensitive or private discussion, examination, and/or procedure are conducted in a manner or environment where these cannot be observed or the risk of being overheard by others is minimized.

Yes

No



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IV. ANCILLARY SERVICES

1. Ancillary services, provided by the hospital itself or through affiliation with other health facilities, are licensed/accredited by the Department of Health. [] Yes [] No Remarks

2. Whether ancillary services are provided by the hospital itself or through affiliation, there is a certification from the head of the health facility that it is capable of providing the ancillary services. [] Yes [] No Remarks

3. The hospital maintains a list of licensed/accredited health facilities providing ancillary services with which it is affiliated. [] Yes [] No Remarks

4. Nuclear Scan is licensed by the Philippine Nuclear Research Institute. [] Yes [] No Remarks

SERVICES	AVAILABILITY (/ if provided by hospital)	NAME OF REFERRAL LABORATORY/ HEALTH FACILITY
A. Laboratory		
1) Routine tests including chemistries		
2) Microbiology/Parasitology		
• AFB Smear		
• Gram's stain		
• Malarial smear		
• Culture & sensitivity		
- Bacteria		
- Fungi		
- TB		
3) Serology/Virology		
• HIV		
• VDRL		
• HbsAg		
• Anti-HCV		

SERVICES	AVAILABILITY (./ if provided by hospital)	NAME OF REFERRAL LABORATORY/ HEALTH FACILITY
• CMV IgG		
• CMV IgM		
• EBV IgG		
4) Histopathology		
5) Blood Banking		
6) Immunosuppressive drug level monitoring studies for the following: *		
• Tacrolimus		
• Sirolimus		
• Cyclosporine A		
B. Imaging		
1) Routine Xray		
2) Ultrasound with Doppler		
3) CT Scan *		
4) Nuclear Scan * (including function studies)		
C. Immunology		
1) Blood group and matching		
2) HLA typing *		
3) Tissue cross-matching *		
D. Dialysis		
* Write the name of the referral laboratory or health facility if these services are not provided		



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V. QUALITY MANAGEMENT

Effective and efficient methods are used to identify areas for improvement of the quality management system performance.

1. The hospital has an established, documented and maintained quality management program on organ donation and transplantation that reflects continuous quality improvement principles. [] Yes [] No Remarks
2. Availability of Quality Assurance Committee. [] Yes [] No Remarks
3. The duties and responsibilities of the Quality Assurance Committee are set in accordance with the guidelines prescribed by the Philippine Organ Donation Program. [] Yes [] No Remarks

Committee	Availability of Documentation on Committee Membership (/ if Available)	Availability of Written Policies and Procedures (/ if Available)	Availability of Minutes of Meetings (/ if Available)	Availability of Monitoring and Evaluation Reports (/ if Available)

4. The committees meet periodically to review and update existing policies and make new policies when necessary. [] Yes [] No Remarks

5. The hospital has a Manual of Operations on Organ Donation and Transplantation that is based on the operational guidelines set by the Philippine Organ Donation Program (PODP) and includes, among others, the following:

Remarks

- | | | | | |
|--|-----|-----|-----|----|
| 5.1 Policies and Ethical Standards | [] | Yes | [] | No |
| 5.2 Protocol for Quality Control | [] | Yes | [] | No |
| 5.3 Protocol for Screening of Donors and Recipients | [] | Yes | [] | No |
| 5.4 Protocol for Pre-Operative Work-up of Donor and Recipients | [] | Yes | [] | No |
| 5.5 Protocol for Intra-Operative Procedures | [] | Yes | [] | No |
| 5.6 Protocol for Post-Operative Management, including Pain Management for: | | | | |
| 5.6.1 Recipients | [] | Yes | [] | No |
| 5.6.2 Donors | | | | |
| 5.6.2.1 One week post-transplant | [] | Yes | [] | No |
| 5.6.2.2 Three months post-transplant | [] | Yes | [] | No |
| 5.6.2.3 One year post-transplant | [] | Yes | [] | No |



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VI. PERSONNEL

The health facility appoints and allocates personnel who are suitably qualified, skilled and/or experienced to provide the service and meet patient needs.

1. Each personnel is qualified, skilled and/or experienced to assume the responsibilities, authority, accountability and functions of the position. [] Yes [] No Remarks

2. Professional qualifications are validated, including evidence of professional registration/license, where applicable, prior to employment. [] Yes [] No Remarks

3. An organized medical and nursing staff shall be responsible for the quality of patient care and for the ethical conduct and professional practices of its members. [] Yes [] No Remarks

COMPOSITION OF THE TRANSPLANTATION TEAM	ACCREDITATION FROM SOCIETY/ CERTIFICATE OF TRAINING	COMPLIANCE (/ if Compliant)	REMARKS
Transplant Surgeon/s			
Donor Surgeon/s			
Nephrologist/s			
Infectious Disease Consultant/s (available for referral)			
Transplant Immunologist/s (optional)			
Anesthesiologist/s			

COMPOSITION OF THE TRANSPLANTATION TEAM	ACCREDITATION FROM SOCIETY/ CERTIFICATE OF TRAINING	COMPLIANCE (/ if Compliant)	REMARKS
OR Nurse/s			
OR Surgical Technician/s			

4. Members of the Transplantation Team are [] Yes [] No Remarks

accredited specialists of their respective societies.

- ✓ A Transplant Surgeon accredited by Philippine Society of Transplant Surgeons
- ✓ A Donor Surgeon accredited by the Philippine Urologic Association
- ✓ A Nephrologist certified by the Philippine Society of Nephrology
- ✓ A Infectious Disease Consultant accredited by the Philippine Society of Microbiology and Infectious Disease
- ✓ A Trained Anesthesiologist certified by the Philippine Society of Anesthesiology
- ✓ Operating Room Nurses registered by the Professional Regulation Commission

6. The following records are attached to the living donor' record:

	Documentation (/ if Available)	Remarks
Pre-transplant Orientation Attendance Certificate		
Psychiatric Evaluation		
Social Service Evaluation for LNRD		
Donor Clinical Summary		
Medical Clearance (photocopy)		
Deed of Donation *		
Written Informed Consent		
Ethics Committee Certificate of Action *		
Abstract of Donor's Operation and Discharge		
Health Status before Discharge		
Follow-ups (1 wk, 3 months, 1 year and thereafter)		
* For LNRD only		

7. The Hospital Ethics Committee submits a report to National Transplant Ethics Committee (NTEC). [] Yes [] No Remarks

8. Informed Consent and Counseling Remarks

The Attending Physician ensures that the donor has given a written, full informed consent to organ donation under the following conditions:

8.1. Informed consent was given voluntarily. [] Yes [] No

8.2. The donor and his/her family are given full information on the risks and benefits of organ donation. [] Yes [] No

8.3. The donor and family were given enough time to discuss the organ donation. [] Yes [] No

8.4. The donor was informed that he has the right to refuse or withdraw consent at any time. [] Yes [] No

9. In addition to the written informed consent obtained from the donor by the attending physician and the Pre-Transplant Orientation Seminar, individualized counseling adapted to the donor's case is provided to the donor by a competent health professional in the presence of the donor's next of kin (family witness). [] Yes [] No Remarks

10. Foreign Organ Donors and Recipient Remarks

Foreign donors are evaluated according to the guidelines of the NTEC [] Yes [] No

	Previous Year		Current Year	
	Adult	Pediatric	Adult	Pediatric
No. of foreign recipients with foreign donors				
No. of foreign recipients with Filipino donors				
No. of Filipino recipients with Filipino donors				



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IX. EQUIPMENT/ INSTRUMENT

All equipment and instruments necessary for the safe and effective provision of services are available and are properly maintained.

1. Records of equipment are maintained and updated regularly. [] Yes [] No Remarks
2. A preventive maintenance program ensures that all equipment are maintained and/or calibrated to an appropriate standard or specification. [] Yes [] No Remarks
3. There is a plan in place for essential equipment replacement. [] Yes [] No Remarks
4. Personnel are competent when using equipment in line with manufacturer's instructions/operational manual. [] Yes [] No Remarks
5. Operational manuals of all equipment and instruments are available for reference and guidance. [] Yes [] No Remarks

ITEM	COMPLIANCE (/ if Compliant)	CONDITION (/ if Serviceable)	REMARKS
Equipment *			
• Anesthesia machine w/ capnograph			
• Pulse Oximeter			
• Cardiac Monitor			
• Electrocautery machine			
Instruments *			
• Standard Laparotomy set			
• Vascular clamps (peripheral and/or curved)			
• Bulldog clamps (curved and straight)			
• Vascular needle holders			
• Vascular loop			

ITEM	COMPLIANCE (/ if Compliant)	CONDITION (/ if Serviceable)	REMARKS
• Rubber shods			
• Balfour retractor/book walter retractor			
• Back table (for kidney perfusion)			
• Fine forceps			
• Fine scissors			
• Fine mosquito clamp			
• Perfusion cannula			
* Other Operating Room Equipment/ Instruments are already included as requirements for hospital license.			



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Name of Hospital: _____

Date of Inspection: _____

RECOMMENDATIONS:

A. For Licensing Process:

For issuance of Certificate of Accreditation as Kidney Transplant Facility.

Validity from _____ to _____

Issuance depends upon compliance to the recommendations given and submission of the following within _____ days from the date of inspection:

Non-Issuance: Specify reason/s. _____

Inspected by:

Printed Name

Signature

Position/Designation

Received by:

Signature _____

Printed Name _____

Position/Designation _____

Date _____



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Name of Health Facility: _____

Date of Monitoring: _____

RECOMMENDATIONS:

A. For Monitoring Process:

Issuance of Notice of Violation

Non-issuance of Notice of Violation

Others (Specify) _____

Monitored by:

Printed Name

Signature

Position/Designation

Received by:

Signature _____

Printed Name _____

Position/Designation _____

Date _____