11. **Registration and functions of recognized medical institution or hospital.**- (1) An application for registration shall be made to the Monitoring Authority as specified in Form 11. The application shall be accompanied by a processing fee of rupees two hundred thousands to the Monitoring Authority paid into Authority’s authorized bank account as processing fee to be used on the activities of the Authority.

(2) The Monitoring Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements, grant a certificate of interim registration as specified in Form 12. After inspecting the hospital physically the Monitoring Authority shall grant a certificate of registration in Form 13 which shall be renewable on the payment of renewal fee of rupees one hundred thousands on yearly basis to be paid into Authority’s authorized bank account to be used on the activities of the Authority.

(3) Every recognized institution shall maintain complete record of all transplants undertaken including details of the donor. All such institutions shall report to the Monitoring Authority on the follow-up of the donor and the recipient. The record of follow-up shall be maintained in a manner as laid down in Form 14 and Form 15.

(4) Transplant Registry Form specified in Form 16, Form 16(a), Form 16(b) and Form 16(c) in respect of each and every transplant done by the recognized institution shall be submitted to Authority on day of operation by electronic mail or fax, followed by a copy by post and processing fee to be fixed by the Authority from time to time.

12. **Renewal of registration.**- (1) An application for the renewal of a certificate of registration shall be made to the Monitoring Authority within a period of three months prior to the date of expiry of the original certificate of registration and shall be accompanied by a fee of rupees two hundred thousands payable to the Monitoring Authority into it’s bank account.

(2) A renewal certificate of registration as specified in Form 17 shall be valid for one year.

(3) If, after an inquiry including inspection of the hospital and scrutiny of its past performance and after giving an opportunity of being heard to the applicant, the Monitoring Authority is satisfied that the applicant, since grant of certificate of registration under sub-rule (2) of rule 11 has not complied with the requirements of the Act and the Rules made thereunder and conditions subject to which the certificate of registration has been granted, shall for reasons to be recorded in writing, refuse to grant renewal of the certificate of registration.

13. **Essential Conditions for grant of certificate of registration.**- No hospital shall be granted a certificate of registration under the Act unless it fulfils the following requirement of manpower, equipment, specialized services and facilities etc., as laid down below,-
(a) General manpower requirement, specialized services and facilities,-

(1) twenty four hours availability of medical and surgical, (senior and junior) staff;

(2) twenty four hours availability of nursing staff, (general and specialty trained);

(3) twenty four hours availability of intensive care units with adequate equipments, staff and supports system, including specialists in anaesthesiology, intensive care;

(4) twenty four hours availability of laboratory with multiple discipline testing facilities including but not limited to microbiology, biochemistry, pathology and hematology and radiology departments with trained staff;

(5) twenty four hours availability of operation theatre facilities for planned and emergency procedures with adequate staff, support system and equipments;

(6) twenty four hours availability of communication system, with power backup, including but not limited to multiple line telephones, public telephone systems, fax, computers and paper photo-imaging machine; and

(7) experts, (other than the experts required for the relevant transplantation) of relevant and associated specialties including but not limited to and depending upon the requirements, the experts in internal medicine, diabetology, gastroenterology, nephrology, neurology, paediatrics, gynaecology, immunology and cardiology etc., should be available to the transplantation centre;

(b) Equipments.- Equipments as per current and expected scientific requirements specific to organ being transplanted. The transplant centre shall ensure the availability of the accessories, spare-parts and back-up, maintenance and service support system in relation to all relevant equipments;

(c) Experts and their qualifications,-

(i) For Kidney transplantation,-

FCPS or M.S. General surgery or Urology or equivalent qualification with three years post FCPS or M.S. training in a recognized centre in Pakistan or abroad and having attended to adequate number of renal transplantation as an active member of team;

(ii) Transplantation of liver and other abdominal organs,-
FCPS or M.S. General surgery or equivalent qualification with at least three years post FCPS or M.S. training in an established centre with reasonable experience of performing liver transplantation as an active member of team;

(iii) Cardiac, pulmonary, cardio-pulmonary transplantation,-

FCPS or M.S Cardio-thoracic and vascular surgery or equivalent qualification in Pakistan or abroad with at least three years experience as an active member of the team performing an adequate number of open heart operations per year and well-versed with coronary by-pass surgery and heart-valve surgery; and

(iv) Cornea transplantation,-

FCPS or M.S. ophthalmology or equivalent qualification with at least one year post FCPS or M.S. training in a recognized hospital carrying out corneal transplant operations.

Form-11
[See Rule 11(1)]

APPLICATION FOR REGISTRATION / RECOGNITION OF INSTITUTION / UNIT FOR TRANSPLANTATION
Proforma to be completed and sent to Human Organ Transplant Authority (HOTA), 36 Aga Khan Road, Super Market, F-6/4, Islamabad, Fax No.051-9216107

Name of the Institution ________________________________
Mailing Address ______________________________________
Tel No._________________ Fax No._________________ Email ______________________________

Name of the Head of the Institution _____________________________
Designation__________________________Mailing Address______________________________
Tel No._________________ Fax No._________________ Email ______________________________

Status of Institution  [ ] Public Sector  [ ] Private  [ ] Any other________________________

Specialty units/departments accredited with CPSP/PMDC/University __________________________

<table>
<thead>
<tr>
<th>S. No</th>
<th>Name of Specialty</th>
<th>Accreditation Authority</th>
<th>Name of Deptt. Heads With postgraduate qualifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Urology (Kidney Transplant)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Nephrology</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3. GI and Hepatology (Liver & intestinal transplant)

4. Pulmonology (Lung Transplant)

5. Cardiology (Cardiac Transplant)

6. Hematology (BMT, Stem cell Transplant)

7. Ophthalmology (Corneal Transplant)

8. Radiology

9. Anesthesiology

10. Pathology

(Please provide list of faculty in all Specialties with qualification and experience in Transplant as Annexure)

Total beds in the institution _________ Male _________ Female _________ Children _________

No. of OPDs _______ Attendanece/year Male _______ Female _______ Children _______

Total beds in Transplant Unit: _________ Male _________ Female _______ Children _______

SUPPORT FACILITIES

**Blood bank**

Is the blood bank present? Yes No

If No please specify about storage ________________________________

Are cross matching facilities available? Yes No

Are blood products available in house? Yes No

If No. what arrangements are in place for 24 hours availability ________________

(Attach separate sheet if needed)

**Laboratory**

Please supply a list of tests, which are done in the laboratory in the following area.

(Attach separate sheet if needed)

Bio- Chemistry __________________________________________________________

Histopathology _________________________________________________________

Microbiology ____________________________________________________________

Hematology _____________________________________________________________

Immunology _____________________________________________________________

Drug Monitoring _________________________________________________________

**Radiology**

Please furnish a list of radiological test routinely carried out in the Institution

(Attach separate Sheet if needed)

Specialized diagnostic facilities:
Ultrasound  Yes ☐ No ☐ MRI Yes ☐ No ☐
CT Scan  Yes ☐ No ☐ Radioisotopes Yes ☐ No ☐
Doppler  Yes ☐ No ☐ Portable X-Ray Yes ☐ No ☐

**Intensive Care Unit**
If yes No. of ICU beds with high end monitoring and ventilation ________________
Number of Monitors __________ Total ventilator available ________________
ABG machine in ICU Yes ☐ No ☐ Other Facilities _______________________

___________________________________________

**Dialysis**  Yes ☐ No ☐ Availability of dialysis facility in ICU  Yes  NO
If yes No. of Dialysis machine in hospital __________ Number of Sessions / day ________
If the following Specialties are not available in house please mention the arrangements for
access at all time (Attach separate sheet if needed).

**Cardiology**

**Pulmonology**

**GI / Hepatology**

**Infectious Disease**

**Neurology**

**Orthopedics**

**Operation Theatre and Anesthesiology**
Please provide List of Equipment available for Transplant surgery as annexure.

**Record Keeping**
System of storage and retrieval of records_______________________________

Do you produce Annual Report? ☐ Yes ☐ No
(If yes please furnish the copy of annual report of last year)

How are the case records maintained? ☐ Manual ☐ Computerized

**Library**
☐ Yes ☐ No
Working days of the library ___________________ Daily working hours ________________
(Please provide the list of Textbooks of Transplant Sciences and Journals available in the Institution
Department)

**Research Facilities:**
No. of in hand projects and title of research conducted by the faculty of the department:
(Attach separate sheet if needed)

**Additional Essential Activities / Facilities**
<table>
<thead>
<tr>
<th>Service</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nursing</strong></td>
<td>Adequate number and of sufficient seniority to cover Transplant ward ICU</td>
</tr>
<tr>
<td><strong>Medical Social Officer (Transplant Coordinator)</strong></td>
<td>Depending on transplant activity minimum of 3 to help put pre transplant assessment and donor selection</td>
</tr>
<tr>
<td><strong>Isolation Facility</strong></td>
<td>1 to 2 rooms for isolation of patients when required</td>
</tr>
<tr>
<td><strong>Pharmacy</strong></td>
<td>Dedicated staff to respond to needs of transplant patients specially immunosuppressant, antibiotics and other drugs</td>
</tr>
<tr>
<td><strong>Seminar Room</strong></td>
<td>For daily patient related Meetings (AM and PM). Morbidity Mortality review, Clinical Audits</td>
</tr>
<tr>
<td><strong>Other resources</strong></td>
<td>Computers, Video films, internet access, multimedia Videoconferencing facilities with reference centre in future</td>
</tr>
</tbody>
</table>
CERTIFICATE OF INTERIM REGISTRATION

In pursuance of Section 6, Sub-section (3) of “The Transplantation of Human Organs and Tissues Act, 2010 (VI of 2010)” ________________ Hospital has been accorded Interim Recognition for ____________________________ transplantation.

2. Interim Recognition will NOT be a guarantee for formal recognition, which will be subject to detailed scrutiny of the hospital record, infrastructure, faculty and facilities available for transplant procedures. Hospital/institutions will facilitate the Inspection Team and provide free access to necessary information/record/data.

Administrator
Human Organ Transplant Authority (HOTA)

Official Seal
CERTIFICATE OF REGISTRATION

In pursuance of section 6, sub-section (3) of “The Transplantation of Human Organs and Tissues Act, 2010 (VI of 2010)” _________________ Hospital has been recognized for _________________ transplantation for a period of one year with effect from the date of issuance of this certificate. Notification in the Official Gazette will be published in due course.

Administrator
Human Organ Transplant Authority (HOTA)

Official Seal