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Notification

S.R.O.....(1)/2012.- In exercise of the powers conferred by section 17 of the Transplantation of Human Organs and Tissues Act, 2010 (VI of 2010), the Federal Government is pleased to make the following rules, namely:-

1. **Short title, commencement and extent.-** (1) These rules may be called the Transplantation of Human Organs and Tissues Rules, 2012.

(2) They shall come into force at once.

(3) These rules shall extend to the Islamabad Capital Territory.

2. **Definitions.** (2) The words and expressions used but not defined in these rules shall have the same meanings as assigned to them in the Act.

In these rules unless there is anything repugnant to the subject or context,-

(a) "Act" means the Transplantation of Human Organs and Tissues Act, 2010 (VI of 2010);

(b) "Authority" means the Monitoring Authority constituted under section 8 of the Act;

(c) "Form" means a form annexed to these rules;

(d) "Institution for retrieval of human organ on brain stem death" means any hospital or institution where a prospective brain death human being is maintained on artificial life support.

(e) "Non close blood relation" means an altruistic genetically unrelated donor or any other relation defined by the Authority in consultation with the Federal Government, from time to time; and

(f) "Evaluation Committee" means a Committee or Committees constituted under the sub-section (1) of Section 5 of the Act.

3. **Authorization for removal of human organ,-** Any donor may authorize the removal, before his death, of any organ of his/her body for therapeutic purposes in the manner and on such conditions as specified in Form 1, 2 or 3, as the case may be.

4. **Duties of the recognized transplant surgeon or physician.-** (1) A recognized transplant surgeon or physician shall, before removing a human organ from the body of a donor before his death, satisfy himself that,-

- (a) the donor has given his/her authorization in the relevant Form 1, 2 or 3;
 - (b) the donor is in proper state of health and is fit to donate the organ or tissues. Thereafter the recognized transplant surgeon or physician shall sign a certificate as specified in Form 4;
 - (c) in case the recipient is spouse of the donor, the donor has given a statement to the effect that they are so related by signing a certificate in Form 2. Thereafter the recognized transplant surgeon or physician shall sign a certificate as specified in Form 5; and
 - (d) the donor has submitted an application in Form 10 jointly with the recipient to grant approval for removal and transplantation of a human organ to the Evaluation Committee.
- (2) A recognized transplant surgeon or physician shall, before removing a human organ or tissue from the body of a person after his/her death satisfy himself that.-
- (a) the donor had, in the presence of two or more witnesses (at least one of whom is a close blood relative of such donor), unequivocally authorized as specified in Form 6 before his death, the removal of the human organ of his body, after his death, for therapeutic purposes and there is no reason to believe that the donor had subsequently revoked the authority as aforesaid; and
 - (b) that the person lawfully in possession of the dead body has signed a certificate as specified in Form 7.
- (3) A recognized transplant surgeon or physician shall, before removing a human organ from the body of a person in the event of his brain-stem death, satisfy himself that.-
- (a) a certificate as specified in Form 8 has been signed by all the members of the Board;
 - (b) in the case of brain-stem death of a person of less than eighteen years of age, an authority as specified in Form 9 has been signed by either of the parents or close blood relatives of such dead person.

5. **Board.-** (1) The Evaluation Committees shall ensure that every hospital or institution shall have a Board to be constituted by that Hospital or Institution for deceased donor, which shall consist of:

- (a) Executive Director or Medical Superintendent or Head of the Hospital;
- (b) a neurosurgeon or neurophysician; and
- (c) an intensivist.

Provided that no medical practitioner who shall be part of transplant team shall be part of the Board.

(2) The quorum of the Evaluation Committee should be four. However, quorum shall not to be considered to be complete without the participation of one of the members from category (b) above.

(3) At the time of the meeting, the Evaluation Committee should take note of all relevant contents and documents in the course of its decision making process and in the event any document or information is found to be inadequate or doubtful, explanation should be sought from the applicant and if it is considered necessary that any fact or information requires to be verified in order to confirm its veracity or correctness, the same be ascertained through the concerned officer of the Government concerned.

6. **Donation from ‘close blood relatives’:-** (1) Where the proposed transplant is between close blood relative, as specified in sub-section (1) of Section (3) of the Act, the concerned Evaluation Committee shall ensure and evaluate,--

- (i) results of tests for Human Leukocyte Antigen (HLA), alleles A, B and DR performed by serology or DNA-PCR methods and if necessary further testing by contemporary technology to confirm relationship i.e. micro satellite gene analysis;
- (ii) documentary evidence of relationship e.g. relevant National Identity Card, birth certificate and marriage certificate;
- (iii) documentary evidence of identity and residence of the proposed donor e.g. computerized National Identify Card, passport, driving license or bank account where possible:

Provided that where such relationship is not conclusively established after evaluating the above evidence, the Evaluation Committee, may in its discretion direct further medical tests as applicable in that case under the current medical best practices and where these test referred to above do not establish a genetic relationship between the donor and the recipient, the same tests are to be performed on preferably both parents or at least one parent. If parents are not available, same tests are to be performed on such relatives of donor and recipient as are available and are willing to be tested failing which, genetic relationship between the donor and the recipient shall be deemed to have not been established.

(2) The papers for approval of transplantation should be processed by the recognized transplant surgeon or physician and administrative division of the recognized institution while the approval shall be granted by the Evaluation Committee concerned.

(3) Where the proposed donor or the recipient or both are foreigners;

- (a) a senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient; and
- (b) Evaluation Committee shall examine the cases of Pakistani donors consenting to donate organs to a foreign national (who is a close blood relative), including a foreign national of Pakistani origin, with greater caution. Such cases should be considered on case to case basis.

7. **Transplants between married couple.-** Where the proposed transplant is between a married couple, the Evaluation Committee shall evaluate all available evidence to establish the factum and duration of marriage and ensure that relevant documents including marriage certificate, is placed before the committee along with the information on the number and age of children and birth certificate of children containing the particulars of parents, if any.

8. **Donation from non close blood relatives.-** (1)Where the proposed transplant is between individuals who are “**non close blood relatives**” the Evaluation Committee shall evaluate that,-

- (a) there is no commercial transaction between the recipient and the donor. No payment of money or money’s worth as referred to in Act, has been made to the donor or promised to be made to the donor or any other person. In this connection, the Evaluation Committee shall take into consideration,-
 - (i) an explanation of the link between recipient and donor and the circumstances which led to the offer being made;
 - (ii) documentary evidence of the link e.g. proof that they have lived together etc; and
 - (iii) reason why the donor wishes to donate;
 - (b) there is no middleman / tout involved;
 - (c) that financial status of the donor and the recipient is probed by asking them to give appropriate evidence of their vocation and income for the previous three financial years. Any gross disparity between the status of the two, must be evaluated in the backdrop of the objective of preventing commercial dealing;
 - (d) the donor is not a drug addict or a known person with criminal record; and
 - (e) the next of kin of the proposed altruistic unrelated donor is interviewed regarding awareness about his / her intention to donate an organ, the authenticity of the link between the donor and the recipient and the reasons for donation. Any strong views of disagreement or objection of such kin may also be recorded and taken note of.
- (2) In the course, of determining eligibility of the applicant to donate, the applicant should be personally interviewed by the Evaluation Committee and minutes of the interview should be recorded. The final interview with the donor should be video recorded.
- (3) In case of female donor, her identity and independent consent should be confirmed by a person other than the recipient.
- (4) Any document with regard to the proof of the residence or domicile and particulars of parentage should be relatable to the photo identify of the applicant in order to ensure that the documents pertain to the same person, who is the proposed donor and in the event of any inadequate or doubtful information to this effect, the Evaluation Committee may in its discretion seek such other information or evidence as may be expedient and desirable in the peculiar facts of the case.

- (5) The Evaluation Committee should state in writing its reason for rejecting or approving, as the case may be, the application of the proposed donor and all approvals should be subject to the following conditions; namely:-
- (a) the approved proposed donor should be subject to all such medical tests as required at the relevant stages to determine his biological capacity and compatibility to donate the organ in question;
 - (b) the psychiatrist clearance shall also be mandatory to certify his mental condition, awareness, absence of any over or latent psychiatric disease and ability to give free consent;
 - (c) all prescribed forms have been filled up by all relevant persons involved in the process of transplantation; and
 - (d) final interview to be video recorded.
- (6) The Evaluation Committee shall expedite its decision making process and use its discretion judiciously and pragmatically in all such cases where, the patient requires transplantation on medical priority.
- (7) The secretariat of the Monitoring Authority shall evaluate and recommend the cases referred to it by the respective Evaluation Committee through treating hospital citing cogent reasons viz: non availability or non compatibility of any close blood relative as a donor after ensuring that no monetary transaction is involved between recipient and the donor. The Evaluation Committee shall proceed in accordance with section 5 read with sub-section 2 of section 3 of the Act. Each application such referred shall be accompanied by a processing fee of ten thousand rupees to be paid into Authority's authorized bank account to be used on the activities of the Authority.
- (8) Every recognized institution shall have its own website. The Evaluation Committee is required to take final decision about donor selection within thirty six hours of holding the meeting for grant of permission or refusal for transplant. The decision of the Evaluation Committee shall reflect transparency and the same shall be posted on the website of the recognized institution within thirty six hours of the decision. Apart from this, the website of the recognized institution must be updated regularly in respect of the total number of the transplantations done in that recognized institution along with the essential details of each transplantation. The same data should be accessible for compilation, analysis and further use by Authority.
9. **Preservation of organs and tissues.**-The organ or tissue removed shall be preserved according to the best scientific methods in order to ensure viability for the purpose of transplantation.
10. **Monitoring Authority.**- (1) Monitoring Authority is a body constituted to monitor, supervise and scrutinize transplantation of human organs and tissues.
- (2) The Monitoring Authority shall determine the basis for the ratification of the approval of the case by the Evaluation Committee.

- (3) The Federal Government shall dissolve or de-notify any Evaluation Committee after an enquiry conducted on the basis of a complaint received in writing or upon receipt of complaint of negligence, misconduct or not complying with any provision of the Act or rules framed thereunder. Such an action shall be notified. The reconstituted Evaluation Committee shall be formed within fifteen days of the dissolution of the earlier Committee.
- (4) The Monitoring Authority may organize events to recognize and acknowledge the act of supreme altruism of living donors and the family of deceased donors.
- (5) The Monitoring Authority shall create national organ sharing network (NOSN) which may liaise with Organ Procurement Organization (OPO) consisting of a doctor, a psychologist or sociologist and a nurse at the capital cities of the provinces and Islamabad which shall generate the request of brain death patients whose families have consented for donation. The OPO will refer the request to the NOSN which shall allocate organs according to the current international practices for allocation.
- (6) The Monitoring Authority under sub-section (4) of section 8 shall request the Federal government to institute an endowment fund which shall be used by the Authority especially for the transplantation of indigent patients including post transplant care, medicines and related costs of the Authority.

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 its 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, bio-chemistry, 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.