

THE TRANSPLANTATION OF HUMAN ORGANS RULES, 1995

(GSR NO. 51(E), dr. 4-2-1995)

[As amended vide GSR 571(E), dt.31-7-2008]

In exercise of the powers conferred by sub-section (1) of section 24 of the Transplantation of Human Organs Act, 1994 (42 of 1994), the Central Government hereby makes the following rules, namely:-

1. Short title and commencement

2. Definitions

3. Authority for removal of human organ

4. Duties of the Medical Practitioner

5. Preservation of organs

6. Composition of Authorisation Committees

7. Registration of hospital

8. Renewal of registration

9. Conditions for grant of certificate of registration

10. Appeal

1. Short title and commencement

- a. These rules may be called the Transplantation of Human Organs Rules, 1995.
- b. They shall come into force on the date¹ of their publication in the Official Gazette.

2. Definitions

- a. "Act" means the Transplantation of Human Organs Act, 1994 (42 of 1994);
- b. "Form" means a form annexed to these Rules;
- c. "Section" means a section of the Act;
- d. ²["National Accreditation Board for Laboratories" (NABL) means a Board set up by the Quality Council of India (set up by the Government of India) for undertaking assessment and accreditation of testing and calibration of laboratories in accordance with the international standard ISO/IEC/17025 and ISO 15189;
- e. the Registered Medical Practitioner, as defined in clause (n) of section 2 of Transplantation of Human Organs Act, 1994 includes an allopathic doctor with MBBS or equivalent degree under the Medical Council of India Act.]
- f. Words and expressions used and not defined in these Rules, but defined in the Act, shall have the same meanings respectively assigned to them in the Act.

3. Authority for removal of human organ

Any donor may authorise the removal, before his death, of any human organ of his body for therapeutic purposes in the manner and so such conditions as specified in 4[Forms 1(A), 1(B) and 1(C)].

4. Duties of the Medical Practitioner

1. A registered medical practitioner shall, before removing a human organ from the body of a donor before his death, satisfy himself-
 - a. that the donor has given his authorization in Form 1(A) or 1(B) or 1(C).
 - b. that the donor is in proper state of health and is fit to donate the organ, and the registered medical practitioner shall sign a certificate as specified in Form 2.
 - c. That the donor is a near relative of the recipient as certified in Form 3, who has signed Form 1(A) or 1(B) as applicable to the donor and that the donor has submitted an application in Form 10 jointly with the recipient and that the proposed donation has been approved by the concerned competent authority and that the necessary documents as prescribed and medical tests, if required, to determine the

factum of near relationship, have been examined to the satisfaction of the Registered Medical Practitioner i.e. Incharge of transplant center.

- d. That 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 1(B) and has submitted an application in Form 10 jointly with the recipient and that the proposed donation has been approved by the concerned competent authority under provision of sub-rule (2) of rule 4A.
- e. In case of a donor who is other than a near relative and has signed Form 1(C) and submitted an application in Form 10 jointly with the recipient, the permission from the Authorisation Committee for the said donation has been obtained.
2. A registered medical practitioner shall, before removing a human organ from the body of a person after his death satisfy himself-
 - (a) that the donor had, in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorized as specified in Form 5 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 aforesaid; 1[(b) that then person lawfully in possession of the dead body has signed a certificate as specified in Form 6.]
3. A registered medical practitioner shall, before removing a human organ from the body of a person in the event of his brain-stem death, satisfy himself-
 - a. that a certificate as specified in Form 8 has been signed by all the members of the Board of Medical Experts referred to in sub-section (6) of section 3 of the Act;
 - b. that in the case of brain-stem death of a person of less than eighteen years of age, a certificate specified in Form 8 has been signed by all the members of the Board of Medical Experts referred to in sub-section (6) of section 3 of the Act and an authority as specified in Form 9 has been signed by either of the parents of such person.

4A. Authorisation committee

1. The medical practitioner who will be part of the organ transplantation team for carrying out transplantation operation shall not be a member of the Authorisation committee constituted under the provision of clauses (a) and (b) of sub-section (4) of section 9 of the Act.
2. Where the proposed transplantation is between a married couple, the Registered Medical Practitioner i.e. Incharge of transplant center must evaluate the factum and duration of marriage and ensure that documents such as marriage certificate, marriage photograph etc. Are kept for records along with the information on the number of age of children and family photograph depicting the entire immediately family, birth certificate of children containing particulars of parents.
3. When the proposed donor or recipient or both are not Indian Nationals/citizens whether 'near relatives' or otherwise, Authorisation Committees shall consider all such requests.
4. When the proposed donor and the recipient are not "near relatives", as defined under clause (i) of section 2 of the Act, the Authorisation Committee shall evaluate that,-
 - i. there is no commercial transaction between the recipient and the donor and that no payment or money or moneys worth as referred to the Act, has been made to the donor or promised to be made to the donor or any other person;
 - ii. the following shall specifically be assessed by the Authorisation Committee:-
 - a. an explanation of the link between them and the circumstances which led to the offer being made;
 - b. reasons why the donor wished to donate;
 - c. documentary evidence of the link, e.g. proof that they have lived together, etc;
 - d. old photographs showing the donor and recipient together;
 - iii. that there is no middleman or tout involved;
 - iv. 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;
 - v. that the donor is not a drug addict or known person with criminal record;
 - vi. that the next of kin of the proposed unrelated donor is interviewed regarding awareness about his or 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 or disagreement or objection such kin shall also be recorded and taken note of.

5. Preservation of organs

The organ removed shall be preserved according to current and accepted scientific methods in order to ensure viability for the purpose of transplantation;

PROVIDED that the eye-ball removed shall be preserved in the following three steps, namely;-

- i. short-term preservation;
 - ii. medium-term preservation;
 - iii. long-term preservation;
- and suitable media shall be used for preservation.

6. The donor and the recipient shall make jointly an application to grant approval for removal and transplantation of a human organ, to the concerned competent authority or Authorisation committee as specified in Form 10. The Authorisation Committee shall take a decision on such application in accordance with the guidelines in rule 6A.

6A. Composition of Authorisation Committees

1. There shall be one State Level Authorisation Committee.
2. Additional authorization committees may be set up at various levels as per norms given below, namely;-
 - i. no member from transplant team of the institution should be a member of the respective Authorisation committee. All Foreign Nationals (related and unrelated) should go to "Authorisation Committee" as abundant precaution needs to be taken in such cases;
 - ii. Authorisation Committee should be Hospital based in Metro and big cities if the number of transplants exceeds 25 in a year at the respective transplantation centers. In small towns, there are State or District level Committees if transplants are less than 25 in a year in the respective districts.
 - A. Composition of Hospital Based Authorisation Committees: (To be constituted by the State Government and in case of Union Territory by the Central Government).
 - a. the senior most person officiating as Medical Director or Medical Superintendent of the Hospital;
 - b. two senior medical practitioners from the same hospital who are not part of the transplant team;
 - c. two members being persons of high integrity, social standing and credibility, who have served in high ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in University Grants Commission approved University or are self-employed professionals of repute such as lawyers, chartered accountants and doctors (of Indian Medical Association) etc.; and
 - d. Secretary (Health) or nominee and Director Health Services or nominee.
 - B. Composition of state or District Level Authorisation Committees: (To be constituted by the State Government and in case of Union territory by the Central Government).
 - a. a Medical Practitioner officiating as Chief Medical Officer or any other equivalent post in the main/major Government Hospital of the District;
 - b. two senior medical practitioners to be chosen from the pool of such medical practitioners who are residing in the concerned District and who are not part of any transplant team;
 - c. two senior citizens, non-medical background (one lady) of high reputation and integrity to be chosen from the pool of such citizens residing in the same district, who have served in high ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in University grants Commission approved University or are self-employed professionals of repute such as lawyers, chartered accountants and doctors (of Indian Medical Association) etc; and
 - d. Secretary (Health) or nominee and Director Health Services or nominee.

(Note: Effort should be made to have most of the members' ex-officio so that the need to change the composition of committee is less frequent.)

6B. The State level committees shall be formed for the purpose of providing approval or no objection certificate to the respective donor and recipient to establish the legal and residential status as a domicile state. It is mandatory that if donor, recipient and place of transplantation are from different states, then the approval or "no objection certificate" from the respective domicile State Government should be necessary. The institution where the transplant is to be undertaken in such case the approval of Authorisation committee is mandatory.

6C. The quorum of the Authorisation Committee should be minimum four. However, quorum ought not to be considered as complete without the participation of the chairman. The presence of Secretary (Health) or Nominee and Director of Health Services or nominee is mandatory.

6D. The format of the Authorisation Committee approval should be uniform in all the institutions in a State. The format may be notified by Respective State Government.

6E. Secretariat of the Committee shall circulate copies of all applications received from the proposed donors to all members of the Committee. Such applications should be circulated along with all annexures, which may have been filed along with the applications. At the time of the meeting, the Authorisation committee should take note of all relevant contents and documents in the course of its decision making process and in the event any 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(s) if the State/Union territory Government.

6F. The Authorisation committee shall focus its attention on the following, namely:-

- C. Where the proposed transplant is between persons related genetically, Mother, Father, Brother, Sister, Son or Daughter Above the age of 18 years), the concerned competent authority shall evaluate:-
 - i. results of tissue typing and other basic tests;
 - ii. documentary evidence of relationship e.g. relevant birth certificates and marriage certificate, certificate from Sub-divisional magis-rate/Metropolitan Magistrate/or Sarpanch of the Panchayat;
 - iii. documentary evidence of identity and residence of the proposed donor e.g. Ration Card or Voters identity Card or Passport or Driving License or PAN Card or Bank Account and family photograph depicting the proposed donor and the proposed recipient along with another near relative;
 - iv. if in its opinion, the relationship is not conclusively established after evaluating the above evidence, it may in its discretion direct further medical tests as prescribed as below:
 - a. the test for Human Leukocyte Antigen (HLA), Human Leukocyte Antigen-B alleles to be performed by the serological and / or Polymerase chain reaction (PCR) based Deoxyribonucleic acid (DNA) methods.
 - b. Test for Human Leukocyte Antigen-DR beta genes to be performed using the Polymerase Chain reaction (PCR) based Deoxyribonucleic acid (DNA) methods.
 - c. The tests referred to in sub-rules (i) to (ii) shall be got done from a laboratory accredited with National Accreditation Board for Laboratories (NABL).
 - d. Where the tests referred to in (i) to (iii) above do not establish a genetic relationship between the donor and the recipient, the same tests to be performed on both or at least one parent, preferably both parents. If parents are not available, same tests 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 will be deemed to have not been established.
 - v. The papers for approval of transplantation would be processed by the registered medical practitioner and administrative division of the Institution for transplantation, while the approval will be granted by the Authorisation Committee.
 - vi. Where the proposed transplant is between a married couple (except foreigners, whose cases should be dealt by Authorisation Committee): The concerned competent authority or authorization committee as the case may be must evaluate all available evidence to establish the factum and duration of marriage and ensure the documents such as marriage certificate, marriage photograph is placed before the committee along with the information on the number and age of children and a family photograph

depicting the entire immediate family, birth certificate of children containing the particulars of parents.

- vii. Where the proposed transplant is between individuals who are not “near relatives”. The authorization committee shall evaluate;-
- i. that there is no commercial transaction between the recipient and the donor. That no payment of money or moneys worth as referred to in the sections of the Act, has been made to the donor or promised to be made to the donor or any other person. In this connection, the Authorisation Committee shall take into consideration:-
 - a an explanation of the link between them and the circumstances which led to the offer being made;
 - b documentary evidence of the link e.g. proof that they have lived together etc;
 - c reasons why the donor wishes to donate; and
 - d old photographs showing the donor and the recipient together.
 - ii. that there is no middleman/tout involved;
 - iii. 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;
 - iv. that the donor is not a drug addict or a known person with criminal record; that the next of kin of the proposed 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 view of disagreement or objection of such kin may also be recorded and taken note of; and
- viii When the proposed donor or the recipient or both are foreigners:- a senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient. Authorisation Committee shall examine the cases of Indian donors consenting to donate organs to a foreign national (who is a near relative), including a foreign national of India origin, with greater caution. Such cases should be considered rarely on case to case basis.
- ix In the course, of determining eligibility of the applicant to donate, the applicant should be personally interview by the Authorisation Committee and minutes of the interview should be recorded. Such interviews with the donors should be videographed.
- x In case where the donor is a woman greater precautions ought to be taken. Her identity and independent consent should be confirmed by a person other than the recipient. Any document with regard to the proof of the residence or domicile and particulars of parentage should be relatable to the photo identity 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 Authorisation committee may in its discretion seek such other information or evidence as may be expedient; and desirable in the peculiar facts of the case.
- xi The Authorisation Committee should state in writing its reason for rejecting / approving the application of the proposed donor and all approvals should be subject to the following conditions:-
- i. that the approved proposed donor would be subjected to all such medical test as required at the relevant stages to determine his biological capacity and

- compatibility to donate the organ in question.
 - ii. further that the psychiatrist clearance would also be mandatory to certify his mental condition, awareness, absence of any overt or latent psychiatric disease and ability to give free consent.
 - iii. all prescribed forms have been and would be filled up by all relevant persons involved in the process of transplantation.
 - iv. all interviews to be video recorded.
- xii The authorization committee shall expedite its decision making process and use its discretion judiciously and pragmatically in all such cases where, the patient requires immediate transplantation.
- xiii Every authorized transplantation center must have its own website. The Authorization Committee is required to take final decision within 24 hours of holding the meeting for grant of permission of rejection for transplant. The decision of the Authorisation committee should be displayed on the notice board of the hospital or institution immediately and should reflect on the website of the hospital or institution within 24 hours of taking the decision. Apart from this, the website of the hospital or institution must update its website regularly in respect of the total number of the transplantations done in that hospital or institution along with the details of each transplantation. The same data should be accessible for compilation, analysis and further use by respective State Governments and Central Government.

7. Registration of hospital

1. An application for registration shall be made to the Appropriate Authority as specified in Form 11. The application shall be accompanied by a fee of rupees one thousand payable to the Appropriate Authority by means of a bank draft or postal order.
2. The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements, grant a certificate of registration as specified in Form 12 and shall be valid for a period of five years from the date of its issue and shall be renewable.
3. Before a hospital is registered under the provisions of this rule, it shall be mandatory for the hospital to nominate a transplant co-ordinator.

8. Renewal of registration

1. An application for the renewal of a certificate of registration shall be made to the Appropriate 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 five hundred payable to the Appropriate Authority by means of a bank draft or postal order.
2. A renewal certificate of registration shall be as specified in Form 13 and shall be valid for a period of five years.
3. If, after an inquiry including inspection of the hospital and scrutiny of its past performance and after giving an opportunity to the applicant, the Appropriate Authority is satisfied that the application, since grant of certificate of registration under sub-rule (2) of rule 7 has not complied with the requirements of this 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.

9. Conditions for grant of certificate of registration

No hospital shall be granted a certificate of registration under this Act unless it fulfills the following requirement of manpower, equipment, specialized services and facilities as laid down below:-

- A. General Manpower Requirement Specialised Services and Facilities:
 1. 24 hours availability of medical and surgical, (senior and junior) staff.
 2. 24 hours availability of nursing staff, (general and speciality trained).
 3. 24 hours availability of Intensive Care Units with adequate equipments, staff and support system, including specialists in anaesthesiology, intensive care.
 4. 24 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. 24 hours availability of Operation Theatre facilities (OT facilities) for planned and emergency procedures with adequate staff, support system and equipments.

6. 24 hours availability of communication system, with power backup, including but not limited to multiple line telephones, public telephone system, fax, computers and paper photo-imaging machine.
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 center.

B Equipments:

Equipments as per current and expected scientific requirements specific to organ or organs being transplanted. The transplant center should ensure the availability of the accessories, spare-parts and back-up/maintenance/service support system in relation to all relevant equipments.

C Experts and their qualifications:

- a Kidney Transplantation M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. training in a recognized center in India or abroad and having attended to adequate number of renal transplantation as an active member of team.
- b Transplantation of liver and other abdominal organs M.S. (Gen.) Surgery or equivalent qualification with adequate post M.S. training in an established center with a reasonable experience of performing liver transplantation as an active member of team.
- c Cardiac, Pulmonary, Cardio-Pulmonary Transplantation M.Ch. Cardio-thoracic and vascular surgery or equivalent qualification in India or abroad with at least 3 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.
- d Cornea Transplantation M.D./M.S. ophthalmology or equivalent qualification with one year post M.D./M.S. training in a recognised hospital carrying out Corneal transplant operations.]

10. Appeal

- 1 Any person aggrieved by an order of the Authorisation Committee under sub-section (6) of section 9, or by an order of the Appropriate Authority under sub-section (2) of section 15 and section 16 of the Act, may, within thirty days from the date of receipt of the order, prefer an appeal to the Central Government.
- 2 Every appeal shall be in writing and shall be accompanied by a copy of the order appealed against.