MINISTRY OF HEALTH AND FAMILY WELFARE
NOTIFICATION
New Delhi, the 4th February, 1995

G.S.R. 51 (E)-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 here by makes the following rules, namely:-

1. SHORT TITLE AND COMMENCEMENT

(1) These rules may be called the Transplantation of Human Organs Rules, 1995.
(2) They shall come into force on the date 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) words and expression 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 authorize the removal, before his death, of any human organ of his body for therapeutic purposes in the manner and on such conditions as specified in Form 1.
4. DUTIES OF THE MEDEICAL 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;
(b) that the donor is in proper state of health and is fit to donate the organ and shall sign a certificate a specified in From2.
(c) that the donor is a near relative of the recipient, and shall sign a certificate as specified in Form3 after carrying out the following tests on the donor and the recipient, namely:-
(i) tests for the antigenic products of the Human Major Histocomparibility system HLA-A, HLA-B and HLA-DR using conventional serological techniques;
(ii) tests to establish HLA-DR beta and HLADQ beta gene restriction fragment length polymorphism;
(iii) where the tests referred to in sub-clause (i) and sub-clause (ii) do not establish a genetic relationship between the donor and the recipient, tests to establish DNA polymorphisms using at least two multi-locus gene probe;
(iv) where the tests referred to in sub-clause (iii) do not establish a genetic relationship between the donor and the recipient further tests to establish DNA polymorphisms using at least five single locus polymorphic probes.
(d) in case recipient is a spouse of the donor, record the statements of the recipient and the donor to the effect that that are so related and shall sign a certificate in Form 4.
(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;

(b)that the person lawfully in possession of the dead body has signed a certificate as specified in Form6 or Form 7.
(3) A registered medical practitioner shall, before removing a human organ from the body of a person I the event of his brainstem 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.
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.
6. the donor and the recipient shall make jointly an application to grant approval for removal and transplantation of a human organ, to the Authorisation Committee as specified in Form 10.
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.

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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 applicant, since grant of certificate of registration under sub-rule (2) of Rule 7 has not complied with the requirements of this Act and Rules made there under 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:-
GENERAL REQUIREMENT
1. Surgical Staff
2. Cardiology Staff
3. Nursing Staff
4. Communication System
5. Intensivist
6. Medical Social Worker

7. Perfusionist

VARIOUS DEPARTMENTS

1. Microbiology
2. Mycology
3. Pathology
4. Virology
5. Nephrology
6. Neurology
7. Psychology
8. G.I. Surgery
9. Anaesthesiology
10. Imaging Facilities
11. Paediatrics
12. Physiotherapy
13. Immunology
14. Haematology
15. Blood Bank
16. Clinical Chemistry
17. Cardiology

NON-TRANSPLANTATION PROGRAMME TEAM

1. Neurologist
2. Neurosurgeon
3. Medical Superintendent
4. And Other Hospital Staff

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BASIC EQIPMENT

Operating Room facilities for routine open heart surgery which includes heart lung machine and accessories.

ADDITIONAL EQUIPMENT REQUIRED FOR TRANSPLANTATION PROGRAMME

1. Cell Saver
2. Assist devices like IABP, Centrifugal Pump and various assist devices, both pneumatic and electric operated.
3. Mobile C-arm image intensifier for routine biopsies in the sterile operating room.
4. Eact/Alert System for early detection of any infection.
5. Radioimmunoassay for measuring Cyclosporine levels.
6. Routine Laboratory facilities for detection of HIV, Australia antigen, CMV, Toxoplasnosis and other Mycology Tests.

EXPERTS

(A) Kidney Transplantation

M.S.(Gen.) surgery or equivalent qualification with three years post M.S. training in a recognized centre in India or abroad and having attended to adequate number of renal transplantation as an active member of team.

(B) Transplantation of Liver & Other Abdominal Organs

M.S(Gen.) Surgery or equivalent qualification with adequate post M.S .training in an established centre with a reasonable experience of performing liver transplantation as an active member of team.

(C) Cardiac, Pulmonary, Cardio-Pulmonary Transplantation

M. Ch. Cardio-thorasis 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.

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.

[F. No. S. 12011/2/94-MS]

O.P. NIGAM, Chief Controller of Accounts

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(d) in case recipient is a spouse of the donor, record the statements of the recipient and the donor to the effect that that are so related and shall sign a certificate in Form 4.

(2) A registered medical practitioner shall, before removing a human organ from the body of a person after his death satisfy himself-

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(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.

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(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 applicant, since grant of certificate of registration under sub-rule (2) of Rule 7 has not complied with the requirements of this Act and Rules made there under 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.

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