MINISTRY OF HEALTH & 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 hereby 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 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 on such conditions as specified in Form 1.

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 authorisation 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 Form 2.

(c) that the donor is a near relative of the recipient, and shall sign a certificate as specified in Form 3 after carrying out the following tests on the donor and the recipient, namely :—

(i) tests for the antigenic products of the Human Major Histocompatibility 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 polymorphysms 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 authorised 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 Form 6 or Form 7.

(3) A registered medical practitioner shall, before removing a human organ from the body of a person in 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.

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 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 registeration under this Act unless it fulfills the following requirement of manpower, equipment, specialised 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

BASIC EQUIPMENT

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 fot early detection of any infection.

5. Radioimmunoassy for measuing Cyclosporin 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 recognised 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-thorasic 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

FORM—1

(See rule 3)

I,....., aged..... s/o, d/o, w/o, Mr.....
.....resident of .....
hereby authorise to remove for therapeutic purposes/consent to donate my organ, namely,.....to

(i) Mr./Mrs. .....s/o, d/o, w/o Mr.....
aged.....resident of .....
who happens to be my near relative as defined in clause (i) of section 2 of the Act.

OR

(ii) Mr./Mrs.....s/o, d/o, w/o Mr. .....
aged.....resident of.....
towards whom I possess special affection or attachments, or for any special reason (to be specified)

I certify that the above authority/consent has been given by me out of my own free will without any undue pressure, inducement, influence or allurement and that the purposes of the above authority/donation and of all possible complications, side-effects, consequences and options have been explained to me before giving this authority of consent or both.

Signature of the Donor

FORM-2

[See rule 4(1)(b)]

I, Dr.....possessing qualification of.....
registered as medical practitioner at serial No.....by the.....
Medical Council, certify that I have examined Shri/Smt./Km.....
s/o, d/o, w/o.....aged.....whose free and
informed consent about donation of the organ, namely.....
to Shri/Shmt./Km.....s/o, d/o, w/o.....who
is near relative of the donor and that the said donor is in proper state of health and is.....medically
fit to be subjected to the procedure of organ removal.

Signature

Place.....
Dated.....

FORM-3

[See rule 4(1)(c)]

I, Dr. .....possessing qualification of .....
registered as med. practitioner at Serial No.....by the.....
Medical Council, certify that Mr./Mrs.....s/o, d/o, w/o.....
.....aged.....the donor, and Mr./Mrs.....
s/o, d/o, w/o.....aged.....the
recipient of the organ donated by the said donor are related to each other as brother/sister/monther/father/son/daughter as per their
statement and the fact of this relationsip has been established by the results of the tests for Antigenic Products of the Huaman
Major Hysto-compatibility System, namely,....., by the Authorisation Committee as per
the information contained in their letter of approval No.....dated.....

Signature

Place.....
Dated .....

FORM-4

[See Rule 4(1)(d)]

I, Dr.....possessing qualification of .....
registered as medical practitioner at serial No.....by the.....
Medical Council, certify that—

(i) Mr.....s/o.....
aged.....resident of .....and Mrs.....
d/o, w/o,.....aged .....resident of
.....are related to each other as spouse accoding to the statement
given by them and their statement has been confirmed by means of following evidence before effecting the organ removal from the
body of the said Shri/Smt/Km.....
(Applicable only in the cases where considered necessary).

OR

(ii) The Clinical condition of Shri/Smt. .....mentinoned above
is such that recording of his/her statement is not practicable.

Signature of Regd. medical practitioner

Place .....
Dated .....

FORM-5

[See rule 4(2)(a)]

I,..... s/o, d/o, w/o,..... aged.....resident of ..... in the present of persons mentioned below hereby unequivocally authorise the removal of my organ/organs, namely,..... from my body after my death for therapeutic purposes.

Signature of the Donor

Dated .....

(Signature)

1. Shri/Smt./Km. .....
   s/o, d/o, w/o .....
   aged.....
   resident of ....

(Signature)

2. Shri/Smt./Km. .....
   s/o, d/o, w/o .....
   aged.....
   resident of .....
   is a near relative to the donor as .....

Dated .....

FORM-6

[See rule 4(2)(b)]

I,.....s/o, d/o, w/o ..... aged.....resident of ..... having lawful possession of the dead body of Shri/Smt./Km.....s/o, d/o, w/o..... .....aged.....resident of ....having known that the deceased has not expressed any objection to his/her organ/organs being removed for therapeutic purposes after his/her death and also having reasons to believe that no near relative of the said deceased person has objection to any of his/her organs being used for therapeutic purposes authorise removal of his/her body organs, namely,.....

Signature

Dated.....

Place.....

Person in lawful possession of the dead body.

Address .....
.....

FORM-7

[See rule 4(2)(b)]

I, Mr./Mrs./Miss....., having lawful possession of the deadbody of Mr./Mrs./Miss..... son of/dauther of/wife of..... aged.....resident of ..... after having known that no objection was expressed by the deceased to any of his human organ being used after his death for therapeutic purposes and also having reason to believe that no near relative of the deceased person has objection to any of the deceased person's organ being used for therapeutic purposes, hereby authorise the removal of the deceased's organ, namely,..... for therapeutic purposes.

Signature .....
Name .....
Address.....
.....
Time and date .....

FORM-8

[See rule 4(3)(a) and (b)]

We, the following members of the Board of medical experts after careful personal examination hereby certify that Shri/Smt./Km. ..... aged about.....son of/wife of/daughter of .....

resident of .....
is dead on account of permanent and irreversible cessation of all functions of the brain-stem. The tests carried out by us and the findings therein are recorded in the brain-stem death Certificate annexed hereto.

Dated :—————

Signature .....

1. R.M.P., Incharge of the Hospital in which brain-stem death has occurred.
2. R.M.P., nominated from the panel of names approved by the Appropriate Authority.
3. Neurologist/Neuro-Surgeon nominated from the panel of names approved by the Appropriate Authority.
4. R.M.P. treating the aforesaid deceased person.

BRAIN-STEM DEATH CERTIFICATE

(A) PATIENT DETAILS :

1. Name of the patient — Mr./Ms. _____

S.O./D.O./W.O. — Mr. _____

Sex———— Age————

2. Home Address

3. Hospital Number.

4. Name and Address of next of kin or person responsible for the patient (if none exists, this msut be specified)

5. Has the patient or next of kin agreed to any transplant?

6. Is this a Police Case? Yes———— No————

(B) PRE-CONDITIONS :

1. Diagnosis : Did the patient suffer from any illness or accident that led to irreversible brain damage? Specify details.————

Date and time of accident/onset of illness ————

Date and onset of non-responsible coma ————

2. Findings of Board of Medical Experts :

(1) The following reversible causes of coma have been excluded :
Intoxication (Alcohol)

Depressant Drugs

Relaxants (Neuromuscular blocking agents)

	First Medical Examination		Second Medical Examination	
	1st	2nd	1st	2nd
Primary hypothermia				
Hypovolaemic shock				
Metabolic or endocrine disorders				
Tests for absence of brain-stem functions				

(2) Coma

(3) Cessation of spontaneous breathing.

(4) Pupillary size

(5) Pupillary light reflexes

(6) Doll's head eye movements.

(7) Corneal reflexes (Both sizes)

(8) Motor response in any cranial nerve distribution, any responses to stimulation of face, limb or trunk.

(9) Gag reflex.

(10) Cough (Tracheal)

(11) Eye movements on coloric testing bilaterally.

(12) Apnoea tests as specified.

(13) Were any respiratory movements seen?

Date and time of first testing: _____

Date and time of second testing : _____

This is to certify that the patient has been carefully examined twice after an interval of about six hours and on the basis of findings recorded above,

Mr./Ms.---------- is declared brain-stem dead.

1. Medical Administrator Incharge of the hospital
2. Authorised specialist.
3. Neurologist/Neuro-Surgeon
4. Medical Officer treating the patient.

NB. I. The minimum time interval between the first testing and second testing will be six hours.

II. No. 2 and No. 3 will be coopted by the Administrator Incharge of the hospital from the Panel of experts approved by the appropriate authority.

FORM—9

[See rule 4(3)(b)]

I, Mr./Mrs.----------son of/wife of----------resident of----------hereby authorise removal of the organ/organs, namely ,----------for therapeutic purpose from the deadbody of my son/daughter Mr./Ms.----------aged----------whose brain-stem death has been duly certified in accordance with the law.

Signature _____

Name _____

Place _____

Date _____

FORM—10

APPLICATION FOR APPROVAL FOR TRANSPLANTATION LIVE DONOR OTHER THAN NEAR RELATIVE

Whereas I----------S/O, D/O, W/O, L/O---------- aged---------- residing at----------have been informed by my doctor that I am suffering from---------- and may be benefitted by transplantation of----------into my body.

and whereas I----------S.O., D.O., W.O.----------aged---------- residing at----------by reason of affection and attachment because:

(reason to be filled in)

would like to donate my----------to----------me----------

(donor)

and----------hereby apply to authorisation committee for permission for such transplantation to be carried out.

(Recipient)

We solemnly affirm that the above decision has been taken without any undue pressure inducement, influence or allurement and that all possible consequences and options of organ transplantation have been explained to us.

Signature and address of prospective donor.

Signature and address of prospective recipient.

FORM II

APPLICATION FOR REGISTRATION OF HOSPITAL TO CARRY OUT ORGAN TRANSPLANTATION

To

The Appropriate Authority for organ transplantation.....
(State or Union Territory)

We hereby apply to be recognised as an institution to carry out organ transplantation. The required data about the facilities available in the hospital are as follows :—

(A) HOSPITAL :

1. Name _____
2. Location _____
3. Govt./Pvt. _____
4. Teaching/Non-teaching _____
5. Approached by : _____

Road :	Yes	No
Rail :	Yes	No
Air :	Yes	No

6. Total bed strength : _____
7. Name of the disciplines in the hospital _____
8. Annual budget _____
9. Patient turn-over/year _____

(B) SURGICAL TEAM :

1. No. of beds _____
2. No. of permanent staff members with their designations _____
3. No. of temporary staff with their designations _____
4. No. of operations done per year _____
5. Trained persons available for transplantation (Please specify organ for transplantation) _____

(C) MEDICAL TEAM :

1. No. of beds _____
2. No. of permanent staff members with their designation _____
3. No. of temporary staff members with their designation _____
4. Patient turnover per year _____
5. No. of potential transplant candidates admitted per year. _____

(D) ANAESTHESIOLOGY :

1. No. of permanent staff members with their designations _____
2. No. of temporary staff Members with their designations _____
3. Name and No. of operations performed _____
4. Name and No. of equipments available _____
5. Total no. of operation theatres in the hospital _____
6. No. of emergency operation-theatres _____
7. No. of separate transplant operation theatre _____

(E) I.C.U./H.D.U. FACILITIES :

1. ICU/HDU facilities : Present——Not present——
2. No. of I.C.U. beds _____
3. Trained

Nurses _____

Technicians _____

4. Name and number of equipments in I.C.U.

(F) OTHER SUPPORTIVE FACILITIES:
Data about facilities available in the hospital.

(G) LABORATORY FACILITIES :

1. No. of permanent staff with their designations.
2. No. of temporary staff with their designations.
3. Names of the investigations carried out in the Deptt.
4. Name and number of equipments available.

(H) IMAGING SERVICES:

1. No. of permanent staff with their designations.
2. No. of temporary staff with their designations.
3. Names of the investigations carried out in the Deptt.
4. Name and no. of equipments available.

(I) HAEMATOLOGY SERVICES:

1. No. of permanent staff with their designations.
2. No. of temporary staff with their designations.
3. Names of the investigations carried out in the Deptt.
4. Name and number of equipments available.

(J) BLOOD BANK FACILITIES : Yes———— No————

(K) DIALYSIS FACILITIES : Yes———— No————

(L) OTHER PERSONNEL :

1. Nephrologist	Yes/No
2. Neurologist	Yes/No
3. Neuro-Surgeon	Yes/No
4. Urologist	Yes/No
5. G.I. Surgeon	Yes/No
6. Paediatrician	Yes/No
7. Physiotherapist	Yes/No
8. Social Worker	Yes/No
9. Immunologists	Yes/No
10. Cardiologist.	Yes/No

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. A Bank Draft/cheque of Rs. 1,000/- is being enclosed.

Sd/-
HEAD OF THE INSTITUTION

FORM-12

CERTIFICATE OF REGISTRATION

This is to certify that————————Hospital located at————————has been inspected by the Appropriate Authority and certificate of registration is granted for performing the organ transplantation of the following organs.

1. ————————
2. ————————
3. ————————
4. ————————

This certificate of registration is valid for a period of five years from the date of issue.

Signature ———— Signature ————

FORM-13

[See sub-rule 8(2)]

OFFICE OF THE APPROPRIATE AUTHORITY

This is with reference to the application, dated ——————— from ——————— (Name of the hospital) for renewal of certificate of registration for performing organ transplantation, under the Act.

After having considered the facilities and standards of the above-said hospital, the Appropriate Authority hereby renews the certificate of registration of the said hospital for the purpose of performing organ transplantation for a period of five years.

Appropriate Authority ———————

Place ———————

Date ———————

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Name of the Ministry/Department _____

Position as on 31st December, 2002

S.No.	Name of the Act (with Act No. and Year)"	Rule/Regulation making power under (give Section)*	Name of Rule/ Regulation notified so far$^{\alpha}$	Date of notification	If Rules/ Regulations are in the process of formulation, their present status	Reasons for not notifying/ laying rules/ regulations in case these are not notified/laid
1.	Indian Red Cross Society Act, 1920 (XV of 1920)	Section 5	Indian Red Cross Society Rules, 1994	20.6.1994	N A	—
2.	Transplantation of Human Organs Act, 1994 (42 of 1994)	sub-section (1) of Section 24	Transplantation of Human Organs Rules, 1995	4.2.1995	N A	—

" Give the name of each Act under the administrative control of the Ministry/Department.

* List out each Section in a separate line to enable corresponding entry of subsequent columns.

$^{\alpha}$ Amendments to existing rules/regulations need not be given.