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Part II—Section 2 (Supplement)

NOTIFICATIONS BY GOVERNMENT

HEALTH AND FAMILY WELFARE DEPARTMENT

Amendment to the Transplantation of Human Organs Rules, 1995

[G.O. Ms. No. 179, Health and Family Welfare (Z-1),
18th June 2009, Aani 4, Thiruvalluvar Aandu-2040.]

No. II(2)/HF/358/2009.—The following Amendment
Notification of Government of India, Ministry of Health and
Family Welfare, dated 4th August 2008 in republished:—

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;

¹(d) "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;

¹Inserted vide Gazette notification dated 04-08-2008

²(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.

²Inserted vide Gazette notification dated 04-08-2008

³(f) 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.

³Re-numbered as clause (f) vide Gazette notification dated 4th
August 2008. of the earlier clause (d)

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
⁴Form 1(A), 1(8) and 1(C).

⁴Amended vide Gazette notification dated 04th August 2008.

4. Duties of the Medical Practitioner:

⁵(1) A registered medical practitioner shall, before removing
a human organ from the body of a donor before his death,
satisfy himself-

Substituted vide Gazette notification dated 04th August 2008.

(a) that the donor has given his authorization in appropriate Form 1 (A) or 1(8) 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 centre.

(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 (8) and has submitted an .J application in Form 10 jointly with the recipient and that the proposed donation has been ' approved by the concerned competent authority under provisions 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 witness (at least one of whom is a near relative of such persons) 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;

⁶(b) that then person lawfully in possession of the dead body has signed a certificate as specified in Form 6⁷"

⁶Substituted vide Gazette notification dated 04th August 2008.

⁷The need for Certificate in form 7 deleted by Gazette Notification, dated 04th August 2008.

(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 is 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.

⁸4-A Authorisation Committee:

(1) The medical practitioner who will be pali of the organ transplantation team for carrying out transplantation operation shall not be a member of the Authorisation Committee constituted under the provisions 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 transplntnt centre 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 and age of children and family photograph depicting the entire immediate 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 followilig 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 wishes 'to 'donate;

(c) documentary evidence of the link, e.g. proof that they have lived together, etc.;

(d) old photographs showing the donor and the 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 the 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 of such kin shall also be recorded and taken note of.'

⁸Inserted vide Gazette notification dated 04th August 2008.

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.

⁹6. 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 6-A."

⁹Substituted vide Gazette notification dated 04th August 2008.

¹⁰6(A) Composition of Authorisation Committees.

1. There shall be one State level Authorisation Committee.

2. Additional authorisation 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 ⁶'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 exceed 25 in a year at the respective transplantation centres. In smaller 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.)

¹⁰Inserted vide Gazette notification dated 04th August 2008.

¹¹6B. 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.

¹¹Inserted vide Gazette notification dated 04th August 2008.

¹²6C. 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.

¹²Inserted vide Gazette notification dated 04th August 2008.

¹³6D. 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.

¹³Inserted vide Gazette notification dated 04th August 2008.

¹⁴6E. 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 annexure, which may have been filed along with the applications. it the title 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 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) of the State/ Union territory Government.

¹⁴Inserted vide Gazette notification dated 04th August 2008.

¹⁵6F. The Authorisation Committee shall focus its attention on the following, namely:—

¹⁵Inserted vide Gazette notification dated 04th August 2008.

(a) 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 magistrate/ 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 tests 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) and (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.

(b) 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.

(c) Where the proposed transplant is between a married couple (except foreigners, whose cases should be dealt by Authorisation Committee):

The concerned competent authority or authorisation committee as the case may be must evaluate all available evidence to establish the factum and duration of marriage and ensure that 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.

(d) 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;

(v) 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 views or disagreement or objection of such kin may also be recorded and taken note of;

and

(e) When the proposed donor or the recipient or both are foreigners:—

(i) a senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient.

(ii) 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 Indian origin, with greater caution. Such cases should be considered rarely on case to case basis.

(f) In the course, of determining eligibility of the applicant to donate, the applicant should be personally interviewed by the Authorisation Committee and minutes of the interview should be recorded. Such interviews with the donors should be videographed.

(g) 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 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.

(h) 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 tests 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.

(i) The authorisation committee shall expedite its decision making process and use its discretion judiciously and pragmatically in all such cases where the patient requires immediate transplantation.

(j) Every authorised transplantation centre must have its own website. The Authorisation Committee is required to take final decision within 24 hours of holding the meeting for grant of permission or 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.

¹⁵Inserted vide Gazette notification dated 04th August 2008.

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.

¹⁶(3) before a hospital is registered under the provisions of this rule, it shall be mandatory for the hospital to nominate a transplant coordinator.

¹⁶ Inserted vide Gazette notification dated 4th August 2008.

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.

¹⁷⁹ Conditions for Grant of Certificate of Registration

No hospital shall be granted a certificate of registration under this Act unless it fulfils 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 Theater 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 systems, 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 centre.

B Equipments:

Equipments as per current and expected scientific requirements specific to organ or organs being transplanted. The transplant centre 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 recognised 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.

¹⁷ Substituted vide Gazette notification dated 4th August 2008.

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. 12011/12/2007-MS]

VINEET CHAUDHRY,

Joint Secretary to the Govt. of India.

1. Principal rules were published in the Gazette of India notification No: S-12011/2/1994-MS dated the 4th February, 1995 Extraordinary, under G.S.R.No, 51 (E).

2. Amendment to the rules were published in the Gazette of India notification, No: S.1201/12/2007-MS dated 31-7-2008 Extraordinary, under G.S.R. 571 (E) dated 4th August, 2008.

(To be completed by the prospective related donor)

(See Rule 3)

My full name is.....
and this is my photograph

Photograph of the Donor
(Attested by Notary Public)

To be affixed
and
attested by
Notary
Public after it is
affixed.

My permanent home address is
.....
.....Tel:

My present home address is
.....
.....Tel:

Date of birth(day/month/year)

* Ration/Consumer Card number and Date of issue & place.....
(Photocopy attached)

and/or

* Voter's I-Card number, date of issue, Assembly constituency.....
(Photocopy attached)

and/or

* Passport number and country of issue
(Photocopy attached)

and/or

* Driving Licence number, Date of issue, licensing authority.....
(Photocopy attached)

and/or

* PAN.....

and/or

* Other proof of identity and address.....

I hereby authorize removal for therapeutic purposes/consent to donate my.....(state which organ)
to my relative(specify son/daughter/father/mother/brother/sister), whose name is
.....and who was born on.....(day/month/year) and whose particulars
are as follows:

Photograph of the Recipient
(Attested by Notary Public)

To be affixed
and
attested by
Notary
Public after it is
affixed.

- * Ration/Consumer Card number and Date of issue & place:.....
(Photocopy attached)
and/or
- * Voter's I-Card number, date of issue, Assembly constituency.....
(Photocopy attached)
and/or
- * Passport number and country of issue.....
(Photocopy attached)
and/or
- * Driving Licence number Date of issue, licensing authority.....
(Photocopy attached)
and/or
- * PAN.....
and/or
- * Other proof of identity and address.....

I solemnly affirm and declare that:

Sections 2,9 and 19 of The Transplantation of Human Organs Act 1994 have been explained to me and I confirm that:

1. I understand the nature of criminal offences referred to in the sections.
2. No payment of money or money's worth as referred to in the sections of the Act has been made to me or will be made to me or any other person.
3. I am giving the consent and authorisation to remove my..... (organ) of my own free will without any undue pressure, inducement, influence or allurement.
4. I have been given a full explanation of the nature of the medical procedure involved and the risks involved for me in the removal of my.....(organ). That explanation was given by(name of registered medical practitioner).
5. I understand the nature of that medical procedure and of the risks to me as explained by that practitioner.
6. I understand that I may withdraw my consent to the removal of that organ at any time before the operation takes place.
7. I state that particulars filled by me in the form are true and correct to my knowledge and nothing material has been concealed by me.

.....
Signature of the prospective donor

.....
Date

NOTE:—To be sworn before Notary public, who while attesting shall ensure that the person/persons swearing the affidavit(s) Signs(s) on the Notary Register, as well.

* √ wherever applicable.

(To be completed by the prospective spousal donor)

(See Rule 3)

My full name is.....
and this is my photograph

Photograph of the Donor
(Attested by Notary Public)

To be affixed
and
attested by
Notary
Public after it is
affixed.

My permanent home address is

.....
.....Tel:

My present home address is.....

.....
.....Tel:

Date of birth(day/month/year)

I authorize to remove for therapeutic purposes/consent to donate my.....(state which organ) to my husband/wife.....whose full name is.....and who was born on.....(day/month/year) and whose particulars are as follows:

Photograph of the Recipient
(Attested by Notary Public)

To be affixed
and
attested by
Notary
Public after it is
affixed.

* Ration/Consumer Card number and Date of issue & place.....
(Photocopy attached)

and/or

* Voter's I-Card number, date of issue, Assembly Constituency.....
(Photocopy attached)

and/or

* Passport number and country of issue
(Photocopy attached)

and/or

* Driving Licence number, Date of issue, licensing authority.....
(Photocopy attached)

and/or

* PAN.....

and/or

* Other proof of identity and address.....

¹⁹Form 1B inserted vide Gazette notification, dated 4th August 2008

I submit the following as evidence of being married to the recipient:-

(a) A certified copy of a marriage certificate

OR

(b) An affidavit of a 'near relative' confirming the status of marriage to be sworn before Class-I Magistrate/Notary Public.

(c) Family photographs

(d) Letter from member of Gram Panchayat/Tehsildar/Block Development Officer/MLA/MP certifying factum and status of marriage.

OR

(e) Other credible evidence

I solemnly affirm and declare that:

Sections 2,9 and 19 of The Transplantation of Human Organs Act, 1994 have been explained to me and I confirm that:

1. I understand the nature of criminal offences referred to in the sections.
2. No payment of money or money's worth as referred to in the Sections of the Act has been made to me or will be made to me or any other person.
3. I am giving the consent and authorisation to remove my..... (organ) of my own free will without any undue pressure, inducement, influence or allurements.
4. I have been given a full explanation of the nature of the medical procedure involved and the risks involved for me in the removal of my.....(organ). That explanation was given by(name of registered medical practitioner).
5. I understand the nature of that medical procedure and of the risks to me as explained by that practitioner.
6. I understand that I may withdraw my consent to the removal of that organ at any time before the operation takes place.
7. I state that particulars filled by me in the form are true and correct to my knowledge and nothing material has been concealed by me.

.....
Signature of the prospective donor

.....
Date

Note:—To be sworn before Notary Public, who while attesting shall ensure that the person/persons swearing the affidavit(s) signs(s) on the Notary Register, as well.

* √ wherever applicable.

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(To be completed by the prospective un-related donor)

(See Rule 3)

My full name is.....
and this is my photograph

Photograph of the Donor
(Attested by Notary Public)

To be affixed
and
attested by
Notary
Public after it is
affixed.

My permanent home address is.....
.....Tel:

My present home address is
.....
.....Tel:

Date of birth(day/month/year)

* Ration/Consumer Card number and Date of issue & place:.....
(Photocopy attached)

and/or

* Voter's I-Card number, date of issue, Assembly Constituency.....
(Photocopy attached)

and/or

* Passport number and country of issue
(Photocopy attached)

and/or

* Driving Licence number, Date of issue, licensing authority.....
(Photocopy attached)

and/or

* PAN.....

and/or

* Other proof of identity and address.....
Details of last three years income and vocation of donor.....
.....
.....

²⁰ Form 1C inserted vide Gazette notification, dated 4th August 2008

I hereby authorize to remove for therapeutic purposes/consent to donate my.....(state which organ) to a person whose fully name is and who was born on

.....(day/month/year) and whose particulars are as follows:

Photograph of the Recipient
(Attested by Notary Public)

To be affixed
and
attested by
Notary
Public after it is
affixed.

- * Ration/Consumer Card number and Date of issue & place:.....
(Photocopy attached)
- and/or
- * Voter's I-Card number, date of issue, Assembly Constituency.....
(Photocopy attached)
- and/or
- * Passport number and country of issue.....
(Photocopy attached)
- and/or
- * Driving Licence number Date of issue, licensing authority.....
(Photocopy attached)
- and/or
- * PAN.....
- and/or
- * Other proof of identity and address.....

I solemnly affirm and declare that:

Sections 2, 9 and 19 of The Transplantation of Human Organs Act, 1994 have been explained to me and I confirm that:

1. I understand the nature of criminal offences referred to in the Sections.
2. No payment of money or money's worth as referred to in the Sections of the Act has been made to me or will be made to me or any other person.
3. I am giving the consent and authorisation to remove my..... (organ) of my own free will without any undue pressure, inducement, influence or allurement.
4. I have been given a full explanation of the nature of the medical procedure involved and the risks involved for me in the removal of my.....(organ). That explanation was given by(name of registered medical practitioner).
5. I understand the nature of that medical procedure and of the risks to me as explained by that practitioner.
6. I understand that I may withdraw my consent to the removal of that organ at any time before the operation takes place.
7. I state that particulars filled by me in the form are true and correct to my knowledge and nothing material has been concealed by me.

.....
Signature of the prospective donor

.....
Date

Note:—To be sworn before Notary Public, who while attesting shall ensure that the person/persons swearing the affidavit(s) signs(s) on the Notary Register, as well.

* √ wherever applicable.

[See rule 4(1) (b)]

(To be completed by the concerned Medical Practitioner)

I, Dr..... possessing qualification of.....registered as medical practitioner at serial noby the.....Medical Council, certify that I have examined Shri / Smt./Km.S/o, D/o., W/o Shri..... agedwho has given informed consent about donation of the organ, namely (name of the organ).....to Shri/Smt./Km..who is a 'near relative', of the donor/other than near relative of the donor; who had been approved by the Authorisation Committee/Registered Medical Practitioner i.e. Incharge of transplant centre (as the case may be) and that the said donor is in proper state of health and is medically fit to be subjected to the procedure of organ removal.

Place:

.....
Signature of Doctor

Date:

Seal

To be affixed (pasted) and attested by the doctor concerned.

The signatures and seal should partially appear on photograph and document without disfiguring the face in photograph.

Photograph of the Donor
(Attested by doctor)

To be affixed (pasted) and attested by the doctor concerned.

The signatures and seal should partially appear on photograph and document without disfiguring the face in photograph.

Photograph of the recipient
(Attested by the doctor)

²¹ Form 2 substituted vide Gazette notification dated 4th August 2008

22 FORM 3

[See Rule 4(1) (C)]

I, Dr./Mr./Mrs..... working as..... at
and possessing qualification of.....certify that Shri/
 Smt./ Km.....S/o, D/o, W/o Shri/Smt. aged.....the donor
 and Shri/Smt.....
 S/o, D/o, W/o. Shri/Smt.....aged.....the proposed recipient of the organ to be donated
 by the said donor are related to each other as brother/sister/mother/father/son/daughter as per their statement and
 the fact of this relationship has been established not established by the results of the tests for Antigenic Products
 of the Human Major Histocompatibility Complex. The results of the tests are attached.

Place

Signature

Date

(To be signed by the Head of the Laboratory)

Seal

²²Form 3 substituted vide Gazette notification dated 4th August 2008

FORM 4

[See Rule 4(1) (d)]

I, Dr./Mr./Mrs.....possessing qualification
 ofregistered 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 according 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 mentioned above is such that recording of his/her
 statement is not practicable.

Place.....

Signature of Regd. Medical Practitioner

Date.....

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,.....

Signature of Donor

(Signature)

Dated:

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 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.....

Dated

Signature

Place

Person in lawful possession of the dead body.
Address.....
.....

[See Rules 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.
Appropriate
- 2. R.M.P. nominated from the panel of
Names approved by the Authority.
- 3. Neurologist/Neuro-Surgeon nominated
deceased from the panel of names
approved by the Appropriate Authority.
- 4. R.M.P. treating the aforesaid person.

BRAIN-STEM DEATH CERTIFICATE.

(A) PATIENT DETAILS.....

- 1. Name of the patient: Mr./Ms.....
S.O./D.O./W.O. Mr./Ms.....
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 must 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)

Examination

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. Neurologis/Neuro-Surgeon
- 4. Medical Officer treating the Patient.

Nb. (I) The minimum time interval between the first testing will be six hours.

(II) No. 2 and No. 3 will be co-opted 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 dead body of my son/daughter Mr/Mrs..... aged.....whose brain-stem death has been duly certified in accordance with the law.

Signature

Name

Place

Date

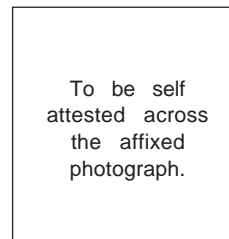
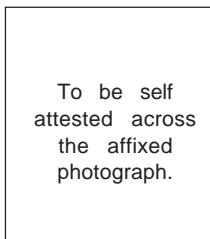
²⁴FORM 10

(Page 1 of 2)

APPLICATION FOR APPROVAL FOR TRANSPLANTATION (LIVE DONOR)

(To be completed by the proposed recipient and the proposed donor)

[See Rule 4 (1) (c)(d)(e)].



Photograph of the Donor (Self-attested)

Photograph of the recipient (Self-attested)

Whereas I S/o, D/o, W/o Shri/Smt.....aged residing at.....have been advised by my doctor.....that I am suffering from.....and may be benefited by transplantation ofinto my body.

And whereas I S/o, D/o, W/o. Shri/Smt.....aged residing at.....by the following reason(s):—

(a) by virtue of being a near relative i.e.....

²⁴ Form 10 substituted vide Gazette notification dated 04-08-2008

(b) by reason of affection/lattachment/other special reason as explained below :—

.....
.....
.....

I would therefore like to donate my (name of the organ).....to
Shri/Smt.....

We.....and.....
(Donor) (Recipient)

hereby apply to Authorization Committee for permission for such transplantation to be carried out.

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.

Instructions for the applicants:—

1. Form 10 must be submitted along with the completed Form 1 (A), or Form 1 (B) or Form 1 (C) as may be applicable.
2. The applicable Form i.e., Form 1 (A) or Form 1 (B) or Form 1 (C) as the case may be, should be accompanied with all documents mentioned in the applicable form and all relevant queries set out in the applicable form must be adequately answered.
3. Completed Form 3 to be submitted along with the laboratory report.
4. The doctor's advice recommending transplantation must be enclosed with the application.
5. In addition to above, in case the proposed transplant is between unrelated persons, appropriate evidence of vocation and income of the donor as well as the recipient for the last three years must be enclosed with this application. It is clarified that the evidence of income does not necessarily mean the proof of income tax returns, keeping in view that the applicant(s) in a given case may not be filing income tax returns.
6. The application shall be accepted for consideration by the Authorisation Committee only if it is complete in all respects and any omission of the documents or the information required in the forms mentioned above, shall render the application incomplete.
7. As per the Supreme Court's judgement dated 31-03-2005, the approval/No Objection Certificate from the concerned State/Union Territory Government or Authorisation Committees is mandatory from the domicile State/Union Territory of donor as well as recipient. It is understood that final approval for transplantation should be granted by the Authorisation Committee/Registered Medical Practitioner i.e., Incharge of transplant centre (as the case may be) where transplantation should be done.

We have read and understood the above instructions.

Signature of the Prospective Donor

Signature of Prospective Recipient

Date:

Date:

Place:

Place:

FORM 11

APPLICATION FOR REGISTRATION OF HOSPITAL TO CARRY OUT ORGAN TRANSPLANTATION

To

The Appropriate Authority for organ transplantation
(State of 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. Government/Private:
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 designation:
3. No. of temporary staff with their designation:
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. I.C.U./H.D.U. facilities: Present.....Not present.....
2. No. of I.C.U. beds:
3. Trained:—
Nurses:
Technicians:
4. Name and member 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 Dept.:
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 Dept.:
4. Name and number 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 Dept.
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 Daft/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.

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 datedFrom..... (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

V.K. SUBBURAJ,
Principal Secretary to Government.