

**GOVERNMENT OF INDIA  
MINISTRY OF HEALTH & FAMILY WELFARE  
DEPARTMENT OF HEALTH & FAMILY WELFARE**

**N O T I F I C A T I O N**

New Delhi, the \_\_\_\_\_, 2008.

G. S. R. .- 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 amendments to the Transplantation of Human Organs Rules, 1995, namely:-

**1. SHORT TITLE AND COMMENCEMENT**

(1) These rules may be called the Transplantation of Human Organs (Amendment) Rules, 2008.

(2) They shall come into force on the date of their publication in the Official Gazette.

**2. After sub-rule (d) of Rule 2, the following shall be inserted:**

(e) “National Accredited 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;

(f) “Transplant Coordinator” means an official of the hospitals registered by the appropriate authority under provisions of Rule 7 for coordinating all matters relating to transplantation of human organs or for the harvesting of organs from a patient declared as brain dead.

**3. The existing Rule 3 shall be substituted by the following:**

**“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 **Forms 1(A), 1(B) and 1(C), as may be applicable to the donor.**”

4. The existing Rule 4 (1) shall be substituted by the following:

**“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 **appropriate** 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 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 authorisation committee/committees of competent jurisdiction(s) and that the necessary medical tests to determine the factum of near relationship, have been performed to the satisfaction of the authorisation committees of competent jurisdiction(s). The tests are as follows:-**

(i) The tests for HLA, HLA-B alleles to be performed by the serological and/or PCR based DNA methods.

(ii) Test for HLA-DR beta genes to be performed using the PCR based DNA methods.

(iii) Where the tests referred to in (i) and (ii) 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. 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.

iv) where the tests referred to in sub-rules (i) to (iii) shall be got done from a laboratory accredited with National Accreditation Board for Laboratories (NABL).”

d) where the tests referred to in sub-rule (i) and sub-rule (ii) do not establish a genetic relationship between the donor and the recipient, (a) tests to establish DNA polymorphisms using at least two multi-locus gene probe, then (b) results of tissue typing and other tests with the name of the HLA laboratory and if possible the estimation of the probability of genetic relationship; (c) documentary evidence of relationship, e.g., relevant birth certificates and marriage certificate, certification from sub-

divisional magistrate / metropolitan magistrate / Sarpanch of the Panchayat; (d) documentary evidence of identity and residence of the proposed donor e.g. ration card / voter's identity card / passport / driving license / Permanent Account Number Card issued Income Tax authorities / Bank account and family photograph depicting the proposed donor and the proposed recipient along with another near relative could be attempted.

- e) that in case the recipient is spouse of the donor, the donor to give 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 authorization committee under provisions of Rule 4-A(2).**
- f) 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.

5. The existing Rule 4 (2)(b) shall be substituted by the following:

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

The existing Form 7 is hereby deleted.”

6. After sub-rule (3)(b) of Rule 4, the following shall be inserted:-

“4-A (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 Committees constituted under the provisions of Sections 9(4)(a) and 9(4)(b) of the Act.”

“(2) where the proposed transplantation is between a married couple, the Authorisation Committee must evaluate the factum and duration of marriage and ensure that documents such as marriage certificate, marriage photograph is placed before the committee alongwith 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, Authorisation Committees shall consider such requests as is done in the case of requests for transplantation of organs between Indian nationals.”

“(4) when the proposed donor and the recipient are not ‘near relatives’, as defined under Section 2(i) of the Act, the Authorisation Committee shall evaluate:-

- (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 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 / 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 / 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 / disagreement / objection of such kin shall also be recorded and taken note of.”

7. The existing Rule 6 shall be substituted by the following:-

“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. The Authorisation Committee shall take a decision on such application in accordance with the guidelines in Rule 6-A.

8. After Rule 6, the following Rule 6-A shall be inserted:-

“6-A. **GUIDELINES FOR WORKING OF THE AUTHORISATION COMMITTEE**

The working of the Authorisation Committee would be in accordance with the guidelines to be issued by the Ministry of Health & Family Welfare, Government of India from time to time.”

9. After Rule 7(2) the following shall be inserted:-

“7(3) before a hospital is registered under the provisions of this Rule, it shall be mandatory for the hospital to have / nominate a transplant coordinator.”

10. The existing Rule 9 shall be substituted by the following:

“9. **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:-

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, physiotherapy.
- (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 specialities 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.

### **Equipments**

Equipments as per current and expected scientific requirements specific to organ / 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.

### **Experts**

#### **(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 operation.

[Vineet Chawdhry]  
Joint Secretary to the Government of India  
[File No: /MS]

**The principal rules were notified *vide* notification No. S.12011/2/94-MS dated the 4th February, 1995, in the Gazette of India, Extraordinary, under GSR No. 51(E).**

*(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)

\* Voter's I-Card number, date of issue, Assembly constituency.....

(Photocopy attached)

\* Passport number and country of issue.....

(Photocopy attached)

\* Driving Licence number, Date of issue, licensing authority.....

(Photocopy attached)

\* PAN.....

\* 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:

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

Photograph of the Recipient  
(Attested by Notary Public)

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



**FORM 1(B)**

*(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

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 License number, Date of issue, licensing  
authority.....  
(photocopy attached)

\* PAN..... and/or  
\* Other proof of identity and address

- I submit the following as evidence of being married to each other:-
- (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.
  - (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 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.

\_\_\_\_\_  
\_\_\_\_\_

**FORM 1(C)**

*(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)

\* Voter's I-Card number, and/or date of issue, Assembly  
constituency.....  
(photocopy attached)

\* Passport number and country of  
issue.....  
(photocopy attached)

\* Driving Licence number, and/or Date of issue, licensing  
authority.....  
(photocopy attached)

\* PAN.....  
and/or

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

I hereby authorize to remove for therapeutic purposes/consent to donate my  
.....

(state which organ) to a person whose full name is  
..... and who was  
.....(day/month/year) and whose particulars are.

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)

\* Voter's I-Card number, and/or date of issue, Assembly  
constituency.....  
(photocopy attached)

and/or

\* Passport number and country of issue.....  
 (Photocopy attached)

\* Driving License number, Date of issue, licensing authority.....  
 (photocopy attached)

\* PAN.....

\* 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.

FORM 2

[See rule 4(1) (b)]  
 (To be completed by the concerned Medical Practitioner)

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 Shri .....aged .....  
 who has given informed consent about donation of the organ, namely.....  
 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 Authorization Committee 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: .....  
.....

Date: .....

Signature of Doctor

To be affixed and  
attested by the  
doctor concerned  
after affixation

To be affixed  
and attested by  
the doctor  
concerned after  
affixation

Photograph of the Donor  
recipient  
(Attested by doctor)

Photograph of the  
recipient  
(Attested by the doctor)

**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 ..... aged ..... the donor and  
Sh./Smt..... s/o, d/o, w/o Shri .....  
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.

Signature  
(To be signed by the Head of the Laboratory)

Seal

Place .....

Date .....

**FORM 10**

**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)]**

To be self  
attested across  
the affixed  
photograph

To be self attested across  
the affixed photograph

Photograph of the Donor  
(Self-attested)

Photograph of the recipient  
(Self-attested)

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

And whereas I ..... S/O, D/O,  
W/O,..... aged ..... residing at  
..... by the following reason(s):-

- a) by virtue of being a near relative i.e. \_\_\_\_\_
- b) by reason of affection/attachment/other special reason as explained below :-

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

I would therefore like to donate my .....to.....  
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 allurements 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.

We have read and understood the above instructions.

Signature of the Prospective Donor

Signature of Prospective Recipient

Date :

Date :

Place :

Place :

**File No: S. 12011/12/2007-MS**  
**Government of India**  
**Ministry of Health & Family Welfare**  
**Department of Health & Family Welfare**  
**MS Section**  
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**S U B J E C T**

***Amendment to Transplantation of Human Organs Rules, 1995***

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Delhi High Court is hearing a petition filed by Balbir Singh regarding transplantation of human organs. During the course of the hearing, the High Court constituted a Committee to look into THO Act and THO Rules and to recommend amendments. The report submitted by the Committee may kindly be seen at **F / A (pp 51 – 1 / cor)**. After the receipt of the report of the committee, it was decided in the Ministry with the approval of HFM that since the issues involved has implications on a large scale, it was necessary for consultation with all stake holders.

2. It was decided to organise one day consultation through Rajiv Gandhi Foundation. A one day national consultation was organised on 18<sup>th</sup> May, 2007. The report submitted by Rajiv Gandhi Foundation may kindly be seen at **F / B (pages 94 – 52/cor)**. The report was considered in a meeting taken by HFM on 19<sup>th</sup> September, 2007. A copy of the minutes of the meeting may kindly be seen at **F / C (pages 152 – 151/cor)**.

3. Delhi High Court in its last hearing held on 30<sup>th</sup> November, 2007, which was attended by JS (VC). After hearing the points put forth, the High Court directed the Ministry to file an affidavit in the Court alongwith draft of the notification to amend THO Rules and fixed the next date of hearing as 18<sup>th</sup> January, 2008.

4. Based on the report of the review committee set up by Delhi High Court; report of the one day consultation organised through Rajiv Gandhi Foundation, a draft extraordinary notification proposed amendments to various Rules in Transplantation of Human Organs Rules, 1995, has been attempted and is placed below for approval, DFA.

(R. Ravi)  
Deputy Secretary  
December 27, 2007

**JS (VC)**