



GOVERNMENT OF KERALA

HEALTH & FAMILY WELFARE (S) DEPARTMENT

No. 14931/S2/2009/H&FWD

Date: 19.11.2010

NOTIFICATION

In exercise of powers conferred by Human Organ Transplantation Act and its Rules Government of Kerala hereby issue guidelines for conducting organ transplantations in the State. These guidelines shall be followed by all authorization committees for organ transplantations working in the State of Kerala. The guidelines are appended herewith.

Sd /-

B.S. MAVOJI
SECRETARY TO GOVERNMENT

To

The Director of Medical Education, Thiruvananthapuram
The Director of Health Services, Thiruvananthapuram
The Principal, Government Medical College, Thiruvananthapuram/ Alappuzha
Kottayam/ Thrissur/ Kozhikode.
All major Private Hospitals in the State.
Stock File/Office Copy

Appendix

GUIDELINES FOR GRANTING APPROVAL FOR ORGAN TRANSPLANTATION IN THE STATE

1. The donor must be a near relative of the recipient as certified in the 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 in charge of transplant center.
2. That in case the recipient is spouse of the donor, the donor has given a statement to the effect that they are so related by signing a certificate in Form 1 (B) and has submitted an application in Form 10 jointly with the recipient and that the proposed donation has been approved by the concerned competent authority under provisions of sub-rule(2) of rule 4A.
3. 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 Authorization Committee for the said donation has to be obtained.
4. Where the proposed transplantation is between a married couple, the Registered Medical Practitioner in charge of transplant center must evaluate the factum and duration of marriage and ensure that documents such as marriage certificate, marriage photograph etc are kept for records along with the information on the number and age of children and family photograph depicting the entire immediate family birth certificate of children containing particulars of parents.
5. When the proposed donor or recipient or both are not Indian Nationals/citizens whether 'near relatives' or otherwise, Authorisation Committee shall consider all such requests.
6. When the proposed donor and the recipient are not 'near relatives' as defined under clause (i) of section 2 of the Act, the authorization Committee shall evaluate that -
 - (i) there is no commercial transaction between the recipient and the donor and that no payment or money or moneys worth as referred to the Act, has been made to the donor or promised to be made to the donor or any other person;
 - (ii) the following shall specifically be assessed by the Authorization 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, eg; proof that they have lived together etc.
 - (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 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.
7. 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 Authorization Committee as specified in Form 10. The Authorization Committee shall take a decision on such application in accordance with the guidelines in rule 6-A.
8. The Authorization Committee shall focus its attention on the following, namely:-
- (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 Bonk 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 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, 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.

- (e) Where the proposed transplant is between a married couple (except foreigners, whose cases should be dealt by Authorization Committee):
The concerned competent authority or authorization committee as the case may be must evaluate all available evidence to establish the factum and duration of marriage and ensure 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.
- (f) 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 Authorization 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 eg., 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 next kin of the proposed unrelated donor is interviewed regarding awareness about his/her intention to donate an organ, the authenticity of link between the donor and the recipient and the reasons for donation. Any strong views or disagreement or objection of such 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) Authorization 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 Authorization Committee an 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 Authorization 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 Authorization 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 tall such medial tests as required at the relevant stages to determine his biological capacity and compatibility to donate the organ in question.
 - (iii) 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.
 - (iv) All prescribed forms have been and would be filled up by all relevant persons involved in the process of transplantation.
 - (v) All interviews to be video recorded.

FORM 1 (A)

(Page 1 of 2)

(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, and Date of issue & place (Photocopy attached)

and/or

• Passport number and country of issue (Photocopy attached)

and/or

• Driving License 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 purpose/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

Photograph of the Recipient
(Attested by Notary Public)

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

FORM 1(A) [Page -2]

- Ration/Consumer Card number and Date of issue & place:.....
(Photocopy attached)
and/or
- Voter's 1-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)
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 authorization 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) sign(s) on the Notary Registrar, as well.

- Wherever applicable.

FORM 1 (B)

(Page 1 of 2)

To be completed by the prospective spousal donor)

(see Rule3)

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, licensing authority
(Photocopy attached)
and/or
- Driving License number, Date of issue, licensing authority
(Photocopy attached)
and/or
- PAN
- Other proof of identity and address

FORM 1 (B) Page-2

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.

(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 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 authorization 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(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 taken 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) sign(s) on the Notary register, as well.

- Wherever applicable.

FORM 1(C)

(Page 1 of 2)

(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 License 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
.....
.....

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 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

FORM 1(C)[Page-2]

- 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)
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

2. I understand the nature of criminal offences referred to 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 authorization 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(organ).
That explanation was given by(name of registered medical practitioner).
5. I under 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 taken 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) sign(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 (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 Authorization Committee/Registered Medical Practitioner ie., incharge of transplant center (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 :
Date:

.....
Signature of Doctor
Seal

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

The signatures and sea 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 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./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 result of the tests are attached.

Place :
Date :

Signature
(To be signed by the Head of the laboratory)
Seal

FORM 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)]

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,
Shri/Smt. 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,
Shri/Smt. Aged residing at
..... by the following reasons(s):-

- a) by virtue of being a near relative ie.,
- b) by reason of affection/attachment/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 allurements and that all possible consequences and
options of organ transplantation have been explained to us.

FORM 10 [Page 2]

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 ie., 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 t 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 Authorization 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 judgment dated 31.03.2005, the approval/No Objection Certificate from the concerned State/Union Territory Government or Authorization 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 Authorization Committee/Registered Medical Practitioner ie., 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 :

Certificate of Altruism

(Sample - to be issued by SP/DY SP of the District having administration where donor and recipient resides)
(For production before the Authorization Committee for Organ Transplantation)

This is to certify that it has been found after due enquiry/investigation that Sri/Smt (name of donor) Years residing at(address of the donor) has voluntarily consented to donate one of his/her kidneys to Sri/Smt name of recipient), upon his/her free will, without any compulsion, influence, or intent of reward or consideration and his altruism is genuine. He has no criminal back ground.

The donor (name) had been associate with the recipient (name) as (specify the nature of association) since the last Specify the period of acquaintance/the degree of association/reciprocity of feelings/gratitude). Enquiries were made about the chances of commercial dealings under the pretext of a Hruistic donation by the DY SP of special branch unit and their report obtained.

The following documents (if any) that support the above facts are attached.

1.
2.

The donor and recipient have been informed about the provisions of THOA 1994 and that any sort of commercial dealings or even an attempt at it will attract primitive action which may extend up to 7 years imprisonment and fine up to Rs.2,00,000/-

Signature with date

Name :

Designation :

(Office Seal)

Affidavit

(Sample - to be attested by the Notary of the District regarding the altruism)

(For production before the Authorization Committee for Organ Transplantation)

I, (name of donor)
son/daughter/wife/husband of aged
..... Years residing at Hereby
solemnly affirm and sincerely state that :-

I am donating one of my kidneys to Sri/Smt.
Aged years residing at without
any compulsion or coercion and without intent for monetary or material gain,
reward or consideration.

I have been associating with the recipient
(name) as (specify the nature of
association) since the last (specify the period of acquaintance/the
degree of association/reciprocity of feelings/gratitude etc..)

The following documents (if any) that support the above facts are attached.

1.
2.

I further declare that I am aware of the Transplantation of Human Organs Act
of 1994 and its penal provisions and I am aware of the penalties imposed should
the provisions of the act be contravened in any way.

I also certify that the above facts are true to the best of my knowledge and
belief.

Date Signature of the donor
Name and Address

Signed before me
Signature

Name & Designation Seal

(Office Seal)