

TO BE PUBLISHED IN PART II SUB-SECTION (i) SECTION 3

(Extraordinary)

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE**

Notification

G.S.R.E.....

New Delhi, dated , 2013

in exercise of the powers conferred by sub-section (1) and (2) of Section 24 of the Transplantation of Human Organs Act, 1994 (42 of 1994) and in supersession of the Transplantation of Organs Rules, 1995, except as respect things done or omitted to be done before such supersession, 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 and Tissues Rules, 2013.
- (2) They shall come into force on the date of their publication in the Official Gazette.
- (3) Cadaver(s), Organ(s), Tissue(s) wherever referred to in these Rules mean human Cadaver(s), human Organ(s) and human Tissue(s), respectively.

2. DEFINITIONS :- In these rules unless there is anything repugnant with subject or content-

- (a) "Act" means the Transplantation of Human Organs Act 1994 (42 of 1994);
- (b) "Form" means a form annexed to these Rules;
- (c) "Section" means a section of the Act;
- (d) National Accreditation Board for Testing and Calibration Laboratories (NABL) is an autonomous body under the aegis of Department of Science and Technology, Government of India. National Accreditation Board for Testing and Calibration Laboratories (NABL) has been established with the objective to provide Government, Regulators and Industry with a scheme of laboratory accreditation through third-party assessment for formally recognizing the technical competence of laboratories. The accreditation services are provided for testing, calibration and medical laboratories in accordance with International Organization for Standardization (ISO) Standards;
- (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, recognised under the Indian Medical Council of India Act, 1956;
- (f) Nurse means a Nurse as defined under the Indian Nursing Council Act 1947, (48 of 1947);

- (g) The technician with following qualification and experience can enucleate cornea:
- Doctors including Registered Medical Practitioners from all recognized systems of medicine, Nurses, Paramedical Ophthalmic Assistant, Ophthalmic Assistant, Optometrists, Eye Donation Counselors and Refractionists, provided the person is duly trained for a minimum period of six weeks to enucleate a donated cornea/eye. The training certificate should mention that he has acquired the required skills to independently conduct enucleation of the eye/removal of cornea from a cadaver.
- (h) "Payment" means payment as defined under the Act and shall also be applicable to tissues. It shall not include the cost incurred on maintenance of the body of brain-stem dead person for the purpose of retrieval of organs and/or tissues.
- (i) Next of Kin means 'closest living relative' linked by direct relationship from either blood or marriage.
- (j) Words and expressions used and not defined in these Rules, but defined in the Act, shall have the same meanings, respectively, assigned to them in the Act.

3. AUTHORITY FOR REMOVAL OF HUMAN ORGANS AND/OR TISSUES

Any donor, may authorize the removal, of any organ and/or tissue of his/her body, during his/her lifetime, as per prevalent medical practices, for therapeutic purposes in the manner and on such conditions as specified in Form 1(A), 1(B) and 1(C).

3A. PANEL OF EXPERTS FOR BRAIN-STEM DEATH CERTIFICATION

For the purpose of certifying the brain-stem death, the appropriate authority shall maintain a panel of experts, as per the Act, in order to ensure that the 'Board of Medical Experts' does not face manpower crunch in its functioning and remains fully operational.

4. DUTIES OF THE REGISTERED MEDICAL PRACTITIONER

- (1) The Registered Medical Practitioner (RMP) of the hospital having ICU facility, in consultation with transplant coordinator (if available) shall ascertain, after certification of brain stem death of the person in ICU, from his/her next of kin or the person in lawful possession of the body, the following:
- (a) Whether the donor had, in the presence of two or more witnesses (at least one of whom is a near relative of such donor), unequivocally authorised before his/her death as specified in Form 5 or in documents like Driving License etc. wherein the provision for donation may be incorporated after notification of these Rules, the removal of his/her organ(s) and/or tissue(s) including eye, after his/her death, for therapeutic purposes and there is no reason to believe that the donor had subsequently revoked the of aforesaid authorisation? If yes, then the RMP, on behalf of the hospital shall request the next of the kin or person in lawful possession of the body, to submit the aforesaid authorisation and sign the Declaration/Authorisation as per Form 6, and submit to the hospital.
- (b) Where the aforesaid authorisation was not made but there is no reason to believe that the person did not want to donate his/her organ(s)/tissue(s) after his/her death, then RMP in consultation with the Transplant Coordinator shall make the next of kin

or person in lawful possession of the body aware of the option to authorize or decline the donation of such human organs or tissues or both (which can be used for therapeutic purposes) including eye / cornea of the deceased person. A declaration/authorisation to this effect shall be signed by the next of kin or person in lawful possession of the body as per Form 6. In case of an unclaimed body, authorization shall be made in form 6A, by the authorised official as per Section 5(1) of the Act.

- (c) After next of the kin or person in lawful possession of the body authorizes removal and gives consent for donation of human organ(s) or tissue(s) or both of the deceased person, the Registered Medical Practitioner (RMP), through Transplant Coordinator shall inform the registered Human Organ Retrieval Centre by Telephone and fax or through electronic mail, for removal, storage or transportation of organ(s)/tissue(s)/or both. The unregistered hospital is only authorized to undertake surgical tissue retrieval on its own.
- (2) The above mentioned duties shall also apply to the Registered Medical Practitioner (RMP) working in an Intensive Care Unit (ICU) in a hospital not registered under this Act, from the date of notification of these Rules.
- (3) The Registered Medical Practitioner (RMP) shall, before removing any human organ and/or tissue from the body of a donor before his/her death, shall satisfy himself –
- (a) That the donor and recipient have been explained all possible side effects, hazards and complications and that the donor has given his/her authorisation 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/ or tissue and that his/her psychiatric evaluation has been done and it has been certified that he/she is not mentally challenged. RMP shall sign the certificate as prescribed in Form 2 for this purpose.
 - (c) that the donor is a near relative of the recipient, as certified in Form 3, and that he/she has submitted an application in Form 10 jointly with the recipient and that the proposed donation has been approved by the Concerned Competent Authority i.e. Incharge/Director/Medical Superintendent of the institution/hospital carrying out transplantation or a committee constituted for this purpose by the institution/hospital, as specified in Form 14A and that the necessary documents as prescribed and medical tests, as required, to determine the factum of near relationship, have been examined to the satisfaction of the Registered Medical Practitioner and Concerned Competent Authority.
 - (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(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.
 - (e) that 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.
 - (f) that if a donor and/or recipient is/are foreign nationals, the approval of the Authorisation Committee for the said donation has been obtained.

- (4) A registered medical practitioner, before removing any organ or tissue from the body of a person after his/her death, in consultation with transplant coordinator shall satisfy himself:-
- (a) that the donor had, in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorised before his/her death as specified in Form 5 or in documents like Driving license etc. wherein the provision for donation may be incorporated after notification of these Rules, the removal of his/her organ(s) and/or tissue(s) after his/her death, for therapeutic purposes and there is no reason to believe that the donor had subsequently revoked the authorisation ,aforesaid;
 - (b) that the next of kin of the deceased person or the person lawfully in possession of the dead body has signed the declaration/authorisation as specified in Form 6.
 - (c) that in the case of brain-stem death of the donor, a certificate as specified in Form 8 has been signed by all the members of the Board of medical experts referred to in Section 3 (6) of the Act; Where a neurologist or a neurosurgeon is not available, an anesthetist or intensivist nominated by the Registered Medical Practitioner(RMP) and who is not member of the transplantation team for the recipient concerned, may certify the brain stem death as a member of the Board.
 - (d) that in the case of brain-stem death of a person of less than eighteen years of age, a certificate specified in Form 8 has been signed by all the members of the Board of medical experts referred to in sub-section (6) of Section 3 of the Act and an authority as specified in Form 9 has been signed by either of the parents of such person. Living organ/tissue donation by minors shall not be permitted except on exceptional medical grounds to be recorded in detail with full justification and with prior approval of the Appropriate Authority and the Government concerned.
- (4) Procedure for donation in medicolegal cases:
- (a) After the authority for removal of organs and/or tissues, as also the consent to donate organs from a brain-stem dead donor are obtained, the Registered Medical Practitioner of the hospital shall make a request to the SHO of the area either directly or through the Police Post located in the hospital to agree for retrieval of organs from the donor. It has to be ensured that, by retrieving organs, the determination of the cause of death is not jeopardized.
 - (b) Only in cases where the definite cause of death is established clinically by the RMP, the post mortem may be waived off by the competent officer on the request of the RMP and Investigating Officer of the case.
 - (c) The Registered Medical Practitioner who is designated to do the post mortem can do the post-mortem in a case of organ retrieval also.
 - (d) Doctor designated to perform Post-Mortem shall be present at the time of retrieval of organs/tissues by the retrieval team. The Post mortem report in respect of the organs/tissues being retrieved shall be prepared at the time of retrieval. Rest of the post mortem procedure shall take place at the designated place for post-mortem.
 - (e) For the purpose of organ(s)/tissue(s) retrieval, request for post mortem beyond specified timings, can be made by the Registered Medical Practitioner and the investigating officer of the case.

4A AUTHORISATION COMMITTEE

(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 Committee constituted under the provisions of clauses (a) and (b) of sub-section(4) of section 9 of the Act.

(2) Where the proposed transplant is between a married couple the Concerned Competent Authority or Authorisation Committee (in case of foreigners) 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 a family photograph depicting the entire immediate family, birth certificate of children containing the particulars of parents and issue a certificate in Form 4.

(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. The transplantation shall not be permitted if the recipient is a foreign national and donor is an Indian national unless they are near relatives.

(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 as referred to in the Act /Rules, 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 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
 - (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 and/or tissue, 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.'
- (5) Cases of swap donation as provided under section 3(A) of Transplantation of Human Organs Act, 1994 shall be approved by Authorisation Committee. Donation of organs shall be permissible only from near relatives of the Swap recipients.

5. REMOVAL AND PRESERVATION OF ORGANS AND/OR TISSUES

The removal of the organ(s)/tissue(s) shall be permissible in any registered retrieval/transplant hospital/Centre and preservation of such removed organ(s)/tissue(s) shall be ensured in registered retrieval/transplant centre/tissue bank according to

current and accepted scientific methods in order to ensure viability for the purpose of transplantation.

5A. COST FOR MAINTENANCE OF CADAVER OR RETRIEVAL OR TRANSPORTATION OR PRESERVATION OF ORGANS OR TISSUES:

The cost for maintenance of the cadaver (brain-stem dead declared patient), retrieval of organs/tissues, their transportation and preservation, may be borne by the recipient or institution or Government or Non-Government Organization or Society as decided by respective State or Union Territory Government.

6. APPLICATION FOR LIVE DONOR TRANSPLANTATION

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 Concerned Competent Authority or Authorisation Committee shall take a decision on such application in accordance with the guidelines in rule 6-F."

6A. 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 'Authorisation Committee' as abundant precautions need to be taken in such cases;
 - (ii) Authorisation Committee should be Hospital based in Metro and cities if the numbers of transplants exceed 25 in a year at the respective transplantation centres. If the number of organ transplants in an institution/hospital, are less than 25 in a year, then the State or District level Authorisation Committee would grant approval(s).
- (A) **Composition of Hospital Based Authorisation Committees:** (To be constituted and notified by the State Government in case of State and by the Union Territory Administration in case of Union Territory).
- (a) the senior most person officiating as Medical Director or Medical Superintendent of the Hospital shall be the Chairperson;
 - (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 from State Government/Union Territory Administration.

- (B) **Composition of State or District Level Authorisation Committees:** (To be constituted and notified by the State Government in case of State and by the Union Territory Administration in case of Union Territory)
- (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 from State Government/Union Territory Administration.

(Note: Effort should be made from State Government to have most of the members' ex-officio so that the need to change the composition of committee is less frequent.)

- 6B. When the donor is unrelated and if donor and/or recipient belongs to a State/ Union Territory, other than the State/Union Territory where the transplantation is proposed to be undertaken, "No Objection Certificate" from the State/Union Territory of domicile of donor and/ or recipient shall be required, as per form 14B. The 'No Objection Certificate' will only be for the purpose of establishing their legal and residential status. The maximum period for granting/rejection of "No Objection Certificate" in such cases shall be thirty days after the submission of required documents. "No Objection Certificate" will not be required for near relatives and Swap donation cases.
- 6C. 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. Secretary (Health) or nominee and Director of Health Services or nominee.
- 6D. 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. Model format is given at Form 14.
- 6E. Secretariat of the Authorisation 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 annexures, which may have been filed along with the applications. At the time 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.

6F. The Authorisation Committee/ Concerned Competent Authority as the case may be, shall focus its attention on the following, namely:-

I. Where the proposed transplant is between near relatives i.e persons related genetically especially Grandmother, Grandfather, Mother, Father, Brother, Sister, Son, Daughter, grandson and granddaughter above the age of eighteen 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, or similar other identity certificates like Electors Photo Identity Card or AADHAAR (issued by **Unique Identification Authority of India**).
- (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, or similar other identity certificates like AADHAAR (issued by **Unique Identification Authority of India**).
- (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 prescribed as below:
 - a) Deoxyribonucleic Acid (DNA) Profiling
 - b) The tests referred to in sub-rules (i) and (iv) a) shall be got done from a laboratory accredited with NABL and certificate shall be given in Form 3.
 - c) where the tests referred to in (i) and (iv) a) above do not establish a genetic relationship between the donor and the recipient, the same tests to be performed on preferably 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 failing which, genetic relationship between the donor and the recipient will be deemed to have not been established.

(II) 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 Concerned Competent Authority or Authorisation Committee, as the case may be.

(III) 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 as per Form 14C. In case a country does not

have an Embassy in India, the certificate of relationship, in the above format, shall be issued by the Government of that country.

- (ii) Authorisation Committee shall examine the cases of all 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.
- (IV) 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 video graphed.
- (V) 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.
- (VI) The Authorisation Committee should state in writing its reason for rejecting/ approving the application of the proposed donor in the prescribed Form 14 and all such 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/her biological capacity and compatibility to donate the organ in question.
 - (ii) further that the psychiatrist clearance would also be mandatory to certify his/her 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.
- (VII) The Authorisation Committee shall expedite its decision making process and use its discretion judiciously and pragmatically in all such cases where, the patient requires transplantation on urgent basis.
- (VIII) Every authorised transplantation centre must have its own website. The Authorisation Committee is required to take final decision within twenty four 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 twenty four hours of taking the decision, while keeping the identity of the recipient and donor hidden. 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 reasonable details of each transplantation,. (The same data should be accessible for compilation, analysis and further use by authorised persons of respective State Governments and Central Government). The website of transplantation center shall be linked to State/Regional/National Networks through online system for organ procurement, sharing and transplantation.

7. REGISTRATION OF HOSPITAL/TISSUE BANK

- (1) An application for registration shall be made to the Appropriate Authority as specified in Form 11 or 11A or 11B. The application shall be accompanied by a fee of Rupees ten 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 it shall be valid for a period of five years from the date of its issue and shall be renewable.
- (3) before a hospital is registered under the provisions of this rule, it shall be mandatory for the hospital to nominate a transplant coordinator.

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 thousand 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.

9. CONDITIONS/STANDARDS FOR GRANT OF CERTIFICATE OF REGISTRATION FOR ORGAN AND/ OR TISSUE TRANSPLANTATION CENTRES

If, after an inquiry including inspection of the hospital or tissue bank 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.

No hospital shall be granted a certificate of registration for transplantation under this Act unless it fulfills the following conditions/standards as laid down below:-

A General Manpower Requirement Specialised Services and Facilities:

- (1) Twenty four hours availability of medical and surgical, (senior and junior) staff.
- (2) Twenty four hours availability of nursing staff (general and speciality trained).
- (3) Twenty four hours availability of Intensive Care Units with adequate equipment, staff and support system, including specialists in anesthesiology and intensive care.
- (4) Twenty four hours availability of laboratory with multiple discipline testing facilities including but not limited to Microbiology, Bio-Chemistry, Pathology, Hematology and Radiology departments with trained staff.

- (5) Twenty four hours availability of Operation Theater facilities (OT facilities) for planned and emergency procedures with adequate staff, support system and equipment.
- (6) Twenty four 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, pediatrics, gynecology immunology and cardiology etc. should be available to the transplantation centre. One medical expert for respective organ/tissue transplant must be available in the transplantation hospital.
- (8) Human Leukocyte Antigen (HLA) matching facilities (in house or outsourced).

B Equipment:

Equipment as per current and expected scientific requirements specific to organ (s) or tissue (s) 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 equipment.

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 transplant 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 three years post M.S. experience in the speciality and having one year training in the respective organ transplantation as an active member of team in an established transplant center.

(C) Cardiac, Pulmonary, Cardio-Pulmonary Transplantation:

M.Ch. Cardio-thoracic and vascular surgery or equivalent qualification in India or abroad with at least three 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.

(E) Other Tissues: Heart Valves, Skin, Bone etc.:

Post graduate degree (MD or MS) or equivalent qualification in the respective specialty with one year post M.D. or M.S training in a recognized hospital carrying out respective tissue transplant operations.

(F) The Hospital registered under Clinical Establishment (Registration and Regulation) Act, 2010 shall also follow the minimum standards prescribed in respect of manpower, equipment etc., as prescribed under the Act.

10. CONDITIONS/STANDARDS FOR GRANT OF CERTIFICATE OF REGISTRATION FOR RETRIEVAL CENTRES: The retrieval centre shall be a hospital having Intensive Care Unit (ICU) facilities along with manpower, infrastructure and equipment as required to diagnose and maintain the brain-stem dead person and to retrieve and transport organs and tissues including their temporary storage.

- (i) All hospitals registered as transplant centres shall automatically qualify as retrieval centres;
- (ii) The retrieval centre should have linkages with nearby Government hospital designated for post-mortem at the time of retrieval in medico-legal cases;
- (iii) Registration of hospital for surgical tissue harvesting from deceased person and for surgical tissue residues, that are routinely discarded, shall not be required.

11. CONDITIONS/STANDARDS FOR GRANT OF CERTIFICATE OF REGISTRATION FOR TISSUE BANKS;

GENERAL GUIDELINES:

A. Facility and Premises:

- (1). Facilities must conform to the standards and guidelines laid down for the purpose.
- (2). The tissue bank must have written guidelines and procedure for maintenance of its premises and facilities which include-

- Controlled access
- Cleaning and maintenance systems
- Waste disposal
- Health and safety of staff
- Risk assessment protocol
- Follow up protocol

(3). Equipment: Equipment as per scientific requirements specific to tissue (s) being procured, processed, stored and distributed. The tissue bank should ensure the availability of the accessories, spare-parts and back-up/maintenance/service support for all equipment.

(4). Air particle count and microbial colony count compliance shall be ensured for safety.

(5). Storage area should be designated to avoid contact with chemicals or atmospheric contamination and any known source of infection.

(6). Storage facility must separate and distinguish tissues, held in quarantine, released and rejected.

B. Donor Screening: Complete screening of donor including medical/social history for medical conditions or disease processes that would contraindicate the donation of tissues.

C. Laboratory Tests: Facility for relevant Laboratory tests for blood and tissue samples shall be available. Testing of blood and tissue samples should begin at the site of retrieval and to be continued throughout processing.

D. Procurement and Other Procedures:

- (1) Procurement of tissue must be carried out by registered health care professionals having necessary experience or special training.
- (2) Consent for the procurement.
- (3) Procurement records
- (4) Standard operating procedure for following shall be followed:
 - a. Procurement or Retrieval
 - b. Processing and Sterilization
 - c. Packaging, Labeling and Storage
 - d. Distribution or Allocation
 - e. Transportation
 - f. Reporting of serious adverse reactions

E. Documentation and Records: A log of Tissue received and distributed

F. Data Protection and Confidentiality

G. Quality Management

H. Patient Information

12. TRANSPLANT COORDINATOR – QUALIFICATION, ROLE ETC.:

The Transplant Coordinator shall be employee of the Hospital registered or to be registered. He or She shall possess any of the following qualifications:

- Graduate of any recognized system of medicine
- Nurse, as defined in the Indian Nursing Council Act
- Master's degree in Public Health/Social Work/Psychology
- Qualified counselor

He or She shall have a minimum experience of two years in a Hospital. He or She shall counsel and encourage the next of kin of the deceased person to donate the human organ and/or tissue and coordinate the process of transplantation.

13. ADVISORY COMMITTEE:

- (1) Qualification of medical experts shall be Postgraduate medical degree and two years experience in the field of organ/tissue transplantation.
- (2) The terms and conditions for appointment to the Advisory Committee
 - (a) The Chairman and members of the Committee shall be initially appointed for two years and the tenure can be extended on year to year basis upto a maximum of five years.
 - (b) The Chairman and members of the Committee shall be entitled to the air fare and other allowances to attend the meeting of the Committee equivalent to the officer of the level of the Joint Secretary to the Government of India.
 - (c) The Central/State Government/Union Territory Administration shall have full power to replace/remove the Chairman and the members.
 - (d) The Chairman and members can also resign from the Committee for personal reasons.
 - (e) There shall not be a corruption/criminal case pending against Chairman and members at the time of appointment.

- (f) The Chairman and members would cease to function if a corruption/criminal etc. case is initiated against them.

14. MANNER OF ESTABLISHING NATIONAL/REGIONAL/STATE HUMAN ORGANS AND TISSUES REMOVAL AND STORAGE NETWORKS AND THEIR FUNCTIONS:

- (1) There would be an apex national networking organization at the centre. There would also be regional and State level networking organizations where large of number of transplantation of organ(s) or tissue (s) are performed. The State units would be linked to hospitals, organ/tissue matching Labs and tissue banks within their area and also to regional and national networking organisations.
- (2) Such networks shall coordinate procurement, storage, transportation, matching, allocation and transplantation of organs/tissues and shall develop norms and standard operating procedures.
- (3) They would coordinate with respective State Government for establishing new transplant and retrieval centres and tissue banks and strengthening of existing ones.
- (4) There shall be designated Organ and/or tissue retrieval teams in State/District/institution as per requirement, to be constituted by the State/Regional Organization.
- (5) Networking would be e-enabled and accessible through dedicated website.
- (6) Reference/allocation criteria would be developed and updated regularly.
- (7) IEC Activities for promotion of deceased organ and tissue donation
- (8) Maintain and update Organ Donation and Transplant Registry at respective level

15. INFORMATION TO BE INCLUDED IN NATIONAL REGISTRY REGARDING DONORS AND RECIPIENTS OF HUMAN ORGAN AND TISSUE:

The Registry will be accessible on-line through dedicated website and shall be in conformation to globally maintained registry(ies), besides having National, Regional and State level specificities. National/Regional registry shall be compiled based on similar registries at State level. The identity of the people in the database shall not be in public domain. Measures shall be taken to ensure security of all collected information. The information to be included shall be updated as per prevalent global practices from time to time. The registry will have following components:

The Transplant Registry

The information shall include demographic data about the patient, hospital, transplant waiting list, priority list for critical patients, medical condition, indication(s) for transplant, details about the treatment, organ procurement, matching, distribution, details of Live/deceased donors, details of transplantation (both donor and recipient), outcome of transplantation, follow up condition of both recipient and Live donor, immunosuppressive therapy, survival and death. Data will be collected from all retrieval and transplant centers. Data collection will occur at two time points. Key events (new patients, deaths and transplants) shall be notified as soon as they occur in the hospital and this information shall be sent to the respective networking

organization, at least monthly. This can be either through a web-based interface or paper submission. A cross sectional survey shall be done yearly at the end of calendar year to collect information of last calendar year. The information will be maintained both specific organ and tissue wise and also in a consolidated format. Yearly reports will be published and also shared with the contributing units and other stakeholders.

Organ Donation Registry

This registry shall include Demographic information on Donor, actual or intended donor, Hospital, height and weight, occupation, primary cause of death in case of deceased donor, associated medical illnesses, relevant laboratory tests, donor maintenance details, driver's license or any other document of pledging donation, donation requested by whom, transplant coordinator, organs/tissue retrieved, Outcome of donated organ/tissue, details of recipient.

Those persons, who, during their lifetime wish to pledge to donate their organ(s)/tissue(s) after their death, may do so, in Form No. 5. The form may be deposited in paper or electronic mode to the respective networking organization(s) or institution where the pledge is made (who shall forward the same to the respective networking organization). The pledger has the option to withdraw the pledge through intimation. The National Registry will be electronically connected to regional and state registries,

16. APPEAL

- (1) Any person aggrieved by an order of the Authorization 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 in case of the Union Territories and respective State Government in case of States.
- (2) Every appeal shall be in writing and shall be accompanied by a copy of the order appealed against.

17. POWER TO AMEND THE RULES

Any amendment or modification in these Rules shall be made with the approval of the Central Government.

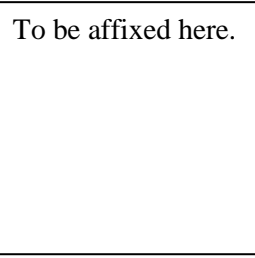
FORM 1(A)
(Form 1A inserted vide Gazette notification dated 04.08.2008)

(Page 1 of 2)

(To be completed by the prospective related donor)
(See Rule 3, 4(3)(a))

My full name is

and this is my photograph



Photograph of the Donor
(Attested by Notary Public
across the photo after affixing)

My permanent home address is

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

My present home address is

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

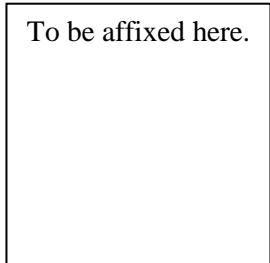
Date of birth(day/month/year)

I enclose the copies of following documents:

- Ration/Consumer Card number and Date of issue and 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
- Permanent Account Number (PAN).....
and/or
- AADHAAR No.
and/or
- Any other proof of identity and address

I authorize removal for therapeutic purposes and consent to donate my
(Name of organ/tissue) to my relative (Specify son/daughter/father/mother/
brother/sister/grand-father/grand-mother/grand-son/grand-daughter), 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
across the photo after affixing)



FORM 1 (A) (Page -2)

The copies of following documents of recipient are enclosed

- 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
- Permanent Account Number (PAN)
and/or
- AADHAAR No (Issued by Unique Identification Authority of India).
and/or
- Any 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 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 (name of organ/tissue) 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 (name of organ)/tissue). 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 the best of my knowledge and belief and nothing material has been concealed by me.

.....

.....

Date

Signature of the prospective donor
(Full Name)

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)
(Form 1B inserted vide Gazette notification dated 04.08.2008)

(Page 1 of 2)

(To be completed by the prospective spousal donor)
(see Rule 3, 4(3)(a)(d))

My full name is
and this is my photograph

Photograph of the Donor
(Attested by Notary Public
across the photo after affixing)

To be affixed here

My permanent home address is

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

My present home address is

..... Tel:

Date of birth(day/month/year)

I authorize removal for therapeutic purposes and consent to donate my (Name of 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
across the photo after affixing)

To be affixed here

I enclose the copies of following documents:

- Ration/Consumer Card number and Date of issue and place:.....
(Photocopy attached) and/or
- Voter's Identity-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
- Permanent Account Number (PAN)
.....

- AADHAAR No. (issued by Unique Identification Authority of India)
and/or
- Other proof of identity and address

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/Member of Legislative Assembly/Member of Parliament 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, 2011, 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 the best of my knowledge and nothing material has been concealed by me.

.....
Signature of the prospective donor
(Full Name)

.....
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.

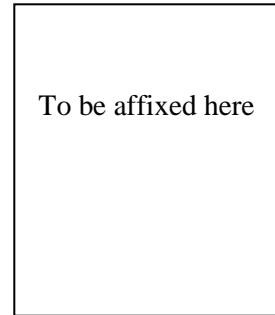
- ✓ wherever applicable.

FORM 1(C)
(Form 1C inserted vide Gazette notification dated 04.08.2008)

(Page 1 of 2)
(To be completed by the prospective un-related donor)
(See Rule 3, 4(3)(a)(e))

My full name is
and this is my photograph

Photograph of the Donor
(Attested by Notary Public
across the photo after affixing)



My permanent home address is Tel:

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

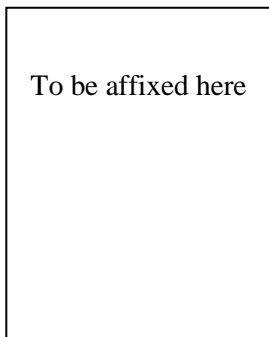
Date of birth (day/month/year)

- Ration/Consumer Card number and Date of issue and 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
- AADHAAR No..... and/or
- Other proof of identity and address

Details of last three years income and vocation of donor (enclose documentary evidence)
.....
.....

I authorize removal for therapeutic purposes and consent to donate my
(Name of organ/tissue) 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 across the
Photo after affixing)



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 Licence number, Date of issue, licensing authority.....
(Photocopy attached)
and/or
- PAN.....
and/or
- AADHAAR No.
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, 2011, 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 (name of organ/tissue) 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 (name of organ/tissue). 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 the 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 the best of my knowledge and nothing material has been concealed by me.

.....
Signature of the prospective donor
(Full Name)

.....
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

(Form 2 substituted vide Gazette notification dated 04.08.2008)

[See rule 4(3)(b)]

(To be completed by the Registered 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 for donation of his/her (Name of the organ) to Shri/Smt./Km who is a 'near relative' of the donor/other than near relative of the donor and has been approved by the Concerned Competent Authority / Authorisation Committee/ (as the case may be) and that the said donor is in proper state of health, not mentally challenged and is medically fit to be subjected to the procedure of organ removal.

Place:

.....
Signature of Doctor

Date:

Seal



Photograph of the Donor
(Attested by doctor)



Photograph of the recipient
(Attested by the doctor)

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

FORM 3

(Form 1A inserted vide Gazette notification dated 04.08.2008)

[See Rule 6(F)(iv)(b)]

(To be completed by the head of Pathology Laboratory certifying relationship)

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 prospective recipient of the organ to
be donated by the said donor are related to each other as
brother/sister/mother/father/son/daughter, grandmother, grandfather, grandson and
granddaughter as per their statement and the documentary evidence. The fact of this
relationship has been established / not established by the results of the tests for DNA profiling.
The results of the tests are attached.

Signature

(To be signed by the Head of the Laboratory)

Seal

Place

Date

FORM 4

[See Rule 4A(2)]

(To be completed by concerned competent authority/Authorization Committee, in case of foreigners, in the case of spousal donor)

I, Dr./Mr./Mrs. possessing qualification of registered as medical practitioner at serial No.by theMedical 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) In case the Clinical condition of Shri/Smt..... mentioned above is such that recording of his/her statement is not practicable, reliance will be placed on the documentary evidence(s). (mention documentary evidence(s) here).....
.....

Signature of concerned competent authority

Place

Date

FORM 5

[See Rule 4(1)(a)]

(To be completed by individual pledging for donation after death)

ORGAN(S) AND TISSUE(S) DONOR FORM

(To be filled in triplicate)

Registration Number (To be allotted by Organ Donor Registry):

I.....S/o,D/o,W/o.....
..... aged.....resident ofin the
presence of persons mentioned below hereby unequivocally authorise the removal of my
following organ(s) / tissue(s), from my body after my death and consent to donate the same for
therapeutic purposes.

Please tick as applicable

Hearts	<input type="checkbox"/>	Corneas	<input type="checkbox"/>
Lungs,	<input type="checkbox"/>	Skin	<input type="checkbox"/>
Kidneys,	<input type="checkbox"/>	Bones	<input type="checkbox"/>
Liver,	<input type="checkbox"/>	Heart Valves	<input type="checkbox"/>
Pancreas	<input type="checkbox"/>	Vessels	<input type="checkbox"/>
Any Other Organ (Pl. specify)	<input type="checkbox"/>	Any other Tissue (Pl. specify)	<input type="checkbox"/>
All Organs	<input type="checkbox"/>	All Tissues	<input type="checkbox"/>

My blood group is (if known).....

Signature of Pledger.....
Telephone No.....
Email :
Dated:

(Signature of Witness 1)

1.Shri/Smt./Km.....S/o,D/o,W/o.....
..... aged.....resident of.....
Telephone No.....Email:.....

(Signature of Witness 2)

2.Shri/Smt./Km.....S/o,D/o,W/o.....
..... aged.....resident of Telephone
No.....Email:..... is a near relative to the donor as
.....

Dated.....
Place

Note: (i) Organ donation is a family decision. Therefore, it is important that you discuss your decision with family members and loved ones so that it will be easier for them to follow through with your wishes.

(ii) One copy to be with respective networking organization, one copy to be retained by institution where the pledge is made and one copy to be handed over to the pledger

(iii) The person making the pledge has the option to withdraw the pledge.

FORM 6

[See Rule 4(1)(a)(b), 4(4)(b)]

(To be filled by Next of Kin/Lawful possessor of brain-stem dead person)

DECLARATION / AUTHORISATION FORM

I.....S/o,D/o,W/o.....
..... aged.....resident ofin the
presence of persons mentioned below, hereby declare that:

1. I have been informed that my relative (specify relation)
S/o,D/o,W/o.....aged.....has been declared
brain-stem dead.

2. To the best of my knowledge

b. He/She. (Name of the deceased)..... had / had not,
authorized before his/her death, the removal of(Name of
organ/tissue/both) of his/her body after his/her death for therapeutic purpose. The
documentary proof of such authorisation is enclosed.

c. He/She. (Name of the deceased)..... had not revoked the
authority as at No. 2 above.

d. There are reasons to believe that no near relative of the said deceased person has
objection to any of his/her organs being used for therapeutic purposes,

3. I have been informed that in the absence of such authorisation, I have the option
to either authorize or decline donation of organ/tissue/both including eye/cornea of
.....(Name of the deceased) for therapeutic purposes.

4. I hereby authorise / do not authorize removal of his/her body organ(s) and/or tissue(s),
namely..... for therapeutic purposes.

(Strike off whichever is not applicable)

Date..... Signature of next of kin/person in lawful possession of the dead body.
Place Telephone No.....Email:

(Signature of Witness 1)

1. Shri/Smt./Km.....S/o,D/o,W/o.....
..... aged.....resident of.....
Telephone No.....Email:

(Signature of Witness 2)

2. Shri/Smt./Km.....S/o,D/o,W/o.....
..... aged.....resident of Telephone
No.....Email:..... is a near relative to the donor as
.....

FORM 6A
[Rule 4(1)(b)]

(To be completed by person in lawful possession of the unclaimed body in a Hospital/Prison)

I.....S/o,D/o,W/o.....
..... aged.....resident ofhaving
lawful possession of the dead body of Shri/Smt./Km.....
S/o,D/o,W/o..... aged.....resident of
.....and having known that no person has come
forward to claim the body of the deceased after 48 hours of death and there being no reason to
believe that any person is likely to come to claim the body I hereby, authorise removal of his/her
body organ(s) and/or tissue(s), namely.....for therapeutic
purposes.

Signature, Name, designation and Stamp of person in lawful possession of the dead body.

Dated.....Place..... Address.....

Telephone No.....Email

(Signature of Witness 1)

1.Shri/Smt./Km.....S/o,D/o,W/o.....
..... aged.....resident of.....
Telephone No.....Email

(Signature of Witness 2)

2.Shri/Smt./Km.....S/o,D/o,W/o.....
..... aged.....resident of Telephone
No.....Email..... is a near relative to the donor as
.....

FORM 7

(Form 7 deleted vide Gazette notification dated 04.08.2008)

FORM 8

[See Rule 4(4)(c)(d)]

(To be completed by the team of experts certifying brain-stem death)

We, the following members of the Board of medical experts after careful personal examination hereby certify that Shri/Smt./Km..... aged about_son of /wife of / daughter of Resident of is dead on account of permanent and irreversible cessation of all functions of the brain-stem. The tests carried out by us and the findings therein are recorded in the brain-stem death Certificate annexed hereto.

Dated.....

Signature.....

- | | |
|--|--|
| 1. R.M.P.- Incharge of the Hospital
In which brain-stem death has occurred. | 2. R.M.P. nominated from the panel of
Names sent by the hospitals and
approved by the Appropriate Authority. |
|--|--|

- | | |
|------------------------------|--|
| 3. Neurologist/Neuro-Surgeon | 4. R.M.P. treating the aforesaid deceased person |
|------------------------------|--|

(where Neurologist/Neurosurgeon is not available, any Surgeon or Physician and Anaesthetist or Intensivist, nominated by Medical Administrator Incharge from the panel of names sent by the hospital and approved by the Appropriate Authority shall be included)

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 Patient Registration Number (CR No.):
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 donation of organ and/or tissue?
6. Is this a Medico-legal 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-reversible coma.....

2. Findings of Board of Medical Experts:

	First Medical Examination		Second Medical Examination	
	1st	2 nd	1 st	2 nd

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

- Intoxication (Alcohol)
- Depressant Drugs
- Relaxants (Neuromuscular blocking agents)
- 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 caloric testing bilaterally.
- (12) Apnoea tests as specified.
- (13) Were any respiratory movements seen?

Date and time of first testing:

Date and time of second testing:

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

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

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

Note.

- I. Where Neurologist/Neurosurgeon is not available, then any Surgeon or Physician and Anaesthetist or Intensivist, nominated by Medical Administrator Incharge of the hospital shall be the member of the board of medical experts for brain-stem death certification.
- II. The minimum time interval between the first and second testing will be six hours.
- III. No.2 and No.3 will be co-opted by the Administrator Incharge of the hospital from the Panel of experts (Nominated by the hospital and approved by the Appropriate Authority).

FORM 9

[See Rule 4(4)(d)]

(To be completed by the person next of the kin of minor)

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

Signature.....
Name.....
Place.....
Date.....

FORM 10
(Form 1 vide Gazette notification dated 04.08.2008)

(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(3) (c)(d)(e), Rule 6]

To be self
attested across
the affixed
photograph
without
disfiguring face

Photograph of the Donor

To be self
attested across
the affixed
photograph
without
disfiguring face

Photograph of the recipient

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 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 (name of the organ) to
Shri/Smt.

We and
(Donor) (Recipient)

hereby apply to Concerned Competent Authority / Authorisation 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 Concerned Competent Authority / 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. When the donor is unrelated and the donor and/or recipient belong to a State/Union Territory other than the State/Union Territory, where the transplant is intended to take place, then the domicile state of the donor or recipient as the case may be, would provide the No Objection Certificate in respect of legal and residential status of donor / recipient as the case may be; while the approval for transplantation would be considered by the authorisation committee of the State/District/hospital (as the case may be) where the transplantation is intended to be done. "No Objection Certificate" will not be required for near relatives including cases involving swapping of organs (permissible between near relatives only).

We have read and understood the above instructions.

Signature of the Prospective Donor

Signature of Prospective Recipient

Date :

Date :

Place :

Place :

FORM 11
(See Rule 7(1))

APPLICATION FOR REGISTRATION OF HOSPITAL TO CARRY OUT ORGAN/
TISSUE TRANSPLANTATION

To

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

We hereby apply to be registered as an institution to carry out organ/tissue transplantation.

Name(s) of Organ (s) or tissue (s) for which Registration is required.....

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 FACILITIES:

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 FACILITIES:

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. Trained persons available for transplantation (Please specify Organ for transplantation):
6. 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. and H.D.U. beds:
3. Trained:-
Nurses:
Technicians:
4. Name of equipment in I.C.U.

(F) OTHER SUPPORTIVE FACILITIES:

Data about facilities available in the hospital:

(F1) LABORATORY FACILITIES:

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

(F2) IMAGING FACILITIES :

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

(F3) HAEMATOLOGY FACILITIES:

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

(F4) BLOOD BANK FACILITIES: Yes No.....

(F5) DIALYSIS FACILITIES : Yes No.....

(F6) OTHER SUPPORTIVE EXPERT 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 |
| 11. | Respiratory physician | Yes /No |
| 12. | Others..... | 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. 10,000/ (for new) and Rs. 5000 (for renewal) is being enclosed.

Sd/-
HEAD OF THE INSTITUTION

FORM 11A
(See Rule 7(1))

APPLICATION FOR REGISTRATION OF HOSPITAL TO CARRY OUT ORGAN/ TISSUE RETRIEVAL

Note: Retrieval Hospitals may also be identified based on pre-defined criteria and registered as retrieval hospital by the appropriate authority.

To

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

We hereby apply to be registered as an institution to carry out organ/tissue retrieval.

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 FACILITIES:

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 retrieval (Please specify Organ and/or tissue for retrieval):

(C) MEDICAL FACILITIES:

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. Trained persons available for retrieval (Please specify Organ and/or tissue for retrieval):
6. 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 retrieval 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. and H.D.U. beds:
3. Trained:-
Nurses:
Technicians:
4. Name of equipment in I.C.U.

(F) OTHER SUPPORTIVE FACILITIES:

Data about facilities available in the hospital:

(F1) LABORATORY FACILITIES:

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

(F2) IMAGING FACILITIES :

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

(F3) HAEMATOLOGY FACILITIES:

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

(F4) BLOOD BANK FACILITIES: 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. I hereby give an undertaking that we shall make the facilities of the hospital including the retrieval team of the hospital available for retrieval of the organ/tissue as and when needed.

Sd/-
HEAD OF THE INSTITUTION

FORM 11B
(See Rule 7(1))

APPLICATION FOR REGISTRATION OF TISSUE BANKS

To

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

We hereby apply to be registered as Tissue bank

Name(s) of tissue (s) for which Registration is required.....

The required data about the facilities available in the institution are as follows:-

1. Name
2. Address
3. Government/Private/NGO
4. Teaching /Non- teaching
5. Approached by:

Rail:	Yes	No
Road:	Yes	No
Air:	Yes	No
5. IEC for Tissue Donation

DONOR SCREENING

REMOVAL OF TISSUE AND STORAGE:

- | | |
|---|--------|
| 1. Availability of adequate trained & qualified Personnel for removal Tissue (annex detail). | Yes/No |
| 2. Names, qualification & address of the doctors who will be doing removal of tissue. (annex details) | Yes/No |
| 1. Facilities for removal of Tissues | Yes/No |
| 2. Whether register of recipient waiting list available. | Yes/No |
| 5. Telephone arrangement available. (Telephone Number.....) | Yes/No |
| 6. Availability of ambulance/ vehicle or funds to Pay taxi for collecting tissue from outside: | Yes/No |
| 7. Sets of instruments for removal of tissue | Yes/No |
| 8. Arrangement of processing of tissue | Yes/No |
| 9. Refrigerator for preservation of tissue | Yes/No |
| 10. Special bottles with stands for preservation of tissue during transit. | Yes/No |
| 11. Suitable preservation media) | Yes/No |
| 12. Any other specific requirement as per tissue | Yes/No |

PRESERVATIONS OF TISSUE

Arrangement of preservation of Tissue Yes/No

RECORDS

1. Arrangement for maintaining the records Yes/No

2. Arrangement for registration of cases, donors and follow up of cases. Yes/ No

EQUIPMENT:

Instruments specific for the tissue Yes/No

LABORATORY FACILITIES(If the information is exhaustive please annex it)

1. Names of the investigations carried out in the department. Yes/No

2. Facility for
i. Human Immunodeficiency Virus Type I and II Yes/No

ii. Hepatitis B Virus – HBc and HBs

iii. Hepatitis C Virus – HCV

iv. Syphilis – VDRL

3. If no where do you avail it ? Please mention name & address of institute.

4. Facility for culture & sensitivity of tissue Yes/No

OTHER MANPOWER

1. No. of permanent staff member with their designation.

2. No. of temporary staff with their designation

3. No. of trained persons

ANY OTHER INFORMATION

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. 10,000/ (for new) and Rs. 5000 (for renewal) is being enclosed.

Sd/-
HEAD OF THE INSTITUTION

FORM 12
(See rule 7(2))

CERTIFICATE OF REGISTRATION

This is to certify that Hospital/Tissue Bank located at..... has been inspected and certificate of registration is granted for performing the organ/tissue retrieval/transplantation/banking of the following organ(s)/tissue(s) (mention the names):-

1.
2.
3.
4.

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

This permission is being given with the current facilities and staff shown in the present application form. Any reduction in the staff and/or facility must be brought to the notice of the undersigned.

Place.....

Signature of Appropriate Authority.....

Date.....

FORM 13
[See sub-rule 8(2)]

(Certificate of Renewal of Registration)

OFFICE OF THE APPROPRIATE AUTHORITY

This is with reference to the application dated..... from..... (Name of the hospital/tissue bank) for renewal of certificate of registration for performing organ(s)/tissue(s) retrieval/transplantation/banking under the THOA.

After having considered the facilities and standards of the above-said hospital/tissue bank, the Appropriate Authority hereby renews the certificate of registration of the said hospital/tissue bank for a period of five years.

This renewal is being given with the current facilities and staff shown in the present application form. Any reduction in the staff and/or facility must be brought to the notice of the undersigned.

Place.....

Signature of Appropriate Authority.....

Date.....

FORM 14
[See Rule 6D]

(Format for the decision of the Authorisation Committee)
Certificate

This is to certify that as per application in form-10 for transplantation of _____(Name of Organ/tissue) from live donor other than near relative under Transplantation of Human Organ Act (Amendment) 2011, submitted on..... by the donor and recipient, whose details and photographs are given below, along with their identifications and verifications documents, the case was considered after the personal interview of donor and recipient (if medically fit to be interviewed) by the Authorisation Committee in the meeting held on

Details of Recipient

Name.....
Age.....

Sex

Father / Husband Name

Address:
.....
.....

Hospital Reg. No

Details of Donor

Name:.....
Age

Sex

Father / Husband name.....

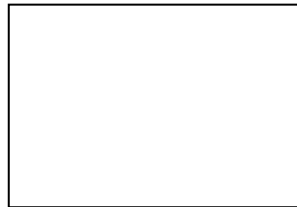
Address:
.....
.....

Hospital Reg. No.....

Relation of donor with Recipient



Recipient



Donor

(Photo of recipient and donor must be signed and stamped across the photo after affixing)

Permission is granted, as to the best of knowledge of the members of the committee, donation is out of love and affection and there is no financial transaction between recipient and donor and there is no pressure/ coercion on donor.

Permission is withheld pending submission of following documents.....
.....

Permission is not granted for the following reasons.....
.....

<i>(Member)</i>	<i>(Member)</i>	<i>(Member)</i>	<i>(Member)</i>
Name & Designation	Name & Designation	Name & Designation	Name & Designation

<i>(Member)</i>	<i>(Member)</i>	<i>(Chairman)</i>
Health Secretary Or Nominee	DHS or Nominee Name & Designation	Name & Designation

Date and place.....

** In case of SWAP transplants, details are to be annexed*

FORM 14A
[See Rule 4(3)(c)]

(Format for the decision of Concerned Competent Authority)

For near relative cases
Certificate

This is to certify that as per application in Form-10 for transplantation of _____(Name of Organ/Tissue) from live donor who is near relative under Transplantation of Human Organs Act (Amendment) 2011, submitted on..... by the donor and recipient, whose details and photographs are given below, along with their identifications and verifications documents, the case was considered after the personal interview of donor and recipient (if medically fit to be interviewed) by the Concerned Competent Authority in the meeting held on

Details of Recipient

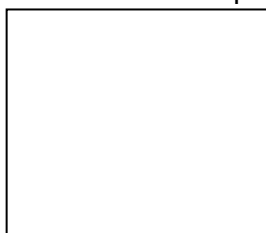
Name.....
Age.....
Sex

Father / Husband Name

Address:
.....
.....

Hospital Reg. No

Relation of donor with Recipient



Recipient

Details of Donor

Name:.....
Age

Sex

Father / Husband name.....

Address:
.....
.....

Hospital Reg. No.....



Donor

(Photo of recipient and donor must be signed and stamped across the photo after affixing)

Permission is granted, as to the best of knowledge of the members of the committee, donation is out of their being near relative and there is no financial transaction between recipient and donor and there is no pressure/ coercion on donor.

Permission is withheld pending submission of following documents.....

Permission is not granted for the following reasons.....

(Concerned Competent Authority)

Date and place.....

FORM 14B
[See Rule 6B]

(Format for "No Objection Certificate" from the Health Department or the State level committee/designated authority of the State Government of the State of domicile of unrelated donor/recipient)

Certificate

This is to certify that as per application for donation of _____(Name of organ/Tissue) from live donor other than near relative under Transplantation of Human Organ Act (Amendment) 2011, submitted on..... by the donor, whose details and photograph are given below, along with his/her identification and verification documents, the case was considered after the personal interview of donor and recipient (if medically fit to be interviewed) by the State level Committee in the meeting held on

Details of Recipient

Name.....
Age.....
Sex

Father / Husband Name

.....

Address:
.....
.....
.....

Hospital Reg. No

Details of Donor

Name:.....
Age

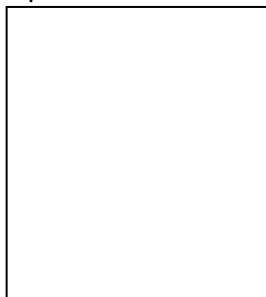
Sex

Father / Husband name.....
.....

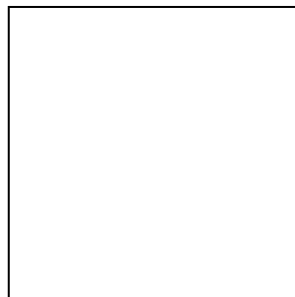
Address:
.....
.....
.....

Hospital Reg. No.....

Relationship between donor with recipient.....



Recipient



Donor

(Photo of recipient and donor must be signed and stamped across the photo after affixing)

'No objection certificate' is granted, as to the best of knowledge of the members of the committee, that the donor and/or recipient have good moral character and their legal status is verified to be satisfactory.

'No objection certificate' is withheld pending submission of following documents.....
.....

"No objection Certificate' is not granted for the following reasons.....
.....

(Member) (Member) (Member) (Member)
Name & Designation Name & Designation Name & Designation Name & Designation

(Chairman)
Name & Designation

Date and place.....

- Note: The NOC from the concerned domicile state is for residential domicile status, legal status and the character of the recipient / donor as the case may be, while the relationship “ love and Affection” will be established by authorization committee of the hospital/district/State where transplant is going to take place.

FORM 14C
[See Rule 6F(III)(i)]

(Format for the certification of relationship between Donor and Recipient in case of foreigners)

Certificate

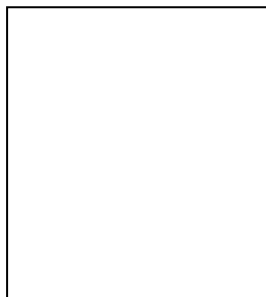
The embassy of _____(Name of Country) in India, is in receipt of an application received from _____(Name of Organ donor and recipient) on _____(Date) recommended by _____(Name of Government Department of country of origin) for facilitation of donation of _____(Name of Organ/Tissue) from live donor _____(Name of donor) to the recipient _____(Name of recipient) for therapeutic purposes under Transplantation of Human Organ Act (Amendment) 2011. The details of donor and recipient and photographs are as given below.

Details of Recipient

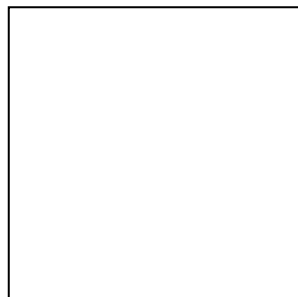
Name.....
Age.....
Sex
Father / Husband Name
.....
Address:
.....
.....
.....

Details of Donor

Name:.....
Age
Sex
Father / Husband name.....
.....
Address:
.....
.....
.....



Recipient



Donor

(Photo of recipient and donor must be signed and stamped across the photo after affixing)

- 1, This is to certify that relationship between donor with Recipient is.....
2. The authenticity of following enclosed identification and verification documents is certified
 - a. _____
 - b. _____

'No objection certificate' is granted, as to the best of my knowledge, the donor is donating out of love and affection or affection and attachment towards the recipient, and there is no financial transaction between recipient and donor and there is no pressure/ coercion on donor.

Date
Place:

(Signature of Senior Embassy Official)
Name:
Designation.....