

# **The Transplantation of Human Organs Act and Rules**

## **The Transplantation of Human Organs Act, 1994**

*An Act to provide for the regulation of removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs and for matters connected therewith or incidental thereto.*

Whereas it is expedient to provide for the regulation of removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs;

And whereas Parliament has no power to make laws for the States with respect to any of the matters aforesaid except as provided in Articles 249 and 250 of the Constitution;

And whereas in pursuance of clause (1) of Article 252 of the Constitution, resolutions have been passed by all the Houses of the Legislatures of the States of Goa, Himachal Pradesh and Maharashtra to the effect that the matters aforesaid should be regulated in those States by Parliament by law;

Be it enacted by Parliament in the Forty-fifth Year of the Republic of India as follows: —

### **CHAPTER I-PRELIMINARY**

#### **1. *Short title, application and commencement.* —**

- (1) This Act may be called the Transplantation of Human Organs Act, 1994.
- (2) It applies, in the first instance, to the whole of the States of Goa, Himachal Pradesh and Maharashtra and to all the Union territories and it shall also apply to such other States which adopts this Act by resolution passed in that behalf under clause (1) of Article 252 of the Constitution.
- (3) It shall come into force in the States of Goa, Himachal Pradesh and Maharashtra and in all the Union territories on such as the Central Government may, by notification, appoint and in any other State which adopts this Act under clause (1) of Article 252 of the Constitution, on the date of such adoption; and any reference in this Act to the commencement of this Act shall, in relation to any State or Union territory, means the date on which this Act comes into force in such State or Union territory.

#### **2. *Definitions.* — In this Act, unless the con otherwise requires. —**

- (a) “advertisement” includes any form of advertising whether to the public generally or to any section of the public or individually to selected persons;
- (b) “Appropriate Authority” means the Appropriate Authority appointed under Section 13;
- (c) “Authorisation Committee” means the committee constituted under clause (a) or clause (b) of sub-section (4) of Section 9;
- (d) “brain-stem death” means the stage at which all functions of the brain-stem have permanently and irreversibly ceased and is so certified under sub-section (6) of Section 3;
- (e) “deceased person” means a person in whom permanent disappearance of all evidence of life occurs, by reason of brain-stem death or in a cardio-pulmonary sense, at any time after live birth has taken place;
- (f) “donor” means any person, not less than eighteen years of age, who voluntarily authorises the removal of any of his human organs for therapeutic purposes under sub-section (1) or sub-section (2) of Section 3;
- (g) “hospital” includes a nursing home, clinic, medical centre, medical or teaching institution for

therapeutic purposes and other like institution;

(h) “human organ” means any part of a human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body;

(i) “near relative” means spouse, son, daughter, father, mother, brother or sister;

(j) “notification” means a notification published in the Official Gazette;

(k) “payment” means payment in money or money’s worth but does not include any payment for defraying or reimbursing —

(i) the cost of removing, transporting or preserving the human organ to be supplied; or

(ii) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any human organ from his body;

(l) “prescribed” means prescribed by rules made under this Act;

(m) “recipient” means a person into whom any human organ is, or is proposed to be, transplanted;

(n) “registered medical practitioner” means a medical practitioner who possesses any recognised medical qualification as defined in clause (h) of Section 2 of the Indian Medical Council Act, 1956 (102 of 1956), and who is enrolled on a State Medical Register as defined in clause (k) of that section;

(o) “therapeutic purposes” means systematic treatment of any disease or the measures to improve health according to any particular method or modality; and

(p) “transplantation” means the grafting of any human organ from any living person or deceased person to some other living person for therapeutic purposes

## **CHAPTER II-AUTHORITY FOR THE REMOVAL OF HUMAN ORGANS**

### **3. Authority for removal of human organs. —**

(1) Any donor may, in such manner and subject to such conditions as may be prescribed, authorise the removal, before his death, of any human organ of his body for therapeutic purposes.

(2) If any donor had, in writing and in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorised at any time before his death, the removal of any human organ of his body, after his death, for therapeutic purposes, the person lawfully in possession of the dead body of the donor shall, unless he has any reason to believe that the donor had subsequently revoked the authority aforesaid, grant to a registered medical practitioner all reasonable facilities for the removal, for therapeutic purposes, of that human organ from the dead body of the donor.

(3) Where no such authority as is referred to in sub-section (2), was made by any person before his death but no objection was also expressed by such person to any of his human organs being used after his death for therapeutic purposes, the person lawfully in possession of the dead body of such person may, unless he has reason to believe that any near relative of the deceased person has objection to any of the deceased person’s human organs being used for therapeutic purposes, authorise the removal of any human organ of the deceased person for its use for therapeutic purposes.

(4) The authority given under sub-section (1) or sub-section (2) or, as the case may be, sub-section (3) shall be sufficient warrant for the removal, for therapeutic purposes, of the human organ; but no such removal shall be made by any person other than the registered medical practitioner.

(5) Where any human organ is to be removed from the body of a deceased person, the registered

medical practitioner shall satisfy himself, before such removal, by a personal examination of the body from which any human organ is to be removed, that life is extinct in such body or, where it appears to be a case of brain-stem death, that such death has been certified under sub-section (6).

(6) Where any human organ is to be removed from the body of a person in the event of his brain-stem death, no such removal shall be undertaken unless such death; is certified, in such form and in such manner and on satisfaction of such conditions and requirements as may be prescribed, by a Board of medical experts consisting of the following, namely: —

(i) the registered medical practitioner, in charge of the hospital in which brain-stem death has occurred;

(ii) an independent registered medical practitioner, being a specialist, to be nominated by the registered medical practitioner specified in clause (i), from the panel of names approved by the Appropriate Authority;

(iii) a neurologist or a neurosurgeon to be nominated by the registered medical practitioner specified in clause (i), from the panel of names approved by the Appropriate Authority; and

(iv) the registered medical practitioner treating the person whose brain-stem death has occurred.

(7) Notwithstanding anything contained in sub-section (3), where brain-stem death of any person, less than eighteen years of age, occurs and is certified under sub-section (6), any of the parents of the deceased person may give authority, in such form and in such manner as may be prescribed, for the removal of any human organ from the body of the deceased person.

#### **4. Removal of human organs not to be authorised in certain cases. —**

(1) No facilities shall be granted under sub-section (2) of Section 3 and no authority shall be given under sub-section (3) of that section for the removal of any human organ from the body of a deceased person, if the person required to grant such facilities, or empowered to give such authority, has reason to believe that an inquest may be required to be held in relation to such body in pursuance of the provisions of any law for the time being in force.

(2) No authority for the removal of any human organ from the body of a deceased person shall be given by a person to whom such body has been entrusted solely for the purpose of interment, cremation or other disposal.

#### **5. Authority for removal of human organs in case of unclaimed bodies in hospital or prison. —**

(1) In the case of a dead body lying in a hospital or prison and not claimed by any of the near relatives of the deceased person within forty-eight hours from the time of the death of the concerned person, the authority for the removal of any human organ from the dead body which so remains unclaimed may be given, in the prescribed form, by the person incharge, for the time being, of the management or control of the hospital or prison, or by an employee of such hospital or prison authorised in this behalf by the person in charge of the management or control thereof.

(2) No authority shall be given under sub-section (1) if the person empowered to give such authority has reason to believe that any near relative of the deceased person is likely to claim the dead body even though such near relative has not come forward to claim the body of the deceased person within the time specified in sub-section (1).

#### **6. Authority for removal of human organs from bodies sent for post-mortem examination for medico-legal or pathological purposes. —** Where the body of a person has been sent for post-mortem examination —

(a) for medico-legal purposes by reason of the death of such person having been caused by accident or any other unnatural cause; or

(b) for pathological purposes, the person competent under this Act to give authority for the

removal of any human organ from such dead body may, if he has reason to believe that such human organ will not be required for the purpose for which such body has been sent for post-mortem examination, authorise the removal, for therapeutic purposes, of that human organ of the deceased person provided that he is satisfied that the deceased person had not expressed, before his death, any objection to any of his human organs being used, for therapeutic purposes after his death or, where he had granted an authority for the use of any of his human organs for therapeutic purposes after his death, such authority had not been revoked by him before his death.

**7. Preservation of human organs.** — After the removal of any human organ from the body of any person, the registered medical practitioner shall take such steps for the preservation of the human organ so removed as may be prescribed.

**8. Savings.** —

(1) Nothing in the foregoing provisions of this Act shall be construed as rendering unlawful any dealing with the body or with any part of the body of a deceased person if such dealing would have been lawful if this Act had not been passed.

(2) Neither the grant of any facility or authority for the removal of any human organ from the body of a deceased person in accordance with the provisions of this Act nor the removal of any human organ from the body of a deceased person in pursuance of such authority shall be deemed to be an offence punishable under Section 297 of the Indian Penal Code (45 of 1860).

**9. Restrictions on removal and transplantation of human organs.** —

(1) Save as otherwise provided in sub-section (3), no human organ removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient.

(2) Where any donor authorises the removal of any of his human organs after his death under sub-section (2) of Section 3 or any person competent or empowered to give authority for the removal of any human organ from the body of any deceased person authorises such removal, the human organ may be removed and transplanted into the body of any recipient who may be in need of such human organ.

(3) If any donor authorises the removal of any of his human organs before his death under sub-section (1) of Section 3 of transplantation into the body of such recipient, not being a near relative, as is specified by the donor by reason of affection or attachment towards the recipient or for any other special reasons, such human organ shall not be removed and transplanted without the prior approval of the Authorisation Committee.

(4) (a) The Central Government shall constitute, by notification, one or more Authorisation Committee consisting of such members as may be nominated by the Central Government on such terms and conditions as may be specified in the notification for each of the Union territories for the purposes of this section.

(b) The State Government shall constitute, by notification, one or more Authorisation Committees consisting of such members as may be nominated by the State Government on such terms and conditions as may be specified in the notification for the purposes of this section.

(5) On an application jointly made, in such form and in such manner as may be prescribed, by the donor and the recipient, the Authorisation Committee shall, after holding an inquiry and after satisfying itself that the applicants have complied with all the requirements of this Act and the rules made thereunder, grant to the applicants approval for the removal and transplantation of the human organ.

(6) If, after the inquiry and after giving an opportunity to the applicants of being heard, the Authorisation Committee is satisfied that the applicants have not complied with the requirements of this Act and the rules made thereunder, it shall, for reasons to be recorded in

writing, reject the application for approval.

### CHAPTER III-REGULATION OF HOSPITALS

#### 10. Regulation of hospitals conducting the removal, storage or transplantation of human organs. —

(1) On and from the commencement of this Act, —

(a) no hospital, unless registered under this Act, shall conduct, or associate with, or help in, the removal, storage or transplanation of any human organ;

(b) no medical practitioner or any other person shall conduct, or cause to be conducted, or aid in conducting by himself or through any other person, an activity relating to the removal, storage or transplantation of any human organ at a place other than a place registered under this Act; and

(c) no place including a hospital registered under sub-section (1) of Section 15 shall be used or cause to be used by any person for the removal, storage or transplanation of any human organ except for therapeutic purposes.

(2) Notwithstanding anything contained in sub-section (1), the eyes or the ears may be removed at any place from the dead body of any donor, for therapeutic purpose, by a registered medical practitioner.

**Explanation.** — For the purposes of this sub-section, “ears” includes ear drums and ear bones.

11. **Prohibition of removal or transplantation of human organs for any purpose other than therapeutic purposes.** — No donor and no person empowered to give authority for the removal of any human organ shall authorise the removal of any human organ for any purpose other than therapeutic purposes.

12. **Explaining effects to donor and recipient.** — No registered medical practitioner shall undertake the removal or transplanation of any human organ unless he has explained, in such manner as may be prescribed, all possible effects, complications and hazards connected with the removal and transplanation to the donor and the recipient respectively.

### CHAPTER IV-APPROPRIATE AUTHORITY

#### 13. Appropriate Authority. —

(1) The Central Government shall appoint, by notification, one or more officers as appropriate Authorities for each of the Union territories for the purposes of this Act.

(2) The State Government shall appoint, by notification, one or more officers as Appropriate Authorities for the purposes of this Act.

(3) The Appropriate Authority shall perform the following functions, namely: —

(i) to grant registration under sub-section (1) of Section 15 or renew registration under sub-section (3) of that section;

(ii) to suspend or cancel registration under sub-section (2) of Section 16;

(iii) to enforce such standards, as may be prescribed, for hospitals engaged in the removal, storage or transplantation of any human organ;

(iv) to investigate any complaint of breach of any of the provision of this Act or any of the rules made thereunder and take appropriate action;

(v) to inspect hospitals periodically for examination of the quality of transplantation and the follow-up medical care to persons who have undergone transplantation and persons from whom organs are removed; and

(vi) to undertake such other measures as may be prescribed.

## **CHAPTER V - REGISTRATION OF HOSPITALS**

### **14. Registration of hospitals engaged in removal, storage or transportation of human organs.**

(1) No hospital shall commence any activity relating to the removal, storage or transplantation of any human organs for therapeutic after the commencement of this Act unless such hospital is duly registered under this Act:

Provided that every hospital engaged, either partly or exclusively, in any activity relating to the removal, storage or transplantation of any human organ for therapeutic purposes immediately before the commencement of this Act, shall apply for registration within sixty days from the date of such commencement:

Provided further that every hospital engaged in any activity relating to the removal, storage or transplantation of any human organ shall cease to engage in any such activity on the expiry of three months from the date of commencement of this Act unless such hospital has applied for registration and is so registered or till such application is disposed of, whichever is earlier.

(2) Every application for registration under sub-section (1) shall be made to the Appropriate Authority in such form and in such manner and shall be accompanied by such fees as may be prescribed.

(3) No hospital shall be registered under this Act unless the Appropriate Authority is satisfied that such hospital is in a position to provide such specialised services and facilities, possess such skilled manpower and equipments and maintain such standards as may be prescribed.

### **15. Certificate of registration. —**

(1) The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements of this Act and the rules made thereunder, grant to the hospital a certificate of registration in such form, for such period and subject to such conditions as may be prescribed.

(2) If, after the inquiry and after giving an opportunity to the applicant of being heard, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of this Act and the rules made thereunder, it shall, for reasons to be recorded in writing, reject the application for registration.

(3) Every certificate of registration shall be renewed in such manner and on payment of such fees as may be prescribed.

### **16. Suspension or cancellation of registration. —**

(1) The Appropriate Authority may, suo moto or on complaint, issue a notice to any hospital to show cause why its registration under this Act should not be suspended or cancelled for the reasons mentioned in the notice.

(2) If, after giving a reasonable opportunity of being heard to the hospital, the Appropriate Authority is satisfied that there has been a breach of any of the provisions of this Act or the rules made thereunder, it may, without prejudice to any criminal action that it may take against such hospital, suspend its registration for such period as it may think fit or cancel its registration:

Provided that where the Appropriate Authority is of the opinion that it is necessary or expedient so to do in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any hospital without issuing any notice.

**17. Appeals. —** Any person aggrieved by an order of the Authorisation Committee rejecting an application for approval under sub-section (6) of Section 9, or any hospital aggrieved by an order of

the Appropriate Authority rejecting an application for registration under sub-section (2) of Section 15 or an order of suspension or cancellation of registration under sub-section (2) of Section 16, may, within thirty days from the date of the receipt of the order, prefer an appeal, in such manner as may be prescribed, against such order to —

(i) the Central Government where the appeal is against the order of the Authorisation Committee constituted under clause (a) of sub-section (4) of Section 9 or against the order of the Appropriate Authority appointed under sub-section (1) of Section 13; or

(ii) the State Government, where the appeal is against the order of the Authorisation Committee constituted under clause (b) of sub-section (4) of Section 9 or against the order of the Appropriate Authority appointed under sub-section (2) of Section 13.

## **CHAPTER VI-OFFENCES AND PENALTIES**

### **18. Punishment for removal of human organ without authority. —**

(1) Any person who renders his services to or any hospital and who, for purposes of transplantation, conducts, associates with, or help in any manner in, the removal of any human organ without authority, shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to ten thousand rupees.

(2) Where any person convicted under sub-section (1) is a registered medical practitioner, his name shall be reported by the Appropriate Authority to the respective State Medical Council for taking necessary action including the removal of his name from the register of the Council for a period of two years for the first offence and permanently for the subsequent offence.

### **19. Punishment for commercial dealings in human organs. —** Whoever —

(a) makes or receives any payment for the supply of, or for an offer to supply, any human organ;

(b) seeks to find a person willing to supply for payment any human organ;

(c) offers to supply any human organ for payment;

(d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human organ;

(e) takes part in the management or control of a body of persons, whether a society, firm or company, whose activities consist of or include the initiation or negotiation of any arrangement referred to in clause (d); or

(f) publishes or distributes or causes to be published or distributed any advertisement, —

(a) inviting persons to supply for payment of any human organ;

(b) offering to supply any human organ for payment; or

(c) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in clause (d), shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to seven years and shall be liable to fine which shall not be less than ten thousand rupees but may extend to twenty thousand rupees;

Provided that the court may, for any adequate and special reason to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than two years and a fine less than ten thousand rupees.

**20. Punishment for contravention of any other provision of this Act. —** Whoever contravenes any provision of this Act or any rule made, or any condition of the registration granted, thereunder for which no punishment is separately provided in this Act, shall be punishable with imprisonment for a term which may extend to three years or with fine which may extend to five thousand rupees.

### **21. Offences by companies. —**

(1) Where any offence punishable under this Act has been committed by a company, every person who, at the time the offence was committed was in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment, if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding any thing contained in sub-section (1), where any offence punishable under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

**Explanation.** — For the purposes of this section, —

(a) “company” means any body corporate and includes a firm or other association of individuals; and

(b) “director”, in relation to a firm, means a partner in the firm.

**22. Cognizance of offence.** —

(1) No court shall take cognizance of an offence under this Act except on a complaint made by —

(a) the Appropriate Authority concerned, or any officer authorised in this behalf by the Central Government or the State Government or, as the case may be, the Appropriate Authority; or

(b) a person who has given notice of not less than sixty days, in such manner as may be prescribed, to the Appropriate Authority concerned, of the alleged offence and of his intention to make a complaint to the court.

(2) No court other than that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

(3) Where a complaint has been made under clause (b) of sub-section (1), the court may, on demand by such person, direct the Appropriate Authority to make available copies of the relevant records in its possession to such person.

## CHAPTER VII-MISCELLANEOUS

**23. Protection of action taken in good faith.** —

(1) No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done in pursuance of the provisions of this Act.

(2) No suit or other legal proceeding shall lie against the Central Government or the State Government for any damage caused or likely to be caused for anything which is in good faith done or intended to be done in pursuance of the provisions of this Act.

**24. Power to make rules.** —

(1) The Central Government may, by notification, make rules for carrying out the purposes of this Act.

(2) In particular, and without prejudice to the generally of the foregoing power, such rules may provide for all or any of the following matters, namely: —

(a) the manner in which and the conditions subject to which any donor may authorise removal, before his death, of any human organ of his body under sub-section (1) of Section 3;

(b) the form and the manner in which a brain-stem death is to be certified and the conditions and



requirements which are to be satisfied for that purpose under sub-section (6) of Section 3;

(c) the form and the manner in which any of the parents may give authority, in the case of brain-stem death of a minor, for the removal of any human organ under sub-section (7) of Section 3;

(d) the form in which authority for the removal of any human organ from an unclaimed dead body may be given by the person in charge of the management or control of the hospital or prison under sub-section (1) of section 5;

(e) the steps to be taken for the preservation of the human organ removed from the body of any person under Section 7;

(f) the form and the manner in which an application may be jointly made by the donor and the recipient under sub-section (5) of Section 9;

(g) the manner in which all possible effects, complications and hazards connected with the removal and transplantation is to be explained by the registered medical practitioner to the donor and the recipient under Section 12;

(h) the standards as are to be enforced by the Appropriate Authority for hospitals engaged in the removal, storage or transplantation of any human organ under clause (iii) of sub-section (3) of Section 13;

(i) the other measures as the Appropriate Authority shall undertake in performing its functions under clause (vi) of sub-section (3) of Section 13;

(j) the form and the manner in which an application for registration shall be made and the fee which shall be accompanied, under sub-section (2) of Section 14;

(k) the specialised services and the facilities to be provided, skilled manpower and the equipments to be possessed and the standards to be maintained by a hospital for registration, under sub-section (3) of Section 14;

(l) the form in which, the period for which and the conditions subject to which certificate of registration is to be granted to a hospital, under sub-section (1) of Section 15;

(m) the manner in which and the fee on payment of which certificate of registration is to be renewed under sub-section (3) of Section 15;

(n) the manner in which an appeal may be preferred under Section 17;

(o) the manner in which a person is required to give notice to the Appropriate Authority of the alleged offence and of his intention to make a complaint to the court, under clause (b) of sub-section (1) of Section 22; and

(p) any other matter which is required to be, or may be, prescribed.

(3) Every rule made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

## **25. Repeal and saving. —**

(1) The Ear Drums and Ear Bones (Authority for Use for Therapeutic Purposes) Act, 1982 (28 of 1982) and the Eyes (Authority for Use for Therapeutic Purposes) Act, 1982 (29 of 1982) are hereby repealed.

(2) The repeal shall, however, not affect the previous operation of the Acts so repealed or anything duly done or suffered thereunder.

## **THE TRANSPLANTATION OF HUMAN ORGANS RULES, 1995**

**(GSR NO. 51(E), dt. 4-2-1995)**

**[As amended vide GSR 571(E), dt.31-7-2008]**

*In exercise of the powers conferred by sub-section (1) if section 24 of the Transplantation of Human Organs Act, 1994 (42 of 1994), the Central Government hereby makes the following rules, namely:-*

### **1. Short title and commencement**

1. These rules may be called the Transplantation of Human Organs Rules, 1995.
2. They shall come into force on the date<sup>1</sup> of their publication in the Official Gazette.

### **2. Definitions**

(a) "Act" means the Transplantation of Human Organs Act, 1994 (42 of 1994);

(b) "Form" means a form annexed to these Rules;

(c) "Section" means a section of the Act;

<sup>2</sup>[(d) "National Accreditation Board for Laboratories" (NABL) means a Board set up by the Quality Council of India (set up by the Government of India) for undertaking assessment and accreditation of testing and calibration of laboratories in accordance with the international standard ISO/IEC/17025 and ISO 15189;

(e) the Registered Medical Practitioner, as defined in clause (n) of section 2 of Transplantation of Human Organs Act, 1994 includes an allopathic doctor with MBBS or equivalent degree under the Medical Council of India Act.]

<sup>3</sup>[(f)] Words and expressions used and not defined in these Rules, but defined in the Act, shall have the same meanings respectively assigned to them in the Act.

### **3. Authority for removal of human organ**

Any donor may authorise the removal, before his death, of any human organ of his body for therapeutic purposes in the manner and so such conditions as specified in <sup>4</sup>[Forms 1(A), 1(B) and 1(C)].

### **4. Duties of the Medical Practitioner**

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

1. that the donor has given his authorization in Form 1(A) or 1(B) or 1(C).
2. that the donor is in proper state of health and is fit to donate the organ, and the registered medical practitioner shall sign a certificate as specified in Form 2.
3. That the donor is a near relative of the recipient as certified in Form 3, who has signed Form 1(A) or 1(B) as applicable to the donor and that the donor has submitted an application in Form 10 jointly with the recipient and that the proposed donation has been approved by the concerned competent authority and that the necessary

documents as prescribed and medical tests, if required, to determine the factum of near relationship, have been examined to the satisfaction of the Registered Medical Practitioner i.e. Incharge of transplant center.

4. 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 provision of sub-rule (2) of rule 4A.
5. In case of a donor who is other than a near relative and has signed Form 1(C) and submitted an application in Form 10 jointly with the recipient, the permission from the Authorisation Committee for the said donation has been obtained.]

(2) A registered medical practitioner shall, before removing a human organ from the body of a person after his death satisfy himself-

1. 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 authorized as specified in Form 5 before his death, the removal of the human organ of his body, after his death, for therapeutic purposes and there is no reason to believe that the donor had subsequently revoked the authority aforesaid;  
<sup>1</sup>[(b) that then person lawfully in possession of the dead body has signed a certificate as specified in Form 6.]

(3) A registered medical practitioner shall, before removing a human organ from the body of a person in the event of his brain-stem death, satisfy himself-

(a) that a certificate as specified in Form 8 has been signed by all the members of the Board of Medical Experts referred to in sub-section (6) of section 3 of the Act;

2. 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.

## <sup>2</sup>[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 provision of clauses (a) and (b) of sub-section (4) of section 9 of the Act.

(2) Where the proposed transplantation is between a married couple, the Registered Medical Practitioner i.e. Incharge of 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 of age of children and family photograph depicting the entire immediately family, birth certificate of children containing particulars of parents.

(3) When the proposed donor or recipient or both are not Indian Nationals/citizens whether 'near relatives' or otherwise, Authorisation Committees shall consider all such requests.

(4) When the proposed donor and the recipient are not "near relatives", as defined under clause (i) of section 2 of the Act, the Authorisation Committee shall evaluate that,-

(i) there is no commercial transaction between the recipient and the donor and that no payment or money or moneys worth as referred to the Act, has been made to the donor or promised to be made to the donor or any other person;

(ii) the following shall specifically be assessed by the Authorisation Committee:-

1. an explanation of the link between them and the circumstances which led to the offer being made; reasons why the donor wished to donate;

2. documentary evidence of the link, e.g. proof that they have lived together, etc;
3. old photographs showing the donor and recipient together;

(iii) that there is no middleman or tout involved;

(iv) that financial status of the donor and the recipient is probed by asking them to give appropriate evidence of their vocation and income for the previous three financial years. Any gross disparity between the status of the two must be evaluated in the backdrop of the objective of preventing commercial dealing;

(v) that the donor is not a drug addict or known person with criminal record;

(vi) that the next of 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 such kin shall also be recorded and taken note of.]

## **5. Preservation of organs**

The organ removed shall be preserved according to current and accepted scientific methods in order to ensure viability for the purpose of transplantation;

<sup>1</sup>[PROVIDED that the eye-ball removed shall be preserved in the following three steps, namely;-

- i. short-term preservation;
- ii. medium-term preservation;
- iii. long-term preservation;

and suitable media shall be used for preservation.]

<sup>1</sup>[6. The donor and the recipient shall make jointly an application to grant approval for removal and transplantation of a human organ, to the concerned competent authority or Authorisation committee as specified in Form 10. The Authorisation Committee shall take a decision on such application in accordance with the guidelines in rule 6A.]

## **<sup>2</sup>[6A. Composition of Authorisation Committees**

1. There shall be one State Level Authorisation Committee.
2. Additional authorization 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 precaution needs to be taken in such cases;
  - ii. Authorisation Committee should be Hospital based in Metro and big cities if the number of transplants exceeds 25 in a year at the respective transplantation centers. In small towns, there are State or District level Committees if transplants are less than 25 in a year in the respective districts.

(A) *Composition of Hospital Based Authorisation Committees:* (To be constituted by the State Government and in case of Union Territory by the Central Government).

1. the senior most person officiating as Medical Director or Medical Superintendent of the Hospital;
2. two senior medical practitioners from the same hospital who are not part of the transplant team;
3. 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

4. Secretary (Health) or nominee and Director Health Services or nominee.

(B) *Composition of state or District Level Authorisation Committees:* (To be constituted by the State Government and in case of Union territory by the Central Government).

1. a Medical Practitioner officiating as Chief Medical Officer or any other equivalent post in the main/major Government Hospital of the District;
2. 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;
3. 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
4. Secretary (Health) or nominee and Director Health Services or nominee.

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

**6B.** The State level committees shall be formed for the purpose of providing approval or no objection certificate to the respective donor and recipient to establish the legal and residential status as a domicile state. It is mandatory that if donor, recipient and place of transplantation are from different states, then the approval or "no objection certificate" from the respective domicile State Government should be necessary. The institution where the transplant is to be undertaken in such case the approval of Authorisation committee is mandatory.

**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.

**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.

**6E.** Secretariat of the Committee shall circulate copies of all applications received from the proposed donors to all members of the Committee. Such applications should be circulated along with all 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 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) if the State/Union territory Government.

**6F.** The Authorisation committee shall focus its attention on the following, namely:-

1. 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 magis-rate/Metropolitan Magistrate/or Sarpanch of the Panchayat;
  - i. 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;
  - ii. if in its opinion, the relationship is not conclusively established after evaluating the above evidence, it may in its discretion direct further medical tests as

prescribed as below:

1. the test 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.
  2. Test for Human Leukocyte Antigen-DR beta genes to be performed using the Polymerase Chain reaction (PCR) based Deoxyribonucleic acid (DNA) methods.
  3. The tests referred to in sub-rules (i) to (ii) shall be got done from a laboratory accredited with National Accreditation Board for Laboratories (NABL).
  4. Where the tests referred to in (i) to (iii) above do not establish a genetic relationship between the donor and the recipient, the same tests to be performed on both or at least one parent, preferably both parents. If parents are not available, same tests to be performed on such relatives of donor and recipient as are available and are willing to be tested failing which, genetic relationship between the donor and the recipient will be deemed to have not been established.
2. The papers for approval of transplantation would be processed by the registered medical practitioner and administrative division of the Institution for transplantation, while the approval will be granted by the Authorisation Committee.
  3. Where the proposed transplant is between a married couple (except foreigners, whose cases should be dealt by Authorisation 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 the 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.

4. Where the proposed transplant is between individuals who are not "near relatives".

The authorization committee shall evaluate;-

(i) that there is no commercial transaction between the recipient and the donor. That no payment of money or moneys worth as referred to in the sections of the Act, has been made to the donor or promised to be made to the donor or any other person. In this connection, the Authorisation Committee shall take into consideration:-

1. an explanation of the link between them and the circumstances which led to the offer being made;
2. documentary evidence of the link e.g. proof that they have lived together etc;
3. reasons why the donor wishes to donate; and
4. old photographs showing the donor and the recipient together.

(ii) that there is no middleman/tout involved;

(iii) that financial status of the donor and the recipient is probed by asking them to give appropriate evidence of their vocation and income for the previous three financial years. Any gross disparity between the status of the two, must be evaluated in the backdrop of the objective of preventing commercial dealing;

(iv) that the donor is not a drug addict or a known person with criminal record;

(v) that the next of kin of the proposed unrelated donor is interviewed regarding awareness about his\her intention to donate an organ, the authenticity of the

link between the donor and the recipient and the reasons for donation.

Any strong view of disagreement or objection of such kin may also be recorded and taken note of; and

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

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

(ii) Authorisation Committee shall examine the cases of Indian donors

consenting to donate organs to a foreign national (who is a near relative), including a foreign national of India 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 interview by the Authorisation Committee and minutes of the interview should be recorded. Such interviews with the donors should be videographed.

(g) In case where the donor is a woman greater precautions ought to be taken. Her identity and independent consent should be confirmed by a person other than the recipient. Any document with regard to the proof of the residence or domicile and particulars of parentage should be relatable to the photo identity of the applicant in order to ensure that the documents pertain to the same person, who is the proposed donor and in the event of any inadequate or doubtful information to this effect, the Authorisation committee may in its discretion seek such other information or evidence as may be expedient; and desirable in the peculiar facts of the case.

(h) The Authorisation Committee should state in writing its reason for rejecting / approving the application of the proposed donor and all approvals should be subject to the following conditions:-

(i) that the approved proposed donor would be subjected to all such medical test as required at the relevant stages to determine his biological capacity and compatibility to donate the organ in question.

(ii) futhter that the psychiatrist clearance would also be mandatory to certify his mental condition, awareness, absence of any overt or latent psychiatric disease and ability to give free consent.

(iii) all prescribed forms have been and would be filled up by all relevant persons involved in the process of transplantation.

(iv) all interviews to be video recorded.

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

(j) Every authorized transplantation center must have its own website. The Authorization Committee is required to take final decision with in 24hours of holding the meeting for grant of permission of rejection for transplant. The decision of the Authorisation committee should be displayed on the notice board of the hospital or institution immediately and should reflect on the website of the hospital or institution within 24 hours of taking the decision. Apart from this, the website of the hospital or institution must update its website regularly in respect of the total number of the transplantations done in that hospital or institution along with the details of each transplantation. The same data should be accessible for compilation, analysis and further use by respective State Governments and Central Government.]

## **7. Registration of hospital**

(1) An application for registration shall be made to the Appropriate Authority as specified in Form 11. The application shall be accompanied by a fee or rupees one thousand payable to the Appropriate Authority by means of a bank draft or postal order.

(2) The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements, grant a certificate of registration as specified in Form 12 and shall be valid for a period of five years form the date of its issue and shall be renewable.

<sup>1</sup>[(3) Before a hospital is registered under the provisions of this rule, it shall be mandatory for the hospital to nominate a transplant co-ordinator.]

## **8. Renewal of registration**

(1) An application for the renewal of a certificate of registration shall be made to the Appropriate Authority within a period of three months prior to the date of expiry of the original certificate of registration and shall be accompanied by a fee of rupees five hundred payable to the Appropriate Authority by means of a bank draft or postal order.

(2) A renewal certificate of registration shall be as specified in Form 13 and shall be valid for a period of five years.

(3) If, after an inquiry including inspection of the hospital and scrutiny of its past performance

and after giving an opportunity to the applicant, the Appropriate Authority is satisfied that the application, since grant of certificate of registration under sub-rule (2) of rule 7 has not complied with the requirements of this Act and the Rules made thereunder and conditions subject to which the certificate of registration has been granted, shall, for reasons to be recorded in writing, refuse to grant renewal of the certificate of registration.

### **1]9. Conditions for grant of certificate of registration**

No hospital shall be granted a certificate of registration under this Act unless it fulfills the following requirement of manpower, equipment, specialized services and facilities as laid down below;-

#### **(A) General Manpower Requirement Specialised Services and Facilities:**

1. 24 hours availability of medical and surgical, (senior and junior) staff.
2. 24 hours availability of nursing staff, (general and speciality trained).
3. 24 hours availability of Intensive Care Units with adequate equipments, staff and support system, including specialists in anaesthesiology, intensive care.
4. 24 hours availability of laboratory with multiple discipline testing facilities including but not limited to Microbiology, Bio-Chemistry, pathology and Hematology and Radiology departments with trained staff.
5. 24 hours availability of Operation Theatre facilities (OT facilities) for planned and emergency procedures with adequate staff, support system and equipments.
6. 24 hours availability of communication system, with power backup, including but not limited to multiple line telephones, public telephone system, fax, computers and paper photo-imaging machine.
7. Experts, (other than the experts required for the relevant transplantation) of relevant and associated specialties including but not limited to and depending upon the requirements, the experts in internal medicine, diabetology, gastroenterology, nephrology, neurology, paediatrics, gynaecology, immunology and cardiology etc. should be available to the transplantation center.

#### **(B) Equipments:**

Equipments as per current and expected scientific requirements specific to organ or organs being transplanted. The transplant center should ensure the availability of the accessories, spare-parts and back-up/maintenance/service support system in relation to all relevant equipments.

#### **(C) Experts and their qualifications:**

##### **1. Kidney Transplantation**

M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. training in a recognized center in India or abroad and having attended to adequate number of renal transplantation as an active member of team.

##### **2. Transplantation of liver and other abdominal organs**

M.S. (Gen.) Surgery or equivalent qualification with adequate post M.S. training in an established center with a reasonable experience of performing liver transplantation as an active member of team.

##### **3. Cardiac, Pulmonary, Cardio-Pulmonary Transplantation**

M.Ch. Cardio-thoracic and vascular surgery or equivalent qualification in India or abroad with at least 3 years experience as an active member of the team performing an adequate number of open heart operations per year and well-versed with Coronary by-pass surgery and Heart-Valve surgery.

##### **(d) Cornea Transplantation**

M.D./M.S. ophthalmology or equivalent qualification with one year post M.D./M.S. training in a recognised hospital carrying out Corneal transplant operations.]

### **10. Appeal**

(1) Any person aggrieved by an order of the Authorisation Committee under sub-section (6) of section 9, or by an order of the Appropriate Authority under sub-section (2) of section 15 and



section 16 of the Act, may, within thirty days from the date of receipt of the order, prefer an appeal to the Central Government.

(2) Every appeal shall be in writing and shall be accompanied by a copy of the order appealed against.

**<sup>1</sup>[FORM 1(A)]**

[To be completed by the prospective related donor]  
[Refer rule 3]

My full name is .....

And this is my photograph

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

Photograph of the Donor  
(Attested by Notary Public)

My permanent home address is

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

My present home address is

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

Date of birth ..... (day/month/year)

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

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

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

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

Photograph of the Recipient  
(Attested by Notary public)

- Ration / Consumer Card number and Date of issue & place .....  
(Photocopy attached)
  - 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 .....
- Other proof of identity and address .....

**I solemnly affirm and declare that:-**

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

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

.....  
Signature of the prospective donor Date

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

- Wherever applicable.

**FORM 1(B)**

[To be completed by the prospective spousal donor]  
(Refer rule 3)

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

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

Photograph of the Donor  
(Attested by Notary Public)

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 .....

Who was born on ..... (day / month / year) and whose particulars are as follows:



Photograph of the Recipient  
(Attested by Notary Public)

- 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 .....
- Other proof of identity and address .....

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

1. A Certified copy of a marriage certificate  
or
2. An affidavit of a "near relative" confirming the status of marriage to be sworn before  
Class-I Magistrate / Notary Public.
3. Family photographs.
4. Letter from member of Gram Panchayat / Tehsildar / Block Development Officer / MLA /  
MP certifying factum and status of marriage.  
or
5. Other credible evidence

**I solemnly affirm and declare that: -**

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

1. I understand that nature of criminal offences referred to in the sections.
2. No payment of money or money's worth as referred to in the sections of the Act has been made to me or will be made to me or any other person.
3. I am giving the consent and authorisation to remove my ..... (organ) of my own free will without any undue pressure, inducement, influence or allurement.
4. I have been given a full explanation of the nature of the medical procedure involved and the risks involved for me in the removal of my ..... (organ). That explanation was given by .....( name of registered medical practitioner).
5. I understand the nature of that medical procedure and of the risks to me as explained by that practitioner.
6. I understand that I may withdraw my consent to the removal of that organ at any time before the operation takes place.
7. I state that particulars filled by me in the form are true and correct to my knowledge and noting material has been concealed by me.

.....

Signature of the prospective donor Date

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

- Tick Wherever applicable.

**FORM 1(C)**

[To be completed by the prospective spousal donor].  
(Refer rule 3)

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

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

Photograph of the Donor  
(Attested by Notary Public)

My permananet home address is .....Tel:.....

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

Date of birth.....(day/month/year)

- Ration/consumer Card number and Date of issue & place.....  
(Photocopy attached) and/or
  - Voter's I-Card number, date of issue, Assembly Constituency.....  
(Photocopy attached) and/or
  - Passport number and country of issue .....  
(Photocopy attached) and/or
  - Driving Licence number, Date of issue, licensing authority .....  
(Photocopy attached) and/or
  - PAN ..... and/or
  - Other proof of identity and address .....
  - Details of last three years income and vocation of donor .....
- .....  
.....

I hereby authorize removal 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:

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

Photograph of the Recipient  
(Attested by Notary public)

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

Other proof of identity and address .....

**I solemnly affirm and declare that:-**

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

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

.....  
Signature of the prospective donor Date

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

- Tick Wherever applicable.

**<sup>1</sup>[FORM 2**

[To be completed by the concerned medical practitioner]

[Refer rule 4(1) (b)]

I, Dr. .... possessing qualification of .....  
registered as medical practitioner at Serial No. .... by the  
..... Medical Council, certify that I have examined Shri/Smt./ Km  
..... s/o, w/o, d/o Shir ..... aged .....who has given in-formed consent  
about donation of the organ, namely (name of the organ ..... to Shri/Smit./Km  
..... who is a "near relative" of the donor / other that near relative of the  
donor, who had been approved by the Authorisation Committee / Registered Medical  
Practitioner i.e. In-charge 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 seal  
should partially  
appear on  
photograph and  
document without  
disfiguring the face in  
photograph.

To be affixed (pasted)  
and attested by the  
doctor concernedThe  
signatures and seal  
should partially appear  
on photograph and  
document without  
disfiguring the face in  
photograph.

Photograph of the Donor

Photograph of the Recipient



(Attested by doctor)

(Attested by doctor)]

**<sup>1</sup>[FORM 3**

*[Refer rule 4(1) (c)]*

I, Dr./Mr./Mrs.. ..... working as ..... at ..... and possessing qualification of ..... certify that Shri / Smt. Km. .... S / o, D / o, Wo 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 /sons /daughter as per their statement and the fact of this relationship has been established / not established by the results of the tests for Antigenic Products of the Human Major Histocompatibility Complex. The results of the test are attached.

Place .....

Signature

(To be signed by the Head of the Laboratory)

Date .....

**FORM 4**

[Refer Rule 4 (1) (d)]

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

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

OR

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

Place ..... Signature of Registered Medical Practitioner  
Date .....

**FORM 6**

[Refer rule 4(2) (b)]

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

Signature

Date .....

Place .....

Person in lawful possession of the dead body

Address .....

.....

**<sup>1</sup>[FORM 7**

*[Refer rule 4(2) (b)]*

*I,.....Shri/Smt./Km. .... having lawful possession of the dead body of Shri/Smt./Km.  
.....s/o, w/o, d/o Shri .....aged ..... resident of ..... after having  
known that no objection was expressed by the deceased to any of his human organ being used  
after his death for therapeutic purposes and also having reason to believe that no near relative  
of the deceased person has objection to any of the deceased person's organ being used for  
therapeutic purposes, hereby authorize the removal of the deceased's organ, namely,  
..... for therapeutic purposes.*

*Name.....*

*Signature .....*

*Address.....*

*Time and date.....]*

**FORM 8**

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

We, the following members of the Board of Medical Experts after careful personal examination, hereby certify that Shri/ Smt. / Km. .... aged about ..... s / o, w /o, d / o, Shri ..... 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.  
Date ..... Signature.....

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

**BRAIN-STEM DEATH CERTIFICATE**

*(A) Patient Details:*

- 1. Name of the Patient Shri/ Smt ./ Km. ....  
S.O. / W.O. / D.O. Shri .....  
Sex..... Age.....
- 2. Home Address .....  
.....  
.....  
.....
- 3. Hospital Number .....
- 4. Name and address of next of kin or person .....  
responsible for the patient (if none exists, this ..... must be specified)  
.....
- 5. Has the patient or next of kin agreed to any transplant? .....
- 6. Is this a Police Case? Yes.....No.....

*(B) Pre-Conditions:*

- 1. Diagnosis: Did the patient suffer from any illness or accident that led to irreversible brain damage? Specify details: .....  
..... Date and time of accident/onset of illness

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

2. Findings of Board of Medical Experts:

1. The following reversible cause of coma have been excluded:-

Intoxication (Alcohol)

Depressant Drugs

Relaxants (Neuromuscular blocking agents)

first Medical Examination Second Medical Examination

1st 2nd 1st 2st

Primary hypothermia

Hypovolaemic shock

Metabolic or endocrine disorders

Test for absence of brain-stem functions

2. Coma

3. Cessation of spontaneous breathing

4. Pupillary size

5. Pupillary light reflexes

6. Doll's head eye movements

7. Corneal reflexes (Both sizes)

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

9. Gag reflex

10. Cough (Tracheal)

11. Eye movements on coloric testing bilaterally

12. Apnoea tests as specified

13. Were any respiratory movements seen ?

..... Date and time of first testing:

.....

Date and time of second testing: .....

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

Shri / Smt / Km. .... 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.

N.B.

I. The Minimum time interval between the first testing and second Testing will be six hours.

II. No. 2 and No. 3 will be co-opted by the Administrator Incharge of the hospital from the panel of experts approved by the Appropriate Authority.

**FORM 9**

**[Refer rule 4(3) (a) (b)]**

**I, Shri/Smt. ....s / o. w / o, Shri ..... resident of .....  
hereby authorize removal of the organ / organs, namely, ..... for  
therapeutic purpose from the dead body of my son / daughter Shri / Km.  
.....aged ..... Whose brain-stem death has been duly  
certified in accordance with the law.**

**Signature .....**

**Name .....**

**Place .....**

**Date .....**

**To be self attested across the affixed photograph**

**<sup>1</sup>[FORM 10**

**APPLICATION FOR APPROVAL FOR TRANSPLANTATION (LIVE DONOR)**

[To be completed by the proposed recipient and the proposed donor]

[Refer Rule 4(1) (a) (b)]

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 form ..... 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): -

1. by virtue of being a near relative i.e. ....
2. 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 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 applications: -

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

**FORM 11**

**APPLICATION FOR REGISTRATION OF HOSPITAL TO CARRY OUT ORGAN  
TRANSPLANTATION**

To

The Appropriate Authority for organ transplantation .....(State of Union Territory)  
We hereby apply to be recognised as an institution to carry out organs transplantation. The required data about the facilities available in the hospital are as follows:-

**(A) HOSPITAL**

1. Name:
2. Location:
3. Govt./pvt. :
4. Teaching/Non Teaching:
5. Approached by:

Road: Yes No

Rail : Yes No

Air : Yes No

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

**(B) SURGICAL TEAM :**

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

(Please

**(C) MEDICAL TEAM:**

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

**(D) ANAESTHESIOLOGY**

1. No. of permanent staff members with their designation:
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 theatres:

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

1. ICU/HDU facilities : Present.....Not Present.....

2. No. of I.C.U beds .....

3.Trained

Nurses .....

Technicians .....

4. Name and number of equipments in ICU

(F) OTHER SUPPORTIVE FACILITIES

Data about facilities available in hospital.

(G) LABORATORY FACILITIES :

No. of permanent staff with their designations

No. of temporary staff with their designations

Names of the investigations carried out in the Dept

Name and number of equipments available

(H) IMAGING SERVICES

1. No. of permanent staff with their designations

2. No. of temporary staff with their designations

3. Names of the investigations carried out in the Dept

4. Name and number of equipments available

(I) HAEMATOLOGY SERVICES

1. No. of permanent staff with their designations

2. No. of temporary staff with their designations

3. Names of the investigations carried out in the Dept

4. Name and number of equipments available

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

(K) DIALYSIS FACILITIES Yes..... No.....

(L) OTHER PERSONNEL

Nephrologist Yes/No

Neurologist Yes/No

Neuro-Surgeon Yes/No

Urologist Yes/No

G.I. Surgeon Yes/No

Paediatrician Yes/No

Physiotherapist Yes/No

Social Worker            Yes/No

Immunologists            Yes/No

Cardiologist            Yes/No

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

sd/-

**HEAD OF THE INSTITUTION**

**FORM-12**

**CERTIFICATE OF REGISTRATION**

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

- 1. ....
- 2. ....
- 3. ....
- 4. ....

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

**Signature**

**Signature**

**FORM-13**

(See sub-rule 8(2))

**OFFICE OF THE APPROPRIATE AUTHORITY**

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

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

**Appropriate Authority.....**

**Place.....**

**Date.....**

## **The Transplantation of Human Organs Rules, 1995**

G.S.R. 51 (E) - In exercise of the powers conferred by sub-section (1) of Section 24 of the Transplantation of Human Organs Act, 1994(42 of 1994), the Central Government hereby makes the following rules, namely -

### **1. SHORT TITLE AND COMMENCEMENT**

(1) These rules may be at the earliest be the transplantation of Human Organs Rules, 1995.

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

### **2. DEFINITIONS**

(a) "Act" means the Transplantation of Human Organs Act, 1994 (42 of 1994);

(b) "Form" means a form annexed to these Rules;

(c) "Section" means a section of the Act;

(d) Words and expressions used and not defined in these Rules, but defined in the Act, shall have the same meanings respectively assigned to them in the Act.

### **3. AUTHORITY FOR REMOVAL OF HUMAN ORGAN**

Any donor may authorise the removal, before the death, of any human organ of his body for therapeutic purposes in the manner and as such conditions as specified in Form 1.

### **4. DUTIES OF THE MEDICAL PRACTITIONER**

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

(a) that the donor has given his authorization in the Form 1

(b) that the donor is in proper state of health and is fit to donate the organ, and shall sign a certificate a specified in Form 2.

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

(i) tests for the antigenic products of the Human Major Histo-compatibility system HLA-A, HLA-B and HLA-DR using conventional serological techniques;

(ii) tests to establish HLA-DR beta and HLA-DQ beta gene restriction fragment length polymorphism;

(iii) Where the tests referred to in sub-clause(i) and sub-clause(ii) do not establish a genetic relationship between the donor and the recipient further tests to establish DNA polymorphism using at least two multi locus gene probe;

(iv) Where the tests referred to in sub-clause (iii) do not establish a genetic relationship between the donor and the recipient further tests do establish DNA polymorphisms using atleast 5 single locus polymorphic probes.

(d) in case recipient is a spouse of the donor, record the statements of the recipient and the donor to the effect that they are so related and shall sign a certificate in Form 4;

(2) A registration medical practitioner shall, before removing a human organ from the body of a person after his death satisfy himself -

(a) that the donor had in the presence of two or more witnesses (at last one of whom is a near relative of such person) unequivocally authorized as specified in Form 5 before his death, the removal of the human organ of his body, after his death, for therapeutic purposes and there is no reason to believe that the donor had subsequently revoked the authority aforesaid.

(b) that the person lawfully in possession of the dead body has signed a certificate as specified in Form 6 or Form 7.

(3) A registered medical practitioner shall before removing human organ from the body of a person in the event of his brainstem death satisfy himself -

(a) that a certificate as specified in Form 8 has been signed by all the members of the Board of medical experts referred to in sub section (6) of section 3 of the Act

(b) that in the case of brain stem death of a person of in 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 the parent of such person.

### **5. PRESERVATION OF ORGANS**

The organ removed shall be preserved according to current and accepted scientific methods in order to ensure viability for the purpose of transplantation.

6. **The donor and the recipient** shall make jointly an application to grant approval for removal and transplantation of a human organ, to the Authorization Committee as specified in Form 10.

### **7. REGISTRATION OF HOSPITAL**

(1) An application for registration shall be made to the Appropriate Authority as specified in Form 11. The application shall be accompanied by a fee of rupees one thousand payable to the Appropriate Authority by means of a bank draft or postal order.

(2) The Appropriate Authority shall after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements, grant a certificate of registration as specified in Form 12 and shall be valid for period of 5 years from the date of its issue and shall be renewable.

### **8. RENEWAL OF REGISTRATION**

(1) An application for the renewal of a certificate or registration shall be made to the Appropriate Authority within a period of three months prior to the date of expiry of the original certificate of registration and shall be accompanied by a fee of rupees five hundred payable to the Appropriate Authority by means of a bank draft or postal order.

(2) A renewal certificate of registration shall be as specified in Form 13 and shall be valid for a period of five years.

(3) If, after an inquiry including inspection of the hospital and security 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 the under sub-rule (2) of Rule 7 has not complied with the requirements of this Act and the 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.

#### **(9) CONDITIONS FOR GRANT OF CERTIFICATE OF REGISTRATION**

No hospital shall be granted a certificate of registration under this Act unless it fulfills the following requirement of manpower, equipment, specialised services and facilities as laid down below -

##### **GENERAL REQUIREMENT**

1. SurgicalStaff
2. CardiologyStaff
3. NursingStaff
4. CommunicationSystem
5. Intensivist
6. MedicalSocialWorker
7. Perfusionist

##### **VARIOUS DEPARTMENT**

1. Microbiology
2. Mycology
3. Pathology
4. Virology
5. Nephrology
6. Neurology
7. Psychology
8. G.I.Surgery
9. Anaesthesiology
10. ImagingFacilities
11. Paediatrics
12. Physiotherapy
13. Immunology
14. Haematology
15. BloodBank
16. ClinicalChemistry
17. Cardiology

##### **NON-TRANSPLANTATION PROGRAMME TEAM**

1. Neurologist
2. Neurosurgeon
3. MedicalSuperintendent
4. Any other hospital Staff

##### **BASIC EQUIPMENT**

Operating Room facilities for routine open heart surgery which includes heart-lung machine and accessories.

##### **ADDITIONAL EQUIPMENT REQUIRED FOR TRANPLANTATION PROGRAMME**

- 1.CellSaver
2. Assist devices like IABP, Centrifugal Pump and various assist devices, both pneumatic and electric-operated.
3. Mobile C-arm image intensifier for routine biopsies in the street operating room
- 4.Euct /Alert system for early detection of any infection levels.
- 5.Radioimmunoassay for measuring Cyclosporin levels.
6. Routine Laboratory facilities for detection of HIV, Australia antigen, CMV, Toxoplasmosis and other Mycology Tests

##### **EXPERTS**

###### **(A) Kidney Transplantation**

M.S. (Gen.) Surgery or equivalent qualification which three years post M.S. training a recognized center in India or abroad and having attended to adequate number of renal transplantation as an active member of team

###### **(B) Transplantation of Liver & Other Abdominal Organs**

M.S. (Gen.) Surgery or equivalent qualification with adequate post M.S. training in an established center with reasonable experience of performing liver transplantation as an active member of team

###### **(a) Cardiac, Pulmonary Cardio-Pulmonary Transplantation.**

M.Ch Cardio-thoracic and vascular surgery or equivalent qualification in India or abroad with at least 3 years experience as an active member of the team performing an adequate number of open heart operations per year and well-versed with coronary by-pass surgery and Heart valve Surgery.

#### **10. APPEAL**

(1) Any person aggrieved by an order of the Authorisation Committee under sub-section (6) of section 9, or by an order of the Appropriate Authority under sub-section (2) of section 15 and Section 16 of the Act, may, within thirty days from the date of receipt of the order, prefer an appeal to the Central Government



(2) Every appeal shall be in writing and shall be accompanied by a copy of the order appealed against

**FORM - 1**  
(See rule 3)

I, ..... aged ..... S/o, D/o, W/o, Mr. .... resident of ..... hereby authorise to remove for therapeutic purposes / consent to donate my organ, namely .....

(1) Mr. .... / Mrs. ....  
S/o, D/o, W/o, Mr. ....  
aged ..... resident of ..... happens to be my near relative as defined in clause (2) of section 2 of the Act.

(Or)

(2) Mr./Mrs. ....  
S/o, D/o, W/o, Mr. ....  
aged ..... resident of ..... towards when I possess special affection, attachments, or for any special reason (to be specified).

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

**Signature of the Donor**

**FORM - 2**  
[(See rule 4(1) (b)]

I, Dr....., possessing the qualification of ..... registered as medical practitioner at serial No. .... by the ..... Medical as Medical Council, certify that I have examined Shri / Smt / Kum. .... S/o, D/o, W/o ..... aged ..... who is free and is near relative of the donor and that the said donor is in proper state of health and is ..... medically fit to be subjected to the procedure of organ removal.

Place: .....

**Signature**

Date: .....

**FORM -3**  
[(See rule 4(1) (c)]

I,Dr.....possessing the qualification of ..... registered as med. practitioner at Serial No. .... by the ..... Medical council, certify that Mr./Mrs. .... S/o, D/o, W/o ..... aged .....the donor, an Mr./Mrs. .... S/o, D/o, W/o ..... aged ....., the recipient of the organ donated by the said donor are related to each other as brother/sister/mother/father/son/daughter as per their statement and the fact of this relationship has been established by the results of the tests for Antigenic Products of the Human Major Hysto-compability System, namely ..... by the Authorisation Committee as per the information contained in their letter of approval No. .... dated .....

Place.....

**Signature**

Date.....

**FORM -4**  
[(See rule 4(1) (d)]

I, Dr ..... possessing qualification of ..... registered as medical practitioner at Serial No. .... by the ....., Medical council, certify that :-

(i) Mr. .... S/o ..... aged ..... resident of ..... and Mrs. .... D/o, W/o ..... resident ..... are related to each other as spouse a according to the statement given by them and their statement has been confirmed by means of following evidence before effecting the organ removal from body of the said Shri / Smt / Km.....

(Applicable only in the cases where considered necessary).

(Or)

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

**Signature of Regd. medical practitioner**

Place.....

Date.....

**FORM -5**  
[(See rule 4(2) (a)]

I ..... S/o, D/o, W/o ..... aged ..... resident of ..... in the presence of persons mentioned below hereby unequivocally authorise the removal of my organ/organs, namely, ..... from my body

after my death for therapeutic purposes.

**Dated:** **Signature of the Donor**

**(Signature)**

1. Shri/Smt./Km.....

S/o, D/o, W/o ..... aged ..... resident of .....

**(Signature)**

2. Shri/Smt./Km.....of.....aged ..... resident of ..... is a near relative to the donor as.....

**Dated.....**

**FORM -6**  
[(See rule 4(2) (b)]

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

Dated.....

**Signature**

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

Address.....

**FORM - 8**  
[(See rule 4(3) (a) and (b)]

We the following members of the Board of medical experts after careful personal examination hereby certify that Shri/Smt/Km.....aged about.....son of/wife of/ daughter of.....resident of .....is dead on account of permanent and irreversible cessation of all function of the brain stem. The test carried out by us and the findings therein are recorded in the brain stem death Certificates annexed hereto.

**Dated** **Signature**

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

**BRAIN STEM DEATH CERTIFICATE**

**(A) PATIENT DETAILS :**

1. Name of the Patient Mr/Ms. .... S.O./D.O./W.O. Mr. .... Sex..... Age .....

2. Home Address .....

3. Hospital Number .....

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

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

6. In this a police Case ? Yes.....No.....

**(A) 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 no-responsible coma .....

2. Finding of Board of Medical Experts : (i) The following reversible causes of coma have been excluded:

