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# THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT, 1994

## INTRODUCTION

At present, there is no comprehensive legislation to regulate the removal of organs from living as well as deceased persons and transplantation of such organs. Some States and Union Territories have enacted some laws which regulate the removal and transplantation of certain organs. Thus a need for a comprehensive legislation for regulating the removal of organs from cadavers and living persons and prohibiting commercial dealings in human organs, was felt as the matter has been agitated by the parliamentarians as well as by various national bodies, medical, legal and social experts. On the other hand, in the absence of any law the removal of organs from persons suffering brain-stem death has not been possible. Transplantation of organs like liver and heart for which latest technology is available in the country, had been impeded. In order to reach a broad consensus of opinion in this regard, a series of seminars were held. A report was also prepared by a Committee of Medical and Legal Experts. Against this background it was considered necessary to enact a comprehensive law on the subject. Accordingly the Transplantation of Human Organs Bill was introduced in the Parliament.

## STATEMENT OF OBJECTS AND REASONS

At present, there is no comprehensive legislation to regulate the removal of organs from living as well as deceased persons and transplantation of such organs. In the Union territory of Delhi, there are two enactments in force, namely, the Eyes (Authority for use for Therapeutic Purposes) Act, 1982 and the Ear Drums and Ear Bones (Authority for Use for Therapeutic Purposes) Act, 1982 which regulate the removal and transplantation of cornea, ear drum and ear bones. In Maharashtra, the Maharashtra Kidney Transplantation Act, 1982 and the Bombay Corneal Grafting Act, 1957 regulate the transplantation of kidneys and corneas respectively. Thus, there is a need for a comprehensive legislation for regulating the removal of organs from cadavers and living persons and prohibiting commercial dealings in human organs.

2. There has been a persistent demand for such a legislation in Parliament, and from various national bodies, medical, legal and social experts, particularly when reports about the commercial dealing in human organs, especially kidneys, have increased. There has been persistent demand for prohibiting this unethical practice. On the other hand, in the absence of any legal sanction the removal of organs from persons suffering brain-stem death has not been possible. It has impeded transplantation of organs like liver and heart for which the necessary technology is available in the country. In order to reach a broad consensus of opinion in this regard, a series of seminars were held in the four metropolitan cities of the country. A report was also prepared by a Committee of medical and legal experts headed by Dr. L.M. Singhvi.

3. Against this background, it is considered necessary to enact a comprehensive law for regulating the removal and transplantation of human

organs and for preventing commercial dealings in organs by providing punishment for such dealings.

4. The Bill seeks to achieve the above objects.

#### **ACT 42 OF 1994**

The Transplantation of Human Organs Bill having been passed by both the Houses of Parliament received the assent of President on 8th July, 1994. It came on the Statute Book as the Transplantation of Human Organs Act, 1994 (42 of 1994). By section 3 of the Transplantation of Human Organs (Amendment) Act, 2011 (16 of 2011) the nomenclature of the Act has been amended. Now it stands as THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT, 1994 (42 of 1994) (*Came into force in the States of Goa, Himachal Pradesh and Maharashtra and all the Union Territories on 4-2-1995 and in other States which adopt this Act on the date of such adoption*).

#### **AMENDING ACT**

The Transplantation of Human Organs (Amendment) Act, 2011 (16 of 2011), (w.e.f. 27-9-2011 and w.e.f. 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, *vide* S.O. 30(E), dated 7th January, 2014).

# THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT, 1994<sup>†</sup>

(42 of 1994)

[8th July, 1994]

An Act to provide for the regulation of removal, storage and transplantation of <sup>1\*</sup>[human organs and tissues for the therapeutic purposes and for the prevention of commercial dealing in human organs and tissues] and for matters connected therewith or incidental thereto.

WHEREAS it is expedient to provide for the regulation of removal, storage and transplantation of <sup>2\*</sup>[human organs or tissues or both] for therapeutic purposes and for the prevention of commercial dealings in <sup>2\*</sup>[human organs or tissues or both];

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 <sup>3\*</sup>[Human Organs and Tissues] 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 State 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 date<sup>4</sup> 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, mean the date on which this Act comes into force in such State or Union territory.

† The nomenclature of the Act has been changed by the Transplantation of Human Organs (Amendment) Act, 2011 (16 of 2011), sec. 3.

1. Subs. By Act 16 of 2011, sec. 2, for "human organs for therapeutic purposes and for the prevention of commercial dealings in human organs" (w.e.f. 27-9-2011).

2. Subs. By Act 16 of 2011, sec. 4, for "human organs" (w.e.f. 27-9-2011).

3. Subs. By Act 16 of 2011, sec. 3, for "Human Organs" (w.e.f. 27-9-2011).

4. Came into force in the States of Goa, Himachal Pradesh and Maharashtra and in all Union Territories on 4-2-1995, vide S.O. 80(E), dated 4th February, 1995.

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, vide S.O. 30(E), dated 7th January, 2014.

**2. Definitions.**—In this Act, unless the context 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 <sup>1\*</sup>[human organs or tissues or both] 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;
- <sup>2\*</sup>[(ha) "Human Organ Retrieval Centre" means a hospital,—
- (i) which has adequate facilities for treating seriously ill patients who can be potential donors of organs in the event of death; and
- (ii) which is registered under sub-section (1) of section 14 for retrieval of human organs;]
- <sup>2\*</sup>[(hb) "minor" means a person who has not completed the age of eighteen years;]
- <sup>3\*</sup>[(i) "near relative" means spouse, son, daughter, father, mother, brother, sister, grandfather, grandmother, grandson or granddaughter;]
- (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 <sup>4\*</sup>[human organ or tissue or both] to be supplied; or

1. Subs. by Act 16 of 2011, sec. 4, for "human organs" (w.e.f. 27-9-2011).

2. Ins. by Act 16 of 2011, sec. 5(a) (w.e.f. 27-9-2011).

3. Ins. by Act 16 of 2011, sec. 5(b) (w.e.f. 27-9-2011).

4. Subs. by Act 16 of 2011, sec. 4, for "human organ" (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, vide S.O. 30(E), dated 7th January, 2014.

- (ii) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any <sup>1\*</sup>[human organ or tissue or both] from his body;
- (l) "prescribed" means prescribed by rules made under this Act;
- (m) "recipient" means a person into whom any <sup>1\*</sup>[human organ or tissue or both] 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; <sup>2\*</sup>[\*\*\*]
- <sup>3\*</sup>[(oa) "tissue" means a group of cells, except blood, performing a particular function in the human body;]
- <sup>3\*</sup>[(ob) "Tissue Bank" means a facility registered under section 14A for carrying out any activity relating to the recovery, screening, testing, processing, storage and distribution of tissues, but does not include a Blood Bank;]
- (p) "transplantation" means the grafting of any <sup>1\*</sup>[human organ or tissue or both] from any living person or deceased person to some other living person for therapeutic purposes.
- <sup>4\*</sup>[(q) "transplant co-ordinator" means a person appointed by the hospital for co-ordinating all matters relating to removal or transplantation of human organs or tissues or both and for assisting the authority for removal of human organs in accordance with the provisions of section 3.]

#### COMMENTS

The definition requires to be interpreted broadly so as to give effect to the legislative intention envisaged under the Act; *Rajeev Metal Works v. The Mineral and Metal Trading Corporation of India Ltd.*, 1996 (1) Supreme 140.

#### CHAPTER II

### AUTHORITY FOR THE REMOVAL OF <sup>5\*</sup>[HUMAN ORGANS OR TISSUES OR BOTH]

**3. Authority for removal of <sup>5\*</sup>[human organs or tissues or both].—**(1) Any donor may, in such manner and subject to such conditions as may be prescribed,

1. Subs. by Act 16 of 2011, sec. 4, for "human organ" (w.e.f. 27-9-2011).
2. The word "and" omitted by Act 16 of 2011, sec. 5(c) (w.e.f. 27-9-2011).
3. Ins. by Act 16 of 2011, sec. 5(d) (w.e.f. 27-9-2011).
4. Ins. by Act 16 of 2011, sec. 5(e) (w.e.f. 27-9-2011).
5. Subs. by Act 16 of 2011, sec. 4, for "human organs" (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, vide S.O. 30(E), dated 7th January, 2014.

authorise the removal, before his death, of any <sup>1\*</sup>[human organ or tissue or both] of his body for therapeutic purposes.

<sup>2\*</sup>[(1A) For the purpose of removal, storage or transplantation of such human organs or tissues or both, as may be prescribed, it shall be the duty of the registered medical practitioner working in a hospital, in consultation with transplant co-ordinator, if such transplant co-ordinator is available,—

- (i) to ascertain from the person admitted to the Intensive Care Unit or from his near relative that such person had authorised at any time before his death the removal of any human organ or tissue or both of his body under sub-section (2), then the hospital shall proceed to obtain the documentation for such authorisation in such manner as may be prescribed;
- (ii) where no such authority as referred to in sub-section (2) was made by such person, to make aware in such manner as may be prescribed to that person or near relative for option to authorise or decline for donation of human organs or tissues or both;
- (iii) to require the hospital to inform in writing to the Human Organ Retrieval Centre for removal, storage or transplantation of human organs or tissues or both, of the donor identified in clauses (i) and (ii) in such manner as may be prescribed.]

<sup>2\*</sup>[(1B) The duties mentioned under clauses (i) to (iii) of sub-section (1A) from such date, as may be prescribed, shall also apply in the case of registered medical practitioner working in an Intensive Care Unit in a hospital which is not registered under this Act for the purpose of removal, storage or transplantation of human organs or tissues or both.]

(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 <sup>1\*</sup>[human organ or tissue or both] 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 <sup>1\*</sup>[human organ or tissue or both] 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 <sup>3\*</sup>[human organs or tissues or both] 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 <sup>3\*</sup>[human organs or tissues or both] being used for therapeutic purposes, authorise the removal of any <sup>1\*</sup>[human organ or tissue or both] of the deceased person for its use for therapeutic purposes.

1. Subs. by Act 16 of 2011, sec. 4, for "human organ" (w.e.f. 27-9-2011).

2. Ins. by Act 16 of 2011, sec. 6(a) (w.e.f. 27-9-2011).

3. Subs. by Act 16 of 2011, sec. 4, for "human organs" (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, vide S.O. 30(E), dated 7th January, 2014.

(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 <sup>1\*</sup>[human organ or tissue or both] but no such removal shall be made by any person other than the registered medical practitioner:

<sup>2\*</sup>[Provided that a technician possessing such qualifications and experience, as may be prescribed, may enucleate a cornea.]

(5) Where any <sup>1\*</sup>[human organ or tissue or both] 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 <sup>1\*</sup>[human organ or tissue or both] 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 <sup>1\*</sup>[human organ or tissue or both] 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; <sup>3\*</sup>[\*\*\*]

<sup>4\*</sup>[Provided that where a neurologist or a neurosurgeon is not available, the registered medical practitioner may nominate an independent registered medical practitioner, being a surgeon or a physician and an anaesthetist or intensivist subject to the condition that they are not members of the transplantation team for the concerned recipient and to such conditions as may be prescribed;]

- (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 <sup>1\*</sup>[human organ or tissues or both] from the body of the deceased person.

**4. Removal of <sup>5\*</sup>[human organs or tissues or both] 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

1. Subs. by Act 16 of 2011, sec. 4, for "human organ" (w.e.f. 27-9-2011).

2. Ins. by Act 16 of 2011, sec. 6(b) (w.e.f. 27-9-2011).

3. The word "and" omitted by Act 16 of 2011, sec. 6(c)(i) (w.e.f. 27-9-2011).

4. Ins. by Act 16 of 2011, sec. 6(c)(ii) (w.e.f. 27-9-2011).

5. Subs. by Act 16 of 2011, sec. 4, for "human organs" (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, vide S.O. 30(E), dated 7th January, 2014.

the removal of any <sup>1\*</sup>[human organ or tissue or both] 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 <sup>1\*</sup>[human organ or tissue or both] 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 <sup>2\*</sup>[human organs or tissues or both] 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 <sup>1\*</sup>[human organ or tissue or both] from the dead body which so remains unclaimed may be given, in the prescribed form, by the person in charge, 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 <sup>2\*</sup>[human organs or tissues or both] 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 <sup>1\*</sup>[human organ or tissue or both] from such dead body may, if he has reason to believe that such <sup>1\*</sup>[human organ or tissue or both] 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 <sup>1\*</sup>[human organ or tissue or both] 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 <sup>3\*</sup>[human organs or tissues or both] being used, for therapeutic purposes after his death or, where he had granted an authority for the use of any of his <sup>3\*</sup>[human organs or tissues or both] for therapeutic purposes after his death, such authority had not been revoked by him before his death.

**7. Preservation of <sup>2\*</sup>[human organs or tissues or both].**—After the removal of any <sup>1\*</sup>[human organ or tissue or both] from the body of any person, the registered medical practitioner shall take such steps for the preservation of the <sup>1\*</sup>[human organ or tissue or both] so removed as may be prescribed.

1. Subs. by Act 16 of 2011, sec. 4, for "human organ" (w.e.f. 27-9-2011).
2. Subs. by Act 16 of 2011, sec. 4, for "human organs" (w.e.f. 27-9-2011).
3. Subs. by Act 16 of 2011, sec. 4, for "human organs" (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, vide S.O. 30(E), dated 7th January, 2014.

**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 <sup>1\*</sup>[human organ or tissue or both] from the body of a deceased person in accordance with the provisions of this Act nor the removal of any <sup>1\*</sup>[human organ or tissue or both] 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 <sup>2\*</sup>[human organs or tissues or both].**—(1) Save as otherwise provided in sub-section (3), no <sup>1\*</sup>[human organ or tissue or both] 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.

<sup>3\*</sup>[(1A) Where the donor or the recipient being near relative is a foreign national, prior approval of the Authorisation Committee shall be required before removing or transplanting human organ or tissue or both:

Provided that the Authorisation Committee shall not approve such removal or transplantation if the recipient is a foreign national and the donor is an Indian national unless they are near relatives.

(1B) No human organs or tissues or both shall be removed from the body of a minor before his death for the purpose of transplantation except in the manner as may be prescribed.

(1C) No human organs or tissues or both shall be removed from the body of a mentally challenged person before his death for the purpose of transplantation.

*Explanation.*—For the purpose of this sub-section,—

- (i) the expression “mentally challenged person” includes a person with mental illness or mental retardation, as the case may be;
- (ii) the expression “mental illness” includes dementia, schizophrenia and such other mental condition that makes a person intellectually disabled;
- (iii) the expression “mental retardation” shall have the same meaning as assigned to it in clause (r) of section 2 of the Persons With Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995 (1 of 1996).]

(2) Where any donor authorises the removal of any of his <sup>4\*</sup>[human organs or tissues or both] after his death under sub-section (2) of section 3 or any person competent or empowered to give authority for the removal of any <sup>1\*</sup>[human organ or tissue or both] from the body of any deceased person authorises such removal,

1. Subs. by Act 16 of 2011, sec. 4, for “human organ” (w.e.f. 27-9-2011).

2. Subs. by Act 16 of 2011, sec. 4, for “human organs” (w.e.f. 27-9-2011).

3. Ins. by Act 16 of 2011, sec. 7(a) (w.e.f. 27-9-2011).

4. Subs. by Act 16 of 2011, sec. 4, for “human organs” (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, *vide* S.O. 30(E), dated 7th January, 2014.

the <sup>1\*</sup>[human organ or tissue or both] may be removed and transplanted into the body of any recipient who may be in need of such <sup>1\*</sup>[human organ or tissue or both].

(3) If any donor authorises the removal of any of his <sup>2\*</sup>[human organs or tissues or both] before his death under sub-section (1) of section 3 for 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 <sup>1\*</sup>[human organ or tissue or both] shall not be removed and transplanted without the prior approval of the Authorisation Committee.

<sup>3\*</sup>[(3A) Notwithstanding anything contained in sub-section (3), where—

- (a) any donor has agreed to make a donation of his human organ or tissue or both before his death to a recipient, who is his near relative, but such donor is not compatible biologically as a donor for the recipient; and
- (b) the second donor has agreed to make a donation of his human organ or tissue or both before his death to such recipient, who is his near relative, but such donor is not compatible biologically as a donor for such recipient; then
- (c) the first donor who is compatible biologically as a donor for the second recipient and the second donor is compatible biologically as a donor of a human organ or tissue or both for the first recipient and both donors and both recipients in the aforesaid group of donor and recipient have entered into a single agreement to donate and receive such human organ or tissue or both according to such biological compatibility in the group,

the removal and transplantation of the human organ or tissue or both, as per the agreement referred to above, shall not be done without prior approval of the Authorisation Committee.]

<sup>4\*</sup>[(4)(a) The composition of the Authorisation Committees shall be such as may be prescribed by the Central Government from time to time.

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

1. Subs. by Act 16 of 2011, sec. 4, for "human organ" (w.e.f. 27-9-2011).

2. Subs. by Act 16 of 2011, sec. 4, for "human organs" (w.e.f. 27-9-2011).

3. Ins. by Act 16 of 2011, sec. 7(b) (w.e.f. 27-9-2011).

4. Subs. by Act 16 of 2011, sec. 7(c), for sub-section (4) (w.e.f. 27-9-2011). Sub-section (4), before substitution, stood as under:

"(4) (a) The Central Government shall constitute, by notification, one or more Authorisation Committees 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."

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, *vide* S.O. 30(E), dated 7th January, 2014.

(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 <sup>1\*</sup>[human organs or tissues or both].—**(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 transplantation of any <sup>2\*</sup>[human organ or tissue or both];
- (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, any activity relating to the removal, storage or transplantation of any <sup>2\*</sup>[human organ or tissue or both] at a place other than a place registered under this Act; <sup>3\*</sup>[\*\*\*]
- (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 transplantation of any <sup>2\*</sup>[human organ or tissue or both] except for therapeutic purposes; <sup>4\*</sup>[and]
- <sup>5\*</sup>(d) no Tissue Bank, unless registered under this Act, shall carry out any activity relating to the recovery, screening, testing, processing, storage and distribution of tissues.]

(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 purposes, 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 <sup>1\*</sup>[human organs or tissues or both] for any purpose other than therapeutic purposes.**—No donor and no person empowered to give authority for the removal of any <sup>2\*</sup>[human organ or tissue or both] shall authorise the removal of any <sup>2\*</sup>[human organ or tissue or both] for any purpose other than therapeutic purposes.

1. Subs. by Act 16 of 2011, sec. 4, for “human organs” (w.e.f. 27-9-2011).

2. Subs. by Act 16 of 2011, sec. 4, for “human organ” (w.e.f. 27-9-2011).

3. The word “and” omitted by Act 16 of 2011, sec. 8(a) (w.e.f. 27-9-2011).

4. Ins. by Act 16 of 2011, sec. 8(b) (w.e.f. 27-9-2011).

5. Ins. by Act 16 of 2011, sec. 8(c) (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, *vide* S.O. 30(E), dated 7th January, 2014.

**12. Explaining effects, etc., to donor and recipient.**—No registered medical practitioner shall undertake the removal or transplantation of any <sup>1\*</sup>[human organ or tissue or both] unless he has explained, in such manner as may be prescribed, all possible effects, complications and hazards connected with the removal and transplantation 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;
- <sup>2\*</sup>(iii) to enforce such standards, as may be prescribed,—
  - (A) for hospitals engaged in the removal, storage or transplantation of any human organ;
  - (B) for Tissue Banks engaged in recovery, screening, testing, processing, storage and distribution of tissues;
- (iv) to investigate any complaint of breach of any of the provisions of this Act or any of the rules made thereunder and take appropriate action;
- <sup>3\*</sup>(iva) to inspect Tissue Banks periodically;
- (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.

<sup>4\*</sup>**13A. Advisory Committees to advise Appropriate Authority.**—(1) The Central Government and the State Governments, as the case may be, by notification, shall constitute an Advisory Committee for a period of two years to aid and advise the Appropriate Authority to discharge its functions.

(2) The Advisory Committee shall consist of—

- (a) one administrative expert not below the rank of Secretary to the State Government, to be nominated as Chairperson of the Advisory Committee;

1. Subs. by Act 16 of 2011, sec. 4, for "human organ" (w.e.f. 27-9-2011).

2. Subs. by Act 16 of 2011, sec. 9(a), for clause (iii) (w.e.f. 27-9-2011). Clause (iii), before substitution, stood as under:

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

3. Ins. by Act 16 of 2011, sec. 9(b) (w.e.f. 27-9-2011).

4. Ins. by Act 16 of 2011, sec. 10 (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, vide S.O. 30(E), dated 7th January, 2014.

- (b) two medical experts having such qualifications as may be prescribed;
- (c) one officer not below the rank of a Joint Director to represent the Ministry or Department of Health and Family Welfare, to be designated as Member-Secretary;
- (d) two eminent social workers of high social standing and integrity, one of whom shall be from amongst representatives of women's organisation;
- (e) one legal expert who has held the position of an Additional District Judge or equivalent;
- (f) one person to represent non-governmental organisations or associations which are working in the field of organ or tissue donations or human rights.
- (g) one specialist in the field of human organ transplantation, provided he is not a member of the transplantation team.

(3) The terms and conditions for appointment to the Advisory Committee shall be such as may be prescribed by the Central Government]

<sup>1</sup>\*[13B. **Powers of Appropriate Authority.**—The Appropriate Authority shall for the purposes of this Act have all the powers of a civil court trying a suit under the Code of Civil Procedure, 1908 (5 of 1908) and, in particular, in respect of the following matters, namely:—

- (a) summoning of any person who is in possession of any information relating to violation of the provisions of this Act or the rules made thereunder;
- (b) discovery and production of any document or material object;
- (c) issuing search warrant for any place suspected to be indulging in unauthorised removal, procurement or transplantation of human organs or tissues or both; and
- (d) any other matter which may be prescribed.]

<sup>1</sup>\*[13C. **National Human Organs and Tissues Removal and Storage Network.**—The Central Government may, by notification, establish a National Human Organs and Tissues Removal and Storage Network at one or more places and Regional Network in such manner and to perform such functions, as may be prescribed.]

<sup>1</sup>\*[13D. **National registry.**—The Central Government shall maintain a national registry of the donors and recipients of human organs and tissues and such registry shall have such information as may be prescribed to an ongoing evaluation of the scientific and clinical status of human organs and tissues.]

## CHAPTER V

### REGISTRATION OF HOSPITALS

**14. Registration of hospitals engaged in removal, storage or transplantation of <sup>2</sup>\*[human organs or tissues or both].—(1) <sup>3</sup>\*[No hospital (including Human**

1. Ins. by Act 16 of 2011, sec. 10 (w.e.f. 27-9-2011).

2. Subs. by Act 16 of 2011, sec. 4, for "human organs" (w.e.f. 27-9-2011).

3. Subs. by Act 16 of 2011, sec. 11(a), for "No hospital" (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, vide S.O. 30(E), dated 7th January, 2014.

Organ Retrieval Centre)] shall commence any activity relating to the removal, storage or transplantation of any <sup>1\*</sup>[human organ or tissue or both] for therapeutic purposes 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 <sup>1\*</sup>[human organ or tissue or both] 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 <sup>1\*</sup>[human organ or tissue or both] 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.

<sup>2\*</sup>[(4) No hospital shall be registered under this Act, unless the Appropriate Authority is satisfied that such hospital has appointed a transplant co-ordinator having such qualifications and experience as may be prescribed.]

<sup>3\*</sup>[14A. Registration of Tissue Bank.—(1) No Tissue Bank shall, after the commencement of the Transplantation of Human Organs (Amendment) Act, 2011, commence any activity relating to the recovery, screening, testing, processing, storage and distribution of tissues unless it is duly registered under this Act:

Provided that any facility engaged, either partly or exclusively, in any activity relating to the recovery, screening, testing, processing, storage and distribution of tissues immediately before the commencement of the Transplantation of Human Organs (Amendment) Act, 2011, shall apply for registration as Tissue Bank within sixty days from the date of such commencement:

Provided further that such facility shall cease to engage in any such activity on the expiry of three months from the date of commencement of the Transplantation of Human Organs (Amendment) Act, 2011, unless such Tissue Bank 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 Tissue Bank shall be registered under this Act unless the Appropriate authority is satisfied that such Tissue Bank is in a position to provide such

1. Subs. by Act 16 of 2011, sec. 4, for "human organ" (w.e.f. 27-9-2011).

2. Ins. by Act 16 of 2011, sec. 11(b) (w.e.f. 27-9-2011).

3. Ins. by Act 16 of 2011, sec. 12 (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, vide S.O. 30(E), dated 7th January, 2014.

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, <sup>1\*</sup>[grant to the hospital or to the Tissue Bank, as the case may be,] 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 <sup>2\*</sup>[hospital or Tissue Bank, as the case may be], 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 <sup>2\*</sup>[hospital or Tissue Bank, as the case may be,] 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 <sup>2\*</sup>[hospital or Tissue Bank, as the case may be,] 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 <sup>2\*</sup>[hospital or Tissue Bank, as the case may be,] 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 <sup>3\*</sup>[or Tissue Bank, as the case may be,] 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.

1. Subs. by Act 16 of 2011, sec. 13, for "grant to the hospital" (w.e.f. 27-9-2011).

2. Subs. by Act 16 of 2011, sec. 14, for "hospital" (w.e.f. 27-9-2011).

3. Ins. by Act 16 of 2011, sec. 15 (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, *vide* S.O. 30(E), dated 7th January, 2014.

## CHAPTER VI

## OFFENCES AND PENALTIES

18. Punishment for removal of <sup>1</sup>[human organ or tissue or both] without authority.—(1) Any person who renders his services to or at any hospital and who for purposes of transplantation, conducts, associates with, or helps in any manner in, the removal of any human organ without authority, shall be punishable with imprisonment for a term which may extend to <sup>2</sup>[ten years and with fine which may extend to twenty lakh 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 <sup>3</sup>[three years] for the first offence and permanently for the subsequent offence.

<sup>4</sup>[(3) Any person who renders his services to or at any hospital and who conducts, or associates with or helps in any manner in the removal of human tissues without authority, shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to five lakh rupees.]

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),
- <sup>5</sup>[(g) abets in the preparation or submission of false documents including giving false affidavits to establish that the donor is making the donation of the human organs, as a near relative or by reason of affection or attachment towards the recipient]

1. Subs. by Act 16 of 2011 sec. 4, for "human organ" (w.e.f. 27-9-2011).  
2. Subs. by Act 16 of 2011 sec. 16(a), for "five years and with fine which may extend to ten thousand rupees" (w.e.f. 27-9-2011).

3. Subs. by Act 16 of 2011, sec. 16(b), for "two years" (w.e.f. 27-9-2011).

4. Ins. by Act 16 of 2011, sec. 16(c) (w.e.f. 27-9-2011).

5. Ins. by Act 16 of 2011, sec. 17(a) (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, vide S.O. 30(E), dated 7th January, 2014.

shall be punishable with imprisonment for a term which shall not be less than 1\*[five years but which may extend to ten years and shall be liable to fine which shall not be less than twenty lakh rupees but may extend to one crore rupees.]

2\*[\*\*\*]

#### COMMENTS

Moral conviction must be replaced by legal conviction; *State of West Bengal v. Bhola Devi*. (1996) 1 Crimes 427 (Cal DB).

<sup>3</sup>\*[19A. **Punishment for illegal dealings in human tissues.**—Whoever—

- (a) makes or receives any payment for the supply of, or for an offer to supply, any human tissue; or
- (b) seeks to find person willing to supply for payment and human tissue; or
- (c) offers to supply any human tissue for payment; or
- (d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human tissue; or
- (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—
  - (i) inviting persons to supply for payment of any human tissue; or
  - (ii) offering to supply any human tissue for payment; or
  - (iii) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in clause (d); or
- (g) abets in the preparation or submission of false documents including giving false affidavits to establish that the donor is making the donation of the human tissues as a near relative or by reason of affection or attachment towards the recipient,

shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and shall be liable to fine which shall not be less than five lakh rupees but which may extend to twenty-five lakh 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

1. Subs. by Act 16 of 2011, sec. 17(b), for "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 which may extend to twenty thousand rupees" (w.e.f. 27-9-2011).

2. Proviso omitted by Act 16 of 2011, sec. 17(c) (w.e.f. 27-9-2011). The Proviso, before omission, stood as under:

"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."

3. Ins. by Act 16 of 2011, sec. 18 (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, vide S.O. 30(E), dated 7th January, 2014.

provided in this Act, shall be punishable with imprisonment for a term which may extend to <sup>1\*</sup>[five years or with fine which may extend to twenty lakh 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 anything 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.

1. Subs. by Act 16 of 2011, sec. 19, for "three years or with fine which may extend to five thousand rupees" (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, vide S.O. 30(E), dated 7th January, 2014.

(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 generality 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 <sup>1\*</sup>[human organ or tissue or both] of his body under sub-section (1) of section 3;
- <sup>2\*</sup>[(aa) the human organs or tissues or both in respect of which duty is cast on registered medical practitioner, the manner of obtaining documentation for authorisation under clause (i) of sub-section (1A) of section 3;]
- <sup>2\*</sup>[(ab) the manner of making the donor or his relative aware under clause (ii) of sub-section (1A) of section 3;]
- <sup>2\*</sup>[(ac) the manner of informing the Human Organ Retrieval Centre under clause (iii) of sub-section (1A) of section 3;]
- <sup>2\*</sup>[(ad) the date from which duties mentioned in sub-section (1A) are applicable to registered medical practitioner working in a unregistered hospital under sub-section (1B) of section 3;]
- <sup>2\*</sup>[(ae) the qualifications and experience of a technician under the proviso to sub-section (4) 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;
- <sup>3\*</sup>[(ba) the conditions for nomination of a surgeon or a physician and an anaesthetist or intensivist to be included in the Board of medical experts under the proviso to clause (iii) of 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 <sup>1\*</sup>[human organ or tissue or both] under sub-section (7) of section 3;
- (d) the form in which authority for the removal of any <sup>1\*</sup>[human organ or tissue or both] 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 <sup>1\*</sup>[human organ or tissue or both] removed from the body of any person under section 7;

1. Subs. by Act 16 of 2011, sec. 4, for "human organ" (w.e.f. 27-9-2011).

2. Ins. by Act 16 of 2011, sec. 20(a) (w.e.f. 27-9-2011).

3. Ins. by Act 16 of 2011, sec. 20(b) (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, *vide* S.O. 30(E), dated 7th January, 2014.

- <sup>1\*</sup>[(ea) the manner of removal of human organs or tissues or both from the body of a minor before his death for transplantation under sub-section (1B) of section 9;]
- <sup>1\*</sup>[(eb) the composition of the Authorisation Committees under sub-section (4) of section 9;]
- (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 <sup>2\*</sup>[human organ or tissue or both] 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;
- <sup>3\*</sup>[(ia) the qualifications of medical experts and the terms and conditions for appointment to Advisory Committee under sub-sections (2) and (3) of section 13A;]
- <sup>3\*</sup>[(ib) the power of the Appropriate authority in any other matter under clause (d) of section 13B;]
- <sup>3\*</sup>[(ic) the manner of establishment of a National Human Organs and Tissues Removal and Storage Network and Regional Network and functions to be performed by them under section 13C;]
- <sup>3\*</sup>[(id) the information in the national registry of the donors and recipients of human organs and tissues and all information under section 13D;]
- (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;
- <sup>4\*</sup>[(ka) the qualifications and experience of a transplant co-ordinator under sub-section (4) of section 14;]
- <sup>4\*</sup>[(kb) 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 14A;]

1. Ins. by Act 16 of 2011, sec. 20(c) (w.e.f. 27-9-2011).

2. Subs. by Act 16 of 2011, sec. 4, for "human organ" (w.e.f. 27-9-2011).

3. Ins. by Act 16 of 2011, sec. 20(d) (w.e.f. 27-9-2011).

4. Ins. by Act 16 of 2011, sec. 20(e) (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, vide S.O. 30(E), dated 7th January, 2014.

- <sup>1</sup>[(kc) the specialized services and the facilities to be provided, skilled manpower and the equipments to be possessed and the standards to be maintained by a Tissue Bank, under sub-section (3) of section 14A;]
- (l) the form in which, the period for which and the conditions subject to which certificate of registration is to be granted to a <sup>2</sup>[hospital or Tissue Bank], 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.

1. Ins. by Act 16 of 2011, sec. 20(e) (w.e.f. 27-9-2011).

2. Subs. by Act 16 of 2011, sec. 20(f), for "hospital" (w.e.f. 27-9-2011).

\* Came into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal and in all the Union territories, *vide* S.O. 30(E), dated 7th January, 2014.

# THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES RULES, 2014<sup>1</sup>

*In exercise of the powers conferred by section 24 of the Transplantation of Human Organs Act, 1994 (42 of 1994) and in supersession of the Transplantation of Human Organs Rules, 1995, except as respects things done or omitted to be done before such supersession, the Central Government hereby makes the following rules, namely:—*

**1. Short title and commencement.**—(1) These rules may be called the Transplantation of Human Organs and Tissues Rules, 2014.

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

**2. Definitions.**—In these rules unless the context otherwise requires,—

- (a) "Act" means the Transplantation of Human Organs Act, 1994;
- (b) "cadaver(s)", "organ(s)" and "tissue(s)" means human cadaver(s), human organ(s) and human tissue(s), respectively;
- (c) "competent authority" means the Head of the institution or hospital carrying out transplantation or committee constituted by the head of the institution or hospital for the purpose;
- (d) "Form" means a Form annexed to these rules;
- (e) National Accreditation Board for Testing and Calibration Laboratories (NABL) means the autonomous body established under the aegis of Department of Science and Technology, Government of India with the objective to provide Government, Regulators and Industry with a scheme of laboratory accreditation through third-party assessment for formally recognising the technical competence of laboratories and the accreditation services are provided for testing and calibration of medical laboratories in accordance with International Organisation for Standardisation (ISO) Standards;
- (f) "the technician who can enucleate cornea" means the technician with any of the following qualifications and experience who can harvest corneas (enucleate eyeballs or excise corneas), namely:—
  - (i) Ophthalmologists possessing a Doctor of Medicine (M.D.) or Master of Surgery (M.S.) in Ophthalmology or Diploma in Ophthalmology (D.O.); and
  - (ii) registered Doctors from all recognised systems of medicine, Nurses, Paramedical Ophthalmic Assistant, Ophthalmic Assistant, Optometrists, Refractionists, Paramedical Worker or Medical Technician with recognised qualification from all recognised systems of medicine, provided the person is duly

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1. *Vide* G.S.R. 218(E), dated 27th March, 2014, published in the Gazette of India, Extra., Pt. II, Sec. 3(i), dated 27th March, 2014.

2. Came into force on 27-3-2014.

trained to enucleate a donated cornea or eye from registered, authorised and functional eye Bank or Government medical college and, the training certificate should mention that he has acquired the required skills to independently conduct enucleation of the eye or removal of cornea from a cadaver;

- (g) words and expressions used and not defined in these rules, but defined in the Act, shall have the same meanings, respectively, assigned to them in the Act.

**3. Authority for removal of human organs or tissues.**—Subject to the provisions of section 3 of the Act, a living person may authorise the removal of any organ or tissue of his or her body during his or her lifetime as per prevalent medical practices, for therapeutic purposes in the manner and on such conditions as specified in Form 1, 2 and 3.

**4. Panel of experts for brain-stem death certification.**—For the purpose of certifying the brain-stem death, the Appropriate Authority shall maintain a panel of experts, in accordance with the provisions of the Act, to ensure efficient functioning of the Board of Medical Experts and it remains fully operational.

**5. Duties of the registered medical practitioner.**—(1) The registered medical practitioner of the hospital having Intensive Care Unit facility, in consultation with transplant coordinator, if available, shall ascertain, after certification of brain stem death of the person in Intensive Care Unit, from his or her adult near relative or, if near relative is not available, then, any other person related by blood or marriage, and in case of unclaimed body, from the person in lawful possession of the body the following, namely:—

- (a) whether the person had, in the presence of two or more witnesses (at least one of who is a near relative of such person), unequivocally authorised before his or her death as specified in Form 7 or in documents like driving license, etc. wherein the provision for donation may be incorporated after notification of these rules, the removal of his or her organ(s) or tissue(s) including eye, after his or her death, for therapeutic purposes and there is no reason to believe that the person had subsequently revoked the aforesaid authorisation;

- (b) where the said authorisation was not made by the person to donate his or her organ(s) or tissue(s) after his or her death, then the registered medical practitioner in consultation with the transplant coordinator, if available, shall make the near relative or person in lawful possession of the body, aware of the option to authorise or decline the donation of such human organs or tissues or both (which can be used for therapeutic purposes) including eye or cornea of the deceased person and a declaration or authorisation to this effect shall be ascertained from the near relative or person in lawful possession of the body as per Form 8 to record the status of consent, and in case of an unclaimed body, authorisation shall be made in Form 9 by the authorised official as per sub-section (1) of section 5 of the Act;

- (c) after the near relative or person in lawful possession of the body authorises removal and gives consent for donation of human organ(s) or tissue(s) of the deceased person, the registered medical practitioner through the transplant coordinator shall inform the authorised registered Human Organ Retrieval Centre through the authorised coordinating organisation by available documentable mode of communication, for removal, storage or transportation of organ(s) or tissue(s).

(2) The above mentioned duties shall also apply to the registered medical practitioner working in an Intensive Care Unit in a hospital not registered under this Act, from the date of notification of these rules.

- (3) The registered medical practitioner shall, before removing any human organ or tissue from a living donor, shall satisfy himself—

- (a) that the donor has been explained of all possible side effects, hazards and complications and that the donor has given his or her authorisation in appropriate Form 1 for near relative donor or Form 2 for spousal donor or Form 3 for donor other than near relative;
- (b) that the physical and mental evaluation of the donor has been done, he or she is in proper state of health and it has been certified that he or she is not mentally challenged and that he or she is fit to donate the organ or tissue;

Provided that in case of doubt regarding mentally challenged status of the donor the registered medical practitioner may get the donor examined by a psychiatrist and the registered medical practitioner shall sign the certificate as prescribed in Form 4 for this purpose;

- (c) that the donor is a near relative of the recipient, as certified in Form 5, and that he or she has submitted an application in Form 11 jointly with the recipient and that the proposed donation has been approved by the competent authority as defined at rule 2(c) and specified in Form 19 and that the necessary documents as prescribed and medical tests, as required, to determine the factum of near relationship, have been examined to the satisfaction of the registered medical practitioner and the competent authority;
- (d) that in case the recipient is spouse of the donor, the donor has given a statement to the effect that they are so related by signing a certificate in Form 2 and has submitted an application in Form 11 jointly with the recipient and that the proposed donation has been approved by the competent authority under the provisions of sub-rule (2) of rule 7;
- (e) that in case of a donor who is other than a near relative and has signed Form 3 and submitted an application in Form 11 jointly with the recipient, the permission from the Authorisation Committee for the said donation has been obtained;
- (f) that if a donor or recipient is a foreign national, the approval of the Authorisation Committee for the said donation has been obtained.

- (g) living organ or tissue donation by minors shall not be permitted except on exceptional medical grounds to be recorded in detail with full justification and with prior approval of the Appropriate Authority and the State Government concerned.

(4) A registered medical practitioner, before removing any organ or tissue from the body of a person after his or her death (deceased donor), in consultation with transplant coordinator, shall satisfy himself the following, namely:—

- (a) that caution has been taken to make inquiry, from near relative or person in lawful possession of the body of a person admitted in Intensive Care Unit, only after certification of Brain Stem death of the person that the donor had, in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorised before his or her death as specified in Form 7 or in documents like driving license etc. (wherein the provision for donation may be incorporated after notification of these rules), the removal of his or her organ(s) or tissue(s) after his or her death, for therapeutic purposes and it has been ascertained that the donor has not subsequently revoked the aforesaid authorisation, and the consent of near relative or person in lawful possession of the body shall also be required notwithstanding the authorisation been made by deceased donor:

Provided that if the deceased person who had earlier given authorisation but had revoked it subsequently and if the person had given in writing that his organ should not be removed after his death, then, no organ or tissue will be removed even if consent is given by the near relative or person in lawful possession of the body;

- (b) that the near relative of the deceased person or the person lawfully in possession of the body of the deceased donor has signed the declaration as specified in Form 8.
- (c) that in the case of brain-stem death of the potential donor, a certificate as specified in Form 10 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:

Provided that where a neurologist or a neurosurgeon is not available, an anesthetist or intensivist who is not part of the transplant team nominated by the head of the hospital duly empanelled by Appropriate Authority may certify the brain stem death as a member of the said Board;

- (d) that in the case of brain-stem death of a person of less than eighteen years of age, a certificate specified in Form 10 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 8 has been signed by either of the parents of such person or any near relative authorised by the parent.

**6. Procedure for donation of organ or tissue in medicolegal cases.—(1)** After the authority for removal of organs or tissues, as also the consent to donate

organs from a brain-stem dead donor are obtained, the registered medical practitioner of the hospital shall make a request to the Station House Officer or Superintendent of Police or Deputy Inspector General of the area either directly or through the police post located in the hospital to facilitate timely retrieval of organs or tissue from the donor and a copy of such a request should also be sent to the designated postmortem doctor of area simultaneously.

(2) It shall be ensured that, by retrieving organs, the determination of the cause of death is not jeopardised.

(3) The medical report in respect of the organs or tissues being retrieved shall be prepared at the time of retrieval by retrieving doctor (s) and shall be taken on record in postmortem notes by the registered medical practitioner doing postmortem.

(4) Wherever it is possible, attempt should be made to request the designated postmortem registered medical practitioner, even beyond office timing, to be present at the time of organ or tissue retrieval.

(5) In case a private retrieval hospital is not doing postmortem, they shall arrange transportation of body along with medical records, after organ or tissue retrieval, to the designated postmortem centre and the postmortem centre shall undertake the postmortem of such cases on priority, even beyond office timing, so that the body is handed over to the relatives with least inconvenience.

**7. Authorisation Committee.**—(1) The medical practitioner who will be part of the organ transplantation team for carrying out transplantation operation shall not be a member of the Authorisation Committee constituted under the provisions of clauses (a) and (b) of sub-section (4) of section 9 of the Act.

(2) When the proposed donor or recipient or both are not Indian nationals or citizens whether near relatives or otherwise, the Authorisation Committee shall consider all such requests and the transplantation shall not be permitted if the recipient is a foreign national and donor is an Indian national unless they are near relatives.

(3) When the proposed donor and the recipient are not near relatives, the Authorisation Committee shall,—

- (i) evaluate that there is no commercial transaction between the recipient and the donor and that no payment has been made to the donor or promised to be made to the donor or any other person;
- (ii) prepare an explanation of the link between them and the circumstances which led to the offer being made;
- (iii) examine the reasons why the donor wishes to donate;
- (iv) examine the documentary evidence of the link, e.g. proof that they have lived together, etc.;
- (v) examine old photographs showing the donor and the recipient together;
- (vi) evaluate that there is no middleman or tout involved;
- (vii) evaluate that financial status of the donor and the recipient by asking them to give appropriate evidence of their vocation and income for the previous three financial years and any gross disparity

between the status of the two must be evaluated in the backdrop of the objective of preventing commercial dealing;

(viii) ensure that the donor is not a drug addict;

(ix) ensure that the near relative or if near relative is not available, any adult person related to donor by blood or marriage of the proposed unrelated donor is interviewed regarding awareness about his or her intention to donate an organ or tissue, the authenticity of the link between the donor and the recipient, and the reasons for donation, and any strong views or disagreement or objection of such kin shall also be recorded and taken note of.

(4) Cases of swap donation referred to under sub-section (3A) of section 9 of the Act shall be approved by Authorisation Committee of hospital or district or State in which transplantation is proposed to be done and the donation of organs shall be permissible only from near relatives of the swap recipients.

(5) When the recipient is in a critical condition in need of life saving organ transplantation within a week, the donor or recipient may approach hospital in-charge to expedite evaluation by the Authorisation Committee.

**8. Removal and preservation of organs or tissues.**—The removal of the organ(s) or tissue(s) shall be permissible in any registered retrieval or transplant hospital or centre and preservation of such removed organ(s) or tissue(s) shall be ensured in registered retrieval or transplant centre or tissue bank according to current and accepted scientific methods in order to ensure viability for the purpose of transplantation.

**9. Cost for maintenance of cadaver or retrieval or transportation or preservation of organs or tissues.**—The cost for maintenance of the cadaver (brain-stem dead declared person), retrieval of organs or tissues, their transportation and preservation, shall not be borne by the donor family and may be borne by the recipient or institution or Government or non-Government organisation or society as decided by the respective State Government or Union territory Administration.

**10. Application for living donor transplantation.**—(1) The donor and the recipient shall make jointly an application to grant approval for removal and transplantation of a human organ, to the competent authority or Authorisation Committee as specified in Form 11 and the papers for approval of transplantation would be processed by the registered medical practitioner and administrative division of the Institution for transplantation.

(2) The competent authority or Authorisation Committee shall take a decision on such application in accordance with the rule 18.

(3) If some State wants to merge Form 11 with Form 1, Form 2 or Form 3, they may do so, provided the content of the recommended Forms are covered in the merged Form and the same is approved by the State Government concerned.

**11. Composition of Authorisation Committees.**—(1) There shall be one State level Authorisation Committee.

(2) Additional Authorisation Committees in the districts or Institutions or hospitals may be set up as per norms given below, which may be revised from

time to time by the concerned State Government or Union territory Administration by notification.

(3) No member from transplant team of the institution should be a member of the respective Authorisation Committee.

(4) Authorisation Committee should be hospital based if the number of transplants is twenty-five or more in a year at the respective transplantation centres, and if the number of organ transplants in an institution or hospital are less than twenty-five in a year, then the State or District level Authorisation Committee would grant approval(s).

**12. Composition of hospital based Authorisation Committees.**—The hospital based Authorisation Committee shall, as notified by the State Government in case of State and by the Union territory Administration in case of Union territory, consist of,—

- (a) the Medical Director or Medical Superintendent or Head of the institution or hospital or a senior medical person officiating as Head – Chairperson;
- (b) two senior medical practitioners from the same hospital who are not part of the transplant team – Member;
- (c) two persons (preferably one woman) 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, doctors of Indian Medical Association, reputed non-Government organisation or renowned social worker – Member;
- (d) Secretary (Health) or nominee and Director Health Services or nominee from State Government or Union territory Administration – Member.

**13. Composition of State or District Level Authorisation Committees.**—The State or District Level Authorisation Committee shall, as notified by the State Government in case of State and by the Union territory Administration in case of Union territory, consist of,—

- (a) a Medical Practitioner officiating as Chief Medical Officer or any other equivalent post in the main or major Government hospital of the District – Chairperson;
- (b) two senior registered 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 – Member;
- (c) two persons (preferably one woman) 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, doctors of Indian Medical Association, reputed non-Government organisation or renowned social worker - Member;

- (d) Secretary (Health) or nominee and Director Health Services or nominee from State Government or Union territory Administration - Member:

Provided that effort shall be made by the State Government concerned to have most of the members' *ex-officio* so that the need to change the composition of Committee is less frequent.

**14. Verification of residential status, etc.**—When the living donor is unrelated and if donor or recipient belongs to a State or Union territory, other than the State or Union territory where the transplantation is proposed to be undertaken, verification of residential status by Tehsildar or any other authorised officer for the purpose with a copy marked to the Appropriate Authority of the State or Union territory of domicile of donor or recipient for their information shall be required, as per Form 20 and in case of any doubt of organ trafficking, the Appropriate Authority of the State or Union territory of domicile or the Tehsildar or any other authorised officer shall inform police department for investigation and action as per the provisions of the Act.

**15. Quorum of Authorisation Committee.**—The quorum of the Authorisation Committee should be minimum four and the quorum shall not be complete without the participation of the Chairman, the presence of Secretary (Health) or nominee and Director of Health Services or nominee.

**16. Format of approval of Authorisation Committee.**—The format of the Authorisation Committee approval should be uniform in all the institutions in a State and the format may be notified by the respective State Government as per Form 18.

**17. Scrutiny of applications by Authorisation Committee.**—(1) Secretariat of the Authorisation Committee shall circulate copies of all applications received from the proposed donors and recipients to all members of the Committee along with all annexures, which may have been filed along with the applications.

(2) At the time of the meeting, the Authorisation Committee should take note of all relevant contents and documents in the course of its decision making process and in the event any document or information is found to be inadequate or doubtful, explanation should be sought from the applicant and if it is considered necessary that any fact or information requires to be verified in order to confirm its veracity or correctness, the same be ascertained through the concerned officer(s) of the State Government or Union territory Administration.

**18. Procedure in case of near relatives.**—(1) Where the proposed transplant of organs is between near relatives related genetically, namely, grandmother, grandfather, mother, father, brother, sister, son, daughter, grandson and granddaughter, above the age of eighteen years, the competent authority as defined at rule 2(c) or Authorisation Committee (in case donor or recipient is a foreigner) shall evaluate;

- (i) documentary evidence of relationship e.g. relevant birth certificates, marriage certificate, other relationship certificate from Tehsildar or Sub-divisional magistrate or Metropolitan Magistrate or Sarpanch of

the Panchayat, or similar other identity certificates like Electors Photo Identity Card or AADHAAR card; and

(ii) documentary evidence of identity and residence of the proposed donor, ration card or voters identity card or passport or driving license or PAN card or bank account and family photograph depicting the proposed donor and the proposed recipient along with another near relative, or similar other identity certificates like AADHAAR Card (issued by Unique Identification Authority of India).

(2) If in the opinion of the competent authority, the relationship is not conclusively established after evaluating the above evidence, it may in its discretion direct further medical test, namely, Deoxyribonucleic Acid (DNA) Profiling.

(3) The test referred to in sub-rule (2) shall be got done from a laboratory accredited with National Accreditation Board for Testing and Calibration Laboratories and certificate shall be given in Form 5.

(4) If the documentary evidences and test referred to in sub-rules (1) and (2), respectively do not establish a genetic relationship between the donor and the recipient, the same procedure be adopted on preferably both or at least one parent, and if parents are not available, the same procedure be adopted 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.

(5) Where the proposed transplant is between a married couple the competent authority or Authorisation Committee (in case donor or recipient is a foreigner) must evaluate the factum and duration of marriage and ensure that documents such as marriage certificate, marriage photograph etc., are kept for records along with the information on the number and age of children and a family photograph depicting the entire family, birth certificate of children containing the particulars of parents and issue a certificate in Form 6 (for spousal donor).

(6) Any document with regard to the proof of residence or domicile and particulars of parentage should be relatable to the photo identity of the applicant in order to ensure that the documents pertain to the same person, who is the proposed donor and in the event of any inadequate or doubtful information to this effect, the Competent Authority or Authorisation Committee as the case may be, may in its discretion seek such other information or evidence as may be expedient and desirable in the peculiar facts of the case.

(7) The medical practitioner who will be part of the organ transplantation team for carrying out transplantation operation shall not be a competent authority of the transplant hospital.

(8) The competent authority may seek the assistance of the Authorisation Committee in its decision making, if required.

**19. Procedure in case of transplant other than near relatives.**—Where the proposed transplant is between other than near relatives and all cases where the donor or recipient is foreign national (irrespective of them being near relative or

otherwise), the approval will be granted by the Authorisation Committee of the hospital or if hospital based Authorisation Committee is not constituted, then by the District or State level Authorisation Committee.

**20. Procedure in case of foreigners.**—When the proposed donor or the recipient are foreigners;

(a) a senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient as per Form 21 and in case a country does not have an Embassy in India, the certificate of relationship, in the same format, shall be issued by the Government of that country;

(b) the Authorisation Committee shall examine the cases of all Indian donors consenting to donate organs to a foreign national (who is a near relative), including a foreign national of Indian origin, with greater caution and such cases should be considered rarely on case to case basis;

Provided that the Indian living donors wanting to donate to a foreigner other than near relative shall not be considered.

**21. Eligibility of applicant to donate.**—In the course, of determining eligibility of the applicant to donate, the applicant should be personally interviewed by the Authorisation Committee which shall be videographed and minutes of the interview shall be recorded.

**22. Precautions in case of woman donor.**—In case where the donor is a woman, greater precautions ought to be taken and her identity and independent consent should be confirmed by a person other than the recipient.

**23. Decision of Authorisation Committee.**—(1) The Authorisation Committee (which is applicable only for living organ or tissue donor) should State in writing its reason for rejecting or approving the application of the proposed living donor in the prescribed Form 18 and all such approvals should be subject to the following conditions, namely:—

- (i) the approved proposed donor would be subjected to all such medical tests as required at the relevant stages to determine his or her biological capacity and compatibility to donate the organ in question;
- (ii) the physical and mental evaluation of the donor has been done to know whether he or she is in proper state of health and it has been certified by the registered medical practitioner in Form 4 that he or she is not mentally challenged and is fit to donate the organ or tissue;
- (iii) Provided that in case of doubt for mentally challenged status of the donor the registered medical practitioner or Authorisation Committee may get the donor examined by psychiatrist;
- (iv) all prescribed forms have been and would be filled up by all relevant persons involved in the process of transplantation;
- (v) all interviews to be video recorded.

(2) The Authorisation Committee shall expedite its decision making process and use its discretion judiciously and pragmatically in all such cases where, the patient requires transplantation on urgent basis.

(3) Every authorised transplantation centre must have its own website and the Authorisation Committee is required to take final decision within twenty-four hours of holding the meeting for grant of permission or rejection for transplant.

(4) The decision of the Authorisation Committee should be displayed on the notice board of the hospital or Institution immediately and should reflect on the website of the hospital or Institution within twenty-four hours of taking the decision, while keeping the Identity of the recipient and donor hidden.

**24. Registration of hospital or tissue bank.**—(1) An application for registration shall be made to the Appropriate Authority as specified in Form 12 or Form 13 or Form 14 or Form 15, as applicable and the application shall be accompanied by fee as specified below, payable to the Appropriate Authority by means of a bank draft, which may be revised, if necessary by the Central or State Government, as the case may be:—

(i) for Organ or Tissue or Cornea Transplant Centre: Rupees ten thousand;

(ii) for Tissue or Eye Bank: Rupees ten thousand;

(iii) for Non-Transplant Retrieval Centre: Nil.

(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 16 and it shall be valid for a period of five years from the date of its issue and shall be renewable.

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

**25. Renewal of registration of hospital or tissue bank.**—(1) An application for the renewal of a certificate of registration shall be made to the Appropriate Authority at least three months prior to the date of expiry of the original certificate of registration and shall be accompanied by a fee as specified below, payable to the Appropriate Authority by means of a bank draft, which may be revised, if necessary by the Central or State Government, as the case may be,—

(i) for Organ or Tissue or Cornea Transplant Centre: Rupees five thousand;

(ii) for Tissue or Eye Bank: Rupees five thousand;

(iii) for Non-Transplant Retrieval Centre: Nil.

(2) A renewal certificate of registration shall be as specified in Form 17 and shall be valid for a period of five years.

(3) If, after an inquiry including inspection of the hospital or tissue bank and scrutiny of its past performance and after giving an opportunity to the applicant, the Appropriate Authority is satisfied that the applicant, since grant of certificate of registration under sub-rule (2) of rule 24 has not complied with the requirements of the Act and these rules and the 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.

**26. Conditions and standards for grant of certificate of registration for organ or tissue transplantation centres.**—(1) No hospital shall be granted a certificate of registration for organ transplantation unless it fulfills the following conditions and standards, namely:—

**A. General manpower requirement specialised services and facilities:**

- (a) Twenty-four hours availability of medical and surgical, (senior and junior) staff;
- (b) twenty-four hours availability of nursing staff (general and specially trained);
- (c) twenty-four hours availability of Intensive Care Units with adequate equipment staff and support system, including specialists in anesthesiology and intensive care;
- (d) twenty-four hours availability of blood bank (in house or access), laboratory with multiple discipline testing facilities including but not limited to Microbiology, Bio-Chemistry, Pathology, Hematology and Radiology departments with trained staff;
- (e) twenty-four hours availability of Operation Theater facilities (OT facilities) for planned and emergency procedures with adequate staff, support system and equipment;
- (f) twenty-four hours availability of communication system, with power backup, including but not limited to multiple line telephones, public telephone systems, fax, computers and paper photo-imaging machine;
- (g) experts (other than the experts required for the relevant transplantation) of relevant and associated specialities including but not limited to and depending upon the requirements, the experts in internal medicine, diabetology, gastroenterology, nephrology, neurology, pediatrics, gynecology, immunology and cardiology, etc., shall be available in the transplantation centre;
- (h) one medical expert for respective organ or tissue transplant shall be available in the transplantation hospital; and
- (i) Human Leukocyte Antigen (HLA) matching facilities (in house or outsourced) shall be available.

**B. Equipments:**

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

**C. Experts and their qualifications:**

- (a) Kidney Transplantation;  
M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. training in a recognised transplant center in India or abroad

and having attended to adequate number of renal transplantation as an active member of team;

- (b) Transplantation of liver and other abdominal organs:  
M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. experience in the speciality and having one year training in the respective organ transplantation as an active member of team in an established transplant center;
- (c) Cardiac, Pulmonary, Cardio-Pulmonary Transplantation:  
M.Ch. Cardio-thoracic and vascular surgery or equivalent qualification in India or abroad with at least three years' experience as an active member of the team performing an adequate number of open heart operations per year and well-versed with Coronary by-pass surgery and Heart-valve surgery;
- (d) the hospital registered under Clinical Establishment (Registration and Regulation) Act, 2010 (23 of 2010) shall also follow the minimum standards prescribed in respect of manpower, equipment, etc., as prescribed under that Act;
- (e) the hospital registered shall have to maintain documentation and records including reporting of adverse events.

(2) No hospital shall be granted a certificate of registration for tissue transplantation under the Act unless it fulfills the following conditions and standards, namely:—

- (a) Cornea Transplantation:  
M.D. or M.S. or Diploma (DO) in ophthalmology or equivalent qualification with three months post M.D. or M.S or DO training in Corneal transplant operations in a recognised hospital or institution;
- (b) Other tissues such as heart valves, skin, bone, etc.:  
Post graduate degree (MD or MS) or equivalent qualification in the respective speciality with three months post M.D. or M.S training in a recognised hospital carrying out respective tissue transplant operations and for heart valve transplantation, and the qualification and experience of expert shall be MCh degree in Cardiothoracic and Vascular Surgery (CTVS) or equivalent qualification with three months post MCh training in a recognised hospital carrying out heart valve transplantation;
- (c) the Hospital registered under Clinical Establishment (Registration and Regulation) Act, 2010(23 of 2010) shall also follow the minimum standards prescribed in respect of manpower, equipment, etc., as prescribed under that Act;
- (d) the Hospital registered shall have to maintain documentation and records including reporting of adverse events.

**27. Conditions and standards for grant of certificate of registration for organ retrieval centres.**—(1) The retrieval center shall be registered only for the purpose of retrieval of organ from deceased donors and the organ retrieval centre shall be a hospital having Intensive Care Unit (ICU) facilities along with

manpower, infrastructure and equipment as required to diagnose and maintain the brain-stem dead person and to retrieve and transport organs and tissues including the facility for their temporary storage.

(2) All hospitals registered as transplant centres shall automatically qualify as retrieval centres.

(3) The retrieval centre should have linkages with nearby Government hospital designated for post-mortem, for retrieval in medico-legal cases.

(4) Registration of hospital for surgical tissue harvesting from deceased person and for surgical tissue residues, that are routinely discarded, shall not be required.

**28. Conditions and standards for grant of certificate of registration for tissue banks.—**

**A. Facility and premises:**

(1) Facilities must conform to the standards and guidelines laid down for the purpose and the States and Union territories may have separate registration fee and procedure to keep track of their tissue bank activities.

(2) The respective State or Union territory Appropriate Authority may constitute an expert committee for advising on the matter related to tissue specific standards and related issues.

(3) The tissue bank must have written guidelines and standard operating procedures for maintenance of its premises and facilities which include—

- (a) controlled access;
- (b) cleaning and maintenance systems;
- (c) waste disposal;
- (d) health and safety of staff;
- (e) risk assessment protocol; and
- (f) follow up protocol.

(4) Equipments as per scientific requirements specific to tissue (s) being procured, processed, stored and distributed and the tissue bank should ensure the availability of the accessories, spare-parts and back-up, maintenance and service support for all equipments.

(5) Air particle count and microbial colony count compliance shall be ensured for safety where necessary.

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

(7) Storage facility shall be separate and distinguish tissues, held in quarantine, released and rejected.

**B. Donor screening:**

(8) Complete screening of donor must be conducted including medical or social history and serological evaluation for medical conditions or disease processes that would contraindicate the donation of tissues

and the report of corneas or eyes not found suitable for transplantation and their alternate use shall be certified by a committee of two Ophthalmologists.

**C. Laboratory tests:**

- (9) Facility for relevant Laboratory tests for blood and tissue samples shall be available and testing of blood and tissue samples shall begin at Donor Screening and continue during retrieval and throughout processing.

**D. Procurement and other procedures:**

- (10) Procurement of tissue must be carried out by registered health care professionals or technicians having necessary experience or special training.
- (11) Consent for the procurement shall be obtained.
- (12) Procurement records shall be maintained.
- (13) Standard operating procedure for following shall be followed, namely:—
- (a) procurement or Retrieval and transplantation;
  - (b) processing and sterilisation;
  - (c) packaging, labeling and storage;
  - (d) distribution or allocation;
  - (e) transportation; and
  - (f) reporting of serious adverse reactions.

**E. Documentation and Records:**

- (14) A log of tissue received and distributed shall be maintained to enable traceability from the donor to the tissue and the tissue to the donor and the records shall also indicate the dates and the identities of the staff performing specific steps in the removal or processing or distribution of the tissues.

**F. Data Protection and Confidentiality:**

- (15) A unique donor identification number shall be used for each donor, and access to donor records shall be restricted.

**G. Quality Management:**

- (16) The Quality Management System shall define quality control procedures that include the following, namely:—
- (a) environmental monitoring;
  - (b) equipment maintenance and monitoring;
  - (c) in-process controls monitoring;
  - (d) internal audits including reagent and supply monitoring;
  - (e) compliance with reference standards, local regulations, quality manuals or documented standard operating procedures; and
  - (f) monitoring work environment.

**H. Recipient Information:**

- (17) All tissue recipients shall be followed up and prompt and appropriate corrective and preventive actions taken in case of adverse events.

**29. Qualification, role, etc., of transplant coordinator.**—(1) The transplant coordinator shall be an employee of the registered hospital having qualification such as:

- (a) graduate of any recognised system of medicine; or
- (b) Nurse; or
- (c) Bachelor's degree in any subject and preferably Master's degree in Social work or Psychiatry or Sociology or Social Science or Public Health.

(2) The concerned organisation or institute shall ensure initial induction training followed by retraining at periodic interval and the transplant coordinator shall counsel and encourage the family members or near relatives of the deceased person to donate the human organ or tissue including eye or cornea and coordinate the process of donation and transplantation.

(3) The transplant coordinator or counselor in a hospital registered for eye banking shall also have qualification specified in sub-rule (1).

**30. Advisory committee of the Central or State Government to aid and advise appropriate authority.**—(1) The Central Government and the State Government, as the case may be, shall constitute by notification an Advisory Committee under Chairpersonship of administrative expert not below the rank of Secretary to the State Government for a period of two years to aid and advise the Appropriate Authority and the two medical experts referred to in clause (b) of sub-section (2) of section 13A of the Act shall possess a postgraduate medical degree and at least five years' experience in the field of organ or tissue transplantation.

(2) The terms and conditions for appointment to the Advisory Committee are as under:

- (a) the Chairperson and members of the Committee shall be appointed for a period of two years;
- (b) the Chairperson and members of the Committee shall be entitled to the air fare and other allowances to attend the meeting of the Committee equivalent to the officer of the level of the Joint Secretary to the Government of India;
- (c) the Central Government or State Government or Union territory Administration shall have full powers to replace or remove the Chairperson and the members in cases of charges of corruption or any other charges after giving a reasonable opportunity of being heard;
- (d) the Chairperson and members can also resign from the Committee for personal reasons;
- (e) there shall not be a corruption or criminal case pending against Chairperson and members at the time of appointment;

- (f) the Chairperson or any of the members shall cease to function if charges have been framed against him or her in a corruption or criminal case after having been given a reasonable opportunity of being heard.

**31. Manner of establishing National or Regional or State Human Organs and Tissues Removal and Storage Networks and their functions.**—(1) There shall be an apex national networking organisation at the centre, as the Central Government may by notification specify.

(2) There shall also be regional and State level networking organisations where large number of transplantation of organ(s) or tissue (s) are performed as the Central Government may by notification specify.

(3) The State units would be linked to hospitals, organ or tissue matching laboratories and tissue banks within their area and also to regional and national networking organisations.

(4) The broad principles of organ allocation and sharing shall be as under,—

- (a) The website of the transplantation center shall be linked to State or Regional cum State or National networks through an online system for organ procurement, sharing and transplantation.
- (b) patient or recipient may get registered through any transplant centre, but only one centre of a State or region (if there is no centre in the State) and his or her details shall be made available online to the networking organisations, who shall allocate the registration number, which shall remain same even if patient changes hospital;
- (c) the allocation of the organ to be shared, is to be decided by the State networking organization and by the National networking organization in case of Delhi;
- (d) all recipients are to be listed for requests of organs from deceased donors, however priority is to be given in following order, namely:—
  - (i) those who do not have any suitable living donor among near relatives;
  - (ii) those who have a suitable living donor available among near relatives but the donor has refused in writing to donate; and
  - (iii) those who have a suitable living donor available and who has also not refused to donate in writing;
- (e) sequence of allocation of organs shall be in following order: State list—Regional List—National List—Person of Indian Origin—Foreigner;
- (f) the online system of networking and framework and formats of national registry as mentioned under rule 32 shall be developed by the apex networking organisation which shall be followed by the States Governments or Union territory Administrations and the allocation criteria may be State specific which shall be finalised and determined by the State Government, in consultation with the State level networking organisation, wherever such organisation exists:

Provided that the organ sharing and networking policy of States or locations of hospitals shall not be binding on the Armed Forces Medical Services (AFMS) and the armed forces shall be free to have their own policy of organ or tissue allocation and sharing, and the Director General Armed Forces Medical Services shall have its own networking between the Armed Forces Medical Services hospitals, who shall be permitted to accept organs when available from hospitals within their State jurisdiction.

(5) The networking organisations shall coordinate retrieval, storage, transportation, matching, allocation and transplantation of organs and tissues and shall develop norms and standard operating procedures for such activities and for tissues to the extent possible.

(6) The networking organisations shall coordinate with respective State Government for establishing new transplant and retrieval centres and tissue banks and strengthening of existing ones.

(7) There shall be designated organ and tissue retrieval teams in State or District or institution as per requirement, to be constituted by the State or Regional networking organisation.

(8) For tissue retrieval, the retrieval teams shall be formed by the State Government or Union territory Administration wherever required.

(9) Networking shall be e-enabled and accessible through dedicated website.

(10) Reference or allocation criteria would be developed and updated regularly by networking organisations in consultation with the Central or State Government, as the case may be.

(11) The networking organisation(s) shall undertake Information Education and Communication (IEC) Activities for promotion of deceased organ and tissue donation.

(12) The networking organisation(s) shall maintain and update organ or tissue Donation and Transplant Registry at respective level.

**32. Information to be included in National Registry regarding donors and recipients of human organ and tissue.**—The national registry shall be based on the following, namely;—

**Organ Transplant Registry:**

- (1) The Organ Transplant Registry shall include demographic data about the patient, donor, hospitals, recipient and donor follow up details, transplant waiting list, etc., and the data shall be collected from all retrieval and transplant centers.
- (2) Data collection frequency, etc., will be as per the norms decided by the Advisory Committee which may preferably be through a web-based interface or paper submission and the information shall be maintained both specific organ wise and also in a consolidated format.
- (3) The hospital or Institution shall update its website regularly in respect of the total number of the transplantations done in that hospital or institution along with reasonable detail of each transplantation and the same data should be accessible for

compilation, analysis and further use by authorised persons of respective State Governments and Central Government.

- (4) Yearly reports shall be published and also shared with the contributing units and other stakeholders and key events (new patients, deaths and transplants) shall be notified as soon as they occur in the hospital and this information shall be sent to the respective networking organisation, at least monthly.

**Organ Donation Registry:**

- (5) The Organ Donation Registry shall include demographic information on donor (both living and deceased), hospital, height and weight, occupation, primary cause of death in case of deceased donor, associated medical illnesses, relevant laboratory tests, donor maintenance details, driving license or any other document of pledging donation, donation requested by whom, transplant coordinator, organs or tissue retrieved, outcome of donated organ or tissue, details of recipient, etc.

**Tissue Registry:**

- (6) The Tissue Registry shall include demographic information on the tissue donor, site of tissue retrieval or donation, primary cause of death in case of deceased donor, donor maintenance details in case of brain stem dead donor, associated medical illnesses, relevant laboratory tests, driving license or any other document pledging donation, donation requested by whom, identity of counsellors, tissue(s) or organ(s) retrieved, demographic data about the tissue recipient, hospital conducting transplantation, transplant waiting list and priority list for critical patients, if these exist, indication(s) for transplant, outcome of transplanted tissue, etc.
- (7) Yearly reports in respect of National Registry shall be published and also shared with the contributing units and other stakeholders

**Pledge for organ or tissue donation after death:**

- (8) Those persons, who, during their lifetime have pledged to donate their organ(s) or tissue(s) after their death, shall in Form 7 deposit it in paper or electronic mode to the respective networking organisation(s) or institution where the pledge is made, who shall forward the same with the respective networking organisation and the pledger has the option to withdraw the pledge through intimation.
- (9) The Registry will be accessible on-line through dedicated website and shall be in conformation to globally maintained registry(ies), besides having national, regional and State level specificities.
- (10) National or regional registry shall be compiled based on similar registries at State level.
- (11) The identity of the people in the database shall not be put in public domain and measures shall be taken to ensure security of all collected information.

(12) The information to be included shall be updated as per prevalent global practices from time to time.

33. 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 or sub-section (2) of section 16 of the Act, may, within thirty days from the date of receipt of the order, prefer an appeal to the Central Government in case of the Union territories and respective State Government in case of States.

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

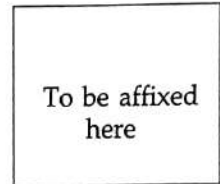
FORM 1

FOR ORGAN OR TISSUE DONATION FROM IDENTIFIED LIVING NEAR RELATED DONOR

(To be completed by him or her)

[See rules 3 and 5(3)(a)]

My full name (proposed donor) is..... and this is my photograph



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

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

My present address for correspondence is ..... Tel: .....

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

I enclose copies of the following documents: (attach attested photocopy of at least two of following relevant documents to indicate your near relationship):

- Ration/Consumer Card number and Date of issue and place..... and/or
• Voter's I-Card number, date of issue, Assembly constituency..... and/or
• Passport number and country of issue..... and/or
• Driving License number, date of issue, licensing authority..... and/or
• Permanent Account Number (PAN)..... and/or
• AADHAAR No. ....

- and/or
- Any other valid proof of identity and address reflecting near relationship.....

I authorise removal for therapeutic purposes and consent to donate my.....

(Name of organ/tissue) to my relative..... (Specify son/daughter/father/mother/brother/sister/grand-father/grand-mother/grand-son/grand-daughter), whose particulars are as follows and name is..... and who was born on..... (day/month/year):

To be affixed here

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

The copies of following documents of recipient are enclosed (attach attested photocopy of at least two relevant documents to indicate your near relationship):

- Ration/Consumer Card number and Date of issue and place.....  
and/ or
  - Voter's I-Card number, date of issue, Assembly constituency.....  
and/ or
  - Passport number and country of issue.....  
and/ or
  - Driving License number, Date of issue, licensing authority.....  
and/ or
  - Permanent Account Number (PAN) .....
  - AADHAAR No ..... (Issued by Unique Identification Authority of India).
- and/ or
- Any other valid proof of identity and address reflecting near relationship.....

**I solemnly affirm and declare that:**

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

1. I understand the nature of criminal offences referred to in the sections.
2. No payment as referred to in the sections of the Act has been made to me or will be made to me or any other person.
3. I am giving the consent and authorisation to remove my..... (name of organ/tissue) of my own free will without any undue pressure, inducement, influence or allurements.
4. I have been given a full explanation of the nature of the medical procedure involved and the risks involved for me in the removal of my..... (name of organ)/tissue). That explanation was given by..... (name of registered medical practitioner).

- 5. I understand the nature of that medical procedure and of the risks to me as explained by that practitioner.
  - 6. I understand that I may withdraw my consent to the removal of that organ at any time before the operation takes place.
  - 7. I state that particulars filled by me in the form are true and correct to the best of my knowledge and belief and nothing material has been concealed by me.
- Date.....

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

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

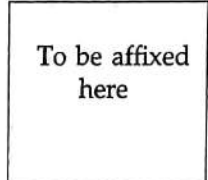
**FORM 2**

**FOR ORGAN OR TISSUE DONATION BY LIVING SPOUSAL DONOR**

*(To be completed by him/her)*

[See rules 3, 5(3)(a) and 5(3)(d)]

My full name (proposed donor) is.....  
 and this is my photograph



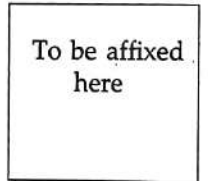
Photograph of the Donor  
 (Attested by Notary Public  
 across the photo after affixing)

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

My present address for correspondence is.....  
 .....Tel:.....

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

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



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

I enclose copies of the following documents (**attach attested photocopy of at least two of following relevant documents to indicate the spousal relationship**):

- Ration/Consumer Card number and Date of issue and place:.....  
 and/or
- Voter's Identity-Card number, date of issue, Assembly  
 constituency.....  
 and/or

- Passport number and country of issue.....  
and/or
- Driving License number, Date of issue, licensing authority.....  
and/or
- Permanent Account Number (PAN).....  
and/or
- AADHAAR No. (issued by Unique Identification Authority of India).....  
and/or
- Any other proof of identity and address establishing spousal relationship.....

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

- (a) A certified copy of a marriage certificate

OR

- (b) An affidavit of a 'near relative' confirming the status of marriage to be sworn before Class-I Magistrate/Notary Public.
- (c) Family photographs
- (d) Letter from Head of Gram Panchayat/Tehsildar/Block Development Officer/Member of Legislative Assembly/Member of Legislative Council (MLC)/Member of Parliament with seal certifying factum and status of marriage.

OR

- (e) Other credible evidence

I solemnly affirm and declare that sections 2, 9 and 19 of the Transplantation of Human Organs Act, 1994 (42 of 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 authorisation to remove my.....(organ) and consent to donate the same of my own free will without any undue pressure, inducement, influence or allurement.
4. I have been given a full explanation of the nature of the medical procedure involved and the risks involved for me in the removal of my ..... (organ). That explanation was given by..... (name of registered medical practitioner).
5. I understand the nature of that medical procedure and of the risks to me as explained by that practitioner.
6. I understand that I may withdraw my consent to the removal of that organ at any time before the operation takes place.
7. I state that particulars filled by me in the form are true and correct to the best of my knowledge and nothing material has been concealed by me.

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

.....  
Date

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

**FORM 3**  
**FOR ORGAN OR TISSUE DONATION BY OTHER THAN NEAR RELATIVE LIVING DONOR**

*(To be completed by him/her)*

*[See rules 3, 5(3)(a) and 5(3)(e)]*

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

To be affixed  
here

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

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

My present address for correspondence is: .....Tel: .....

Date of birth.....(day/month/year)  
**I enclose copies of the following documents: (attach attested photocopy of at least two of following relevant documents to prove your identity):**

- Ration/Consumer Card number and Date of issue and place:  
(Photocopy attached) ..... and/or
  - Voter's I-Card number, date of issue, Assembly constituency.....  
(Photocopy attached) ..... and/or
  - Passport number and country of issue.....  
(Photocopy attached) ..... and/or
  - Driving Licence number, Date of issue, Licensing authority.....  
(Photocopy attached) ..... and/or
  - PAN..... and/or
  - AADHAAR No. .... and/or
  - Other proof of identity and address.....
- Details of last three years income and vocation of donor (enclose documentary evidence).....

I authorize removal for therapeutic purposes and consent to donate my..... and who was born on..... (Name of organ/tissue) to a person whose full name is..... and whose particulars are as follows: (day/month/year)

Photograph of the Recipient  
(Attested by Notary Public across the  
Photo after affixing)

To be affixed  
here

(Attach attested photocopy of at least two relevant documents to prove identity of recipient)

- Ration/Consumer Card number and Date of issue and place:  
(Photocopy attached) and/or
  - Voter's I-Card number, date of issue, Assembly constituency..... and/or (Photocopy attached)
  - Passport number and country of issue..... and/or (Photocopy attached)
  - Driving Licence number, Date of issue, Licensing authority..... and/or (Photocopy attached)
  - PAN..... and/or
  - AADHAAR No. .... and/or
  - Other proof of identity and address.....
- I solemnly affirm and declare that sections 2, 9 and 19 of the Transplantation of Human Organs Act, 1994 (42 of 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..... (name of organ/tissue) of my own free will without any undue pressure, inducement influence or allotment.
  4. I have been given a full explanation of the nature of the medical procedure involved and the risks involved for me in the removal of my..... (name of organ/tissue). That explanation was given by..... (name of registered medical practitioner).
  5. I understand the nature of that medical procedure and of the risks to me as explained by the practitioner.
  6. I understand that I may withdraw my consent to the removal of that organ at any time before the operation takes place.

7. I state that particulars filled by me in the form are true and correct to the best of my knowledge and nothing material has been concealed by me.

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

.....  
Date

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

#### FORM 4

### FOR CERTIFICATION OF MEDICAL FITNESS OF LIVING DONOR

*(To be given by the Registered Medical Practitioner)*

[See proviso to rule 5(3)(b)]

I, Dr. .... possessing qualification of..... by the.....  
registered as medical practitioner at serial no. ....  
..... Medical Council, certify that I have examined Shri/ Smt./Km. ....  
S/o, D/o, W/o Shri..... aged..... who has given informed consent for  
donation of his/her..... (Name of the organ) to Shri/Smt./Km. ....  
who is a 'near relative' of the donor/other than near relative of the donor and has been  
approved by the competent authority or Authorisation Committee (as the case may be)  
and it is certified that the said donor is in proper state of health, not mentally challenged\*  
and is medically fit to be subjected to the procedure of organ or tissue removal.

Place.....

.....

Date.....

Signature of Doctor  
Seal

To be affixed  
(pasted) here

To be affixed  
(pasted) here

Photograph of the Donor  
(Attested by doctor)

Photograph of the recipient  
(Attested by the doctor)

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

\* In case of doubt for mentally challenged status of the donor, the Registered Medical Practitioner may get the donor examined by psychiatrist.

#### FORM 5

### FOR CERTIFICATION OF GENETIC RELATIONSHIP OF LIVING DONOR WITH RECIPIENT

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

[See rules 5(3)(c) and 18(3)]

I, Dr./Mr./Mr./Miss. .... working as .....at..... and  
possessing qualification of..... certify that Shri/ Smt./ Km. ....S/o,

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

Signature

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

Place .....

Date .....

FORM 6

FOR SPOUSAL LIVING DONOR

(To be filled by competent authority\* and Authorisation Committee,  
of the hospital or district or state in case of foreigners)

[See rule 18(2)]

I, Dr./Mr./Mrs./Miss. .... possessing qualification of..... registered  
as medical practitioner at serial No. .... by the..... Medical Council,  
certify that—

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

OR

In case the Clinical condition of Shri/Smt. .... mentioned above is such that  
recording of his/her statement is not practicable, reliance will be placed on the  
documentary evidence(s). (mention documentary evidence(s) here) .....

- (a) Marriage certificate indicate date of marriage
- (b) Marriage photographs
- (c) Date when transplantation was advised by the hospital (to be compared with  
duration of marriage):
- (d) Number and age of children and their birth certificates
- (e) Any other document

.....  
Signature of competent authority\*  
Authorisation committee in case of  
foreigners along with Seal/Stamp

Place.....

Date.....

\*Director or Medical Superintendent or In Charge of the hospital or the internal  
committee of the hospital formed for the purpose as defined under the rules of  
Transplantation of Human Organ Act, 1994 (42 of 1994).

FORM 7

FOR ORGAN OR TISSUE PLEDGING

(To be filled by individual of age of 18 year or above)

[See rule 5(4)(a)]

ORGAN(S) AND TISSUE(S) DONOR FORM

(To be filled in triplicate)

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

I. ....S/o, D/o, W/o..... aged.....and date of birth..... resident of.....in the presence of persons mentioned below hereby unequivocally authorise the removal of following organ(s) and/or tissue(s), from my body after being declared brain stem dead by the board of medical experts and consent to donate the same for therapeutic purposes.

Please tick as applicable

(Following tissues can also be donated after brain stem death as well as cardiac death)

- Heart
- Lungs
- Kidneys
- Liver
- Pancreas
- Any Other
- Organ (Pl. specify)
- All Organs

- Corneas/Eye Balls
- Skin
- Bones
- Heart Valves
- Bloodvessels
- Any other
- Tissue (Pl specify)
- All Tissues

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

Signature of Pledger.....  
Address for correspondence.....  
Telephone No .....  
Email: .....

Dated.....

(Note.—In case of online registration of pledge, one copy of the pledge will be retained by pledger, one by the institution where pledge is made and a hard copy signed by pledger and two witnesses shall be sent to the nodal networking organisation.)

(Signature of Witness 1)

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

(Signature of Witness 2)

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

Dated.....

Place.....

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

(ii) One copy of the pledge form/pledge card to be with respective networking organisation, one copy to be retained by institution where the pledge is made and one copy to be handed over to the pledger.

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

**FORM 8**

**FOR DECLARATION CUM CONSENT**

(To be filled by near relative or lawful possessor of brain-stem dead person)

[See rules 5(1)(b), 5(4)(b) and 5(4)(d)]

**DECLARATION AND CONSENT FORM**

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

1. I have been informed that my relative (specify relation) .....S/o, D/o, W/o..... aged..... has been declared brain-stem dead/dead.
2. To the best of my knowledge (Strike off whichever is not applicable):
  - (a) He/She. (Name of the deceased)..... had/had not, authorised before his/her death, the removal of..... (Name of organ/tissue/both) of his/her body after his/her death for therapeutic purpose. The documentary proof of such authorisation is enclosed/not available
  - (b) He/She. (Name of the deceased) .....had not revoked the authority as at No. 2 (a) above (If applicable).
  - (c) There are reasons to believe that no near relative of the said deceased person has objection to any of his/her organs/tissue being used for therapeutic purposes.
3. I have been informed that in the absence of such authorisation, I have the option to either authorise or decline donation of organ/tissue/both including eye/cornea of..... (Name of the deceased) for therapeutic purposes. I also understand that if corneas/eyes are not found suitable for therapeutic purpose, then may be used for education/research.
4. I hereby authorise/do not authorize removal of his/her body organ(s) and/or tissue(s), namely (Any organ and tissue/Kidney/Liver/Heart /Lungs /Intestine/Cornea /Skin/Bone /Heart Valves /Any other; please specify) .....for therapeutic purposes. I also give permission for drawing of a blood sample for serology testing and am willing to share social/behavioural and medical history to facilitate proper screening of the donor for safe transplantation of the organs/tissues.

Date.....

.....  
Signature of near relative/person  
in lawful possession of the dead body,  
and address for correspondence\*.

Place.....

Telephone No. ....

Email: .....

\* in case of the minor the declaration shall be signed by one of the parent of the minor or any near relative authorised by the parent. In case the near relative or person in lawful possession of the body refuses to sign this form, the same shall be recorded in writing by the Registered Medical Practitioner on this Form.]

.....  
(Signature of Witness 1)

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

.....  
 (Signature of Witness 2)

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

**FORM 9**

**FOR UNCLAIMED BODY IN A HOSPITAL OR PRISON**

(To be completed by person in lawful possession of the unclaimed body)

[See rule 5(1)(b)]

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

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

Dated.....Place.....  
 Address for correspondence.....

.....  
 Telephone No. .... Email: .....

.....  
 (Signature of Witness 1)

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

.....  
 (Signature of Witness 2)

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

**FORM 10**

**FOR CERTIFICATION OF BRAIN STEM DEATH**

(To be filled by the board of medical experts certifying brain-stem death)

[See rules 5(4)(c) and 5(4)(d)]

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

Dated.....

Signature.....

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

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

### BRAIN-STEM DEATH CERTIFICATE

#### (A) PATIENT DETAILS.....

1. Name of the patient: Mr./Ms. ....  
S.O./D.O./W.O. Mr./Ms. ....  
Sex.....Age.....
2. Home Address: .....
3. Hospital Patient Registration Number (CR No.): .....
4. Name and Address of next of kin or person.....  
responsible for the patient.....  
(if none exists, this must be specified) .....
5. Has the patient or next of kin agreed .....  
to any donation of organ and/or tissue? .....
6. Is this a Medico-legal Case? Yes.....No.....

#### (B) PRE-CONDITIONS:

1. Diagnosis: Did the patient suffer from any illness or accident that led to irreversible brain damage?  
Specify details .....
- Date and time of accident/onset of illness.....  
Date and onset of non-reversible coma.....
2. Findings of Board of Medical Experts:  
First Medical Examination..... Second Medical Examination.....

---

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

- Intoxication (Alcohol)
  - Depressant Drugs
  - Relaxants (Neuromuscular blocking agents)
  - Primary Hypothermia
  - Hypovolacemic shock
  - Metabolic or endocrine disorders
  - Tests for absence of brain-stem functions
- (2) Coma
  - (3) Cessation of spontaneous breathing
  - (4) Pupillary size
  - (5) Pupillary light reflexes

- (6) Doll's head eye movements
- (7) Corneal reflexes (Both sizes)
- (8) Motor response in any cranial nerve distribution, any responses to stimulation of face, limb or trunk.
- (9) Gag reflex
- (10) Cough (Tracheal)
- (11) Eye movements on caloric testing bilaterally.
- (12) Apnoea tests as specified.
- (13) Were any respiratory movements seen?

.....

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

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

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

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

Date.....

Signatures of members of Brain Stem Death (BSD) Certifying Board as under:

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

**Note.**

- I. Where Neurologist/Neurosurgeon is not available, then any Surgeon or Physician and Anaesthetist or Intensivist, nominated by Medical Administrator Incharge of the hospital shall be the member of the board of medical experts for brain-stem death certification.
- II. The minimum time interval between the first and second testing will be six hours in adults. In case of children 6 to 12 years of age, 1 to 5 years of age and infants, the time interval shall increase depending on the opinion of the above BSD experts.
- III. No. 2 and No.3 will be co-opted by the Administrator Incharge of the hospital from the Panel of experts (Nominated by the hospital and approved by the Appropriate Authority).

**FORM 11**

**APPLICATION FOR APPROVAL OF TRANSPLANTATION FROM LIVING DONOR**

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

[See rules 5(3)(d), 5(3)(e) and 10]

To be self attested across the affixed photograph without disfiguring face

To be self attested across the affixed photograph without disfiguring face

Photograph of the Donor

Photograph of the recipient

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

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

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

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

hereby apply to competent authority/Authorisation Committee for permission for such transplantation to be carried out.

We solemnly affirm that the above decision has been taken without any undue pressure, inducement, influence or allurement and that all possible consequences and options of organ transplantation have been explained to us.

**Instructions for the applicants—**

1. Form 11 must be submitted along with the completed Form 1 or Form 2 or Form 3 as may be applicable.
2. The applicable Form i.e. Form 1 or Form 2 or Form 3 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 5 must 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 competent authority/ Authorisation Committee only if it is complete in all respects and any omission of the documents or the information required in the forms mentioned above, shall render the application incomplete.

7. When the donor is unrelated and the donor and/or recipient belong to a State/ Union Territory other than the State/Union Territory, where the transplant is intended to take place, then the Tehsildar or the officer authorised for the purpose of the domicile state of the donor or recipient as the case may be, would provide the verification certificate of domicile of donor/recipient as the case may be as per Form 20. The approval for transplantation would be considered by the authorisation committee of the State/District/hospital (as the case may be) where the transplantation is intended to be done. Such verification Certificate will not be required for near relatives including cases involving swapping of organs (permissible between near relatives only).

We have read and understood the above instructions.

Signature of the Prospective Donor

Signature of Prospective Recipient

Address for correspondence:

Address for correspondence:

Date.....

Date.....

Place.....

Place.....

**FORM 12****APPLICATION FOR REGISTRATION OF HOSPITAL TO CARRY OUT ORGAN OR TISSUE TRANSPLANTATION OTHER THAN CORNEA****(To be filled by head of the institution)***[See rule 24(1)]*

To

The Appropriate Authority for organ transplantation.....

(State or Union territory)

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

Name(s) of organ (s) or tissue (s) for which registration is required.....

The required data about the facilities available in the hospital are as follows:—

**(A) HOSPITAL:**

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

Road:	Yes	No
Rail:	Yes	No
Air:	Yes	No

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

**(B) SURGICAL FACILITIES:**

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

**(C) MEDICAL FACILITIES:**

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

5. Trained persons available for transplantation (Please specify Organ for transplantation):

6. No. of potential transplant candidates admitted per year:

## (D) ANAESTHESIOLOGY:

1. No. of permanent staff members with their designations:
2. No. of temporary staff members with their designations:
3. Name and No. of operations performed:
4. Name and No. of equipments available:
5. Total No. of operation theatres in the hospital:
6. No. of emergency operation-theatres:
7. No. of separate transplant operation theatre:

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

1. I.C.U./H.D.U. facilities: Present .....Not present.....
2. No. of I.C.U. and H.D.U. beds:
3. Trained:—

Nurses:

Technicians:

4. Name of equipment in I.C.U.

## (F) OTHER SUPPORTIVE FACILITIES:

Data about facilities available in the hospital:

## (F1) LABORATORY FACILITIES:

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

## (F2) IMAGING FACILITIES:

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

## (F3) HAEMATOLOGY FACILITIES:

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

## (F4) BLOOD BANK FACILITIES (Inhouse or access):

Yes..... No.....

## (F5) DIALYSIS FACILITIES:

Yes..... No.....

(F6) Transplant coordinators (Eye Donation Counsellors, in case of Cornea Transplantation):

Yes

No

Number Posted:

Number Trained



8. Annual budget:
9. Patient turn-over/year:

**(B) SURGICAL FACILITIES:**

1. No. of beds:
2. No. of permanent staff members with their designation:
3. No. of temporary staff with their designation:
4. No. of operations done per year:
5. Trained persons available for retrieval (Please specify Organ and/or tissue for retrieval):

**(C) MEDICAL FACILITIES:**

1. No. of beds:
2. No. of permanent staff members with their designation:
3. No. of temporary staff members with their designation:
4. Patient turnover per year:
5. Trained persons available for retrieval (Please specify Organ and/or tissue for retrieval):
6. No. of critical trauma cases admitted per year.
7. No. of brain stem death declared per year.

**(D) ANAESTHESIOLOGY:**

1. No. of permanent staff members with their designations:
2. No. of temporary staff members with their designations:
3. Name and No. of operations performed:
4. Name and No. of equipments available:
5. Total No. of operation theatres in the hospital:
6. No. of emergency operation-theatres:
7. No. of separate retrieval operation theatre:

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

1. I.C.U./H.D.U. facilities: Present..... Not present.....
2. No. of I.C.U. and H.D.U. beds:
3. Trained:—

Nurses:

Technicians:

**(F) OTHER SUPPORTIVE FACILITIES:**

Data about facilities available in the hospital:

**(F1) LABORATORY FACILITIES:**

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

(F2) IMAGING FACILITIES:

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

(F3) HAEMATOLOGY FACILITIES:

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

(F4) BLOOD BANK FACILITIES: (in house or access)      Yes.....      No....

(F5) Transplant coordinators:      Yes      No

Number Posted:

Number Trained

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. I hereby give an undertaking that we shall make the facilities of the hospital including the retrieval team of the hospital available for retrieval of the organ/tissue as and when needed.

.....  
HEAD OF THE INSTITUTION

FORM 14

APPLICATION FOR REGISTRATION OF TISSUE  
BANKS OTHER THAN EYE BANKS

(To be filled by head of the institution)

[See rule 24(1)]

To

The Appropriate Authority for organ transplantation .....

(State or Union Territory)

We hereby apply to be registered as Tissue bank, Name:

Name(s) of tissue (s)(Bone, heart valves, skin, cornea etc) for which Registration is required.....

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

A. General Information:

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

Rail:	Yes	No
Road:	Yes	No
Air:	Yes	No

5. Information Education and Communication (IEC) for Tissue Donation  
 6. Type of tissue bank: Auto Logons/Allograph/Both  
**B. DONOR SCREENING REMOVAL OF TISSUE AND STORAGE:**

1. Availability of adequate trained and qualified Personnel for removal of Tissue (annex detail): Yes/No
2. Names, qualification and address of the doctors/technician who will be doing removal of tissue. Yes/No  
 (annex details)
3. Facilities for removal of Tissues Yes/No
4. Whether register of recipient waiting list available. Yes/No
5. Telephone arrangement available. Yes/No

- (Telephone Number.....)
6. Availability of ambulance/ vehicle or funds to Pay taxi for collecting tissue from outside: Yes/No
7. Sets of instruments for removal of tissue Yes/No
8. Facilities for processing of tissue Yes/No
9. Refrigerator for preservation of tissue Yes/No
10. Special containers for preservation of tissue during transit. Yes/No
11. Suitable preservation media Yes/No
12. Any other specific requirement as per tissue Yes/No

**C. PRESERVATIONS OF TISSUE**

Arrangement of preservation of Tissue

**D. RECORDS**

1. Arrangement for maintaining the records Yes/No
2. Arrangement for registration of cases, donors and follow' up of cases. Yes/No

**E. EQUIPMENT:**

Instruments specific for the tissue Yes/No

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

- (a) Names of the investigations carried out in the department. Yes/No
- (b) Facility for testing for:
- (i) Human Immunodeficiency Virus Type I and II Yes/No
- (ii) Hepatitis B Virus – HBc and HBs
- (iii) Hepatitis C Virus – HCV
- (iv) Syphilis – VDRL
- (c) If no, where do you avail it? Please mention name and address of institute. Yes/No
- (d) Facility for culture and sensitivity of tissue Yes/No

**G. OTHER PERSONNEL**

1. No. of permanent staff member with their designation.
2. No. of temporary staff with their designation
3. No. of trained persons

## ANY OTHER INFORMATION

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. A Bank Draft/cheque of Rs. 10000/ (for new registration) and Rs. 5000 (for renewal) in favour of..... is enclosed.

.....  
 HEAD OF THE INSTITUTION

## FORM 15

APPLICATION FOR REGISTRATION OF EYE BANK, CORNEAL  
 TRANSPLANTATION CENTRE, EYE RETRIEVAL CENTRE UNDER  
 TRANSPLANTATION OF HUMAN ORGANS ACT

[See rule 24(1)]

## 1. EYE BANKING:

## A. EYE BANK and institution affiliated Ophthalmic/General Hospital

1. Name

2. Address

3. Government/Private/Voluntary

4. Teaching /Non- teaching

5. IEC for Eye Donation

## B. REMOVAL OF EYE BALLS AND STORAGE:

1. Availability of adequate trained and qualified personnel  
 for removal of whole globe or corneal (annex detail) Yes/No

2. Names, qualification and address of the designated staff who  
 will be doing removal of whole globe/cornea retrieval.  
 (annex details) Yes/No

3. Availability of following as per requirement: Yes/No

a. Whether register maintained for tissue request received  
 from surgeon of corneal transplant centre. Yes/No

b. Telephone arrangement available. Yes/No  
 (Dedicated Telephone Number.....)

c. Transport facility for collecting Eyeballs from outside: Yes/No  
 d. Sets of instruments for removal of whole globe/  
 cornea as per requirement Yes/No

e. Special bottles with stands for preservation of Eye  
 balls/cornea during transit. Yes/No

f. Suitable preservation media Yes/No

g. Biomedical Waste Management. Yes/No

h. Uninterrupted Power supply. Yes/No

**C. Manpower**

1. Incharge/Director (Ophthalmologist)-1
2. Eye Bank Technician-2
3. Eye Donation Counselors (EDC)-2 per attached HCRRP (Hospital Cornea Retrieval Cornea Programme) Hospital, who will be posted at eye Bank.
4. Multi task Staff (MTS)-2

D. Space requirement for eye Banks (400 sqft minimum)

Yes/No

**E. RECORDS**

1. Arrangement for maintaining the records
2. Arrangement for registration of pledges./donors and maintenance of utilization report
3. Computer with internet facility and Printer

Yes/No

Yes/No

Yes/No

**F. EQUIPMENT:**

1. Slit Lamp Biomicroscope-
2. Spectral Microscope for Eye Bank-1
3. Laminar flow (Class II)-1
4. Sterilization facility (In-house or outsourced)
5. Refrigerator with temperature monitoring for preservation of eye balls/Cornea-1

1Yes/No

Yes/No

**G. LABORATORY FACILITIES**

1. Facility for HIV, Hepatitis B and C testing.
2. If no, where do you avail it? Please mention Name and address of institute.
3. Facility for culture and sensitivity of Corneoscleral ring.

Yes/No

Yes/No

**H. RENEWAL OF REGISTRATION:**

Period of renewal 5 years after last registration.

Minimum of 500 corneas to be collected in 5 years.

Maintenance of eye bank standards (as per Guidelines)

**II. EYE RETRIEVAL CENTRE (ERC):****A. RETRIEVAL CENTRE- A Centre affiliated to an Eye Bank**

1. Name
2. Address
3. Government/Private/Voluntary
4. Teaching/Non-teaching
5. Information, Education and Communication Activities for Eye Donation
6. Name of Eye Bank to which ERC is affiliated.

**B. REMOVAL OF EYE BALLS AND STORAGE:**

1. Manpower: Adequate trained and qualified personnel for removal of eye balls/cornea (annex detail):

a. Incharge/Director) -1

b. Technician -1

c. MTS (Multi task Staff) -1

2. Transport facility (or outsource) with storage medium

C. Names, qualification and address of the personnel who will be doing enucleation/ removal of cornea. (annex details)

**D. AVAILABILITY OF FOLLOWING:**

1. Telephone

(Number.....)

2. Ambulance/ vehicle or funds to pay taxi for collecting eyeballs from outside:

3. Sets of instruments for removal of Eye Balls/cornea

4. Special bottles with stands for preservation of Eye balls/cornea during transit:

5. Suitable preservation media

6. Waste Disposal (Biomedical waste Management)

7. Space requirement: Designated area

**E. RECORDS**

1. Arrangement for maintaining the records

**F. EQUIPMENT:**

1. Sterilization facility

2. Refrigerator temperature control 24 hrs for preservation of Eye balls/Cornea. (power back up) - 1

3. The retrieval centre is affiliated with an Eye bank and Eye bank is only authorised to distribute corneas.

**III. CORNEAL TRANSPLANTATION CENTRE**

A. 1. Name of the Transplant Centre/hospital:

2. Address:

3. Government/Private/Voluntary:

4. Teaching/Non-teaching:

5. IEC for Eye Donation: Yes/No

6. Name of the registered Eye Bank for procuring tissue:

**B. Staff details:**

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

(Note: Eye Surgeon's Experience: 3 month post MD/MS/DNB/DO)

2. No. of temporary staff with their designation

3. Trained persons for Keratoplasty and Corneal Transplantation with their names and qualifications: 2 (one Corneal Transplant surgeon should be on the pay roll of the Institute)
- C. Equipment : Slit lamp, Clinical Specular, Keratoplasty or intraocular instruments
- D. OT facilities
- E. Safe Storage facility
- F. Records Registration and follow up
- G. Any other information

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. A Bank draft/cheque of Rs. 10000 for new registration and Rs. 5000/ for renewal of registration drawn in favour of.....is enclosed.

.....  
Head of the Institute  
(Name and designation)

### FORM 16

#### CERTIFICATE OF REGISTRATION FOR PERFORMING ORGAN/TISSUE TRANSPLANTATION/RETRIEVAL AND/OR TISSUE BANKING

[See rule 24(2)]

This is to certify that.....Hospital/Tissue Bank located at..... has been inspected and certificate of registration is granted for performing the organ/tissue retrieval/transplantation/banking of the following organ(s)/tissue(s) (mention the names) under the Transplantation of Human Organs Act, 1994 (42 of 1994):-

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

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

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

Place..... Signature of Appropriate Authority.....  
Seal .....

Date.....

### FORM 17

#### CERTIFICATE OF RENEWAL OF REGISTRATION

(To be given by the appropriate authority on the letter head)

[See rule 25(2)]

This is with reference to the application dated..... from..... (Name of the hospital/tissue bank) for renewal of certificate of registration for performing organ(s)/tissue(s) retrieval/transplantation/banking under the Transplantation of Human Organs Act, 1994 (42 of 1994).

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

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

Place.....  
Date.....

Signature of Appropriate Authority.....  
Seal.....

**FORM 18**

**CERTIFICATE BY THE AUTHORISATION COMMITTEE OF HOSPITAL**

*(If Hospital Authorisation committee is not available then the Authorisation Committee of the district/State) where the transplantation has to take place  
(To be issued on the letter head)*

*(See rules 16 and 23)*

This is to certify that as per application in form-10 for transplantation of.....  
(Name of Organ/tissue) from living donor, other than near Relative/ swap donation cases/all foreigner under the Transplantation of Human Organs Act, 1994 (42 of 1994) submitted on.....by the donor and recipient, whose details and photographs are given below, along with their identifications and verification documents, the case was considered after the personal interview of donor and recipient (if medically fit to be interviewed) and their relatives as applicable by the Authorisation Committee in the meeting held on..... dated.....

**Details of Recipient**

**Details of Donor**

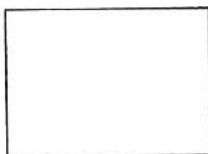
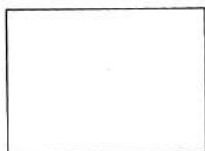
Name.....  
Age.....  
Sex.....  
Father/Husband Name.....  
Address:

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

Hospital Reg. No. ....

Hospital Reg. No. ....

Relation of donor with Recipient .....



**Recipient**

**Donor**

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

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

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

.....

(Member)	(Member)	(Member)	(Member)
Name and Designation	Name and Designation	Name and Designation	Name and Designation
(Member)	(Member)		(Sign of Chairman with stamp)
Health Secretary or Nominee	DHS or Nominee		Name and Designation

Date and place .....

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

**FORM 19**

**CERTIFICATE BY COMPETENT AUTHORITY**

[as defined at rule 2(c)] For Indian near relative, other than spouse, cases (In case of spousal donor, Form 6 will be applicable)

[See rule 53(3)(c)]

(Format for the decision of Competent Authority)

This is to certify that as per application in Form-11 for transplantation of.....(Name of Organ or Tissue) from living donor who is a near relative of the recipient under the Transplantation of Human Organs Act, 1994 (42 of 1994), submitted on ..... by the donor and recipient, whose details and photographs are given below, along with their identifications and verification documents, the case was considered after the personal interview of donor and recipient (if medically fit to be interviewed) by the competent authority in the meeting held on.....

Details of Recipient

Name.....  
Age.....  
Sex.....  
Father or Husband Name.....

Address:

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

Hospital Reg. No. ....

Relation of donor with Recipient.....

Details of Donor

Name: .....  
Age.....  
Sex.....  
Father or Husband Name.....

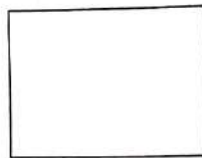
Address:

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

Hospital Reg. No. ....



Recipient



Donor

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

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

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

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

(Signature and stamp of competent authority)

Date and place.....

FORM 20

VERIFICATION CERTIFICATE IN RESPECT OF DOMICILE STATUS OF RECIPIENT OR DONOR

[To be issued by tehsildar or any other authorised officer for the purpose (required only for the donor-other than near relative or recipient if they do not belong to the state where transplant hospital identified for operation is located)]

(See rule 14)

PART I

(To be filled by applicant donor or recipient separately in triplicate)

In reference to application for verification of domicile status for donation of.....(Name of Organ/Tissue) from living donor (other than near relative) or recipient under Transplantation of Human Organ Act, 1994 (42 of 1994), submitted on (date) .....by the applicant donor or recipient, with following details and photograph, along with his or her identification and domicile status for verification.

Details of Applicant Recipient or Donor

Name.....

Age.....

Sex.....

Father or Husband Name.....

.....

Address:

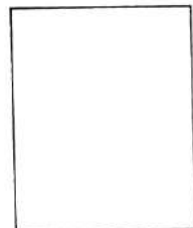
.....

.....

.....

Hospital Reg. No. ....

.....



(Recent Photo of Applicant must be signed by him or her across the photo after affixing it)

The detail of my donor or recipient are as under and I have enclosed his or her self-signed recent photograph:

Name.....

Age.....

Sex.....

Father or Husband Name.....

.....

Address:

.....  
.....

Hospital Reg. No. ....  
.....

Signature of Applicant

Enclosure: Self signed copy of the donor or recipient for the applicant (to be enclosed)

**PART II**

**(To be filled by the certificate issuing authority):**

*The above request has been examined and it is certified that the domicile status of the applicant donor or recipient mentioned as above has been verified as under:*

Name..... Son or Daughter or Wife of.....  
resident of village or ward....., Tehsil or Taluka..... District.....  
State or UT.....

and found correct or incorrect

.....  
.....

Date.....

Place.....

.....  
Authorised Signatory

.....  
Name and Designation

Office Stamp

Reference No

2. The authorised signatory will hand over this verification certificate to the applicant or his or her representative for submission to the Chairperson of the Authorisation Committee of the hospital or district or state (as the case may be), where transplantation has to take place.

3. The authorised signatory shall keep one copy of the above verification certificate for his records and send a copy to the Secretary, Health and Family Welfare of the State Government (Attention Appropriate authority for organ transplant) for information.

4. In case of any suspicion of organ trading, the authorised signatory mentioned above or Appropriate Authority of the state may inform police for making enquiry and taking necessary action as per the Transplantation of Human Organs Act, 1994 (42 of 1994).

**FORM 21**

**CERTIFICATE OF RELATIONSHIP BETWEEN DONOR AND RECIPIENT IN CASE OF FOREIGNERS**

(To be issued by the Embassy concerned)

[See rule 20(a)]

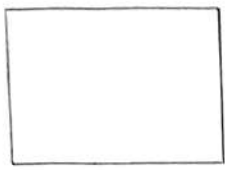
The embassy of..... (Name of Country) in India, is in receipt of an application received from..... (Name of Organ donor and recipient) on ..... (Date) recommended by..... (Name of Government Department of country of origin) for facilitation of donation of.....(Name of Organ or Tissue) from living donor..... (Name of donor) to the recipient.....(Name of recipient) for therapeutic purposes under the Transplantation of Human Organ Act, 1994 (42 of 1994). The details of donor and recipient and photographs are as given below.

Details of Recipient

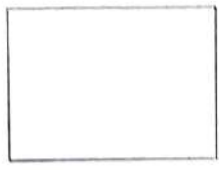
Name.....  
Age.....  
Sex.....  
Father or Husband Name.....  
.....  
Address:  
.....  
.....  
.....

Details of Donor

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



Recipient



Donor

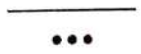
(Photo of recipient and donor must be signed and stamped across the photo after affixing)

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

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

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

Date.....  
Place.....



# List of Universal's Bare Acts & Rules

• Latest • Accurate • Up-to-date • Reasonably Priced

## CIVIL, CRIMINAL, COMMERCIAL, LABOUR & SERVICES

### A

- A-20. Aadhaar (Targeted Delivery of Financial and other Subsidies, Benefits and Services) Act, 2016 with Order and Regulations
- A-17. Actuaries Act, 2006 along with Allied Rules
- A-1. Administration of Evacuee Property Act, 1950 with Rules, 1950
- A-2. Administrative Tribunals Act, 1985 along with CAT (Procedure) Rules, 1987, CAT Rules of Practice, 1993 and Contempt of Courts (C.A.T.) Rules, 1992
- A-22. Admiralty (Jurisdiction and Settlement of Maritime Claims) Act, 2017
- A-3. Advocates Act, 1961
- A-4. Advocates' Welfare Fund Act, 2001
- A-5. Aircraft Act, 1934 along with allied Rules
- A-6. Air Force Act, 1950 along with allied Act and Rules
- A-7. Air (Prevention and Control of Pollution) Act, 1981 along with Rules, 1982
- A-15. Airport Authority of India Act, 1994 along with Rules and Regulations
- A-8. Ancient Monuments and Archaeological Sites and Remains Act, 1958 along with allied Acts & Rules
- A-21. Anti-Hijacking Act, 2016 with Rules, 2017
- A-9. Antiquities and Art Treasures Act, 1972 along with Rules, 1973
- A-10. Apprentices Act, 1961 along with allied Act and Rules
- A-11. Arbitration and Conciliation Act, 1996 along with Scheme, 1996
- A-19. Architects Act, 1972, along with Rules and Regulations
- A-12. Armed Forces (Special Power) Act, 1958 along with allied Acts
- A-18. Armed Forces Tribunal Act, 2007 along with allied Rules
- A-13. Arms Act, 1959 along with Rules, 2016
- A-14. Army Act, 1950 with Rules, 1954
- A-16. Atomic Energy Act, 1962 with allied Rules

### B

- B-1. Bankers' Books Evidence Act, 1891
- B-2. Banking Companies (Acquisition and Transfer of Undertakings) Act, 1970 along with allied Act and Schemes
- B-3. Banking Regulation Act, 1949 along with allied Rules and Scheme
- B-4. Bar Council of India Rules along with allied Rules and Advocates Act, 1961
- B-5. Beedi and Cigar Workers (Conditions of Employment) Act, 1966 along with Welfare Cess and Welfare Fund Act and Rules
- B-6. Prohibition of Benami Property Transactions Act, 1988 [Earlier Known as Benami Transactions (Prohibition) Act, 1988] with Rules, 2016
- B-7. Biological Diversity Act, 2002 along with Rules, 2004
- B-13. Black Money (Undisclosed Foreign Income and Assets) and Imposition of Tax Act, 2015
- B-8. Boilers Act, 1923 along with allied Rules
- B-9. Bonded Labour System (Abolition) Act, 1976 along with Rules, 1976
- B-10. Border Security Force Act, 1968 along with allied Rules

- B-11. Building and Other Construction Workers (Regulation of Employment and Conditions of Service) Act, 1996 along with Rules, 1998 with Cess Act and Rules
- B-12. Bureau of Indian Standards Act, 1986 along with Rules and Regulations
- B-14. Bureau of Indian Standards Act, 2016

### C

- C-1. Cable Television Networks (Regulation) Act, 1995 along with allied Rules & Regulations
- C-2. Cantonments Act, 2006 with allied Rules
- C-4. Carriage by Air Act, 1972 *see* Carrier Laws (Land • Sea • Air)
- C-44. Carriage by Road Act, 2007
- C-4. Carriage of Goods by Sea Act, 1925 *see* Carrier Laws (Land • Sea • Air)
- C-4. Carriers Act, 1865 *see* Carrier Laws (Land • Sea • Air)
- C-4. Carrier Laws (Land • Sea • Air)
- C-5. Cattle Trespass Act, 1871
- C-63. Census Act, 1948 with Rules, 1990
- C-43. Central Educational Institutions (Reservation in Admission) Act, 2006
- C-48. Central Electricity Authority Regulations
- C-49. Central Electricity Regulatory Commission Rules and Regulations
- C-6. Central Excise Act, 1944
- C-7. Central Industrial Security Force Act, 1968 along with Rules
- C-8. Central Reserve Police Force Act, 1949 along with Rules, 1955
- N-6. Central Road and Infrastructure Fund Act, 2000 *see* National Highways Act, 1956 along with allied Acts & Rules
- C-9. Central Sales Tax Act, 1956 along with Rules, 1957
- C-10. Central Vigilance Commission Act, 2003
- C-11. Charitable and Religious Trusts Act, 1920 along with Charitable Endowments Act, 1890 and Religious Endowments Act, 1863
- C-11. Charitable Endowments Act, 1890 *see* Charitable and Religious Trusts Act, 1920
- C-52. Chartered Accountants Act, 1949
- C-42. Chemical Weapons Convention Act, 2000 along with allied Rules
- C-12. Child and Adolescent Labour (Prohibition and Regulation) Act, 1986 along with Rules, 1988 and Children (Pledging of Labour) Act, 1933
- C-13. Child Marriage Restraint Act, 1929
- C-14. Chit Funds Act, 1982
- C-15. Christian Marriage Act, 1872
- C-16. Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 along with allied Rules
- C-17. Cine-Workers and Cinema Theatre Workers (Regulation of Employment) Act, 1981 along with Rules, 1984, Welfare Cess Act, 1981 along with Rules, 1984, Welfare Fund Act, 1981 and Rules, 1984
- C-18. Cinematograph Act, 1952 along with Cinematograph (Certification) Rules, 1983
- C-19. Citizenship Act, 1955 along with Citizenship Rules, 2009
- C-20. Civil Defence Act, 1968 along with Rules and Regulations
- C-50. Civil Liability for Nuclear Damage Act, 2010 with Rules, 2011

- C-17. Clinical Establishments (Registration and Regulation) Act, 2010 with Rules, 2012
- C-21. Code of Civil Procedure, 1908
- C-23. Code of Civil Procedure, 1908 with State Amendments (Hb)
- C-45. Code of Civil Procedure, 1908 with State & High Court Amendments with Letters Patent (Hb)
- C-24. Code of Criminal Procedure, 1973
- C-26. COFEPOSA Act, 1974 and SAFEEMFOP Act, 1976 with Rules, 2006
- C-51. Coinage Act, 2011
- C-59. Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act, 2015
- C-46. Collection of Statistics Act, 2008 with Rules, 2011
- C-41. Commission for Protection of Child Rights Act, 2005 along with Rules
- C-27. Commissions of Inquiry Act, 1952 along with Rules, 1972
- C-28. Commission of Sati (Prevention) Act, 1987 along with Rules
- C-29. Companies Act, 2013
- C-57. Companies Act, 2013 with allied Companies Rules along with Companies (Removal of Difficulties) Orders
- C-58. Companies (Indian Accounting Standards) Rules, 2015
- C-53. Company Secretaries Act, 1980
- C-30. Competition Act, 2002 with allied Rules
- C-31. Constitution of India
- C-33. Consumer Protection Act, 1986 along with Rules, 1987 and Regulations, 2005
- C-34. Contempt of Courts Act, 1971 along with Rules to Regulate Proceedings for Contempt of the Supreme Court, 1975
- C-35. Contract Act, 1872
- C-36. Contract Labour (Regulation and Abolition) Act, 1970 along with Rules, 1971
- N-6. Control of National Highways (Land and Traffic) Act, 2002 see National Highways Act, 1956
- C-37. Copyright Act, 1957 along with Rules, 1958 and International Copyright Order, 1999
- C-54. Cost and Works Accountants Act, 1959
- C-38. Court Fees Act, 1870
- C-39. Credit Information Companies (Regulation) Act, 2005 along with Rules and Regulations, 2006
- C-55. Criminal Law (Amendment) Acts and Ordinances
- C-56. Criminal Law (Amendment) Act, 2013
- C-40. Customs Act, 1962
- M-18. Cutchi Memos Act, 1938 see Muslim laws

#### D

- D-1. Dangerous Machines (Regulation) Act, 1983 along with Rules, 2007
- D-11. Dentists Act, 1948 with allied Rules
- D-2. Depositories Act, 1996 along with Rules, 1998
- D-10. Designs Act, 2000 along with Rules, 2001
- D-13. Disaster Management Act, 2005 along with allied Rules
- M-18. Dissolution of Muslim Marriages Act, 1939 see Muslim laws
- D-4. Divorce Act, 1969
- D-5. Dock Workers (Regulation of Employment) Act, 1948 along with Rules, 1962, Advisory Committee Rules, 1962, Safety, Health and Welfare Act, 1966, Regulation of Employment (Inapplicability of Major Ports) Act, 1997
- D-6. Dowry Prohibition Act, 1961 along with Rules
- D-12. Dramatic Performances Act, 1976
- D-7. Drugs & Cosmetics Act, 1940
- D-8. Drugs & Cosmetics Act, 1940 along with Rules, 1945
- D-9. Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 along with Rules, 1955
- D-13. Drugs (Prices Control) Order, 2013

#### E

- E-1. Easements Act, 1882
- E-2. Electricity Act, 2003 along with Rules, 2005 and allied Rules and Orders
- E-3. Electricity (Supply) Act, 1948
- E-5. Electricity Rules, 2005 along with allied Rules and Orders
- E-6. Emblems and Names (Prevention of Improper use) Act, 1950 along with allied Act and Rules
- E-7. Emigration Act, 1963 along with Rules, 1963
- E-19. Employee's Compensation Act, 1923 along with allied Rules
- E-8. Employees' Provident Funds and Miscellaneous Provisions Act, 1952, along with E.P.F. Scheme, 1952 with allied Schemes, Rules and Forms
- E-9. Employees' Provident Funds and Miscellaneous Provisions Act, 1952
- E-10. Employees' State Insurance Act, 1948 along with Rules and Regulations
- E-11. Employment Exchanges (Compulsory Notification of Vacancies) Act, 1959 along with Rules, 1960
- E-12. Employers' Liability Act, 1938
- E-20. Enemy Property Act, 1968 along with Enemy Property Rules, 2015
- E-13. Energy Conservation Act, 2001 along with allied Rules
- E-14. Environment (Protection) Act, 1986 along with allied Rules
- E-15. Equal Remuneration Act, 1976 along with allied Rules
- E-16. Essential Commodities Act, 1955 along with allied Acts
- E-17. Evidence Act, 1872
- E-18. Explosives Act, 1984 along with The Explosive Substances Act, 1908 and The Explosives Rules, 2008

#### F

- F-1. Factories Act, 1948
- F-2. Family Courts Act, 1984
- F-3. Fatal Accidents Act, 1985
- F-4. Fiscal Responsibility and Budget Management Act, 2003 along with Rules, 2004
- P-24. Flag Code of India, 2002 see Prevention of Insult to National Honour Act, 1971
- F-15. Food Safety and Standards Act, 2006 along with allied Rules, Regulations and Order
- F-5. Foreign Contribution (Regulation) Act, 2010 along with Rules and Regulations
- F-6. Foreign Exchange Management Act, 1999
- F-7. Foreign Exchange Management Act, 1999 along with allied Rules and Regulations & Orders
- F-8. Foreign Exchange Regulation Act, 1973 along with Rules, 1974
- F-9. Foreign Marriage Act, 1969 along with Foreign Marriage Rules, 1970
- F-10. Foreign Trade (Development and Regulation) Act, 1992 along with Rules, 1993
- F-11. Foreigners Act, 1946 along with Foreigners Orders, 1948 with Registration of Foreigners Act, 1939 and Rules, 1992
- F-12. Forest Act, 1927 along with The Forest (Conservation) Act, 1980 and Rules, 2003 with The Compensatory Afforestation Fund Act, 2016
- F-13. Forward Contracts (Regulation) Act, 1952
- F-14. Freedom of Information Act, 2002
- F-17. Fugitive Economic Offenders Act, 2018

**G**

- G-1. Gas Cylinders Rules, 2016 along with allied Rules and Orders
- G-2. General Clauses Act, 1897
- G-3. General Insurance Business (Nationalisation) Act, 1972 *see* Insurance Act, 1938
- G-5. Geographical Indications of Goods (Registration and Protection) Act, 1999 along with Rules, 2002
- G-9. Goods and Services Tax Acts with allied Orders (Containing 4 Acts)
- G-10. Goods and Services Tax Acts with allied Rules and Orders
- G-7. Government Securities Act, 2006 along with Regulations
- G-8. Gram Nyayalayas Act, 2008
- G-6. Guardians and Wards Act, 1890

**H**

- H-1. Hindu Laws (Containing 5 Acts)
- H-2. Hindu Adoption & Maintenance Act, 1956
- H-12. Hindu Disposition of Property Act, 1916 *see* Hindu Laws (Containing 5 Acts)
- H-3. Hindu Marriage Act, 1955
- H-4. Hindu Minority & Guardianship Act, 1956
- H-5. Hindu Succession Act, 1956
- H-6. Hire-Purchase Act, 1972 along with Hire-Purchase (Repeal) Act, 2005

- I-1. Identification of Prisoners Act, 1920
- I-2. Immoral Traffic (Prevention) Act, 1956
- I-18. Income Tax Act, 1961
- I-3. Indecent Representation of Women (Prohibition) Act, 1986 along with Rules, 1987
- I-4. Indian Penal Code, 1860 with Classifications of offences and State Amendments
- I-21. Indo-Theretan Border Police Force Act, 1992 along with Rules, 1994
- I-6. Industrial Employment (Standing Orders) Act, 1948 along with Rules, 1946
- I-7. Industrial Disputes Act, 1947 along with (Central) Rules, 1957 and allied Rules
- I-8. Industries (Development and Regulation) Act, 1951
- I-9. Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 along with Rules, 1993
- I-10. Information Technology Act, 2000 along with Rules & Regulations
- I-19. Inland Vessels Act, 1917 with Rules, 2016
- I-11. Insecticides Act, 1968 along with Rules and Order
- I-23. Insolvency and Bankruptcy Code, 2016 with Rules, Regulations and Order
- I-12. Insurance Act, 1938 along with allied Act and Rules
- I-13. Insurance Regulatory and Development Authority Act, 1999 along with allied Rules and Regulations
- I-14. Insurance Regulatory and Development Authority Act, 1999
- I-15. Inter-State Migrant Workmen (Regulation of Employment and Conditions of Service) Act, 1979 along with Rules, 1980
- I-16. Interest Act, 1978
- I-17. Interest on Delayed Payments to Small Scale and Ancillary Industrial Undertakings Act, 1993

**J**

- J-1. Juvenile Justice (Care and Protection of Children) Act, 2015 along with Juvenile Justice (Care and Protection of Children) Act, 2000 and Rules, 2016

**K**

- M-18. Kazis Act, 1880 *see* Muslim laws (Containing 8 Acts & Rules)

**L**

- L-1. Land Acquisition Act, 1894
- L-9. Land Ports Authority of India Act, 2010
- L-7. Legal Metrology Act, 2009 along with Allied Rules
- L-2. Legal Services Authorities Act, 1987 along with allied Rules and Regulations
- L-3. Life Insurance Corporation Act, 1956 along with Rules, 1956
- L-4. Limitation Act, 1963
- L-6. Limited Liability Partnership Act, 2008 along with Notification and Allied Rules
- L-8. Limited Liability Partnership Act, 2008
- L-10. Lokpal and Lokayuktas Act, 2013
- L-5. Lotteries (Regulation) Act, 1998

**M**

- M-26. Mahatma Gandhi National Rural Employment Guarantee Act, 2005
- M-22. Major Port Trusts Act, 1963
- M-1. Majority Act, 1875 along with Guardian and Wards Act, 1890
- M-24. Maintenance and Welfare of Parents and Senior Citizens Act, 2007
- M-2. Maternity Benefit Act, 1961 along with Rules, 1963
- M-3. Medical Council Act, 1956 along with Allied Act, Rules and Regulations
- M-4. Medical Termination of Pregnancy Act, 1971 along with Rules and Regulations
- M-5. Medicine Central Council Act, 1970
- M-6. Medicinal and Toilet Preparations (Excise Duties) Act, 1955
- M-7. Mental Health Act, 1987 along with Central Mental Health Authority Rules, 1990 and State Mental Health Rules, 1990
- M-27. Mental Healthcare Act, 2017
- M-8. Merchant Shipping Act, 1958 along with allied Rules
- M-25. Metro Railways (Construction of Works) Act, 1978 *see* Metro Railways (Operation and Maintenance) Act, 2002
- M-25. Metro Railways (Operation and Maintenance) Act, 2002 along with allied Rules and Metro Railways (Construction of Works) Act, 1978
- M-21. Micro, Small and Medium Enterprises Development Act, 2006 along with allied Act and Rules
- M-10. Mineral Concession Rules, 1960 *see* Mines & Minerals (Development and Regulation) Act, 1957
- M-9. Mines Act, 1952 along with allied Rules
- M-10. Mines and Minerals (Regulation and Development) Act, 1957 along with Mineral Concession Rules, 1960 and allied Rules
- M-11. Minimum Wages Act, 1948 along with Central Rules, 1950
- M-12. Monopolies and Restrictive Trade Practices Act, 1969
- M-13. Motor Transport Workers Act, 1961
- M-14. Motor Vehicles Act, 1988
- M-15. Motor Vehicles Rules, 1989 along with allied Material
- M-16. Multimodal Transportation of Goods Act, 1993 along with allied Rules
- M-17. Multi-State-Co-operative Societies Act, 2002 along with Rules, 2002
- M-18. Muslim Laws (Containing 8 Acts & Rules)
- M-19. Muslim Personal Law (Shariat) Application Act, 1937

- M-20. Muslim Women (Protection of Rights on Divorce) Act, 1986 along with Rules, 1986
- M-18. Mussalman Wakf Act, 1923, Mussalman Wakf Validating Act, 1913 & 1930 **see** Muslim Laws
- N**
- N-1. Narcotic Drugs & Psychotropic Substances Act, 1965 along with allied Act, Rules and Order
- N-18. National Anti-Doping Agency (NADA) Anti-Doping Rules, 2015
- N-2. National Commission Acts [Containing 5 Acts-Women Act, 1990, Minorities Act, 1992, Education Institutions Act, 2004, Backward Classes Act, 1993, Satala Karamcharis Act, 1993 and allied Information]
- N-3. National Commission for Minority Educational Institutions Act, 2004 along with allied Rules, 2006
- N-6. National Food Security Act, 2013
- N-16. National Highways Act, 1956 along with allied Acts & Rules
- N-6. National Highway Authority of India Act, 1988 **see** National Highways Act, 1956
- N-15. National Green Tribunal Act, 2010 with Order, 2010 alongwith The National Green Tribunal (Practice and Procedure) Rules, 2011
- N-14. National Investigation Agency Act, 2008
- N-17. National Judicial Appointment Commission Act, 2014
- M-26. National Rural Employment Guarantee Act, 2005 with allied Rules
- N-7. National Security Act, 1980
- N-13. National Security Guard Act, 1986
- N-12. National Tax Tribunal Act, 2005
- P-9. National Trust for Welfare of Persons with Autism, Cerebral Palsy, Mental Retardation with Multiple Disabilities Act, 1999 **see** Persons with Disabilities (Equal Opportunities.....) Act, 1995
- N-19. National Waterways Act, 2016
- N-8. Navy Act, 1957
- N-9. Negotiable Instruments Act, 1881
- N-10. Notaries Act, 1952 along with Rules, 1956
- O**
- O-1. Oaths Act, 1969
- O-2. Official Languages Act, 1963
- O-3. Official Secrets Act, 1923
- P**
- P-1. Partition Act, 1893
- P-2. Parsi Marriage and Divorce Act, 1936
- P-3. Partnership Act, 1932
- P-4. Passports Act, 1967 along with Rules, 1980
- P-5. Patents Act, 1970 along with Rules, 2003
- P-46. Payment and Settlement Systems Act, 2007
- P-6. Payment of Bonus Act, 1965 along with Rules, 1975
- P-7. Payment of Gratuity Act, 1972 along with Rules, 1972
- P-8. Payment of Wages Act, 1936 along with (Procedure) Rules, 1937
- P-9. Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995 along with Rules, 1996 and National Trust for Welfare of Persons with Disabilities Act, 1999 with Rules, 2000
- P-10. Petroleum Act, 1934 along with Rules, 2002
- P-11. Pharmacy Act, 1948
- P-12. Places of Worship (Special Provisions) Act, 1991
- P-13. Police Acts (6 Acts in 1)
- P-13. Police (Incitement of Disaffection) Act, 1922 **see** Police Acts (6 Acts in 1)
- P-13. Police Forces (Restriction of Rights) Act, 1966 **see** Police Acts
- P-14. Post Office Act, 1898

- P-15. Powers of Attorney Act, 1882
- P-16. Prasar Bharati (Broadcasting Corporation of India) Act, 1990
- P-17. Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 along with Rules
- P-18. Press & Registration of Books Act, 1867 along with Rules & Order
- P-19. Press Council Act, 1978 along with allied Rules and Regulations
- E-16. Prevention of Blackmarketing and Maintenance of Supplies of Essential Commodities Act, 1955 **see** Essential Commodities Act, 1955
- P-20. Prevention of Corruption Act, 1988
- P-21. Prevention of Cruelty to Animals Act, 1960 along with allied Rules
- P-22. Prevention of Damage to Public Property Act, 1984 along with The Delhi Prevention of Defacement of Property Act, 2007
- P-23. Prevention of Food Adulteration Act, 1954 along with Rules, 1955
- P-27. Prevention of Illicit Traffic in NDPS Act, 1988 **see** Preventive Detention Laws
- P-24. Prevention of Insults to National Honour Act, 1971 along with Flag Code of India, 2002 and Orders Relating to the National Anthem of India
- P-25. Prevention of Money Laundering Act, 2002 along with allied Rules
- P-27. Preventive Detention Laws (Containing 4 Acts)
- P-29. Prisoners Acts (Containing 6 Acts & Rules)
- P-29. Prisoners (Attendance in Courts) Act, 1955 **see** Prisoners Acts
- P-30. Private Security Agencies (Regulation) Act, 2005 with Rules, 2006
- P-31. Prize Chits and Money Circulation Schemes (Banning) Act, 1978
- P-32. Probation of Offenders Act, 1958
- B-6. Prohibition of Benami Property Transactions Act, 1988 (Earlier Known as Benami Transactions (Prohibition) Act, 1968) with Rules, 2016
- P-45. Prohibition of Child Marriage Act, 2006 along with Allied Acts
- P-47. Protection of Children from Sexual Offences Act, 2012
- P-33. Protection of Civil Rights Act, 1955 along with Rules, 1977
- P-34. Protection of Human Rights Act, 1993 along with Regulations and Rules
- P-35. Protection of Plant Varieties and Farmers' Rights Act, 2001 along with Rules & Regulations
- P-44. Protection of Women from Domestic Violence Act, 2005 along with Rules, 2006
- P-36. Provincial Insolvency Act, 1920
- P-37. Provincial Small Cause Courts Act, 1887
- P-38. Public Gambling Act, 1867
- P-39. Public Liability Insurance Act, 1991 along with Rules, Forms & Notification
- P-40. Public Premises (Eviction of Unauthorised Occupants) Act, 1971 along with Rules, 1971
- P-42. Public Records Act, 1993 along with Rules, 1997
- P-43. Public Servants (Inquiries) Act, 1850
- R**
- R-1. Railways Act, 1989 along with allied Acts and Rules
- R-13. Railway Claims Tribunal Act, 1987 along with allied Rules
- R-2. Railway Protection Force Act, 1957 along with Rules, 1987
- R-17. Real Estate (Regulation and Development) Act, 2016 with Allied Order
- R-16. Real Estate (Regulation and Development) Act, 2016 with Allied Order and Rules for UTs and NCT of Delhi

- R-3. Recovery of Debt and Bankruptcy Act, 1993  
 R-4. Registration Act, 1908  
 R-5. Registration of Births and Deaths Act, 1969 and The Births, Deaths and Marriages Registration Act, 1886  
 R-11. Registration of Foreigners Act, 1939 along with Rules, 1992 *see* Foreigners Act, 1946  
 R-12. Religious Endowments Act, 1963 *see* Charitable and Religious Trusts Act, 1920  
 R-13. Representation of the People Act, 1950 and Representation of the People Act, 1951 along with allied Act & Rules  
 R-7. Renovation of Prisoners Act, 2003 along with allied Acts  
 R-12. Requisitioning and Acquisition of Immovable Property Act, 1952  
 R-8. Research and Development Cess Act, 1986 along with Rules, 1996  
 R-10. Reserve Bank of India Act, 1934; Specified Bank Notes (Cessation of Liabilities) Act, 2017 along with allied Rules  
 R-14. Right of Children to Free and Compulsory Education Act, 2009  
 R-18. Rights of Persons with Disabilities Act, 2016  
 R-15. Right to Fair Compensation and Transparency in Land Acquisition, Rehabilitation and Resettlement Act, 2013  
 R-9. Right to Information Act, 2005 along with allied Rules and Regulations  
 R-11. Road Transport Corporation Act, 1950
- S**
- S-26. SAFEFOP Act, 1976 *see* COFEPOSA Act, 1974  
 S-1. Sale of Goods Act, 1930  
 S-2. Sales Promotion Employers (Conditions of Service) Act, 1976 along with Rules, 1976  
 S-23. Sarais Act, 1987  
 S-26. Saraswati Seema Bai Act, 2007 along with Rules, 2009  
 S-3. Scheduled Castes and Scheduled Tribes (Prevention of Atrocities) Act, 1989 along with Rules  
 S-25. Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006  
 S-4. Securities and Exchange Board of India Act, 1992 with SEBI (Issue of Capital and Disclosure Requirements) Regulations, 2009  
 S-5. Securities Contracts (Regulation) Act, 1956 along with Allied Rules  
 S-6. Securitisation and Reconstruction of Financial Assets and Enforcement of Security Interest Act, 2002 along with Allied Rules and Orders  
 S-7. Seeds Act, 1966 along with Rules, & Order  
 S-8. Semiconductor Integrated Circuits Layout-Design Act, 2000 along with Rules, 2001  
 S-27. Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act, 2013  
 S-9. Sick Industrial Companies (Special Provisions) Act, 1985 along with BIFR and other allied Rules  
 S-10. Slum Areas (Improvement and Clearance) Act, 1956 along with Rules, 1957  
 S-11. Small Industries Development Bank of India, 1989 along with Rules, 2003  
 S-12. Societies Registration Act, 1860 with State Amendments  
 S-13. Special Economic Zones Act, 2005 along with Rules, 2006  
 S-14. Special Marriage Act, 1954  
 S-24. Special Protection Group Act, 1988  
 S-15. Specific Relief Act, 1963

- R-10. Specified Bank Notes (Cessation of Liabilities) Act, 2017 along with allied Rules *see* Reserve Bank of India Act, 1934  
 S-16. Stamp Act, 1899  
 S-17. Standards of Weights and Measures Act, 1976 along with allied Rules and Act, 1985  
 P-13. State Armed Police Forces (Extension of laws) Act, 1992 *see* Police Act  
 S-18. State Bank of India Act, 1955  
 S-19. State Financial Corporations Act, 1951 along with Rules, 2003  
 S-28. Street Vendors (Protection of Livelihood and Regulation of Street Vending) Act, 2014  
 S-20. Succession Act, 1925  
 S-21. Suits Valuation Act, 1887 with State Amendments  
 S-22. Supreme Court Rules, 2013 along with Regulations Regarding Advocate-on-Record Examination and Rules to Regulate Proceedings for Contempt of Supreme Court, 1975
- T**
- T-8. Tarni Nadu Ancient and Historical Monuments and Archaeological Sites and Remains Act, 1986 *see* Ancient Monuments and Archaeological Sites and Remains Act, 1958  
 T-1. Telecom Regulatory Authority of India Act, 1997  
 T-11. Telecom Regulatory Authority of India Act, 1997 with allied Rules & Regulations  
 T-2. Telegraph Act, 1885 along with allied Rules  
 T-10. Terrorist Affected Areas (Special Courts) Act, 1984  
 T-3. Trade Marks Act, 1999  
 T-4. Trade Marks Act, 1999 along with allied Rules  
 T-5. Trade and Merchandise Marks Act, 1958  
 T-6. Trade Unions Act, 1926 along with Central Trade Unions Regulations, 1938  
 P-29. Transfer of Prisoners Act, 1950 *see* Prisoners Acts  
 T-7. Transfer of Property Act, 1882  
 T-8. Transplantation of Human Organs and Tissues Act, 1994 along with Rules, 1995  
 T-9. Tustis Act, 1882
- U**
- U-1. Unlawful Activities (Prevention) Act, 1967 along with Rules, 1968  
 U-3. Unorganised Workers' Social Security Act, 2008 along with Rules, 2009  
 U-2. Urban Land (Ceiling and Regulation) Act, 1976 along with Repeal Act, 1999
- W**
- W-1. Waqf Act, 1995 along with Central Waqf Council Rules, 1998  
 W-9. Warehousing (Development and Regulation) Act, 2007 with allied Rules and Regulations  
 W-2. Water (Prevention and Control of Pollution) Act, 1974 along with Rules, 1975, Cess Act, 1977 and Cess Rules, 1978  
 W-3. Wealth-tax Act, 1957  
 W-4. Weapons of Mass Destruction and their Delivery Systems (Prohibition of Unlawful Activities) Act, 2005  
 W-5. Weekly Holidays Act, 1942  
 W-10. Whistle Blowers Protection Act, 2014  
 W-6. Wild Life (Protection) Act, 1972 along with allied Rules  
 W-7. Working Journalists and Other Newspaper Employees (Conditions of Service) and Miscellaneous Provisions Act, 1955 along with allied Acts & Rules
- Y**
- Y-1. Young Persons (Harmful Publications) Act,

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