THE TELANGANA TRANSPLANTATION OF HUMAN ORGANS ACT, 1995.

(ACT NO. 24 OF 1995) ARRANGEMENT OF SECTIONS

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THE TELANGANA TRANSPLANTATION OF HUMAN ORGANS ACT, 1995.¹

ACT No.24 OF 1995.

CHAPTER - I Preliminary

1. (1) This Act may be called the ²Telangana Transplantation of Human Organs Act, 1995.

²Telangana Short title, extent and commencement.

- (2) It extends to the whole of the State of ²Telangana.
- (3) It shall be deemed to have come into force on the 9th March, 1995.
- 2. In this Act, unless the context otherwise requires,—

Definitions.

- (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 sub-section (4) of section 9;

^{1.} The Andhra Pradesh Transplantation of Human Organs Act, 1995 received the assent of the Governor on the 22nd April, 1995. The said Act in force in the combined State, as on 02.06.2014, has been adapted to the State of Telangana, under section 101 of the Andhra Pradesh Reorganisation Act, 2014 (Central Act 6 of 2014) vide. the Notification issued in G.O.Ms.No.34, Health, Medical & Family Welfare (D1) Department, dated 25.05.2016.

^{2.} Substituted by G.O.Ms.No.34, Health, Medical & Family Welfare (D1) Department, dated 25.05.2016.

(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 in full consciousness after being explained the full consequences of removing the organ by the Doctor who would be removing the organ, the removal of any of his human organs for therapeutic purposes under sub-section (1) or subsection (2) of section 3;
 - (g) "Government" means the State Government;
- (h) "hospital" includes a nursing home, clinic, medical Centre, medical or teaching institution for therapeutic purposes and other like institution;
- (i) "human organ" means any part of a human body consisting or a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body;
- (j) "near relative" means spouse, son, daughter, father mother, brother or sister;
- (k) "notification" means a notification published in the ³Telangana Gazette;

^{3.} Substituted by G.O.Ms.No.34, Health, Medical & Family Welfare (D1) Department, dated 25.05.2016.

(I) "payment" means payment in money or money's worth but does not include any payment for defraying or reimbursing,-

- (i) the cost of removing, transporting or preserving the human organ to be supplied; or
- (ii) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any human organ from his body;
- (m) "prescribed" means prescribed by rules made under this Act;
- (n) "recipient" means a person into whom any human organ is, or is proposed to be, transplanted;
- (o) "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, and who is enrolled on a State Medical Register as defined in clause (k) of that section:

Central Act 102 of 1956.

- (p) "therapeutic purposes" means systematic treatment of any disease or the measures to improve health according to any particular method or modality; and
- (q) "transplantation" means the grafting of any human organ from any living person or deceased person to some other living person for therapeutic purposes.

CHAPTER – II AUTHORITY FOR THE REMOVAL OF HUMAN ORGANS

Authority for removal of human organs.

- 3. (1) Any donor may, in such manner and subject to such conditions as may be prescribed, authorise the removal, in full consciousness and after being explained the full consequences of removing the organ by the doctor who would be removing the organ in presence of his spouse, if living, and in the presence of daughter or son or sister or brother in the same order and in the presence of mother or father in case of un-married persons before his death, of any human organ of his body for therapeutic purposes.
- (2) If any donor had, in writing and in presence of two or more witnesses spouse if living, and in the presence of daughter or son or sister or brother in that order and in the presence of mother or father or sister or brother in the case of un-married persons unequivocally authorised at any time before his death, the removal of any human organ of his body, after his death, for therapeutic purposes, the person lawfully in possession of the dead body of the donor shall unless he has any reason to believe that the donor had subsequently revoked the authority aforesaid grant to a registered medical pracitioner all reasonable facilities for the removal, for therapeutic purposes, of that human organ from the dead body of the donor.
- (3) Where no such authority as is referred to in subsection (2), was made by any person before his death but no objection was also expressed by such person to any of his human organs being used after his death for therapeutic purposes the person lawfully in possession of the dead body of such person may, unless he has reason to believe that any near relative of the deceased person has objection to any of the deceased person human organs being used for therapeutic purposes, authorise the removal of any

human organ of the deceased person for its use for therapeutic purposes.

- (4) The authority given under sub-section (1) or subsection (2) or, as the case may be, sub-section (3) shall be sufficient warrant for the removal, for the therapeutic purposes, of the human organ; but no such removal shall be made by any person other than the registered medical practitioner.
- (5) Where any human organ is to be removed from the body of a deceased person, the registered medical practitioner shall satisfy himself, before such removal, by a personal examination of the body from which any human organ is to be removed, that life is extinct in such body, or where it appears to be case of brain-stem death that such death has been certified under sub-section (6).
- (6) Where any human organ, 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 unanimoulsy 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 occured;
- (ii) an independent registered medical practitioner, being a specialist to be nominated by the registered medical practitioner specified in clause (i) from the panel of names approved by the Appropriate Authority;
- (iii) a neurologist or a neurosurgeon to be nominated by the registered medical practitioner specified in clause (i),

from the panel of names approved by the Appropriate Authority; and

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

Removal of human organs not to be authorised in certain cases.

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

Authority for removal of human organs in case of unclaimed bodies in hospital or prison. 5. (1) In the case of a dead body lying in hospital or prison and not claimed by any of the near relatives of the deceased person within forty-eight hours from the time of the death of the concerned person, the authority for the removal of any human organ from the dead body which so remained unclaimed may be given, in the prescribed form by the person incharge, for the time being, of the management or control of the hospital or prison, or by an employee of such hospital or prison authorised in this behalf

by the person incharge of the management or control thereof.

- (2) No authority shall be given under sub-section (1) if the person so 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. Where the body of a person has been sent for postmortem examination,-
- (a) for medico-legal purposes by reason of the death of such person having been caused by accident or any other un-natural cause; or
- (b) for pathological purposes, the person competent under this Act to give authority for the removal of any human organ from such dead body may, if he has reason to believe that such human organ will not be required for the purpose for which such body has been sent for postmortem authorise the removal. examination. for therapeutic purposes, of that human organ of the deceased person provided that he is satisfied that the deceased person had not expressed, before his death, any objection to any of his human organs being used, for therapeutic purposes after his death or, where he had granted an authority for the use of any of his human organs for therapeutic purposes after his death, such authority had not been revoked by him before his death.
- 7. After the removal of any human organ from the body of any person, the registered medical practitioner shall take such steps for the preservation of the human organ so removed as may be prescribed.

Authority for removal of human organs from bodies sent for post-mortem examination for medico-legal or pathological purposes.

Preservation of human organs.

Savings.

8. (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 of authority for the removal of any human organ from the body of a deceased person in accordance with the provisions of this Act nor the removal of any human organ from the body of a deceased person in pursuance of such authority shall be deemed to be an offence punishable, under section 277 of the Indian Penal Code.

Central Act 45 of 1860.

Restrictions on removal and transplantation of human organs.

- 9. (1) Save as otherwise provided in sub-section (3), no human organ removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient.
- (2) Where any donor authorises the removal of any of his human organs after his death under sub-section (2) of section 3 or any person competent or empowered to give authority for the removal of any human organ from the body of any deceased person authorises such removal, the human organ may be removed and transplanted into the body of any recipient who may be in need of such human organ.
- (3) If any donor authorises the removal of any of his human organs before his death under sub-section (1) of section 3 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 human organ shall not be removed and transplanted without the prior approval of the Authorisation Committee.

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

- (5) On an application jointly made in such form and in such manner as may be prescribed by the donor and the recipient the Authorisation Committee shall after holding an inquiry and after satisfying itself that the applicants have complied with all the requirements of this Act and the rules made thereunder, grant to the applicants approval for the removal and transplantation of the human organ.
- (6) If after the inquiry and after giving an opportunity to the applicants of being heard the Authorisation Committee is satisfied that the applicants have not complied with the requirements of this Act and the rules made thereunder it shall for reasons to be recorded in writing reject the application for approval.

CHAPTER III REGULATION OF HOSPITALS

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

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

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

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

Explanation. For the purposes of this sub-section "ears" include ear drums and ear bones.

Prohibition of removal or transplantation of human organs for any purpose other than therapeutic purposes.

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

Explaining effects etc., to donor and recipient.

12. No registered medical practitioner shall undertake the removal or transplantation of any human organ, unless he had 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

Appropriate Authority.

- 13. (1) The Government shall appoint, by notification, one or more officers as Appropriate Authorities for the purpose of this Act.
- (2) 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 subsection (2) of section 16;
- (iii) to enforce such standards, as may be prescribed for hospitals engaged in the removal, storage or transplantation of any human organ;
- (iv) to investigate any complaint or breach of any of the provisions of this Act or any of the rules made thereunder and take the appropriate action;
- (v) to inspect hospitals periodically for examination of the quality of transplantation and the follow-up medical care to persons who have undergone transplantation and persons from whom organs are removed; and
- (vi) to undertake such other measures as may be prescribed.

CHAPTER V REGISTRATION OF HOSPITALS

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

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

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

- (2) Every application for registration under sub-section (1) shall be made to the Appropriate Authority in such form and in such manner and shall be accompanied by such fees as may be prescribed.
- (3) No hospital shall be registered under this Act unless the Appropriate Authority is satisfied that such hospital is in a position to provide such specialised services and facilities, possess such skilled man power and equipments and maintain such standards as may be prescribed.

Certificate of registration.

- 15. (1) The Appropriate Authority shall, after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of this Act and the rules made thereunder grant to the hospital a certificate of registration in such form for such period and subject to such conditions as may be prescribed.
- (2) If, after the inquiry and after giving an opportunity to the applicant of being heard, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of this Act and the rules made thereunder, it shall, for reasons to be recorded in writing, reject the application for registration.
- (3) Every certificate of registration shall be renewed in such manner and on payment of such fees as may be prescribed.

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

Suspension or cancellation of registration.

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

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

17. Any person aggrieved by an order of the Authorisation Committee rejecting an application for approval under subsection (6) of section 9, or any hospital aggrieved by an order of the Appropriate Authority rejecting an application for registration under sub-section (2) of section 15 or an order of suspension or cancellation of registration under sub-section (2) of section 16, may within thirty days from the date of the receipt of the order, prefer an appeal, in such manner as may be prescribed, against, such order to the Government.

Appeals.

CHAPTER - VI OFFENCES AND PENALTIES

18. (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

Punishment for removal of human organ without authority.

imprisonment for a term which may extend to five years and with fine which may extend to ten thousand rupees.

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

Punishment for commercial dealings in human organs.

19. 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,-
- (i) inviting persons to supply for payment of any human organ;

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

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

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

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

Punishment for contravention of any other provision of this Act.

21. (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:

Offences by companies.

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 deligence 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.

Cognizance of offences.

- 22. (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 Government or, as the case may be, the Appropriate Authority; or
- (b) a person who has given notice of not less than thirty 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 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. (1) No suit, prosecution or other legal proceedings 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.

Protection of action taken in good faith.

- (2) No suit or other legal proceedings shall lie against the 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. (1) The Government may, by notification, make rules power to make for carrying out all or any of the purposes of this Act.

rules.

- (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 human organ of his body under sub-section (1) of section 3:
- (b) the form and the manner in which a brain-stem death is to be certified and the conditions and requirements which are to be satisfied for that purpose under sub-section (6) of section 3;
- (c) the form and the manner in which any of the parents may give authority, in the case of brain-steam death of a minor, or the removal of any human organ under subsection (7) of section 3;

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

- (e) the steps to be taken for the preservation of the human organ removed from the body of any person, under section 7;
- (f) the form and the manner in which an application may be jointly made by the donor and the recipient under sub-section (5) of section 9;
- (g) the manner in which all possible effects, complications and hazards connected with the removal and transplantation is to be explained by the registered medical practitioner to the donor and the recipient under section 12;
- (h) the standards as are to be enforced by the Appropriate Authority for hospitals engaged in the removal, storage or transplantation of any human organ under clause (iii) of sub-section (2) of section 13;
- (i) the other measures as the Appropriate Authority shall undertake in performing its functions under clause (vi) of sub-section (2) of section 13;
- (j) the form and the manner in which an application for registration shall be made and the fees 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;

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

- (m) the manner in which and the fees on payment of which certificate of registration is to be renewed under subsection (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) to provide for a registry to document all the organ transplants to evaluate the performance of each transplants centre and for matters connected therewith or incidental thereto; and
- (q) any other matter which is required to be, or may be prescribed.
- (3) Every rule made under this Act shall immediately after it is made, be laid before the Legislature of the State, if it is in session and if it is not in session, in the session immediately following for a total period of fourteen days which may be comprised in one session or in two successive sessions and if, before the expiration of the session in which it is so laid or the session immediately following, the Legislature agrees in making any modification in the rule or in the annulment of the rule, the rule shall, from the date on which the modification or annulment is notified, have effect only in such modified form or shall stand and annulled as the case may be, so however, that any such

modification, annulment shall be without prejudice to the validity of anything previously done under that rule.

Repeal of Act 22 of 1963 and Ordinance of 1995. 25. The Andhra Pradesh Corneal Grafting Act, 1963 and the Andhra Pradesh Transplantation of Human Organs Ordnance, 1995 are hereby repealed.

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असाधारण

EXTRAORDINARY

भाग II — खण्ड 1 PART II — Section 1 प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

सं॰ 22] नई दिल्ली, बुधवार, सितम्बर 28, 2011/ अश्विन 6, 1933 (शक) No. 22] NEW DELHI, WEDNESDAY, SEPTEMBER 28, 2011/ASVINA 6, 1933 (SAKA)

इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके। Separate paging is given to this Part in order that it may be filed as a separate compilation.

MINISTRY OF LAW AND JUSTICE

(Legislative Department)

New Delhi, the 28th September, 2011/Asvina 6, 1933 (Saka)

The following Act of Parliament received the assent of the President on the 27th September, 2011, and is hereby published for general information:—

THE TRANSPLANTATION OF HUMAN ORGANS (AMENDMENT) ACT, 2011

(No. 16 of 2011)

[27th September, 2011.]

An Act to amend the Transplantation of Human Organs Act, 1994.

Whereas it is expedient to amend the said law enacted by Parliament relating to regulation of removal, storage and transplantation of human organs for therapeutic purposes and for prevention of commercial dealings in human organs;

And whereas Parliament has no power to make or amend 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 West Bengal to the effect that the aforesaid Act should be amended by Parliament;

BE it enacted by Parliament in the Sixty-second Year of the Republic of India as follows:—

1. (1) This Act may be called the Transplantation of Human Organs (Amendment) Act, 2011.

Short title, application and commencement.

- (2) It applies, in the first instance, to the whole of the States of Goa, Himachal Pradesh and West Bengal 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 West Bengal and in all the Union territories on such date as the Central Government may, by notification, appoint and in any other State which adopts this Act under clause (1) of article 252 of the Constitution on the date of such adoption; and any reference in this Act to the commencement of this Act shall, in relation to any State or Union territory, means the date on which this Act comes into force in such State or Union territory.

Amendment of long title.

2. In the Transplantation of Human Organs Act, 1994 (hereinafter referred to as the principal Act), in the long title, for the words "human organs for therapeutic purposes and for the prevention of commercial dealings in human organs", the words "human organs and tissues for therapeutic purposes and for the prevention of commercial dealings in human organs and tissues" shall be substituted.

42 of 1994

- Amendment of section 1.
- Substitution of references to certain expressions by certain other expressions.

 Amendment of section 2.
- **3.** In section 1 of the principal Act, in sub-section (1), for the words "Human Organs", the words "Human Organs and Tissues" shall be substituted.
- **4.** Throughout the principal Act [except clause (h) of section 2, sub-section (5) of section 9, sub-section (1) of section 18 and section 19], unless otherwise expressly provided, for the words "human organ" and "human organs", wherever they occur, the words "human organ or tissue or both" and "human organs or tissues or both" shall respectively be substituted with such consequential amendments as the rules of grammar may require.
 - 5. In section 2 of the principal Act,—
 - (a) after clause (h), the following clauses shall be inserted, namely:—
 - '(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;
 - (hb) "minor" means a person who has not completed the age of eighteen years;";
 - (b) for clause (i), the following clause shall be substituted, namely:—
 - '(i) "near relative" means spouse, son, daughter, father, mother, brother, sister, grandfather, grandmother, grandson or granddaughter;';
 - (c) in clause (o), the word "and" shall be omitted;
 - (d) after clause (o), the following clauses shall be inserted, namely:—
 - '(oa) "tissue" means a group of cells, except blood, performing a particular function in the human body;
 - (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;';
 - (e) after clause (p), the following clause shall be inserted, namely:—
 - (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.".

6. In section 3 of the principal Act,-

Amendment of section 3.

- (a) after sub-section (1), the following sub-sections shall be inserted, namely:—
- ``(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.
- (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.";
- (b) in sub-section (4), the following proviso shall be inserted, namely:—

"Provided that a technician possessing such qualifications and experience, as may be prescribed, may enucleate a cornea.";

- (c) in sub-section (6), in clause (iii),—
 - (i) the word "and" shall be omitted; and
 - (ii) the following proviso shall be inserted, namely:—

"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;".

7. In section 9 of the principal Act,—

Amendment of section 9

- (a) after sub-section (1), the following sub-sections shall be inserted, namely:—
- '(1A) Where the donor or the recepient 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 transplanation 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.

- (b) after sub-section (3), the following sub-section shall be inserted, namely:—
 - "(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;
 - (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.";

- (c) for sub-section (4), the following sub-section shall be substituted, namely:—
- "(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.".

Amendment of section 10.

- 8. In section 10 of the principal Act, in sub-section (1),—
 - (a) in clause (b), the word "and" occurring at the end shall be omitted;
 - (b) in clause (c), the word "and" shall be inserted at the end;
 - (c) after clause (c), the following clause shall be inserted, namely:—
 - "(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.".

Amendment of section 13

- 9. In section 13 of the principal Act, in sub-section (3),—
 - (a) for clause (iii), the following clause shall be substituted, namely:—
 - "(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;";
- (b) after clause (iv), the following clause shall be inserted, namely:—
 - "(iva) to inspect Tissue Banks periodically;".
- 10. After section 13 of the principal Act, the following sections shall be inserted, namely:—

Insertion of new sections 13A, 13B, 13C and 13D.

"13A. (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.

Advisory Committees to advise Appropriate Authority.

- (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;
 - (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.
- 13B. 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 and, in particular, in respect of the following matters, namely:—

Powers of Appropriate Authority.

- (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.
- 13C. 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.

National Human Organs and Tissues Removal and Storage Network.

5 of 1908.

National registry.

13D. 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."

Amendment of section 14.

- 11. In section 14 of the principal Act,—
- (a) in sub-section (1), for the words "No hospital", the words "No hospital (including Human Organ Retrieval Centre)" shall be substituted;
 - (b) after sub-section (3), the following sub-section shall be inserted, namely:—
 - "(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.".

Insertion of new section 14A. Registration of Tissue Bank.

- 12. After section 14 of the principal Act, the following section shall be inserted, namely:—
 - "14A. (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 specialised services and facilities, possess such skilled manpower and equipments and maintain such standards as may be prescribed."

Amendment of section 15.

13. In section 15 of the principal Act, in sub-section (1), for the words "grant to the hospital", the words "grant to the hospital or to the Tissue Bank, as the case may be," shall be inserted.

Amendment of section 16.

14. In section 16 of the principal Act, for the word "hospital", wherever it occurs, the words "hospital or Tissue Bank, as the case may be," shall be substituted.

Amendment of section 17.

15. In section 17 of the principal Act, after the words, brackets and figure "under subsection (6) of section 9, or any hospital", the words "or Tissue Bank, as the case may be," shall be inserted.

Amendment of section 18.

- 16. In section 18 of the principal Act,—
- (a) in sub-section (1), for the words "five years and with fine which may extend to ten thousand rupees", the words "ten years and with fine which may extend to twenty lakh rupees" shall be substituted;

- (b) in sub-section (2), for the words "two years", the words "three years" shall be substituted.
 - (c) after sub-section (2), the following sub-section shall be inserted, namely:—
 - "(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.".

17. In section 19 of the principal Act,—

Amendment of section 19

- (a) after clause (f), the following clause shall be inserted, namely:—
- "(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.";
- (b) for the words "two years but which may extend to seven years and shall be liable to fine which shall not be less than ten thousand rupees but may extend to twenty thousand rupees", the words "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" shall be substituted;
 - (c) the proviso shall be omitted.
- 18. After section 19 of the principal Act, the following section shall be inserted, Insertion of namely:-

new section 19A

"19A. Whoever--

- Punishment for illegal dealings in human tissues.
- (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.".

Amendment of section 20.

19. In section 20 of the principal Act, for the words "three years or with fine which may extend to five thousand rupees", the words "five years or with fine which may extend to twenty lakh rupees" shall be substituted.

Amendment of section 24.

- 20. In section 24 of the principal Act, in sub-section (2),—
 - (a) after clause (a), the following clauses shall be inserted, namely:—
 - "(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;
 - (ab) the manner of making the donor or his relative aware under clause (ii) of sub-section (1A) of section 3;
 - (ac) the manner of informing the Human Organ Retrieval Centre under clause (iii) of sub-section (1A) of section 3;
 - (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;
 - (ae) the qualifications and experience of a technician under the proviso to sub-section (4) of section 3;";
 - (b) after clause (b), the following clause shall be inserted, namely:—
 - "(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) after clause (e), the following clauses shall be inserted, namely:—
 - "(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:
 - (eb) the composition of the Authorisation Committees under sub-section (4) of section 9;";
 - (d) after clause (i), the following clauses shall be inserted, namely:—
 - "(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;
 - (ib) the power of the Appropriate Authority in any other matter under clause (d) of section 13B;
 - (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;
 - (id) the information in the national registry of the donors and recipients of human organs and tissues and all information under section 13D;";
 - (e) after clause (k), the following clauses shall be inserted, namely:—
 - "(ka) the qualifications and experience of a transplant co-ordinator under sub-section (4) of section 14;
 - (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;

(kc) 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 Tissue Bank, under sub-section (3) of section 14A;";

(f) in clause (l), for the word "hospital", the words "hospital or Tissue Bank" shall be substituted.

V. K. BHASIN, Secy. to the Govt. of India.

Transplantation of Human Organs and Tissues Act (THOTA), National Organ Transplant Program (NOTP) including NOTTO/ROTTOs/SOTTOs

Updated 16-7-2020

General Background

- There is huge shortage of Organs available for carrying out Transplants as compared to the number of patients who require Organ transplants. There is huge Gap between demand and supply of organs.
- There is a need to promote deceased organ donation, rather than relying on living donors, because of risk of commercial trading and inherent risk to the health of living donor.
- Cadaveric organ donor transplant can be done from "brain stem dead" persons before the heart stops beating.
- About 1.5 lakhs deaths happen annually due to road traffic accidents in India a
 large number of these cases could be harvested for organs.
- Organ donation rate (Number of persons who donate organs after death in one million population) in India is less than one as compared to maximum of around 48 in the Spain. However, it is encouraging to note that Organ donation rate has increased to about four times as compared to 2012, when it was 0.16.

Legal Framework

- The Transplantation of Human Organs Act (THOA), 1994 was enacted in the year 1994 and has been adopted in all States except erstwhile State of J&K and Andhra Pradesh which have their own legislation in this regard. Main purpose of the Act is to regulate the removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs.
- The Act was amended in 2011 and the Transplantation of Human Organs (Amendment) Act 2011, has come into force on 10-1-2014 in the States of Goa, Himachal Pradesh, West Bengal, and Union Territories. Other States who have adopted the amendment Act till date are Rajasthan, Sikkim, Jharkhand, Kerala, Orissa, Punjab, Maharashtra, Assam, Haryana, Manipur, Gujarat, Bihar and Uttar

Pradesh. The amended Act is now named **Transplantation of Human Organs and Tissues Act (THOTA), 1994**.

- Brain Stem death is recognized as a legal death in India under the Transplantation of Human Organs and Tissues Act, since 1994 like many other countries, which has revolutionized the concept of organ donation after death. After natural cardiac death only a few organs/tissues can be donated (like cornea, bone, skin and blood vessels) whereas after brain stem death almost 37 different organs and tissues can be donated including vital organs such as kidneys, heart, liver and lungs.
- In pursuance to the Amendment Act, the Transplantation of Human Organs and Tissues Rules have been notified on 27th March, 2014. The amended Act and revised Rules have many provisions for promotion of organ donations from cadavers.

Important amendments under the (Amendment) Act 2011 are as under:-

- (i) Tissues have been included along with the Organs.
- (ii) 'Near relative' definition has been expanded to include grandchildren, grandparents.
- (iii) Provision of 'Retrieval Centres' and their registration for retrieval of organs from deceased donors. Tissue Banks shall also be registered.
- (iv) Provision of Swap Donation included.
- (v) There is provision of mandatory inquiry from the attendants of potential donors admitted in ICU and informing them about the option to donate if they consent to donate, inform retrieval centre.
- (vi) Provision of Mandatory 'Transplant Coordinator' in all hospitals registered under the Act
- (vii) To protect vulnerable and poor there is provision of higher penalties has been made for trading in organs.
- (viii) Constitution of Brain death certification board has been simplified- wherever Neurophysician or Neurosurgeon is not available, then an anaesthetist or intensivist can be a member of board in his place, subject to the condition that he is not a member of the transplant team.
- (ix) National Human Organs and Tissues Removal and Storage Network and National Registry for Transplant are to be established.
- (x) There is provision of Advisory committee to aid and advise Appropriate Authority.
- (xi) Enucleation of corneas has been permitted by a trained technician.
- (xii)Act has made provision of greater caution in case of minors and foreign nationals and prohibition of organ donation from mentally challenged persons

Source of Organs for Transplant:

Source may be, Living or Deceased Donor:

Living Donor Transplant:

• Near Relative donor (mother, father, son, daughter, brother, sister, spouse)

- Other than near relative donor: Such a donor can donate only for the reasons of affection and attachment or for any other special reason and that too with the approval of the authorisation committee.
- By SWAPPING of near relative donors between pairs of unmatched donor and recipient

Deceased donor Transplant:

- Donor after Brain stem death: Organ Donation is practically possible in the situation
 of Brain stem death e.g. a victim of road traffic accident etc. where the brain stem is
 dead and person cannot breathe on his own but can be maintained through
 ventilator, oxygen, fluids etc. to keep the heart and other organs working and
 functional.
- **Donor after cardiac death(DCD):** Practically in Indian scenario only tissues are donated after cardiac death. But few centres like PGI Chandigarh has started DCD

Issues and Challenges

- High Burden of Organ failure cases
- Poor availability of Donors (Demand Vs. Supply gap)
- Lack of Awareness of concept of Brain Stem Death
- Poor Brain Stem Death Certification by Hospitals
- Availability of Infrastructure esp in Government sector
- Awareness and attitude towards organ donation
- Organ Trading
- Reluctance of many States to adopt THOA amendment Act 2011
- Transportation of Donated Organs (especially inter State)
- Allocation of deceased donor organs especially heart to foreigners
- Gaps in Data Reporting especially online entry by hospitals/ States in National Registry
- Functional Organized networking systems
- High Cost (especially for uninsured and poor)
- Maintenance of Standards in Transplantation

Initiative taken

National Organ Transplant Programme

- Government of India is implementing National Organ Transplant Programme for carrying out the activities as per amendment Act, training of manpower and promotion of organ donation from deceased persons.
- Hon'ble Prime Minister has highlighted the importance of organ donation in the Mann Ki Baat Programme broadcast in October and November 2015. This has given impetus to the Organ Donation in the country.
- National Organ Transplant Programme aims to improve access to the life transforming transplantation for needy citizens of our country by promoting deceased organ donation.

Objectives of National Organ Transplant Programme:

- To bridge the gap between demand and supply of organs and/or tissues for transplantation.
- To improve access to the transplantation for needy citizens by promoting deceased organ/tissue donation.
- To organize an efficient mechanism for organ and tissue procurement/retrieval from deceased donors and its distribution for transplantation.
- To establish new organ and tissue retrieval and transplant facilities and strengthen existing facilities.
- To train required manpower.
- To monitor organ and tissue transplant services and bring about policy and program corrections/ changes whenever needed.

Situation before NOTP

- Till now who is handling transplant in States?: Health Department
- Registering / Appropriate Authority (Secretary/DHS)
- · No dedicated staff
- No awareness/surveillance/no systems for organ donation /transplant/registry/training

Solution provided through NOTP:

- Dedicated Institutional mechanisms
- SOTTO is an institutional mechanism to support States
- ROTTO are identified institutions which are champions field in to take care of a group of states
- NOTTO at apex level

Components of National Organ Transplant Programme (2017-20)

1. National THOTA and NOTP Cell

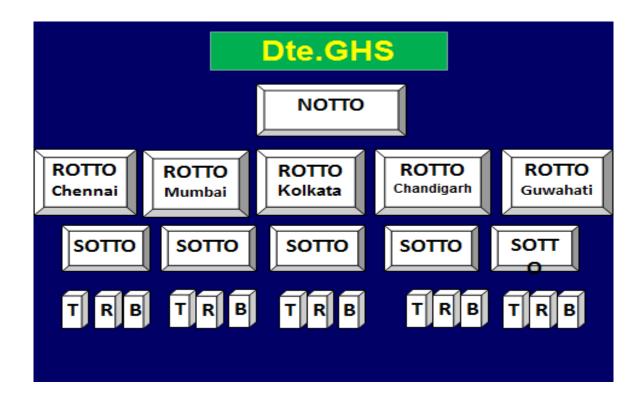
Located in MG section, DteGHS Headquarter, Nirman Bhawan, New Delhi.

The functions are

- 1. Registration and renewal of organ & tissue transplant centers, eye bank in all Union territories except Delhi as part of work of DGHS being the appropriate authority for all Union territories except Delhi. Organizing inspections for the same.
- 2. Monitoring of the transplant centers and Tissue Banks through regular data collection and inspections.
- Cases of appeal against the decisions of authorization committee or appropriate authorities under THOTA 1994 of Union territory of Delhi and other UTs
- 4. RTI and Court matters etc. related to THOTA and NOTP
- 5. All technical, administrative and financial matters of NOTP including NOTTO/ROTTOs/SOTTOs
- 6. Implementation and Monitoring of various components of National Organ Transplant Programme through respective State Governments and NOTTO/ROTTOs/SOTTOs, as applicable
- 7. Facilitating Organizing Indian Organ Donation Day annually
- 8. Consultancy on all transplant law and program related matters.

2. Networking: through creating institutional mechanisms

Through National Human Organs and Tissues Removal and Storage Network



NOTTO: National Organ and Tissue Transplant Organization ROTTO: Regional Organ and Tissue Transplant Organization SOTTO: State Organ and Tissue Transplant Organization

T: Transplant Centre R: Retrieval Centre

B: Biomaterial Centre (Tissue Bank)

I. National Organ & Tissue Transplant Organization (NOTTO):

An apex level organization, National Organ and Tissue Transplant Organization (NOTTO) having components of National networking, National Registry, National level Biomaterial centre and facility of cadaver organ and tissue retrieval Operation theatre has been established in the Safdarjung Hospital Campus, New Delhi under Directorate General of Health Services.

Broad Functions of NOTTO are

- · Drafting Policy guidelines and protocols
- Web based Networking
- Maintaining National Registry
- Advocacy and awareness
- Co-ordination when organ is allocated outside region and to PIO/Foreigner and in Delhi
- Research
- Dissemination of information
- Coordinate and Organize trainings
- Consultancy support on all aspects of donation and transplantation
- National Biomaterial centre
- SOTTO for Delhi

Detail of Achievements of NOTTO and Activities being undertaken is as under.

1) Website

A dedicated website (www.notto.gov.in) has been launched for providing information on organ and tissue donation, organ and tissue pledging, networking of hospitals and establishing National registry of organ and tissue transplantation and Donation. The work is being done through NIC.

2) <u>Helpline/Call centre</u>

A 24x7 days call centre has been made operational with provision of a toll free helpline (No. 1800114770) since 1-7-2015.

3) Registration of Hospitals with NOTTO Website

Online facility for registration of hospitals for networking and data collection for National registry has been made functional.

4) National Registry:

NOTTR was launched on 6th Indian Organ Donation Day celebration on 27thNovember 2015. It has three components:

Pledge Registry: Online and offline provision to register your wish for organ donation is already in place

Waiting List Registry: Patients waiting for transplant can register themselves through hospitals in the National Waiting list registry

Transplant Registry: Provision of entering the data of transplant cases and follow up is already in place. Hospital can enter the data.

5) Pledging for Donation

Facility for Offline and Online pledging for donation of organ and/or tissue after death has been made functional.

6) Allocation Policy:

Polices for allocation of Vital organs Kidney, Liver, Heart & Lung and Cornea have been approved by DGHS. Approved Organ Policies are available on NOTTO website.

7) Standard Operative Procedures (SOPs)

SOPs for retrieval of various organs and management of Donors have been drafted and uploaded on NOTTO website

- **8)** Operational Guidelines of National Organ and Tissue Transplant Programme for its implementation was also released on 27th March 2015 during NATIONAL ADVOVACY CONFERENCE.
- 9) Registration of Tissue Bank or Bio Material Centre: Tissue banks for Cornea, Skin, & Heart Valve have been registered and functional.

- **10)** <u>Apex Technical committees</u> are functional and developed Broad Guiding Principle for the Allocation of organs for have been constituted for development of organ specific guidelines.
- **11)** <u>Coordination & Collaboration with Other Organization</u>: Yes bank, Red Cross Society, ORGAN India to promote deceased organ donation and various other small NGOs.
- **12)** Coordination for Allocation of Organs: when organs are to be allocated nationally and for foreigner cases and for Delhi NCR

13) Capacity Building:

Various Training programs are organized either directly by NOTTO or under its aeigis.

- **14) IEC AND AWARENESS ACTIVITIES** are organized including annual Indian organ donation day.
- 15) National Transplant Specific Guidance during Covid 19 situation has been framed.

II. ROTTO: Regional Organ and Tissue Transplant Organization

| Name of ROTTO | States covered |
|-----------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| Seth GS medical college and KEM Hospital, Mumbai (Maharashtra) | Maharashtra, Gujarat, Goa, UTs of DNH, Daman, Diu, M.P., Chhattisgarh |
| Govt. Multispecialty Hospital, Omnadurar, Chennai (Tamil Nadu) | TN, Kerala, Telangana, Seem Andhra, Karnataka, Pondicherry, A & N Islands, Lakshadweep |
| Institute of PG Medical Education and Research, Kolkata (West Bengal) | West Bengal, Jharkhand, Sikkim, Bihar and Orissa |
| PGIMER Chandigarh(UT of Chandigarh) | Punjab, Haryana, HP, J &K , Chandigarh , Rajasthan, Uttar Pradesh and Uttarakhand |
| Guwahati Medical College (Assam) | Assam, Meghalaya, Arunachal Pradesh, Manipur, Nagaland, Mizoram, Tripura. |

Broad Functions of ROTTO are

- Networking including allocation, where SOTTOs not functional
- Co-ordination when organ is allocated outside State
- Collection of data and statistics from SOTTOs including registry of the region
- Monitoring and surveillance
- Training and workshops
- Developing IEC materials as per regional need
- Intersectoral meetings, IEC and advocacy for deceased organ donation in the region

- Technical guidance and Support
- Establishing and operationalizing regional biomaterial centre

It is envisaged to have a biomaterial centre at each ROTTO centre and till now funds have been given to Tamil Nadu for one State Biomaterial Centre.

Grant in Aid provided to each ROTTO

Financial Assistance of Rs. 81 lakh per year as Recurring grant and Rs. 68 lakh as Non-Recurring grant (Non-recurring was released already in 2014-2017 tom ROTTOs

III. SOTTO: State Organ and Tissue Transplant Organization

It is envisaged to establish one SOTTO each State. So far following 12 SOTTOs have been sanctioned:

- 1) Government Medical College, Thiruvananthapuram, Kerala
- 2) Sawai Man Singh Medical College (SMS), Jaipur, Rajasthan
- 3) Mahatma Gandhi Medical College (MGMC), Indore, Madhya Pradesh
- 4) Goa Medical College (GMC), Bambolim, Goa
- 5) Government Medical College (GMC), Jammu, J & K
- 6) Pandit Bhagwat Dayal Sharma PGIMS, Rohtak, Haryana
- 7) Sriram Chand Bhanj Medical College (SCB), Cuttack, Odisha
- 8) Institute of Kidney Diseases and Research Centre (IKDRC), Ahmedabad, Gujarat
- Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Lucknow, UP
- 10) Indira Gandhi Institute of Medical Sciences (IGIMS), Patna, Bihar
- 11) Government Medical College, Patiala, Punjab
- 12) RIMS: Rajendra Institute of Medical Sciences, Ranchi

5 ROTTOs are also SOTTOs for the States where they are located

NOTTO is **SOTTO** for Delhi

Broad Functions of SOTTO are

- 1) Coordinate for Implementation all schemes under NOTP in consultation with State Government
- 2) Maintain State wise Waiting list of patients
- 3) Networking and State level registry
- 4) Co-ordination from organ and tissue procurement, matching, allocation, transportation, storage and transplantation
- 5) Coordinate for BSD certification and retrieval teams
- 6) Dissemination of information to hospitals, organizations & individuals
- 7) IEC Activities
- 8) Training and CMEs with in the State

Grant in Aid provided to each SOTTO

Financial Assistance of Rs. 33 lakh per year as Recurring grant and Rs. 38 lakh as Non-Recurring grant.

3. Online system of networking and Registry

- Software developed and under further updation
- Website www.notto.gov.in
- Aim is to have a Computerised Impartial, and transparent organ allocation system
- networking & sharing as per allocation policy
- **4. Biomaterial Centres:** National Biomaterial centre is now registered. One has been sanctioned for Tamilnadu. Other regional centres are also planned to have biomaterial centre

There is provision of Non recurring financial grant @ 100 lakh per regional / state biomaterial centre (For: Refurbishment of space, furniture, equipment) for upto 10 centres.

5. Developing New / Strengthening Existing Retrieval and/or Transplant Centres: Financial support in the form of one time grant

- @ Rs. 50 lakh per new retrieval centre
 - @Rs. 100 lakh per new transplant centre
 - @Rs. 50 lakh for up gradation of existing retrieval/transplant unit

6. Training and Capacity Building

There is provision of training of various cadres and stakeholders related to Transplant including Transplant Coordinators.

7. Financial Support for immune- suppressants, maintenance of deceased donor:

There is provision for financial assistance to BPL transplant recipients, who have gone under transplantation in Govt. Hospitals at the rate of Rs.10000/- per month for immunosuppressant therapy.

8. Financial support for maintenance of deceased donor to retrieval (Non-Transplant Organ Retrieval Centres) /Transplant Centres @ Rs 1 lakh per donation for maintenance of Cadavers and promoting Deceased Organ Donation with the condition that at least one organ is donated to a Government hospital for up to 50 donations per year.

9. Financial Support for hiring of Transplant Coordinators for the purpose of Coordination with Govt. Medical Colleges, Good Performing Private institutions and trauma Centers

There is provision of **Financial Support for hiring of Transplant Coordinators** as per norms given below:

- ❖ Government Medical Colleges (2 Transplant Coordinators per medical college),
- Trauma Centers (1 Transplant Coordinator)
- ❖ Good performing private medical Institutions (1 Transplant Coordinator)

10. Information, Education and Communication (IEC) activities:

The programme has main component of Information, Education and Communication (IEC) activities to promote organ donation from deceased donors. The focus is to dispel myths and misconceptions related to Organ Donation. Organ is a National Resource and not even one should be wasted if at all possible.

Various Activities include

- Indian Organ Donation Day
- Poster competitions
- Broadcasting Audio messages
- Video Spot: Telecast of video Spot.
- Information Kiosk during Trade Fair
- Walkathon/Organothon
- Newspaper Advertisement
- Various Awareness Talks during BSF function, CISF, Schools, Delhi Medical Association, IMA, Corporates offices, various Ministries
- Sending SMS to Mobiles
- Etc.

For further information please visit website www.notto.gov.in