

HIGH LIGHTS OF NATIONAL ORGAN AND TISSUE TRANSPLANT PROGRAMME & OPERATIONAL GUIDELINES FOR ITS IMPLEMENTATION



NOTP Cell

Directorate General of Health Services
Ministry of Health & Family Welfare, Govt. of India
Nirman Bhawan, New Delhi





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AND TISSUE TRANSPLANT PROGRAMME
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**NOTP CELL
DIRECTORATE GENERAL OF HEALTH SERVICES
NIRMAN BHAWAN, NEW DELHI**



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Abbreviations:

AIIMS	: All India Institute of Medical Sciences
ANM	: Auxiliary Nursing Midwifery
BPL	: Below Poverty Line
BSD	: Brain Stem Death
BSDC	: Brain Stem Death Committee
CBSE	: Central Board of Secondary Education
CHC	: Community Health Centre
DBD	: Donation after Brain Death (formerly referred to as a "heart-beating" donor)
DCD	: Donation after Cardiac Death (formerly referred to as a "non heart-beating" donor)
EFC	: Expenditure Finance Committee
FRTR	: Follow-up Register of Transplant Recipient
GOI	: Government of India
HE	: Health Educator
ICU	: Intensive Care Unit
IEC	: Information Education Communication
IGNOU	: Indira Gandhi National Open University
ILBS	: Institute of Liver & Biliary Science
MO	: Medical Officer
MOHFW	: Ministry of Health & Family Welfare
NCERT	: National Council of Education Research & Training
NGO	: Non Governmental Organization
NHBD	: Non Heart Beating Donation
NOTP	: National Organ and Tissue Transplant Programme
NOTTO	: National Organ and Tissue Transplant Organisation
OTDR	: Organ/Tissue Donation Register
ORBO	: Organ Retrieval Banking Organisation
OTDTC	: Organ and Tissue Donation Transplant Coordinator
OTRH	: Organ and Tissue Retrieval Hospital
OTTH	: Organ and Tissue Transplant Hospital
OTRC	: Organ and Tissue Retrieval Coordinator

OTDRC	:	Organ and Tissue Donation Retrieval Coordinator
PPP	:	Public Private Partnership
PDCCDM	:	Post Doctoral Certificate Course in Dialysis Medicine
PHC	:	Primary Health Centre
RC	:	Regional Centre
RMP	:	Registered Medical Practitioner
ROTO	:	Regional Organ and Tissue Transplant Organisation
SEARO	:	South East Asia Regional Office
SNOD	:	Specialist Nurse Organ Donation or Transplant Coordinator
SOTTO	:	State Organ and Tissue transplant Organisation
TBC	:	Tissue Bank Coordinator
THOA	:	Transplantation of Human Organ Act
TNOS	:	Tamilnadu Network for Organ Sharing
WHA	:	World Health Assembly
WHO	:	World Health Organization
ZTCC	:	Zonal Transplant Coordination Centre (Registered society in Maharashtra)



जगत प्रकाश नड्डा
Jagat Prakash Nadda



सत्यमेव जयते



स्वास्थ्य एवं परिवार कल्याण मंत्री
भारत सरकार
Minister of Health & Family Welfare
Government of India

MESSAGE

The acme of the concept of selfless act is Organ Donation. In essence a human body can truly help another with altruism as its prime mover.

To further the search for greater good and health for its citizens, the Government of India reaffirms its faith and commitment to this activity. I exhort every citizen of this country sitting on the edge of its unfulfilled potential to realize the same. Its constituent people drive a movement. I hope this document helps to generate discussion, awareness and action towards organ donation.

The Government has realised the vast scope of using deceased organ and tissue and potential available in the country. To achieve the above objective Government has already amended the Transplantation of Human Organ Act (THOA) 1994 in 2011 and subsequently on 27th March 2014, THOA Rules have been notified. A National Programme of Organ and Tissue Transplantation (NOTP) has been approved under which a national networking system and a tissue bank is being developed under National Level Organ & Tissue Transplant Organization (NOTTO) and the programme plans to develop five such mini centres in different regions of the country under Regional Organ & Tissue Transplant Organization (ROTTO) and State level networking system in other States using six AIIMS like medical institutions under State Level Organ & Tissue Transplant Organization (SOTTO).

Laws reside in Statute books and serve as the steel framework of governance and polity. It gives me particular delight to be associated with this venture in the sphere of National Organ and Tissue Transplant programme which has the potential to sew into fabric of our great nation the threads of altruism, yeomanry and the basic urge of human behaviour namely "to help".

I wish all the stakeholders the very best in carrying forward this noble task.

Jai Hind.

(Jagat Prakash Nadda)

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Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

MESSAGE

The Ministry of Health and Family Welfare feels privileged to bring out "Highlights of National Organ & Tissue transplant Program and Operational Guidelines for its implementation."

We are aware that demand for organ significantly surpasses the availability of donors. There are more potential recipients on organ donation waiting list than donors, resulting in tragic consequences. Cadaveric donation is significantly lower in India than in other countries. The Government of India has amended the Transplantation of Human Organ Act (THOA) 1994 in 2011 and subsequently on 27th March 2014, THOA Rules have been notified.

It is imperative to highlight that with advancement in medical skills and technology, these patients in need have a new ray of hope and more precisely a second chance to live!

Needless to say, this noble cause requires the integrated effort of the community, healthcare professionals and non-government organizations. We strive to create a culture of voluntary deceased organ and tissue donation in India.

I sincerely appeal to the people of this country to come forward and sign up for organ donation and to make your wish known to your family members, as their consent will be required. This noble act will give a second chance to another perhaps otherwise lost life.

The State Level Organ & Tissue Transplant Organization (SOTTO), Regional Level Organ & Tissue Transplant Organization (ROTO) and National Level Organ & Tissue Transplant Organization (NOTTO) should work in close coordination and they are the platform for implementing Organ & Tissue donation and transplant services. Government of India is committed to provide the support already approved under NOTP to facilitate the initiatives taken by the States/UTs. I encourage you to plan & prepare proposal using this guideline to educate community, train hospital staff, and develop a sound coordination and networking system for this life saving act.

(B.P. SHARMA)

Dr. Jagdish Prasad
M.S. M.Ch., FIACS
Director General of Health Services



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MESSAGE

Deceased Organ Donation rate in India is less than one per million population compared to 35 per million population in Spain. According to the data compiled by WHO in 2007, a total of 94 countries have organizational and legislative framework of organ transplantation. Government of India enacted the legislation on Transplantation of Human Organ (THOA) Act in 1994 and amended THOA act in 2011. Government of India Expenditure Finance Committee (EFC) has approved Rs. 149.50 crore for the 12th Five Year Plan for implementation of the National Organ & Tissue Transplantation Programme (NOTP) with the objective to promote deceased organ and tissue donation, procurement and distribution for transplantation.

The organizational framework designed for promoting deceased organ and tissue donation and transplantation has to be sent to all the States/UTs who have to make their plan and submit the proposal to this Directorate. There is a greater need for collaboration between Central, State Government and various institutions for effective networking, for preparation and implementation of the programme through which many lives can be saved in the country.

The action points suggested at various levels such as National Organ and Tissue Transplantation Organization (NOTTO), Regional Organ and Tissue Transplantation Organization (ROTO) and State Organ and Tissue Transplantation Organization (SOTTO) level needs to be taken on top priority so that the required activities may carried out properly and on time. Grouping of States under ROTTOs and clarification of the role of NOTTO, ROTTOs, SOTTOs in the guidelines will help them to make the plan and proposal. The style of presentation on various components of National Organ and Tissue Transplantation Programme (NOTP) in the guidelines keeping in view its various aspects will also help the States to bring out proper proposal.

I congratulate Dr. N.S. Dharmshaktu, Addl. DG looking after NOTP, for preparing the Draft operational Guidelines based on his rich experience as a programme manager and Dr. Anil Kumar, CMO for his support and especially, Dr. Sanjay Aggarwal, Professor, Department of Nephrology, AIIMS and Dr. H. Jauhari, Advisor NOTTO and Sr. Consultant, Sir Ganga Ram Hospital, New Delhi for editing this document and offering valuable suggestions.

I wish NOTP all the success.

(Dr. Jagdish Prasad)

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PREFACE

I was very much motivated by Dr. Jagdish Prasad, Director General of Health Services by his concern about the demand for organ which is far exceeding its supply in India and presenting a challenge to the Health Authorities and potential unethical practices. His constant concern over many issues related to organ transplant and urgency for developing an effective mechanism for promoting deceased organ and tissue donation, raised by himself in many meetings chaired by him, made me realize the necessity and urgency for bringing out these guidelines.

Measures being taken for organ transplantation in various countries, initiative taken by WHO and various other available references and deliberations of a series of meetings held on the related subject were very helpful to me in preparing the draft document of "Highlights of National Organ and Tissue Transplantation Programme (NOTP) and the Operational Guidelines for its implementation." This document has been prepared to inform the State/UTs about the importance of the subject, successful action taken in various countries and provisions and opportunities available and included in NOTP, grouping of the States, under National and Regional Organizations to help them in preparing plan and submitting sound proposal and developing a team approach towards the challenge of increasing Deceased Organ and Tissue Donation and Transplantation in the country.

I am extremely thankful to Dr. Sanjay Agarwal, Professor, Department of Nephrology, AIIMS and Dr. H. Jauhari, Advisor, NOTP and Sr. Consultant, Sir Gangaram Hospital, New Delhi for sparing their valuable time, editing this document and offering their suggestions, in view of their rich professional experience and passion in the subject. Almost all of the corrections suggested have been adopted leaving finer detail for the technical committees suggested under appropriate item in the guidelines.

I am grateful for the valuable guidance offered by Spl. DG, Dr. B.D. Athani and assistance provided by Dr. Anil Kumar, CMO, NOTP Cell, Directorate General of Health Services.


(Dr. N. S. Dharmshaktu)

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1. Introduction:

A. Principles of Organ and Tissue Donation & Transplantation:

The improvements in medical technology, particularly in relation to organ and tissue rejection, have enhanced the cost-effectiveness and utility of transplantation and has enhanced the quality of life. This, however, has also led to an increase in the demand for organs which exceeds their supply, presenting a challenge to health authorities and potential unethical practices. Many countries now have the legal frameworks on transplantation of human organs, however, commercialization and trafficking in human organs continues. The moral dilemma as being faced are said to be in the allocation of organs to recipients, the problem of shortage of organs available for transplantation, commercialization of organ donation and the emerging concerns regarding transplant tourism. In 1987, the WHA expressed concern at the trade for profit in human organs among living human beings and affirmed that such trade is inconsistent with the most basic human values and contravenes the Universal Declaration of Human Rights and the spirit of the WHO Constitution. It requested that WHO, through Resolution WHA 40.13, would develop guiding principles for human organ transplants. Accordingly, in 1991, WHO developed the Guiding Principles with the following key elements:

- 1) Preference for deceased over living organ donors
- 2) Preference for genetically related over unrelated living donors
- 3) Preconditions in all cases
 - (a) Informed consent by a competent person
 - (b) Free of undue influence or pressure
- 4) Non-commercialization (no sale or purchase, no payment for organ, no profit from organ)
- 5) Fair distribution of organs (equitable access to common resource)

In 2004, The WHO member countries later requested WHO for updating of the above principles which led to updating the WHO Guiding Principles which pertain to the following 11 key elements:

- (1) Consent for deceased donor's donation
- (2) Clear definition and determination death
- (3) Consent from deceased and live donors
- (4) Protection of minors and incompetent person
- (5) No sale or purchase of organs, tissues and cells
- (6) Altruistic promotion of donation, no advertising or brokering
- (7) Responsibility on origin of transplant
- (8) Justifiable professional fees
- (9) Allocation rules
- (10) Quality, safety, efficacy of procedures and transplants
- (11) Transparency and confidentiality

B. Global view of Organ and Tissue Donation and Transplantation:

WHO has collected data through a structured questionnaire from all Member States. The current Global Database compiles organ activity data from 97 countries, representing nearly 80% of the global population. Of these, 94 countries have an organizational and legislative framework for organ transplantation. While 74% of the countries have an official body for overseeing and coordinating donation and transplantation, 82% have specific legislation on organ transplantation. The global estimates of organs transplanted during 2007 indicate that around 100 000 solid organ transplantations take place every year and organ wise estimated number of organ transplant done in 2007 is as under:

Kidney	Liver	Heart	Lung	Pancreas
68,250	19,850	5,179	3,245	2,797

Total 21,489 deceased donors were reported to the data base.

The total WHO region wise numbers estimated organ transplant done are as under:

Region	Number
Africa Region	457
Region of Americas	40,876
Eastern Mediterranean	6,765
Region European	31,234
Region South East Asia	5,656
Region Western Pacific Region	14,333
Total	99,331

Number of countries n=97

C. Status of Organ/ Tissue Donation & Transplantation in SEARO region:

Organ, tissue and cell transplantation is in varying stages of development in the Region. Transplantations take place for organs (kidney, lung, liver, heart, spleen, small bowel); tissues (cornea, skin, bone, tendon, ligaments, islets of Langerhans, parathyroid, iliac artery and vein, pulmonary valves); cells (hematopoietic stem cells, spleen cells and mesenchymal stem cells). The estimated numbers of annual transplantations done in the SEARO Region as of 2007 were : >5490 kidneys; >132 livers; approximately 30 hearts, >1 lungs and >3 pancreases.

D. The Organ Transplant System Developed and Transplant done in other neighbouring countries:

China:

China has a successful national transplantation programme under the Ministry of Health. Facilities for the transplantation of the following organs (kidney, liver, heart, lung, pancreas, spleen, small intestine); tissues (cornea, islet of Langerhans, parathyroid gland); cells (hematopoietic stem cells and spleen cells) are available in the country. There is a National Organ Transplantation Programme and the National Ministry of Health has established two registry centres in 2008: the Chinese Scientific Registry of Kidney Transplantation and the China Liver Transplant Registry. 164 hospitals are qualified to perform transplants and this permission is granted and approved by the Ministry of Health's Committee on the Clinical Application of Technologies of Human Organ Transplantation and the Human Organ Transplant Branch of Chinese Medical Association.

The National regulations for transplantation evolved in two steps. In 2006, the regulations applied to the Management of Clinical Application of Human Organ Transplantation to regulate the practice of medical institutions and practitioners. In 2007, the regulations define the liabilities of illegal removal, trade and transplantation of organs (liver, kidney, lung and heart). These regulations are effective and adequate and under the committee on the clinical application of technologies and ethics of human organ transplantation. These regulations oppose transplant tourism where trans-border organ transplantation is banned (2006) and the export/import of organs, tissues or cells is prohibited.

Selection criteria for a potential donor are carefully scrutinized. Only those are capable of competently making their own decision and are willing/free of any undue influence are selected. They are given a thorough explanation of the probable risks and benefits before donation, informed and voluntary consent of the living donor is taken, professional care is ensured, and follow-up is well organized.

The Red Cross Society of China has been designated as the National Human Organ Donation Organization and oversees the present network of Organ Banks. However, a National network is being planned in the next three to five years. This would include a donation registry and an organ sharing and allocation system. The Red Cross Society of China has also set up special institution and volunteer groups for organ donation and plan to expand this through education and encouragement of local communities.

Data for 2007-2008 shows that nearly 11,000 transplantations have taken place in China, with kidney transplants being the highest number followed by liver transplants. Less than 50% of kidneys and more than 75% of livers come from deceased donors. The reported survival rates for both kidney and liver donors is 100%, while for recipients survival rates are 96% and 89%, respectively.

Malaysia:

The transplantation programme in Malaysia started in 1975 with kidney transplants and by 2006, liver and lung transplants had been successfully carried out in the country. Data from 2007 shows that nearly 50% of kidney and liver donors are deceased donors. Majority of the transplantation centres are public hospitals with a few private institutions also having the facilities. Malaysia has seen improvements in its National Transplantation Programme with the restructuring of its organizational structure, resulting in a more streamlined and accountable framework. It has in place the Human Tissues Act (1974) which, however, addresses only cadaveric organ, tissue and cell removal. This Act is currently under revision in order to include the definition of death and provisions prohibiting commercialism. In addition, there is a need for a comprehensive act to address issues of live donation, transparency, traceability and surveillance. In 2007, the national organ, tissue, and cell transplantation policy was formulated by various stakeholders. This policy provides governance for private and public sectors as well as national ethical guidelines on organ transplantation. The national transplant registry (established in 2004) provides various information and outcome data on organ, tissue, and cell transplant recipients.

Singapore:

The national organ transplant programme in Singapore started in 1970 and is operated currently by the National Organ Transplant Unit which has the following responsibilities:

- Coordinating the deceased organ donation programme
- Maintaining national registry of organ donors and recipients
- Managing the national organ waiting list.

Facilities for kidney, liver, lungs, heart, corneas, skin, bone, and bone marrow transplants are available in both public and private hospitals. The data from 2007 shows that there was nearly equal distribution of live related, live unrelated and deceased donors for kidney transplantation. Nearly half of the donors for liver transplants were live related donors.

National regulations have been implemented since 1970 and its salient features include:

- Regulation of deceased and live organ donation
- Live organ donations need to be approved by a transplant ethics committee
- Transplantation of organs on patients from abroad is allowed but regulated and transfer of organs /cells across the border is allowed but regulated.

Singapore is reported to be committed to and undertaking major initiatives to promote ethical organ donations. Major legislative initiatives include the following:

- Removal for age-limit of deceased organ donation under presumed consent
- Allowing for paired donations
- Reimbursement to donor for reasonable and verifiable costs incurred and associated with the donation
- Increased penalties for organ trading

There is a high level of community awareness due to the national programme and also through NGOs and involvement of other institutions. In addition, efforts are under way to maximize the potential for deceased donation, to ensure the welfare of living donors and public education.

E. The Status of Organ / Tissue Donation & Transplant in India:

- a) The organ donation rate in India is currently less than 1 per million compared to Spain having 35 donation per million. The deceased donation is almost insignificant in a country of 1.2 Billion populations in India.
- b) Government of India enacted the Transplantation of Human Organs Act, 1994 to provide for the regulation of removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs and for matters connected therewith or incidental thereto. A Committee was constituted by the Hon`ble High Court of Delhi (as per the judgement dated 6.9.2004 in W.P. No.813/2004) to review the provisions of the Transplantation of Human Organs Act, 1994 and the Transplantation of Human Organs Rules, 1995. In order to streamline the process of organ transplantation and curb instances of illegal dealings, the GOI enacted the Transplantation of Human Organs (Amendment) Act, 2011 by amending the Transplantation of Human Organ Act, 1994. 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. In supersession of the Transplantation of Organs Rules, 1995, Govt of India notified the Transplantation of Human Organs and Tissues Rules, 2014.

The THOA (amended) Act & Rule are provided in the website of NOTTO www.notto.nic.in. The THOA Act encourages deceased donation, permits donations from living persons who are near relatives and expands the definition of "near relative" to include grandparents and grandchildren in addition to parents, children, brother, sister and spouse. Swap donation is also permitted where pair of donor and recipient who are near relatives but whose organs do not medically match for transplantation are permitted to swap organs with another pair of such person. The Act enhances the penalty for unauthorised removal of human organs and for receiving or making payment for human organs.

- c) The National Organ and Tissue Transplant Programme has been approved by MOHFW for implementation from current year. It is estimated that about 240

health facilities in the country now registered & performing solid organ transplantation although about 80 % of these centres are doing mainly Kidney transplant. Most of the transplant centres are in the private sector.

It is estimated that currently about 7,000 solid organ transplant are being done annually in the country which includes about 6,000 kidney transplant (against annual requirement of 1.5 Lac), about 1,200 Liver transplant (against annual requirement of 30,000), 17 heart against annual requirement of about 50,000), 7 lung and 2 Pancreas, 1 small bowel. The states of Tamil Nadu and Maharashtra contribute maximum number of organ transplant.

Approximately above 600 Clinical faculties are also registered for conducting corneal transplant. Against the requirement of about one lakh cornea transplant per year about 25,000 corneal transplants are being done annually.

d) The major issues that are being faced pertain to:

- National framework: Advocacy
 - Lack of a National coordinating agency
 - Lower number of patients being declared with brain stem death
- Access: Health system
 - Availability of organs from deceased donors
 - Development of trained manpower in the transplant centres particularly in the public sector.
 - Allocation review process
 - Transparency of procurement and transplantation
- Ethics and regulations
 - Compensation vs Reimbursement
 - Inducement vs incentives
- Quality Systems
 - Safety and quality of practices
- Community awareness and participation
 - Community acceptance on organ donation
 - Media interaction

e) The NOTP has been designed to address all the issues and guiding principles laid down by WHO. This guideline is developed to help and guide the states/UTs prepare their action plan; submit the same to GOI for participation in the programme.

A need for strong partnership between the public and private sectors will also be required, along with an effective regulatory oversight.

F. Aims, Objectives & strategies of National Organ & Tissue Transplant Programme (NOTP):

Vision: Save life by preventing premature death within the framework of THO (Amended) Act and revised Rules.

Aim: To improve access to life transforming transplantation for needy citizens by promoting deceased organ donation.

Mission: To set up an effective national deceased organ & tissue donation system.

Our Core Values: Effective team work involving states, Registered NGOs, Registered Public & Private institutions and other stakeholders to rise to challenge.

Objectives:

- To organize a system of deceased organ and Tissue procurement & distribution for transplantation.
- To promote deceased organ and Tissue donation following THOA Rules 2014
- To protect vulnerable poor from organ trafficking.

Strategies:

- Advocacy for promoting deceased organ and tissue donation and conduct IEC for bringing awareness among general public. Follow the "opt-in" system of deceased organ/tissue donation – where individuals are asked to register their willingness to be a donor after death Develop Networking for organ and tissue removal, storage, allocation and transplantation and develop national registry.
- Capacity building of staff for coordination, retrieval and transplantation of organs and tissues and to train required manpower for retrieval of organ/tissue and transplantation.
- To create suitable infrastructure for implementation

2. Core Activities under the Programme:

Strategies:

- Advocacy for promoting deceased organ and tissue donation and IEC of general public. Develop Networking for organ and tissue removal, storage, allocation and transplantation and develop National Registry. Development of national/ regional/ state/ hospital register for organ and tissue donation & transplantation. Increasing the availability of deceased organs/tissue by giving emphasis on cadaver donors. Develop standard procedure for Regulation of live organ donation as per THOA Rules. Capacity building of staff for coordination, retrieval and transplantation of organs and tissues. Post-transplant services to transplant recipients and living donors.

3. Institutional Frame work and action to be initiated by central & state/UTs Govt for implementation of the programme:

- NOTTO centre at Safdarjung Hospital campus having a Networking Division for organ/tissue donation and Transplant Registry and a National Biomaterial laboratory. It is planned to have five Regional level similar structures called ROTTO cum SOTTO with Regional Tissue Bank.
- Six AIIMS like institutes to be equipped to take role of SOTTO in long run for each of 6 these states .Other states which have already set up a system for coordination & allocation of organ and tissue shall also be taken as SOTTO eg. Karnataka, Kerala, Gujarat etc. Five trauma Centres and 100 Medical colleges/tertiary hospitals to work as additional Organ & Tissue Retrieval centres.
- Currently 20 Tertiary care hospitals in Delhi NCR region are already doing organ & tissue Transplant out of which 5 are in the Govt sector. NOTTO Head Quarter will take role of coordination & organ allocation for these centres of Delhi NCR Region. ROTTO, SOTTOs will be given flexibility of developing PPP within the broad national principles.

A. Central Govt Work & Action:

NOTP cell in the Dte G. H.S. will coordinate following activities:

- GOI shall appoint, by notification, one or more officers as Appropriate Authorities for each of the Union territories for examination and registering/licensing of organ & tissue transplantation centre he/she will have power of civil court trying to suit under the code of Civil Procedures, 1908, and, in particular, in respect of following matters namely
- Summoning of person, who is in possession of information relating to violation of the provision of act
- Discovery and production of any document or material object,
- Issuing search warrant for any place suspected to be indulging in unauthorised removal, procurement & transplantation of human organ or tissue or both as given under Section 13 B of the Act.

It has already been done by issuing notification for making DGHS as Appropriate authority for all the UTs except Delhi.

- Notify THOA Rules which has been done in March 2014. A letter is being issued to all the State Chief Secretaries informing the same for necessary action.
- Facilitate for establishment of NOTTO, Identify 5 major hospitals which can take role of ROTTO from current year , prepare 6 AIIMS like institution to take full technical role of SOTTO in close coordination with the concerning state, identify other states which are in position to form SOTTO eg. Karnataka, Kerala, Gujarat etc& have meeting with the Health Secretaries & Head of 6 AIIMS like institutes and selected 5 Trauma centres.

- Develop this operational Guidelines of NOTP for the states/UTs, NOTTO, ROTTO cum SOTTO, SOTTOs, Other states for involvement of Medical Colleges/Tertiary care hospitals, Trauma centres for developing action plan by them. (States where there is no ROTTO, SOTTO, Organ/Tissue Transplant Hospital/Retrieval Hospital will also conduct advocacy for organ/tissue pledging and IEC for implementation of THOA Act/Rules.
- Provide budget as per requirement and approved EFC to the states/UTs.
- GOI will constitute an advisory committee by notification for a period of 2 years to aid & advice above Appropriate Authority of GOI to discharge its function as per Section 13 A (2) of the THOA Amended Act.

B. State/UT Work & Action:

The States should inform the State Assembly about THOA act 1994 amended in 2011, its notification & THOA Rules notified in March 2014 by GOI & appoint one or more responsible officer as **State Appropriate Authority** (also District Appropriate Authority where needed) for examining and issuing Registration/licensing of Transplant Centres.

- Notification should also be issued by states/UTs Govt for forming **Hospital/District/State based Authorisation Committee** (depending on the number of registered organ & tissue transplant hospitals) for examination of applications of live Donor & recipient applications for approval. The composition of State/UT/District level authorisation committee is given in THOA Rule.
- Establish **State THOA Cell** under the State **Appropriate Authority** for registration of Organ & Tissue transplant centres and Retrieval Hospital of medical college or tertiary care institution. The state Appropriate Authority shall have chairman, an administrative expert not below rank of Secretary to the state Govt, two medical experts having such qualification, not below Joint Director level officer as Member Secretary, two eminent social worker of high social standing & integrity one of whom should be representative of women organisation, One legal expert who held the position of an additional District Judge or equivalent, One NGO representative working in organ and tissue donation or human right, one specialist in the field of human organ transplant who is not a member of transplant team
- Submit proposal for establishing networking office by all selected ROTTO & SOTTO, so that these are electronically linked to all the registered transplant hospitals, retrieval centres in the Region/State as well as to NOTTO. Tissue Bank also to be included in the plan of ROTTOs.
- Each state will constitute an **Advisory Committee** by notification for a period of two years to aid & advice above **State Appropriate Authority** to discharge its function as per Section 13 A (2) of the THOA amended Act 2011.

Composition of State or District Level Authorisation Committees for removal of organ: 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.

4. Organ & Tissue Donation Criteria:

The types of organs and tissues that can be donated will depend on the cause of death, the age of the donor, past medical history and the current function and pathology of these organs and tissues.

A. Organ Donation:

Organ Donation after brain death:

Patients, who have suffered irreversible loss of brain function (brain death) but still have an intact cardiovascular system, are potential donors of heart, lungs, liver, pancreas, intestines, stomach and kidneys. Organ donation after brain death can only occur when the patient has died in the Intensive Care or Emergency Department setting and is still maintained by mechanical ventilation. Organ donation cannot take place until death has been confirmed and authorisation has been obtained.

Organ Donation after Cardiac Death (ODCD):

DCD formerly known as non-heart-beating donation (NHBD) and also called Donation after cardiac death is a procedure that makes it possible for individuals who do not fulfil the criteria for brain death, to donate organs & Tissue. Currently only tissues will be retrieved from such donors under NOTP. However there is no bar in doing it by following standard procedures prescribed and a technical committee of NOTTO should examine it.

General Organ Donor's medical criteria for Donation after Brain Death:

Everyone is considered individually but the patient must have:

- Suffered irreversible loss of brain function (brain stem death)
- Person has to be maintained on a ventilator with intact circulation

Specific Organ Donation criteria:

As advancement in science and transplantation any criteria and medical conditions which are earlier contraindications may not be contraindications today. The professional guidelines available should be examined by the technical committee of NOTTO from time to time.

Variations in age limits apply to all solid organs for donation. Listed are the current general age limits for most donors. However, these limits are advisory guidelines only, All the potential organ donors be referred to the nearest registered transplant Hospital/ Registered Retrieval Hospital with intimation to nodal officer at nearest SOTTO, ROTTO cum SOTTO or NOTTO.

- Heart donor – age up to 60 years
- Heart/lung and single lung donor – age up to 65 years
- Liver donor – age up to 80 years
- Pancreas donor – age up to 50 years
- Pancreas islet cell donor – age up to 70 years
- Intestines/stomach – age up to 55 years
- Kidney donor – age up to 80 years.

Exclusion criteria for Organ Donation:

Human Immunodeficiency Virus (HIV)

Current neoplastic disease other than primary brain tumours and non-malignant skin cancers. Further details are given under heading “Donor Tissue Suitability”.

B. Tissue Donation:

Eye and other tissue donation is possible after brain death and cardiac death. Unlike organs, tissues do not require an intact cardiovascular system to be viable for transplantation. Therefore, all hospital and coronial deaths (by unnatural cause) are considered potential tissue donors. Tissues can be retrieved up to 6 hours after circulation ceases. Patients may be eligible to donate heart valves, bone, skin and eye tissue up to 12 hours if the body is kept under refrigeration. Tissue transplantation is made possible through tissue banks, which receive and prepare tissue for transplantation.

General tissue donor medical criteria are given below as advisory in brief. Further detail guidelines would be provided NOTTO.

Donor Tissue Suitability:

All potential donors are screened to exclude any pathology, diseases or risk behaviour that may present a risk to the recipient. Screening includes medical records review, completion of a medical/social history questionnaire by next of kin, and testing of a donor blood sample for mandatory infectious diseases (HIV, HBV, HCV, HTLV and syphilis). The following general medical exclusion criteria, social exclusion criteria & tissue specific criteria are advisory. The individual state /UT may have their own selection criteria:

General Medical Exclusion Criteria for Tissue Donors:

- Clinical or laboratory evidence of HIV, Hepatitis B or Hepatitis C infection Clinical history of tuberculosis , Clinical or laboratory evidence of syphilis or history of incomplete or untreated case of tuberculosis and syphilis
- Presence of systemic infection or severe localised infection of tissue to be retrieved
- Persons with haemophilia or related clotting disorders treated with human-derived clotting factor concentrates
- Non-medical injected drug use including intravenous, intramuscular, and subcutaneous injections
- Active or past history of slow virus disease
- Presence of malignancy (exceptions exist for primary CNS tumours, basal cell carcinomas)
- Risk of prion-associated disease
- History or presence of serious illness of unknown aetiology
- History of multi-system autoimmune disease or systemic diseases with severe effects on the organs& tissue to be transplanted (collagen diseases, vasculitis)
- Heavy irradiation to the area of tissues being removed
- Toxic substances in potentially toxic amounts in tissues to be collected
- Exposures to poisons, heavy metals, and other toxins

Any other as may be decided by the state /UT Govt

Social Exclusion Criteria:

Certain social behaviours may put the donor at risk of HIV, Hepatitis B, Hepatitis C. People who may not donate for these reasons include:

- Persons who have injected drugs for non-medical reasons
- Persons who within 6 months of donation have undergone tattooing/ piercing.

Tissue-Specific Exclusion Criteria

There may also be specific exclusion criteria for each tissue type. These can be discussed with the tissue bank at the time.

Eligibility for a heart/ heart valve donor:

All patients from new-born to 60 years of age with no history of cancer should be considered as potential donors. Heart tissue grafts can be used for:

- Treatment of adults and children with heart disease
- Replacement of diseased or defective heart valves
- Reconstruction of congenital abnormalities in children.

Eligibility for a skin donor:

Patients up to 70 years of age with no history of cancer and whose skin is in good condition can be skin donors. Skin can be donated within 24 hours of (circulatory) death. A very thin layer of skin (1/1600 of an inch thick) is removed using a dermatome from the back of the donor's torso and legs.

Allograft skin can be used for:

- Treatment of burns
- Chronic unhealed wounds

- Decubitus ulcers
- Traumatically denuded areas.

Eligibility for a Musculoskeletal donor:

Bone is donated by patients who are undergoing total hip replacement surgery, and from donors up to 65 years of age who have expressed their willingness to become organ/tissue donors in the event of death. Musculoskeletal tissue grafts (bone, tendons, and ligaments) can be used for orthopaedic, neurosurgical and plastic surgery to replace damaged bone and aid growth.

C. Donor Referral/Information Required:

At the time of potential donor referral, it is helpful to have patient charts available for additional information.

- Patient's name and sex
- Age and date of birth
- Blood group (if available)
- Status of brain death testing (time of death if available)
- Potential exclusion criteria (if known)
- Past medical history
- Blood results (if available)
- Cause of death
- Course of treatment throughout admission
- Family details and needs.

5. Targets of NOTP:

Physical Target:

S.No	Compo-nent	(2012-13)	(2013-14)	(2014-15)	(2015- 16)	(2016-17)
1	(NOTTO) including National Tissue Bank	Building Renovated	Preparation for website & posting of staff	Website functional, provide manpower Networking between TC, RC of Delhi & national Tissue bank Functional	NOTTO activities continued	NOTTO activities continued
2	ROTO (5)		Identification of State and institution where ROTTO to be set up, Renovation dialogue started (3)	ROTO renovation work started (3+2)	ROTOs made operational	ROTO work continued

3	SOTTO (5)		Identification of State and institution where SOTTO to be set up,	Establishment work initiated (4) AIIMS like Institute	2 SOTTOs made operational	2 more SOTTOs made operational and establishment work initiated (1)
4	State Tissue Banks (5 States)			Selection of institutions where Regional biomaterial centre is to be set up, start Grant for Biomaterial centre (2)	Grant for Biomaterial centre (2)	Grant for Biomaterial centre (1)

Staff Structure:

Detail	Common Staff	National Workshop for Organ/Tissue Removal & Transplant	Tissue Bank	Total
NOTTO	13(4 Executive+9)	12(5 Executive+7)	15(5 Executive+ 10)	40
ROTO	11(4 Executive+7)			11x5
SOTTO	4(3 Executive+1)			4x6
Transplant Hospital	Transplant coordinator (2) for each Govt OTTH			Govt OTTH
Organ Retrieval Centre/Trauma Centre	Retrieval Coordinator (1) For each of 100 OTRH			100

Note : Exe = Executive level staff + Other category of staff

Objective Targets:

Sno.	Component	(2012-13)	(2013-14)	(2014-15)	(2015-16)	(2016-17)
1	Training (By NOTTO)	Post Doctoral certificate Course in Dialysis Medicine (through IGNOU)	-do-	-do + Training workshop of TC(1)/ for police and medico-legal personals (1)/ for nodal officers(1)/ Training of key programme officers-in country-3-outside country-3 Training workshop of Transplant Hospital/ Retrieval Hospital: Anaesthetists/ Intensivists (1)/ for Transplant Co-ordinator/ Retrieval surgeons and Nursing staff (1)/	-do-	-do-
2	IEC Activities	Regional Awareness Workshop National Organ Donation Day	Awareness workshops (2) National Organ Donation Day	Meeting with ROTTOs Development of IEC Materials, video spot 1, 2 Audio spots Awareness workshops (4) National Organ Donation Day, Audio Video campaign.	Awareness workshops meetings (4). National Organ Donation Day. Audio Video campaign	-do-
3	Miscellaneous			Immuno-suppressant Drugs, Monitoring transplant service and Research etc	-do-	-do-

Financial Target:

NOTTO/ROTO will submit their annual financial requirement every year for under two categories Organ/Tissue Networking Centre and Tissue Banking under following components: Equipment's Minor work, Salary, Travel, Material Supply including surgical instruments, preservatives for organ/tissue, immunosuppressive drugs, Office Expenses, Professional service, Training including workshops, seminars, development of Guidelines and Manual etc, IEC including advocacy, Review meetings . The financial support needed for the selected medical college/hospitals (Govt/Private) as per NOTP targets for each region and one trauma centres of each region shall be included separately through respective ROTTO budget.

ROTO cum SOTTO: Budget

Item	2013-14	2014-15	2015-16	2016-17	Total Rs Lakhs
No. of ROTTO cum SOTTO	Planning	4	2	-	
Non recurring (Furniture, Equipment, Planning Software)	272	68 (can start all 5)	-	340	
Recurring (staff per year)	-	76.3x1= 76.3	76.3x5= 381.5	76.3x5= 381.5	839.3
Total	-	348.3	449.5	381.5	1179.3

Unit Cost: Rs 1.44 Crore (0.68 Non Recurring + 0.763 Recurring/year)

SOTTO: Budget (in Lakhs)

Item	2013-14	2014-15	2015-16	2016-17	Total Rs Lakhs
No. of SOTTO	Preparation	3	2	-	
Non recurring	Do	159	106	-	265
Recurring (per year)	do	36x1 = 36	36x3= 108	36x5=180	324
Total	do	195	214	180	589

Unit Cost: Rs 0.89 Crore (0.53 Non Recurring + 0.36 Recurring/Year)

6. Institution Identified and their Role:

A. NOTTO including National Tissue Bank:

NOTTO shall prepare list of organ and tissue transplantation centres state/UT and Organ/Tissue wise and will analyse such monthly/quarterly data .It will

facilitate for development of following guidelines/information's with help of its technical expert advisory groups:

- i. Guidelines to be followed for diagnosis & certification of brain stem death in adult, children and infant.
- ii. Guidelines for transplant coordinators and their role.
- iii. Guidelines for approaching family and possible family question answers for transplant/retrieval coordinators.
- iv. Guidelines for Donor management including paediatric donor management, donor screening, donor investigation, general nursing care
- v. Information for anaesthetist on management of the multi organ donor including pre operative donor management, donor procedure, surgical outline, post operative care of donor.
- vi. Information for operating theatre staff on procurement requirements covering general theatre requirements, staff specific theatre requirements, preliminary dissection, organ specific requirements for nephrectomy /intestine/ pancreactomy/ cardiectomy/ pneumonectomy, heart valve donation/ corneal or whole eye donation/bone donation/ skin donation etc.
- vii. Shall conduct orientation training of various categories of staff and selected persons from general public with help of identified training institutes.
- viii. With help of appropriate identified institution will conduct a national workshop for finalisation of standard training duration & curriculum for different categories of staff under NOTP. It will also develop training manual for the staff & SOPs for the laboratory staff. Identify the centres capable of doing State of art training for following categories of staff namely OTTCs/OTRCs, State Nodal Officers, NOTTO/ROTTTO/SOTTO Programme managers & Consultants for Transplant networking and tissue banks, Orientation of Transplant Programme Managers from each registered organ/tissue hospital.
- ix. Will advertise expression of interest for development of IEC campaign material for NOTP.
- x. Will conduct annual half yearly meeting with ROTTO, NOTTO, Tissue banks, trauma centres.
- xi. Will monitor NOTP and prepare programme evaluation proposal after 3 years of implementation.
- xii. A 24 hour help line shall be established as part of IEC when NOTTO becomes fully functional.
- xiii. It shall coordinate the Organ and tissue transplant centres of Delhi NCR region for which it will prepare list of Brain Stem Death Committees of Registered Transplant and Retrieval hospitals and selected trauma centres of Delhi NCR Region so that a model networking of organ procurement and allocation system is developed in Delhi NCR region.

**B. ROTTO cum SOTTO including Regional Tissue Bank (Tentative plan):
Identification: 5 ROTTO'S**

Five ROTTO cum SOTTO are to be set up one each at

States	ROTTTO	SOTTO
Maharashtra, Gujrat, Goa & Uts of Dadar Nagar Haveli, Daman & Diu + Bhopal & Chattisgarh	KEM Hospital Mumbai	MP under SOTTO -AIIMS Bhopal & Chattisgarh under SOTTO-AIIMS Raipur
Tamil Nadu, Kerala, Telangana & Seemandhra, Karnataka, Pondicherry, Andaman & Nicobar, Lakshadweep	Govt Medical College Chennai	
WB, Jharkhand, Tripura, Sikkim + Bihar, Orissa	PG MER Kolkatta	Bihar under SOTTO- AIIMS Patna& Orissa under SOTTO- AIIMS Bhubneshwar
Punjab, Haryana, HP, J &K , Chandigarh + Rajasthan, Utrakhand	PGI Chandigarh	Rajasthan Under SOTTO- AIIMS Jodhpur & Uttra Khand under SOTTO- AIIMS Rishikesh
Assam, Meghalaya, Arunachal Pradesh, Manipur, Nagaland, Mizoram	Guwahati Medical College	
Delhi/NCR & UP	NOTTO	Till SGPGI is prepared to cover UP

Functions of ROTTO cum SOTTO:

- i. All ROTTO shall develop their office & equip it for networking linkage for organ donation /pledge centres through registered retrieval hospital/retrieval medical colleges, registered transplant centres & registered trauma centres as retrieval centres.
- ii. Organize Organ & Tissue retrieval by identifying organ retrieval teams for each major hospital & get these hospitals registered for retrieval.
- iii. Make a transplant hospital& retrieval centre wise list of Transplant coordinators, Surgeons/ other specialists/staff needing training for their specific jobs of organ & tissue donation/retrieval/ organ transplant, Tissue banking and arrange their training.
- iv. Prepare BSD committee (BSDC) of each of transplant hospital (OTTH) & Retrieval Hospital (OTRH) and encourage them for conducting training on BS death. Prepare educational material for General Medical staff eg MO, Nurses/ANMs, HE, other health care staff, Health volunteers/social workers.
- v. Conduct short orientation training of doctors, PG & UG students, LTs, OTTCs, Nurses, Health educators etc.

- Develop standard syllabus and duration for training of transplant coordinators (OTTCs) & Retrieval coordinators (OTRCs).
- vi. Prepare educational material for General Medical staff eg MO, Nurses/ANMs, HE, other health care staff, Health volunteers/social workers. Sensitization & orientation of general Health Care staff, eg MO, Nurses/ANM, Health educators, other paramedical staff, media personnel, Health volunteers/social workers.
 - vii. IEC for the general public /relatives of ICU patients. Display of attractive poster, Audio visual message on organ transplant. Conduct advocacy campaign.
 - viii. The eye bank should continue to get support from National programme for the Control of Blindness. The facility of storage of eye /cornea will be housed at NOTTO Tissue Bank as well as ROTTO tissue banks.
 - ix. A 24 hour National Helpline shall be made functional by NOTTO after it becomes fully functional as part of IEC component .

C. SOTTO:

Identification of 6 AIIMS like Institutes:

SOTTOs will be established one each for the following major states to be located in 6 AIIMS like institutes namely Jodhpur, Raipur, Bhubneshwar, Rishikesh, Patna, and Bhopal. These AIIMS like institute will coordinate with the medical institute in their states where Organ transplantation /retrieval is being done/or have the potential to start it.

The AIIMS like institution namely Jodhpur, Raipur, Bhopal, Rishikesh, Patna, Bhubneswar will work as SOTTO in close coordination with the respective state govt, OTTH, OTRH for establishing networking. They will conduct networking activities for the state as SOTTO.

Functions of SOTTO:

The SOTTO will do activities similar to ROTTO in the state and take help of nearest tissue banks of the ROTTO/NOTTO. It will help the state in the matter of advocacy & IEC for Organ donation, Registry of organ pledge and cadaveric organ donation registry, training & sensitization of various personnel, brain stem death certification team formation, and retrieval team formation in the line as mentioned under functions of ROTTO. It will send regular reports in the format to the ROTTO & NOTTO.

SOTTO will coordinate with all the eye banks and other registered tissue banks and other stake holders in the state eg. Transplant Hospitals (OTTHs), Retrieval Hospitals (OTRHs), Medical Colleges provided transplant coordinators, Trauma centres, hospitals with ICU.

D. EYE Bank:

Support for eye bank should be continued from National Programme for Control of Blindness in addition to eye storage facility at National Banks and its branches. The eye /cornea will also be stored at ROTTO tissue banks. The national eye bank already exists at RP Centre AIIMS, which is doing screening test for quality of cornea and serological tests, the eye storage will also be done at NOTTO Office. The 6 Regional Eye retrieval centres in Delhi /NCR region will continue to coordinate with National eye centre and NOTTO will maintain close link with National Eye Bank.

C. Medical colleges/tertiary hospitals:

Government Medical Colleges/tertiary care hospitals registered & functioning as organ transplant hospital & Organ retrieval hospital will be provided support for organ transplant and organ retrieval. The support in the form of two Transplant Coordinators and one computer facility to each identified 100 medical college/tertiary care hospital to be taken up in a phased manner (25 medical colleges/tertiary care hospitals every year)which will also include 25 Private Retrieval Hospitals to be covered with approved pattern of assistance. Two Transplant Coordinators (salary of Organ Transplant & Retrieval Coordinator–ORDC) @ Rs. 20,000 p.m.) and office expenses & maintenance grant of Rs. 50,000 each year will be provided to such centres which together works out to be recurring grant of Rs.5.3 Lakhs per year per medical college/tertiary care hospital . The centre will also be provided non recurring grant for a office Computer set with internet and printer costing about Rs. 1.0 Lakhs.

The provisions for Medical College/tertiary care hospital functioning as transplant hospital:

(Rs. In lakhs)

Year	No. of Medical Colleges/ Tertiary Hospitals	Budget for Transplant/Retrieval Coordinators @2 per college at salary of Rs20,000/- each	Support for computers @ Rs. 1.00 lakh for one computer set	Office Expenses @ Rs.50,000/- per year	Total Rs in Lakhs
2013-14	Preparation	Recurring	Non Recurring	Preparation	Nil
2014-15	50	300	50	25	375.00
2015-16	25 new + 50 old	360	25	37.5	422.50
2016-17	25 new +75 old	480	25	50.00	555.00
				Total	1352.50

Unit Cost in Lakhs: Non Recurring Rs 1.0; Recurring Rs 5.30 Total Rs 6.30

Total for 4 years: 1352 Lakh = 13.65 Crore

Total support for Private Centres (through NOTTO/ROTTTO/SOTTO):

Rs. One Crore per year so Rs. 4 Crore for 12th plan.

Total fund under this component: Rs. 17.65 Crore.

Out of 100 medical colleges 25 will be from private sector.

Out of 100 Medical Colleges/Tertiary care hospital to be supported, 5 will be the medical college identified as ROTTTO Cum SOTTO centers, and about 20 will be from Delhi /NCR Region.

The Eye Retrieval system and eye bank will continue their present system of getting support from National Programme for Prevention & Control of Blindness and above support will not be applicable for the Medical College/Tertiary Care hospital/ Private or NGO centres which are covered under National Programme for Prevention and Control of Blindness. The above support will also not be applicable for any centres which are involved or retrieving of tissues only. The NOTTO training centres should target to provide an IEC kit to each coordinator at time of their training conducted under the programme which should include items like flip book, adequate number of copies of pledge card, forms required etc.

F. Role of Registered Organ/Tissue Transplant Hospital (OTTH) :

- a. The OTTH will computerize all the formats designed and indicated under THOA Rules, have sufficient number of available copies with the transplant coordinator of their hospital. They will form hospital based transplant authority. One senior officer of the hospital will also act as Hospital Organ Transplant Manager. He will represent the hospital in all the matter related to organ/tissue transplant and will regularly guide and supervise the Transplant coordinators/ Counsellors in their duties.
- b. The information to be included in national registry regarding donors and recipients of human organ & tissue will be based on following: Organ transplant registry, Organ donation registry, tissue donation/retrieval registry. It will maintain the registers & records required for transplant purpose and will keep analyze monthly data on transplant and follow up data after transplant.
- c. Its hospital based committee will take decision about the suitability of live organ donation based on the examination in detail and interview of the donor, proposed recipient and other family members.
- d. Training of transplant coordinators, training of lab technicians, retrieval teams.
- e. Conduct training on Brain Stem death for doctors. Short orientation training for doctors, nurses, technicians, etc. and development of training material for above categories of staff.
- g. Conduct IEC for the general public, relatives of patients from ICU, display attractive audiovisuals material. IEC activities for selected groups of people, community for encouraging organ/ tissue pledge and organ/tissue donation. Conduct advocacy workshop/seminar on organ donation.

- h. Organ Retrieval and transplantation
- i. The Centres registered separately for Eye/Cornea transplant would continue to do their activities under the National Programme for control of Blindness.

G. Activities of Govt Medical Colleges/tertiary hospitals registered for Organ & Tissue Retrieval:

- i. Deputation of specialists needing training for transplant surgery, organ/tissue retrieval and training of lab technicians.
- ii. Conduct short orientation training of doctors, PG & UG students, Lab Technicians, OTTCs/OTRCs, Nurses, Health educators etc and also conduct training on BS death for doctors .
- iii. Conduct IEC activities for the public, relatives of patients in ICUs. Display attractive audiovisuals material.
- iv. Conduct Organ retrieval and transplantation.
- v. The Organ &Tissue Retrieval coordinators will coordinate with other training activities going on in the hospital to provide talk on organ transplant for sensitization of other staff and will also display the IEC material available with him. Advocacy workshop/seminar on organ donation will also be conducted by these centers.
- vi. They will also play role for maintenance of cadaver donor i.e brain stem death persons in ICU, and for follow up immunosuppressive treatment of beneficiaries under the programme.

The Medical College/tertiary care registered transplant hospitals in Delhi could be given support in the first year after consultation with the respective Govt and head of these institutions: GB Pant Hospital, ILBS, RML Hospital, Safdarjung Hospital, which are also registered as transplant centres. Currently a total of 22 hospitals in Delhi are registered for one or more organ transplant. Out of these 22 hospitals, 5 are Govt.

Other Govt /Medical Colleges/hospitals not having transplant centres but that can play role as retrieval centres have to be identified for support. They should have above 100 beds and should be providing round the clock service. Following Hospitals of Delhi NCR could be included for support as Retrieval Centres after discussion with Govt of Delhi and their approval if these hospital are willing to be registered as Retrieval Centres: GTB Shahadra, Lady Harding Medical College & Sucheta Kriplani Hospital, Lok Nayak Jai Prakash hospital Maulana Azad Medical College, Delhi Govt hospitals at Motinagar, Deen Dayal Hospital, Baba Ambedkar Hospital, Babu JagJeevan Ram Hospital, Lal Bahadur Shastri Hospital etc. For confirmation of their role a dialogue should be held with Secretary Health Govt of Delhi and with the heads of these hospitals and list of hospital should be finalised with approval of Secretary Govt of Delhi. The private hospitals which are willing to be Organ &Tissue Retrieval Centre will have to be registered as retrieval centre.

Some of the following private hospitals in Delhi /NCR which are not registered as Transplant centres / Retrieval Centres for Organ Transplant but could play role as retrieval centre in view of round the clock service available and total bed size above 100: Holi Family Hospital, Max Hospital 2 centres, City Hospital Pusa Road, Jeeva Hospital, Sant Parmanand Hospital Ring Road, Mata Chanan Devi Hospital etc. A meeting should also be held with their heads and Govt of Delhi to finalise list of such retrieval hospital after taking their willingness and acceptance and decision should also be taken whether support should be provided to them through NOTTO or through Delhi Govt.

7. Type of assistance for the Private Medical Colleges/tertiary care hospitals, Private Organization, NGO:

a). Private Medical Colleges/Private tertiary level Hospitals having organ Transplant Facility :

The registered Private Organ & Tissue Transplant Hospital will have their own transplant coordinators as per act and detail given by them in their registration for conducting organ & tissue transplant.

Private Institution which is recognized for training of transplant coordinators, specialists in organ & tissue retrieval, tissue bank specialists, would be provided support for conducting training activities which will include nominal training fee and course material of govt participants and TA/DA of the Govt nominated persons would be met by the respective govt. Private training centre if conducts, special training of national, state, district programme officers or any person nominated by the govt (such as Police personnel, lawyers, religious heads, media persons) may also get lump- sump advance for cost of such training based on the number of Govt nominated persons to be provided training after approval of their proposal.

Activities of such institution:

They will conduct following activities for the surrounding areas/districts/states of their location

- i. Training of deputed transplant/retrieval coordinators, specialists for transplant surgery and organ & tissue retrieval , Tissue bank specialists, Transplant managers of hospitals, training of transplant coordinators, training of lab technicians, the national /state programme officers and other persons deputed by the Govt.
- ii. Conduct training on BS death for doctors. Short orientation training for doctors, nurses, technicians,
- iii. Development of training material for above categories of staff.
- iv. Conduct IEC for the general public , relatives of patients from ICU, display attractive audiovisuals material.

- v. Advocacy workshop/seminar on organ donation
- vi. Organ /tissue Retrieval and transplantation
- vii. Conduct IEC activities for the own hospital staff.

b). Private Medical Colleges/tertiary care hospital not having Organ Transplant centre but capable of doing Organ Retrieval:

25 such Private colleges/tertiary level hospitals will be identified as Private Organ & tissue Retrieval Hospital (OTRH) and shall be given the support of one Transplant coordinators (who will be called as organ & tissue retrieval coordinators) subject to the condition that the college is registered as Organ & Tissue retrieval centre and minimum of > 1 cadaveric donation on an average per month for both organs & tissues are to be retrieved in a year (i.e. 12/year). The Hospitals which are only retrieving eye/other tissue alone will not be provided support of addition retrieval coordinators. However, such hospital covered under National Programme for Control of Blindness should not be affected by this scheme.

These hospitals will play role in promotion of organ donation & retrieval activities and recording, reporting of organ & tissues will be done as per THOA rules & this guideline.

Activities of such institution: These hospitals with help of other staff will conduct following activities for the surrounding districts of their location:

- i. Conduct training on BSD, Develop educational material to popularize cadaveric organ & tissue donation for General Medical staff eg MO, Nurses/ANMs, HE, other health care staff, Health volunteers/social workers.
- ii. Organ & Tissue retrieval
- iii. Sensitization & orientation of general Health Care staff, eg MO, Nurses/ANM, Health educators, other paramedical staff, media personnel, Health volunteers/social workers.
- iv. Conduct advocacy campaign, workshop/seminar on organ and tissue donation especially cadaveric donation, brain stem death certification.
- v. Conduct Orientation training of staff on organ donation organ pledge, role of Transplant coordinators, Retrieval Coordinators and other staff.
- vi. Conduct sensitization training for staff and other nominated persons on organ/tissue pledge, donation.

8. Trauma Centres:

Support shall be provided in the form One Organ/ Tissue Retrieval coordinator (OTRC) and Computer to the identified Government Trauma Centres. These coordinators would be designated as Organ & Tissue Retrieval Coordinators (OTRC). However, these trauma centres will have to be registered as Organ/tissue retrieval centres by the concerning central/state/UT Govt.

Five Major Trauma centres will be identified and provided with above additional support from NOTP as planned below : (Rs in Lakhs)

Year	No. of Trauma Centres	Budget for OTRC @1 per Trauma Centre at salary of Rs 20,000/- each	Support for computers @ Rs.1.00 lakh for one computer set	Office Expenses @ Rs.50,000/- per year	Total in lakhs
2013-14		Preparation			
2014-15	5 for 6 months	6	5	2.5	13.5
2015-16		12	-	2.5	14.5
2016-17		12	-	2.5	14.5
				Total	42.50

Unit cost: Recurring Rs 2.90 Lakh, Non Recurring Rs 1.0 Lakh, Total Rs Rs 3.90 Lakh

Type of assistance for such trauma centres:

One Organ & tissue retrieval Coordinator salary on contractual basis as per rate approved by the Govt Rs. 2.4 lakh per year and for maintenance of office Rs. 0.5 Lakh. Thus a total Recurring grant of Rs2.9 Lac /year and Non recurring grant for Computer set with internet and printer Rs. 1.0 lakh would be provided.

After identification these trauma centres will have to be registered as organ/tissue retrieval centres.

Activities of such Trauma Centres:

Trauma Centres will conduct following activities in the surrounding districts of their location:

- i. Conducting training on BS death Certification , prepare educational material for General Medical staff eg MO, Nurses/ANMs, HE, other health care staff, Health volunteers/social workers.
- ii. Organ & Tissue retrieval.
- iii. Sensitization & orientation of general Health Care staff, eg MO, Nurses/ANM, Health educators, other paramedical staff, media personnel, Health volunteers/social workers etc.
- iv. IEC for the general public /relatives of ICU patients for organ &tissue donation especially cadaveric. Display of attractive poster, audio visual message on organ transplant.
- v. Conducting advocacy campaign for the patients, relatives, selected groups, community.

The number of executive and non executive categories of staff required for the various kind of institution under NOTP is as under:

Unit	Executive	Non Executive	Total
ROTO	6 (Director + Joint Director + Consultant IEC, Data Management, Consultant TC-2) *(PS:JD Micr)	5 (Data Entry Operator) *(Personal Secretary : 2 Lab Technician + 3 DEO)	11
SOTTO	3(Joint Director, Consultant IEC, Consultant TC)	1	4
Med College/Tertiary Hospital	-	2 (OTTC or OTRC) Govt 1(OTRC) Private	100x2
Trauma Centre	-	1 (OTRC)	5
Regional Bio-material Centre (Depending on load)	Regional Tissue Bank 3(DD, St Officer, Coordinator)	Regional Tissue Bank 7(LT2, LA2, DEO 1, PS 1, MTS 1)	10

*Regional Tissue Bank staff within provision of 11 staff suggested.

Annual Funds requirement (institution wise) for each category of institution:
(Rs in Lakhs)

Institution & Number	Non Recurring	Recurring /year	Total Unit Cost
ROTO cum SOTTO-each (5)	68(3 Room renovation + Office equipment detail on EFC page 26)	76.3 (2 Regional Office Director & Joint Director, 2 Consultant IEC & Data Management , 2TC, 5 DEO)	144.3
Regional T.Bank-each (5)	285(270Eq+15 other)	144.4(35 Consumable +100 Res+3QC+6.4 contingency)+ Staff salary	429.4 + Staff salary depending on load++ Unit
SOTTO each(6)	53	36	89
Medical College -each /Tertiary level Hospital (100)	1.0 Computer+ internet	5.3(4.8 Sal+).5 OE)	6.3
Trauma Centre -each (5)	1.0 Computer	2.90(2.4sal+0.5 OE)	3.90

9. Training:

The year wise target for training is as following:

S.N	Component	(2012-13)	(2013-14)	(2014-15)	(2015-16)	(2016-17)
	Training (By NOTTO)	Organized training of Transplant coordinator Post Doctoral certificate Course in Dialysis Medicine (through IGNOU)	PDCDM Course Training activities continue	PDCDM Course Training activities continued. Training workshop of Transplant coordinators (2) Training workshop for police and medico-legal personals (1) Training Workshop for nodal officers (1). Training of key programme officers -in country -outside Country. Training workshop for anaesthetists and intensivists (1) Training for Transplant/ Retrieval surgeons and Nursing staff (1)	PDCDM Course Training activities continued Training workshop of Transplant coordinators (1) Training for Transplant/ Retrieval surgeons and Nursing staff (1) Training of key programme officers -in country -outside country	PDCDM Course Training activities continued Training workshop of Transplant coordinators (1) Training workshop for Nurses (1) Training for Transplant/ Retrieval surgeons and Nursing staff (1) Training of key programme officers -in country -outside country

Training of personnel (Human Resource Development) is most important aspect for the success of the program. There are mainly two aspects

- (i) Increasing the opportunities for basic training programs for different categories
- (ii) Training the existing personnel for skill in the area of transplantation in various categories.

No. of trainees and cost of various training programs:

S. No.	Trainees No.	Total Cost (Rs. crore)
Dialysis Physician Training through IGNOU	60	2.0
Training MOHFW/Dte.GHS/NOTTO/ROTO/SOTTO Staff	30	3.0
Participation in International trainings & workshops for key programme officers	10	2.0
Transplant Surgeons	40	1.0
Transplant Coordinators	400	1.0
Transplant physicians	200	1.0
Nurses	500	1.0
Pathologist/Immunologist	50	0.5
Anaesthesiologists, intensivist, radiologist etc.	50	0.5
Total		12.0

NOTTO shall organize training activities in collaboration with institutions having capacity to undertake such training.

10. Information Education Communication:

S.N	Component	(2012-13)	(2013-14)	(2014-15)	(2015-16)	(2016-17)
1	IEC Activities, Meetings Workshops	Regional Awareness Workshops National Organ Donation Day	Draft Rules published for inviting public comments.	One national level meeting of Appropriate Authorities of States, Development of IEC Materials: 1 Video spot 2 Audio spots. Awareness workshops (4). National Organ Donation Day. Development of other IEC Materials Audio Video campaign	Awareness workshops/ meetings (4), National Organ Donation Day Audio Video campaign	Awareness workshops/ meetings (4), National Organ Donation Day Audio Video campaign

Total of Rs 28.68 Cr has been allocated for IEC.

Public Awareness Activities:

The objective of the IEC activities would be Promotion of deceased organ and tissue donation, Prevention of organ trafficking, Encourage pledging for donating organ & tissue after death. Following advocacy measures would be undertaken:

- i. **Advocacy:** Engage the support of religious sector/leaders for organ donation actively. Lobby with NCERT and CBSE for a small reference on organ donation in the curriculum.
Rashtriya Arogya Nidhi(RAN) would be modified to make provision for transplantation in private centres. Patients on regular dialysis or on continuous medication with immunosuppressant should be provided yearly financial assistance rather than one year as existing at present. At present the grant for kidney transplant is 1.8 lakhs and Rs. 10,000 for first year only is given. The efforts would be made to enhance the grant as well as provide financial assistance on regular basis for follow up medication etc..Provision of National Award for promoting cadaver donations, to the Institutes, Doctors, Transplant Coordinators & Donor Families
- ii. **Organizing Meetings/Advocacy including Awareness about Legal Provisions** – people should be aware of the law on donation of organs and the penalties for illegal transactions. Regional and State level Organ Donation Awareness Workshops through ROTTO/SOTTO/Regional Offices of Health and Family Welfare and State/UT govt. Active NGOs will also be involved.
- iii. **Orientation and Sensitization Workshops:** Annual workshop for appropriate authorities of states (one/year).
- iv. **Felicitation for donor families.**
- v. **National level inter-sectoral Stakeholders Meetings** (2 meetings per year): Various stakeholders would be invited for national level inter-sectoral meetings. The stakeholders would include following:-
Surface transport Ministry, Railways, Licensing authorities, Social Justice, Women and Child Development, Ministry of Human Resource Development (NCERT, CBSE, Kendriya Vidyalaya), Professional associations, Religious Organizations, Transplant Centers, Retrieval centers, Tissue Banks, Professional councils e.g. MCI etc.
- vi. Undertaking **KAP study for different religious heads** and **Development of IEC Material** (both electronic and print).
- vii. **Mass Media Campaign** for creating awareness about organ donation so that the general public will be made aware about the concept that human organs can be donated to save lives. This campaign would be organised from time to time. Engage 'celebrities' to promote organ donation. This would encourage people to be inspired to emulate such celebrities. National level IEC would be done through TV/Radio/Print media. Website would also be created for mass scale information about rights, benefit, legal protection of donors besides functioning of NOTTO/ROTTTO/SOTTO. Distribution and Display of Materials developed. Mass Information campaigns for different groups like schools, college, youth groups and organizations.

- viii. Organizing **National Organ Donation Day and release of Press Advertisement.**
- ix. Develop a **24 hour functional National Helpline** shall be made functional at NOTTO
- x. Develop FAQs and their reply on the website of NOTTO: e.g. who can donate, location of authorized transplant centres etc.

Approximate IEC Budget Provision under the programme:

Item wise details Cost (Rs. In Lakhs)

Item	No.	Cost per unit or cost per year	Total for 4 years
Video spots development in 10 regional languages	2	20 lakh per spot	40 lakh
Audio messages in 10 regional languages	2	5 lakh per spot	10 lakh
TV telecasting	2 spots/week at 10 locations	250 lakh per year	10 Crore
Radio Broadcasting	2 spots/week at 10 locations	100 lakh per year	4 Crore
IEC material development, printing and distribution	Pamphlets, booklets, hand-outs, posters, calendar etc.	100 lakh per year	4 crore
Newspaper Advertisement	2 in 15 languages per year	100 lakh per year	4 Crore
Vibrant Website	1	10 lakh per year	40 lakh
National level Meetings including National Organ Donation Day	3 (One big @55 lakh+ 2 small@ 25 lakh/meeting)	105 lakh per year	4.2 Crore
Regional Awareness workshops	5 per year @ 2 lakh per year	10 lakh per year	40 lakh
National Award Scheme		10 lakh per year	40 lakh
Advocacy and campaign activities for stakeholders and different social groups, field publicity	5 per year	15 lakh per year	60 lakh
National Helpline including round the clock staff	Rs. 50000 per month	2013-2014: Only telephone Line for 6 months @ 10000 per month 2014- 2017: 6 Lakh per year for 3 years	18.6 lakh
Total			28.686 Crore

11. Immunosuppressive Drugs:

Provision of immunosuppressive regimen would be provided with cost ranging from Rs 6000 to 12000 per month to per cadaveric transplant recipient for upto 100 patients per year which will be given to the BPL category patients who have received organ/tissue through NOTP networking system. The drugs approved on EFC will only be included.

12. Organ Pledging and Registration of Eligible Recipients:

The "opt-in" system of organ donation – where individuals are asked to register their willingness to be a donor after their death will be followed under NOTP as education and awareness level of people is not sufficient to adopt a system of "presumed consent", where it could be assumed that an individual wishes to be a donor unless he or she has "opted out" by registering their objection to donation after their death. Any person who has received one organ/tissue transplant would be counselled to give his/her consent for organ pledge in form no.7.

Pledge for Organ and/or Tissue Donation after Death:

Persons, who have pledged, during their lifetime to donate their organ(s) & tissue(s) after their death, in Form No.7 & deposited it in paper or electronic mode to any PHC/CHC/State District Hospital/District Hospital / Private hospital where organ /tissue donation is pledged; These hospitals will send the form to the nearest registered retrieval hospital or registered transplant centre or SOTTO/ROTTA/NOTTO which are electronically connected in the networking organization. The pledger has the option to withdraw the pledge through intimation in the same way.

Pledging can also be promoted by NOTTO/OTTO/SOTTOs by involving transport authority of the state/UT issuing driving license. If it is approved by them each person seeking a driving license would need to fill pledge form7 also. Person willing to pledge could be given the license with a green sticker pasted on it, showing "Organ Donor". Copy of form signed by pledger should be sent to the nearest registered Retrieval Centre or registered transplant centre or SOTTO/ROTTA which are electronically connected to the networking organization NOTTO.

Two witness should also sign the pledge form 7 for Organ/Tissue pledging where ever possible. In case of online registration of pledge, one copy of the pledge will be retained by pledger and a hard copy signed by pledger shall be sent to nearest registered retrieval centre or registered transplant centre/SOTTO/ROTTA which is connected to the national networking organisation by sending communication in the same way as done for pledging the organ & tissue. NGO/ Foundations which work for promotion of organ donation should be encouraged under the programme.

13. Organ & Tissue Donation Register (OTDR) :

It is a register which records the decision /pledge given by the people about becoming an organ & tissue donor for transplantation after death. It just keeps record of consent of individual for possible organ donation and helps for legal purpose. This register does not maintain list of prospective recipients. Authorized medical personnel may access the register to see what an individual choice, and whether the family is also consulted or not. Registering is purely on voluntary basis and people have complete choice over whether to donate or not and which organs and tissues they wish to donate. If a person does not want to become an organ and tissue donor after having given such decision in past they can withdraw their decision not to donate on the Donor Register.

The Donor Register makes sure a person's donation decision can be accessed 24 hours a day, seven days a week by authorized personnel, anywhere in the country. In the event of a person's death, information about their donation decision may be accessed from the Donor Register by authorized personnel and provided to the family of the deceased. It's therefore important for individual, prospective donors to discuss their donation decision with their family or those close to them as they'll be asked to give consent in future. This Donor Register is for registering decisions about donating organs and tissue for therapeutic purpose for the needy patients and not for the scientific research purposes. An individual may consent to the use of all organs and tissues, or just some (if someone has strong views about particular body parts for instance). An individual must be 18 years or older to give their consent. When only an intention is recorded by the individual then family will be asked to give consent in the event of death.

14. National Registry of Organ and Tissue Donors and Transplantation:

The information to be included in national registry regarding donors and recipients of human organ & tissue will be based on following:

a) Organ Transplant Registry

The information shall include demographic data about the patient, donor, hospitals, recipient and donor follow up details, transplant waiting list etc. Data will be collected from all retrieval and transplant centres. Data collection frequency etc will be initially monthly but it will be later on as per the norms decided by the NOTTO advisory committee. This will preferably be through a web-based interface or paper submission. The information will be maintained both specific organ wise and also in a consolidated format. Yearly reports will be published and also shared with the contributing units and other stakeholders.

The transplant register having above information will be maintained at the

Transplant centre, SOTTO, ROTTO cum SOTTO, & at NOTTO. The formats of Organ & tissue register at Transplant hospital/ROTTTO cum SOTTO & NOTTO are to be prepared by NOTTO Technical Advisory body.

This 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 & tissue retrieved, Outcome of donated organ/tissue, details of recipient etc. The content of organ & Tissue donation register to be maintained at Retrieval Centre, Transplant centre, ROTTO cum SOTTO and NOTTO are to be decided by NOTTO Technical Advisory Body.

b) The Tissue Donation/Retrieval Registry:

This registry shall include demographic information on the tissue donor, site of tissue retrieval/donation, primary cause of death in case of deceased donor, donor maintenance details in case of brain dead donor, associated medical illnesses, relevant laboratory tests, driver's license or any other document of pledging donation, donation requested by whom, identity of counsellors, tissue(s) and/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 . Yearly reports will be published and also shared with the contributing units and other stakeholders. The Tissue donation /retrieval register to be maintained at Retrieval Centre, Transplant hospital, ROTTO Cum SOTTO and NOTTO are to be decided by NOTTO Technical Advisory Body.

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

Organ and Tissue waiting list register to be maintained at The Transplant Centre is to be prepared by NOTTO Technical Advisory body.

c) Organ Donor Registry:

The National Organ Donor Register is a national database of details on

individuals who have registered their decision in regards to donation of organs and tissues in the event of their death. The database is managed by NOTTO initially and following 5 ROTTO cum SOTTO and 5 other SOTTOs will be doing the same at later stage in a phased manner

The data is collected by the Transplant coordinator, organ & tissue retrieval coordinator during the organ donation and retrieval process. The purpose of the Organ donation registry is to:

- Maintain a complete record of donated organs and tissue retrieved and transplanted in India from multi-organ donors
- Relate organ donor characteristics and terminal management to subsequent outcome of organ transplantation
- Identify demographic factors, such as age, gender, religion, ethical/racial group Facilitate education and public awareness activities regarding organ donation
- Distribute widely the results of data tabulation and analysis to all relevant groups.

The exchange of data between the National Organ donation registry and Regional ROTTO/SOTTO Organ transplant Registries allows transplant-recipient survival to be linked to donor factors. Annual reports are to be posted to all SOTTO, ROTTO transplant hospitals, retrieval hospitals/centres and MOHFW.

15. Organ and Tissue donation Networking & Coordination:

Manner of establishing national/regional/state human organ & tissue removal & storage networking and their functioning would be as following:

(The organ sharing and networking policy of States/locations of hospitals will not be binding on the Armed Forces Medical Services (AFMS) and the armed forces will be free to have their own policy of organ/tissue allocation and sharing. The Director General AFMS is permitted to have their own networking between the AFMS hospitals. However the AFMS hospitals are permitted to accept organs when available from civil hospitals with in their state jurisdiction).

- (i) There would be an apex national networking organization at the centre. There would also be regional and State level networking organizations where large number of transplantation of organ(s) and/or tissue (s) are performed. The State units would be linked to hospitals, organ & tissue matching Labs and tissue banks within their area and also to regional and national networking organizations. The broad principles of organ allocation and the criteria there of and framework & formats of national registry as mentioned under clause 15 shall be developed by the apex networking organization which shall be followed by the States/UTs.

- (ii) Such networks shall coordinate retrieval, storage, transportation, matching, allocation and transplantation of organs and shall develop norms and standard operating procedures for such activities and for tissues to the extent possible.
- (iii) These networks shall coordinate with respective State Government for establishing new transplant and retrieval centres and tissue banks and strengthening of existing ones.
- (iv) There may be designated Organ and/ retrieval teams in State/District/institution as per requirement, to be constituted by the State/Regional networking Organization. For tissue retrieval, the retrieval teams shall be formed by state/UT where ever required.
- (v) Networking would be e-enabled and accessible through dedicated website.
- (vi) Reference/allocation criteria would be developed and updated regularly by networking organizations in consultation with central/state Government.
- (vii) The networking organization(s) shall undertake Information Education and Communication (IEC) Activities for promotion of deceased organ and tissue donation.
- (viii) It shall Maintain and update Organ and /or Tissue Donation and Transplant Registry at respective level.

16. Organ Retrieval, Storage, Transportation:

Following guidelines are advisory. Depending on the local situation It may vary in the state. States are therefore advised to prepare clear guidelines in case of any variation and send a copy to Dte.GHS and NOTTO.

Organ retrieval:

- i. A national system of multi-organ retrieval zones will be established under each ROTTO/ SOTTO centred upon national multi-organ retrieval teams appointed by Registered Transplant Hospital and Registered Retrieval Centres approved by respective SOTTO/ROTTTO or by NOTTO. .
- ii. The Organ &tissue Retrieval teams will be responsible for retrieving organs& tissues from DBD (Donation after Brain Death) donors and from controlled DCD (donation after Circulatory Death) donors.
- iii. The retrieval zones will be based primarily upon the proximity (measured by response time by ambulance from liver or cardiac centres) of multi-organ retrieval teams to donor hospitals and not strictly by states/UT.
- iv. Organ retrieval at each donor hospital will be provided primarily by the closest (1st on-call) abdominal and cardiothoracic retrieval teams, with backup from the closest available retrieval team (2nd, 3rd, 4th etc on-call) if that 1st on-call retrieval team is already committed to retrieval elsewhere. Because of the critical impact of cold ischaemia on cardiac transplant outcomes, the heart should be dispatched as soon as possible after explants. For paediatric cardiothoracic donors of <30 kg, a paediatric cardiothoracicretrieval team will be asked to attend.

In the event of a paediatric liver donor, the paediatric liver recipient centre will be given the option to provide the abdominal retrieval team or to send a surgeon to assist the designated retrieval team if they wish to do so. Abdominal retrieval teams are expected to be capable of retrieving kidneys, pancreas and liver from paediatric donors aged five years or older. For small paediatric donors aged less than five years, a first on-call abdominal team that is not confident to retrieve from a small paediatric donor may request that the closest available centre with experience in paediatric liver transplantation attend in their stead.

Donor Hospital: The donor hospital will provide a fully equipped operating theatre for the retrieval procedure, including appropriate anaesthetic equipment and drugs to support the donor. The donor hospital is responsible for the safe transfer of the donor to the operation theatre. The donor or retrieval hospital should provide an anaesthetist to support DBD (Donation after Brain Death) donors in the operating theatre during the retrieval procedure. The donor hospital should provide a suitable helping staff, such as a qualified theatre nurse and/or operating department assistant, who is familiar with the theatre facilities and the whereabouts of the surgical and anaesthetic equipment, instruments and drugs which may be needed by the retrieval surgeons and anaesthetist. This/these individual(s) will remain in theatres during the retrieval procedure to provide assistance to the scrub nurse/Doctor/technician (provided by the retrieval team) and the anaesthetist, and assist the Transplant coordinator/ SN-OD (The Specialist Nurse – Organ Donation) with the final act of care.

Organ Retrieval Centers:

Abdominal and cardiothoracic retrieval centres must provide fully staffed on call retrieval teams available 24 hours per day, 7 days per week for organ retrieval if it is recognised as a regular retrieval team for organ. But if the retrieval centre is a smaller peripheral hospital registered for retrieval but not having all required staff for retrieval. It will provide facility available in OT and staff that may be required by the visiting retrieval team from a regular retrieval centre/Transplant hospital.

Retrieval Teams:

- i. All team members must be qualified and competent to perform the roles assigned to them.
- ii. When the retrieval is confined to abdominal organs only, the team should include, as a minimum, a lead abdominal surgeon, an assistant surgeon and a scrub nurse. If they wish, centres may also provide an abdominal perfusionist; otherwise, the SN-OD/transplant coordinator will assist with setting up and running the perfusion fluids for the abdominal organs.

Detail guidelines for the organ & tissue team would be prepared by technical committee of NOTTO and the same will be issued to all the states/UT and to the registered Transplant Hospitals and Retrieval hospitals.

17. Consent, retrieval, processing, storage and distribution of eye/other tissue grafts:

Different arrangements may be in place in each State for tissue retrieval. Once a potential donor is identified, the Tissue Donor Coordinator should liaise with their regional tissue bank to discuss the suitability of the potential donor, and how retrieval will be achieved. Generally, after retrieval, the tissue is taken to the tissue bank for processing according to their specific protocols.

Once processed, tissue may be stored in defined conditions for up to 5-10 years before it is used in transplantation.

After all testing results and retrieval and processing information is available, the responsible person in the tissue bank will decide whether the tissue is suitable for transplantation. If it is deemed suitable, the tissue will then be supplied by the tissue bank to surgeons in response to their specific requests.

Whole Eye/Corneal Donation:

The problems that may require a transplant include a clouding over and loss of transparency in the cornea in later life, herpes virus infection of the eye, accidental injury to the eye, corneal scarring due to other trauma, hereditary or congenital corneal clouding, or severe bacterial infection.

Eye/Tissue / Banks:

Eye Banks are responsible for managing the process of eye donation. Working closely with hospitals, coronial services, tissue banks and Organ Donation Services, eye banks cover all aspects of donation including donor transplant coordination services, the evaluation of donor medical history to assess donor risk and the surgical procedure of donation.

Consent for eye/ other tissue donation:

For tissue donation consent to be informed, it should contain the following elements:

- Permission for removal of ocular tissue either as whole eyes, or as corneas only/permission for removal of particular tissue
- Information as to the tissues that can potentially be used for transplantation
- Information about the process
- The requirement for blood testing of the donor to test for infectious viral diseases
- The possible requirement for further medical information to be obtained, and permission for this e.g. from GP, specialist
- Information concerning potential unsuitability of tissue, and uses for which permission is given in these instances e.g. research, clinical training or education should be obtained as a separate signed consent as being followed for cornea/eye donation. However, this issue should be discussed by the technical group of NOTTO and should be included in the guideline for the tissue retrieval team.
- Information on follow-up and notification of outcome

- Information on no cost to the donor and/or their family for any expenses relating to donation.

Permission must be specific for removal of ocular tissue either as whole eyes, or as corneas only. Some eye banks offer the service of cornea removal only but the preference is for whole eyes. Please contact your regional eye bank for further information.

Death Criteria and Time Interval for eye/other tissue donation:

- Eye tissue does not require an intact cardiovascular system to be viable for transplantation. People who have suffered circulatory death can potentially be eye donor.
- Acceptable time intervals from death to donation may vary according to the circumstances of death, the interim means of storing the body and method of corneal preservation. Maximum times vary from 12 – 24 hours. The regional eye bank should be contacted as soon as possible following death in regard to donor suitability.

Age:

- The lower limit for donation is two years.
- There is no definite relationship between quality of donor tissue and advanced age. Do not assume the donor is too old – the regional eye bank should be contacted in regard to donor suitability.

Blood tests: (Mandatory tests are)

- HIV-1 and HIV-2 antibody
- HCV antibody
- HBV surface antigen.
- In addition, if the donor has received intravenous infusions within 48 hours of death, a pre-transfusion blood sample may be required if plasma dilution has occurred. The National/regional eye bank will be able to advise on specific cases.

18. Support for maintenance of cadaver:

Provision has been made in the programme for providing support upto Rs 50000 per cadaver (through NOTTO, ROTTO, SOTTO) for maintenance of 50 deceased donors per year. Up to Rs 25 lakh per year will be provided for this purpose. Each ROTTO can support about 10 deceased donors in its region in a year. However, based on actual need some region may use for more than 10 deceased donors. Approval of ROTTO of the region where cadaveric donor is maintained will have to be obtained for this support.

19. Types of main staff engaged for organ/tissue coordination work at various levels:

NOTTO office will have one Consultant cum Sr Transplant Coordinator with consolidated salary of @ RS 60000 pm. Each ROTTO cum SOTTO will have 2 junior level Transplant coordinators with consolidated salary of @ Rs 20,000

pm. Each SOTTO will have 2 Junior level Transplant Coordinators with consolidated salary of @Rs 20,000 pm .

The retrieval hospital & Trauma Centre have one Organ/tissue donation cum retrieval coordinator have one Transplant coordinator (Junior level) with consolidated salary of @ Rs 20000 pm. Each of 75 Govt Medical Colleges/tertiary care hospitals will have two Organ & Tissue Donation cum Retrieval Coordinators (OTDRC) (JR) to be designated as Organ & Tissue Retrieval Coordinators (OTRC) on Contractual basis with consolidated salary @Rs 20000 pm each and 25 approved Private Medical Colleges retrieval hospital will have 1 to 2 OTDRC (JR). The National Tissue Bank of NOTTO and State tissue banks will have consultant coordinators. The ROTTO cum SOTTO consultant coordinator will liaise with tissue bank of same state and with NOTTO tissue bank. The detail role of Organ & Tissue Transplant Coordinators (OTTC), Organ & Tissue Donation cum Retrieval coordinator (OTDRC), Tissue Bank Coordinator (TBC), will have to be defined by Director, NOTTO. For eye donation Coordinator/counsellor the role already assigned by national eye bank will be continued and in addition they will also conduct IEC and coordinate for other tissue and organ donation as well.

20. Policy for Organ sharing & allocation:

Detail actual technical criteria for organ allocation will be prepared by technical committee of NOTTO. General policy guidelines to be adopted by the NOTTO, ROTTOs and SOTTOs are as under:

A) Guiding principles (Army will be exempted):

- i. All organs should be utilised and wastage should be avoided as organs are scarce and it can save life.
- ii. Sharing will apply for all the organs and sharing should take into account blood group, the waiting time, matching of organs and geographical proximity within one state. accordingly, the recipient should be selected
- iii. Organs donated from children should generally be allocated to paediatric age group patients to ensure that they best match in size but, when there are no suitable recipients; organs can be allocated to adult patients.
- iv. Regular auditing of shared number of organs and their results need to be accounted and discussed to further evolve the system. Auditing should be open. Further, the clinical information with respect to various practices, experience of various regimes followed, complications encountered may be shared among the experts and hospital so as to avoid errors and adopt best practices. The Government may consider exempting this clinical information from the purview of RTI.
- v. A patient awaiting transplantation will not be allowed to register with more than one hospital simultaneously within the same State/UT. The patient may change the hospital; however, the registration number shall remain the same, even after the patient changes the hospital. It will be the responsibility of the concern hospital to update details of the patients in their care, so that the ranking and allocation will be appropriate.

- vi. A common waiting list of recipients from all hospitals wishing to undergo cadaver organ transplant in the State should be maintained on a centralized secure web-based system at State Organ and Tissue Transplant Organization (SOTTO)/ Regional Organ and Tissue Transplant Organization (ROTO) cum SOTTO. A network will be developed and a web based waitlist and organ matching ID planned to be done by National Organ and Tissue Transplant Organization (NOTTO) involving SOTTOs, ROTOs based on software to be developed .However, India being a large country & health being a state subject, the web based waiting list, organ matching and allocation should be flexible as the model of PPP shall vary from state to state.
- vii. For entering patients on waiting list, the transplant clinician and the hospital should follow the guidelines for implementation of National Organ Transplant Programme (NOTP) that shall be issued by the National/State Govt.
- viii. Organ retrieval shall be done at registered Transplant hospital, Registered Retrieval Centre and can also be done by authorized retrieval team (by the Central/State Govt.) at unregistered retrieval hospital if brain stem death is declared, by giving a temporary registration by SOTTO/ROTO/NOTTO. Alternatively such unregistered hospital should shift the patient to transplantation hospital/retrieval hospital before the patients is declared brain stem dead.

B) Logistics for equitable distribution of organ:

The logistics of equitable distribution and sharing of organ will depend on following logistic factors:

- i. The maximum acceptable ischemia time of the organ.
- ii. The waiting list of the hospitals for various organs among the participating hospitals in the city & state.
- iii. The participating hospitals contribution to the programme-Gives and takes or only takes.
- iv. The waiting list of the hospitals for various organs among the participating hospitals in the neighbouring states.
- v. The transport logistics between cities.
- vi. To check whether funds received for organ & tissue retrieval by the hospital or for only organ retrieval.

C) Criteria for Organ Allocation:

The ROTO cum SOTTO and SOTTO should develop these criteria within the general principles given at above. For the states/UTs directly covered under NOTTO eg Delhi /NCR a committee of NOTTO should be formed on priority to submit suggestions to NOTTO.

D) Specific Criteria for inclusion and exclusion of registration of patient and other criteria:

Like urgent, super urgent for particular organ (for the states/UTs directly

covered under NOTTO) a Technical Advisory Committee will be formed for each specific organ & Tissue so as to utilize organs optimally in the states/UTs covered directly under NOTTO. A committee will also be formed for fixing the ceiling on the cost of maintenance of deceased donor and retrieval of organ.

21. Allocation of donor's Organ and Tissue:

Serological techniques on deceased donors and to perform cross-matching on all potential recipients of the appropriate A, B, O blood group and detail allocation criteria shall be prepared by advisory committee of NOTTO which will also decide factors to be used for allocating kidney, heart, lung, and other organ/tissues.

22. Performance reporting:

- i) Monthly and Annual report may be prepared by each registered organ/tissue hospital, registered organ & tissue retrieval hospital, reporting to the state SOTTO on monthly basis. Based on which ROTTO & NOTTO will also prepare similar month wise total number of actual deceased donors (and whose organs retrieved or organ with tissue were retrieved) per million populations (also in a separate table for only tissue were retrieved) as under:

Centre Name	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
1.X:													
a.Deceased Donor													
b.Retrieved.													
2.Y													
State													

Note: similar table for total deceased persons who offered to donate organ/tissue should be prepared.

- ii). Similarly **month wise Number of pledged INTENDED DECEASED DONORS** per million population state wise and month wise (Consent Obtained - Donation did not proceed) should be prepared.
- iii). Similarly a table state wise month wise reflecting **number and types of tissue donation** should be prepared indicating Number of donors following cardiac death per million population .

- iv). The following monthly state wise totals representing the **number of recipients transplanted with tissue** from the donors following BSD and cardiac death.
- v). Total **Recipient transplanted from all solid organ after BSD** should be prepared month wise and state wise per million population. Multiple transplants (> 1 organ transplant on one person are counted as one recipient.
- vi). Similar state wise month wise table be prepared to reflect **Mean Recipients Transplanted Per Deceased Donor**.
- vii) **Organs Retrieved And Actually Transplanted From All Donors after BSD:** The monthly state wise totals of organs transplanted represent the number of recipients from all donors should be given in separate table for each organ eg:
 - Kidney** (Number of recipients also includes combined transplant eg kidney/pancreas) create table.
 - Liver** (Number of Recipients) create the table.
 - Heart** - do
 - Heart & Lung**- do
 - Pancreas** - do
 - Pancreas islets** – do
 - Intestine** - do
 - Hepatocytes** - do
- viii) **Multiple transplants** (other than Heart/Lung) will be counted under each of the organs.

23. Audit and Monitoring of Retrievals:

Guidelines will be provided by the technical committee of NOTTO covering following aspects audit and monitoring of retrievals:

- A. Times to be recorded.
- B. Constituent Personnel of Retrieval Team Identity, Role and status
- C. Record of Organ Damage:
- D. Reasons for Non-Use of an Organ
- E. Outcome Measures: Three to five year survival of every individual transplant hospital should be prepared following a follow up register of transplant recipient (FRTR).
- F. Protocols for Organ & Tissue Retrieval
 - i. Each centre must have clear, written protocols for the retrieval procedures that they will undertake, DBD operations (for tissue after DCD).
 - ii. For General instructions/precautions to be taken for handling of retrieved organ & tissue & for its transporting procedure, the technical committee of NOTTO will give protocol to be followed for organ retrieval as suggestions to the states/UTs.

24. Conditions/ Standards for Grant Of Certificate Of Registration For Organ Retrieval Centres:

The retrieval centre shall be registered only for the purpose of retrieval of organ from deceased donors. 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.

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

Registration of Hospital/Tissue Bank

- (i). An application for registration shall be made to the Appropriate Authority as specified in Form 12 or 13 or 14 as applicable. The application shall be accompanied by fee as prescribed below, payable to the Appropriate Authority by means of a bank draft, which may be revised, if necessary by the Central/State Government.

For Organ Transplant Centre: Rupees Ten Thousand
For Tissue Transplant Centre: Rupees Two Thousand
For Tissue and Eye Bank: Rupees Five Thousand
For Non-Transplant Retrieval Centre: Nil

- (ii). 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.
- (iii). Before a hospital is registered under the provisions of this rule, it shall be mandatory for the hospital to appoint a transplant coordinator (which will not be applicable for tissue bank)

Renewal of Registration of Hospital/Tissue Bank

- (i). An application for the renewal of a certificate of registration shall be made to the Appropriate Authority within a period of three months prior to the date of expiry of the original certificate of registration and shall be accompanied by a fee as prescribed below, payable to the Appropriate Authority by means of a bank draft, which may be revised, if necessary by the Central/State Government.

For Organ Transplant Centre: Rupees Five Thousand

For Tissue Transplant Centre: Rupees One Thousand
For Tissue and Eye Bank: Rupees Two Thousand Five Hundred
For Non-Transplant Retrieval Centre: Nil

- (ii) A renewal certificate of registration shall be as specified in Form 17 and shall be valid for a period of five years.
- (iii) If, after an inquiry including inspection of the hospital or tissue bank and scrutiny of its past performance and after giving an opportunity to the applicant, the Appropriate Authority is satisfied that the applicant, since grant of certificate of registration under sub-rule (2) of Rule 7 has not complied with the requirements of this Act and Rules made there under and conditions subject to which the certificate of registration has been granted, shall, for reasons to be recorded in writing, refuse to grant renewal of the certificate of registration.

25. Composition of Authorisation Committees

There shall be one State level Authorisation Committee.
Additional Authorisation Committees in the districts or Institutions/ Hospitals may be set up as per norms given below, which may be revised from time to time by the concerned State government / Union Territory through Notification /Government Order.

- (i) No member from transplant team of the institution should be a member of the respective Authorisation Committee.
- (ii) Authorisation Committee should be Hospital based, if the number of transplants is 25 or more in a year at the respective transplantation centres. If the number of organ transplants in an institution/hospital, are less than 25 in a year, then the State or District level Authorisation Committee would grant approval(s).

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

- (a) The senior most person officiating as Medical Director or Medical Superintendent of the Hospital shall be the Chairperson;
- (b) Two senior medical practitioners from the same hospital who are not part of the transplant team;
- (c) Two persons (preferably one lady) of high integrity, social standing and credibility, who have served in high ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in University Grants Commission approved

University or are self-employed professionals of repute such as lawyers, chartered accountants and doctors (of Indian Medical Association) reputed NGO or renowned Social Worker etc.; and

- (d) Secretary (Health) or nominee and Director Health Services or nominee from State Government/Union Territory Administration.

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

- a) A Medical Practitioner officiating as Chief Medical Officer or any other equivalent post in the main/major Government Hospital of the District.
- b) Two senior medical practitioners to be chosen from the pool of such medical practitioners who are residing in the concerned District and who are not part of any transplant team.
- c) Two persons (preferably one lady) of high integrity, social standing and credibility, who have served in high ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in University Grants Commission approved University or are self-employed professionals of repute such as lawyers, chartered accountants and doctors (of Indian Medical Association) ,reputed NGO or renowned Social Worker etc.; and Secretary (Health) or nominee and Director Health Services or nominee from State Government/Union Territory Administration

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

(III).When the living donor is unrelated and if donor and/or recipient belongs to a State/ Union Territory, other than the State/Union Territory where the transplantation is proposed to be undertaken, Verification of Residential status by Tehsildar/any other authorized officer for the purpose and with a copy marked to the Appropriate Authority of the State/Union Territory of domicile of donor and/ or recipient for their information shall be required, as per form No. 20. In case of any doubt of organ trafficking the appropriate authority of the state of domicile or the Tehsildar / any other authorized officer shall inform police department for investigation and action as per THOA.

The quorum of the Authorisation Committee should be minimum four. However, quorum ought not to be considered as complete without the participation of the Chairman, The presence of Secretary (Health) or nominee and Director of Health Services or nominee is also mandatory.

The format of the Authorisation Committee approval should be uniform in all the institutions in the State. The format may be notified by respective State Government. Model format is given at Form 18.

Secretariat of the Authorisation Committee shall circulate copies of all applications received from the proposed donors to all members of the Committee. Such applications should be circulated along with annexure, which may have been filed along with the applications. At the time of the meeting, the Authorisation Committee should take note of all relevant contents and documents in the course of its decision making process and in the event any document or information is found to be inadequate or doubtful, explanation should be sought from the applicant and if it is considered necessary that any fact or information requires to be verified in order to confirm its veracity or correctness, the same be ascertained through the concerned officer(s) of the State/ Union territory Government.

- (IV). Where the proposed transplant of organs is between near relatives i.e persons related genetically namely Grandmother, Grandfather, Mother, Father, Brother, Sister, Son, Daughter, grandson and grand-daughter above the age of eighteen years, the Concerned Competent Authority hospital in charge as defined at 2 I shall evaluate:-
- (i) Documentary evidence of relationship e.g. relevant birth certificates , marriage certificate, other relationship certificate from tehsildar/Sub-divisional magistrate/ Metropolitan Magistrate/or Sarpanch of the Panchayat, or similar other identity certificates like Electors Photo Identity Card or AADHAAR (issued by Unique Identification Authority of India).
 - (ii) Documentary evidence of identity and residence of the proposed donor e.g. Ration Card or Voters identity Card or Passport or Driving License or PAN Card or Bank Account and family photograph depicting the proposed donor and the proposed recipient along with another near relative, or similar other identity certificates like AADHAAR (issued by Unique Identification Authority of India).
 - (iii) If in its opinion, the relationship is not conclusively established after evaluating the above evidence, it may in its discretion direct further medical tests prescribed as below:
 - a. Deoxyribonucleic Acid (DNA) Profiling
 - b. The tests referred to in sub-rule (iii) a. shall be got done from a laboratory accredited with NABL and certificate shall be given in Form 5.
 - c. Where the tests referred to in point (i) and point (iii) a, above do not establish a genetic relationship between the donor and the recipient, the same tests to be performed on preferably both or at least one parent. If parents are not available, same tests to be performed on

such relatives of donor and recipient as are available and are willing to be tested failing which, genetic relationship between the donor and the recipient will be deemed to have not been established.

- (iv) The Concerned Competent Authority may seek the assistance of the Authorisation Committee in its decision making, should it feel the need for it.
- (V). Where the proposed transplant is between other than near relatives and all cases where the donor/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/state level Authorisation Committee
- (VI). When the proposed donor and/ or the recipient are foreigners:-
- (i) A senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient as per Form 21. In case a country does not have an Embassy in India, the certificate of relationship, in the above format, shall be issued by the Government of that country.
 - (ii) Authorisation Committee shall examine the cases of all Indian donors consenting to donate organs to a foreign national (who is a near relative), including a foreign national of Indian origin, with greater caution. Such cases should be considered rarely on case to case basis. Indian Living Donors wanting to donate to a foreigner other than near relative shall not be considered.
- (VII). In the course, of determining eligibility of the applicant to donate, the applicant should be personally interviewed by the Authorisation Committee and minutes of the interview should be recorded. Such interviews with the donors should be video recorded.
- (VIII). In case where the donor is a woman, greater precautions ought to be taken. Her identity and independent consent should be confirmed by a person other than the recipient. Any document with regard to the proof of residence or domicile and particulars of parentage should be relatable to the photo identity of the applicant in order to ensure that the documents pertain to the same person, who is the proposed donor and in the event of any inadequate or doubtful information to this effect, the Authorisation Committee may in its discretion seek such other information or evidence as may be expedient and desirable in the peculiar facts of the case.
- (IX). The Authorisation Committee (which is applicable only for living organ/tissue donor) should state in writing its reason for rejecting/ approving the application of the proposed living donor in the prescribed Form 18 and all such approvals should be subject to the following conditions:-

- (i) That the approved proposed donor would be subjected to all such medical tests as required at the relevant stages to determine his/her biological capacity and compatibility to donate the organ in question.
 - (ii) That the physical and mental evaluation of the donor has been done, He/she is in proper state of health and it has been certified by the RMP that he/she is not mentally challenged in Form 4. He /She is fit to donate the organ and/ or tissue. In case of doubt for mentally challenged status of the donor the RMP/authorisation committee may get the donor examined by psychiatrist.
 - (iii) All prescribed forms have been and would be filled up by all relevant persons involved in the process of transplantation.
 - (iv) All interviews to be video recorded.
- (X). 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.
- (XI). Every authorised transplantation centre must have its own website. The Authorisation Committee is required to take final decision within twenty four hours of holding the meeting for grant of permission or rejection for transplant. The decision of the Authorisation Committee should be displayed on the notice board of the hospital or Institution immediately and should reflect on the website of the hospital or Institution within twenty four hours of taking the decision, while keeping the identity of the recipient and donor hidden. Apart from this, the hospital or institution must update its website regularly in respect of the total number of the transplantations done in that hospital or institution along with reasonable details of each transplantation, (The same data should be accessible for compilation, analysis and further use by authorised persons of respective State Governments and Central Government). The website of the transplantation centre shall be linked to State/Regional/National Networks through and online system for organ procurement, sharing and transplantation.

C. Removal and Preservation of Organs and/or Tissues:

The removal of the organ(s) and / or tissue(s) as mentioned under THOA Rules shall be permissible in any registered retrieval/transplant hospital/Centre and preservation of such removed organ(s) and /or tissue(s) shall be ensured in registered retrieval/transplant centre/tissue bank according to current and accepted scientific methods in order to ensure viability for the purpose of transplantation.

D. Cost for Maintenance of Cadaver or Retrieval or Transportation or Preservation of Organs or Tissues:

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

E. Removal of Human organ and/tissue from a living donor:

The Registered Medical Practitioner (RMP) shall, before removing any human organ and/or tissue from a living donor, shall satisfy himself –

- (a) That the donor has been explained all possible side effects, hazards and complications and that the donor has given his/her authorisation in appropriate Form 1 for near relative donor or 2 for spousal donor or 3 for donor other than near relative.
- (b) That the physical and mental evaluation of the donor has been done, he/she is in proper state of health and it has been certified that he/she is not mentally challenged. He /She is fit to donate the organ and/ or tissue. In case of doubt for mentally challenged status of the donor the RMP may get the donor examined by psychiatrist. RMP 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/she has submitted an application in Form 11 jointly with the recipient and that the proposed donation has been approved by the Concerned Competent Authority carrying out transplantation or a committee constituted for this purpose by the institution/hospital, as 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 Concerned Competent Authority
- (d) That in case the recipient is spouse of the donor, the donor has given a statement to the effect that they are so related by signing a certificate in Form 2 and has submitted an application in Form 11 jointly with the recipient and that the proposed donation has been approved by the Concerned Competent Authority under provisions of sub-rule (2) of Rule 4A.
- (e) That in case of a donor who is other than a near relative and has signed Form 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 and/or recipient is/are foreign nationals, the approval of the Authorisation Committee for the said donation has been obtained.

- (g) Living organ/tissue donation by minors (less than 18 years) shall not be permitted except on exceptional medical grounds to be recorded in detail with full justification and with prior approval of the Appropriate Authority and the Government concerned. (As allowed in Section 9(1) (1 B) of amended THOA 2011).

F. Removal of Human organ and tissue from a body of a person after his/her death: A registered medical practitioner, before removing any organ or tissue from the body of a person after his/her death (Deceased Donor), in consultation with transplant coordinator shall satisfy himself:-

- (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 ICU, 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/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/her organ(s) and/or tissue(s) after his/her death, for therapeutic purposes and it has been ascertained that the donor has not subsequently revoked the aforesaid authorisation. However, the consent of near relative /person in lawful position of the body shall be required even if aforesaid authorisation had been made by deceased donor. In case the deceased person who had earlier given authorisation but had revoked it subsequently and in cases where the person had given in writing that his organ should not be removed after his death, then organ/tissue will not be removed even if consent is given by the near relative/person in lawful position of the body.
- (b) That the near relative of the deceased person or the person lawfully in possession of the dead body has signed the declaration as specified in Form 8.
- (c) That in the case of brain-stem death of the donor, a certificate as specified in Form 10 has been signed by all the members of the Board of medical experts referred to in Section 3 (6) of the Act; Where a neurologist or a neurosurgeon is not available, an anaesthetist 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 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 authorized by the parent.

G. Other duties of a registered Medical practitioner:

- (l) The Registered Medical Practitioner (RMP) of the hospital having ICU facility, in consultation with transplant coordinator (if available) shall ascertain, after certification of brain stem death of the person in ICU, from his/her adult near relative / 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:
 - (a) Whether the person had, in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorised before his/her death as specified in Form 5 or in documents like Driving License etc. wherein the provision for donation may be incorporated after notification of these Rules, the removal of his/her organ(s) and/or tissue(s) including eye, after his/her death, for therapeutic purposes and there is no reason to believe that the person had subsequently revoked the aforesaid authorisation? If yes, then the RMP, on behalf of the hospital shall request the near relative or person in lawful possession of the body, to submit the aforesaid authorisation if available and he/she will fill the Form 8 for declaration indicating the position and submit the same to the hospital.
 - (b) Where the aforesaid authorisation was not made but there is no reason to believe that the person did not want to donate his/her organ(s)/tissue(s) after his/her death, then RMP in consultation with the Transplant Coordinator shall make the near relative or person in lawful possession of the body, aware of the option to authorize or decline the donation of such human organs or tissues or both (which can be used for therapeutic purposes) including eye/cornea of the deceased person. A declaration/authorisation to this effect shall be ascertained from the near relative or person in lawful possession of the body as per Form 8 to record the status of consent. In case of an unclaimed body, authorisation shall be made in form 9 by the authorised official as per Section 5(1) of the Act.
 - (c) After the near relative or person in lawful possession of the body authorizes removal and gives consent for donation of human organ(s) and/or tissue(s) of the deceased person, the Registered Medical Practitioner (RMP), through Transplant Coordinator shall inform the authorized registered Human Organ Retrieval Centre through authorized coordinating organization by available documentable mode of communication, for removal, storage or transportation of organ(s) and or tissue(s). Tissue retrieval can be done in a hospital, which is not registered under this Act provided the retrieval is done by a authorized person/team.

- (II). The above mentioned duties shall also apply to the Registered Medical Practitioner (RMP) working in an Intensive Care Unit (ICU) in a hospital not registered under this Act, from the date of notification of these Rules.

H. Procedure for Donation of Organ & Tissue in Medico- legal cases:

- (a) After the authority for removal of organs and/or tissues, as also the consent to donate organs from a brain-stem dead donor are obtained, the Registered Medical Practitioner of the hospital shall make a request to the Station House Officer In-charge (SHO) or Superintendent of Police/DIG of the area either directly or through the Police Post located in the hospital to facilitate timely retrieval of organs and/or tissue from the donor. It has to be ensured that, by retrieving organs, the determination of the cause of death is not jeopardized. A copy of such a request should also be sent to the designated post mortem doctor of area simultaneously.
- (b) The Medical report in respect of the organs and / or tissues being retrieved shall be prepared at the time of retrieval by retrieving doctor (s) and shall be taken on record in post-mortem notes by RMP doing post-mortem. Wherever it is possible, attempt should be made to request the designated post-mortem RMP, even beyond office timing, to be present at the time of organ /tissue retrieval. In case a private retrieval hospital is not doing post mortem, they shall arrange transportation of body along with medical records, after organ/tissue retrieval, to the designated post-mortem centre and back to the retrieval hospital. The post mortem centre shall undertake the post-mortem of such cases on priority, even beyond office hour, so that the body is handed over to the relatives with least inconvenience.

I. Donor Screening for tissue/cornea:

Complete screening of donor must be conducted including medical/social history for medical conditions or disease processes that would contraindicate the donation of tissues. The Cornea not found suitable for transplantation shall be certified by a committee under the Chairmanship of Head of ophthalmology with members involving two eye surgeons out of which at least one is a Cornea transplant surgeon and the committee shall suggest the alternate use of the same.

26. ADVISORY COMMITTEE of the Central/State Govt. to aid and advise Appropriate Authority:

- (1) The central /state Govt will constitute an advisory committee by notification under the chairmanship of administrative expert not below the rank of Secretary to the state Govt for period of two years at a time. Qualification of two medical experts shall be Postgraduate medical degree and at least five years' experience in the field of organ/tissue transplantation.

(2) The terms and conditions for appointment to the Advisory Committee

- (a) The Chairman and members of the Committee shall be initially appointed for two years and the tenure can be extended on year to year basis upto a maximum of five years.
- (b) The Chairman and members of the Committee shall be entitled to the air fare and other allowances to attend the meeting of the Committee equivalent to the officer of the level of the Joint Secretary to the Government of India.
- (c) The Central/State Government/Union Territory Administration shall have full power to replace/remove the Chairman and the members.
- (d) The Chairman and members can also resign from the Committee for personal reasons.
- (e) There shall not be a corruption/criminal case pending against Chairman and members at the time of appointment.
- (f) The Chairman and members would cease to function if a corruption/criminal etc. case is initiated against them.

27. INTERNAL MONITORING:

The nodal officer for organ/tissue transplant or retrieval of the transplant hospital, retrieval hospital/trauma centre will conduct internal monitoring on weekly basis. Monthly reports will ensured by them. The head of SOTTO, ROTTO will regularly monitor the activities.

28. EVALUATION:

The Independent evaluation of the programme will be done after two years of implementation.

29. ANNEXURE:

NATIONAL ORGAN & TISSUE TRANSPLANT ORGANISATION (NOTTO)

LIST OF FORMS REQUIRED FOR ORGAN DONATION & TRANSPLANT

(As per THOA)

- FORM 1- FOR ORGAN/TISSUE DONATION FROM IDENTIFIED LIVING NEAR RELATED DONOR (to be completed by ***Donor***).
- FORM 2- FOR ORGAN/TISSUE DONATION BY LIVING SPOUSAL DONOR (to be completed by ***Donor***).
- FORM 3- FOR ORGAN/TISSUE DONATION BY OTHER THEN NEAR RELATIVE LIVING DONOR (to be completed by ***Donor***).
- FORM 4- FOR CERTIFICATION OF MEDICAL FITNESS OF LIVING DONOR (to be given by The ***Registered Medical Practitioner***).
- FORM 5- FOR CERTIFICATION OF GENETIC RELATIONSHIP OF LIVING DONOR WITH RECIPIENT (to be filled by the head of ***Pathology Laboratory*** certifying relationship).
- FORM 6- FOR SPOUSAL LIVING DONOR (to be filled by concerned ***competent authority**** and Authorization Committee, of the hospital or district or State in case of foreigners)
- FORM 7- FOR ORGAN TISSUE PLEDGING (To be filled by ***individual*** pledging for donation after death).
- FORM 8- FOR DECLARATION CUM CONSENT (To be filled by ***near relative/ Lawful possessor*** of brain-stem dead person).
- FORM 9- FOR UNCLAIMED BODY IN A HOSPITAL/PRISON (To be completed by ***person in lawful possession*** of the unclaimed
- FORM 10- body). FOR CERTIFICATION OF BRAIN STEM DEATH (To be filled by the ***team of experts*** certifying brain-stem death).
- FORM 11- APPLICATION FOR APPROVAL OF TRANSPLANTATION FROM LIVING DONOR (to be completed by the proposed ***Recipient & the proposed Living Donor***).
- FORM 12- APPLICATION FOR REGISTRATION OF HOSPITAL TO CARRY OUT ORGAN/TISSUE TRANSPLANTATION OTHER THEN CORNEA (To be filled by ***head of the institution***).



NATIONAL ORGAN & TISSUE TRANSPLANT ORGANISATION (NOTTO)

LIST OF FORMS REQUIRED FOR ORGAN DONATION & TRANSPLANT

(As per THOA)

- FORM 13- APPLICATION FOR REGISTRATION OF HOSPITAL TO CARRY OUT ORGAN/TISSUE RETRIEVAL OTHER THEN EYE/ CORNEA RETRIEVAL (to be filled by head of the ***institution***)
- FORM 14- APPLICATION FOR REGISTRATION OF TISSUE BANKS OTHER THEN EYE BANKS (to be filled by head of the ***institution***).
- FORM 15- APPLICATION FOR REGISTRATION OF EYE BANK & CORNEAL TRANSPLANTATION CENTRE, EYE RETRIEVAL CENTRE UNDER THE **THOA**.
- FORM 16- CERTIFICATE OF REGISTRATION FOR PERFORMING ORGAN/TISSUE TRANSPLANTATION/RETRIEVAL AND /OR TISSUE BANKING.
- FORM 17- CERTIFICATE OF RENEWAL OF REGISTRATION (To be given by the ***appropriated authority*** on the letter head).
- FORM 18- CERTIFICATE BY THE ***AUTHORIZATION COMMITTEE*** OF HOSPITAL (If Hospital authorization committee is not available then the Authorization Committee of the district/state) where the transplantation has to take place (To be issued on the letter head).
- FORM 19- CERTIFICATE BY CONCERNED ***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).
- FORM 20- VERIFICATION CERTIFICATE IN RESPECT OF DOMICILE STATUS OF RECIPIENT OR DONOR {To be issued by Tehsildar or any other ***authorized officer*** for the purpose (required only for the donor-other than near relative/recipient if they do not belong to the state where transplant hospital identified for operation is located)}.
- FORM 21- CERTIFICATE OF RELATIONSHIP BETWEEN DONOR AND RECIPIENT IN CASE OF FOREIGNERS (To be issued by the ***Embassy concerned***).



30. REFERENCES:

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6. Third WHO Global Consultation on organ donation and transplantation: Striving to achieve self-sufficiency, March 23-25, 2010, Madrid, Spain.
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11. Global Observatory and database on donation and transplantation: World overview on transplantation activities, "Transplant Proceedings 41 , 2297-2307 (2009)".



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