

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

Updated 16-7-2020

General Background

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

Legal Framework

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



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

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

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

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



Source of Organs for Transplant:

Source may be, Living or Deceased Donor:

Living Donor Transplant:

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

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

Deceased donor Transplant:

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

Issues and Challenges

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


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Initiative taken

National Organ Transplant Programme

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

Objectives of National Organ Transplant Programme:

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

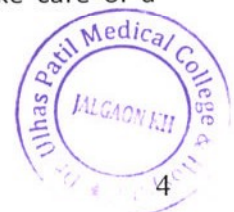
Situation before NOTP

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

Solution provided through NOTP:

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

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Components of National Organ Transplant Programme (2017-20)

1. National THOTA and NOTP Cell

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

The functions are

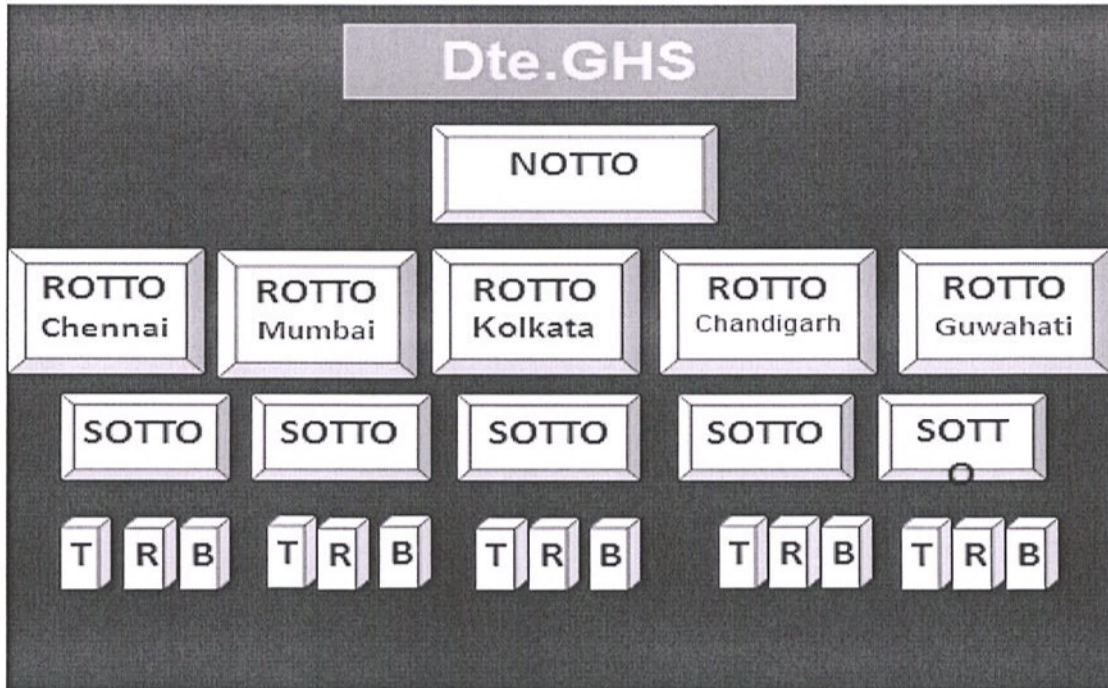
1. Registration and renewal of organ & tissue transplant centers, eye bank in all Union territories except Delhi as part of work of DGHS being the appropriate authority for all Union territories except Delhi. Organizing inspections for the same.
2. Monitoring of the transplant centers and Tissue Banks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

2. Networking: through creating institutional mechanisms

Through National Human Organs and Tissues Removal and Storage Network

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NOTTO: National Organ and Tissue Transplant Organization

ROTO: Regional Organ and Tissue Transplant Organization

SOTTO: State Organ and Tissue Transplant Organization

T: Transplant Centre

R: Retrieval Centre

B: Biomaterial Centre (Tissue Bank)

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

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

Broad Functions of NOTTO are

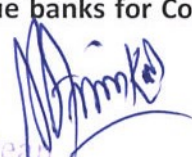
- Drafting Policy guidelines and protocols
- Web based Networking
- Maintaining National Registry
- Advocacy and awareness
- Co-ordination when organ is allocated outside region and to PIO/Foreigner and in Delhi
- Research
- Dissemination of information
- Coordinate and Organize trainings
- Consultancy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



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

- 1) **Website**
A dedicated website (www.notto.gov.in) has been launched for providing information on organ and tissue donation, organ and tissue pledging, networking of hospitals and establishing National registry of organ and tissue transplantation and Donation. The work is being done through NIC.
- 2) **Helpline/Call centre**
A 24x7 days call centre has been made operational with provision of a toll free helpline (No. 1800114770) since 1-7-2015.
- 3) **Registration of Hospitals with NOTTO Website**
Online facility for registration of hospitals for networking and data collection for National registry has been made functional.
- 4) **National Registry:**
NOTTR was launched on 6th Indian Organ Donation Day celebration on 27th November 2015. It has three components:
Pledge Registry: Online and offline provision to register your wish for organ donation is already in place
Waiting List Registry: Patients waiting for transplant can register themselves through hospitals in the National Waiting list registry
Transplant Registry: Provision of entering the data of transplant cases and follow up is already in place. Hospital can enter the data.
- 5) **Pledging for Donation**
Facility for Offline and Online pledging for donation of organ and/or tissue after death has been made functional.
- 6) **Allocation Policy:**
Policies for allocation of Vital organs Kidney, Liver, Heart & Lung and Cornea have been approved by DGHS. Approved Organ Policies are available on NOTTO website.
- 7) **Standard Operative Procedures (SOPs)**
SOPs for retrieval of various organs and management of Donors have been drafted and uploaded on NOTTO website
- 8) **Operational Guidelines of National Organ and Tissue Transplant Programme** for its implementation was also released on 27th March 2015 during NATIONAL ADVOCACY CONFERENCE.
- 9) **Registration of Tissue Bank or Bio Material Centre:** Tissue banks for Cornea, Skin & Heart Valve have been registered and functional.


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- 10) **Apex Technical committees** are functional and developed Broad Guiding Principle for the Allocation of organs for have been constituted for development of organ specific guidelines.
- 11) **Coordination & Collaboration with Other Organization:** Yes bank, Red Cross Society, ORGAN India to promote deceased organ donation and various other small NGOs.
- 12) **Coordination for Allocation of Organs:** when organs are to be allocated nationally and for foreigner cases and for Delhi NCR
- 13) **Capacity Building:**
Various Training programs are organized either directly by NOTTO or under its aegis.
- 14) **IEC AND AWARENESS ACTIVITIES** are organized including annual Indian organ donation day.
- 15) **National Transplant Specific Guidance during Covid 19 situation** has been framed.

II. ROTTO: Regional Organ and Tissue Transplant Organization

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

Broad Functions of ROTTO are

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



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

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

Grant in Aid provided to each ROTTO

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

III. SOTTO: State Organ and Tissue Transplant Organization

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

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

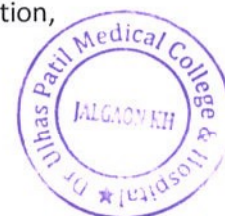
5 ROTTOs are also SOTTOs for the States where they are located

NOTTO is SOTTO for Delhi

Broad Functions of SOTTO are

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

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Grant in Aid provided to each SOTTO

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

3. Online system of networking and Registry

- Software developed and under further updation
- Website www.notto.gov.in
- Aim is to have a Computerised Impartial, and transparent organ allocation system
- networking & sharing as per allocation policy

4. Biomaterial Centres: National Biomaterial centre is now registered. One has been sanctioned for Tamilnadu. Other regional centres are also planned to have biomaterial centre

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

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

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

6. Training and Capacity Building

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

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

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

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

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

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

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


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

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

Various Activities include

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

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


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World Health
Organization

WHO GUIDING PRINCIPLES ON HUMAN CELL, TISSUE AND ORGAN TRANSPLANTATION¹

PREAMBLE

1. As the Director-General's report to the Executive Board at its Seventy-ninth session pointed out, human organ transplantation began with a series of experimental studies at the beginning of the twentieth century. The report drew attention to some of the major clinical and scientific advances in the field since Alexis Carrel was awarded the Nobel Prize in 1912 for his pioneering work. Surgical transplantation of human organs from deceased, as well as living, donors to sick and dying patients began after the Second World War. Over the past 50 years, the transplantation of human organs, tissues and cells has become a worldwide practice which has extended, and greatly enhanced the quality of, hundreds of thousands of lives. Continuous improvements in medical technology, particularly in relation to organ and tissue rejection, have led to an increase in the demand for organs and tissues, which has always exceeded supply despite substantial expansion in deceased organ donation as well as greater reliance on donation from living persons in recent years.
2. The shortage of available organs has not only prompted many countries to develop procedures and systems to increase supply but has also stimulated commercial traffic in human organs, particularly from living donors who are unrelated to recipients. The evidence of such commerce, along with the related traffic in human beings, has become clearer in recent decades. Moreover, the growing ease of international communication and travel has led many patients to travel abroad to medical centres that advertise their ability to perform transplants and to supply donor organs for a single, inclusive charge.
3. Resolutions WHA40.13 and WHA42.5 first expressed the Health Assembly's concern over commercial trade in organs and the need for global standards for transplantation. Based on a process of consultation undertaken by the Secretariat, the Health Assembly then endorsed the WHO Guiding Principles on Human Organ Transplantation in resolution WHA44.25. Over the past 17 years the Guiding Principles have greatly influenced professional codes and practices as well as legislation around the world. In the light of changes in practices and attitudes regarding organ and tissue transplantation, the Fifty-seventh World Health Assembly in resolution WHA57.18 requested the Director-General, inter alia, "to continue examining and collecting global data on the practices, safety, quality, efficacy and epidemiology of allogeneic transplantation and on ethical issues, including living donation, in order to update the Guiding Principles on Human Organ Transplantation".
4. The following Guiding Principles are intended to provide an orderly, ethical and acceptable framework for the acquisition and transplantation of human cells, tissues and organs for therapeutic purposes. Each jurisdiction will determine the means of implementing the Guiding Principles. They preserve the essential points of the 1991 version while incorporating new provisions in response to current trends in transplantation, particularly organ transplants from living donors and the increasing use of human cells and tissues. The Guiding Principles do not apply to transplantation of gametes, ovarian or testicular tissue, or embryos for reproductive purposes, or to blood or blood constituents collected for transfusion purposes.

¹ As endorsed by the sixty-third World Health Assembly in May 2010, in Resolution WHA63.22

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Cells, tissues and organs may be removed from deceased and living persons for the purpose of transplantation, only in accordance with the following Guiding Principles.

Guiding Principle 1

Cells, tissues and organs may be removed from the bodies of deceased persons for the purpose of transplantation if:

- (a) any consent required by law is obtained, and
- (b) there is no reason to believe that the deceased person objected to such removal.

Commentary on Guiding Principle 1

Consent is the ethical cornerstone of all medical interventions. National authorities are responsible for defining the process of obtaining and recording consent for cell, tissue and organ donation in the light of international ethical standards, the manner in which organ procurement is organized in their country, and the practical role of consent as a safeguard against abuses and safety breaches.

Whether consent to procure organs and tissues from deceased persons is “explicit” or “presumed” depends upon each country’s social, medical and cultural traditions, including the manner in which families are involved in decision-making about health care generally. Under both systems any valid indication of deceased persons’ opposition to posthumous removal of their cells, tissues or organs will prevent such removal.

Under a regime of explicit consent – sometimes referred to as “opting in” – cells, tissues or organs may be removed from a deceased person if the person had expressly consented to such removal during his or her lifetime; depending upon domestic law, such consent may be made orally or recorded on a donor card, driver’s license or identity card or in the medical record or a donor registry. When the deceased has neither consented nor clearly expressed opposition to organ removal, permission should be obtained from a legally specified surrogate, usually a family member.

The alternative, presumed consent system – termed “opting (or contracting) out” – permits material to be removed from the body of a deceased person for transplantation and, in some countries, for anatomical study or research, unless the person had expressed his or her opposition before death by filing an objection with an identified office, or an informed party reports that the deceased definitely voiced an objection to donation. Given the ethical importance of consent, such a system should ensure that people are fully informed about the policy and are provided with an easy means to opt out.

Although expressed consent is not required in an opting-out system before removal of the cells, tissues or organs of a deceased person who had not objected while still alive, procurement programmes may be reluctant to proceed if the relatives personally oppose the donation; likewise, in opting-in systems, programmes typically seek permission from the family even when the deceased gave pre-mortem consent. Programmes are more able to rely on the deceased’s explicit or presumed consent, without seeking further permission from family members, when the public’s understanding and acceptance of the process of donating cells, tissues and organs is deep-seated and unambiguous. Even when permission is not sought from relatives, donor programmes need to review the deceased’s medical and

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behavioural history with family members who knew him or her well, since accurate information about donors helps to increase the safety of transplantation.

For tissue donation, which entails slightly less challenging time constraints, it is recommended always to seek the approval of the next of kin. An important point to be addressed is the manner in which the appearance of the deceased's body will be restored after the tissues are removed.

Guiding Principle 2

Physicians determining that a potential donor has died should not be directly involved in cell, tissue or organ removal from the donor or subsequent transplantation procedures; nor should they be responsible for the care of any intended recipient of such cells, tissues and organs.

Commentary on Guiding Principle 2

This Principle is designed to avoid the conflict of interest that would arise were the physician or physicians determining the death of a potential donor to be responsible in addition for the care of other patients whose welfare depended on cells, tissues or organs transplanted from that donor.

National authorities will set out the legal standards for determining that death has occurred and specify how the criteria and process for determining death will be formulated and applied.

Guiding Principle 3

Donation from deceased persons should be developed to its maximum therapeutic potential, but adult living persons may donate organs as permitted by domestic regulations. In general living donors should be genetically, legally or emotionally related to their recipients.

Live donations are acceptable when the donor's informed and voluntary consent is obtained, when professional care of donors is ensured and follow-up is well organized, and when selection criteria for donors are scrupulously applied and monitored. Live donors should be informed of the probable risks, benefits and consequences of donation in a complete and understandable fashion; they should be legally competent and capable of weighing the information; and they should be acting willingly, free of any undue influence or coercion.

Commentary on Guiding Principle 3

The Principle emphasizes the importance both of taking the legal and logistical steps needed to develop deceased donor programmes where these do not exist and of making existing programmes as effective and efficient as possible.

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While favouring the maximal development of transplant programmes that avoid the inherent risks to live donors, the Principle also sets forth basic conditions for live donation. A genetic relationship between donor and recipient may be therapeutically advantageous and can provide reassurance that the donor is motivated by genuine concern for the recipient, as can a legal relationship (such as that between spouses). Many altruistic donations also originate from emotionally related donors, though the strength of a claimed connection may be difficult to evaluate. Donations by unrelated donors have been a source of concern, though some such cases are unexceptionable, such as in hematopoietic stem cell transplantation (where a wide donor pool is therapeutically advisable) or when an exchange of kidneys is made because the donors are not immunologically well matched with the recipients to whom they are related.

With live donation, particularly by unrelated donors, psychosocial evaluation is needed to guard against coercion of the donor or the commercialism banned by Principle 5. The national health authority should ensure that the evaluation is carried out by an appropriately qualified, independent party. By assessing the donor's motivation and the donor's and recipient's expectations regarding outcomes, such evaluations may help identify – and avert – donations that are forced or are actually paid transactions.

The Principle underscores the necessity of genuine and well-informed choice, which requires full, objective, and locally relevant information and excludes vulnerable persons who are incapable of fulfilling the requirements for voluntary and knowledgeable consent. Voluntary consent also implies that adequate provisions exist for withdrawal of consent up until medical interventions on the recipient have reached the point where the recipient would be in acute danger if the transplant did not proceed. This should be communicated at the time of consent.

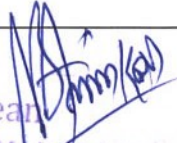
Finally, this Principle stresses the importance of protecting the health of living donors during the process of selection, donation, and necessary aftercare to ensure that the potential untoward consequences of the donation are unlikely to disadvantage the remainder of the donor's life. Care for the donor should match care for the recipient, and health authorities have the same responsibility for the welfare of both.

Guiding Principle 4

No cells, tissues or organs should be removed from the body of a living minor for the purpose of transplantation other than narrow exceptions allowed under national law. Specific measures should be in place to protect the minor and, wherever possible the minor's assent should be obtained before donation. What is applicable to minors also applies to any legally incompetent person.

Commentary on Guiding Principle 4

This Principle states a general prohibition on the removal of cells, tissues or organs from legal minors for transplantation. The major exceptions that may be authorized are familial donation of regenerative cells (when a therapeutically comparable adult donor is not available) and kidney transplants between identical twins (where avoiding immunosuppression represents a benefit to the recipient adequate to justify the exception, in the absence of a genetic disorder that could adversely affect the donor in the future).

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While the permission of the parent(s) or the legal guardian for organ removal is usually sufficient, they may have a conflict of interest if they are responsible for the welfare of the intended recipient. In such cases, review and approval by an independent body, such as a court or other competent authority, should be required. In any event, a minor's objection to making a donation should prevail over the permission provided by any other party. The professional counselling provided to potential living donors in order to assess, and when needed, address any pressure in the decision to donate, is especially important for minor donors.

Guiding Principle 5

Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned.

The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.

Commentary on Guiding Principle 5

Payment for cells, tissues and organs is likely to take unfair advantage of the poorest and most vulnerable groups, undermines altruistic donation, and leads to profiteering and human trafficking. Such payment conveys the idea that some persons lack dignity, that they are mere objects to be used by others.

Besides preventing trafficking in human materials, this Principle aims to affirm the special merit of donating human materials to save and enhance life. However, it allows for circumstances where it is customary to provide donors with tokens of gratitude that cannot be assigned a value in monetary terms. National law should ensure that any gifts or rewards are not, in fact, disguised forms of payment for donated cells, tissues or organs. Incentives in the form of "rewards" with monetary value that can be transferred to third parties are not different from monetary payments.

While the worst abuses involve living organ donors, dangers also arise when payments for cells, tissues and organs are made to next of kin of deceased persons, to vendors or brokers, or to institutions (such as mortuaries) having charge of dead bodies. Financial returns to such parties should be forbidden.

This Principle permits compensation for the costs of making donations (including medical expenses and lost earnings for live donors), lest they operate as a disincentive to donation. The need to cover legitimate costs of procurement and of ensuring the safety, quality and efficacy of human cell and tissue products and organs for transplantation is also accepted as long as the human body and its parts as such are not a source of financial gain.

Incentives that encompass essential items which donors would otherwise be unable to afford, such as medical care or health insurance coverage, raise concerns. Access to the highest attainable standard of health is a fundamental right, not something to be purchased in exchange for body parts. However, free periodic medical assessments related to the donation and insurance for death or complications that arise from the donation may legitimately be provided to living donors.

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Health authorities should promote donation motivated by the need of the recipient and the benefit for the community. Any measures to encourage donation should respect the dignity of the donor and foster societal recognition of the altruistic nature of cell, tissue and organ donation. In any event, all practices to encourage the procurement of cells, tissues and organs for transplantation should be defined explicitly by health authorities in a transparent fashion.

National legal frameworks should address each country's particular circumstances because the risks to donors and recipients vary. Each jurisdiction will determine the details and method of the prohibitions it will use, including sanctions which may encompass joint action with other countries in the region. The ban on paying for cells, tissues and organs should apply to all individuals, including transplant recipients who attempt to circumvent domestic regulations by travelling to locales where prohibitions on commercialization are not enforced.

Guiding Principle 6

Promotion of altruistic donation of human cells, tissues or organs by means of advertisement or public appeal may be undertaken in accordance with domestic regulation.

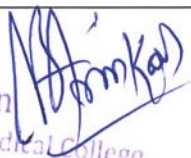
Advertising the need for or availability of cells, tissues or organs, with a view to offering or seeking payment to individuals for their cells, tissues or organs, or, to the next of kin, where the individual is deceased, should be prohibited. Brokering that involves payment to such individuals or to third parties should also be prohibited.

Commentary on Guiding Principle 6

This Principle does not affect general advertisements or public appeals to encourage altruistic donation of human cells, tissues or organs, provided that they do not subvert legally established systems of organ allocation. Instead, it aims to prohibit commercial solicitations, which include offering to pay individuals, the next of kin of deceased persons, or other parties in possession (such as undertakers), for cells, tissues or organs; it targets brokers and other intermediaries as well as direct purchasers.

Guiding Principle 7

Physicians and other health professionals should not engage in transplantation procedures, and health insurers and other payers should not cover such procedures, if the cells, tissues or organs concerned have been obtained through exploitation or coercion of, or payment to, the donor or the next of kin of a deceased donor.

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Commentary on Guiding Principle 7

Health care professionals should only proceed with the removal, intermediate management or implantation of cells, tissues or organs when donations are unpaid and truly voluntary. (In the case of live donors, a psychosocial evaluation of the donor is usually indicated, as described in Guiding Principle 3). Failing to ensure that the person consenting to the donation has not been paid, coerced or exploited breaches professional obligations and should be sanctioned by the relevant professional organizations and government licensing or regulatory authorities.

Physicians and health care facilities should also not refer patients to transplant facilities in their own or other countries that make use of cells, tissues or organs obtained through payments to donors, their families or other vendors or brokers; nor may they seek or accept payment for doing so. Post-transplant care may be provided to patients who have undergone transplantation at such facilities, but physicians who decline to provide such care should not face professional sanctions for such refusals, provided that they refer such patients elsewhere.

Health insurers and other payers should reinforce adherence to high ethical standards by refusing to pay for transplants that violate the Guiding Principles.

Guiding Principle 8

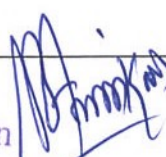
All health care facilities and professionals involved in cell, tissue or organ procurement and transplantation procedures should be prohibited from receiving any payment that exceeds the justifiable fee for the services rendered.

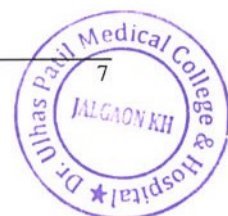
Commentary on Guiding Principle 8

This provision reinforces Guiding Principles 5 and 7 by forbidding profiteering in cell, tissue and organ recovery and implantation. Health authorities should monitor the fees charged for transplantation services to ensure that they are not disguised charges for the cells, tissues or organs themselves. All persons and facilities involved should be accountable for all payments for transplantation services. A medical or other health care practitioner uncertain whether a fee is justifiable should seek the opinion of an appropriate licensing or disciplinary authority before proposing or levying the fee. Fees charged for similar services may be used as a reference.

Guiding Principle 9

The allocation of organs, cells and tissues should be guided by clinical criteria and ethical norms, not financial or other considerations. Allocation rules, defined by appropriately constituted committees, should be equitable, externally justified, and transparent.

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Commentary on Guiding Principle 9

Where donation rates do not meet clinical demand, allocation criteria should be defined at national or subregional level by a committee that includes experts in the relevant medical specialties, bioethics and public health. Such multidisciplinary is important to ensure that allocation takes into account not only medical factors but also community values and general ethical rules. The criteria for distributing cells, tissues and organs should accord with human rights and, in particular, should not be based on a recipient's gender, race, religion, or economic condition.

This principle implies that the cost of transplantation and follow-up, including immunosuppressive treatment where applicable, should be affordable to all patients concerned — that is, no recipient should be excluded solely for financial reasons.

The concept of transparency is not exclusive to the allocation process but is central to all aspects of transplantation (as is discussed in the commentary on Guiding Principle 11, below).

Guiding Principle 10

High-quality, safe and efficacious procedures are essential for donors and recipients alike. The long-term outcomes of cell, tissue and organ donation and transplantation should be assessed for the living donor as well as the recipient in order to document benefit and harm.

The level of safety, efficacy and quality of human cells, tissues and organs for transplantation, as health products of an exceptional nature, must be maintained and optimized on an ongoing basis. This requires implementation of quality systems including traceability and vigilance, with adverse events and reactions reported, both nationally and for exported human products.

Commentary on Guiding Principle 10

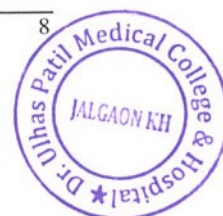
Optimizing the outcome of cell, tissue and organ transplantation entails a rules-based process that encompasses clinical interventions and *ex vivo* procedures from donor selection through long-term follow-up. Under the oversight of national health authorities, transplant programmes should monitor both donors and recipients to ensure that they receive appropriate care, including information regarding the transplantation team responsible for their care.

Evaluation of information regarding the long-term risks and benefits is essential to the consent process and for adequately balancing the interests of donors as well as recipients. The benefits to both must outweigh the risks associated with the donation and transplantation. Donors should not be permitted to donate in clinically hopeless situations.

Donation and transplant programmes are encouraged to participate in national and/or international transplant registries. All deviations from accepted processes that could elevate the risk to recipients or donors, as well as any untoward consequences of donation or transplantation, should be reported to and analysed by responsible health authorities.

Transplantation of human material which does not involve maintenance treatment may not require active, long-term follow-up, though traceability should be ensured for the anticipated lifetime of the

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donor and the recipient. Internationally agreed means of coding to identify tissues and cells used in transplantation are essential for full traceability.

Guiding Principle 11

The organization and execution of donation and transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected.

Commentary on Guiding Principle 11

Transparency can be summarized as maintaining public access to regularly updated comprehensive data on processes, in particular allocation, transplant activities and outcomes for both recipients and living donors, as well as data on organization, budgets and funding. Such transparency is not inconsistent with shielding from public access information that could identify individual donors or recipients while still respecting the necessity of traceability recognized in Principle 10. The objective of the system should be not only to maximize the availability of data for scholarly study and governmental oversight but also to identify risks – and facilitate their correction – in order to minimize harm to donors or recipients.

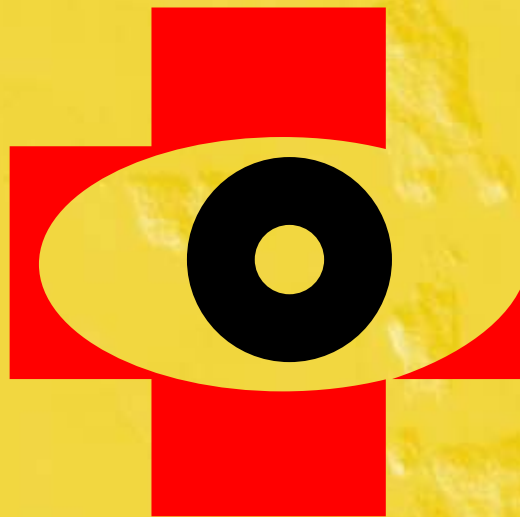
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NATIONAL PROGRAMME FOR CONTROL OF BLINDNESS (NPCB)



Standards of Eye Banking in India

2009



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FOREWARD

I am happy to announce that National Programme for Control of Blindness [NPCB], Directorate General of Health Services, Ministry of Health and Family Welfare, New Delhi has conceptualized and produced this module on "Standards of Eye Banking in India, 2009" so as to establish & communicate quality standards to all stakeholders involved at various level of eye care services.

With the implementation of Eleventh five year plan period of NPCB, a new thrust and vigor has been infused for improvement of eye donation, collection, processing, maintenance of quality standards, equitable distribution of scarce tissue, strengthening of institutional capacity for undertaking corneal transplantation, community awareness and training of health personnel.

I hope that the valuable information given in the module will guide the programme managers, eye surgeons, and health personnel in establishing, strengthening, maintaining and delivering highest level of quality services in eye banking activities.

I appreciate the efforts & contributions of the entire team from governmental and non-governmental sector efficiently led by Dr. [Mrs.] R Jose, Additional DG in producing this visionary document.

[Dr. R.K. Srivastava]



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PREFACE

Over the last three decades, country has seen a phenomenal rise in socio-economical, industrial, manufacturing, information-technology, infrastructural development, human resource management, service sector, so on and so forth with far reaching consequences on health. Today, we have reached a very commendable stage of Cataract Surgical Rate and the momentum thus generated would continue in future also. In this context, National Programme for Control of Blindness [NPCB] has taken a lead in addressing other issues of blindness as well in a comprehensive manner.

Eleventh plan [2007-12] of NPCB has attempted to cover and address emerging eye diseases other than cataract like Diabetic Retinopathy, Glaucoma, Childhood blindness, Low Vision and ocular injuries in a mission mode through successful Public Private Partnership. The endeavor of -the programme is to eliminate all causes of avoidable blindness and to reach a sustainable level where people have access to level appropriate eye care service.

Corneal blindness is one of the eye diseases that is being covered under the global initiative of VISION 2020: The Right to Sight Initiative to which India is also signatory. Eye banking activities becomes a critical component and pillar for managing this disease wherein infrastructure, human resource, logistics & service delivery should match international quality standards and the needs of patients in effective and efficient manner.

Eye Banking Standard manual would not have been possible without constant supervision, encouragement and direction from Dr. R.K. Srivastava DGHS and Ms. Shalini Prasad, Joint Secretary, to Government of India. I would also like to place on record my appreciation to my team members especially Dr. A.S. Rathore, Additional Director General [0], Dr. V. Rajshekhar, Dy. Assistant Director General [0], Dr. V.K. Tewari, Education Health Officer and Dr. Sandeep Sachdeva, National Consultant in supporting and contributing immensely in program activities.

The outcome was spearheaded by various consultative processes and deliberation with stakeholders from Government and Non-Governmental Organization working closely with NPCB since inception. I extend my gratitude to representative from All India Institute of Medical Sciences [New Delhi], Guru Nanak Eye Centre [New Delhi] Eye Bank Association of India [Hyderabad], Arvind Eye Hospital [Madurai], LV Prasad Eye Institute [Hyderabad], Disha Eye Hospital [Barrackpore], HV Desai Hospital [Pune], International Eye Bank [Bangalore], Venu Eye Institute Research Centre [New Delhi], All India Ophthalmic Society [New Delhi], ORBIS [New Delhi] in supporting the larger platform of critical discussion, deliberation and producing the template of Eye Banking Standard.

I strongly believe that implementation of these standards in letter and spirit will pave way to amelioration of corneal blindness from our country in near future.

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The production of the module "Standards of Eye Banking in India" has been a collective effort of all stakeholders including non-governmental organization especially Eye Bank Association of India [EBAI]. Nevertheless, constant support and sustained guidance has been made available from Dr. R.K Srivastava, DG, HS and Dr. [Mrs.] R. Jose, Additional DG.

The standard for eye banking though existed in the past however it was urgently felt that it required updation. The outcome in the present format was realized over a period of time through intense consultative processes, deliberations and meetings. Every attempt has been made while compiling keeping in view international eye banking protocols & standards and suitably adapted to meet local regulations so as to be applicable and relevant in the Indian context. We look forward to suggestions and feedback for improvement by our learned colleagues and readers.

The language used in the module has been kept simple, lucid and at the same time comprehensive to cover all aspect on Eye Banking activities. Module has been divided into chapters and sub-section for easy reference, clarity and understanding. It covers aspects relating to type of facilities, infrastructure, human resource, equipment, instruments, infection control practices; standard operating procedures [SOP]; cornea tissue/preservation/evaluation standards; retrieval procedures, screening of donors, contraindications, quality control, procedures for storage, labeling and equitable distribution of cornea for Keratoplasty.

The exercise was made possible by active contribution of experts especially Dr. Ritu Arora [New Delhi], Dr. Radhika Tandon [New Delhi], Dr. M. Srinivasan [Madurai], Dr. Usha Gopinathan [Hyderabad], Dr. Samar Basak [Barrackpore], Dr. Ayan Mohanta [Barrackpore], Dr. Gobinda Mukherjee [New Delhi], Dr. AVN Chetty [Vishakhapatnam], Dr. Bageshri Gogate [Pune], Dr. Prashant Garg [Hyderabad], Dr. Rekha Gyanchand [Bangalore], Ms. Tanuja Joshi [New Delhi], Mr. G Ganesh [Hyderabad], Dr. GV Rao [New Delhi], Dr. Preeti Singh [New Delhi] and Ms. Deepti Bajaj [New Delhi].

I extend my heartiest appreciation to all the people who contributed directly or indirectly in our journey of achieving this endeavour.

[Dr. A.S. Rathore]

Standards of Eye Banking in India

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Chapter-1

**FACILITIES, EQUIPMENT &
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1.1 Facilities, Equipment & Maintenance

1.1.1. Facilities (Organization and Infrastructure)

For an efficient eye banking system, a three tier organization structure has been recommended. At the top of the pyramid is the Eye Bank Training Center followed by Eye Banks and at the base of the pyramid is the eye donation center. Activities, responsibilities, manpower required for each of the above viz., Eye Bank Training Center (EBTC), Eye Bank (EB) and Eye Donation Center (EDC) has been dealt in detail under section A1.100 to section A1.300

1.2.2. Procedures manual

Each eye bank shall maintain its own procedures manual (SOP) that details all aspects of its specific retrieval, processing, testing, storage, distribution and quality assurance practices. Each procedure must be initially approved signed and dated by the Medical director or Officer-in-charge of the eye bank. An annual review of each eye bank’s procedures manual with signing and dating by the Medical director or Officer-in-charge is required. Each eye bank must maintain copies of each procedure it uses and the length of time the procedure was in use. The current standards of eye banking document can be used as the procedures manual with a document detailing any deviations or modifications with justification as required.

The following facilities and infrastructure is required

1.1.3. Physical Space

A minimum area of 600 Sq.Ft is required which accommodates a serology lab, tissue processing lab and evaluation, storage & shipping lab.

INFRASTRUCTURE	EBTC	E B	EDC
Instrument Cleaning Lab: 1. Sink – For washing instruments 2. Autoclave for sterilizing 3. Counter top & storage space for storing instruments & supplies	Required Required Required	Required Access Required	Required Access Required
Serology Lab 1. Sink for washing 2. Refrigerator – For storing blood samples & kits 3. Counter tops, cabinets & drawers for workspace and storing supplies 4. Centrifuge & Serum testing equipment like ELISA Reader, Rapid test etc.	Required Required Required Required	Access to accredited testing lab or all facilities are required. Accredited lab should have all the mentioned facilities and would be inspected before accreditation is given to eye bank.	Serology lab is not required. However, sink for washing and facility for storing blood samples in refrigerator should be available.
Tissue Processing Lab 1. Sterile counter / table top for processing (Laminar Flow Hood / Bio-Hazard Cabinet) 2. Counter tops, drawers and cabinets for storage	Required Required	Required Required	
Evaluation, Storage & Shipping Lab 1. Slit Lamp and Specular Microscope for Tissue Evaluation. 2. Counter Tops and Cabinets for Storage of Supplies Packing and Shipping. 3. Refrigerator for Storing Donor Tissue	Required Required Required	Required, but access to a specular microscope is also acceptable. Required Required	Not required Required Required

1.1.4. Equipment & Other Facilities

Each eye bank must have the following equipment and facilities to perform the volume of laboratory services with optimal accuracy, efficiency, sterility, timelines, and safety.

EQUIPMENT	EYE BANK TRAINING CENTRE	EYE BANK	EYE DONATION CENTRE
Slit Lamp	Required	Required	Not required
Refrigerators for storing blood sample, tissues and storage media	Required	Required In case the Eye Bank has tie up with accredited lab for testing, one Refrigerator is sufficient	Preferable For storing blood sample, ice packs, storage media, eye or tissue collected etc
Serology Equipment	Required	Yes Required. Access to an accredited lab is also acceptable	Not required
Specular Microscope	Required	Yes required if collection is >200 per year. Access to specular microscope is also acceptable	Not required
Sufficient sets of instruments for corneal excision and enucleation	Required. Numbers to be decided on level of collections	Required. Numbers to be decided on level of collections	Required Numbers to be decided on level of collections
Autoclave or gas sterilizer	Required	Required/or access to sterilizing facility For accreditation, sterilizing facility practice and procedure shall be reviewed	Should have access to sterilizing facility
Laminar Flow Hood (Class II) (This is required for the preservation of ocular tissue in the laboratory in case of whole globe removal (enucleation) and for processing scleral tissue)	Required	Required	Not required
OTHER FACILITIES			
Transportation Facility	24 Hours 365 days	24 Hours 365 days	Should have access
Furniture	Required	Required	Preferable
Computer with email facility	Required	Required	Preferable
Two exclusive lines (one with 1919 or public service number allotted and another for outgoing calls)	Required	Required	Universal public service number to be allotted
Audio visual equipment for publicity	Required	Required	Preferred

1.1.5. Eye Bank Maintenance

The room including walls, floor and sink must be kept clean at all times. Appropriate documentation of regular laboratory cleaning schedules must be maintained and kept on file for a minimum of three years. For cleaning procedure refer Section III.

Each eye bank laboratory must have an adequate, stable electrical source and sufficient number of grounded electrical outlets for operating laboratory equipment.

1.1.6. Equipment maintenance and cleaning

Refrigerator

Each eye bank laboratory shall have a refrigerator with a device, internal or external for recording temperature variations. Temperature variations must be recorded twice daily and should remain within the range of 2° – 6° C.

The refrigerator should be maintained exclusively for use by the eye bank. It must contain clearly defined and labeled areas for all tissues stored e.g. surgical tissue, awaiting distribution, quarantined tissue, tissue for research etc.

The refrigerator should be calibrated once a year.

Laminar Airflow Hood / Cabinet

The cleaning schedule should be maintained.

Particle counts should be performed once a year.

Appropriate maintenance and accreditation records must be maintained for each piece of equipment. The eye bank must include in its procedure manual, the monitoring, inspection and cleaning procedures and schedules, for laboratory equipment. These must be kept on file for a minimum of three years.

In the event of power failure there must be provision for immediate notification and action to be taken, which may include an emergency power supply to maintain essential refrigeration.

1.1.7. Instruments and reagents

Adequate instruments must be available to provide for sterile removal of whole eye and corneas. Instruments must be inspected frequently enough to assure that they function properly.

All sterilized instruments, supplies and reagents, such as corneal preservation medium, must contain expiry dates that are current at all times.

1.1.8. Infection control and safety

All eye bank personnel must operate under the universal precautions for health care workers. These written procedures must be included in the eye bank's procedure manual. All technical personnel should receive Hepatitis B vaccination and any other recommended vaccination that may be announced from time to time.

1.1.9. Waste disposal

Human tissue and waste items shall be disposed off in such a manner as to minimize any hazard to eye bank personnel and the environment and comply with applicable regulations. Dignified and proper disposal procedures shall be used to obviate recognizable human remains.

1.2 Donor Cornea / Eye Retrieval Related Standards

1.2.1. Donor eye / cornea retrieval

Care must be taken that eye bank resources are utilized optimally and eye bank personnel are not exposed to any health hazards. The following guidelines ensure that resources are put to optimum use and that eye bank personnel are not exposed to any health hazards.

1.2.2. Personnel authorized to retrieve eyes / corneas

A registered medical practitioner trained in enucleation / excision from an Eye Bank Training Center is only allowed to retrieve eyes / corneas from the donor after satisfying self that life is extinct, in the absence of a death certificate.

1.2.3. Pre Recovery Procedure

Before proceeding for recovery eye bank personnel should ascertain the following details:

- | | |
|-------------------|---------------------|
| a) Location | b) Age of the donor |
| c) Cause of death | d) Time of death |

1.2.4. Retrieval Procedure

- Retrieval procedure could be either Enucleation or Corneal scleral rim excision. The retrieval procedures for both of the above mentioned techniques are given in detail in Section III H8.340 under Donor Ocular Tissue Recovery.
- Eye Bank team should carry only validated sterile instruments for retrieval.
- Eye Bank Team on arrival at the location should locate the next of kin and convey condolence and obtain death certificate.
- In the absence of a death certificate the registered medical practitioner should satisfy self that life is extinct as per procedures laid down in Section III H 8.320,330 and Appendix II.
- The eye bank team should obtain consent on a consent form from the legal custodian of the donor.
- After obtaining consent the donor should be identified either through a tag or through the next of kin
- The eye bank team should then proceed to prepare the site as per guidelines in Section III H8.340
- Gross physical examination should be conducted with utmost respect for observations regarding build: average / healthy / emaciated
- Eye bank team should look out for needle marks on the arm, skin lesions etc
- Eye Bank Team should look out for Ulcers / gangrene in exposed areas
- Ocular examination should be conducted as per guidelines in Section III, H8.340
- Medical records / Medical information should be obtained as per guidelines in Section III, H8.350
- Information for hemodilution should be obtained as per guidelines in Section III, H8.300, H8.400
- Social history of the donor should be obtained wherever possible from the next of kin
- Once all the above are completed the retrieval can be started. The retrieval procedure should be as per guidelines in Section III, H8.500

1.2.5. Screening of donors

Tissue from donors with the following is potentially hazardous to eye bank personnel and harvesting eyes should be strictly avoided.

Contraindications for Retrieval:

Active viral Hepatitis

Acquired immunodeficiency syndrome (AIDS) of HIV

Active viral encephalitis or encephalitis of unknown origin

Creutzfeldt-Jakob disease

Rabies

1.2.6. Contraindications

Tissue from donors with the following are potentially health threatening and also affects the success of the surgery and shall not be offered for surgical purposes. In conditions considered absolute contraindications for transplantation (marked with an asterix*), donor family should be informed clearly and made fully aware of this fact. Eyes should not be harvested unless the donor family is fully aware of this and still wishes to donate

(I) Conditions with potential risk of transmission of local or systemic communicable from donor to recipient

- a Death of unknown cause*
- b Death with neurologic disease of unestablished diagnosis*
- c Subacute sclerosing panencephalitis
- d Progressive multifocal leukoencephalopathy
- e Active meningitis or encephalitis*
- f Encephalopathy of unknown origin or progressive encephalopathy*
- g Active septicemia* (bacteremia, fungemia, viremia, parasitemia)
- h Active viral hepatitis*
- i Creutzfeldt-Jakob disease*
- j Congenital rubella
- k Reye's Syndrome
- l Rabies*
- m Active miliary tuberculosis or tubercular meningitis*
- n Patients on ventilator for > 72 hrs
- o Hepatitis B surface antigen positive donors*
- p HTLV-I or HTLV-II infection*
- q Hepatitis C Seropositive donors*
- r HIV seropositive donors*
- s HIV or high risk for HIV corneas from: persons meeting any of the following criteria should not be offered for transplantation.*

- t Active ocular or intraocular inflammation conjunctivitis, scleritis, iritis, uveitis, vitreitis choroiditis and retinitis (at the time of death)

(II) Conditions with potential risk of transmission of non-communicable disease from donor to recipient.

- a Death due to cyanide poisoning
- b Intrinsic eye disease
- c Retinoblastoma
- d Malignant tumours of the anterior ocular segment or known adenocarcinoma in the eye of primary or metastatic origin
- e Leukemias*
- f Active disseminated lymphomas*

(III) Conditions that will affect graft outcome.

- a Congenital or acquired disorders of the eye that would preclude a successful outcome for the intended use e.g., a central donor corneal scar for an intended penetrating keratoplasty preserve of keratoconus and keratoglobus. Corneas which have undergone refractive surgical procedures etc.
- b patients on ventilator for >72 hrs.

Behavioral / History, Laboratory and Medical Exclusion Criteria.

- a. Men who have had sex with other men in the preceding 5 years (homosexual behaviour)
- b. Persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years. (IV drug abusers)
- c. Persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrate.
- d. Men and women who have engaged in sex for money or drugs in the preceding 5 years (commercial sex workers)
- e. Persons who have had sex in the preceding 12 months with any person described in item a-d above or with a person known or suspected to have HIV infection.
- f. Persons who have been exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, or mucous membrane.
- g. Children meeting any of the exclusionary criteria listed above for adults should not be accepted as donors.
- h. Children born to mother with HIV infection or mothers who meet the behavioral or laboratory exclusionary criteria for adult donors regardless of their HIV status should not be accepted as donors unless HIV infection can be definitely excluded in the child as follows:
 - (i) Children >18 months of age who are born to mothers with or at risk for HIV infection, who have

not been breast fed within the last 12 months, and whose HIV antibody tests, physical examination and review of medical records do not indicate evidence of HIV infection can be accepted as donors.

- (ii) Children < 18 months of age who are born to mothers with or at risk for HIV infection or children of mothers with or at risk of HIV infection who have been breast fed within the past 12 months should not be accepted as donors regardless of their HIV tests results.
- i. Persons who cannot be tested for HIV infection because of refusal, inadequate blood samples (e.g. haemodilution that could result in false-negative tests), or any other reasons.
- j. Persons with a repeatedly reactive screening assay for HIV-1 or HIV-2 antibody regardless of the results of supplemental assays.
- k. Persons whose history, physical examination, medical records, or autopsy reports reveal other evidence of HIV infection or high-risk behaviour, such as diagnosis of AIDS, unexplained mucous membranes hemorrhages kaposi's sarcoma, unexplained lymphadenopathy lasting > 1 month, unexplained temperature > 100.5 F (38.6C) for > 10 days, unexplained persistent diarrhea, male-to-male sexual contact, sexually transmitted diseases, or needle tracks or other signs of parental drug abuse.

Donor tissue will be harvested and transported to the eye bank for further processing, evaluation, storage and distribution. Surgical use of tissue for transplantation will be determined by technical considerations as decided by the medical director and operating surgeon. Tissues can be used for penetrating keratoplasty, lamellar keratoplasty, stem cell culture and/or transplantation and scleral transplantation and any residual parts can be used for educational or research purpose as appropriate.

1.2.7. Donor age

Since no definite relationship has been established between the quality of donor tissue and age the upper and lower age limit is left to the discretion of the medical director.

1.2.8. Interval between death, enucleation, excision and preservation

Acceptable time intervals from death, enucleation or excision to preservation may vary according to the circumstances of death and interim means of storage of the body. It is generally recommended that corneal preservation should occur as soon as possible after death. All time intervals for each donor, e.g., the time of death to the time of enucleation and preservation and/or the time to corneal excision, shall be recorded. If the donor has been refrigerated prior to enucleation or in situ corneal excision, this information shall be noted.

1.2.9. Recovery Procedure

1.2.10. Donor Blood Sample

The authorized personnel retrieving the tissue should obtain an adequate blood sample. Please refer Section III, for detailed procedure.

1.3 Donor Tissue Preservation Standards

1.3.1 In situ and laboratory removal of the corneoscleral rim

Individuals specifically trained for in situ retrieval and/or laboratory removal of the corneal scleral segment shall perform removal of the corneal scleral rim using sterile technique. If the procedure is done in a laboratory the removal must be performed in a laminar flow hood, cabinet or in an operation room. For corneal scleral removal, the eye shall be examined with the use of a penlight preferably and a slit lamp prior to excision.

1.3.2 Use of short or intermediate term preservation medium

Eye Bank shall use approved corneal storage medium (such as MK, Optisol GS, EUSOL, etc) from a reliable source. The medium shall be used and stored according to the manufacturer's recommendations for temperature, date and other factors. The manufactured medium purchased and shipped to the eye bank shall be inspected for damage upon arrival and the lot number of medium used for each cornea shall be recorded on the tissue tracking and recall.

1.3.3 Long term preservation

Some eye banks employ long-term preservation of corneal tissue, such as glycerine preservation or organ culturing. An eye bank that use long-term preservation shall carefully document the procedure in their procedure manual, and adhere to rigid aseptic technique.

1.3.4 Whole globe preservation

Eye Banks that store whole eye shall employ aseptic practice. The selected preservation method must be documented in the eye bank's own procedures manual.

1.3.5 Sclera preservation

Eye banks shall preserve scleral tissue aseptically. The selected preservation method must be documented in the eye bank's own procedure manual.

A preservation date for scleral tissue shall be indicated.

1.4 Tissue Evaluation Standards

The ultimate responsibility for determining the suitability of the tissue for transplantation rests with the transplanting surgeon.

1.4.1 Gross examination

The corneal-scleral segment shall be initially examined grossly for clarity, epithelial defects, foreign objects and contamination and scleral color. e.g., jaundice. Refer Section III, H8.800 for details.

1.4.2 Slit-lamp examination

The cornea shall be examined for epithelia and stromal pathology and in particular endothelial disease. Enucleated globes shall be examined in the laboratory prior to distribution and/or corneal excision. If in situ corneal excision is performed, examination of the donor eye anterior segment with a penlight or a portable slit lamp is required. After corneal excision, the corneal-scleral rim shall be evaluated by slit lamp

biomicroscopy, even if the donor eye has been examined with the slit lamp prior to excision of the corneal-scleral rim, to ensure that damage to the corneal endothelium or surgical detachment of Descemet's membrane did not occur.

Information obtained with slit lamp biomicroscopic examination must be documented.

1.4.3. Specular Microscopy:

Determination of endothelial cell density via specular microscopy shall be a standard method of corneal tissue evaluation for all Eye Banks. When it is impossible to obtain an endothelial cell count this requirement may be waived on a case-by-case basis by the MD.

1.5. Donor Blood Screening

The following sections specify the required serologic tests, which must be performed for each donor. Refer Section III, H8.900 for details and procedures.

1.5.1 HIV Screening

All eye banks must have an operational HIV screening programme using an approved test for all donors of surgically designated tissue. A negative screening test must be documented prior to release of tissue for transplantation.

1.5.2. Hepatitis B & C screening

All eye banks must have operational hepatitis B & C screening programme using approved tests for hepatitis B & Hepatitis C antigen for all donors of surgically designated tissue. A negative screening test or neutralization or confirmatory test must be documented prior to release of tissue for transplantation.

1.5.3. HTLV-I and HTLV-II screening

Donor Screening for HTLV-I and HTLV-II is not required. However, if donor screening for HTLV-I and/or HTLV-II has been performed, a negative screening test must be documented prior to release of tissue for transplantation.

1.5.4. Syphilis screening

All eye banks must have operational syphilis screening programme using an approved test for all donors. If the screening test is positive, a negative confirmatory test must be documented before tissue is released.

1.5.5. Non-required laboratory results

If laboratory results of non-required test for infectious disease are available for tissue, for transplantation, they must be taken into account and/or acted upon by the MD. Any relevant information shall be provided to the transplanting surgeon.

1.6 Quality Assurance

1.6.1 Quality Assurance (QA)

Each eye bank shall have a formally established quality assurance programme. This program shall include ongoing monitoring and development of plans for corrective action. These standards shall provide the basis for development of the QA programme. Each eye bank shall document all aspects of its QA programme and maintain record of all QA activities for a minimum of ten years. These include any corrective or remedial action taken for detected deficiencies. These records shall be available for review.

The eye bank's quality assurance programme shall include a method for the receiving surgeon to report adverse reactions from the transplantation of corneal, scleral or other ocular tissue to the source eye bank. The Eye Bank in turn must forward the adverse reaction information within a reasonable time to the EBAI or MOH for review by the Medical Standards Policy sub-committee. An adverse reaction file shall be available for review by the accreditation team at the time of inspection and must be kept for minimum of three years.

1.7 Quality Control

The MD shall prescribe tests and procedures for measuring, assaying or monitoring properties of tissues essential to the evaluation of their safety for transplantation, e.g., hepatitis B surface antigen and human immunodeficiency virus (HIV) antibody, and conform with legal and regulatory requirements. Results of all such tests or procedures, together with evaluations based on these findings, shall become part of the permanent record of all tissue processed.

1.7.1 Testing

If an eye bank performs its own microbiologic or serologic testing it must meet applicable accreditation requirements.

1.7.2. Microbiologic Culturing

Culturing of Eye Bank donor eyes is advised despite the recognition by many that bacteriologic contamination of donor eyes does not necessarily lead to infection and that pre-surgical or surgical cultures may not correlate with postoperative infection if it should occur. Cultures may be performed either before and/or at the time of surgery.

A. Pre-surgical cultures (Optional)

Eye Banks may elect to perform corneal-scleral rim cultures at the time of corneal preservation in tissue culture medium. Positive culture reports shall be reported to the receiving surgeon or recipient eye bank.

B. Surgical culturing

Each eye bank shall recommend culturing of the corneal scleral rim for corneal transplantation, or a piece of sclera for scleral implantation at the time of surgery. Positive results in cases of postoperative infection shall be reported to the eye bank/or eye donation centre that procured the tissue as well as to the eye bank that distributed the tissue.

1.8 Non-Surgical Donor Tissue

1.8.1. Non-Surgical Donor Tissue

If donor tissue is provided for purposes other than surgery, e.g., research, practice surgery, etc., that donor tissue should also have been screened for HIV or Hepatitis. In case the donor has not been screened for some unavoidable reason and the tissue has to be sent for research or other purpose, then a label stating that screening for HIV-antibody, Hepatitis B or Hepatitis C has not been carried out or stating "Potentially hazardous biological material" or some other indication must be attached to the container used for the donor tissue storage and/or transport.

1.9 Storage

1.9.1. Storage

All surgical tissue shall be stored in quarantine until results of HIV, HbsAg, HCV, and any other relevant donor screening tests have been recorded as non-reactive.

All tissue shall be stored aseptically at a temperature appropriate to the method of preservation used. Eye banks must precisely document their procedures for storage of corneal tissue, whether it is in the form of the whole eye or the cornea only in an appropriate medium.

1.10 Labeling

1.10. Labeling

Each corneal or scleral tissue container shall be clearly and indelibly labeled to include at least the information below:

- Name of source eye bank
- Tissue identification number. There must be unique identification number for each ocular tissue or fraction thereof that is distributed for surgical use.
- Type of tissue
- Date and time of donor's death
- Date and time of Cornea/scleral preservation
- Preservation date for scleral tissue and long-term preserved tissue
- A statement that the tissue is intended for single patient application only and that it is not to be considered sterile and culturing or re-culturing is recommended.
- Type of preservation medium

1.11 Distribution of Tissue

1.11.1. Review of donor medical history

Prior to distribution of tissue for transplantation, the MD or his/her designee shall review and document the medical and laboratory information in accordance with medical standards.

1.11.2 Receivers of tissue

Tissue shall be distributed only to ophthalmologists, institutions and other eye banks who are registered under applicable laws like Transplantation of Human Organs Act.

All tissues sent from an accredited eye bank must comply with the recommended medical standards.

1.11.3. Fair and equitable system

Eye banks shall establish and document a system of distribution that is just, equitable and fair to all patients served by the eye bank. Documentation of distribution time and date of requests and delivery of eye tissue to be maintained. Access to tissue shall be provided without regard to recipient sex, religion, race, creed, colour or caste.

1.11.4. Returned tissue

For corneas returned and redistributed, tissue transportation and storage information must be documented and made available to the transplanting surgeon.

1.11.5. Tissue recalls

Eye banks must have a policy and procedure for potential recall of tissue

Chapter-2

**STANDARDS FOR NON-
TECHNICAL ACTIVITIES OF
EYE BANKS**

CHAPTER - 2

Standards for Non-Technical Activities of Eye Banks

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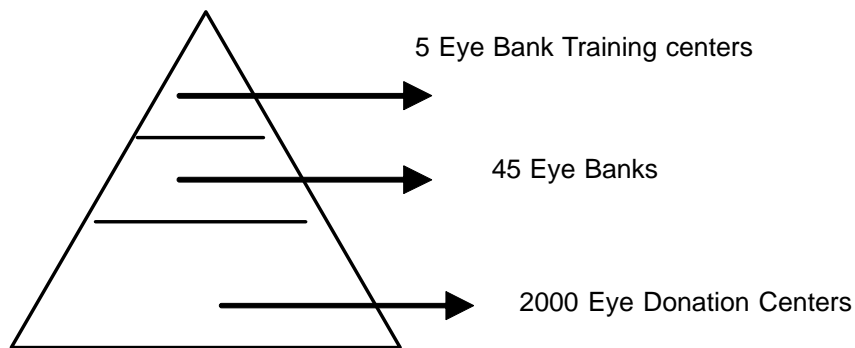
2.1. Eye Banking System

Objective

The objective of this section is to standardize all non technical activities of eye banking like administration, awareness and Human Resource development so that management becomes simple. This section also clearly defines the ideal and preferred eye banking system and lays down specific responsibilities and scope of each of the component of the eye banking system.

2.1. Eye Banking System

For efficient functioning of eye banking system a three tier structure has been developed. At the top are Eye Bank Training Centers numbering five, one each for the five zones in the country, followed by 45 eye banks. These 50 eye banks and eye bank training centers are networked with 2000 eye donation centers.



In developing countries such as India, one has to develop a system that is effective, efficient and financially relevant. A 3-tier structure encompassing all activities of eye banking will address this issue rather well and the determinants will be the infrastructure and manpower available with a profile of functions covered.

2.1.1. Eye Donation Center (EDC)

Eye Donation Center is affiliated to a registered eye bank, which should provide

- (1) public and professional awareness about eye donation
- (2) co-ordinate with donor families and hospitals to motivate eye donation
- (3) to harvest corneal tissue and collect blood for serology
- (4) to ensure safe transportation of tissue to the parent eye bank.

2.1.2. Eye Bank (EB) is an institution that should

Provide a round-the-clock public response system over the telephone and conduct public awareness programmes on eye donation.

Co-ordinate with donor families and hospitals to motivate eye donation Hospital Cornea Retrieval Programme – (HCRP)

To harvest corneal tissue

To process, preserve and evaluate the collected tissue

To distribute tissue in an equitable manner for Keratoplasty

To ensure safe transportation of tissue.

2.1.3. Eye Bank Training Centre (EBTC)

All of the eye bank functions plus training for all levels of personnel in eye banking and research.

2.2. Awareness

The main activity of an eye donation center, eye bank or eye bank training center is to create awareness about eye donation and also educate public about the need for eye donation. In the present scenario awareness campaigns have to be planned in such a way that the overall objective is achieved.

Awareness campaigns can be **General awareness campaigns** and **Focused awareness campaigns**.

2.2.1. General Awareness

In general awareness various media like Print, Electronic and Movie are used and the message about eye donation is spread among the general public. This form of awareness though does not yield immediate results, helps in changing the mindset of the people gradually. EBTC, EB and EDCs in all their awareness programs and campaigns should ensure that:

1. Public are educated about magnitude of corneal blindness, cure for corneal blindness and the need for eye donation.
2. Only published statistics of NPCB or EBAI should be quoted so that there is consistency.
3. Education for formalities related to eye donations. Public is educated about precautions to be taken after death and after decision for eye donation is made, till the eye bank team reaches the spot
4. Public are educated that eyes cannot be removed in certain medical contraindications.
5. Families are educated about the need to arrange for death certificate etc before the eye bank team arrives.

2.2.2. Focussed Awareness Campaigns

Voluntary eye donation is a result of realization of ones social responsibility towards the corneal blind. However, in moments of grief this realization may not materialize into actual eye donation. Eye donation counselling or grief counselling is a motivational approach whereby the family members of the deceased are directly motivated for an eye donation. This process provides direct access to the family members of the deceased to attempt counselling. Moreover, several advantages follow tissue retrieval from hospitals. Availability of medical history, availability of tissues from younger individuals, reduction in the time interval between death and enucleation / corneal excision and cost effectiveness are some of these. The program also allows the EDCs to get to know of potential eye donors within the hospital.

Only Eye Banks shall have the Hospital Cornea Retrieval Program. In cases where the hospital is far from the eye bank and is closer to an eye donation center, the eye donation center shall offer all necessary assistance like retrieve eyes and transport to the eye bank but nevertheless the Eye Donation Counselor shall be under direct control of the eye bank.

2.2.3. Choice of hospitals

An important step in the initiation of HCRP is identification of the hospitals to be included in the program. Ideally the hospitals to be chosen are

Large multispeciality hospitals with a high mortality rate (3 to 4 per day or more) >3000/year.

Medium multispeciality hospitals with moderate mortality rate (of 1 to 2 per day or more) > 2000/year.

2.2.4. Link between the hospital and the eye bank

Role of the Director of the Eye Bank or equivalent designee

The Director of the Eye Bank shall initially meet the Hospital management and sign a memorandum of understanding. The eye bank Directors or equivalent committee members shall meet the hospital authorities (Administrators, Public Relations Officer, Medical Officer and Nurses) and educate them on the basics of eye banking and the HCRP.

They shall seek permission for the display of publicity materials and posters about eye donation in the wards and patient lounges in the hospitals.

The administrative and medical staff of the hospital shall be requested to cooperate well with the eye donation counsellor (EDC), and provide information regarding the potential eye donor.

The eye bank Directors shall periodically meet the hospital authorities to make enquiries about the progress / problems encountered during counselling and to strengthen the bond between the eye bank and the hospital.

The eye bank Management to make arrangements for training the eye donation counsellor on grief counselling techniques.

The eye bank Directors shall periodically verify the records of EDCs and advise the counsellor on improving the counselling techniques.

2.2.5. Attributes of an Eye Donation Counsellor (EDC)

The EDC shall be initially told and taught the concept of eye banking through classes comprising of both theory and demonstration. He/She shall also be instructed about the dress codes while on duty.

A candidate selected to the post of eye donation counsellor shall be committed to the cause of eye donation.

The EDC shall have good communication skill and shall be well conversant with the regional language.

The EDC shall be dressed professionally.

The EDC shall wear a white apron and an identity card.

The EDC shall attend the following classes (theory and demonstration) (On job training of at least 1 month).

Ocular anatomy (Theory & demonstration).

Corneal anatomy and physiology (Theory & demonstration)

Corneal blindness (Theory).

Corneal transplantation (Theory & Video demonstration).

Eye bank and its level of operation (Theory).

Corneal excision (Theory & demonstration).

Grief counselling (Theory).

The EDC shall initially be posted in the Eye Bank for one week in order to acquaint himself/herself with all aspects of eye bank functioning.

2.2.6. Grief counselling techniques

The EDC shall approach the family members of the deceased at an appropriate time. The EDC shall not present the matter in a hurry to the family member. He/she shall wait until the family members are found mentally relaxed. The EDC shall initially introduce himself/herself by name and the eye bank he/she belongs to.

The EDC shall talk to limited family members in an ideal surrounding.

The EDC shall only talk to those who are found supportive to the cause.

The EDC shall provide comfort, moral support and sympathy to the family members while attempting to motivate them for an eye donation.

The EDC shall respect the feelings of the family members.

The EDC shall listen to the bereaved family members patiently.

The EDC shall address the fears and queries raised by the family members (**Frequently Asked Questions – Appendix – 14**).

The EDC shall have adequate knowledge about the myths and facts about eye donation (**Facts & Myths About Eye Donation – Appendix - 15**).

The EDC shall be aware of the procedure to be followed in Medico-legal cases. It is important that the EDC gets written approval from the police personnel before alerting the eye bank.

The EDC shall assure the family members that there will be no delay caused in making funeral arrangements.

The EDC shall give adequate time for the family members to discuss and decide about eye donation.

The EDC shall only suggest eye donation to the family members and not force them to make an eye donation.

The EDC shall express his/her gratitude to the family member upon obtaining consent. The EDC shall express gratitude to the family members of the deceased even in the absence of obtaining consent for eye donation.

2.2.7. Alerting the eye bank team

The EDC shall alert the eye bank soon after obtaining consent for eye donation. He/She shall inform the eye bank team where exactly the body is placed so as to enable the team to reach the site without delay. The EDC shall keep a copy of the death certificate ready before the eye bank team reaches the site as it is mandatory to have a death certificate prior to proceeding for corneal excision.

2.2.8. Expression of gratitude

The EDC shall express gratitude to the family members of the deceased after obtaining the consent for eye donation as well as after performing corneal excision.

2.2.9. Documentation of case reports

On a daily basis, the EDC shall document relevant details of every case approached and motivated during the work period in the form designed for the purpose (**HCRP Daily Report – Appendix – 16**). The daily reports will be analyzed at the closure of every month and recorded (**HCRP Monthly Report – Appendix – 17.**)

2.3. Manpower Requirements

Eye Bank Training Centers, Eye Banks and Eye Donation Centers should have the following personnel. Government eye banks should also set up a team within their administrative framework and designate the responsibilities as per the requirements and at the discretion of the head of the hospital or institute as applicable.

MANPOWER*	EBTC	EB	EDC
Board of Directors or equivalent Committee	Yes	Yes	No
Medical Director (MD) or equivalent	Yes	Yes	No
Executive Director (ED) or equivalent such Officer-in-charge	Yes	Yes	No
Eye Bank Manager (EBM) or equivalent	Yes	Yes	No
Eye Bank Technicians (EBT)	Yes	Yes	Yes
Eye Donations Counselors (EDC)	Yes	Yes	No
Administrative Secretary cum telephone operator	Yes	Yes	No
Driver	Yes	Yes	No
Panel of Registered Medical Practitioners to enucleate round the clock	Yes	Yes	Yes

*An eye bank can designate and delegate multiple responsibilities to a person as appropriate if necessary.

2.3.1 Responsibilities of various eye banking personnel

2.3.2 Board of Directors

All EBs and EBTCs need to have a board of directors or equivalent committee composed of medical professionals and other professionals who could contribute to the smooth functioning of the organization. In case of Eye Banks & Eye Bank Training Centres attached to Government hospitals, Director of Eye Hospital, Main Hospital with administrators from Health Department of the State to serve as board of directors

2.3.3. Medical Director / Eye Bank Incharge

The Medical Director (MD) must be an Ophthalmologist who has completed a corneal fellowship or who has demonstrated expertise in external eye disease, corneal surgery, research or teaching in cornea and/or external disease or has an experience in corneal transplantation. If the eye bank does not have such a person it should have a consulting relationship with an ophthalmologist who satisfies the above criteria.

All policies and procedures of each eye bank shall be under the supervision of the MD.

The MD shall be providing all staff members with adequate information to perform their duties safely and completely.

The MD shall oversee and provide advice on all medical aspects of the Eye Bank operations. These include but are not limited to:

Formulation, approval, and implementation of medical policies and procedures. Participation in training and oversight of technical staff with regard to tissue procurement, preservation, and its evaluation. Participation in establishment and operation of a quality assurance programme.

The MD may delegate responsibility for tissue procurement, preservation, and tissue evaluation to qualified eye bank personnel; however, the MD shall ensure that the eye bank operates in compliance with the "Existing Medical Standards". Ultimate responsibility of determining the suitability of donor tissue for transplantation is of the transplanting eye surgeon.

2.3.4. Executive Director or Designated Equivalent

Will be responsible for managing the entire operations of the eye bank. It is the responsibility of the Executive Director to follow the policies of the Board or committee and wherever necessary shall consult the Medical director/Eye Bank incharge or other specialists for discharging the responsibilities.

2.3.5. Eye Bank Manager or Designated

Eye bank manager will be responsible for the day to day functioning of the eye bank and ensure compliance with the set standards. Non-compliance should be noted and brought to the attention of the MD.

2.3.6. Eye Bank Technicians

Shall be responsible for the entire activities of eye banking like retrieval, processing, evaluation, documentation, distribution of tissue and maintenance of the laboratory and instruments and equipment. He / She shall be Higher Secondary qualified with Science or Higher Secondary education with experience in a diagnostic or similar lab or experience in operation theatre procedures. He / she shall undergo training and qualify from designated training centers for Eye Bank Technicians.

2.3.7. Eye Donation Counselor or Designate

Shall be responsible for counseling families at Hospitals and coordinate with eye bank and hospital for retrieval of cornea. Shall also be responsible for awareness campaigns both within the hospital and outside the hospital. Trained Eye Bank Technicians trained in counselling can also perform these duties if the situation warrants.

2.3.8. Administrative Secretary cum telephone operator or Designate

To perform the routine office work.

2.3.9. Training & Human Resource Development

It is essential that the eye bank personnel are abreast of the latest developments in eye banking and corneal transplantation. Each eye bank shall ensure that their personnel are adequately trained and their skills are constantly upgraded.

2.3.10. Medical Director

The Medical Director shall undergo regular continuing education in Eye Banking and related issue. The eye bank shall provide written documentation of such attendance at the time of the eye bank site inspection.

2.3.11. Executive Director & Eye Bank Manager

The Executive Director and / or Eye Bank Manager shall undergo a refresher training module at an eye bank training center at least once a year. The eye bank shall provide written documentation of such attendance at the time of eye bank inspection.

2.3.12. Eye Bank Technician

Eye Bank Technician shall undergo a refresher training module at an eye bank training center at least once a year. The eye bank shall provide written documentation of such attendance at the time of eye bank inspection.

2.3.13. Eye Donation Counselor

Every eye bank shall have a specially designed counseling cum training module for the eye donation counselor. This is necessary because the EDC deals with morbidity continuously. The frequency of such training & counseling sessions shall be atleast once in four months. The eye bank shall provide written documentation of such attendance at the time of eye bank inspection.

HR Policy

The eye bank training center, eye bank and eye donation center should have a HR policy for regular appraisal of performance, in house skill upgrading & training programs, recruitment policies, incentives for performance and counseling of all personnel.

2.4. Documentation

Every EBTC, EB and EDC shall follow uniform documentation protocol as described in this section.

2.4.1. Length of storage

All records shall be kept for a minimum of ten years (or comply with appropriate laws) from the date of transplantation/implantation.

2.4.2. Confidentiality

All eye bank records and communications between the eye bank and its donors and recipients shall be regarded as confidential and privileged.

2.4.3. Documents & Logbooks

The following documents, logbooks and records are to be maintained by EBTC, EB and EDCs:

Name of the document / log book	EBTC	EB	EDC
Donor initial information form (Appendix 1)	Yes	Yes	Yes
Death Certificate / Eye Donor Medical Particulars (Appendix 2)	Yes	Yes	Yes
Consent form (Appendix 3)	Yes	Yes	Yes
Donor Information Sheet (Appendix 4)	Yes	Yes	Yes
Serology Report (Appendix 5)	Yes	Yes	No
Tissue Evaluation Report (Appendix 6)	Yes	Yes	No
Haemodilution form (Appendix 7)	Yes	Yes	Yes
Tissue distribution form (Appendix 8)	Yes	Yes	No
Surgeons' adverse finding report form (Appendix 9)	Yes	Yes	Yes

Name of the document / log book	EBTC	EB	EDC
Instrument cleaning log (Appendix 10)	Yes	Yes	Yes
Sterilisation log (Appendix 11)	Yes	Yes	Yes
Lab cleaning log (Appendix 12)	Yes	Yes	Yes
Equipment cleaning log (Appendix 13)	Yes	Yes	No
Equipment maintenance log (Appendix 14)	Yes	Yes	No
Equipment calibration records	Yes	Yes	Yes
Eye Bank Personnel training records and qualification certificates	Yes	Yes	Yes

The recommended formats for the above are given in appendices 1-14.

2.5. Registration & Accreditation

Each eye bank unit, should be registered under Transplantation of Human Organs Act and also should undergo the Accreditation appraisal.

2.5.1. Registration

Eye Bank Training Centers, Eye Banks and Eye Donation Centers should apply to their respective state government health authorities and get registered under Transplantation of Human Organs Act 1994. They should perform their activities as prescribed in the applicable law like Transplantation of Human Organs Act until the registration is completed.

2.5.2 Accreditation

After registration the eye bank units should offer themselves for appraisal by an Accreditation Authority (AA) within one year to obtain valid accreditation documents before they are declared as fully operational to the public.

Accreditation will include evaluation of the following:

- Demonstrate compliance with Medical Standards
- Demonstrate compliance of all requirements during site inspection.
- Demonstrate proficiency in all aspects of eye banking viz. procuring, processing and distributing corneal tissue. The eye bank should collect at least 25 surgical grade tissues (i.e. tissues for optical keratoplasty) annually and provide documentation of their performance.
- Certify compliance with applicable laws and regulation. Once accredited, an eye bank must be inspected and reaccredited at a frequency as defined by the accreditation authority.
- In cases of non compliance a reasonable time period will be given to rectify deficiencies and satisfy accreditation requirements.
- If the eye bank does not meet the standards within the deadline it may not receive accreditation as

an eye bank and may be re-designated as an eye collection center. The State Registration Authority shall be informed about failure to meet accreditation requirements and to cancel registration under Transplantation of Human Organs Act.

2.5.3. Accreditation Authority

Shall be a body comprising of nominees by Government of India, State Government, any other nominated by NPCB and EBAI.

2.6. Eye Bank Inspection

The Accreditation Committee shall be responsible for inspecting each Eye Bank as outlined in the written procedures of the EBAI and the Government of India.

Accreditation and reaccreditation site inspections shall be scheduled following written notification of the impending inspection. Unannounced inspections may be conducted in case of receipt of any allegation of violation of "Medical Standards" by any eye bank. Failure to permit an inspection will result in suspension or revocation of an eye bank's accreditation and registration under Transplantation of Human Organs Act.

2.6.1. Procurement of Eye Bank Essentials

The Eye Bank should have a policy and procedure for maintaining sufficient stocks of essential eye bank supplies and also a procedure for procuring eye bank supplies. Procurement procedure has to be documented and produced at the time of site inspection.

Chapter-3

**STANDARD OPERATING
PROCEDURES OF EYE BANKS**

CHAPTER - 3

Standard Operating Procedures of Eye Banks

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Chapter-3

Standard Operating Procedures of Eye Banks

3.1 Scope of the Manual

The Eye Bank manual on 'Policies and Standard Operating Procedures' is structured to comply with the laws, regulations and prescribed standards in eye banking so that the information contained in the manual will contribute to the establishment, application and maintenance of effective, efficient and safe technical and medical standards in eye banking.

The manual is subject to change, to allow acceptable variation within the scope of eye bank policies and ophthalmologic practice. The Medical Director/Eye Bank Incharge and the Executive Director or Designate will review the manual once a year.

The manual describes i). policies related to recruitment of staff, trainees (from eye donation centers for CME), HCRP, accreditation, data documentation and reporting, and ii). procedures related to maintenance of eye bank laboratories, instruments and equipment, infection control and safety, identification and screening of donors, donor cornea recovery, tissue evaluation, preservation & distribution and scleral tissue processing.

Personnel

3.1.1. Recruitment

The staff requirement of the organization is initially discussed between the Directors (Medical Director and the Executive Director or Designate) of the eye bank. A written request is then submitted to the Board or competent authority after whose approval, it is forwarded to the Personnel department for releasing an advertisement. In the Eye Banks attached to Govt. Institutions the staff available from Govt. source to be designated and trained specifically for Eye Bank purpose.

All recruits shall be under observation for the first 6 months. They are required to submit their bio data along with copies of educational and experience certificates to the Personnel department.

3.1.2. Personnel & Responsibilities

3.1.3. Medical Director/Officer Incharge Eye Bank

The Medical Director of the eye bank shall be an Ophthalmologist appointed by the Management and as per the Standards of Eye Banking in India.

1. The Medical Director shall provide advice for all medical aspects of the eye bank operations.
2. He/She shall be responsible for the formulation, approval, and implementation of medical policies and procedures.
3. He/She shall ensure that the medical issues are in compliance with the existing Medical standards.
4. The final responsibility for determination of suitability of each tissue for transplantation is with the corneal transplant surgeon. In cases of discrepancies, the Medical Director shall be consulted.
5. He/She shall contribute to the training and CME programs of the eye bank.
6. The Medical Director shall work in close association with the Executive Director or Designate of the eye bank in all administrative and scientific matters concerning eye banking.

3.1.4. Executive Director or Designate

The Executive Director shall be a qualified and experienced person with experience in a laboratory atmosphere or hospital management, appointed by the Board or competent authority, and trained in all technical, administrative, and scientific aspects of eye banking.

1. All administrative policies and procedures of the eye bank shall be under the supervision of the Executive Director or designate.
2. He/She shall be responsible for the day to day administrative, medical and scientific operations of the eye bank under the supervision of the Medical Director.
3. He/She shall devise and implement systems for quality assurance at all levels of eye bank operations.
4. He/She shall be responsible for delegating responsibilities to the technical and other staff of the eye bank.
5. He/She shall train and supervise technical staff in operations related to donor cornea procurement, tissue storage and distribution.
6. He/She shall be responsible for conducting the annual appraisals of the technical staff of the eye bank.
7. He/She shall organise training and CME programs of the eye bank..
8. He/She shall be responsible for organising the accreditation procedures as per requirements.
9. He/She shall be responsible for monitoring the Cornea Retrieval programs in various hospitals.
10. He/She shall be responsible for providing donor tissue utility reports/project reports to the eye donation centers, funding agencies, EBAI, Government and other agencies.

3.1.5. Technical Staff

An eye bank technician shall be qualified (who has undergone certification course in eye banking techniques from certified training centers) and appointed by the Board as per “Standards of Eye Banking In India” document.

1. He/She Shall carry out work related to donor cornea procurement, donor cornea storage & distribution, screening of donor blood, data documentation, cleaning and maintenance of instruments and equipment, scleral tissue.
2. He/She shall maintain the daily log forms and laboratory log books as prescribed in the “Standards of Eye Banking In India” .
3. He/She shall generate daily, monthly, quarterly and annual reports and submit to the Executive Director or Designate of the eye bank.
4. He/She shall report to the Medical Director / Executive Director or Designate of Eye Bank in all matters related to eye banking.

3.1.6. Eye Donation Counselors

An eye donation counselor shall be selected by the Directors of the eye bank selection committee of GOI who shall be familiar with all issues related to eye banking, and trained in the art of grief counseling.

1. He/She shall work in a multi specialty hospital to motivate family members of the deceased to make an eye donation.

2. He/She shall generate daily and monthly reports and submit it to the Executive Director or Designate.
3. He/She shall report to the Executive Director or Designate in all matters related to HCRP.

3.1.7. Secretary

The Secretary shall be appointed by the board or competent authority and provides full time secretarial service to the eye bank as per the requirements of the organization.

1. He/She shall handle work related to donor call, pledge cards, providing certificate of appreciation to donor families, all correspondence, reports, monthly statement of expenditure, purchase, documentation of donor data entry in the system, leave status of eye bank staff
2. He/She shall report to the Executive Director or Designate of Eye Bank in all matters.

3.2. Appraisal & Promotion

Annual appraisal for all recruits of the eye bank (technical staff and the Secretary) is held by an appraisal committee consisting of the Nominees from the Board, Executive Director or Designate and Medical Director of the Eye Bank. The appraisal letters are issued to the staff through the Executive Director or Designate of Eye Bank.

Skill Enhancement

The Eye Bank Directors (Medical Director and the Executive Director or Designate) are required to participate in meetings and workshops related to eye banking. The technical staff members are required to regularly attend CME programs.

TRAINING & CERTIFICATION (In case of an Eye Bank Training Center)

3.2.1 TRAINING CENTRE (Applicable for Eye Bank Training Centers Only.)

The center shall strive to offer certification course to different cadres of eye bank personnel, and shall be a pioneer in setting standards of excellence in the field of eye banking. Eye bank professionals from India and other countries shall be educated in the planning of eye banking services, policy making in eye banking and eye banking techniques. The eye bank shall conduct workshops periodically to update eye bank professionals in the basics and advances in eye banking. The eye bank training PROSPECTUS shall be made available to all members of EBAI. The details of different training courses/Observership offered at the training center, admission and certification procedures etc shall be provided.

3.3 EYE BANK FACILITIES

The eye bank is away from areas that are open to unrestricted traffic flow and has area for carrying out its operations. The eye bank has a reception room and 4 eye bank laboratories, each separated from the other by a self-closing door. All laboratories are fitted with UV lamps.

3.3.1. Eye Bank Laboratories & Operations

3.3.2. Laboratory 1 – Handling Contaminated Materials

All materials for decontamination are handled in this laboratory. The laboratory has a sink and a work bench.

3.3.3. Laboratory 2 - Laboratory Corneal Excision

Laboratory 2 is used for i). laboratory corneal excision from whole globes received from other eye banks/ eye donation centers ii). processing of sclera . The laboratory houses a Laminar Flow Hood and a work bench.

3.3.4. Laboratory 3 – Cornea evaluation

This laboratory houses the specular microscope for the evaluation of donor corneas. The donor corneas (in storage medium) are also stored in a refrigerator kept in this laboratory.

3.4. Cleaning, Maintenance & Calibration

3.4.1. Cleaning of Laboratories

The floor is first cleaned with a disinfectant (phenyl 1:100) before and after work. The floor is then mopped with a clean dry cloth. The work- benches are wiped with Dettol or equivalent before and after work and then mopped with a clean dry cloth. Any spill is first wiped with absorbent cotton soaked in the disinfectant (70% ethanol or 0.5 to 1.0% sodium hypochlorite). The surface is wiped twice again with fresh cloth soaked in the disinfectant.

3.4.2. Cleaning, Packing and Sterilization of Instruments

Used instruments are placed in a tray containing 1% ACEPTIK (Chlorhexidine gluconate (7.5%), cetrimide (15%), isopropyl alcohol 7%) for 15 minutes. After soaking the instruments for 15 minutes, instruments are scrubbed with a soft bristled brush. Instruments are brushed under tap water flow to avoid splashing of contaminated material with foam water. After scrubbing, each instrument is rinsed thoroughly. The procedure is repeated to ensure sterility.

The rinsed instruments are placed on a fresh washed cloth to allow the instruments dry. No instrument should be wiped with a cloth.

Wrapping Instruments for Sterilization

The washed instruments are placed in a clean washed cloth before placing them in a washed steel tray. The cloth is laid to protect the instruments. Then the instruments are covered with 2 cotton pads to give extra security for the instruments. A SIGNALOC indicator is placed inside the tray before wrapping the instrument tray. The tray is then double wrapped. A label giving the item number, contents, mode of sterilization, date and time of packing, signature of the technician, along with another SIGNALOC indicator is stuck on the outside of the wrapped instrument tray before sending for sterilisation to the Operation Theatre.

Corneal excision set

- Drapes, torch, loupe
- Disposable Syringes (5 ml-1, 10 ml - 1) with disposable needles (21 G & spinal needle) with 2 test tubes or plain vials to collect blood sample.
- Conjunctival Scissors
- Corneal scissors (Right & Left)

- Fixation forceps
- Iris forceps
- Spring or Wire Speculum
- Bard Parker handle with sterile surgical blade (no. 11 or 15)

Enucleation set

- Torch
- Disposable Syringes (5 ml-1, 10 ml - 1) with disposable needles (21 G & spinal needle) with 2 test tubes or plain vials to collect blood sample.
- Conjunctival Scissors
- Fixation forceps
- Artery forceps
- Muscle hook
- Enucleating spoon
- Strabismus Scissor
- Wire or Spring Speculum
- Bard Parker Handle with sterile surgical blade (no. 11 or 15)

3.4.3. Cleaning, maintenance and calibration of equipment

The following equipment are maintained in the eye bank

- Refrigerators
- Laminar Flow Hoods
- Specular Microscope
- Slit Lamp Microscope

3.4.4. Equipment cleaning

The outside and inside of the equipment is wiped with 70% alcohol once daily. When there is a spill of infected material on any of the equipment, the surfaces are wiped with absorbent cotton or gauze piece soaked in 70% alcohol or sodium hypochlorite solution.

3.4.5. Equipment maintenance & calibration

The equipment is maintained as per the instruction manual supplied along with the equipment by the manufacturer. It is calibrated by the manufacturer or manufacturer authorized representative once a year.

An **EQUIPMENT INSTRUCTION MANUAL** is maintained on each equipment with the following details pertaining to the equipment.

- Name of the equipment

- Date of purchase/Model Number
- Supplier/Service Agent (Name & Address)
- Calibration certificate
- Service report
- Instruction manual
- Performance record
- List of authorised users

A tag is displayed on each of the equipment, mentioning the following details

- Date of calibration
- Calibration due on
- Service due on

6. Refrigerators

In house calibration for the Refrigerator.

Laminar Flow Hood: An external agency has to be used for calibration and maintenance. The LFH calibration using a “Laser Particle Counter (0.5 and 5.0 μ size) velocity is measured by velometer and the results and date is to be recorded.

3.5. Complaints

A **COMPLAINT/ACCIDENTS/ERRORS LOG** for documenting the following information is maintained at the Eye Bank.

- Date of complaint
- Complaint made by
- Complaint recorded by
- Corrective measure taken
- Date of corrective action
- Complaint closed on
- Signature of the Medical Director

Complaints (errors, accidents) are brought to the notice of the Executive Director or Designate who deposes a person to take corrective action.

New Work (Applicable for Eye Bank Training Centers)

New work/test is undertaken or any modification in the methodology is introduced based on the feasibility and the logistics of introducing new tests. Once a decision is made for introducing the new work, SOP will

be prepared, technician will be trained and new records will be introduced. The **NEW WORK LOG** is maintained in the eye bank for the documentation of all details pertaining to the work initiated.

Waste Disposal

Sharps (needles and blades) are discarded in puncture proof containers (containing 1% sodium hypochlorite solution) through a hole in the lid of the container.

Bio Medical Waste is segregated in color coded bags as followed by local regulations:

Yellow Bag (Infectious)

Discarded eye balls

Used cotton

Massage pads

Red or Blue Bag (Infectious)

Gloves

Disposable syringes

Swabs

Saline bottle

Black Bag (Non infectious)

Paper

Stationary

Separate plastic bins containing thick yellow and red plastic covers are placed in all the Laboratories of the eye bank. Plastic bins with black bags are placed in the reception room.

All waste bags depending upon the classification are handled by authorised personnel and disposed in appropriate manner as prescribed in the Transplantation of Human Organs Act.

All waste bags placed at a designated place for the pick up by Biomedical waste collection agency. The records of disposable material are maintained by the eye bank.

WASTE DISPOSAL LOG is maintained in the eye bank for recording daily activities related to waste disposal.

Infection Control & Safety

The laboratory personnel are required to be trained to minimise the risk of contracting infectious disease and accidents.

3.5.1. Infection

1. The eye bank shall be away from areas that are open to unrestricted traffic flow.
2. The eye bank laboratory doors and windows shall be kept closed all the time.
3. The laboratory furnishings shall be cleaned and disinfected immediately after use.

4. Universal precautions shall be followed while dealing with donor samples.
 - i. Attire: Confine long hair and loose clothing, wear shoes and not sandals, wear front opening laboratory coats.
 - ii. Handling of clinical samples: Handle clinical samples only with gloved hands while working in serology laboratory, avoid contaminating ungloved hands, skin or eyes while handling clinical samples, remove gloves and wash hands with soap and water after handling clinical samples, avoid dropping clinical samples, avoid spillage.
5. UV lights shall be provided in the eye bank.
6. Donor materials shall be handled in biosafety cabinets.
7. Surfaces of LFH shall be decontaminated after a spill.
8. Eye bank personnel shall be vaccinated against Hepatitis B.
9. Pipette aids shall be used.
10. Protective clothing such as gloves, gown and mask shall be used by the eye bank technician while dealing with donor material.
11. Hands shall be washed before and after handling infected materials.
12. No drinking and eating shall be allowed inside the eye bank.
13. Air sampling shall be performed at regular intervals and recorded.
14. Particle count of the LFH shall be performed at regular intervals.
15. LFH filters shall be replaced if particle count is beyond the acceptable limit.
16. UV lamps shall be replaced as per the manufacturers' specifications.
17. Proper system of waste disposal shall be followed.

3.5.2. Accidents

1. Smoke detectors shall be provided in the eye bank.
2. A safety station with showers and an eye wash facility shall be provided close to the eye bank
3. Open cuts shall be bandaged while working in the eye bank
4. First aid kit shall be placed in a reachable place in the eye bank laboratory.

3.5.3. Immunisation

Eye bank technicians who comes in contact with needles, blood or blood products are immunized for Hepatitis B.

3.5.4. Training

The eye bank personnel are trained in the following

1. to follow the instructions of the manufacturer for using the equipment
2. to follow SOPs in the cleaning of laboratories, equipment and instruments.
3. to report to the Executive Director or Designate of the eye bank if equipment is found non functional.
4. to maintain the log on a daily basis.
5. to use the **FIRST AID KIT** which is placed in strategic position in the laboratory.
6. to check the contents of the first aid kit expiry dates and replace the items.
7. to manage cuts and bruises (Clean the foreign body, clean the area with a disinfectant, bandage adequately, and to consult a physician if required)
8. to manage burns (Plunge the affected part in cold water to soothe the pain, dry the surface, apply burn ointment, cover the part loosely with a dry gauze piece, consult a physician if required.
9. to manage eye injuries (wash out the chemical with large quantity of clean water, rush the subject to safety station for eye wash, apply antibiotic drops, consult a physician if there is foreign matter to be removed.

Standards in Eye Banking Medical Standards - Manual

This manual is a document based on the Medical Standards of Eye Banking, prescribed by Ministry of Health & Family Welfare, Government of India and EBAI. This is to serve as a guideline and each eye bank should maintain procedures and follow regulations as mentioned in the Standards document.

3.6. Donor Tissue Recovery & Screening of Donor Blood

3.6.1. Introduction

This manual describes the standard operating procedures followed at the Eye Bank:

1. Pre recovery procedures
2. In situ corneal excision & preservation
3. Cornea evaluation
4. Scleral processing & preservation
5. Drawing of blood sample from the donor
6. The screening of donor blood sample for HIV, Hepatitis B surface antigen, Hepatitis C and Syphilis.

3.6.2. Objectives

To provide comprehensive uniform eye donor screening, a standard method for the aseptic removal of human donor corneas for surgical use (in situ and laboratory excision) that would minimise the endothelial cell loss, to describe the donor cornea evaluation procedures (slit lamp & specular microscopy), preparation and storage of sclera, procedure for obtaining blood sample from a donor for the purpose of serological testing, and serological screening methods.

3.7. Pre Recovery Procedures

3.7.1. Pre Recovery Review and Donor Preparation

- Check expiration dates on sterile instrument kits and other supplies before traveling to the donor site
- Pack necessary instruments kits as well as all necessary supplies into a clean transport case (steel bin) for transport to the donor site.
- Transport supplies to the donor site
- The following documentation forms are required for all donor recoveries:
 - Donor call - initial information sheet
 - Consent form
 - Donor information sheet
 - Eye donor medical particulars
 - Hemodilution Assessment sheet

3.7.2. Consent for Ocular Tissue Recovery

Ensure documentation of consent is consistent with existing policy as prescribed by EBAI.

Ensure that the consent has been obtained from the correct individual according to hierarchy of persons who may make an anatomical gift specified by state law.

Ensure that the consent clearly authorizes recovery of the specific tissues for which the recovery is planned.

Ensure that the consent gives authorization to obtain blood specimen for infectious disease screening, including HIV, Hepatitis B, and syphilis

If legislative consent is applicable, ensure that all required conditions are met.

Review the donor's medical history before proceeding with the recovery.

Verify the accuracy of any verbally reported information.

Complete medical history in the Eye Donor Medical Particulars sheet.

Complete Hemodilution form.

3.7.3. Identify the donor

- Match the name on the consent form to the name on the donor's ID tag, toe tag, bracelet, etc.
- Do not presume the identity of the donor or rely on a nurse or morgue attendant to point out the donor.
- Institutional staff shall participate in documentation of steps taken to confirm the ID of an untagged or unidentified potential donor.

3.7.4. Worksite Preparation

- Identify a suitable workplace (counter space near the donor on which to set up your paperwork and sterile fields).
- Clean this area with a suitable disinfectant and wipe it dry with paper towels.
- Wear gloves and mask

3.7.5. Gross Inspection of the Donor

- Examine the donor's entire body for evidence of high risk behaviour and infectious disease including physical evidence for risk of sexually transmitted disease such as herpes simplex, Syphilis, physical evidence of non medical percutaneous drug use such as needle tracks, disseminated lymphadenopathy, oral thrush, blue or purple spots consistent with Kaposi's sarcoma, unexplained jaundice, hepatomegaly or icterus.

If the body was rejected for routine autopsy due to infectious criteria or if the autopsy was done in an infectious disease control room or under any special precautions obtain reasons for these procedures.

If evidence of high risk behaviour or infectious disease is identified **DO NOT proceed with the recovery.**

- Perform a penlight examination of the donor's eyes and periorbital area.
- Obtain a suitable blood sample for serological testing (See section H8.520)

3.8. Donor Preparation

3.8.1. Donor face cleaning

The following steps should be performed only when gross debris is observed on the donor's face during the periocular exam.

- Don non-sterile examination gloves.
- Irrigate the donor's eyes and face with a sufficient quantity of sterile balanced salt solution to remove all visible debris from the eyes and to moisten the face.
- Use non-sterile 4 x 4 inch cotton squares to remove residual debris from the moistened face.
- Remove the non-sterile exam gloves and place them in an appropriate biohazard waste container.

3.8.2. Application of 5% Povidone-Iodine Solution Preparation

3.8.3 Lid Margin and Lash Prep

Use a Cotton Tip Applicator (CTA) to open the upper lid and roll the lid margin and lashed away from the globe.

Use a second CTA dipped in 5% povidone-iodine solution to scrub the upper lid margin and lashes one time across in a circular motion for approximately 20 seconds.

Next, use a CTA to open the lower lid and roll the lid margin and lashes away from the globe.

Use another CTA dipped in 5% povidone-iodine solution to scrub the lower lid margin and lashes one time across in a circular motion for approximately 15 seconds.

Repeat the povidone-iodine solution scrubbing of the upper and lower lid margin and lashes two more times with fresh CTAs.

Repeat this procedure for the other eye.

3.8.4. Conjunctiva Prep

Dip a cotton tipped applicator (CTA) in the 5% povidone-iodine solution and sweep the lower conjunctival fornix from the lateral canthus towards the nose one time.

The bulb of the CTA should be fully immersed since dry cotton will stick to the eye. Be careful not to rub the CTA across the cornea.

Holding the CTA perpendicularly to the donor will make the sweep easier to perform correctly. If necessary, a CTA may be used to open the eye.

Dip a second CTA in 5% povidone-iodine solution and sweep the upper conjunctival fornix from the lateral canthus towards the nose one time.

Repeat this procedure for the other eye.

3.8.5. Globe Prep

Fill the sterile syringe with approximately 1.5cc of the 5% povidone-iodine solution.

Use a CTA to gently roll back the upper lid and slowly drip approximately 0.75 cc of the 5% povidone-iodine solution on the eye.

Gently roll back the lower lid with a CTA and slowly drip the rest of the povidone-iodine solution on the eye.

Repeat this procedure for the other eye.

3.8.6. Lids and Face Prep

Prep the skin and facial area extending from the scalp to baseline of the nose by swabbing with folded sterile 4 x 4's dipped in 5% povidone-iodine solution.

Blot off the excess 5% povidone-iodine solution on the side of the plastic tray to avoid dripping on the work area.

The prep begins at the lid margins and works in a circular pattern outward.

Repeat this procedure for each eye two more times alternating eyes.

It is very important that the povidone-iodine is left on the eyes and skin for at least three to five minutes before irrigating the eyes. Irrigation will be performed after opening sterile supplies for the appropriate surgical procedure performing a 3 – 5 minute surgical scrub, and donning sterile gloves and sleeves.

Carefully place the bottle of balanced salt solution off the sterile field in an upright position.

Discard remaining prep supplies in a biohazard waste container.

Remove sterile prep gloves and discard them in an appropriate biohazard waste container.

3.8.7. Sterile Field Preparation

Open the outside packages of two pair of sterile gloves then open the inner envelopes using aseptic technique and leaving gloves on their sterile fields.

Use a dry foam skin disinfectant product on hands and forearms to reduce microbial flora prior to gloving and sleeving.

Open the outer wrap of the appropriate surgical instrument pack taking care to avoid contaminating the sterile field being created by touching anything other than the wrapper edges or reaching over the field.

Carefully open and aseptically drop sterile 4 x 4 inch gauze squares, sterile cotton tipped applicators, and sterile rubber bands on to the sterile portion of the outer wrap of the surgical instrument pack.

Open the sterile eye drape, taking care to avoid contaminating the sterile field being created by touching anything other than the wrapper edges or reaching over the field and leave the drape on its sterile field.

Label the eye jars or corneal storage media vials (a unique number specific to the donor, or the donor's name, and whether the specimen is left or right), loosen the caps to the top thread and place the jars or vials adjacent to a top corner of the instrument sterile field.

Place labeled containers for blood and/or vitreous samples near the sterile field along with hypodermic equipment and cosmetic restoration materials.

3.8.8. Attire of Field Personnel

Don sterile gloves taking care to fully extend the cuffs and to avoid contaminating the outer surface of the gloves.

Open the inner wrap of the instrument kit taking care to avoid contaminating gloves by contact with unsterile surfaces while handling the edges of the instrument wrapper. If necessary, place a sterile rubber band over each cuff of the sterile sleeves to ensure a good seal.

Irrigate the povidone-iodine solution from the eyes then drape the donor.

Use one hand to pick up the balanced salt solution bottle and the other hand to pick up a sterile CTA from the sterile instruments.

The hand used to pick up the balanced salt solution is now contaminated. Do not use the contaminated hand to retrieve items from the sterile field or to touch the donor.

Gently open the lids with the sterile CTA, then flush the povidone-iodine solution off the glove and conjunctiva. Be certain to irrigate off all povidone-iodine solution.

Pick up a sterile CTA with the sterile hand and repeat the irrigation procedure for the other eye.

Using the hand that was used to open the lids (clean hand) pick up the sterile 4 x 4 inch gauze and gently blot dry the lid of the first eye to remove excess moisture from the lid skin. Take care not to touch the cornea with the 4 x 4 inch gauze.

Perform the same blotting procedure on the other eye.

Remove outer pair of gloves being careful not to contaminate the inner pair of gloves and ensure that they are discarded in an appropriate biohazard container.

Carefully position the sterile bilateral eye drape on the donor.

3.9. In Situ Corneal Excision Materials

1.	Corneal excision set	(autoclaved)
2.	Enucleation set	(autoclaved)
3.	Linen pack	(autoclaved)
4.	Other materials	
1.	Corneal Excision set	
	i. S.S. Tray (Small)	1
	– Disposable Syringes (5 ml, 10 ml)	1 (each with disposables needles (21 G)
	– Test tubes or plain vials	2
	ii. Spring Scissors	1
	iii. Castro-veijo Corneal scissors (L&R)	1 (each)
	iv. Fixation forceps	2
	v. Iris forceps	1
	vi. Spring Speculum	1
	vii. Wire Speculum	1
	viii. B.P. Blade Handle	1
	ix. Lens Spoon	1 (optional)
	x. Surgical Blades (11 & 15)	1 (each)
2.	Enucleation set	
	i. S.S. Tray	1
	– Disposable Syringes (5 ml, 10 ml)	1 (each with disposables needles (21 G)
	– Test tubes or plain vials	2
	ii. Spring Scissors	1
	iii. Strabismus Scissors	1
	iv. Enucleating Scissors	1
	v. Fixation forceps	1
	vi. Artery forceps	1
	vii. Enucleating spoon	1

	viii. Muscle Hook	1
	ix. Needle holder	1
	x Sutures	1
	xi. Moist Chambers (Eye Jars)	2
	xii. Speculum	1
3.	Linen set	
	i. Eye Towel	1
	ii. Small Drapes	4
	iii. Body Drape and Head Drape	1 (each)
	iv. Sponge Holder	1
	v. S.S. Bowl with 4 Cotton Balls	1
	vi. Gown	1
4.	Other materials	
	i. Betadine	1 Bottle
	ii. Surgical Spirit	1 Bottle
	iii. Normal Saline	1 Unit
	v. Gentamicin eyedrops	2 Vials
	v. Bandage Rolls	4 nos.
	vi. Meditape	1 Roll
	vii. Cotton Massage Pads	Sufficient
	viii. Gloves - 6, 6 ½, 7, 7 ½, 8	Each size 2 pairs
	ix. Surgical Blades Nos.11&15	Sufficient
	x. Scissors	1 no.
	xi. Disposable Syringe – 10 cc	4 nos.
	xii.. Vacutainer	2 or 3 nos.
	xiii. Polythene Bags (Biohazard receptacles)	2 nos.
	xiv. Reusable Caps	2 nos.
	xv. Disposable Masks	2 nos.
	xi. Soap Solution	1 bottle
	xii. Artificial Eyes	4 pairs (Different sizes)
	xiii. Transparent Eye Caps	10 nos.
	ix. Torch with fresh Batteries	1nos.
	xx. Sterile Cotton swabs	Sufficient
	xxi. Pledge forms	10 or 15
	xxii Visiting cards	25

3.9.1. Corneo scleral rim excision

Removal of the corneal-scleral rim requires rigid sterile technique employing accepted aseptic practice. The potential for endothelial cell damage, contamination and infection are greatly increased and this procedure therefore shall be performed by individuals specifically trained in in-situ retrieval by RMPs trained in removal.

Open the eyelids using a sterile cotton tipped applicator or a muscle hook and insert a spring/wire speculum. Take care to avoid scratching the cornea.

Use small clawed forceps and iris or tenotomy scissors to lift and cut the conjunctiva at the limbus 360 degrees. Any adhesion between the conjunctiva and the anterior globe is separated using blunt and sharp dissection technique to ensure that the conjunctiva is not in contact with the anterior globe within 5 mm of the limbus. It may be necessary to make several relaxing cuts in the conjunctiva radially to accomplish this.

The exposed sclera is carefully scraped from the limbus outward with a scalpel blade (#11 or #15) to remove all remaining conjunctival tissue. It is important to remove all conjunctiva flush to the limbus because the conjunctival tissue may contain microbial contaminants which should not accompany the cornea to the storage media.

Isolate the scalpel and other instruments used to scrape the conjunctiva from the other instruments on the sterile field. These instruments should be placed mid peripherally on the sterile field and never placed centrally on top of the sterile instruments, which have not been contaminated by conjunctiva. Use the instruments which have touched conjunctiva only for the conjunctival removal on the other eye.

Use a second scalpel with a #15 blade and small clawed forceps to make an incision through the sclera 2 mm to 4 mm from the limbus and parallel to the limbus approximately 5 mm in length. Care must be taken to cut all the way through the sclera without perforating the choroid, as, this would cause vitreous leakage which may cause collapse of the globe including the anterior chamber and compromise the cornea.

Continue the scleral incision 360 degrees using corneal section scissors (Castroviejo or Abeli) and small tissue forceps to stabilize the posterior aspect of the scleral incision if necessary. Take great care to avoid perforating the choroid breaking into the anterior chamber or causing any deformation of the cornea's normal curvature.

Trauma to the cornea during scissoring due to bending, loss of the anterior chamber or collapse of the globe through vitreous loss would severely compromise its suitability for surgical use. If such trauma is suspected to have occurred, make a note on the recovery form, carefully. Evaluate the cornea with a slit lamp, and if damage cannot be ruled out the cornea shall not be offered for penetrating keratoplasty. If the incision has been made properly, the corneal-scleral button should be attached to the ciliary body-choroid only at the scleral spur.

Complete the corneal removal by using one pair of small smooth dressing forceps to hold the scleral rim stationary and a second set of small smooth dressing forceps or an iris spatula to gently push the ciliary body-choroid downward and away from the corneal-scleral button. Aqueous fluid should escape from the anterior chamber at this point assuring that the anterior chamber was indeed intact.

Remaining adhesions should be pushed gently away from the corneal-scleral button working side to side and taking great care to avoid pulling on the cornea and creating folds. The corneal-scleral button may be rolled side to side but never pulled in such a way as to cause cross cornea tension. Do not contaminate the cornea by allowing it to touch the eyelids or other facial skin. In the event that this occurred, make a note on the tissue recovery form.

Continue to hold the cornea by the scleral rim with the small smooth dressing forceps and aseptically transfer it to a labeled vial of storage media.

Lift the pre-loosened cap off the corneal media vial using a plastic backed sterile 4 x 4 inch gauze sponge immediately prior to placing the cornea in the media and replace the cap immediately after placing the cornea in the media. Do not touch the threads on the media vial with the contaminated underside of the plastic backed gauze square. Remove the speculum and place it with the conjunctiva instruments on the mid peripheral area of the instrument field.

After the second cornea is placed in storage media, remove contaminated surgical gloves, dispose of the gloves in a bio hazardous waste container, don non sterile exam gloves, then tighten the caps on both media vials.

Gently palpate the iris and pupil of each remaining posterior segment with a blunt instrument to rule out aphakia or pseudophakia. Do not tear the iris or remove the lens.

Insert eye caps in front of the remaining posterior poles and gently close the eyelids. Do not use forceps to close the lids, use only cotton tipped applicators or gloved fingers.

Place the corneal media vials in an ice box to which ordinary ice (NOT DRY ICE) has previously been added.

Discard all used disposables in a biohazard bag and all sharps in sharps container.

Rewrap instruments for transport, cleaning and sterilization.

Place a biohazard label on the contaminated instrument pack.

Replace the instrument pack in the bin until such time as it may be cleaned and re sterilized.

Clean the work area with disinfectant solution.

Discard personal protective attire in a biohazard bag.

Record information about the recovery (time of recovery, recovered by, etc.) on the donor recovery form and also on a form to leave in the donor's medical record to document the donation.

Place a garland before the donor as a mark of respect.

Thank the donor family before leaving the donor site (hospital or residence).

3.9.2. Lab Corneal excision

Removal of the corneal-scleral rim requires rigid sterile technique employing accepted aseptic practice. The potential for endothelial cell damage contamination and infection are greatly increased and this procedure therefore shall be performed by individuals specifically trained in corneal excision.

The corneal excision from a whole eye donor shall be done in a laminar flow hood.

Don hair cover, surgical mask, and non sterile exam gloves then wipe down the work surface of the laminar flow hood and any side tables which will be used to set up supplies with disinfectant solution.

Remove exam gloves and dispose of them in a suitable biohazard waste container.

Turn the laminar flow hood blower on and allow it to run for 15 minutes prior to beginning the procedure.

Place the sterile instrument pack, jars containing the donor eyes, labeled corneal storage medium vials, two 5 or 10cc syringes, two sterile specimen cups, 10% povidone-iodine solution, a non sterile hemostat, and balanced salt solution in the work area.

Open the outer wrap of the instrument pack on the work surface of the laminar flow hood taking care to avoid reaching over the field or touching anything except the outside edges.

Open two sterile 5 or 10 cc syringes and drop them on to the sterile field.

Place sterile specimen cups with the lids removed adjacent to the sterile field.

The eye jars are positioned so that they are adjacent to the top corner of the sterile field. Eye jars and media vials should be positioned to insure that left and right specimen identification remain correct. The eye jar lids are removed and placed with the inner side up next to their respective jars.

The labeled storage media vials are positioned so that they will be next to one side of the sterile field and the caps of the vials are removed and placed with the inner side up next to their respective vials.

Don sterile gloves.

Use the first sterile syringe to obtain 2.5 – 5.0 cc of the 5% povidone-iodine solution. The solution is carefully dropped on to the eye making sure to coat the entire globe. In order to ensure complete coating of the globe it may be necessary to move or tilt the eye cage using a sterile cotton tipped applicator (CTA). Repeat steps for the other eye. It is very important that the povidone-iodine solution is left on the eyes for at least five minutes before irrigation.

Discard sterile gloves in appropriate biohazard container.

Don sterile gloves taking care to fully extend the cuffs and to avoid contaminating the outer surface of the gloves.

Pick up the second sterile syringe and draw up at least 5cc of balanced salt solution.

Irrigate the eyes until all the povidone-iodine is rinsed off.

Aseptically open the inner wrap of the instrument kit.

Unfold a sterile 4 x 4 gauze sponge then refold it to form a long strip of gauze.

Aseptically lift the eye cage from the jar with a sterile hemostat, CTA, or plastic backed sterile gauze. Be sure to allow excess povidone-iodine and balanced salt solution to drip off the globe and eye cage (if applicable) before bringing the globe on to the sterile field, to avoid wetting the sterile field. If eye jar does not have an eye cage, use a sterile forceps to lift the eye from the jar to the sterile field and allowing excess fluid to drip off to avoid wetting the sterile field.

Remove the eye from the cage or dental roll using a small clawed forceps to grasp the rectus muscle then wrap the eye securely several times around the equator with the long strip of gauze.

Use small clawed forceps and iris or tenotomy scissors to lift and cut any remaining conjunctiva at the limbus and extending out 5 mm from the limbus.

Scrape the exposed sclera carefully from the limbus outward with a scalpel blade (#11 or 15) to remove all remaining conjunctival tissue.

It is important to remove all conjunctiva flush at the limbus because the conjunctival tissue may contain microbial contaminants that should not accompany the cornea to the storage media.

The scalpel and any other instruments used to remove the conjunctiva should be isolated from the other instruments on the sterile field. Place these instruments mid peripherally on the sterile field (not on top of the centrally located instruments which have not been contaminated by conjunctiva).

These instruments should not be used again except to remove the conjunctiva of the second eye.

- Use a second scalpel with a #15 blade to make an incision through the sclera 2 mm to 4mm from the limbus and parallel to the limbus approximately 5 mm in length.
- Place the wrapped eye down near the center of the sterile field.
- Gently separate the corneal-scleral button from the posterior segment of the globe.
- After the second cornea is placed in storage media, remove contaminated surgical gloves and non sterile exam gloves, then replace and tighten the caps on both media vials.
- Replace and tighten the lids on both eye jars.
- Discard all used disposables in a biohazard bag and all sharps in a sharps container.
- Rewrap instruments for cleaning and sterilization.
- Place a biohazard label on the contaminated instrument pack until such time as it may be cleaned and re sterilized.
- Leave the hood blower motor on for 15 minutes following completion of the procedure.
- Clean the hood and work area with a suitable disinfectant solution.

Discard personal protective and surgical attire in a biohazard bag.

3.9.3. Donor Cornea Evaluation

3.9.4. Slit lamp examination

An Ophthalmologist is responsible for performing this procedure. Allow the cornea in storage media vial or whole globe in eye jar to reach room temperature to make the endothelium easier to visualize. Cornea or whole globe shall not be allowed to remain in room temperature for more than 1 hour. Limit the number of warming and cooling cycles no more than 3 times.

The slit lamp examination shall be an orderly and stepwise examination of the different layers of the cornea. Each layer of the cornea shall be evaluated from front to back, and from back to front.

A wide slit of light is directed on the cornea with a 20 to 30 degree angle of incidence and moved to scan the entire cornea.

Epithelium: Examine the epithelium for integrity and overall condition.

The location, extent, and depth of any epithelial defect should be fully examined and described on the Cornea Evaluation Form.

Note any abrasions, lacerations, foreign bodies, microcystic edema, or severe drying.

Note any epithelial haze, exposure, or sloughing if present.

If epithelium is missing, it is necessary to carefully rule out underlying stromal injury.

Note the degree, location, type, and amount of epithelial haze, exposure and sloughing on the Cornea Evaluation Form.

Bowman's layer

Examine the Bowman's layer for any defect.

Examine the Bowman's layer for corneal lacerations and scars by focusing a hairline slit on the epithelium and carefully observing the defect margin for reflection off the Bowman's layer.

If the hairline slit reforms at a deeper level, the depth of the defect is apparent and is usually minimal.

If the hairline slit does not reform at a deeper level, the Bowman's layer may have been injured and the cornea would not be suitable for transplant.

Stroma

Examine the stroma to determine overall clarity and rule out marked edema.

Stromal edema may be evaluated by directing a hairline slit on the cornea at a 15 to 20 degree angle of incidence, and observing the distance between the epithelial and endothelial reflexes.

Corneas without significant stromal edema results with the two reflexes to converge centrally and diverge peripherally.

Corneas with significant stromal edema results with the two reflexes nearly parallel or will diverge centrally.

Examine for imbedded foreign bodies, old scars, or stromal infiltrates.

At high magnification use a narrow slit beam to define the extent, depth, location and appearance of stromal opacities.

A central stromal opacity would rule out a cornea for transplant surgery.

- Small peripheral stromal opacity (extending no more than 1-2 mm from the limbus) may or may not rule out a cornea for transplant surgery depending on whether or not the stromal opacity is determined to be an infectious stromal infiltrate.
- Stromal scars generally have a more gray appearance without adjacent stromal edema.
- Examine for degenerative conditions such as arcus senilis.
- The presence of moderate to heavy arcus senilis that is evident within the central 8 mm of the cornea should be described and may disqualify the cornea for elective penetrating keratoplasty.

- Note the degree, location, type, and amount of stromal arcus, stretch lines, cloudiness, and opacities on the Corneal Evaluation Form.

Descemet's membrane

- Examine the Descemet's membrane for the presence, location and severity of Descemet's folds (striae).
- The presence of Descemet's folds are determined by directing a narrow slit on the mid-peripheral cornea at an angle of 30 to 40 degrees, and focusing on the endothelial reflex at a medium power of magnification.
- The endothelial mosaic may be observed in the light colored areas, while the Descemet's folds may appear like dark lines, which transect the illuminated areas of the endothelium.
- The severity of the folds may generally be determined by the width of the folds and the amount of endothelial area that they obscure from view.

The degree, location, type, and amount of folds shall be noted on the Corneal Evaluation Form.

Endothelium

Examine the overall integrity of the endothelial cell layer.

Examination of the endothelial cell layer is done by directing a narrow slit on the mid-peripheral cornea at an angle of 30 to 40 degrees, and focusing on the endothelial cell layer.

The endothelial layer is examined to rule out major defects or missing areas of the endothelium.

General appearance of the endothelium shall be compared from one area to another.

Examine the limbal area of excised corneas on the endothelial side with a broad slit at low to medium magnification to rule out delamination of the Descemet's membrane.

Examine the endothelial layer using specular illumination at high power magnification with a narrow slit directed on the mid-peripheral cornea at a 30 to 40 degree angle of incidence.

Note the uniformity of cell size, estimated cell population, overall health of the cells, and uniformity of cell shape.

Look for presence of guttata, that occur with Endothelial Dystrophy. The presence of guttata shall rule out the cornea for surgical use.

Examine for vacuolated cells that may be precursor to Decemet's folds or striae due to trauma during recovery. The presence of vacuolated cells must be considered to be a degenerative condition of the endothelium and whether or not the cornea would be suitable for penetrating keratoplasty would depend on the relative number observed and their location.

A cornea with less than 15 or 20 vacuolated cells located mainly in the peripheral area may be entirely suitable whereas a cornea with numerous bodies centrally located would not.

Examine for keratic precipitates, which appear as opaque and white piles of debris on the endothelial surface.

The presence of significant number of keratic precipitates maybe the result of inflammatory response and may exclude the cornea for penetrating keratoplasty procedure.

Determine an overall rating of the endothelium based on the estimated cell population, overall health of the cells, uniformity of the cell size and shape.

The rating is expressed in terms of Excellent, Very Good, Good, Fair or Poor.

The rating of less than Good renders the cornea unsuitable for elective penetrating keratoplasty.

A final endothelial rating shall be established after a specular examination is performed.

3.9.5. Specular examination

Eye bank personnel are responsible for performing this procedure.

Corneas may be examined in standard corneal storage media vials when the Konan eye bank keratoanalyser is used.

Allow the cornea in viewing chamber or storage media vial to reach room temperature to make the endothelium easier to visualize.

Cornea shall not be allowed to remain in room temperature for more than 1 hour prior to viewing.

□ Limit the number of warming and cooling cycles no more than 3 times.

If corneas are brought to the Eye Bank laboratory within 1 hour of recovery, corneas may be examined prior to refrigeration.

Secure the viewing chamber or storage media vial on the holding device of the specular microscope.

Examine Endothelium

Methods of bringing the endothelium into focus may vary for different specular microscopes. Refer to the manufacturer's handbook for proper focusing procedure.

View endothelial cells.

Adjust the focus knob on the specular microscope to move the objective lens until it almost contacts the bottom of the viewing chamber window or storage media vial. Avoid touching the media vial or viewing chamber with the objective lens.

Turn the knob slowly to move the objective lens away from the media vial or viewing chamber until dark cells come into focus and scan the cornea for light areas.

Once light areas are in view, slowly move the focus knob or use the fine focus to reveal the endothelial mosaic.

Examine the central endothelium in focus for the following:

Uniformity of the endothelial cell shapes and sizes.

Density of the cells.

Presence of ghost vessels in the stroma.

Vacuolated cells.

The presence of inflammatory cells, bacteria, or debris on the endothelial surface.

Select a representative area on the central endothelium for cell counts.

When the endothelial mosaic is in view, scan the entire central endothelium to select the most representative area for the cell count.

Perform cell count according to equipment specific protocol found in the manufacturer's instruction manual.

Cell counts are expressed in cells per square millimeter.

Save the image of the representative area of the central endothelium in focus.

The image of the representative area of the central endothelium shall be archived by a printed photo, video, or electronic photo image. The image may be included in the donor chart.

Photos may be provided to surgeons routinely except by special order at time of tissue request.

Criteria for Penetrating keratoplasty

The following criteria eliminates the cornea for penetrating keratoplasty procedure:

- Cell density less than 2000 cells per square millimeter. Corneas with cell density less than 2000 cells / sq. mm may be suitable for lamellar procedures.
- Extreme polymegathism or pleomorphism.
- Presence of significant guttata.
- Presence of many non-hexagonal or abnormally shaped cells.
- Presence of inflammatory cells, bacteria, or debris on endothelial surface.
- Numerous vacuolated cells.
- Never to base decision for suitability for the use of cornea purely or specular microscope report combine with clinical examination.

3.10. Sclera processing & Preservation

Eye bank personnel are responsible for performing this procedure.

Preparation of Alcohol Tissue Storage Units

Aseptically set up a sterile field in the HEPA hood using a sterile moisture impermeable table drape or similar.

Place the vials, sterile 30 ml syringe and sterile beaker on the sterile field using aseptic technique.

Don sterile gloves and place the beaker upright near the side of the sterile field.

Remove sterile gloves and pour 95% ethyl alcohol in the beaker ensuring not to contaminate the sterile field.

Don surgical mask, hair cover, eye protection and surgical gown or similar.

Open the outer and inner wrap of sterile gloves and sterile sleeves using aseptic technique and set aside.

Perform surgical hand scrub and don sterile gloves and sterile sleeves using aseptic technique.

Create alcohol storage units for sclera preservation.

Draw 20 ml of alcohol from the beaker using the syringe and add the 20 ml of alcohol to each vial.

Cap the alcohol storage vials tightly.

Label the vial "ALCOHOL PRESERVATION UNIT" along with the date of manufacture, an expiration date 3 years after the date of manufacture, and initials of technician preparing units.

Store the alcohol preservation units at room temperature.

Scleral Processing

- Processing of sclera shall be performed in the HEPA hood using aseptic technique.
- Clean the HEPA hood before use. Refer to the HEPA Hood Cleaning, Operation and Maintenance standard operating procedure in the Laboratory & Facilities Module.
- Aseptically set up a sterile field in the HEPA hood using a sterile moisture impermeable table drape or similar.
- Aseptically open sterile 4 x 4 gauze pads, Ocular Donor Surgical Instrument Kit, cotton tipped applicators, and a #10 scalpel blade and present them onto the sterile field.
- Remove the specimen cups or eye jars containing the scleral tissue from the "Quarantine" area of the tissue storage refrigerator and place in the HEPA hood near the sterile field.

Verify the tissue identification number on the specimen cups or eye jars.

Remove the specimen cup covers and place near the cup away from the sterile field.

- Label the alcohol vials with the unique tissue identification number and fraction of sclera, which will be in the vial after processing.
- Remove the caps of the alcohol vials and place near outside the sterile field. Ensure not to contaminate the inside of the vials.

Set up the sterile ocular irrigation solution (i.e. AK Rinse) and the antibiotic solution (i.e. Gentamycin or Neosporin).

- Pour one 10ml bottle of the sterile ocular antibiotic into each of the specimen cups containing irrigating solution.
- Pour one half of the sterile ocular irrigation solution into two specimen cups. Ensure to not contaminate the inside of the specimen cup.
- Label the specimen cups with the tissue identification number and indicate right or left sclera.

Don surgical mask, hair cover, eye protection and moisture impermeable apron.

Open the outer and inner wrap of sterile gloves and sterile sleeves using aseptic technique and set aside.

Perform surgical hand scrub and don sterile gloves and sterile sleeves using aseptic technique.

Processing Procedure

Pick up one of the posterior poles with a tissue forceps and place on sterile 4 x 4 inch gauze in the sterile field.

Remove remaining conjunctiva and cut the remaining ocular muscles attachments at their insertion point using iris forceps and scissors.

Remove remaining intra-ocular material using sterile gauze and forceps.

Clean the inside of the posterior pole with cotton tipped applicators and gauze to remove all choroids and tissue fragments.

Pick up the posterior pole with tissue forceps and place into the appropriate specimen cup containing the

sterile ocular irrigation and antibiotic solution mix. Ensure the posterior pole is completely filled with the solution and let soak for 5 minutes.

Remove the first posterior pole from the antibiotic solution using forceps and allow solution to drain before transferring to a clean sterile 4 x 4 gauze in the sterile field.

Dissect the posterior pole into halves, quarters, and eighths or leave whole as directed by supervisor.

Remove all pigments and blood vessels from both surfaces of the sclera by scraping the sclera with the scalpel blade. Ensure sclera surfaces are clean, smooth and free of any pigmentation and blood vessels.

Presence of pigmentation may cause inflammation when transplanted.

If the sclera is stained with pigments return into the antibiotic solution for additional soak.

If the pigmentation or blood vessels cannot be removed after second attempt of scraping with scalpel blade, discard the scleral tissue.

Scleral Preservation

Alcohol Fixation of Scleral Tissue

Transfer a piece of processed scleral tissue into appropriately labelled alcohol storage vials using aseptic technique.

Assure each piece of scleral tissue is placed into a vial which specifies whether the sclera is a whole, half, quarter, or eighth.

Each piece of scleral tissue shall have a unique identification number.

Post-Processing and Preservation

Remove the sterile gloves and don new pair of non-sterile examination gloves.

Place the caps on the eye jars ensuring not to contaminate the inside of the eye jar.

Discard non-biohazard waste in the waste receptacle and biohazard waste in the biohazard waste receptacle.

Document appropriate processing information on the Ocular Tissue Processing Record form.

Serological testing of donor blood sample

3.10.1. Blood sample for serological testing

All eye tissue that is used for transplantation shall be screened for HIV Ab, HBs Ag, and Syphilis Ab.

Never draw blood downstream from an IV site to avoid hemodilution.

Draw blood only from intact vasculature.

Angle the needle the same direction as the vessel flows to avoid puncturing all the way through the vein.

As soon as the tip of the needle is under the skin, apply a slight back pressure on it by withdrawing the plunger about one half inch.

This creates suction to draw in blood when the vessel is found, indicated by the sudden flow of blood into the syringe.

When this occurs, withdraw the plunger enough to fill the syringe completely. It usually takes gentle probing with the needle to locate the vessel.

3.10.2. Drawing of donor blood sample

1. Subclavian Vein

Use a 10cc syringe with a 18 gauge x 1½ inch needle.

Turn the head in the opposite direction of the blood vessel being used.

Feel for the notch one-third of the way away from the midline of the body along the clavicle (collarbone).

Insert the needle at a 30 degree angle into the vein toward the sternum.

2. Cardiac Puncture

Cardiac puncture shall not be used on a coroner's or medical examiner's case except when specific permission for the cardiac puncture has been given by the coroner or medical examiner.

Use a large gauge 3 ½ inch spinal needle and a 50 – 60 cc syringe.

From the left clavicle count down four ribs and over two inches from the sternum (breast-bone).

Puncture the chest wall between the ribs at the nipple line just left of the sternum. You will need to use quite a bit of force.

Angle the needle toward the midline in a slightly upward direction.

If the flow does not begin, try repositioning the needle until you feel it puncture the wall of the heart.

Aspirate the syringe as the needle is slowly withdrawn.

3. Femoral vein

This vein is found in the groin region and is usually the easiest site to obtain the blood sample.

Use a 10cc syringe with an 18 gauge x 1 1/2 inch needle.

Palpate the groin crease for a soft area-this area is the femoral ring.

Insert the needle into this area, aspirate the syringe and slowly withdraw the needle.

When blood appears in the syringe, hold the needle in place and aspirate the syringe intermittently, this allows blood to fill the collapsed vessel and reach the needle opening.

It is understood that sometimes it is not possible to obtain a proper blood sample, however, every effort must be made, since without a proper blood sample a donor ocular tissue is not suitable for transplant. If you are unable to obtain blood after reasonable attempts (it may take several sticks), note it on the Donor Work-up Sheet and advise your supervisor right away. All donor eyes must be accompanied by a 10 cc, standard clotted blood sample or serum.

Ensure that the blood sample obtained has not been diluted by transfusion or infusion to a degree sufficient to affect test results. Check with the hospital laboratory to see if any blood samples from the donor available. Verify the time and site of the draw to rule out serodilution. A sample of 10 cc or more is preferred-minimum acceptable sample size would be 2 cc of serum.

Either serum or plasma may be used for testing. Record if the sample is serum or plasma. Anticoagulants typically used for blood collection do not interfere with the tests; however, it must be recognized that

serum from heparinized patients may be incompletely coagulated and could cause falsely reactive results for the HBs Ag test. If it is known that the patient had heparin therapy, the specimen should be treated with thrombin or protamine sulfates to assure complete clotting. The serum or plasma should be removed from the clot or red cells as soon as possible to avoid hemolysis.

Specimens may be stored, prior to testing, in a refrigerator at 2°C to 8°C for up to 7 days or frozen at –15°C or colder for short term storage. For frozen specimens multiple thaws should be avoided.

3.10.3. Transferring blood from syringe to vacutainer tubes

Hold the plunger of the syringe firmly as the needle is withdrawn from the skin and also as the rubber stopper of the vacutainer is pierced to prevent blood from escaping the syringe.

When the needle point enters the tube, the vacuum within the tube draws the blood in.

Hold the plunger firmly between tubes.

Discard the syringe in a safe manner. Never attempt to replace the sheath that covered the needle in its original wrapper since many needle stick injuries have occurred while attempting to do this.

The needle and syringe must be placed in a sharps container. Never dispose of needles in an ordinary trash container or in a biohazard bag.

3.10.4. Blood tube labeling and handling

All tubes must be labeled with the corresponding donor number. If the donor received transfusions, the blood tubes must be labeled as pre or post transfusion.

Upon return to the laboratory, blood samples are centrifuged, a serum separator is pushed into the spun tube, separated serum is placed in a new labeled tube, then the separated serum sample is refrigerated (2°C to 8°C) until tested.

Used test tubes and serum separators are disposed in a biohazard sharps container.

3.10.5. Screening of Human Donor Blood Sample for HIV, Hepatitis B, Surface Antigen, Hepatitis C & Syphilis

ELISA methodology is followed using the ELISA kits, as per the instructions of the manufacturer.

NACO approved Rapid test kits can also be used as per the instructions of the manufacturer.

Appendix - 1

DONOR CALL – INITIAL INFORMATION

Time _____ Date _____

Name of the donor _____

Age of the donor _____ Sex of the donor _____

Time of death _____ Cause of death _____

Name of the caller _____

Relationship with the donor _____ Contact Phone _____

Body availability _____

Placed at: _____ House _____ Hospital _____ Mortuary _____

Will be taken away to the house from Hospital / mortuary in about _____ mins./hrs.

Address (where the body is available) _____

Specific landmarks & detailed directions to reach the above address: _____

Death Certificate Available Not available

Comments & additional remarks _____

Receiver's Name _____ Designation _____

Case# _____ Month _____ Year _____

Signature

Appendix - 2

EYE DONOR MEDICAL PARTICULARS

1. Name of the Deceased : _____
2. Age & Sex : _____
3. Permanent address : _____

4. Date of Death : _____

5. Time of Death : _____

6. Place of Death : _____

7. Manner of Death : Natural Accident Suicide Homicide Pending investigation

8. Cause of Death : _____

9. Secondary Causes : _____

10. Visible Identification Marks : _____

11. Information given by next-of-kin : _____
& Relationship with the donor

12. Death Certificate : Available _____ Not Available _____

Reason for not obtaining death certificate copy: _____

13. The certificate is under process & will be submitted later _____

Signature _____

Name of Next-of-kin _____

I hereby certify the death of Mr. / Mrs. / Ms. _____

Signature _____

(Doctor attending Eye donation call)

Date: _____ Name: _____

Place: _____ Regn. No. _____

Appendix - 3

FAMILY PLEDGE FORM FOR EYE DONATION

In the hope that I/We may help others. I/We hereby make this anatomical gift, if medically acceptable, to take effect upon my/our death. The statement below indicates my/our desire (s).

I and the following members of our family give my / our eyes for the purposes of transplatation, therapy, medical research or education.

Relationship / Witness	Name in Block Letters	Date of Birth	Signature
Self	Mr./Ms _____	_____	_____
_____	Mr./Ms _____	_____	_____
_____	Mr./Ms _____	_____	_____
_____	Mr./Ms _____	_____	_____
_____	Mr./Ms _____	_____	_____
_____	Mr./Ms _____	_____	_____
_____	Mr./Ms _____	_____	_____
_____	Mr./Ms _____	_____	_____
_____	Mr./Ms _____	_____	_____
_____	Mr./Ms _____	_____	_____

Address _____

_____ City _____

Pin Code _____ District _____ State _____

Tel. (O/R) _____ Date ____/____/____

Appendix - 4

DONOR INFORMATION SHEET

Eye Bank No: _____ / _____ / _____ / _____ / (Right / Left)

Name of the donor _____

Institution _____

Autopsy / History Number _____

Medical Examiner / Attending Physician _____

Age : _____ Religion : _____ Sex : _____

Date of injury / Admittance : _____

Death : Date _____ Hours _____

Enucleation / In situ Excision : Date _____ Hours _____

Type of Tissue : _____

Type of Preservation : _____

Lot Number : _____

Death to Preservation : _____

Immediate cause of death : _____

Medical / Case History : _____

Physical Appearance of Body _____

PATHOLOGIST'S COMMENTS concerning autopsy & Date of Interview _____

If Pathologist observed signs of IV drug use or infection? Yes / No _____

Donor visited a hospital? Yes / No if yes, length of stay _____

Hospital chart available to examine : Yes / No _____

Donor on a respirator? Yes / No if Yes, how long _____

Donor received blood products within 48 hours of death? Yes / No _____

If yes : Number of Units : _____ Last date / time obtained _____

In Situ Observation : _____

Check / If any of the following apply : DO NOT USE FOR SURGERY

AIDS OR HIGH RISK GROUP _____ LYMPHOMAS / LYMPHOSARCOMA _____

ACTIVE HEPATITIS _____ INTRINSIC EYE DISEASE _____

BACTEREMIA / SEPTICEMIA _____ BLAST FORM S _____

CONGENITAL RUBELLA _____ RABIS _____

CNS DISEASE OF UNKNOWN ETIOLOGY _____ REYES SYNDROME _____

CREUTZFELD / JACOB DISEASE _____ ACTIVE SYPHILLIS _____

ENCEPHALITIS _____ CONJUNCTIVITIS _____

MULTIFOCAL LEUKOENCEHALOPATHY _____ DEMENTIA _____

JAUNDICE / except when due to non-infectious causes / _____

SUBACUTE SCLEROSING PANENCEPHALITS _____

Donor refrigerated? Yes / No, If Yes : Date & Time of refrig _____

NA : NOT APPLICABLE

NRA : NO REPORT AVAILABLE

DEATH TO REFRIGERATION TIME : _____

LAB TEST RESULTS : _____

WBC / DATES / COUNT : _____

Temp, trends : _____

CULTURE TYPE : Blood _____ Date _____ Growth _____

CULTURE TYPE : Blood _____ Date _____ Growth _____

MEDICATIONS : _____

Name & Signature of fellow

HARVESTED DONOR EYE DATE

EYE DONATION Voluntary []

Motivated [] Motivated by : _____

Designation : _____

DONOR DATA

Consent taken at : _____ a.m. / p.m.

Consent given by : _____

Position of body : _____

Phakic : _____ Aphakic : _____

of tissues : [] Blood sample obtained : Yes / No []

During the procedure : Problems : _____

: Solutions : _____

Procedure done by : _____ Time _____ a.m./ p.m.

Procedure done at : _____

Assisted by : _____

Team members : _____

Mode of transport: Eye Bank to donor site _____

Donor site to Eye Bank _____

Case # _____ Month _____ Year _____

Date received _____

Time received _____

Appendix - 5

IMMUNOLOGY LABORATORY SEROLOGY REPORT

Name : _____ Date : _____

MR. No : _____ Serology No : _____

Age & Sex : _____ Category : Eye Bank _____

Nature of specimen : Blood :

Referring Eye Bank :

Reference No. :

Tests Done	Report
1. HIV :	
2. HBs Ag :	
3. VDRL :	

Date :

Note :

1. The results relate only to items tested
2. This report shall not be reproduced except in full without written approval of the laboratory.

Technician :

Microbiologist :

Appendix - 6

TISSUE EVALUATION REPORT

Eye Bank No : _____ / _____ / _____ / _____ / (Right / Left) Size of cornea _____mm

1. Intact surface : Yes / No
2. Haze : Yes / No
Degree : Light / Moderate / Heavy
3. Exposure Keratitis: Yes / No
Amount _____% (of surface)
Degree Light / Moderate / Heavy
Location Central / Periphery / Mid-periphery
Type Diffuse / Band
4. Sloughing : Yes / No
Amount _____% (of surface)
Degree Light / Moderate / Heavy
Location Central / Periphery / Mid-periphery
5. Other defects Yes / No
Type _____
Location Central / Periphery / Mid-periphery
Dimension _____mm

STROMA

1. Clear : Yes / No
2. Cloudiness: Yes / No
Degree : Light / Moderate / Heavy
3. Arcus Senilis: Yes / No
Amount _____mm (from limbus)
4. Opacities : Yes / No

Comments _____

DESCEMET'S MEMBRANE

1. Folds
Amount : None / Few / Several / Numerous
Degree : Light / Moderate / Heavy
Location : Periphery / Central / Mid-periphery/ Diffuse (total surface)
-

ENDOTHELIUM

Excellent / Very Good / Good / Fair / NSFS

Comments _____ Cells per mm _____

OVERALL RATING OF TISSUE

EXCELLENT / VERY GOOD / GOOD / FAIR / POOR (Reason for rejection-Preventable / Partly preventable / Non-preventable)

Suitability for Surgical Use < Yes

No

Reason _____

Particles in Medium

Yes / No

Medium (if transferred) _____

Ratings changed

Yes / No

Media changed Yes / No

Lables

Very Good / Adequate / Poor

Scleral Rim

Very Good / Adequate / Poor

Checked by Technician _____ Date & Time _____

Fellow _____ Date & Time _____

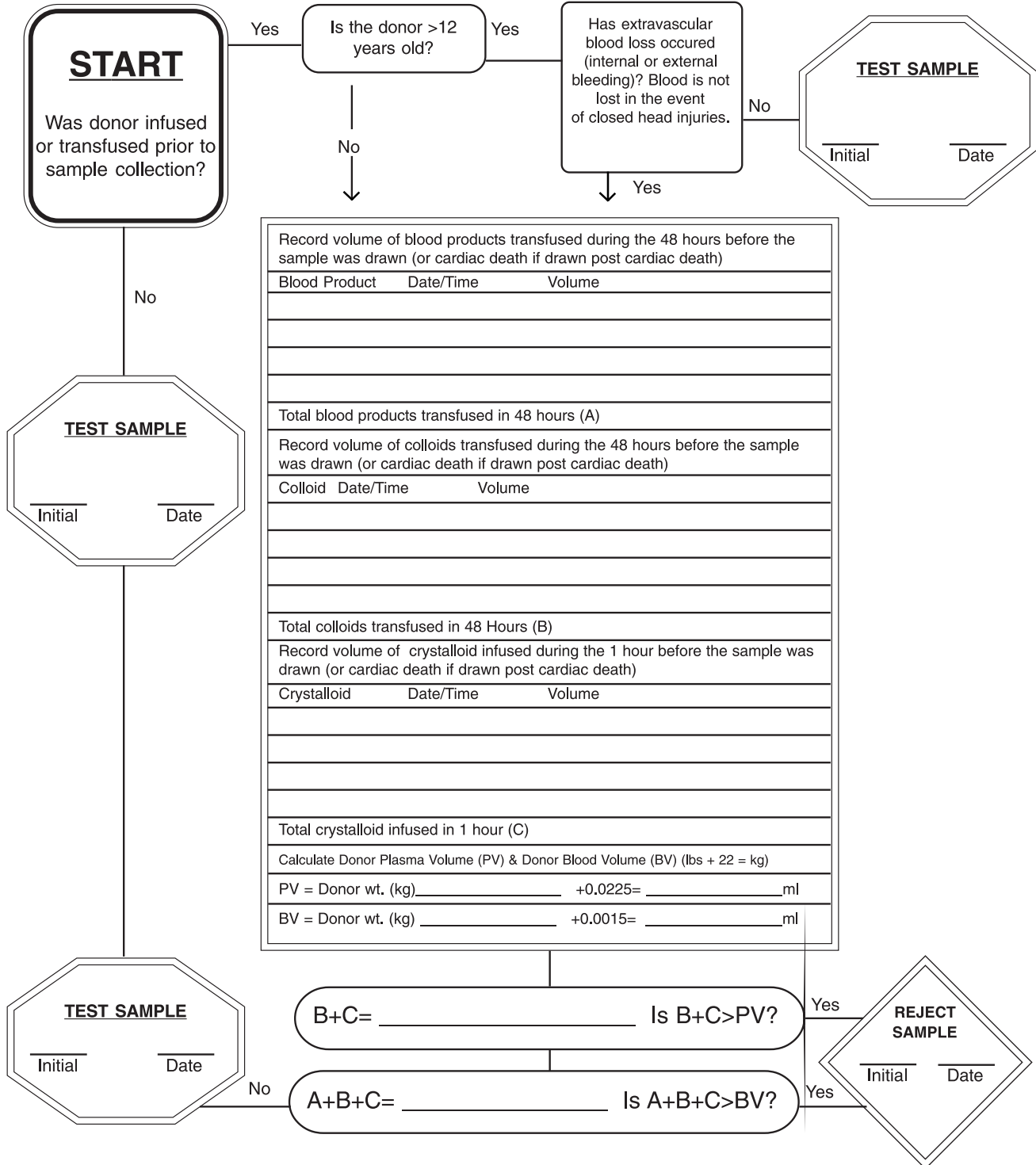
Consultant _____ Date & Time _____

DONOR DATA FOR CORNEAL TRANSPLANTATION

1. Consignment No: _____ No. of tissues received _____ Eyes _____ Corneas _____
Blood Sample / Report received _____
2. Name of Eye Bank / Place / Code _____
3. Time lapse between Enucleation & Receipt of Consignment _____ Hours _____ Minutes
4. Age of the Donor / Initials _____
5. Time of Death / Date _____
6. Time of Enucleation / Date _____
7. Time lapse between Death and Enucleating _____ Hours _____ Minutes
8. Cause of Death _____
9. Method of Preservation:
Moist Chamber : _____ Medium Preserved : _____
Condition of bottle _____ Name of Medium _____
Condition of Cap _____ Lot No. _____
Bottle had _____ 1/4 1/2 3/4 Full _____ Water Condition of Vial _____
Colour of the water present _____ Colour of Medium _____
Trimming of conjunctiva Yes / No _____ Any foreign body present in medium _____
Discolouration of sclera _____ Position of cornea _____
Presence of foreign matter _____
10. Condition of thermocol box _____
11. Position of ice in the thermocol box _____
12. General Evaluation of Eye Ball _____
13. Aphakia : Yes / No
14. Lens Slit Lamp Evaluation :
Nuclear Sclerosis _____
Posterior Sub Capsular _____
Cortical Cataract _____
Total Cataract _____
Clear _____
Lens No. _____

Appendix - 7

Hemodilution Assessment		Donor Name or Number	
Sample Drawn	Date	Time	By



Final Review Hemodilution has been reviewed and determined acceptable		_____ Signature	_____ Date
---	--	--------------------	---------------

Appendix - 8

Case # _____

Month _____

Year _____

TISSUE DISTRIBUTION INFORMATION

Eye Bank No : _____ / _____ / _____ / _____ / (Right / Left)

ORIGINAL
Should be filed and
kept in the eye
bank

Age : _____ Religion : _____ Sex : _____

Injury / Admittance Date _____ Hour _____

Death : Date _____ Hour _____

Enucleation / Excision : Date _____ Hour _____

Preservation : Date _____ Hour _____

Cause of Death : _____

Medical History : _____

Ocular History : _____

Medications : _____

TISSUE PRESERVATION AND CORNEAL STATUS INFORMATION

Death – Preservation : (Time) _____ Hrs. _____ Mins.

Tissue Type : _____ Storage Method: _____

Lot Number: _____

Status: _____

Corneal Rating : _____

Epithelium : _____

Stroma : _____

Desceme't : _____

Endothelium : _____

Count : _____ Cells / mm

Serology test for : HIV Antibody

(Performed – Yes / No) Results _____

(Hepatitis B surface Antigen test

(Performed – Yes / No) Results _____

Test for : HCV

(Performed – Yes / No) Results _____

Test for : Syphilis

(Performed – Yes / No) Results _____

General Comments : _____

Research only –

Name & Signature of EB Tech

RECIPIENT DATA (TO BE FILLED AT THE TIME OF SURGERY)

M.R. No: _____ Name: _____ Age: _____

Eye / Diagnosis _____

Time lapse between Enucleation and Utilization _____ Hours

Date of Surgery / Time _____

Operating Surgeon's Name _____

Surgical Procedure _____

Name & signature of the surgeon

(Duplicate form of Appendix - 8)

Case # _____

Month _____

Year _____

TISSUE DISTRIBUTION INFORMATION

Eye Bank No : _____ / _____ / _____ / _____ / (Right / Left)

Duplicate Should be kept in the patient folder

Duplicate
(Should be kept
in the
patient folder)

Age : _____

Religion : _____

Sex : _____

Injury / Admittance

Date _____

Hour _____

Death :

Date _____

Hour _____

Enucleation / Excision :

Date _____

Hour _____

Preservation :

Date _____

Hour _____

Cause of Death : _____

Medical History : _____

Ocular History : _____

Medications : _____

TISSUE PRESERVATION AND CORNEAL STATUS INFORMATION

Death – Preservation : (Time) _____ Hrs. _____ Mins.

Tissue Type : _____ Storage Method: _____

Lot Number: _____

Status: _____

Corneal Rating : _____

Epithelium : _____

Stroma : _____

Descement : _____

Endothelium : _____

Count : _____ Cells / mm

**Name & Signature of
Doctor / Technician**

Serology test for : HIV Antibody
(Performed – Yes / No) Results _____

(Hepatitis B surface Antigen test
(Performed – Yes / No) Results _____

Test for : HCV
(Performed – Yes / No) Results _____

Test for : Syphilis
(Performed – Yes / No) Results _____

General Comments : _____

Research only –

Name & Signature of EB Tech

Appendix - 9

DONOR TISSUE TENTATIVE UTILITY DATA & ADVERSE REPORT FORM

ID # : _____ Date : _____ Time : _____
Age : _____ Death : _____
Sex : _____ Preservation : _____
Received : _____

ORIGINAL
(Should be
sent back to
the eye bank)

Tissue sent by : _____

Proposed date to use the tissue : _____

Name of the Surgeon : _____

Name of the Patient : _____

Hospital registration /Medical records I.D. no. of Patient : _____

Date of Surgery : _____

Date :

COUNSELLOR'S SIGNATURE & NAME

ADVERSE REPORT

Details of adverse findings:

Likely Reasons for adverse findings:

Suggestions:

Signature of Operating Surgeon / Team

ID # : _____ Date : _____ Time : _____

Age : _____ Death : _____

Sex : _____ Preservation : _____

Received : _____

Tissue sent by :

DONOR TISSUE TENTATIVE UTILITY DATE & Adverse Report Form

Proposed date to use the tissue :

Name of the Surgeon :

Name of the Patient :

Hospital Registration No. /Medical Record No. of Patient :

Date of Surgery :

Date :

COUNSELLOR'S SIGNATURE & NAME

ADVERSE REPORT (to be sent back to the eye bank)

Details of adverse findings:

Likely Reasons for adverse findings:

Suggestions:

Signature of Operating Surgeon / Team

Appendix - 12

LABORATORY CLEANING LOG

Month : _____ /

Year : _____

	Week 1	Week 2	Week 3	Week 4
Initials of person (s) performing cleaning				
Cleaning Agent Used				
Date of Cleaned				
Counters				
Sink (s)				
Light Switches / Donor and Cabinet Handles				
HEPA Hood / Biosafety Cabinet				
Floors Mopped				
Instrument Lubricant Solution Changed				
Other _____				
Other _____				
Cabinets		Monthly cleaning only		
Centrifuge		- do-		
Slit Lamp Microscope		- do-		
Specular Microscope		- do-		
Centrifuge		- do-		
Refrigerator (Internal & External)		- do-		
Freezer (External)		- do-		
Other _____				
Other _____				

Refer to the Laboratory and Facilities Module for SOPs regarding Laboratory Cleaning and Maintenance

प्रकरण 10 / पृष्ठ 2/

1. प्रकरण 10 पूरे किए हुए प्रकरण 1(क), या प्रकरण 1(ख) या प्रकरण 1(ग) जैसा भी लागू हो, के साथ प्रस्तुत किए जाने चाहिए।
2. यथास्थिति लागू होने वाले प्रकरण, जैसे प्रकरण 1(क), या प्रकरण 1(ख) या प्रकरण 1(ग) के साथ लागू प्रकरण में उचित सभी दस्तावेजों होनी चाहिए और लागू प्रकरण में की गई सभी सुसंगत पूछताछों का प्रयाप्त रूप से उत्तर दिया जाना चाहिए।
3. पूरा किया हुआ प्रकरण 3 प्रयोगशाला रिपोर्ट के साथ प्रस्तुत किया जाए।
4. आवेदन के साथ प्रतिरोपण की सिफारिश करने संबंधी चिकित्साक की समझ संलग्न की जानी चाहिए।
5. उपर्युक्त के अतिरिक्त यदि प्रस्तावित प्रतिरोपण गैर नरतेज्य व्यक्तिओं के बीच है तो दाता और प्राप्तिकर्ता की कम से कम गत तीन वर्षों के व्यवसाय और आय का समुचित साक्ष्य आवेदन के साथ संलग्न किया जाना चाहिए यह स्पष्ट किया जाता है कि इस बात को ध्यान में रखते हुए कि दिए गए मामले में आवेदक/आवेदकों से आवश्यक विवरणियाँ फाईल नहीं किए हैं, आय का साक्ष्य से आवश्यक रूप से आय-कर विवरणियों का संभूत सम्बंधित नहीं है।
6. प्राधिकार समिति द्वारा विचार के लिए आवेदन केवल तभी स्वीकार किया जाएगा यदि वह सभी बाबत पूर्ण है और ऊपर वर्णित प्रकरण में अपेक्षित किन्हीं दस्तावेजों या जानकारी का लोप आवेदन को अपूर्ण बना देगा।
7. उच्चतम न्यायालय के तारीख 31.03.2008 के निर्णय के अनुसार संबद्ध राज्य/संघ राज्यक्षेत्र शासन या प्राधिकार समिति से अनुमोदन/अनापत्ति प्रमाणपत्र दाता और प्राप्तिकर्ता के अधिवास राज्य/संघ राज्यक्षेत्र से प्राप्त करना अनिवार्य है। यह समझा जाता है कि प्रतिरोपण के लिए अंतिम अनुमोदन (यथास्थिति) प्राधिकारी समिति/ रजिस्ट्रीकृत चिकित्सा व्यवसायी अर्थात् प्रतिरोपण केन्द्र के चार साक्षक, जहाँ प्रतिरोपण किया जाना चाहिए, द्वारा अनुमत्त किया जाना चाहिए।

हमने उपर्युक्त अनुदेशों के पढ़ और समझ लिया है।

भावी दाता के हस्ताक्षर
तारीख
स्थान

भावी प्राप्तिकर्ता के हस्ताक्षर
तारीख
स्थान

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 31st July, 2008

G.S.R. 571(E).— In exercise of the powers conferred by sub-section (1) of section 24 of the Transplantation of Human Organs Act, 1994 (42 of 1994), the Central Government hereby makes the following amendments to the Transplantation of Human Organs Rules, 1995, namely:-

1. Short title and Commencement

(1) These rules may be called the Transplantation of Human Organs (Amendment) Rules, 2008.

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

2. In the Transplantation of Human Organs (Amendment) Rules, 2008 (hereinafter referred to as the said rules) - (i) clause (d) shall be renumbered as clause (f), thereof and before clause (f) as so renumbered the following clauses shall be inserted, after clause (c), namely

(i). after sub-rule (c) of Rule 2, the following shall be inserted:

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

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

3. In the said rules, in rule 3, for the words and figure "Form.1" the words, figures and letters "Forms 1(A), 1(B) and 1(C) shall be substituted:

4. In the said rules, - (i) in rule 4 for sub-rule(1) the following sub-rule shall be substituted, namely:-

"(i) Duties of the Medical Practitioner:

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

- (a) that the donor has given his authorization in appropriate Form 1(A) or 1(B) or 1(C).
- (b) that the donor is in proper state of health and is fit to donate the organ, and the registered medical practitioner shall sign a certificate as specified in Form 2.
- (c) that the donor is a near relative of the recipient, as certified in Form 3, who has signed Form 1(A) or 1(B) as applicable to the donor and that the donor has submitted an application in Form 10 jointly with the recipient and that the proposed donation has been approved by the concerned competent authority and that the necessary documents as prescribed and medical tests, if required, to determine the factum of near relationship, have been examined to the satisfaction of the Registered Medical Practitioner i.e. Incharge of transplant centre.
- (d) that in case the recipient is spouse of the donor, the donor has given a statement to the effect that they are so related by signing a certificate in Form 1(B) and has submitted an application in Form 10 jointly with the recipient and that the proposed donation has been approved by the concerned competent authority under provisions of sub-rule(2) of rule 4A.
- (e) In case of a donor who is other than a near relative and has signed Form 1(C) and submitted an application in Form 10 jointly with the recipient, the permission from the Authorisation Committee for the said donation has been obtained.

(ii) In rule 4 in sub-rule(2) for clause (b) the following clause shall be substituted, namely:-

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

(iii) the existing Form 7 shall be omitted.

5. In the said rules, after rule 4 the following rule shall be inserted, namely:-

"4-A (1) The medical practitioner who will be part of the organ transplantation Authorisation Committee shall not be a member of the Authorisation Committee constituted under the provisions of clauses (a) and (b) of sub-section(4) of section 9 of the Act.

- (2) Where the proposed transplantation is between a married couple, the Registered Medical Practitioner i.e. Incharge of transplant centre must evaluate the factum and duration of marriage and ensure that documents such as marriage certificate, marriage photograph etc. are kept for records along with the information on the number and age of children and family photograph depicting the entire immediate family, birth certificate of children containing particulars of parents.
 - (3) When the proposed donor or recipient or both are not Indian Nationals/citizens whether 'near relatives' or otherwise, Authorisation Committees shall consider all such requests.
 - (4) when the proposed donor and the recipient are not 'near relatives', as defined under clause(i) of section 2 of the Act, the Authorisation Committee shall evaluate that,-
 - (i) there is no commercial transaction between the recipient and the donor and that no payment or money or moneys worth as referred to the Act, has been made to the donor or promised to be made to the donor or any other person;
 - (ii) the following shall specifically be assessed by the Authorisation Committee:-
 - (a) an explanation of the link between them and the circumstances which led to the offer being made;
 - (b) reasons why the donor wishes to donate;
 - (c) documentary evidence of the link, e.g. proof that they have lived together, etc.;
 - (d) old photographs showing the donor and the recipient together;
 - (iii) that there is no middleman or tout involved;
 - (iv) that financial status of the donor and the recipient is probed by asking them to give appropriate evidence of their vocation and income for the previous three financial years. Any gross disparity between the status of the two must be evaluated in the backdrop of the objective of preventing commercial dealing;
 - (v) that the donor is not a drug addict or known person with criminal record;
 - (vi) that the next of the kin of the proposed unrelated donor is interviewed regarding awareness about his or her intention to donate an organ, the authenticity of the link between the donor and the recipient and the reasons for donation. Any strong views or disagreement or objection of such kin shall also be recorded and taken note of.
6. In the said rules:-
- (i) For rule 6 the following rules shall be substituted, namely:-

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

(ii) after rule 6, the following rule shall be inserted, namely:-

*6A. Composition of Authorisation Committees:

1. There shall be one State level Authorisation Committee.

2. Additional authorisation committees may be set up at various levels as per norms given below, namely:-

(i) no member from transplant team of the institution should be a member of the respective Authorisation Committee. All Foreign Nationals (related and unrelated) should go to 'Authorisation Committee' as abundant precaution needs to be taken in such cases;

(ii) Authorisation Committee should be Hospital based in Metro and big cities if the number of transplants exceed 25 in a year at the respective transplantation centres. In smaller towns, there are State or District level Committees if transplants are less than 25 in a year in the respective districts.

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

(a) the senior most person officiating as Medical Director or Medical Superintendent of the Hospital;

(b) two senior medical practitioners from the same hospital who are not part of the transplant team;

(c) two members being persons of high integrity, social standing and credibility, who have served in high ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in University Grants Commission approved University or are self-employed professionals of repute such as lawyers, chartered accountants and doctors (of Indian Medical Association) etc : and

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

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

- (a) a Medical Practitioner officiating as Chief Medical Officer or any other equivalent post in the main/major Government Hospital of the District.
- (b) two senior medical practitioners to be chosen from the pool of such medical practitioners who are residing in the concerned District and who are not part of any transplant team.
- (c) two senior citizens, non-medical background (one lady) of high reputation and integrity to be chosen from the pool of such citizens residing in the same district, who have served in high ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in University Grants Commission approved University or are self-employed professionals of repute such as lawyers, chartered accountants and doctors (of Indian Medical Association) etc.; and
- (d) Secretary (Health) or nominee and Director Health Services or nominee.

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

- 6B. The State level committees shall be formed for the purpose of providing approval or no objection certificate to the respective donor and recipient to establish the legal and residential status as a domicile state. It is mandatory that if donor, recipient and place of transplantation are from different states, then the approval or 'no objection certificate' from the respective domicile State Government should be necessary. The institution where the transplant is to be undertaken in such case the approval of Authorisation Committee is mandatory.
- 6C. The quorum of the Authorisation Committee should be minimum four. However, quorum ought not to be considered as complete without the participation of the Chairman. The presence of Secretary (Health) or nominee and Director of Health Services or nominee is mandatory.
- 6D. The format of the Authorisation Committee approval should be uniform in all the institutions in a State. The format may be notified by respective State Government.
- 6E. Secretariat of the Committee shall circulate copies of all applications received from the proposed donors to all members of the Committee. Such applications should be circulated along with all annexures, which may have been filed along with the applications. At the time of the meeting the Authorisation Committee should take note of all relevant contents and documents in the course of its decision making process and in the event any document or information is found to be inadequate or doubtful explanation should be sought from the applicant and if it is considered

necessary that any fact or information requires to be verified in order to confirm its veracity or correctness, the same be ascertained through the concerned officer(s) of the State/ Union territory Government.

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

(a) Where the proposed transplant is between persons related genetically, Mother, Father, Brother, Sister, Son or Daughter above the age of 18 years).

the concerned competent authority shall evaluate:-

- (i) results of tissue typing and other basic tests;
- (ii) documentary evidence of relationship e.g. relevant birth certificates and marriage certificate; certificate from Sub-divisional magistrate/ Metropolitan Magistrate/or Sarpanch of the Panchayat;
- (iii) documentary evidence of identity and residence of the proposed donor e.g. Ration Card or Voters identity Card or Passport or Driving License or PAN Card or Bank Account and family photograph depicting the proposed donor and the proposed recipient along with another near relative;
- (iv) if in its opinion, the relationship is not conclusively established after evaluating the above evidence, it may in its discretion direct further medical tests as prescribed as below:
 - (a) the tests for Human Leukocyte Antigen (HLA), Human Leukocyte Antigen-B alleles to be performed by the serological and/or Polymerase chain reaction (PCR) based Deoxyribonucleic acid (DNA) methods.
 - (b) test for Human Leukocyte Antigen-DR beta genes to be performed using the Polymerase chain reaction (PCR) based Deoxyribonucleic acid (DNA) methods.
 - (c) the tests referred to in sub-rules (i) and (ii) shall be got done from a laboratory accredited with National Accreditation Board for Laboratories (NABL).*
 - (d) where the tests referred to in (i) to (iii) above do not establish a genetic relationship between the donor and the recipient, the same tests to be performed on both or at least one parent, preferably both parents. If parents are not available, same tests to be performed on such relatives of donor and recipient as are available and are willing to be tested failing which, genetic relationship between the donor and the recipient will be deemed to have not been established.

- (b) The papers for approval of transplantation would be processed by the registered medical practitioner and administrative division of the Institution for transplantation, while the approval will be granted by the Authorisation Committee.
- (c) Where the proposed transplant is between a married couple (except foreigners, whose cases should be dealt by Authorisation Committee);

The concerned competent authority or authorisation committee as the case may be must evaluate all available evidence to establish the factum and duration of marriage and ensure that documents such as marriage certificate, marriage photograph is placed before the committee along with the information on the number and age of children and a family photograph depicting the entire immediate family, birth certificate of children containing the particulars of parents.

- (d) Where the proposed transplant is between individuals who are not "near relatives". The authorization committee shall evaluate:-
- (i) that there is no commercial transaction between the recipient and the donor. That no payment of money or moneys worth as referred to in the sections of the Act, has been made to the donor or promised to be made to the donor or any other person. In this connection the Authorisation Committee shall take into consideration:-
- (a) an explanation of the link between them and the circumstances which led to the offer being made;
 - (b) documentary evidence of the link e.g. proof that they have lived together etc.;
 - (c) reasons why the donor wishes to donate; and
 - (d) old photographs showing the donor and the recipient together.
- (ii) that there is no middleman/tout involved;
- (iii) that financial status of the donor and the recipient is probed by asking them to give appropriate evidence of their vocation and income for the previous three financial years. Any gross disparity between the status of the two, must be evaluated in the backdrop of the objective of preventing commercial dealing;
- (iv) that the donor is not a drug addict or a known person with criminal record;
- (v) that the next of kin of the proposed unrelated donor is interviewed regarding awareness about his/her intention to donate an organ, the authenticity of the link between the donor and the recipient and the reasons for donation. Any strong views or disagreement or objection of such kin may also be recorded and taken note of and

- (e) When the proposed donor or the recipient or both are foreigners:-
- (i) a senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient.
 - (ii) Authorisation Committee shall examine the cases of Indian donors consenting to donate organs to a foreign national (who is a near relative), including a foreign national of Indian origin, with greater caution. Such cases should be considered rarely on case to case basis.
- (f) In the course of determining eligibility of the applicant to donate, the applicant should be personally interviewed by the Authorisation Committee and minutes of the interview should be recorded. Such interviews with the donors should be videographed.
- (g) In case where the donor is a woman greater precautions ought to be taken. Her identity and independent consent should be confirmed by a person other than the recipient. Any document with regard to the proof of residence or domicile and particulars of parentage should be relatable to the photo identity of the applicant in order to ensure that the documents pertain to the same person, who is the proposed donor and in the event of any inadequate or doubtful information to this effect, the Authorisation Committee may in its discretion seek such other information or evidence as may be expedient and desirable in the peculiar facts of the case.
- (h) The Authorisation Committee should state in writing its reason for rejecting/ approving the application of the proposed donor and all approvals should be subject to the following conditions:-
- (i) that the approved proposed donor would be subjected to all such medical tests as required at the relevant stages to determine his biological capacity and compatibility to donate the organ in question.
 - (ii) further that the psychiatrist clearance would also be mandatory to certify his mental condition, awareness, absence of any overt or latent psychiatric disease and ability to give free consent.
 - (iii) all prescribed forms have been and would be filled up by all relevant persons involved in the process of transplantation.
 - (iv) all interviews to be video recorded.
- (i) The authorisation committee shall expedite its decision making process and use its discretion judiciously and pragmatically in all such cases where the patient requires immediate transplantation.

(j) Every authorised transplantation centre must have its own website. The Authorisation Committee is required to take final decision within 24 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 24 hours of taking the decision. Apart from this, the website of the hospital or institution must update its website regularly in respect of the total number of the transplantations done in that hospital or institution along with the details of each transplantation. The same data should be accessible for compilation, analysis and further use by respective State Governments and Central Government.

7. In the said rules, in rule 7, after clause(2) the following clause shall be inserted, namely:-

"7(3) before a hospital is registered under the provisions of this rule, it shall be mandatory for the hospital to nominate a transplant coordinator."

8. In the said rules, for rule 9 the following rule shall be substituted, namely:-

"9. Conditions for grant of Certificate of Registration:

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

A. General Manpower Requirement Specialised Services and Facilities:

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

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gastroenterology, nephrology, neurology, paediatrics, gynaecology immunology and cardiology etc. should be available to the transplantation centre.

B Equipments:

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

C Experts and their qualifications:-

(A) Kidney Transplantation:

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

(B) Transplantation of liver and other abdominal organs

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

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

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

(D) Cornea Transplantation:

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

[F. No. S-12011/12/2007-MS]
VINEET CHAUDHRY, Jt. Secy.

Note :— The principal rules were published in the Gazette of India *vide* notification No. S-12011/2/1994-MS, dated the 4th February, 1995, Extraordinary, under G.S.R. No. 51(E).

FORM 1(A)

(Page 1 of 2)

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

My full name is

and this is my photograph

Photograph of the Donor
(Attested by Notary Public)To be affixed and
attested by Notary
Public after it is
affixed.My permanent home address is
.....

..... Tel:

My present home address is
.....

..... Tel:

Date of birth(day/month/year)

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

I hereby authorize removal for therapeutic purposes/consent to donate my
(state which organ) to my relative (specify son/daughter/father/mother/
brother/sister), whose name is and
who was born on(day/month/year) and whose particulars are as
follows:

Photograph of the Recipient
(Attested by Notary Public)To be affixed and
attested by Notary
Public after it is
affixed.

FORM 1(A) (Page- 2)

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

I solemnly affirm and declare that:

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

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

.....
Signature of the prospective donor

.....
Date

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

- ✓ wherever applicable.

FORM 1(B)

(Page 1 of 2)

*(To be completed by the prospective spousal donor)**(see Rule 3)*

My full name is
and this is my photograph

Photograph of the Donor
(Attested by Notary Public)

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

My permanent home address is

.....

.....

Tel:

My present home address is

.....

.....

Tel:

Date of birth(day/month/year)

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

Photograph of the Recipient
(Attested by Notary Public)

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

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

FORM 1(B) (Page-2)

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

- (a) A certified copy of a marriage certificate
- OR
- (b) An affidavit of a 'near relative' confirming the status of marriage to be sworn before Class-I Magistrate/Notary Public.
- (c) Family photographs
- (d) Letter from member of Gram Panchayat / Tehsildar / Block Development Officer/ MLA/ MP certifying factum and status of marriage.
- OR
- (e) Other credible evidence

I solemnly affirm and declare that:

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

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

.....
Signature of the prospective donor

.....
Date

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

- ✓ wherever applicable.

FORM 1(C)

(Page 1 of 2)

(To be completed by the prospective un-related donor)
(See Rule 3)

My full name is
and this is my photograph

Photograph of the Donor
(Attested by Notary Public)

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

My permanent home address is Tel:

My present home address is Tel:

Date of birth (day/month/year)

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

Details of last three years income and vocation of donor

I hereby authorize to remove for therapeutic purposes/consent to donate my
(state which organ) to a person whose full name is
and who was born on
(day/month/year) and whose particulars are as follows:

Photograph of the Recipient
(Attested by Notary Public)

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

FORM 1(C) [Page-2]

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

I solemnly affirm and declare that:

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

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

.....
Signature of the prospective donor

.....
Date

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

- ✓ wherever applicable.

FORM 2

[See rule 4(1)(b)]

(To be completed by the concerned Medical Practitioner)

I, Dr. possessing qualification of
 registered as medical practitioner at serial no. by the
 Medical Council, certify that I have examined
 Shri/ Smt./ Km. S/o, D/o, W/o Shri
 aged who has given informed consent about donation of the organ, namely (name
 of the organ) to Shri/Smt./Km
 who is a 'near relative' of the donor/other than near relative of the donor, who had been
 approved by the Authorisation Committee/ Registered Medical Practitioner i.e. Incharge of
 transplant centre (as the case may be) and that the said donor is in proper state of health
 and is medically fit to be subjected to the procedure of organ removal.

Place:

Date:

Signature of Doctor
Seal

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

Photograph of the Donor
(Attested by doctor)

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

Photograph of the recipient
(Attested by the doctor)**FORM 3**

[See Rule 4(1)(c)]

I, Dr./Mr./Mrs. working as
 at and possessing qualification of certify
 that Shri/ Smt./ Km. S/o, D/o, W/o
 Shri/ Smt. aged the donor
 and Shri/ Smt. S/o, D/o, W/o
 Shri/Smt. aged the proposed recipient of the organ to
 be donated by the said donor are related to each other as
 brother/sister/mother/father/son/daughter as per their statement and the fact of this
 relationship has been established / not established by the results of the tests for Antigenic
 Products of the Human Major Histocompatibility Complex. The results of the tests are
 attached.

Place

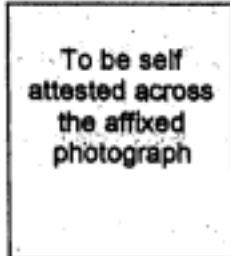
Date

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

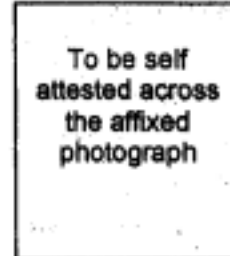
Seal

FORM 10

(Page 1 of 2)

APPLICATION FOR APPROVAL FOR TRANSPLANTATION (LIVE DONOR)*(To be completed by the proposed recipient and the proposed donor)***[See Rule 4 (1) (c)(d)(e)]**

Photograph of the Donor
(Self-attested)



Photograph of the recipient
(Self-attested)

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

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

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

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

We and
(Donor) (Recipient)

hereby apply to Authorization Committee for permission for such transplantation to be
carried out.

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

FORM 10 [Page 2]**Instructions for the applicants:-**

1. Form 10 must be submitted along with the completed Form 1(A), or Form 1(B) or Form 1(C) as may be applicable.
2. The applicable Form i.e. Form 1(A) or Form 1(B) or Form 1(C) as the case may be, should be accompanied with all documents mentioned in the applicable form and all relevant queries set out in the applicable form must be adequately answered.
3. Completed Form 3 to be submitted along with the laboratory report.
4. The doctor's advice recommending transplantation must be enclosed with the application.
5. In addition to above, in case the proposed transplant is between unrelated persons, appropriate evidence of vocation and income of the donor as well as the recipient for the last three years must be enclosed with this application. It is clarified that the evidence of income does not necessarily mean the proof of income tax returns, keeping in view that the applicant(s) in a given case may not be filing income tax returns.
6. The application shall be accepted for consideration by the Authorisation Committee only if it is complete in all respects and any omission of the documents or the information required in the forms mentioned above, shall render the application incomplete.
7. As per the Supreme Court's judgement dated 31.03.2005, the approval/ No Objection Certificate from the concerned State/ Union Territory Government or Authorisation Committees is mandatory from the domicile State/ Union Territory of donor as well as recipient. It is understood that final approval for transplantation should be granted by the Authorisation Committee/ Registered Medical Practitioner i.e. Incharge of transplant centre (as the case may be) where transplantation should be done.

We have read and understood the above instructions.

Signature of the Prospective Donor

Signature of Prospective Recipient

Date :

Date :

Place :

Place :

Appendix - 14

LABORATORY EQUIPMENT CLEANING LOG

Year _____

EQUIPMENT	DATE OF MAINTENANCE	STATUS (Pass or Fail)	PERSON PERFORMING MAINTENANCE
<p>Laminar Air Flow hood / Biosafety Cabinet Requires annual re-certification</p>			
<p>Transplant Tissue Storage Refrigerator. Check Temperature recorder device for accuracy against an NIST calibrated thermometer. De-ice and clean interior and exterior</p>			
<p>Non-Transplant tissue storage Refrigerator and Freezer. clean refrigerator (internal and external) and de-ice freezer. Check the working condition</p>			
<p>Specular Microscope. Requires annual re-calibration</p>			
<p>Centrifuge. Inspect for proper function ability according to manufactures handbook</p>			
<p>Serology equipment to be certified by the manufacturer. (In case of ELISA) Incubator . Reader</p>			
<p>UV Lights. Inspect the effectiveness of all UV lights in lab. Or change annually</p>			
<p>Transplant Tissue Storage Freezer. Cheque the working condition. De-ice and clean interior and exterior</p>			

Appendix - 15

FREQUENTLY ASKED QUESTIONS ABOUT EYE DONATION

Q. What is an eye bank?

A. It is the link between donor and recipient/eye surgeon. It is an organization recognized by the government to collect and distribute human eyes to those requiring corneal transplantation.

Q. Who can be an eye donor?

A. Anyone can be a donor irrespective of age, sex or blood group.

Q. Do religious authorities approve of donating one's eyes?

Yes, all religious faiths support this vital sight restoration program.

Q. Is the whole eye used for transplant?

No. Only the thin transparent layer in front of the iris called the cornea is used for transplant.

Q. What is a cornea?

A. Cornea is a transparent tissue without any blood vessels. A clear cornea enables one to have a good vision.

Q. How is the tissue harvested from a donor?

A. Tissue is retrieved either through enucleation (whole eye ball removal) or corneal excision. Presently many eye banks in the country, retrieve cornea by IN SITU CORNEAL EXCISION PROCEDURE. This procedure involves removing just the cornea from the whole eye of the deceased/donor.

During corneal excision, the cornea along with the white part of the eye known as the sclera is excised out. Two to three mm scleral rim is excised 360 degrees. The procedure takes 20 to 30 minutes.

The excised cornea is introduced into a preservative medium, the Mc Carey Kaufman medium (MK medium) which is prepared by the Rotary Club of Hyderabad, Cornea Preservation Center of the RIEB and distributed to all eye banks in the country and South East Asian countries. The MK medium allows preservation of the cornea for a period of 4 days.

Q. What is meant by corneal transplantation?

A. It is a surgical procedure whereby an impaired cornea of the patient is replaced by a healthy cornea from a donor for gaining the lost vision.

Q. How quickly should the corneas/eyes be removed after death?

Corneas/eyes should be removed within 6 hours of demise.

Q. Is it necessary to transport the donor to the hospital after death for donating eyes?

A. No. The eye bank personnel will go to the donor's residence and remove the eyes. The procedure takes approximately 20 to 30 minutes.

- Q Do cataracts or the use of spectacles render the corneas unfit?**
- A. No. Both these conditions relate to the lens of the eye and not the cornea.
- Q. Does eye donation disfigure the donor's face?**
- A. No. The removal of corneas/eyes does not cause disfigurement.
- Q. Is there any delay in funeral arrangements?**
- A. No. Tissue procurement is performed within 20 to 30 minutes. Therefore family members of the deceased may proceed as planned with funeral arrangements.
- Q. What conditions render corneas unfit for donations?**
- A. Corneas of persons suffering from AIDS, jaundice, rabies, syphilis, tetanus, septicemia and viral diseases are considered unfit for donation.
- Q. What about diabetes or hypertension?**
- A. Even donors with these conditions can donate their eyes.
- Q. Does the human body reject the transplanted donor cornea?**
- A. A cornea does not have direct blood supply. Therefore the risk of rejection is very low. If rejection occurs, it can be suppressed by timely medication.
- Q How will the donated eyes be used?**
- A. After the cornea is removed from the whole eye, it is evaluated and then supplied to the eye surgeon for use in a patient.
- Q. Is there any use of corneas that are for some reason not utilised for surgery?**
- A. Corneas that are rejected for technical reasons may be used for research or education purposes.
- Q. Will the donor or recipient family be told who donated or received the cornea?**
- A. No. The Donor - recipient information is maintained confidential.
- Q. Will the donor family be given fees?**
- A. No. It is illegal to buy or sell human eyes, organs or tissues. Any cost involved with cornea retrieval is borne by the eye bank.

Appendix - 16

FACTS AND MYTHS ABOUT DONATING EYES

- Myth** - Eyes can be removed out of living human beings.
Fact - Eyes are removed only after death.
- Myth** - Eyes can be donated even by a live person.
Fact - Eyes can only be pledged by a live person. Eyes can be donated only after death.
- Myth** - Removal of eyes causes disfigurement of the face.
Fact - Removal of eyes does not produce any disfigurement of the face.
- Myth** - Eye donation interferes with, or delays customary final rites.
Fact - Eye donation does not interfere with or delay final rites, as the corneal excision procedure takes less than 20 minutes.
- Myth** - Eyes of aged donors are not acceptable.
Fact - All donor eyes are acceptable irrespective of the donor's age, including eyes of premature/ still-born babies.
- Myth** - Indian eyes are not good to be used for corneal transplantation.
Fact - Eyes of any deceased person anywhere in the world can be used for corneal transplantation following evaluation.
- Myth** - An entire eye can be transplanted.
Fact - Only the cornea is used for transplantation.
- Myth** - Corneal transplantation is an experimental procedure.
Fact - Corneal transplantation is a proven, routinely performed surgery and is a successful procedure.
- Myth** - Corneal transplantation is not effective and successful in Indian eyes.
Fact - Corneal transplantation is effective in all eyes, if performed under optimal conditions.
- Myth** - Human eyes can be bought or sold.
Fact - Selling or buying of human eyes is illegal.
- Myth** - Only those who have pledged their eyes can donate them after death.
Fact - Pledging of eyes is not important, because even in the case of a pledgee, the consent of the family member is essential, without which an eye cannot be removed.

Appendix - 17

Eye Donation Counsellor (EDC)

DAILY REPORT FORM

1. DATE/MONTH/YEAR : _____

2. HOSPITAL ATTENDED : _____

3. PLACE : _____

4. NO. OF HRS WORKED : _____

FROM : TO: _____

5. NO. OF DEATHS DECLARED : _____

FROM 6.00 AM TO 6.00 PM : _____

FROM 6.00 PM TO 6.00 AM : _____

6. NO. OF DEATHS DECLARED : _____

WITHIN THE WORK PERIOD

7. NO. OF CASES APPROACHED : _____

8. NO. OF CASES NOT : _____

APPROACHED

(Give reasons)

9. NO. OF CASES SUCCEDED : _____

10. NO. OF CASES NOT : _____

SUCCEDED

11. Donors: Male: Nos Female: Nos

NAME OF THE EDC/TRAINEE : _____

SIGNATURE WITH DATE : _____

SIGNATURE OF THE EYE BANK : _____

MANAGER / DIRECTOR

Appendix - 18

Eye Donation Counsellor (EDC) Report

CASE SUMMARY

1. Date / Month / Year : _____
2. Case No : _____
3. **Particulars of the Donor :**
 - Name : _____
 - Religion : _____
 - Age & Sex : _____
 - Cause of death : _____
 - Pledge : Yes _____ No _____
4. **Particulars of the Donor Family:**
 - No. of family members present at
The time of motivation : _____
 - Family Educated : Yes _____ No. _____
 - Awareness about eye donation : Yes _____ No _____
 - Encountered difficulty in convincing : Yes _____ No _____

Questions raised by the family members:

5. Time Lapse Between death and Motivation : _____
6. Time taken for motivation : _____
7. Motivation outcome : _____
8. Consent Given by : _____
9. Briefly describe how motivation was carried Out : _____
10. Reasons for getting the consent (Describe) : _____

11. Reasons for not getting the consent (Describe): _____

Appendix - 19

Eye Donation Counsellor (EDC)

MONTHLY REPORT FORM

01. MONTH/YEAR : _____
02. HOSPITAL ATTENDED : _____
03. PLACE : _____
04. NO. OF DAYS WORKED : _____
05. NO. OF HOURS WORKED PER DAY : _____
06. NO. OF DEATHS DECLARED
IN THE MONTH (DAY & NIGHT) : _____
07. NO. OF DEATHS DECLARED
WITHIN THE WORK PERIOD : _____
08. NO. OF CASES APPROACHED : _____
09. NO. OF CASES NOT APPROACHED
(Give reasons) : _____
10. PARTICULARS OF THE CASES
APPROACHED : _____

Religion : Hindu: ___ ; Muslim: ___ ; Christian: ___

Age Group : 0 – 9 _____; 10 – 19 _____;
20 – 29 _____; 30 – 39 _____;
40 – 49 _____; 50 – 59 _____;
60 – 69 _____; 70 – 79 _____;
80 and above _____.

Sex : Male _____; Female _____

Cause of Death : **Heart Disease** _____
Cancer _____
Trauma _____
Brain Disease _____
Infectious Disease _____
Others _____

Pledgees : No. of Pledgees _____

Not pledgees _____

Family educated : _____

Awareness about eye donation : _____

Encountered difficulty in counselling : _____

11. AVERAGE TIME LAPSE BETWEEN DEATH & MOTIVATION : _____

12. AVERAGE TIME TAKEN FOR MOTIVATION : _____

13. NO. OF CASES SUCCEEDED (DONORS) : _____

14. NO. OF CASES NOT SUCCEEDED : _____

15. PARTICULARS OF DONORS : _____

Religion : Hindu: __ ; Muslim: __ ; Christian: __

Age Group : 0 – 9 _____; 10 – 19 _____;
 20 – 29 _____; 30 – 39 _____;
 40 – 49 _____; 50 – 59 _____;
 60 – 69 _____; 70 – 79 _____;
 80 and above _____.

Sex : Male _____; Female _____

Cause of Death : Heart Disease _____
 Cancer _____
 Trauma _____
 Brain Disease _____
 Infectious Disease _____
Others _____

Pledgees : No. of Pledgees _____
 : Not pledgees _____

Family educated : _____

Awareness about eye donation : _____

Encountered difficulty in counselling:

Utilisation: Op.PK Th.PK L.K Others

Miscellaneous

TEMPERATURE RECORD REFRIGERATOR No.

Month : _____

Year : _____

Date	7.00 A.M.	1.00 P.M	7.00P.M
1			
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Appendix - 20

Financial Assistance available under NPCB

II Non-recurring grant-in-aid for Eye Banks in Government/Voluntary Sector (upto maximum Rs. 15.00 lakhs);

The objective of this scheme is to promote Eye banking activity in the country through Government facilities, NGOs and other stake holders to get adequate tissue for corneal transplantation for treatment of corneal blindness.

1. **Financial assistance** : Under the scheme, financial assistance will be provided up to a maximum of Rs. 15 Lakh for purchase of equipment, furniture and fixtures (list attached)
2. **Eligibility criteria** : The organization should:
 - i. Satisfy general eligibility conditions mentioned.
 - ii. Should fit into the definition of Eye Bank as mentioned.
 - iii. Organizations having experience in providing eye care services will be given preference.
 - iv. Should have collected at-least 100 Eye Balls in any of the preceding two years of application. In case of difficult terrain (eg. North eastern states), relaxed criteria of 25 Pair of Eyes shall be applicable

OR

 - v. Should have conducted at least 600 cataract operations including other eye disease operations in the proceeding two years. In case of difficult terrain (eg. North eastern states), relaxed criteria of 300 cataract operation including other eye disease operations shall be applicable.

3. Infrastructure Requirement:

a. Manpower Requirement:

□ Ophthalmic Surgeons (Full time / on Panel)	1
□ Ophthalmic Technician	1
□ Eye Donation Counselor / Social Worker / Health Educator / Clerk	2

4. Expected Output NGOs receiving non-recurring grants shall:

- i. Utilize the entire grant within period of 12 months from receipt of grant after following due procedures
- ii. Provide & maintain detailed records of Eye Balls collected and utilized in the prescribed format and submit monthly report to the District Health Society.
- iii. The NGO should be committed to collect at-least 200 eye balls in the next two years. In case of difficult terrain (eg. North eastern states), relaxed criteria of 100 cataract operation including other eye disease operations shall be applicable.

5. Procedure for Approval of Grants

Two copies of application in prescribed formats would be submitted by applicant NGO along with

necessary documents in support of qualifying criteria to the State Programme Officer (SPO), NPCB. The SPO would examine the proposal in terms of eligibility criteria, and depute a team of expert(s) (2-3) from the State to visit the NGO for assessing present facilities and requirements. This entire work should be completed within maximum of three months from the date of receipt of applications complete in all respects. The SPO may thereafter, forward his recommendation to the competent authority for final disposal.

S.No	Equipment/Furnishing
1.	Slit Lamp Microscope
2.	Specular Microscope
3.	Laminar Flow
4.	Serology Equipment
5.	Instruments for corneal excision and enucleation including containers
6.	Autoclave
7.	Keratoplasty instruments
8.	Transport Facility (One 2 Wheeler)
9.	Refrigerator
10.	Computer & Accessories
11.	Telephone Line
12.	Air-Conditioner
13.	Renovation, Repair, Furniture & Fixtures
	Maximum Assistance = Rs. 15 Lakh

III Non-recurring grant-in-aid for Eye Donation Centres (EDC) in Government/ Voluntary Sector (upto maximum Rs. 1.00 lakh)

1. Eye Donation Centre: For the purpose of the above scheme, an Eye Donation Centre will mean an organization that is:
 - i) Is affiliated to a registered Eye Bank
 - ii) Harvest corneal tissue and collect blood for serology;
 - iii) Ensure safe transportation of tissue to the parent eye bank
 - iv) Provide a round the clock public response system for eye donation;
 - v) Coordinate with donor families and hospitals to motivate eye donation;
 - vi) Conduct Public and professional awareness on eye donation;

2 Financial Assistance:

Under the scheme, financial assistance will be provided up to a maximum of Rs. 1 Lakh (Rupees One Lakh Only) for the purchase of equipment.

3 Eligibility criteria:

(a) Should satisfy general eligibility conditions mentioned. (except the 2 year clause, i.e. new organization can also apply)

(b) The organization should have the following staff as a minimum requirement:

Sl. No	Personnel	Number
1	Ophthalmic Technician	1
2	Eye Donation Counselor/ Social Worker / Health Educator	1

4 Expected Output: NGOs receiving non-recurring grants shall:

- i. Utilise the entire grant within period of 12 months from the receipt of grant after following due procedures
- ii. Provide & maintain detailed records of Eye Balls collected and deposited in linked Eye Bank in the prescribed format and submit monthly report to the District Health Society.
- iii. The NGO should be committed to collect at-least 20 eye balls in the next two years.

Appendix - 21

Eye Banks* in India

ANDHRA PRADESH

• **Netra Eye Bank Rotary Netra Eye Hospital**, Saripalli, Pendurthi, **Visakhapatnam** - 531173 , Ph.: 2763574 • **Ongole Eye Bank**, Kurnool Road, Near RTC Bus Stand, **Ongole**-523002 , Ph.: 233767 • **Aravind Eye Bank**, Aravind Eye Hospital, Venkataratnam Street, Suryaraopet **Vijayawada**-520002, Ph.: 866433018 • **L.V. Prasad Eye Institute**, L.V. Prasad Marg, Road No-2, Banjara Hills, **Hyderabad**-500034, Ph.: 30612345 • **Swetcha Gora Eye Bank**, C/o Vasaya Mahila Mandali, Benz Circle, **Vijayawada**-520010, Ph.: 2472370 • **S.L. Mishra Memorial Eye Bank Lions Club of Hyderabad**, Sadhuram Eye Hospital Charitable Trust & P.G. Inst. of Ophthalmology, 1-2-8 Gagan Mahal Road, Domalguda, **Hyderabad**-500029, Ph.: 23221094 • **Chiranjeevi Eye & Blood Bank Research and Development Centre**, D.No. 8-2-293/82/A/CEBB, Road No-1, Jubilee Hills Check Post **Hyderabad**-500033, Ph.: 23554849 • **Sarojini Devi Eye Hospital**, T.L. Kapadia Eye Bank, Hymayun Nagar, **Hyderabad**-500028, Ph.: 23317274 • **The Khammam Eye Bank**, Near Munneru Bridge, Ranganayakulagutta Road, **Khammam**, Ph.: 223756 • **V.T. Thakur Memorial Lions Hospital & Eye Bank** , Godown Road, **Kamareddy** - 503111 , Ph .: 225888 • **Mohsin Eye Bank**, C/o. L.V. Prasad Eye Institute, GMR Varalakshmi Campus, D.No. 11-113/1, Hanumanthuwaka Junction, **Visakhapatnam**-530040, Ph.: 2714000 • **Lions Citizens Eye Bank-ONGOLE**, C/o. Urban Health Centre, Papa Colony, **ONGOLE**, Ph.: 82835 • **Khammam District Police Eye Bank**, Distt. Police Office, **Khammam**. Ph.: 25333 • **Eye Bank**, Govt. General Hospital, **Guntur**, Ph.: 2221818 • **Eye Collection Centre**, District Hospital, **Cuddapah**, Ph.: 242152 • **Eye Collection Centre**, District Hospital, **Mahaboob Nagar**, Ph.: 243032 • **Eye Collection Centre**, District Head Quarters Hospital, **Karim Nagar**, Ph.: 2262478 • **Dr. Smita Sriman Memorial Eye Bank**, Sudarsani Eye Hospital, Kothapet Main Road, **Guntur**-522001, Ph.: 2220028 • **Indian Red Cross Society Eye Bank**, Near Govt. General Hospital, Opp. Ravi Talkies **Kurnool**-518002, Ph.: 255347 • **N.J.R. Eye Bank**, Rose Trust, QTR. No-98-B, Sector-I, Ukkunagaram, **Visakhapatnam**-530032 • **Badam Balakrishna Eye Bank**, 34-1-8, Temple Street, **Kakinada**-533001, Ph.: 2379184 • **Lions Manibai Bhagathram Gupta Eye Bank**, Lions Dundoo Eye Institute, 10-1-254, West Marredpalli, **Secunderabad** - 500026, Ph . : 27802124 • **Narayana Medical College Hospital & Eye Bank**, Narayana Medical Institutions, Chintareddypalem, **Nellore**-524002, Ph.: 2317966 • **Jnanananda Eye Bank Association**, Jnanananda Ophthalmic Institute, Mayur Town, Railway Station Road, P.O. Siva Rao Pet, **Bhimavaram**-534202, Ph.: 223321 • **Swargdham Cornea Collection Centre**, A unit of Lions Club of Medchal Charitable Trust, B/H-Job bank, Madhavi Nagar Colony , Alwal, **Secunderabad** • **Red Cross Society Eye Donation Center**, IRCS & INTAC BUILDING, BESIDE-I-Town P.S. Potti Sriramulu Jn. Old Bus Stand **Srikakulam**, Ph.: 226555

ASSAM

• **Jeuti Eye Bank**, Chandra Prabha Eye Hospital, K.K. Handigüe Road, Jorhat-785001, Ph.: 2304500 • **Lions Drishti Eye Bank**, Amolapatty Railway Gate, Dibrugarh-786001, Ph.: 2320507

ANDAMAN & NICOBAR

Department of Ophthalmology, DBCS DHS G.B. Pant Hospital, **Port Blair**-744104

BIHAR

• **Piyush Eye Bank**, Pujya Tapaswi Sri Jagjeevanjee Maharaj Chakchu Chikitsalaya, **Petarbar-Post**-829121, Ph.: 265609 • **Dr. Kashyap Memorial Eye Bank**, C/o Kashyap Eye Hospital, Purulia Road, **Ranchi**-834001, Ph.: 651301198

CHANDIGARH

• **Department of Ophthalmology P.G. Institute of Medical Education & Research Centre, Chandigarh-160012**, Union Territory of **Chandigarh**, Ph.: 2747837 • **Command Hospital**, Western Command, **Chandigarh-160022**, Ph.: 867549 • **Department of Ophthalmology**, Govt. Medical College & Hospital, Sector-32, Level-IV, B-Block, **Chandigarh-160022**, Ph.: 2607707 • **Eye Bank Society**, Eye Department, P.G. Institute of Medical Education & Research Centre, Ph.: 172544589 • **Chandigarh Eye Bank**, C/o Grewal Eye Institute, SCO 166-169, Madhya Marg, Sector 9C, Ph.: 2747118 • **City Eye Bank Chandigarh**, SCO-833-834, Sector-22A, Ph.: 3099731

DELHI

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• **Department of Ophthalmology**, LLRM Medical College, **Meerut**, Ph.: 2763133 • **Eye Department, OIC**, Army Medical Corps, **Meerut Cantt-250001**, Ph.: 696535 • **Varanasi Eye Bank Society Sah Modern Clinic**, K-16/102, Bulanala(East), **Varanasi - 221001**, Ph.: 2333272 • **Eye Bank-Gandhi Eye Hospital**, Dr. Mohan Lal Memorial Gandhi Eye Hospital, Ram Ghat Road, **Aligarh-202001**, Ph.: 2505968 • **Eye Bank Dhampur**, Nagina Road, **Dhampur-246761**, Ph.: 20222 • A-1040, Indira Nagar, **Lucknow-226016**, Ph.: 2347930 • **Sarfrazganj**, Moosabagh, Picnic Spot, Hardoi Road, **Lucknow-226003**, Ph.: 2248122 • **Lucknow Eye Bank**, Precision Eye Care, B-145, Sector-A, Mahanagar, **Lucknow**, Ph.: 2381919 • **Denaji**

Eye Bank, Rajani Eye Care Centre, Parkar College Road, **Moradabad-244001**, Ph.: 2317975 • **Indian Medical Association**, Banaras Branch, C7/31, Chetganj, I.M.A. House, **Varanasi-221001**, Ph.: 2354197 • **ICARE Charitable Eye Hospital & P.G. Inst. Glucoma Research Centre**, E-3A, Sector-26, **NOIDA-201301**, Ph.: 4068800 • **Sahyog Viklang Seva Sansthan**, 426-9, Lalkothi Baruzai, **Shahjahanpur-242001**, Ph.: 222472 • **B.H.U. Eye Bank**, Deptt. of Ophthalmology, Institute of Medical Sciences, Banaras Hindu University, **Varanasi-221005**, Ph.: 2307590 • **C.L. Gupta Eye Bank Welfare Society**, C.L. Gupta Eye Hospital, Swami Vivekananda Road, Opp-Govt. Polytechnic, **Moradabad**, Ph.: 2450681 • **Ganga Mata Charitable Eye Hospital & Research Institute**, Sapt Rishi Link Road, **Hardwar-249410**, Ph.: 260190 • **SRMS Eye Bank**, Shri Ram Murthi Smarak Trust, N-3, Rampur Garden, **Bareilly**, Ph.: 2582014 • **Department of Ophthalmology**, King George's Medical University Chowk, **Lucknow-226003**, Ph.: 225840 • **Eye Bank & Keratoplasty Centre**, C/o. Commandant, Command Hospital (CC), **Lucknow**, Ph.: 2296548 • **Roshni Eye Bank**, Flat No-7, Guru Nanak Marke, Ambala Road, **Saharanpur-247001**, Ph.: 2663779 • **Institute of Ophthalmology**, J.N.Medical College, Aligarh Muslim University, **Aligarh-202002**, Ph.: 2504576 • **Raj Eye Bank Association**, C-168/18, Near Jhankar Cinema, Naseerabad, Saraidhola, **Gorakhpur**, Ph.: 2292340 • **Post-Pharsar**, Barhalganj, **Gorakhpur**, Ph.: 2325055 • **Apex Eye Hospital**, Polytechnic Chouraha, **Jaunpur - 222002**, Ph.: 69532 • House No. 491, Near Water Tank, Brahm Puri, Fafran Road, **Modi Nagar - 201204**, Ph.: 245542 • 94, Civil Lines, **Sitapur**, Ph.: 242769 • **Rajbahadur Singh Smarak Jan Kalyan Seva Sansthan**, 187, Raghav Nagar, Deoria, Ph.: 222029 • **Jankikund, Chitrakoot - 210320**, Ph.: 265330 • **Agrasen Chowk**, Masani Chouraha, **Mathura**, Ph.: 2401665 • 165, Nehru Nagar, Near Shree Talkies, **Agra-282002**, Ph.: 2156515 • **S.N. Medical College, Agra**, Ph. : 2530619 • **Lohandi Kalan**, Rewa Road, **Mirzapur-231001**, Ph.: 245200 • **Swaroop Nagar, Kanpur-208002**, Ph.: 294134

UTTARAKHAND

• **Jolly Grant**, Doiwala, **Dehradun-248140**, Ph.: 2412081 • **Shree Swami Bhumanand Charitable Eye & Dental Hospital & Research Institute**, Bhuma Niketan, Nyassanstnam, Sapt Sarowar Marg, **Haridwar-249410**, Ph.: 260722 • **Gandhi Satabdi Eye Hospital**, 2-C, Preetam Road, Dalanwala, **Dehradun-248001**, Ph.: 2654279 • **Ganga Mata Charitable Eyes Hospital & Research Institute**, Sapt Rishi Link Road, **Hardwar-249410**, Ph.: 260190

WEST BENGAL

• **Gujarati Relief Society Mukta Eye Bank**, 20, Pollock Street, **Kolkata-700001**, Ph.: 33255188 • **International Eye Bank, Calcutta**, AD-202, Salt Lake, **Kolkata-700064**, Ph.: 23585758 • **Prova Eye Bank**, B.C.Memorial Eye Foundation, Disha Eye Hospital & Research Centre, 88 (63A), Ghosh Para Road, **Barrackpore-700120**, Ph.: 25931729 • **Howrah Lions Hospital (Unit of Corneal Grafting)**, 9, Nityadhan Mukherjee Road, **Howrah-711101**, Ph.: 26605470 • **Regional Institute of Ophthalmology**, Medical College & Hospital Campus, **Kolkata-700073**, Ph.: 2413853 • **Midnapore Eye Bank & Eye Care Unit**, Adibasipare, Prembazar, P.O. Hijli Co-Operative **Kharagpur-721306**, Ph.: 2277331 • **Eye Bank-Command Hospital**, Eastern Command, Alipore Road, **Kolkata-700027**, Ph.: 22226391 • **Serampore Seva Kendra & Chakshu Bank**, 51, Thakurdas Babu Lane, **Serampore-712201**, Ph.: 26524612 • **Vanmukta Eye Bank**, Susrut Eye Foundation & Research Centre, HB-36/A/1, Sector-III. Salt Lake, **Kolkata-700091**, Ph.: 23580201 • **Ramraja Nabin Sangla Eye Bank & Seba Kendra**, 31, Ram Charan Seth Road, Santragachi, **Howrah-711104**, Ph.: 26272995 • **Lions Eye Bank & Visual Care Centre**, 118, Raja Ram Mohan Roy Sarani, **Kolkata-700009**, Ph.: 22414168 • **Siliguri Lions Eye Bank**, Siliguri Lions Netralaya Hill Cart Road, Near Mahananda Bridge, **Siliguri-734403**, Ph.: 2511004 • **Prayash Atreyee Eye Bank**, Raghunathpur, Post-Beltalpark, **Balurghat-733103**, Ph.: 255989 • **Siliguri Greater Lions**

Eye Bank, 2-Mile Sevoke Road, B/HV Vaishali Cinema Hall , **Siliguri** - 734402, Ph.: 2543301 • **M.P. Birla Eye Donation Centre**, C/o M.P. Birla Eye Clinic, 8-Floor, Maruthi Building, 12, DR. U.N.Brahmachari Street, **Kolkata**-700017, Ph.: 22817780 • **Basirhat Chowmatha Sebyan Eye Collection Centre**, Sir R.N.Mukherjee Foad, Chowmatha, **Basirhat**-743411 • **Netraloke Eye Collection Centre**, P.O.Taki, **Taki**-743429 , Ph. : 233003 • **Red Cross Eye Collection Centre**, Indian Red Cross Society, Madhaitala More, **Katwa**-713130, Ph.: 257308 • **Alokdisha Eye Collection Centre**, Than Road, Tarakeswar, **Hooghly**-712410, Ph.: 276080 • **Atul Ballav Eye Bank**, Department of Ophthalmology, N.R.S. Medical College & Hospital, **Kolkata**-700014.

* The list of Eye banks is an extract from the list maintained by the Eye Bank Association of India.



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