

# **TRANSPLANT POLICY MANUAL**



**TRICHY SRM MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE**

**SRM NAGAR, IRUNGALUR, TRICHY (DISTRICT) - 621 105**



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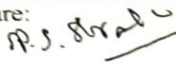


TRANSPLANT POLICY MANUAL

ISSUE NO.

01

**TRANSPLANT POLICY  
MANUAL**

**TSRMMCH&RC/TR/55**

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### AMENDMENT SHEET

<b>No.</b>	<b>Section and Page</b>	<b>Date</b>	<b>Amendment</b>	<b>Signature</b>

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### **1.PURPOSE**

This is purpose of organ transplant programme in consonance with current and established good practices.

### **2.SCOPE**

The scope of this manual to follow the process, responsibilities and Monitoring mechanisms by each department(s) where the organ donation programme is implemented

### **3.RESPONSIBILITY**

Transplant coordinator, Consultants and who are all involving in the process

### **4. POLICIES AND PROCEDURE FOR ORGAN TRANSPLANT PROGRAM**

#### **a. Donor identification**

The more donors we identify, the more we are likely to lose but still have a sufficient numbers to meet demands for organs. If we want to have successful conversion of all donors then we have to identify them early and manage them well. This can be only done if you are an ICU staff. It is best to build a rapport with the ICU staff and do daily rounds



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to know if there are any potential deceased donors. If the ICU staffs are sensitized to the cause they can telephone to a coordinator if this happens in out of hours.

**b. Donor Screening**

It is important to screen potential donors for serious diseases such as malignancy or infection that could be transmitted to the recipient. Since there is a serious shortage of donors we now tend to accept elderly patients and donors with hypertension and diabetes and sometimes even viral diseases-a pool that was not accepted as donors previously (extended or expanded donor criteria). We have to create a balance between accepting organs and tissues that are not good enough and not turning down that are sufficiently be used. The screening tests are mentioned in the brain death chapter.

**c. Donor Management**

Proper maintenance of donors is extremely important for procuring viable organs. Please see chapter on brain death.

**d. Consent**

In India informed consent is valid, which means that relatives always have to give consent for retrieval of the organs. They will be consulted to help evaluate the attitude of the deceased to donation, which can be positive , negative or unknown.

**e. Organ Retrieval**

Good routines facilitate the procedures and minimize organ damage during the procurement operation. An ethical issue is what should be done with an organ that in spite of all precautions is not useable. If the organ gets damaged beyond repair-as happens



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sometimes during retrieval surgery, if cannot be used anymore. But if it is damaged and can be repaired, should you use it

In own institution or can it be sent to another centre with a discussion with the surgeon  
There are centres that use organs that have been discarded elsewhere with good result.

### **Arranging for Organ Retrieval Surgery**

- Surgeons have to be informed and arrangements for retrieval have to be made.
- Simultaneously, arrangements for recipients have to be made.
- Blood samples for cross matching have to be taken.
- When the recipient has reached the hospital and all parameters match, the deceased person is taken to the operation theatre and retrieval surgery will start.
- The transplant coordinator thanks the family and assures them that they can always contact him/her for questions or doubts.
- After transplantation has been carried out, ensure that the donor family receives a letter of appreciation or a certificate thanking them for the organ donation (can be done on the same day or after several days/weeks).

### **f. Post mortem formalities**

If a post mortem is required this has to be arranged after organ retrieval. Ensure all organs removed have been listed in the form provided to forensic department. Police procedures may delay handing over the body to relatives and this may cause undue anxiety and often out-bursts of anger. The relatives generally feel that once they have done this selfless act a lot of paper work can be done away with.

### **g. Counselling and consent**

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In the hospital, brain death has to be certified by two involved and two non-involved medical practitioners.

- The hospital informs the transplant coordinator about the brain dead case.
- The transplant coordinator gathers all information about the patient.
- The transplant coordinator will be introduced as a social worker to the family members of the brain dead patient.
- In a separate room (to assure privacy) the coordinator counsels the family members about the possibility of organ donation (in a separate conversation; not at the same time as the news of brain death)

**h. If the family agrees for donation:**

- At an interval of 6 hours after the first brain death declaration, a second declaration has to be carried out according to Government Form no 8. After this a death summary has to be prepared.
- The family has to give consent for the donation by signing Government Form no 6 or 9.

**i. Procedures to be followed depending on the circumstances**

- If it is a medico-legal case (in case of an accident), the concerned police has to be informed. The forensic expert has to be called for a post-mortem report. If possible the post mortem should be done at the same time as the organ retrieval. If the post mortem is not done in the retrieving hospital, then the body has to be sent for post mortem.
- If a hospital hasn't got a qualified team of surgeons at its disposal for certain transplants (for example liver), surgeons from other hospitals can help.

Only the organs for which the consent has been given can be retrieved

**j. Flow of Cadaver transplant and harvesting protocol**

- Brain dead to be declared/Confirmed by neurosurgeon/neurophysician and they have to inform transplant co-ordinator regarding the brain dead patient.
- To check the blood group.
- Counselling to patient attenders.



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- Family consent.
- Dead declaration intimation to Medical records department and intimate the police.
- To started 1st apnoea test, if positive, inform to cadaver transplant program.
- After 6 hours 2nd apnoea test, to confirm the brain dead.
- CPT allotted to the hospital and co-ordinate the patient results and harvesting plans.
- To co-ordinate transplant team.
- MRD following the police intimation and procedures.
- CPT allotted the hospital to receiving the letter and cadaver transplant approval copy.
- Patient shift to OT, after harvesting plan for post mortem.
- To arrange transport for organs shifting.
- Post mortem doctors to check the body and shift to Govt hospital following post mortem.
- After post mortem body handover to patient attenders.
- All documented to submitted in Medical records departments.

**k. Flow of Cadaver transplant (kidney) receiving from other hospital**

CPT inform to Transplant co-coordinator, potential brain dead donor in this hospital. To check the patient blood group

- To intimate the Nephrologist.
- To check the awaiting patient list.
- If our hospital seniority and decided taken for organs.
- To arrangements of recipient.
- To check blood cross matching.
- Recipient patient to be decided through nephrologist.
- To arrangement of transplant team and operation theatre.
- Transplant Co-ordinator and staff nurse from the OT are required for collecting the cadaver organ from other places.





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- To follow up recipient consent.
- Recipient patient get admitted and shift to OT.
- To co-ordinate the transplant team.

## 5. LEGAL REQUIREMENTS

Consent Forms in Transplantation of Human Organs Rues, 1995 to be followed

Authority for removal of human organ- Any donor may authorize the removal, before his death, of any human organ of his body for therapeutic purpose as specified in forms 1(A), 1(B) and 1(C). The new forms have been made more comprehensive and are to be submitted with proof of identity and address, marriage registration certificate, family photographs, etc. With attestation by a Notary Public.

The gazette states that a medical practitioner before removing a human organ from the body of a donor before his death, should satisfy himself-

- That the donor has given authorization in
  - \_ Form 1(A), if “near relative” i.e. mother/father/brother/sister/son/daughter.
  - \_ Form 1(B), if spouse.
  - \_ Form 1(C), if other than near relative.
- That the donor is in proper state of health and is fit to donate the organ. The registered medical practitioner should then sign a certificate as specified in Form 2.
- That the donor is a near relative of the recipient as certified in Form 3 and has signed Form 1(A); 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 fact of near relationship, has been examined to the satisfaction of the Registered Medical Practitioner i.e. In-charge of transplant center.
- 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



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- submitted an application in Form 10 jointly with the recipient and that the proposed donation has been approved by the concerned competent authority.
- In case of a donor who is other than a near relative has signed Form 1(C), submitted an application in Form 10 jointly with the recipient, and permission from the Authorization committee for the said donation has been obtained.

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

- That the donor had, in the presence of two or more witnesses(at least one of whom is a near relative of such person), unequivocally authorized as specified in Form 5 before his death, the removal of the human organ of his body, after his death, for therapeutic purposes and there is no reason to believe that the donor had subsequently revoked the authority aforesaid;
- That the person lawfully in possession of the dead body has signed a certificate as specified in Form 6.

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

- That a certificate as specified in Form 8 has been signed by all the members of the Board of Medical Experts.
- That in the case of brain-stem death of person of less than eighteen years of age, a certificate specified in Form 8 has been signed by all the members of the board of Medical Experts and an authority as specified in Form 9 has been signed by either of the parents of such a person.

(Note the previously available Form 7 for consent in the THO act is no longer valid)

### **Donor Card Concept**

To express the wish to donate organs after death, one can carry a 'Donor Card'. This is a universal organ donor card for all organs- unlike the Eye pledge cards. The next of kin needs to be informed about the wishes of donation. It is one way of putting Form 5 of



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THO act into action. One should remember that despite carrying the card when it actually comes to organ donation after death the family would be asked for consent as in India we follow the informed consent principle. One may wonder then as to the role of such a card. In fact, the card serves many purposes as follows-

- The next of kin or relative knows about the wishes of the person.
- The card helps doctors broach the subject of organ donation with the family in the hospital.
- The person becomes a public advocate of organ donation when they carry it in their wallet as many people are likely to notice it.
- The card also carries important information such as the blood group and emergency contact details of the person.

## **6. GRIEF COUNSELLING**

### **a. Counselling of recipient and donor**

**At every stage there are ethical issues that have to be considered.** Many questions arise that cannot be answered easily. It all depends on time, place and other circumstances.

#### **The Deceased Donation Conversation Factor**

### **b. Discussing death**

Most people need honest and accurate information regarding the status of a patient. People communicate their fears and concerns in many ways: crying, yelling, ignoring others, seeking information from others, and writing letters. **These feelings of sadness, confusion, anger, and fear are all acceptable.** It is essential to react in an appropriate way to these emotional reactions and to connect with whatever the relatives want to tell or ask.

It is important to understand that **each person and family is different. Give that different cultures have varying beliefs about, there is no single right way to discuss death.** In general, an open communication style atmosphere allows the family members to



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express their fears and desires. **The ultimate goal in discussing death with the family of a deceased person is to optimize their comfort and alleviate any fears.**

let the family know you are ready to talk to them whenever they re ready for it. Forcing information will usually result in anger, distrust, and emotional distance from others.

Waiting until someone is ready to handle the situation will allow for better communication. For the purpose of organ donation, counselling the family is something that has to be done within a short period of time. **However, the relatives will most likely be in a state of grief and denial.** Below, the different stages of grief will be described.

### c. Different Stages of Grief

Grieving is a normal response to a loss. The grieving process varies from person to person in terms of the order in which one deals with the stages of grief, as well as the time it takes to go through the stages of grief. Spouses of the deceased, children, parents, siblings, and other family members will all experience grief. Grief is usually divided into five stages, described by

**Denial:** "This can't be happening to me."

Denial is a stage where people try to believe that the event is not happening to them or their family. **They refuse to accept facts, information \, reality, etc.,** relating to the situation concerned. One may feel numb, or in a state of shock. Denial is a protective emotion when a life event is too overwhelming to deal with all at once. It's a defence mechanism and perfectly natural.

**Anger:** "Why is this happening? Who is to blame?"

Anger is a stage in which you understand the demise but are very upset and angry that it has happened to your friend or family member. One of the best ways of dealing with bursts of anger is to exercise or participate in another type of physical activity. Talking with



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family and friends, other people who have gone through the same process, and the hospital staff may also be helpful.

**Bargaining: “Make this not happen, and in return I will climb the seven hills of Tirupati by foot or will make a big donation to a poor home and so on.....”**

Questioning God, asking “Why us?” and “What did we do to deserve this?” are common questions in this stage. It is normal for the family of the deceased person to make bargains with themselves or God, in the hope that this will make the event to be undone. Guilt is a primary emotion during this stage. Searching for something that you personally did. Which could have contributed to the death, is all part of bargaining. People tell themselves or God that they promise not to do something they previously did (such as arguing with family members), or to start doing something they have not done (such as going to church regularly) in exchange for their did that contributed to the death. It is one’s fault.

**Depression (and sadness): “I’m too sad to do anything.”**

This is a stage in which the death can no longer be denied and those involved may feel a profound sense of sadness. This is normal. It can be accompanied by physical changes such as trouble sleeping or excessive sleeping, changes in appetite, difficulty with concentrating on simple daily activities, or feeling a constant fear that something will happen to someone else in the family. It can be helpful to talk about depression with a healthcare professional such as a social worker, or counselor, or meet with a support group to help you cope with your feelings.

**Acceptance:”I’m at peace with what is going to happen/has happened.”**

Acceptance is a stage in life. You have made an adjustment to the loss. This does not mean that you will never feel the loss, but you have accepted the death and are at a point where it has been incorporated as part of your other emotions. Usually families find that they are better able to manage their lives overall upon reaching this stage. Going through the



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grieving process is the best way to cope with a death. By giving yourself and your family permission to grieve, you will be able to cope.

The way of reporting the death to the family and the moment at which the topic of organ donation is broached exerts great influence on the experience of the donation procedure. Disappointment, anger or frustration with regard to the procedure should be prevented by handling the situation as carefully as possible.

It is important, for example, to have clarity when explaining brain death and how the doctor or nurse reacts to the relatives' emotional outburst. **Relatives respect calmness in the conversation, attentiveness from doctors and nurses, and they need to be treated with respect.** Also, they prefer no medical jargon to be used. These interactions need to always be done courteously and credibility needs to be established over a period of time when the relatives are going through extreme grief.

Unless-the family comes forward to donate the organs of their loved ones, it is better to raise the issue of organ donation after declaration of death after the initial period of grief and shock starts sinking in. Relatives generally indicate that they often get too little time to realize that their beloved one has passed away. They appreciate it if they are not pressurized to decide quickly about the donation request. When they get the opportunity to say goodbye in their own manner, they will look back on the donation procedure with more satisfaction.

#### **d. Request for donation**

Before organ donation can take place, family consent has to be given. This is the most important, but also the most sensitive and difficult step in the process. Depending on this will depend the lives of many potential recipients

The movement to ask for donation can be difficult to pick especially in a situation like road traffic accident where time is the essence. You cannot wait too long after the first declaration of brain death as most cadavers are unstable and will generally collapse. But



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on the other hand you don't want to approach the family at the wrong time. Therefore, the first thing to do is to observe the state of the family. **The counselor should avoid making a request for organ donation when the family is in the stage of anger, denial or bargaining. It is best to be with the family right from the time a serious patient is admitted to the intensive care unit and counsel all patient's family irrespective of brain death. Such an ICU counselor is the best person to ask for consent for organ donation and will understand the family better.**

To start the conversation, it is always good to ask the family what happened and show compassion for their loss.

In the next step it is good to repeat the explanation of brain death, to ensure that the family has understood it and create a rapport with them at the same time. Because eye donation has become quite common in India, it is logical to start with a request for the eyes.

Subsequently you can proceed with explaining about organ donation and make the request for the organs. You should always communicate gently and offer options without any pressure. If the family agrees you can take the family consent on form no 6 or 9.

**Some do's, don'ts conversation tips and frequently asked question are listed below**

#### **Do's**

- Arrange for a room with privacy for the family.
- Identify next of kin or decision maker of the family and talk to them. In India it is usually a male member.
- Sometimes it is better to talk to them as a group as there maybe dissenting members in the family who are against organ donation- on the spot judgment often required.
- Be yourself and be spontaneous.
- Make the family feel comfortable (get water and food if desirable)
- Act without bias regarding religion and financial status
- Show compassion for those in grief
- Explain everything repeatedly



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- Listen well to what the family wants to tell and ask
- Overcome myths
- Express acceptance and give them support anyhow
- Give them enough time to think
- Stay with the family till the body is handed over

**e. Conversation tips**

- Donation is an opportunity to help others
- It's the only hope for many patients
- Death can bring something positive in this way

**Don'ts**

- Ask for donation directly after news of death
- Give false promises regarding time of giving back the body
- Force to donate
- Show pressure of time
- Show irritation in case of a 'no'

**f. Personal Appearance-**

**For Women-** Don't wear too much make up if a women counsellor, avoid too much jewellery, perfumes and flashy or revealing clothes. Avoid sleeveless, avoid jeans.


**For men-** Be shaved, wear shoes and wear light coloured cloths that are clean and pressed. Avoid jeans.

Don't be shy to make eye contact with relatives.

**Responsibility**

The counsellor is responsible for organizing and coordinating the counselling of the family members of the possible donor and arranging everything for the organ retrieval to be carried out. The concerned hospital is responsible for providing overall direction to the activities to be carried out regarding the transplantation surgery.



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## 7. Recipient Counselling

Besides counseling family members of a brain dead patient, the recipients have to be counseled as well. They have to be prepared for the transplant in all respects. In case of a cadaveric transplant the time of availability of an organ will never be predictable, so the patient always has to be 'ready to go'. For them it is very important to know how to cope as effective as possible with their illness before the transplant, and furthermore they need guidance in and explanation on:

- Registration on the waiting list and consequences: how far from home can you go, how often do you have to visit the hospital?
- Medication after the transplant: what are immunosuppressants and how long to take them?
- Financial preparation: what will be the costs of the transplant, and afterwards for medication.
- Unplanned nature of transplant
- Waiting period & priority
- Way of organ distribution
- Regular follow up & pre-operation tests
- Inform about changed contact numbers
- Support group of listed patients

## 8.ANNEXURE

- Transplant File

## MEDICO-LEGAL, ETHICAL, SOCIAL ISSUES INVOLVED IN ORGAN TRANSPLANTATION

### ETHICAL ISSUES:

**Medical integrity:** Patients and the public must be able to trust their doctors not to sacrifice the interest of one to that of another. Individual may make that sacrifice, but not their doctors.

**Scientific validity:** The basic biology and technology must be sufficiently assured to offer a probability of beneficial outcome, case by case.

**Consent:** based upon information adequately presented, weighted, understood, unforced.

### **There are certain ethical principles evolved to suggest that transplantation would be ethical**

The removal of the tissue or organ does not impair the health or functional integrity of the Donor.  
The benefits expected to be given to the recipient bear an acceptable proportion to the harm likely to the Donor.

The donation should be altruistic and given without any coercion or any other form of external pressure.

The Donor must be fully informed of the nature of the procedure and possible complications.

Follow-up of the donor's health is essential.

The views of close relatives, spouse or adult children is accountable.

There must be no element of commercialization, exploitation in the donation.

### MEDICO-LEGAL ISSUES:

The Organ Transplantation Act –GOI 1994 has undergone major, minor changes in the form of addition of rules, amendments to make it acceptable legally.

### Offences & Punishments:

Punishment for removal of human organ without authority:

- Imprisonment for term or 2 to 5yrs, fine up to Rs.10,000 / to Rs.20,000 /-
- A Registered Medical Practitioners name will be removed from the Council for a period of 2yrs first offence and permanently for subsequent offence.

Makes or receives any payment for supply of or for an offer to supply any human organs or selects a person or involves in negotiation.

- Publishes or distributes any advertisement

### SOCIAL ISSUES:

Many social issues need to be considered when promoting organ transplant in the community.

-The first misconception that needs to be corrected is the perception that the body of the donor would be mutilated and treated badly. whereas the organs would be removed surgically in a routine operation.

- The second misconception that even if the person wanted to donate one organ, that other organs would also be taken. Counseling done that only organs specified for donation will be taken from the body

- The third misconception is that if a person was involved in an accident, the doctors would not save his life, if they knew that he was a Donor. Doctors at the accident unit are different from those in the transplant Team. The Organ Procurement Team would only be notified after all lifesaving efforts had failed ,after death declaration , family had consented to organ donation. The fourth misconception is that a person's religion do not approve donation. Generally, all organized religions, support organ donation, as it is typically considered a generous act.

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