Consenting—An experience from Homograft Valve Bank Programme at SCTI MST, TVM

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DEPUTY MEDICAL SUPERINTENDENT
SCTIMST
TRIVANDRUM
The Institute started the Homograft Valve Bank project in 2006 in collaboration with Medical college, Thiruvananthapuram for harvesting Cardiac valves from the dead bodies undergoing post mortem examination in the mortuary of department of Forensic Medicine.
A Memorandum of Understanding G. O. (MS) No. 22/05/ H&FWD Dtd 19/01/2005 was signed between Sree Chitra Tirunal Institute for Medical Sciences & Technology and Medical College, Thiruvananthapuram for establishing the Homograft Valve Bank at SCTIMST as per the approval of the Government of Kerala.
Licence to carry out Organ Transplantation

- The Certificate of Registration for Carrying out Organ Transplantation was granted by Government of Kerala to the Institute valid for five years w.e.f. 14-11-2006.

- Subsequently the certificate was renewed for another five years w.e.f. 07/12/2011.
Team

• Dr. K. Jayakumar
  Sr.Prof & HOD Dept of CVTS, PI Proj. # 5199

• Dr. Molly Antony
  Scientist G, Dept. of Microbiology, Co PI Proj. # 5199

• Dr. S. K Jawahar
  Deputy Medical Superintendent, Co-Investigator Proj # 5199

• Mrs. Beena B Pillai
  Transplant Co-ordinator

• Mrs. Cinta Rose
  Lab Technician

• Mr. Rejith Ismael
  Project Attendant
Criteria for consent

The Homograft Valve Bank Co-ordinator, who is appointed for coordinating the process of consent taking visits the mortuary, of the Forensic Dept, Medical College, Thiruvananthapuram on a regular basis. Majority of medico-legal postmortems from the districts of Thiruvananthapuram & Kollam in the state of Kerala are carried out at this mortuary. The Homograft Valve Bank Co-ordinator approaches the relatives of deceased based on the following criteria:

Criteria for the valve harvest

- Age < 55
- Death within 24 hours
- Death due to Road Traffic Accident, hanging & fall from height
- No septicemia, cancer or communicable diseases
- No serological evidence of HIV, HCV or syphilis
- Not a transplant recipient or hemophiliac
- No Marfan’s syndrome or evidence of collagen vascular disease
- No prior irradiation to chest area
- No dementia or neurodegenerative disease
Harvest procedure

- Once the consent is given by the immediate relatives, doctors from the cardiac surgery department are informed about the probable time of harvest.

- Harvest is done prior to postmortem using sterile precautions at the mortuary of Medical College, Tvm. The heart is then transported to the Homograft valve Bank of the Institute where they are trimmed and sized.
Processing & Sterility Checking

- The homograft valves collected are subjected to bacterial and fungal culture for thirty days to ensure that it is sterile and safe to be implanted in patients.

- The blood sample collected from the donor body is screened for HIV, HBsAg, HCV & VDRL.
Cryopreservation of Homograft Valves

• The Valves collected are stored initially at 4°C in the refrigerator for 72 hrs after which they are gradually freezed from 4°C to
• -150°C using the Yorkshire Regenar Tissue Banking programme of freezing and preserving the heart valves.

• These valves are then transferred to the storage vessel containing LN2 at -196°C.

• The valves thus freezed and preserved have a shelf life of five years.
Clinical Implantation of Homografts

- Homograft valves conduits is a necessity to achieve correction of certain complex congenital heart defects.
- The first surgical correction using homograft in a patient with cardiovascular disease in the state was initiated at the Sree Chitra Tirunal Institute for Medical Sciences and technology on 20th Dec 2011.
- A total of 47 patients have been operated using homografts. This has widened the spectrum of cases being offered treatment at our institute in Pediatric Cardiac Surgery.

Ms. Sini, the first recipient of the Homograft Valve along with the Homograft Valve Bank Team on December 20, 2011.
### No. of procedures performed using Homograft Valves

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number</th>
</tr>
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<tbody>
<tr>
<td>Pulmonary valve replacement</td>
<td>10</td>
</tr>
<tr>
<td>RV to PA conduit</td>
<td>4</td>
</tr>
<tr>
<td>Rastelli procedure</td>
<td>14</td>
</tr>
<tr>
<td>Aortic root replacement</td>
<td>3</td>
</tr>
<tr>
<td>Conduit replacement</td>
<td>1</td>
</tr>
<tr>
<td>Truncus Arteriosus</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>35</strong></td>
</tr>
</tbody>
</table>

![Pie chart showing the distribution of procedures](chart.png)
Implantation Details

• Since the inception of homograft valve at Sree Chitra Thirunal Institute of Medical science and technology on 20th Dec 2011, when the first homograft conduit was implanted, 46 more patients have received the benefits of homograft implantation.

• Out of the 47 patients who have received homograft tissue for correction of their complex cardiac condition, 35 patients received it as valved conduits and in 7 patients homograft was used as a patch.
Follow Up

All patients who underwent homograft valve placement are being followed up and are clinically fine and the homografts are functioning well as assessed by echocardiography.

The number of homograft procedures are expected to rise in the coming years as we start operating on more complex cases.
CONSENT

Donor( Relative of Deceased)
Ethics Committee - Medical college, TVPM-dtd. 28/08/2003

• To submit the consent form with certain modifications.
Ethics Committee - Medical college, TVPM- dtd. 29/10/2003

• Clearance was granted for the Homograft valve bank project after the consent form was submitted with modifications as suggested by the ethics committee on 28/08/2003.
P.I should submit the following:

- The details of the mechanisms to be followed for obtaining informed consent
- The persons involved in obtaining consent
- Replacement of the word “Charitable” with “non-profit” in the protocols and the Informed consent forms.
Procedures for obtaining the informed consent from children who undergo the valve replacement

The consent form should be written in simple language so that it is easily understandable by a common person.

Ethics Committee - SCTI MST suggestions dtd. 02/08/2004
INFORMED CONSENT FORM

I ............................................. F/o, M/o, S/o, D/o, W/o, H/o, Sis/o, Br/o
............................................. aged .......... resident of
............................................. having lawful possession of the dead body of
Mr./Ms. ............................................. F/o, M/o, S/o, D/o, W/o, H/o, Sis/o, Br/o
............................................. aged .......... years, resident of ............................................. hereby
consent to the procedure hereinafter elucidated, after having fully comprehended the
implications and stipulations resulting from such a consent.

I have been informed that the Sree Chitra Tirunal Institute for Medical
Sciences and Technology and Medical College, Thiruvananthapuram have jointly
formulated a blueprint to harvest apparently normal heart valves and accessory parts of
the heart under international scientific regulations prevailing from time to time,
by due technical process, during the medico-legal autopsies conducted at the
Thiruvananthapuram Medical College. I also understand that the heart valves and
parts so harvested, will be processed and kept in the proposed Homograft Valve Bank
in SCTIMST and thereafter dispersed without profit intent to clinical use in cardiac
surgical patients in SCTIMST, Institutions controlled by the Directorate of Medical
Education, Kerala and other heart surgery centers formulated on philanthropic intent.
I have known that the deceased (Name)............................................. during
his lifetime, or any near relatives of the said deceased have not expressed objections
to the therapeutic use of the body parts of the deceased after death in patients.

I hereby permit the concerned doctor to go ahead with harvesting the heart
valves and parts of the heart for the above mentioned therapeutic purposes on other
patients and I further add that in arriving at this decision to give this consent, I was
not influenced by any reward, financial or otherwise.

I also agree that, in the event of the harvested heart valves and accessory
parts not achieving quality assurance as evaluated by biotechnological means, the
hospital authorities may dispose them off suitably the said parts of hearts, without
further notification to me and without any further consent from me.

I also understand that this process of harvest of heart valve and accessory
parts will in no way compromise the regular steps, process, protocols, outcome and
deductions which emanate from a medico-legal autopsy.

This donation had been made out of my free will, without any sort of
prejudice, influence or coercion.

<table>
<thead>
<tr>
<th>Name and Address</th>
<th>Signature of the person in lawful possession of the body</th>
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Place:

Date:

Name & Signature of one or two witnesses:

<table>
<thead>
<tr>
<th>Witness I</th>
<th>Name and Address</th>
<th>Signature</th>
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<th>Witness II</th>
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This consent will be obtained from a near relative.
For the purpose of this consent, near relative implies 1) Father 2) Mother 3) Husband
4) Wife 5) Son 6) Daughter 7) Sister 8) Brother
Consent form approved by the Ethics Committee for Harvest of Homograft valve
വിഭാഗം സംവിധാനം വിഭാഗസംവിധാനം

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<th>1.</th>
<th>2.</th>
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എന്തായാണ്‌ നിയമനം നല്ലതെന്ന്‌ ?

1. താളജലം 2. ജോലി 3. ആധിപത്യം 4. നിയമനം
5. തീർക്കം 6. സാമ്പത്തിക ഭാര്യൻ 8. പാർവ്വതി

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<th>സംവിധാനം</th>
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</table>
Consent-Donor

• Bilingual
• For harvest
• Deceased had no objection for donation
• Philanthropic intent
• Consent to destroy (Unfit)
• Harvest do not influence autopsy
• Free will, without coercion
Transplantation of Human Organs Act 1994

• Relatives who can give consent
  – Father
  – Mother
  – Husband
  – Wife
  – Son
  – Daughter
  – Brother
  – Sister
Amendment THOA - 2011

• Additional Inclusion
  – Grand Parents
  – Grand Children
CONSENT

Recipient
The Consent form should mention that the heart valve is from cadaver

The consent form should not indicate any suggestion that the homograft is the better choice than other valves.

In the Informed consent form it should be mentioned that the homograft may require a repeat surgery after 10-15 years.
Ethics Committee - SCTI MST
DECISION dtd. 10/11/2007

- Modified consent forms in English & Malayalam received on 19/11/2007
- The IEC approves the study.
നിലവിലുള്ള പാരമ്പര്യ ഭാഷകോണ്ടായി നിർമ്മിക്കപ്പെട്ട കേരളത്തിലെ ശാസ്ത്രീയ രീതിയിൽ നിരീക്ഷിക്കുന്നത് മനുഷ്യരുടെ ജീവിതവിശ്വാസം മൂലം നിക്ഷേപിക്കപ്പെടുന്ന വ്യാപ്തിയാണ് നിരീക്ഷണങ്ങൾ നടത്തുന്നത്. ഇത് പ്രകൃതിയിൽ നിന്നും നമ്മുടെ അനുഭവങ്ങളെ സാമൂഹ്യമാക്കുന്നതിനു പ്രളയം കൊള്ളുന്നതാണ്. 

കേരളത്തിൽ മനുഷ്യരുടെ ജീവിതവിശ്വാസത്തിന്റെ പഠനത്തിനു തുക്കമുള്ള ഫലമാണ് കേരളത്തിലെ പാരമ്പര്യങ്ങളുടെ കൂട്ടത്തിലെ പ്രധാനപ്പെട്ട പങ്ക്. ഇത് നമ്മുടെ ജীവിതങ്ങളുടെ പിന്തുണയ്ക്കുവാനും അതിന് സജീവസമ്പന്നമായ അടിസ്ഥാനങ്ങളുടെ സംരക്ഷണത്തിനായി നിരീക്ഷണങ്ങൾ നടത്തുന്നതിനായി കേരളത്തിലെ പാരമ്പര്യം പ്രാധാന്യമേറ്റു. 

വാസ്തുശിൽപ്പശാസ്ത്രത്തെ പാരമ്പര്യത്തിന്റെ പ്രധാനമാർഗ്ഗം പ്രായോഗിക ശാസ്ത്രത്തിലേയ്ക്ക് നന്നായി നിരീക്ഷിക്കുകയും പാരമ്പര്യത്തിന്റെ മനുഷ്യരുടെ ജീവിതവിശ്വാസത്തിന് പിന്തുണയ്ക്കുക. ഇത് വാസ്തുശിൽപ്പശാസ്ത്രത്തിന്റെ പാരമ്പര്യത്തിന് മനുഷ്യരുടെ ജീവിതവിശ്വാസത്തിന് പിന്തുണയ്ക്കുക എന്നതിന് പ്രതിപാദം പറയുന്നു. 

വിജ്ഞാനശാസ്ത്രം മനുഷ്യരുടെ ജീവിതവിശ്വാസത്തിന് പിന്തുണയ്ക്കുക. ഇത് വിജ്ഞാനശാസ്ത്രത്തിന് അനുസ്മരണിക്കുന്നതിനെക്കുള്ള പാരമ്പര്യം പരിശീലനം നടത്തുന്നതിന് പ്രാധാന്യമേറ്റു. 

മനുഷ്യരുടെ ജീവിതവിശ്വാസത്തിന് പിന്തുണയ്ക്കുക എന്നുപ്പോലെ ജീവിതവിശ്വാസത്തിന് പിന്തുണയ്ക്കുക. ഇത് ജീവിതവിശ്വാസത്തിന് പിന്തുണയ്ക്കുക എന്നുപ്പോലെ ജീവിതവിശ്വാസത്തിന് പിന്തുണയ്ക്കുക. 

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മനുഷ്യരുടെ ജീവിതവിശ്വാസത്തിന് പിന്തുണയ്ക്കുക എന്നുപ്പോലെ ജീവിതവിശ്വാസത്തിന് പിന്തുണയ്ക്കുക. ഇത് ജീവിതവിശ്വാസത്തിന് പിന്തുണയ്ക്കുക എന്നുപ്പോലെ ജീവിതവിശ്വാസത്തിന് പിന്തുണയ്ക്കുക.
Consent form approved by the Ethics Committee for Implantation of Homograft valve
Sree Chitra Tirunal Institute for Medical Sciences and Technology
Thiruvananthapuram- 695011

INFORMED CONSENT FOR HOMOGRAFT VALVE IMPLANTATION

Name of the patient: .................................................................
Hospital No: .................................................................
I, ..................................................................................... (relationship)
................................................................................................ who has been
scheduled for cardiovascular surgery at the Sree Chitra Tirunal Institute for Medical
Sciences and Technology, Thiruvananthapuram, understand that the operation will be
carried out on ........................................ by the cardiac surgical team led by Dr.
Jayakumar
It has been explained to me/ my relatives that the homograft valve to be used in the
operation has been harvested from human heart during autopsy at Medical College
Thiruvananthapuram by cardiac surgeons of Sree Chitra Tirunal Institute for Medical
Sciences and Technology, in compliance with the guidelines of International
Standard Organisation, has undergone vigorous bacterial surveillance at SCTIMST
and its clinical use has been approved by the Ethics Committee of the Institute. It has
also been explained to me / my relatives that the use of homograft is unlikely to carry
any risk higher than that with the use of a mechanical valve or bioprosthetic valve
now in common use. Though this valve does not need life long anticoagulation, I am
aware of the need for a re-operation for changing this valve after 10 to 15 years in
case of possible structural dysfunction. The risks and benefits of the operation and its
probable minor and major complications have also been explained to me / my
relatives. On the basis of the detailed explanation given by Dr.
................................................................................. I give the consent for my cardiac operation using the
homograft valve under General Anaesthesia.

I am fully aware that the services rendered to me are under a contract of
personal service.

.................................................................................. (Signature of the patient / relative)
(Signature of the witness (next to kin))
Relationship: .................................................................
Name and Address:

........................................................................................
Signature of the witness (doctor)
Signature of the Consultant: ................................ Date: .........................
NEXT OF KIN INFORMED CONSENT FORM
SPONSORED BY SCTIMST

Your relative ........................................ has been asked to participate in a clinical study. Sign this consent form after you have carefully read the next of kin information sheet. Please ask the study doctor or nurse if you have not clearly understood any words or statements in this document. It is your as a study patient to know about all the procedures that are done in this study and understand them. By understanding the potential risks and benefit, you can decide whether to participate or not.

I have been explained to of the aims and procedures of the clinical study that I have been asked to participate in by Dr. ......................

I have read and understood the patient information sheet and also have been informed about the potential benefit to myself and any possible risk or discomfort.

I have been given an opportunity to ask questions and think about the answers that were given.

I understand that my participation in this study is voluntary. If I withdraw on my own free will at any time, it will not alter the care and attention I get from my doctor, in future.

I agree that Sctimst or their representatives and regulatory authorities (In this country and elsewhere) may see the important parts of my medical records but they should agree to keep all information confidential.

Hereby I voluntarily give my full informed consent to my relative’s participation in this clinical study.
(His/her legal rights does not get affected by signing this form)

Name of next Kin ....................................................

Signature of next of Kin ................................. Date :

Name of the Patient ....................................................

Signature of the Patient ........................................... Date :
(Where possible)
Impartial Witness:

☐ N/A

I, the undersigned, was present when the entire informed consent discussions were being done. I confirm that the patient and the patient’s legally acceptable representative were explained to about the study in all aspects. I confirm that each one was given an opportunity to ask questions and that each one seemed satisfied with the given answers and that the patient gave his willing and informed consent to participate in this study.

Name of the Witness............................................

Signature of the Witness........................................... Date :

Investigators statement

I confirm that the above named patient and his/her Next of Kin were explained the nature of the above mentioned investigation; by me and that I have answered all the questions.

Name of the Clinician............................................

Clinician’s Signature............................................. Date :

PLEASE PROVIDE THE PATIENT/NEXT OF KIN /LEGAL GUARDIAN WITH A COPY OF THIS CONSENT FORM.
Consent-Recipient

• Brochure given to patient/relative for education
  – Benefits
  – Risks
  – Alternative treatment
  – Cost (Free)
  – Permission to view records (confidential)
  – Separate consent for next of kin
Consent-Recipient

• Opportunity to ask questions
• Option for withdrawing from study
• Impartial witness
• Harvested from deadbodies
• Need for repeat surgery in 10-15 years
Data ( N = 7425 )

- 31.28% - cause of death (hanging, RTA)
- 2.2% - Considered for harvest
- 1.4% - Harvested
- 0.8% - No consent (36% from cases satisfying all criteria)
Issues while consent taking

- Relatives as per Act may not be present
- (Telephonic consent not accepted)
- Estimation of time of death
- Constraints of time, resources