JEEVANDAN

CADAVER TRANSPLANATATION PROGRAMME

State Government of Telangana

JEEVANDAN SKIN BANKING AND TRANSPLANTAITON GUIDELINES AND OPERATING PRINCIPLES MANUAL

Jeevandan Office

Nizams Institute of Medical Sciences, Punjagutta, Hyderabad, Telangana, India

T: +91 40 2348 9494 | M: +91 88850 60092, +91 88850 60093

E: Jeevandan.telangana@gmail.com | **www.jeevandan.gov.in**


JEEVANDAN
అవయవదానం
మహాదానం

INDEX

Table of Contents	Page No
Purpose and Scope of the Manual	5
Part 1: Guidelines for Skin Banking and Transplantation	
1. Definition and Scope	6
2. Facilities	6
3. Operations	7
4. Personnel	8
5. Quality Management	9
6. Sources of Skin Allograft	10
7. Counselling and Consent	10
8. Donor Screening and Donor Testing	11
9. Practices	12
10. Records	16
Part II: Standard operating principles of Skin bank and skin transplantation	
1. Identification And Traceability of Donor Skin	17
2. Donor Selection Criteria	18
3. Absolute Contraindications for Donor Selection Criteria	18
4. Relative Contraindications for Donor Selection Criteria	24
5. Skin Recovery, Processing and Packaging, Labelling, Storage and Distribution	25
Phase 1: Starts with Skin Recovery and Preservation in 50% Glycerol, and ends with handing over of the retrieved Skin to the Skin Bank	26
Skin Bank FORM 1	30
Skin Bank FORM 2	31
Skin Bank FORM 3	32
Skin Bank FORM 4	34
Skin Bank FORM 5	36
Skin Bank FORM 6	37

Table of Contents Page No

Skin Bank FORM 7 39

Skin Bank FORM 8 40

Skin Bank FORM 9 41

Phase 2: Includes Processing donor skin and sending blood sample for serology test and cleaning, packaging and sterilizing of dermatome. 42

Skin Bank FORM 10 43

Skin Bank FORM 11 44

Cleaning and Packaging of Dermatome 45

Sterilization of Dermatome

Procedure for Skin Processing to 85% Glycerol

Skin Bank FORM 12 49

Skin Bank FORM 13 50

Phase 3: Final Processing and Pof the Skin into final Containers. 51

Skin Bank FORM 14 54

Skin Bank FORM 15 55

6. Labelling And Storage 56

7. Distribution 57

Skin Bank FORM 16 59

Skin Bank FORM 17 60

Skin Bank FORM 18 62

8. Microbiology Media Preparation and Storage in 10ml bottle 63

9. Microbial testing of Donor Skin 64

Part III: Skin Allograft Allocation and Distribution Policy of Jeevandan Cadaver Transplantation Programme of Government of Telangana 66

The purpose of this Manual is to

1. To lay down guidelines and the standard operating principles necessary for the procurement and processing, storage and distribution of the of human deceased donor skin under Jeevandan Scheme, Governmet of Telangana.

2. To provide high quality skin allograft to achieve success in burn wound management thereby decreasing suffering and increasing survival of severely burnt patients.

Scope

1. All the existing skin banks and skin banks to be established in future in the state of Telangana shall follow these guidelines and operating principles.

2. All the skin banks in the state would be under the supervision of the appropriate authority including the skin retrieval, storage and distribution through web–portal .

PART I

Guidelines for Skin Banking and Transplantation

I. DEFINITIONS AND SCOPE

Unless used in another context in these guidelines, the following terms shall be defined as follows:

a. a. Skin Allograft: Human skin tissue donated from either a living or deceased donor intended for grafting on a genetically different person.

b. A Skin Bank is deemed to exist when it conducts integrated activities stipulated in 1c for skin allografts defined under 1.a.

c. In this context, Skin Banking refers to the activities that include but are not limited to donor recruitment, screening and testing, procurement, processing, labelling, storage and distribution of human skin allografts intended for treatment of an injury. If the Skin Bank contracts with any other entity for service related to the above processes and/or any other aspect of skin banking, the responsibility of the entity shall meet these guidelines and their responsibilities shall be clearly documented.

d. A skin donor refers to either a deceased donor, who is the source of the skin allografts governed by these guidelines unless otherwise stated.

e. A recipient is the individual who receives the skin allograft for the purpose of treatment of an injury.

g. Recovery – refers to obtaining tissue from a donor that is intended for use in human transplantation, therapy.

II. FACILITIES

1. A dedicated space for skin banking accommodating all personnel, fittings and equipment and to allow all activities, procedures and movements to be carried out in comfort and safety is ideal.

2. There should be adequate segregation of non–sterile, clean and sterile zones with separate access.

3. Movement in sterile zone should be unidirectional.

4. There should be separate air conditioning for all three zones without air mixing. Sterile area should be equipped with high efficiency particulate air filter and positive air pressure ventilation.

5. An in–house microbiology, serology, tissue typing and cell culture laboratory should be available.

6. The facilities shall have reliable water and electricity supply, and be maintained in a clean, tidy and sanitary condition.

7. Biohazards and other hazardous waste items shall be disposed off in a manner that would minimize the hazards to the Skin Bank, including personnel and the environment, in accordance with all prevailing local legislation(s).

8. Access to the Skin Bank and the tissue inventory shall be strictly limited to authorised personnel, who are appointed by the Director.

9. Equipment and Supplies

    a. Instruments for skin graft procurement

    b. Dermatome

    c. Refrigerator

    d. Incubator

    e. Ultra–cool refrigerator for –70° C temperature

    f. Laminar flow cabinet

    g. Biosafety cabinet

    h. Laboratory articles, reagents, chemicals, furniture

    i. All instruments and equipment shall be subjected to regular maintenance and calibration.

    j. Maintenance manuals for all instruments and equipment shall be kept updated and available at all times.

III. OPERATIONS

1. The Skin Bank shall establish a operational framework to ensure adequate coverage on all aspects of its operations to safeguard the interest of the people (donors, recipients and employees) and processes within the framework.

2. The Governance Framework shall have

    a. The organization structure;

    b. Responsibility and accountability matrix which sets the roles and responsibilities;

    c. A process for emplacing appropriately qualified persons to the skin bank; and

    d. A quality assurance programme to ensure that the product of each process is of sound quality to meet the intended use of the tissue and a process for review and improvement.

3. There shall be adequate oversight on the recovery sites of the skin tissues, which shall be performed by competent professionals. Written Agreements and Contracts.

IV. PERSONNEL

Administrative Head

1. The Skin Bank shall have a Administrative Head / Manager (preferably superintendent of the hospital or nomine from administration department) to manage the administration and be responsible for all the activities performed by the Bank.

2. The manager shall be qualified by training and/or experience for the scope of activities being performed by the Skin Bank and be familiar with the local regulations governing skin banking. He/She may or may not be a medical doctor.

3. The manager may delegate the administrative, technical, regulatory, compliance, safety issues, financial and other general activities to suitably qualified designee(s). However, all skin banking activities shall remain the final responsibility of the Administrative Head/manager. Skin banking activities include, but are not limited to:

    a. Approval and periodic review of all standard operating procedures (SOPs);

    b. Review and evaluation of all reports and investigation of errors, accidents, adverse reactions/outcomes and complaints;

    c. Review and notification of appropriate parties of confirmed infectious disease test results in accordance to SOPs; and

    d. Approving job descriptions, staff responsibilities, and ensuring that staffs responsible for performing homograft banking activities are adequate in number, qualified for the tasks to be performed and that appropriate training is conducted for all staff.

Medical Head

4. There shall be a Medical Head preferably Plastic Surgeon registered with the local Medical Council. He/She shall be qualified by training and experience in evaluating and determining donor eligibility, particularly with regards to infectious diseases and microbiology. He/She can seek assistance from a Medical Advisory Committee, consisting of consultants to assist in these areas.

5. The responsibilities of a Medical Head Doctor include:

    a. Establishing donor suitability criteria and all standard operating procedures of a medical nature prior to implementation to ensure they comply with the local laws and regulations;

    b. Reviewing and approving all policies and procedures of a medical nature in the Skin Bank;

    c. Documentation of donor suitability in a timely manner in order to qualify the tissue for preventive or therapeutic use prior to its release into the inventory for distribution;

    d. Approval of the release of each batch of skin tissue following processing;

    e. Review and evaluation of reports and investigation of errors, accidents, adverse reactions/outcomes and complaints of a medical nature.

6. The Administrative Head and Medical head Doctor shall ensure that his/her designee/s, who will provide coverage during his/her absence, shall have the relevant experience and a clear understanding of the scientific principles and techniques involved in the skin banking activities.

Technical Staff

7. There shall be an adequate number of qualified and trained technical personnel to supervise and perform all activities of the Skin Bank.

8. The technical personnel shall have an educational background, documented training and experience commensurate with their assigned duties and a thorough understanding of the procedures and activities they perform.

V. QUALITY MANAGEMENT

General

1. The Skin Bank shall establish an effective quality assurance programme, which shall be reviewed annually.

2. The Director shall be responsible for the overall Quality Assurance Programme of the Skin Bank.

3. The quality manual shall include:

   a. Philosophy (including mission, vision and core values) and objectives of the Skin Bank;

   b. Policies and procedures for the Skin Bank;

   c. Staff training; and

   d. Monitoring and evaluation on practices and standards of the Skin Bank.

4. The Skin Bank shall establish policies and procedures for the qualification, verification and/or validation of critical components of the facility, processes, equipment and supplies.

5. Process validations shall be performed where the results of a process cannot be fully verified by subsequent inspection and test.

6. Validations shall be assessed when process changes are made and revalidation shall be performed as and when required.

7. Determination of the frequency and which elements or items are to be qualified, verified, and/or validated shall be made by individuals responsible for Quality Assurance and regulatory compliance.

8. Evaluation of parameters tested shall be performed and adequacy of the study to demonstrate necessary outcomes shall be determined.

Quality Control

1. Standard Operating Procedures (SOPs) including skin tissue processing, preservation, packaging and storage, shall be validated to demonstrate the consistent effectiveness of the aseptic procedures.

2. Instruments and equipment shall be validated and certified fit for use. Processes are in place to ensure that the instruments and equipment 6 are operated by suitably trained personnel.

3. Tests and procedures shall be performed periodically to measure or monitor processing, preservation and storage methods, equipment and reagents to ensure compliance with established tolerance limits. Results of all such tests or procedures shall become part of the permanent record.

Errors, Accidents and Adverse Reactions/Outcomes

1. There shall be written procedures for receiving, evaluating, investigating and documenting errors and accidents related to donor screening, tissue procurement, quarantine, processing, labelling, storage and distribution.

2. There shall be written procedures for receiving, evaluating, investigating and documenting suspected adverse reactions/outcomes after transplantation.

3. There shall be written procedures for prompt recall of skin tissues or notification of transplant hospitals of the possibility of tissue contamination, defects in processing, preparation of distribution, or other factors affecting suitability of the tissue for their intended application. Conversely, there shall be a process for notification of the source in the event of any adverse event or suspected contamination of skin tissue.

4. The recall procedure shall include a detailed description of the actions to be taken in the event of a recall and the notification timeframe.

5. All adverse reactions shall be reviewed by the Administrative and Medical Head of the Skin Bank.

6 he Skin Bank shall ensure that the transplant hospitals or receiving healthcare institutions are aware of the responsibility to notify the Skin Bank of any suspected transmission of infectious diseases through transplanted skin tissues.

VI. SOURCES OF SKIN ALLO GRAFTS

Skin Allograft Donors can be Brain Death or Cardiac Death

1. The skin allograft transplant differs from organ transplantation as the skin grafts are used to provide temporary long term protection and are not expected to survive in the recipient permanently as transplanted organ.

2. Neither ABO blood group nor HLA matching is required for allograft skin transplantation. So, literally any human being can be a donor for anyone else.

3. The source of skin allograft from deceased donor can be brain dead or within 6 hours of cardiac death

VII. COUNSELLING AND CONSENT

1. Counselling shall be conducted by transplant counsellors/ coordinators appropriately qualified and trained personnel.

2. The counselor/coordinator shall ensure that full and factual information is delivered in plain language, which is comprehensible by the person/s receiving the counselling.

3. Under no circumstances shall the Skin Bank withhold crucial information or give misleading information, which may directly or indirectly influence the decision of the donor and/or recipient, or attempt to mislead, compel, coerce, patronise or incentivise the persons receiving counselling.

4. There shall be adequate documentation on:

   a. The information delivered/received;

b. Identification and endorsement by the person taking consent;

c. The witness and/or the interpreter, where applicable;

d. An acknowledgement on the information received and endorsement by the person being asked for consent; and

e. Identification details of the person being asked for consent, i.e. name, address, identification number, phone number and relationship to the donor.

5. Donor consent shall be obtained from the next–of–kin for deceased donors (the "Authorised Persons") as defined under prevailing organ transplantation act before the skin tissues are recovered

6. The Skin Bank shall provide the following information to the transplant hospitals or healthcare institutions where treatment is carried out:

   a. The source of skin tissues;

   b. The donor screening process and necessary tests performed to ensure product safety and compatibility; and

   c. Any regulatory obligation of the Skin Bank and the regulatory agencies involved as a result of receiving the tissues.

7. The Skin Bank shall ensure that the following information is provided by the transplant hospital or healthcare institution to the recipient:

   a. The assessments conducted to assess the suitability of the recipient to receive the tissues/cells;

   b. The indications and contra–indications;

   c. The efficacy of the treatment regime;

   d. The risks, adverse reactions and any potential future complications as a result of the treatment; and

   e. Disclosure of conflict of interest.

Reimbursements and Charges

8. No monetary compensation or payment, can be made to the donors' next–of–kins.

VIII. DONOR SCREENING AND DONOR TESTING

Clinical Evaluation

1. Evaluation of each potential donor shall include a review of the clinical history and a thorough physical assessment.

   Prior to skin donation,

   a. Preliminary review of readily available medical records shall be conducted by a trained individual.

b. Physical assessment shall be performed by a trained individual to identify and exclude evidence of high risk behaviour, signs of transmissible diseases, infections or trauma to the potential recovery sites.

c. Donor risk assessment shall be conducted through a form of interview with the nearest available next–of–kin, using a standardized questionnaire, to evaluate past medical and social history that could constitute a contraindication to the release of tissue for transplantation.

2. There shall be clearly documented criteria for the selection and acceptance of tissues. Skin tissue shall be rejected if there is a clinical history of one of the following diseases:

   a. Malignant cancers. Primary brain tumours and carcinomas in situ, which have been successfully treated more than 5 years ago without relapse, may be accepted;

   b. Viral hepatitis, HIV infection, active tuberculosis, untreated syphilis, malaria, dengue fever, rabies;

   c. Septicaemia, mycosis, systemic viral diseases or prior diseases, e.g. Creutzfeldt–Jakob disease (CJD);

   d. High risk of transfusion or tissue–transmissible diseases; and

   e. High risk genetic, autoimmune or degenerative diseases, e.g. haemophilia, multiple sclerosis, etc.

Screening Tests

3. The Tissue Bank shall ensure that, at minimum, the following screening tests are carried out by accredited testing laboratories for donor screening:

   a. Human immunodeficiency virus antibody (Anti–HIV),

   b. Hepatitis B virus surface antigen (HBsAg),

   c. Hepatitis C virus antibody (Anti–HCV).

4. Tests for other transmissible tests shall also be carried out when necessary and if determined to be appropriate

5. All microbial culture results shall be reviewed prior to release of skin tissue for transplantation. Any variance in the culture results from established parameters shall be reviewed and approved by the Medical Head or designee prior to release.

6. The Skin Bank can adopt the archiving of serum and/or tissue specimens from each donor wherever possible. These specimens are retained for use for possible unforeseen future investigational purposes.

IX. PRACTICES

The procedures and practices for all Skin Banking activities shall be set out in detail in procedure manuals. These procedure manuals shall be kept updated and made available at all times to all personnel of the Skin Bank.

Skin Recovery

1. Skin tissues from donors shall be recovered and preserved within the time interval appropriate for retention of biological functions compatible with the intended use of those tissues. Prolonged delay causes bacterial and fungal colonization of the donor skin

2. Every effort shall be made to minimise contamination of the skin tissues during the recovery.

3. An evaluation of the recovery site shall be performed to identify potential source of contamination before recovery can be conducted. No other activities can occur simultaneously in the same room during skin recovery.

4. The procurement should be conducted with aseptic precautions in Operation Theater whenever possible. If this is impractical, the procedure can be carried out in the side room of ward, hospital bed, morgue or home of the deceased.

5. The process involves removal of epidermis along with superficial layers of dermis from both thighs and back of the donor

6. About 10 ml of blood of the deceased is collected at the same time for serological testing

7. Reconstruction of the body of deceased skin donors shall be conducted with dignity and sensitivity.

8. The grafts are transported to the skin bank in Phosphate buffered saline in glass

Skin Processing

1. Skin tissues shall be processed according to the SOPs established by the Skin Bank. Where applicable, the Skin Bank shall document a detailed description of the condition of the skin tissue, including any observed tissue abnormalities and/or imperfections, which shall be maintained as a part of the permanent donor processing records.

2. Skin tissues from more than one donor shall not be pooled during processing, preservation and storage.

3. Skin procurement teams should consist of at least two people operating under aseptic conditions and appropriately clothed for the type of procurement.

4. Methods used for skin tissue preservation shall be appropriate and shall ensure the retention of the properties of the skin tissue consistent with the intended use.

5. Storage containers shall be appropriate for the type of tissue and its intended application.

Traceability

1. The Skin Bank shall ensure that all tissues and cells recovered, processed, stored or distributed can be traced from the donor to the recipient and vice versa. The Skin Bank shall maintain traceability at all stages, which includes equipment and materials used for the recovery, processing and storage of tissues.

2. The Skin Bank shall ensure the implementation of a donor identification system, which assigns a unique code to each donor and to each of the skin packages associated with the donor.

Labelling

1. All containers of tissues shall be clearly labelled and shall include, at minimum, the following:

    a. Product identification number and/or batch, if applicable;

    b. Descriptive (or commonly–used) name of tissue;

    c. Quantity of tissue in the container expressed as volume, weight, dimension etc., as appropriate;

    d. Expiry date, as appropriate;

    e. Recommended/optimum storage condition;

    f. Preservative media or cryo–protectant used, if applicable;

    g. Name, address and contact information of the Skin Bank;

    h. Biohazard legend or warning labels, where appropriate; and

    i. Any other relevant information.

2. All labels shall be designed and qualified to be legible and affixed firmly to the container under all anticipated storage conditions for the shelf life of the tissue. Labels applied by the Skin Bank shall not be removed, altered or obscured except to correct labelling errors.

Storage

1. The temporary storage container used for unprocessed tissues shall be appropriate for the tissue.

2. The storage requirements for a tissue, including storage conditions and expiry date, shall be appropriate to the type of tissue, packaging, processing as well as to its intended application.

3. Storage equipment shall be regularly maintained, calibrated and monitored according to written procedures.

4. The maximum storage period for skin tissues shall be appropriate to the type of tissue, required storage temperature, packaging, and processing techniques, as well as its intended use. Expiration dates shall be qualified to demonstrate that the packaging is suitable to maintain product integrity (e.g. sterility, moisture content) for the entire shelf life.

5. If serology and microbiology reports are satisfactory, the grafts are shifted to –70^{o} C. with 98% Glycerol as cryo–protectant. The grafts can be preserved upto 6 months at this temperature. Liquid Nitrogen technology permits preservation upto 3 years. The grafts are thawed to room temperature before use and once thawed, restorage is not recommended

Quarantine

1. Skin tissues shall be quarantined at any phase of the operation when their release could affect the safety, effectiveness or quality of those tissues.

2. Quarantined skin tissues shall be clearly labelled and segregated from tissues meant for distribution.

Imported skin tissue

1. The Skin Bank shall ascertain that the recovery, processing, storage, transportation and distribution of imported tissues comply with the local legislations and standards set out in these guidelines.

2. The Skin Bank shall be responsible for the quality and safety of the tissues imported by the Bank. These include, but are not limited to:

    a. Operational license from local health authority or medical license of local institute.

    b. Donor summary of records, which contains Infectious and microbiological culture diseases results.

    c. Package insert, which accompanies the tissue allograft bearing further information about the tissue, directions for use, and any applicable warnings.

Skin Tissue Inventory

The Skin Bank shall maintain a proper inventory system of stored tissues, including those under quarantine, which shall be periodically audited.

Tissue Distribution

1. Release of tissues for clinical use shall be restricted to other Tissue Banks, licensed healthcare institutions and registered transplant medical practitioners and shall be approved by the Medical Director.

2. The Skin Bank shall ensure that skin tissues are packaged and transported in a validated container that is appropriate for preserving the required biological or functional characteristics and minimising the risk of contamination. The packaging shall be appropriate to ensure the safety of those responsible for packaging and transportation.

3. An instruction sheet shall accompany all skin tissues that are distributed. It shall contain the following information, if relevant:

    a. The appropriate storage condition prior to clinical use,

    b. Information regarding any special care required by the registered practitioner for the safe and most effective use of the skin tissue,

    c. Actions to be taken if there is evidence of breakage, mislabelling, etc.

4. Donor medical history, tissue–related information and tissue processing details shall be made available to the transplant medical practitioners, local authorities and other Tissue Banks on request, except where such information may infringe on confidentiality of the donor.

5. Benefits of Skin Allografts: The chief benefits of use of allograft on excised full thickness burn wounds are,

    a. Effective control of protein and fluid loss from wounds.

    b. Reversal of hyper metabolic state with improvement in nutritional status

c. Augmentation of immunological response.

d. Control of wound infection and improvement in the wound bed making it ready for acceptance of precious skin auto grafts.

e. Immediate pain relief and general feeling of well being.

f. Excellent biological wound cover till the auto graft donor sites become ready for reharvesting.

X. RECORDS

1. All donor information (which includes, but not limited to biographic and medical information), processing, storage and distribution records shall be maintained in accordance with the prevailing local legislation(s) and/or guidelines.

2. The Skin Bank shall ensure that there shall be an identification system to link the recipient of each human tissue to its donor. The system must permit the tracking of the human skin tissues, including tissues that are procured from or used outside the country, from their procurement to their final use.

3. Records shall be maintained so that tissues can be promptly tracked and located.

4. Records shall indicate the dates and identities of the staff involved in each significant step of the process from donor screening through final disposition of the skin tissues.

5. All measures shall be taken to keep the records securely and to maintain the confidentiality of information relating to donors and their tissues.

PART II

Standard operating principles of Skin Bank and Skin Transplantation

1. Identification and Traceability of Donor Skin

Record keeping and storage:

A skin donor receives a unique Donor Identification Number from the moment of recovery. The same identification number should be applied to all forms used for a particular skin donor. Also, the blood tubes should be identified with this identification number. All essential data of materials used during procurement, processing and storage should be completed on the forms where necessary. In this way it is always possible to trace which product is used when and where and on which skin donor.

Donor information should be stored in such way in accordance with the local, national or international agreements for the protection of personal data.

The following forms should be recorded by Skin Bank under Jeevandan Scheme, Hyderabad.

Sl No.	Form Number	Name of form
01	SB Form 1	Checklist for Skin collection kit
02	SB Form 2	Next of Kin Consent form
03	SB Form 3	Donor information form
04	SB Form 4	Donor Physical examination form
05	SB Form 5	Phase 1 Glycerol Preservation (GLYCEROL 50%)
06	SB Form 6	Checklist for skin recovery and procedure completion
07	SB Form 7	Handing over of donor skin and blood sample tube dermatome box and Skin Collection Kit upon arrival at Skin Bank during Non–Office hours
08	SB Form 8	Checklist for transport of skin from Skin Collection Centre to Skin Bank

09	SB Form 9	Checklist for Handing over of donor skin, Blood Sample Tubes, Der–matome box and Skin collection Kit upon arrival at Skin Bank during Office hours.
10	SB Form 10	Checklist for storing donor skin in quarantine before the start of Phase 2 processing.
11	SB Form 11	Checklist for sending blood sample for serology test
12	SB Form 12	Form for the phase 2 glycerol preservation procedure
13	SB Form 13	Check–list for Skin Processing Phase 2 in 85% Glycerol
14	SB Form 14	Requirement checklist
15	SB Form 15	Checklist for phase 3 processing packaging of donor skin
16	SB Form 16	Recipient details
17	SB Form 17	Donor Skin Stock Form
18	SB Form 18	Donor Skin Stock Form To be Filled During Phase 3 Processing

2. Donor Selection Criteria

1. A skin donor should be 18 Years or above.
2. If the skin donor is cooled or refrigerated within six hours after death, skin can be retrieved within 24 hours after death. If not, skin must be retrieved within 6 hours after death.
3. Skin Donation from the DBD can be taken after retrieval of the organs within 6 hours of cross clamp.
4. A suitable skin donor applies to the following rule: Height (cm) – Weight (kg) 100. When the donor is female, the margins are applied somewhat less strict.
5. If autopsy is carried out on the skin donor, the results shall be written down on the donor information form.
6. Contra–indications are reviewed at least once a year. This review is performed by Skin Bank, Hyderabad which will inform it to appropriate authority.
7. The following contra–indications are reasons for the skin bank to refuse or reject a skin donor.

3. Absolute Contraindications for Donor Selection Criteria

1. Unknown time of death
2. Unknown cause of death (unless autopsy will be performed)
3. Sepsis at time of death

Definition of sepsis does encompass:

- fever (=T >38.3°C) or low temperature (=T <35.5°C)
- breathing frequency >20/min
- heart rate >90/min
- urine output <5 ml/kg/hour (= <35 ml/hour for a weight of 70 kg) (relatively late symptom)
- possible locus of infection?

AND one or more signs of reduced tissue perfusion, such as:

- anxiety, agitation, confusion
- cold, clammy skin (sometimes, not always)
- gastro–intestinal symptoms
- blood pressure <100 mm Hg systolic (or a drop of >20 mm Hg from the usual value)
- lactate >2mM/L
- decreased urine osmolarity: OSM(urine): OSM (plasma) <1.5: 1

Most important is the assessment by the attending physician. In case of doubt the following could help:

- Were and/or are blood cultures pending, and on what date were they taken?
- Extra high (>15x109/L, leukocytosis with left shift) or low (3.5 x 109/L) white blood count or low plate let count (thrombocytes <100x109/L)?
- Signs of disturbed blood clotting (diffuse intravascular coagulation, DIC)?

If sepsis is definite or probable: reject donor. In case of good response to a treatment that was initiated more than 24 hours before death with antibiotics to which the organism was sensitive, the donor can be accepted.

If sepsis is possible (but not likely): consult medical staff.

4. **Active (Systemic) Infections** including but not limited to:

- Active Bacterial or Fungal Endocarditis
- Active Viral Hepatitis
- Babesiosis, Brucellosis
- Chagas (South– American trypanosomiasis)
- Hepatitis B or C seropositivity
- Jaundice of unknown aetiology

- HIV seropositivity or Acquired Immunodeficiency Syndrome (AIDS)

  Signs which may indicate AIDS are:

  Unexplained weight loss

  Nocturnal transpiration

  Blue purple spots on the skin or mucous membranes which are typical of Kaposi's sarcoma

  Unexplained lymphadenopathy (for longer than 1 month)

  Unexplained temperature(>38.6°C for more than 10 days)

  Unexplained persistent diarrhoea

- Tuberculosis / Leprosy / Lime's disease / Malaria

  Symptoms of lyme disease (borreliosis)

  Stage I : migrating red spot (erythema migrans)

  Stage II : (after days to weeks) Ring–shaped skin disorders, meningitis, neuritis, carditis, migrating joint complaints

  Stage III : (after years) Chronic arthritis, nerve disorders and/or skin disorders

  MMalaria < 3 years diagnosed and/or treated for Malaria

- Active Herpes Zoster (also if not near the eye but located elsewhere on
- Diphtheria / Scarlatina
- Leishmaniasis
- Leprosy
- Lymphocytic Choriomengingitis Virus
- Microfilarisis
- History of, or clinical evidence or suspicion for Active Syphilis
- History of, or clinical evidence or suspicion for Active Poliomyelitis
- Rabies (including post–exposure prophylaxis)
- Reyes syndrome
- Meningitis/Encephalitis (bacterial, viral or unknown origin)
- Subacute Sclerosing Panencephalitis Encephalitis or Encephalitis of unknown aetiology (SSPE)
- SARS, Strongyloidiasis

- Tick–borne diseases (Lyme, Rickettsia)
- Tularemia,
- West–Nile virus

5. **Risk factors for HIV, Hepatitis B or C, HTLV** (incl. chronic hemodialysis)

The risk factors for Hepatitis B, C, HIV and Human T–lymphotropic Virus (HTLV) are more or less similar.

The following are known risk factors, which are reason to reject a donor:

- Men who have had sex with another man in the preceding 5 years.
- Persons that report non–medical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years.
- Men and women who have engaged in sex in exchange for money or drugs in the preceding 5 years.
- Persons with haemophilia or related clotting disorders who have received human–derived clotting factor concentrates.
- Persons that, in the past 12 months, were sexual partners of persons having a HIV or C or B hepatitis history, manifestations, or any of the risk factors described here.
- Persons that, in the preceding 12 months, were exposed to (possibly) infected blood via accidental per cutaneous puncture or through contact with an open wound and non–intact skin or mucous membrane.
- Inmates of correctional systems in past 12 months.
- Children of 18 months or younger born to mothers with risk of HIV, or children from these mothers who were breastfed
- Diagnosed or treated for syphilis or gonorrhoea in past 12 months.
- Persons emigrated from countries where transfer of HIV infection through heterosexual contracts plays an important role in the spreading of the HIV virus. These are specifically Haiti, and countries from Central Africa, Cameroun, Central African Republic, Tsaad (Chad), Congo (Zaire), Equatorial Guinea, Gabon, Niger, Nigeria.
- HTLV is endemic in South Japan and the Caribbean. At present, it is extremely rare (still) in the Nether lands.
- Tattoo: if the donor has had a tattoo, piercing or needle accident in the previous 6 months, there may be a reason for not accepting. Please contact the medical staff for evaluation. We do not accept piercings made with the use of shared needles or genital piercings.

In addition the following should be considered a risk factor:

- Jaundice of unknown but possibly infectious origin

- "Close contact" with another individual with infectious hepatitis, such as shared household (kitchen and toilet) or sexual partner
- Chronic haemodialysis

6. Vaccinations with a live, attenuated virus (if < 4 weeks prior to death)

   Such as but not limited to:

   - Measles
   - Parotitis (Epidemic–)
   - Poliomyelitis (oral vaccine only)
   - Rubella
   - Yellow Fever

7. Clinical evidence or suspicion for human Transmissible Spongiform Encephalopathy (or history thereof in the genetic family)

   - Creutzfeldt–Jakob disease (sporadic, iatrogenic, familial and new variant)
   - Gerstmann–Sträussler–Scheinker syndrome
   - Kuru
   - Fatal Familial Insomnia (FFI)

8. History of transplantation with Cornea, Sclera or Dura Mater Allograft
9. Use of Growth hormone of human origin
10. Dementia (unless definitely and solely age related, i.e.vasosclerosis)
11. Degenerative neurologic diseases of unknown aetiology:

    - Amyotrophic lateral sclerosis
    - Multiple sclerosis
    - Alzheimer's disease
    - Parkinson
    - Other non–specified, "probable" degenerative neurologic disease or neurologic disease of unestablished diagnosis

12. Intoxication due to:

    - Intravenous drug abuse (e.g. heroin overdose)
    - Lead, Chromium, other heavy metals

- Pesticides
- Defoliants (e.g. Parathion)
- Mercury
- Arsenic

13. Chemotherapy and use of Immunosuppressive drugs (if < 3 months prior to death)
14. Tissue specific contra–indications
    - Auto–immune dermatoses (e.g. Lupus Erythematoses, Scleroderma, Pemphigus, Pemphigoid)
    - Systemic Connective Tissue Disease (e.g.Marfans syndrome, Ehlers–Danlos syndrome, Pseudoxanthoma Elasticum)
15. Malignancy:
    - Leukaemia
    - Malignant lymphomas (incl. primary lymphoma of the CNS) \
    - basal cell carcinoma
    - Some primary tumours of the central nervous system are acceptable provided a histopathological report is available (Table–1)

Table –1 Absolute and relative contraindication in primary CNS tumors(Ref.: "International consensus docu–ment Standardisation of organ donor screening to prevent transmission of neoplastic disease" of the Council of Europe).

Can be considered for donation	**Can NOT be accepted for donation**
GLIOMAS	
Pilocytic Astrocytoma (Astrocytoma Grade I)	Low Grade Astrocytoma (Astrocytoma Grade II), Anaplastic Astrocytoma (Astrocytoma Grade III)
	Glioblastoma multiforma (Astrocytoma Grade IV)
Low–grade Oligodendroglioma (A and B de Schmidt)	Anaplastic Oligodendroglioma (C and D de Schmidt)
Ependymoma	Malignant Ependymoma
Choroid–Plexus Papilloma	Choroid–Plexus Carcinoma
Colloid cyst of the third ventricle	

MENINGIOMAS AND PERIPHERAL NERVE SHEATH TUMORS	
Benign Meningioma	Anaplastic and Malignant Meningioma
Acoustic Schwannoma	
POORLY DIFFERENTIATED NEOPLASMS	
	Medulloblastoma
	Chordoma
OTHER PARENCHYMAL TUMORS	
	Primary Cerebral Lymphoma
Well–differentiated Teratoma	Germ–cell tumour (except well–differentiated Terato–ma)
Epidermoid cyst	
NEURONAL TUMORS	
Ganglionar cell tumour (Ganglioglioma or Gangliocytoma)	
OTHER	
Pituitary Adenoma	
Craniopharyngioma	
Hemangioblastoma*	Hemangioblastoma*
Pineocytoma	Pineoblastoma

*Should NOT be considered for donation when associated with the von–Hippel–Lindau Disease

4. Relative Contraindications for Donor Selection Criteria

1. Long lasting alcohol abuse.
2. Extensive laceration of the skin.
3. Addison's disease, Cushing's syndrome, Hypothyroidism.
4. Chronic use of corticosteroids.

5. Insulin Dependent Diabetes Mellitus (IDDM, type I) in the elderly donor.
6. Non–Insulin Dependent Diabetes Mellitus (NIDDM, type II).
7. Skin disease with extensive involvement, such as:
    - Pyoderma, mycosis and other infectious skin diseases.
    - Decubitus ulcers, mechanical laceration (excoriation), punctures.
    - Ulceration, nodules, papilloma's.

5. Skin Recovery, Processing and packaging, labelling, storage and distribution

Phase 1

Starts with skin recovery and preservation in 50% glycerol, and ends with handing over of the retrieved skin to the skin bank

Steps	Procedure	SB forms
A	Process of skin recovery and preservation in 50 % glycerol	Form 1, 2, 3, 4, 5, 6
B	Handing over of retrieved skin to skin collection centre during non office hours	Form 7
C	Handing over of skin to skin bank by skin collection center	Form 8
D	Handing over of retrieved skin to skin bank directly during office hours, by retrieval team	Form 9

Phase 2

Procedure includes sending blood sample to serology, cleaning, packaging and sterilization of dermatome, quar–antine and Skin processing in 85% glycerol

Steps	Procedure	SB forms
A	Sending blood sample for serology testing	Form 11
B	Cleaning, packaging and sterilization of dermatome	––––
C	Skin processing to 85 % glycerol	Form 10, 12 and 13

Phase 3

I. Final processing and packing of the donor skin. Form 14, and 15

II. Labelling and storage of donor skin

III. Distribution: SB Form 16, 17

Phase 1: Starts with skin recovery and preservation in 50% glycerol, and ends with handing over of the retrieved skin to the skin bank

1. Preparation for skin recovery

Surgical gloves have to be worn at all times when handling the donor!!

a. The skin recovery procedure is a team effort. It requires the coordination of all the team members. The recovery team includes minimum 3 persons. Every person has his task. While the first one is the cleaning and disinfecting the donor, the other one is preparing the sterile materials for recovery. One has to fill up the donor information form and interact with the relatives.

b. The team leader will check the details of the donor: Name, date and time of death and consent for do–nation. The other two members will first take out the materials for disinfecting the donor from the kit.

c. All three members will wear disposable gloves, a face mask and a head–cap.

d. Two persons will take out the donor from the cold store/bed/floor (home) and put him on his back on a mobile trolley/bed/floor (if not possible keep the body in the supine position on the floor or bed) and undress the body if applicable.

e. The team leader will perform a physical check on the donor, such as skin abnormalities. If the donor is physically not acceptable or unacceptable skin abnormalities are observed, the donor is refused for skin donation.

f. Put two sterile plastic sheets below the donor.

g. Take blood: a best anatomic place to take blood from is the vena femoralis. The next choice is the arteria subclavia. If blood is very difficult to get, the arteria carotis is also possible or directly from the heart. Two tubes of blood must be collected (clotting tubes).

h. Shave the donor: legs, side, upper arms and armpits. The area from which the skin is to be procured is to be shaved completely as this is an important step for ensuring good quality homograft. Complete the shaving of the donor area. After shaving, If any table is available, disinfect the table with savlon. Put a sterile sheet on the table. Then place the donor body chest facing down on the table.

i. Place the donor on his thorax on a sterile sheet on the top of the table. Put the thoracic block under the thorax of the donor, with his head hanging over the block. Use square gauze to give support under his chin. Put his arms along with the table.

j. If the table is not available, then after the completion of shaving of the donor area, take out the upper sterile sheet from underneath the donor's body and get ready for disinfecting the donor area.

2. Disinfecting the donor

a. The first step in disinfecting the donor area is the use of sterile gauze with sufficient Betadine scrub with some spirit. Armpits and feet must also be cleaned. The anal cleft is not cleaned but the surrounding area has to be cleaned. Work from the head towards the feet, from clean to dirty. After applying the Betadine scrub all over the donor area, wait for ten minutes before washing off the Betadine with normal saline. The waiting time will ensure the action of Betadine is completed.

b. Dry the body with sterile square gauze.

c. Pull another sterile sheet between the donor and the previous sheet with the assistance of the other person. This is best achieved by pulling the donor's feet into the air and pull the sheet underneath the donor as far as possible towards the neck.

d. Change surgical gloves and wear a new sterile surgical glove and disinfect the donor with sufficient Sterilium.

e. Take the third sterile sheet and repeat the procedure as with the second sheet. The sheet goes between the body and the second sterile sheet.

f. Wash hands carefully, disinfect with Hibisol / Sterilium, put on a sterile overcoat and sterile gloves. Cover all anatomical parts of the donor which will not be recovered, i.e. feet, bottom, underarms and head

3. Preparation of the sterile materials for recovery

a. While the first person is cleaning the donor, the other person is preparing the sterile table. Wear a dis–posable glove. Take out the procurement package from the plastic bag and unfold the package on a sterile plastic sheet with stable underground, not touching the inside of the sterile sheet. Touching the materials inside the package should always be done with sterile surgical gloves.

b. All sterile materials should be sorted in such a way that the other person can take materials without touching the other materials.

c. Unpack the sterile dermatome and place it on the sterile sheet. Take care that the sterilization label is saved to fill in the sterilization code and batch number on the form.

d. Unpack sterile dermatome blade and place it on the sterile table.

e. Open the lead of the sterile plastic jar containing 50% glycerol. Dissolve the Penicillin and Streptomycin in 0.9% Sodium Chloride, using a syringe and needle and inject the solution in the 50% glycerol solution. Make sure the antibiotics are well dissolved in Sodium Chloride, this can take some time!!

Pour the sterile liquid paraffin into the small bowl

4. Skin recovery

a. Once both persons put on their sterile gown and sterile surgical gloves, the skin recovery procedure can start. Both the sterile container, one containing the glycerol solution and the other one liquid paraffin, are put on a sterile sheet on which the donor lies, in between both legs of the donor.

b. Recovered skin must be put in a container containing glycerol immediately after procuring.

c. The skin recovery procedure is divided into two stages.The first stage is when one person is recovering one half of the donor,the second part is when the other person recovers the other half of the donor.

d. Skin is taken from the back, legs (circular) and sides.

e. Also, a small part of the bottom can be taken provided that the dermatome does not contact the anal cleft.

f. In some cases skin from the upper arms can be recovered too, depending on e.g. sex, autopsy and the amount of bleeding during the procedure.

g. Care must be taken on the thickness of the skin during recovery, also straight pieces of skin are pre–ferred with minimal curves.

h. It is also the responsibility of the two persons to change a blade whenever they think it is necessary. The person not taking the skin will assist that person, creating an optimal situation to recover the skin.

i. After the skin procurement, close the jar containing 50% glycerol and skin with a screw cap tightly. Make sure the jar is entirely closed by putting the jar upside down, and observe if there is leakage through the rims of the lid. The sterile procedure is complete with closure of jar.

5. Bandaging the Donor area:

To prevent leakage of body fluids after recovery, the anatomical sides where the skin is recovered from are treated with dressing. Adequate padding is done to prevent any leakage of body fluid.

6. Dermatome cleaning

Clean the dermatome to remove all skin pieces still sticking (if any),open the knob at the bottom of the der–matome, take out the battery and motor from the dermatome and keep them in the dermatome box. Close the knob of the dermatome.

Keep the dermatome in an autoclavable pack and put it back into the dermatome box.

Keep the extra unused blade in the dermatome box

7. Completion of skin recovery process

CClean the thoracic block and keep it back in the kit bag.

Collect all the unused consumables and put them back into Skin Collection Kit.

Collect all the wrappers and used gauzes, waste materials into a proper disposable bag.

Clean up the room in which recovery took place. All materials are taken back to the skin bank, including the dis–posable bag with (possible contaminated) waste materials. Write down the date of skin procurement on the label with prewritten donor number on the jar. Write down the donor number, donor name, age and sex of the donor on the blood tubes and the jar with donor skin. The blood sample tubes are to be stuck to the jar containing donor skin with the help of micropore tape to avoid misplace blood tubes.

The donor Certificate is to be filled up and handed over to the next of the kin of the donor.

SB FORM–1

Checklist for Skin Collection Kit

To be filled at Retrieval

Kit Prepared By _____ Kit Preparation Date ____ /____ /_____ Kit Bag No _____

Sr. No.	Name of Materials for Skin Procurement	Quantity	Used	Not Used
1	Skin Donor forms file containing Form No 1–17			
2	Skin donor Certificate			
3	Skin Donation acknowledgement letter			
4	4 pairs sterile work gowns (green color)			
5	1 set sterile Dressing kit			
6	12 pairs of Sterile surgical gloves No– 6.5 ,7, 7.5, 8 (3no.of each)			
7	6 Disposable Face Masks			
8	6 Disposable Caps			
9	Plain blood collection tube x2			
10	Disposable Prep Razor x2			
11	1 Spinal needle 20 G			
12	5ml Syringe × 2			
13	10ml Syringe x 2			
14	Syringe needle 21Gx1.5inch x4			
15	1 vial Penicillin IP (1,200,000 U)			
16	1 vial Streptomycin Sulfate 1gm			
17	2xSterile water for injection			
18	110 pairs of examination gloves			
19	1x500 ml Povidone Iodine solution IP scrub			
20	1x500ml sterilium			
21	1x500ml Antiseptic liquid (Intalon /Savlon soln.)			
22	1x400 ml liquid paraffin			
23	3x100 ml Normal Saline			
24	1x 500 ml liquid soap			
25	Elastocrepe bandages 6” × 4			
26	Shoe cover for foot × 4			
27	50ml tube for disposing blade × 1			
28	1 piece 3 inches micro–pore tape			
29	5 sterile Plastic sheets			
30	1 sterile hand napkins			
31	1 pair of sterile Forceps			
32	1 pair of sterile Scissors			
33	2 packed sterile Bowls			
34	2 disposable yellow bag			
35	2 disposable blue bag			
36	1 liter 50% glycerol solution In sterile bottle with donor label			
37	Sterile Dermatome Serial Number:			
38	Battery for Dermatome. Serial Number:			
39	Spare battery serial Number:			
40	4x Skin Donor Pledge form English			
41	4xHospital Visiting card			
42	Marker × 1			
43	Pen × 1			

Verified By _____

SB FORM–2

Donor's Next of Kin Consent Form

To be filled at Retrieval

I Authorize the Removal of Skin from both the legs, thighs and the back of Mr/Ms: _____

_____ who has expired on Date: _____ at _____ AM / PM for donation to Skin Bank under Jeevandan Scheme, and for such purpose as the skin bank may see fit.

Date: _____ Time: _____

Details of Next Kin:

Name: _____

Signature: _____

Email Id: _____

Contact No: _____

Details of Witness:

Name: _____

Signature: _____

Email Id: _____

Contact No: _____

Postal Address: _____

_____ PIN Code: _____

Relationship of next kin with the Donor: _____

How did you come to know about Skin Donation? _____

Do you want the skin bank team to speak few lines about skin donation done by departed soul at Condolence prayer meeting?

_____

Time and Date: _____

SB FORM–3

Donor Information Form

To be filled at Retrieval

Procedure Start Time _____

Tissue Donor Information Form

DONOR INFORMATION

Donor No: _____ Hospital: _____

Name: _____ Age: _____ Male / Female

Date of Death: _____ Time of Death: _____ Type of death DBD / DCD

PERMISSIONS

Has donor expressed last will on a document No /Codicil / Other: _____

Relatives of donor were informed? No/Yes

Conclusion of permission for:

All tissues / Cornea – sclera /Skin / Organs / Other:

Consent documentation: No/Codicil / Medical record / Consent form / other:

MEDICAL INFO: CAUSE OF DEATH AND RELATED MATTERS

Date of admission (dd.mm.yy): _____ Time (hr.min) _____

Date of circ. arrest (dd.mm.yy): _____ Time (hr.min) _____

Date of brain death (dd.mm.yy): _____ Time (hr.min) _____

Donor was refrigerated within 6 hours after death? Y / N

Was medical documentation available: No: List information source: _____

Yes: Hospital chart / Autopsy report / other

Was the donor hospitalized? N / Y: How long? _____

Presumed cause of death _____

Was the physician interviewed? N / Y:

Donor physical examination performed N / Y:

MEDICAL INFO: GENERAL CONTRA–INDICATIONS

	Medical info given by				
	Reporter/Relative	**GP**	**Other**		**Judgment Physician**
Active systemic infections (e.g., sepsis / bacterial endocar–ditis / meningitis / tb / lyme disease / recent vaccinations (MMR/Oral Polio/Any other))	N / Y / U				N / Y
Risk factors for HIV / Hepatitis / HTLV (e.g., intravenous drug abuse, hemophilia, syphilis)	N / Y / U				N / Y
Degenerative neurological disease (e.g., prion–disease / "slow virus" / unexplained dementia)	N / Y / U				N / Y
Leukemia / Lymphatic malignancies	N / Y / U				N / Y
Other malignancies: Present: History:	N / Y / U				N / Y
Alcoholism or toxic intoxication	N / Y / U				N / Y

MEDICAL INFO: MEDICATION AND TRANSFUSIONS

Height:		**Weight:**		**DERMIS PROCURED?**	**YES**		**NO**
				Medical info given by			
				Reporter	**GP**	**Other**	**Judgment Physician**
Antibiotics				N / Y / U			N / Y
Cytostatics/ Chemotherapy (< 3 months before death)				N / Y / U			N / Y
Corticosteroids				N / Y / U			N / Y
Immunosuppressant's (<3 months before death)				N / Y / U			N / Y
Transfusion / Infusions within last 48 hours*				N / Y / U			N / Y
Anticoagulants / Thrombolytics				N / Y / U			N / Y
Use of insulin for diabetes mellitus				N / Y / U			N / Y
Other relevant information / medication(e.g.: antimalarial (dura–tion <3yrs/>3yrs), antivirus)				N / Y / U			N / Y

Name of Skin Retrieving Doctor: _____

Signature _____

Hospital _____

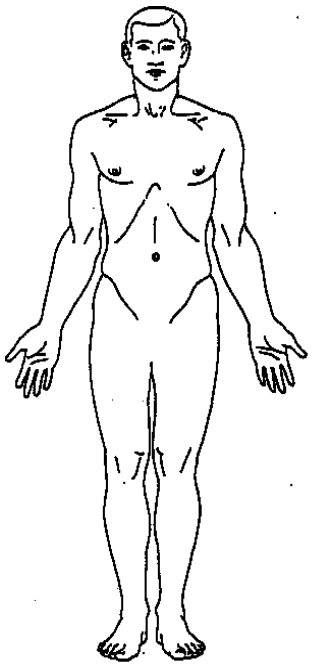
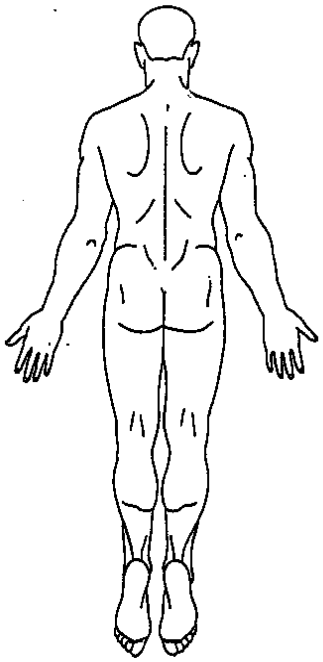
Skin Bank _____

Date:/Time _____

SB FORM–4

Donor Physical Examination Form

To be filled at Retrieval

<table>
<tr><td colspan="2">Donor Physical Examination</td><td colspan="4">Donor No:</td></tr>
<tr><td rowspan="6">VERIFICATION</td><td>Identification
(mark all suitable options)</td><td>❑ Wrist band</td><td>❑ Ankle band</td><td>❑ Toe tag</td><td>❑ other _____</td></tr>
<tr><td colspan="3">Consent verified by:</td><td>Date</td><td>Time</td></tr>
<tr><td colspan="3">Identification verified by:</td><td>Date</td><td>Time</td></tr>
<tr><td colspan="2">Body Height
Cm _____</td><td>❑ estimated
❑ actual</td><td>Body Weight
KG _____</td><td>❑ estimated
❑ actual</td></tr>
<tr><td colspan="2">Donor cooled?</td><td>❑ Yes</td><td>❑ No</td><td>Date</td><td>Time</td></tr>
<tr><td colspan="6"></td></tr>
<tr><td rowspan="2">EXAMINATION</td><td colspan="5">Check boxes to indicate examined areas:</td></tr>
<tr><td colspan="2">❑ head, eyes, ears
❑ mouth– gums/tongue/sublingual
❑ neck– anterior and posterior
❑ external jugular
❑ axilla
❑ arms– upper & forearm–ant. &post.</td><td>❑ brachial veins / arteries
❑ radial veins / arteries
❑ hands– dorsal, fingers, web space
❑ abdomen
❑ genitals
❑ inguinal area</td><td colspan="2">❑ back
❑ anus
❑ popliteal area
❑ feet– toes, web space
❑ dorsalispedis
❑ legs – upper & lower– ant. &post.</td></tr>
<tr><td rowspan="2">FINDINGS</td><td colspan="5">Indicate findings on the body silhouettes. Use numbers to facilitate documentation</td></tr>
<tr><td colspan="2">  </td><td colspan="2">1. Abrasion
2. Bandage/gauze
3. Gypsum
4. Defibrillator tracks
5. Endotracheal tube
6. EKG pads / tracks
7. Verruca
8. Fracture
9. Gunshot wound
10. Haematoma / contusions
11. I.V. / I.A.line
12. Identification
13. Jewellery
14. Surgical wound
15. Lividity (purple stains)
16. Birthmark
17. Needle puncture
18. Nasogastric tube
19. Postautopsy incision /
Postorgan procurement incision
20. Piercing
21. Scar
22. Tattoo
23. Pacemaker
24. Strangulation groove
25. Hyperpigmentation
26. Postenucleation state
27. Crust</td><td>  </td></tr>
</table>

SPECIFICATIONS			
RISK FACTORS?	Record any evidence of potential risk factors for the disease transmission found during the physical examination of the donor		
	– Sexually transmitted diseases such as genital ulcers, herpes simplex, Syphilis, or chancroid	❑ no evidence	❑ evidence found
	– Anal intercourse including perianal condyloma (warts) or insertion trauma	❑ no evidence	❑ evidence found
	– Non–medical intravenous or percutaneous drug use (examine tattoos closely)	❑ no evidence	❑ evidence found
	– Disseminated lymphadenopathy (swollen lymph nodes—neck, axillary, inguinal)	❑ no evidence	❑ evidence found
	– Oral thrush (whitish infection on the tongue, in the mouth)	❑ no evidence	❑ evidence found
	– Blue or purple (gray or black) spots consistent with Kaposi's sarcoma	❑ no evidence	❑ evidence found
	– Jaundice or Icterus (yellow skin or sclera)	❑ no evidence	❑ evidence found
	– Hepatomegaly (enlarged liver)	❑ no evidence	❑ evidence found
PACE	We have performed complete evaluation of the procurement place and found no contraindicative conditions for the procurement realization. Place– Hospital/Home/Other (Specify)		
DONOR	We have performed complete visual examination of the donor and found no evidence that could be considered as contraindication for the tissue donation.		
COMMENTS			

Signature of Skin Retrieval Team: Date: _____ Time: _____

Team Leader: **Assistant 1:**

Name:

Hospital and address:

Assistant 2 : **Assistant 3:**

Name:

Hospital & Address:

SB FORM–5

Phase 1 Glycerol Preservation (GLYCEROL 50%)

To be filled at Retrieval

Donor Number: _____

Date of harvesting: _____ End Time of Procedure: _____

Team Members Name: 1 _____ 2 _____

3 _____ 4 _____

Dermatome Serial No: _____

Date of Sterilization: _____ Expiry date of Sterilization: _____

Battery Serial No: _____

MATERIALS

Donor No: _____ Hospital: _____

1.	Lot Number of glycerol 50%	:	_____	Expiry Date	: _____
2.	Lot Number syringe	:	_____	Expiry Date	: _____
3.	Lot Number plastic sheets	:	_____	Expiry Date	: _____
4.	Lot Number ampoule Streptomycin	:	_____	Expiry Date	: _____
5.	Lot Number ampoule Penicillin	:	_____	Expiry Date	: _____
6.	Lot Number Betadine Scrub	:	_____	Expiry Date	: _____
7.	Lot Number savlon	:	_____	Expiry Date	: _____
8.	Lot Number liquid paraffin	:	_____	Expiry Date	: _____
9.	Lot Number Sterilium	:	_____	Expiry Date	: _____
10.	Lot Number sterile gowns	:	_____	Expiry Date	: _____
11.	Lot Number Forceps	:	_____	Expiry Date	: _____
12.	Lot Number Scissors	:	_____	Expiry Date	: _____
13.	Lot Number Sterile gloves	:	_____	Expiry Date	: _____
14.	Lot Number dermatome blades	:	_____	Expiry Date	: _____

Signature of harvesting doctor (Team Leader) : _____

Date: _____ Time: _____

Remarks/Observation/Suggestion

_____

_____

_____

SB FORM–6

Checklist for Skin Recovery & Procedure Completion

To be filled at Retrieval by Retrieval team

Donor Number: _____

Sl. No.	Procedure Details	Yes / No
1	Have I checked the exclusion Criteria?	
2	Have I checked the cause of death from Death certificate?	
3	Have I taken the consent for donation?	
4	Have I done a physical check of the donor body and filled–up the appropriate column in form 4?	
5	Have I taken the blood sample 10ml?	
6	Have the team shaved the donor area?	
7	Have I waited for 10 minutes after Betadine scrubbing before going for next step?	
8	Have the antibiotics been added to glycerol bottle?	
9	From which area, the skin was procured?	Legs, Thighs, Back, Buttock
10	Remarks from not taking from a particular area	
11	How many blades were used?	
12	Were all the procedures followed as per the Jeevandan guidelines	
13	Have I filled up all the forms?	

Area	Recommended Thickness	Thickness Recovered	Remark
Leg	0.3–0.4mm		
Thighs	0.4mm		
Back	0.4mm		
Buttock	0.4–0.6mm		

Name of Skin retrieval Doctor: _____ Sign of Duty doctor: _____

Finishing the Procedure:

Responsibility: Duty Brother _____ Supervision: Duty Doctor: _____

Sl. No.	Procedure Details	Yes / No
1	Was the date of procurement put on glycerol bottle?	
2	Was the date, time, name,age, sex of donor and donor number written on blood sample tubes?	
3	Was the dermatome cleaned and kept as per the SOP?	
4	Was the battery removed from the dermatome?	
5	Were all the materials brought back from the skin collection place?	

Name of Duty paramedic : _____ Name of duty doctor : _____

Sign of Duty Paramedic : _____ Sign of duty doctor : _____

Procedure start Time : _____ Procedure End Time : _____

Procedure for handing over of donor skin and blood sample, dermatome and Skin collection Kit upon arrival at Skin Bank during non–office hours.

Responsibility: Team Leader (Duty Doctor) at Skin bank

1. Upon arrival at skin bank, the skin bank will be opened by the security staff in presence of team leader. The team leader will sign a log book of Skin bank mentioning opening and closing time of the skin bank.

2. The skin collection kit will be kept at the designated place by the duty paramedic staff with the label USED on it.

3. The duty paramedic staff will open the dermatome box and check if the battery is taken out of the dermatome and keep the battery in dermatome box. Take the dermatome out of the dermatome box. check whether the lower knob of the dermatome is closed properly or not. Keep the dermatome box near the Collection Kit.

4. Open the Skin bank laboratory, switch on the light, take the used dermatome to the washing area of skin bank. Near the washing area open the dermatome blade and discard the blade in the sharp bin. Dip the dermatome in the washing solution already present in the washing area.

5. The duty paramedic staff will store the donor skin and blood sample tube attached to it in red color freeze in the skin bank not in the walk–in fridge.

6. Do not touch any other machines in the skin bank lab, and switch–off the light and close the skin bank lab.

7. The team leader will store the file containing the donor certificate and forms in the designated place in the skin bank office

8. After all the above procedures are over the team leader will ensure that the skin bank is closed and will sign the Skin Bank log book kept in the skin bank office.

9. On the next day morning, the team leader will hand–over the documents and donor skin, blood sample and skin collection kit to skin Bank in–charge for further processing.

10. The team leader will sign a log book mentioning the date and time of hand over and ensure that the Skin Bank person counter sign on it.

.

SB FORM–7

Handing over of donor skin and blood sample tube dermatome box and Skin Collection Kit upon arrival at Skin Bank during Non–Office hours

To be filled at Skin bank

Responsibility	Function
Ownership	Skin Procurement team leader

A: Handing over checklist

Sl. No.	Procedure Details	Yes / No
1	Was the skin bank opened in my presence?	
2	Did I sign the Skin Bank Log book?	
3	Did the staff keep the collection kit and dermatome box at predefined place?	
4	Did the staff dip the dermatome without battery in washing solution?	
5	Did the staff keep the skin bottle and blood sample tubes in red color freeze in skin Bank	
6	Did I keep the donor file in the designated place in skin bank office?	
7	Was the skin bank closed in my presence?	

B: Receiver checklist of Donor Skin and Blood sample Tubes:

Responsibility	Function
Ownership	Skin Bank In–charge

Sl. No.	Procedure Details	Yes / No
1	Was the donor skin bottle lid completely tight and kept in skin bank red color freeze?	
2	Were all the materials returned to Skin Bank?	
3	Were all forms filled as per the SOP?	
4	Were the blood sample tubes present with skin bottle in red freeze?	
5	Was the dermatome dipped in washing solution?	
6	Was the dermatome battery kept in dermatome box?	

Name of Receiver : _____ Time of Receiving : _____

Sign of Receiver : _____ Date of receiving : _____

Designation of Receiver : _____

SB FORM–8

Checklist for transport of skin from Skin Collection Centre to Skin Bank

To be filled at Skin bank

Responsibility	Function
Ownership	Skin Bank In–charge.

1. On receiving a call from any skin collection centre informing that the skin is ready for transport, the skin bank in charge must ensure that skin must reach the SB within 20 hrs of harvesting after enquiring the following details

   A. Whether the serology test is negative ?

   B. Whether all harvesting documents are ready ?

2. The Skin bank person will receive the donor skin, original skin procurement documents, and serology report in hand and will sign a log book .

3. The skin bank person will carry an ice box to transport the skin. He should ensure that the donor skin bottle lid is closed tightly.

4. A handing over register is to be maintained by the skin collection center, which will include the date & time of the handing over, signed by the Skin Collection Centre Coordinator & the Skin Bank personnel.

5. On arrival at Skin Bank the skin bank person who transported the skin from SCC to SB will hand over the donor skin, serology report and documents to Skin Bank in charge and sign a hand over log book. The Skin Bank in charge will counter sign in the hand over log book after verification..

Sl. No.	Procedure Details	Yes / No
1	What is the time of receiving the call from SCC?	
2	Have I asked all the questions to SCC in charge?	
3	What time the person was sent for collection?	
4	What time the person returned to Skin Bank with Skin?	
5	Have I done a physical check of the skin containing bottle, documents, blood reports, death certificates?	

Signature and Designation of Person Receiving the skin at Skin bank

Date/ Time of receiving:

Name and address of the skin bank : _____

Signature of Skin bank In– Charge

Date/ Time

SB FORM–9

Checklist for Handing over of donor skin, Blood Sample Tubes, Dermatome box and Skin collection Kit upon arrival at Skin Bank during Office hours.

To be filled at Skin bank

Responsibility	Function
Ownership	Skin Bank in–charge
Notification	QA Manager, Skin bank Assistance.

Upon arrival at Skin bank, the team leader will hand over the skin collection kit, dermatome box , donor skin, blood sample and donor documents to the skin bank in–charge.

The team leader will sign the log book for handover and ensures that the receiver also sign the same.

Sl. No.	Procedure Details	Yes / No
1	Was the donor number on Skin bottle and form matching?	
2	Was the donor skin bottle lid completely tight	
3	Did all the materials return to Skin Bank?	
4	Were all forms filled as per the SOP?	
5	Were the blood sample tubes present with skin bottle?	
6	Did the dermatome return to Skin Bank?	
7	Was the dermatome battery kept in dermatome box?	
8	Was the skin stored at 4–8 degree Celsius in skin bank?	
9	Was the blood sample stored along with the donor skin	

Name of team leader: _____ Sign of team leader: _____

Name of paramedic staff: _____ Sign of paramedic staff: _____

Name and designation of Receiver: _____ Time of Receiving: _____

Sign of Receiver: _____ Date of receiving: _____

Name and address of the skin bank: _____

Remarks: _____

Phase 2

Includes Processing donor skin and sending blood sample for serology test and cleatning pack aging and sterilizing of dermatome

Procedure includes sending blood sample to serology, cleaning, packaging and sterilization of dermatome, quarantine and Skin processing in 85% glycerol

Steps	Procedure	SB Forms
A	Sending blood sample for serology testing	Form 11
B	Cleaning, packaging and sterilization of dermatome	————
C	Skin processing to 85 % glycerol	Form 10, 12 and 13

Responsibility of Skin bank incharge on receiving the donor skin

Skin bank in–charge will receive the donor skin from team leader and take the entire responsibility of that skin till the final phase of processing and further storage and distribution.

On receiving the donor skin and blood sample the skin bank in–charge will immediately fill up a Donor details log book and enter the details of the skin donation.

He will then enter the details of blood sample in Blood test log book and fill up a Serology Test requisition slip for HIV, HCV, HBsAg and CBC

He will send the blood sample and filled–up requisition slip and log book to Laboratory for testing. The receivers will sign in the Blood test log book after receiving the blood sample.

On receiving the serology report the result of test will be entered in the blood test log book with date, time of receiving the report with receiver signature.

SB FORM–10

Checklist for storing donor skin in quarantine before the start of Phase 2 processing

To be filled at Skin Bank

Responsibility	Function
Ownership	Skin Bank in–charge

Skin bank in–charge will receive the donor skin from team leader and take the entire responsibility of that skin till the final phase of processing and further storage. If Skin bank In Charge is absent at the time of arrival of skin harvesting team then whoever is present in the skin bank will receive the skin and act as the skin bank in charge and perform the duties as per the below mentioned SOP.

After receiving the donor skin, Skin bank in charge will check if the bottle containing the donor skin in 50% glycerol with proper la–beling is properly tight without any leakage. If any leakage or any other abnormality is observed he will write his remark in the storage check–list.

The skin bank in–charge will then store the donor skin in skin bank fridge at the rack designated for storing quarantine donor skin. He will ensure that the skin is processed after 2 hrs and within 24hrs of skin procurement. He will mobilize the team and required consumables for phase –2 processing.

The skin bank in charge will send the skin collection kit for refilling.

The Skin bank In charge will send the dermatome for washing.

The skin bank In Charge will send the used battery for recharge

Date of receiving the donor skin : _____

Time of receiving the donor skin: _____

Time of storing the donor skin: _____

Display temperature on the Skin bank: _____

Did I send the skin collection kit No _____ for refill? _____ To whom did I give? _____

Did I send the Dermatome serial No: _____ for washing? _____ Person Name: _____

Did I send the battery Serial No: _____ for recharge? _____ Person Name: _____

Signature of Skin bank In charge: _____

SB FORM–11

Checklist for sending blood sample for serology test

To be filled at Skin Bank

Responsibility	Function
Ownership	Skin Bank In–charge.

Sl. No.	Procedure Details	Yes / No
1	Was the blood sample Ok? (Yes/No)	
2	Time of receiving the blood sample	
3	Time of sending the sample for testing	
4*	Time of performing the test	
5*	Test Report attached to donor file	Yes/No

Name of person receiving the test report: _____

Signature of person receiving the test report _____

*to be filled after getting the test report _____

Cleaning and Packaging of Dermatome

Responsibility	Function
Ownership	Skin Bank Assistant.

Cleaning of Dermatome:

1. Take out the dermatome from the washing solution soaked from previous night.
2. Put the dermatome in hot boiling water and soap for 20 minutes. After 20 minutes allow it to cool.
3. After cooling, clean the dermatome specially its upper part with a tooth– brush to completely clean the area and to remove if any skin piece is still attached.
4. Rinse the dermatome in running water to remove excess soap.
5. Wipe the dermatome to soak out excess water and keep in hot air oven not exceeding 70 degree Celsius till it is fully dry.

Packing of dermatome for sterilization:

1. After the dermatome is dried and cooled, It is now ready for packing.
2. Open the locking cap.
3. Open the autoclave case, clean the case with spirit. Inside the case there are some cams.
4. Put the locking cap between two cams 16d as shown in Fig 25B of page Number–25 of Humeca Instruction manual.
5. Put the thickness adjustment lever at maximum thickness position.
6. Put the dermatome with blade compartment cover (8) opened in the case in such away the security cam 16b comes in the backside of the lower shaft. The two cams 16C interlocks with the slots indicated as 2f in Fig 25.
7. Close the cover of the autoclave case.
8. Pack the case in autoclavable plastic pack and seal with sealer.
9. Stick the label mentioning date of sterilization and expiry date of sterilization on the pack.
10. Stick a sterilization indicator stripe on the pack.
11. Send the pack to the central Sterilization department for autoclaving.
12. The receiver will sign after receiving the sterilization materials.
13. All the sterilization details are entered into the sterilization log book and sterilization form for future reference.

Cleaning and Packaging of Dermatome

Responsibility	Function
Ownership	Central Sterilization In–charge

1. Enter the date, time of sterilization in the Autoclave log book.
2. Write the date of sterilization and expiry date of sterilization on the label.
3. Check if the autoclavable plastic sheet is intact and air tight.
4. Put the packed dermatome in steam autoclave machine and sterilize at either one of the two below mentioned temperature.
   - 134 degree Celsius – 10minutes
   - 121 degree Celsius– 20minutes
5. After the sterilization process is complete, check if the sterilization indicator stripe is turned black.

   Change of color indicates proper sterilization. If color change does not happen , that means sterilization is not complete, in that case inform the same to Skin bank in charge.
6. The person who carried out the sterilization will write down the date, time of sterilization in the log book and sign it .
7. While handing over the sterilized materials, the sterilization in– charge will take the signature of the receiver and counter sign it.

Procedure for Skin Processing to 85% Glycerol

Responsibility	Function
Ownership	Skin Processing person

Processing donor skin from 50% to 85% glycerol

The time between the first phase (in which the donor skin is submerged in 50% glycerol) and second phase (processing donor skin to 85% glycerol) should be at least two hours and maximal 24 hours.

Processing takes place in a safety cabinet. Make sure the safety cabinet is operating for at least 30 minutes before starting the second phase prior to the processing.

Materials for the 2nd phase

1. Form for the second glycerol preservation
2. Jar with donor skin submerged in 50% glycerol
3. 1 sterile jar containing 85% glycerol
4. Sterile apron.
5. Sterile surgical gloves
6. 70% alcohol
7. Scissors and sterile scissors
8. Sterile gauzes
9. Sterile cover sheet, 120x40cm
10. Safety Cabinet, category 2
11. Incubator with shaking facilities
12. Liquid soap
13. 2%Sodium Hypo Chloride solution

Working Instructions:

1) If the flow was not switched on yet, switch on the Safety Cabinet, The Safety Cabinet must be operating for at least ½ hour before any operations can be performed in the Safety Cabinet.
2) Collect all necessary equipment to transfer the donor skin to 85% glycerol.
3) Fill out Form 10, and make sure that the unique Donor Identification Number is attached to it.
4) Disinfect the inside of the Safety Cabinet with 70% alcohol (use gauzes), including working area, sides and back.
5) Place the sterile cover sheet in the Safety Cabinet.
6) Check the Donor Identification Number on the jar with the Identification Number on the form (FORM 10). Put some non–sterile surgical gloves on and disinfect the outside of the jar with 70% alcohol, place it in the Safety Cabinet, open the jar.
7) Transfer the container containing 85% glycerol into the bio–safety cabinet after giving a IPA spray.
8) Wash hands, put on the sterile apron and put on sterile surgical gloves.

9) Take one piece of skin from the 50% glycerol and pull it between two fingers in such a way that most of the 50% glycerol solution is removed, skin is unwrinkled and no dermis is sticked together. especially take care of the edges.

10) Transfer the piece of skin into the sterile container containing 85% glycerol solution.

11) After all pieces are transferred to the 85% glycerol, take off the gloves, put on non sterile surgical gloves again and close the jar containing skin, take the jar out of the Safety Cabinet and Make sure the jar is perfectly closed to avoid unwanted leaking of fluid.

12) Put the unique Donor Identification Number on the jar.

13) Put the jar in the shaking incubator and incubate it for 3 hours at 33°C at 100RPM. Remove all equipments from the Safety Cabinet and put the disposables in the appropriate trash can. Take out the gloves.

14) Clean the Safety Cabinet with 70% alcohol, using gauzes and switch off the Cabinet if necessary.

15) Dip all non–disposables in 2% Sodium Hypo chloride solution overnight followed by cleaning in liquid soap on next day.

16) Discard all the disposable waste materials appropriately as per the waste disposal and cleaning protocol.

17) Complete FORM 10. Fill up the skin Processing log sheet with date of Phase 2 processing and scheduled date of Phase 3 processing (After 21 days from the date of Phase 2 processing) then enter the date of Phase 3 in year planner book of Skin Bank.

18) After three hours when the incubation is completed, switch off the incubator and take out the container from the incubator and keep it in walk–in fridge.

.

SB FORM–12

Form for the phase 2 glycerol preservation procedure

To be filled at Skin Bank

Donor Number: _____

Date of Phase 2: _____

Start Time: _____ End Time: _____

Name of Operator: _____

Lot No: glycerol 85% : _____ Expiry Date : _____

Lot No: sterile Container : _____ Expiry Date : _____

Lot Number sterile cover sheet : _____ Expiry Date : _____

Lot number of scissors : _____ Expiry Date : _____

Lot No: sterile forceps : _____ Expiry Date : _____

Lot Number of Sterile Gown : _____ Expiry Date : _____

Lot Number sterile surgical gloves : _____ Expiry Date : _____

Lot Number sterile face mask : _____ Expiry Date : _____

Lot No:sterile head cap : _____ Expiry Date : _____

Lot No: sterile wipe : _____ Expiry Date : _____

Donor ID label attached to bottle? : _____

RED color Label attached? : _____

Signature of operator : _____

Date : _____ Time : _____

Remarks/Observation : _____

_____

_____

Overall quality of Skin: _____

SB FORM–13

Check–list for Skin Processing Phase 2 in 85% Glycerol

To be filled at Skin Bank

Responsibility	Function
Ownership	Skin Processing person

Sl. No.	Details of Procedure	Yes / No
1	Was the Bio safety cabinet switched on for last 30 minutes?	
2	Was all the materials sterilized with label of date of Autoclaving and exp date?	
3	Was the donor number and date of procurement written on skin bottle?	
4	For how long the skin was kept in incubator?	
5	What was the temp, and RPM display in incubator?	Yes / No
6	Was the donor skin kept in Skin Bank freeze after end of incubation?	
7	Was the display temperature of Skin bank freeze between 4–80C?	
8	Was all the procedure done according to SOP	
9	Was the donor number attached to the skin bottle containg 85% glycerol?	
10	Was the date of processing entered into the processing log sheet and Year planner for Phase 3 pro–cessing?	
11	Was all the waste materials discarded appropriately?	
12	Was all the reusable materials put in the Hypo chloride solution	

Time of switching on of Biosafety cabinet : _____

Time of switching off of Biosafety cabinet : _____

Name of Skin Processing In–Charge : _____ Signature : _____

Start time of Skin Processing : _____ End Time : _____

Date of Processing : _____

Remarks : _____

After the second glycerol preservation process, donor skin must be stored in the cold room between 4°–8° C. preferably not exceeding 10°C. It is advised to use a temperature controlled refrigerator or a data collection system to record the temperature of the refrigerator at all times. To ensure the segregation of the untested skin sample, label the container with RED sticker.

Phase 3

Final processing and packing of the skin into final containers.

Selection criteria for phase 3 processing and Packaging of donor skin

Responsibility	Function
Ownership	Skin Processing person

Three weeks (or more) after the recovery of the skin, one can start with phase three if the donor is released based on the serology results and medical history.

Materials for the 3rd phase

1. Donor Batch Record File
2. Plastic container containing donor skin in 85% glycerol
3. Sterile 50 ml tubes
4. Calculator wrapped in sterile plastic
5. 85% glycerol
6. Sterile working suit, PPE (personal protection equipment)
7. Sterile surgical gloves
8. Sterile meshing board
9. Sterile holder for surgical blades
10. Sterile surgical blades
11. Sterile forceps
12. Sterile scissors
13. Sterile ruler
14. Labels with Donor Identification Number and date of processing
15. Sterile pencil
16. Sterile cover sheet,
17. Sterile containers
18. 70% Alcohol.
19. Washing solution
20. 2% sodium hypo chloride solution.

Preparations

1. On the Donor skin stock form (FORM 16), a list of all the suitable pieces of skin from one donor will be made. Place the donor identification number on the form. The bottle with donor skin with the corresponding number can be taken out of the refrigerator. The packaging process has to be carried out in the laboratory.
2. If the flow was not in the operation mode, switch on the Safety Cabinet. The Safety Cabinet must be operating for at least half an hour before any operation can be performed in it.

3. Collect all necessary equipment for the packaging of the donor skin
4. Fill in the charge numbers and expiry dates on Form 14
5. Wear non sterile gloves and disinfect the inside of the Safety Cabinet using 70% alcohol (use gauzes), including working area, sides and back.
6. Place the sterile cover sheet in the Safety Cabinet and all other sterile materials and calculator after giving an IPA spray.
7. Open the plastic container with donor skin and put the skin in the draining pan.
8. Wash hands, put sterile clothes on with sterile surgical gloves
9. Put the calculator in the plastic bag.

Packaging and inspection of donor skin

Take one piece of donor skin each time from the pan and control the skin for quality

Good	**Bad**
Overall same thickness	Differences in thickness, thin skin
Elastic	Fragile skin
Supple	Hard, sticked borders
Width > 4cm	Width < 4cm
Well preserved	Hydrolysis / epidermolysis
No abnormalities	Naevi, hairs, warts Non–aesthetic skin (i.e., stained with blood)

1. Cut off all bad parts for the good skin
2. Cut off irregular borders
3. Measure the skin, multiply with 1.15 since there is shrinkage of the skin due to the preservation process. Round off at 5 cm2
4. Minimum size of a skin piece is 50 cm2 and maximum 450 cm2, depending on the thickness of the skin.
5. The thickness of the skin has to be between 0.2 and 0.4 mm
6. Roll the donor skin, dermal side to dermal side
7. Place the piece of skin into a container and write the size on the label using the pencil. Write down the thickness of the skin on the label:
    a. Thickness 1 = thin skin, almost no dermal tissue
    b. Thickness 2, 3, 4 = increasing thickness
    c. Thickness 5 = thick skin, too much dermal tissue

8. Do not put more than 450 cm2 into a container and not more than one piece of skin

Finishing packaging of donor skin

Samples for microbiological testing must be prepared after placing all the pieces of donor skin into the containers. Fill 5 containers with remnants of skin; this must be a representative part of the packaged donor skin.

A. In case the skin is not meshed:

1. Fill all containers (also the sample containers for the microbiological test) with 85% glycerol till 0.5 cm from the rim.
2. Place the lids on the containers and close them completely to make them air tight

B. In case the skin is meshed: (meshing is done manually)

1. Put on sterile surgical gloves.
2. Take a sterile meshing board
3. Take a piece of skin from the container and place it on the board. Place the epidermal side facing up.
4. Start meshing the skin using sterile blade in 1:1 ratio.
5. Put the meshed skin back in the same container
6. Take from the last pieces of skin that you mesh, some samples and add them to the samples for microbiological testing.
7. Put on clean gloves
8. Fill all containers including the containers for microbiological testing with 85% glycerol till 0.5 cm for the rim.
9. Place the lids on the containers and close them completely to make them air tight.
10. The sterile procedure is now finished.

Finishing of Phase 3 Processing:

1. Wear non sterile examination gloves.
2. Remove all the materials from the inside of bio–safety cabinet.
3. Throw the remnants of donor skin into the appropriate biomedical waste bag.
4. The disposables material like the cover sheet must be thrown away in appropriate biomedical plastic bag
5. Dip all the reusable equipment and materials in 2% Hypo chloride solution overnight.
6. Clean the inside of biosafety cabinet with IPA spray
7. Turn off the Safety Cabinet.
8. Keep all the sterile small bottle containg skin of the donor in one big plastic box, label the box with the corresponding donor Number.
9. Fill in the storage form (FORM 09), Phase–3 Processing form and check list for Phase 3 processing.
10. Hand–over all the filled–up forms to Skin bank In–charge to be attached to batch Record form of that Skin donor.

SB FORM–14

Checklist of the material required for phase 3 processing

To be filled during Phase 3 processing

Donor Number: _____

Date of third Phase processing: _____

Start Time: _____ End Time: _____

Name of Operator: _____

		Expiry date
Lot No.85% glycerol	: _____	: _____
Lot No. Empty sterile 50ml bottle	: _____	: _____
Lot No. Sterile gown	: _____	: _____
Lot No. Meshing Board	: _____	: _____
Lot No. Surgical blade holder	: _____	: _____
Lot No. sterile Forceps	: _____	: _____
Lot No. Sterile Scissor	: _____	: _____
Lot No. Sterile Ruler	: _____	: _____
Lot No. Sterile Pencil	: _____	: _____
Lot No. sterile Cover sheet	: _____	: _____
Lot No. Sterile Surgical blade	: _____	: _____
Lot No. Face mask	: _____	: _____
Lot No.Sterile head cap	: _____	: _____
Lot No. Sterile gloves	: _____	: _____

Donor Skin Meshed or Unmeshed? : _____

Number of microbiological testing containers : _____

Containers labelled? : _____

Donor Identification Number on bin? : _____

Data completed on Donor Skin Storage Form 16? : _____

Signature of operator : _____

Date: _____ Time: _____

Remarks/Observation: _____

Overall Quality of Skin _____

SB FORM–15

Checklist for phase 3 processing packaging of donor skin

To filled during Phase 3 processing

Responsibility	Function
Ownership	Skin Processing person

Sl. No.	Details of Procedure	Yes/No
1	Was the Bio safety cabinet switched on for last 30 minutes?	
2	Were all the materials sterilized with label of date of Autoclaving and exp date?	
3	Was the donor number and date of procurement written on skin bottle?	
4	Were all the procedures done according to SOP	
5	Was the date of processing entered into the processing log sheet ?	
6	Were all the bottles labelled with measurement details	
7	Were all the forms filled up?	
8	Were all the waste materials discarded appropriately?	
9	Were all the reusable materials put in the Hypo chloride solution	
10	Was the donor skin stock form filled in?	

Name of Skin Processing In–Charge: : _____ Signature: _____

Start time of Skin Processing: _____ End Time: _____

Date of Processing: _____

Remarks : _____

II. Labelling and Storage

Labelling of the donor skin containers

Responsibility	Function
Ownership	Skin Processing person

1. Place labels with the Donor Identification Number corresponding with the number and description in the storage form on the back of the containers.
2. Place labels with the Donor Identification Number on the containers with the samples for microbiological testing and number them.
3. Put the label with Donor Identification Number on the bin where all containers will be stored. Indicate if donor skin is meshed using a M or M 1:2.
4. Put the sample containers for microbiological testing in the same bin
5. Place the bins with containers in the refrigerator.
6. Finish the form for the 3rd phase (FORM 14)
7. Until transport, the containers have to be stored in the refrigerator

III. Distribution

Making invoice for distribution of donor Skin to Recipient

Responsibility	Function
Ownership	Skin Processing person

Request for donor skin can be made to Skin bank for medical use by treating clinician on hospital letter–head stating the following details:

Name of the patient:

Percentage of Burns

Requirement:

Name of treating doctor:

1. On receipt of hard copy or scanned copy of the request letter from the treating doctor, the skin bank in–charge will ask for the processing fee of the required quantity from the person requiring donor skin.
2. Payment can be made by Demand draft or by cheque or by online fund transfer.
3. After receiving the request letter and DD or cheque, the skin bank in–charge will prepare 3 copies of invoice copy, and deposit the processing fee and 3 copies of invoice letter to the concerned authorities
4. The billing department on receipt of payment will sign on the invoice copy stating amount received and give back three signed copies of invoice and the receipt of payment to the skin bank in–charge or his representative.
5. The skin bank in– charge then will get the authorization signature of Administrator of Burns Centre on the three invoice copies of invoice.
6. First copy of the invoice will be given to Account department of Burns Centre for record.
7. Second copy will be given to recipient of donor skin.
8. Third copy will be signed by recipient (stating that donor skin received) and account department (stating that copy of invoice received).
9. The third copy of the invoice bearing the signature of recipient and account department will be stored in skin bank in the desig–nated file containing invoice copies.
10. After the paper work is completed the skin bank in–charge will follow SOP for packing and distribution of donor skin to recipient
11. Donor skin will be packed as per the packing and distribution.
12. All the information related to donor skin dispatched from Skin bank like Donor number, amount of skin, number of bottles given are to be entered into the Donor Skin stock form (Form 17) and donor details log book.

Instruction for packing and distribution of donor Skin to Recipient

1. On receipt of authorization to issue donor skin, the skin bank in–charge will prepare a note mentioning the following details
   a. Donor Number:
   b. Bottle Number:
   c. Date of Dispatch:

d. Signature of Skin bank In–charge:

e. Signature of Skin bank store in–charge:

f. Collect recipient details as per form 16:

2. The donor number and number of bottles should match on the Form 8 and the note. The note will be given to the skin bank store in charge for packing the donor skin bottles.

3. The note should be retained by the skin bank store in–charge in a separate file for future reference.

Packing of Donor Skin:

1. Donor skin must be packed in a firm thermocol box, together with some cooling units in it and should be clearly labelled from the outside that the box contains Donor Skin.

2. The thermocol box containing the donor skin should be handed over to the skin bank in–charge who will hand it over to the recipient along with the invoice copy and receipt of payment.

SB FORM–16

Recipient details

Name of the recipient: _____ Age/Sex: _____

Name and address of admitting hospital: _____

_____

Diagnosis : _____

Percentage of burns : _____

Comorbidity : _____

Date of the call received : _____

Time of the call received : _____

Name and designation of treating doctor : _____

Date of admission : _____

Date of requirement of donor skin : _____

Time of requirement of donor skin : _____

Indication for skin grafting : _____

_____

_____

SB FORM–17

Donor Skin Stock Form

Donor No :	Meshing Details	Quantity (units inSq.Cm.)	Bottle No
Date of Processing :	Meshed 1:2		
Operator Name :	Meshed 1:3		
Quality : Good / Moderate / Bad :	Research		
MICROBIOLOGY : 1st	2nd :	3rd:	
QUALITY EVALUATION :			

Processed Skin Details						Distribution Details					Stock Details		
S. No.	Bottle No	Size			Thickness	Invoice No	Invoice Date	Recipient	Given By	Checked By	Particulars	Date	Qty.
		Length	Width	Total Size									
1				0							Opening Stock		0
2				0							Distributed		
3				0							Balance Stock		0
4				0							Distributed		
5				0							Balance Stock		0
6				0							Distributed		
7				0							Balance Stock		0
8				0							Distributed		
9				0							Balance Stock		0
10				0							Distributed		
11				0							Balance Stock		0
12				0							Distributed		
13				0							Balance Stock		0
14				0							Distributed		
15				0							Balance Stock		0
16				0							Distributed		
17				0							Balance Stock		0
18				0							Distributed		
19				0							Balance Stock		0
20				0							Distributed		
21				0							Balance Stock		0
22				0							Distributed		
23				0							Balance Stock		0
24				0							Distributed		
25				0							Balance Stock		0
26				0							Distributed		

27				0							Balance Stock		0
28				0							Distributed		
29				0							Balance Stock		0
30				0							Distributed		
											Balance Stock		0
											Distributed		
Total	0	0	0								Balance Stock	0	

SB FORM–18

Donor Skin Stock Form

To be Filled During Phase 3 Processing

Name of Procedure : _____ Details: _____ Sign / Remarks : _____

Cause of death		
Date/time of receiving call		
Date/ time of harvesting		
Team leader name		
Time of reaching skin bank		
Person receiving the skin		
Time of storing blood samle		
Time of sending for test		
Date of receiving the report		
Hiv		
Hcv		
Hbsag		
Date and time of phase 2		
Start time of incubation		
End time of incubation		
Date /time of storing in walkin fridge		
Scheduled date of phase 3		
Date/time of phase 3 done		
Amount of skin stored/number of bottles		
Scheduled date of 1st microbilogy test		
Date of microbiology test done		
Date of test report received		
Result of test		
Action taken		
Schedule of date of 2nd microbiology test		
Date of 2nd microbiology test done		
Date of test result received		
Result		
Action taken		

Microbiology Media Preparation and Storage in 10ml Bottle

Materials requirement:

1. Thioglycollate medium powder (check for expiry date)
2. Soybean Casein digest mediumpowder(check for expiry date)
3. Bio safety cabinet.
4. Stirrer 2
5. Tube rack 2
6. Sterile disposable 15ml test tubes– As per requirement.
7. Sterile water– As per requirement.
8. Measuring cylinder.
9. Sterile conical flask–3
10. Weighing balance
11. Aluminium foil
12. Sterile pipettes 10ml.
13. Permanent marker.
14. Conical flask plug.

Method:

1. Switch on the UV light of bio safety cabinet for 15 minutes.
2. Wear the disposable examination gloves. Switch off the UV light and wipe the inside of the cabinet with IPA.
3. Wipe the glassware with IPA and take them inside the cabinet.
4. Add @ 3 gm of Thioglycollate medium to 100ml of sterile Millipore water in a beaker.
5. Add @3 gm of soyabean casein digest medium to 100 ml of sterile Millipore water in a separate beaker.
6. Stir the powder in the water to dissolve completely separately.
7. Cover both the beaker with aluminium foil so as to make it air tight and bring it out of the biosafety cabinet.
8. Close the safety cabinet and switch off the flow.
9. Autoclave the beaker to sterilize the medium.
10. Allow the medium to cool down
11. In the meantime, switch on the flow of the cabinet again and wipe the inside of the cabinet with IPA.
12. Wipe the sterile tubes with stand with IPA and transfer them into biosafety cabinet.
13. Transfer the cooled media inside the bio safety cabinet.
14. Label two sets of tubes one for Thioglycollate and other for Soyabean casein digest medium. The date of media preparation and date of expiry is to be mentioned on the tubes. The expiry date is counted as 30 days from the date of preparation.
15. Pour 10ml of each medium in two sets of tubes with the help of sterile pipettes and close the caps tightly.
16. Store the media tubes between 4–8–degree Celsius maximum up–to 1 month from the date of preparation
17. Wipe and clean the inside of the cabinet with IPA.
18. Switch off the flow and close the cabinet.

Microbial Testing of Donor Skin

Responsibility	Function
Ownership	Quality Manager
Notification	Skin Bank In charge, Skin Processing team.

Time of 1stMicrobiologial Test : On the day of Phase 3 processing.

Time of 2nd Microbiological Test : After 12 weeks of 1st test.

Time of 3rd Microbiological test : After 12 weeks of 2nd test in case of positive result

Time of 4th Microbiological Test : After 12 weeks of 3rd test in case of positive result.

Scope:

1. Fluid thioglycollate medium for detection of bacteria, culture temperature 30–35ºC in the incubator.
2. Soya–bean casein digest medium for detection of aerobic bacteria and fungi, culture at room temperature, around 25ºC.

Materials Requirement:

1. Prepared media tubes.
2. Marker pen.
3. Representative sample of donor skin to be tested.
4. Sterile foreceps–2 nos.
5. Biosafety cabinet.
6. Sterile IPA spray.
7. Sterile swipes.
8. Sterile Gloves.
9. Examination gloves
10. Sterile coat, face mask, head cap.

Method:

1. Switch on the flow of Biosafety cabinet for 15 minutes.
2. Bring all the materials near the cabinet.
3. Wear the sterile gown and examination gloves.
4. Wipe all the tubes with IPA and take them inside the cabinet.
5. Label the two media tubes with corresponding donor number and date of incubation.
6. Take out pieces of skin from the representative sample bottle with the help of two sterile forceps in such a way that the glycerol is squeezed out from the skin. Put the skin pieces into both thetubes containing liquid thyioglycollate and soyabean casein digest medium.
7. Close the cap of the media tubes and seal the cap with paraffin to make it air tight.
8. Incubate the Tube A with fluid thioglycollate medium for detection of anaerobic bacteria at temperature 30–35 degrees Celcius in the incubator.

9. Incubate the Tube B with soya bean casein digest medium for detection of aerobic bacteria and fungus at room temperature around 25 degrees Celcius.
10. Enter the records in the Form 18, and door details log book.
11. All the tubes are cultured for 14 days The media is checked every day for turbidity

Daily Observation:

Every day the tubes have to be inspected, if the media turns to turbid from clear , the tube has to be sent to microbiology department for identification of organisms and the report to be obtained and attached to the file.

Final Observation:

1. If no growth occurs in 14 days, the tubes are sent to microbiology department for confirmation of no growth.
2. Batches with positive result must be kept in quarantine for 12 weeks before the 2nd test is done.
3. If after 3rd microbiology test, the skin sample is positive for microbial growth, then the whole lot of donor skin is disposed.

PART 3

Skin allograft allocation and distribution policy of Jeevandan Cadaver Transplantation Programme of Government of Telangana

1. As on Aug 2021 there is only one skin bank established in the entire state of Telangana at Osmania General Hospital. Hence all the distribution policy shall be framed accordingly, However these are subjected to change with the establishment of other skin banks and through proper procedure.

2. All the brain dead donor shall be counseled for skin donation at the time of counseling for organ donation and intimated to Jeevandan officials, if family member agree for skin donation a separate consent form shall be taken in addition to all the legal formalities of brain death.

4. Skin donation from cardiac death shall be considered within 10–12 hrs of cardiac arrest and after proper counseling and consent of the family members in a consent form. No other legal procedure required unless it is medico legal case. In case of medicolegal case, inquest should be done before skin retrieval

5. Skin retrieval shall be done only after all the organ are retrieved from the brain dead

6. All the skin allograft retrieved from any of the private or government hospital in the state shall be sent to Skin bank at Osmania General Hospital for processing and storage

7. Retrieval team shall be constituted from the faculties of department of Plastic Surgery from Osmania General Hospital, Gandhi Hospital and NIMS Hospital and would be posted in rotation for skin retrieval

8. The stored skin graft shall be distributed to the burns patients being treated in government Hospital in the following order

   1. Osmania General Hospital

   2. Gandhi Hospital

   3. NIMS Hospital

9. The request for the skin graft from the private hospitals shall only be considered after permission from the appropriate authority

10. The records of all the data related to skin graft; the donor details, skin graft details, skin stock in the skin bank, recipient details shall be linked to and maintained in the existing Jeevandan portal.

Committee Members

Dr. Madhusudhan Naik
Assistant Prof, Plastic Surgery
Osmania General Hospital

Dr. Jyothilakshmi
Microbiology
Osmania General Hospital

Dr. R. Parvathi
Additional Professor
Plastic Surgery NIMS

Dr. Prasanthi
Microbiology
Osmania General Hospital

Dr. Ram Babu
Senior Consultant, Plastic Surgery
Yashoda Hospital Somajiguda

Dr. Kiran
Assistant Prof, Plastic Surgery
Osmania General Hospital

Dr. Mahender
Associate Prof, Plastic Surgery
Gandhi Hospital

Dr. Suneel Kumar
Additional Prof & HoD, Emergency Medicine
NIMS

Dr. G. Swarnalatha
Senior Medical Professional
I/C Jeevandan Scheme

Dr. K. Manohar
Director, NIMS
Co–Chairman, AACT Jeevandan

Dr. K. Ramesh Reddy
Director Medical Education
Chairman, AACT Jeevandan

www.jeevandan.gov.in

Jeevandan Office
Nizams Institute of Medical Sciences, Punjagutta, Hyderabad, Telangana, India
T: +91 40 2348 9494 | M: +91 88850 60092, +91 88850 60093
E: Jeevandan.telangana@gmail.com