Supply and Reagent Form

Supply Information

Item		Quantity	Manufacturer	Lot Number	Exp. Date
SST Gel Vacutainer (yellow, tiger)	☐ N/A				
K_3EDTA Vacutaner (purple)	☐ N/A				
ACD (yellow)	☐ N/A				
Vacutainer (red)	☐ N/A				
Skin Recovery Pack	☐ N/A				
Bone Recovery Pack	☐ N/A				
Other:					
Other:					
Other:					

Solution/Reagent Information

Item		Manufacturer	Lot Number	Exp. Date
RPMI 1640	☐ N/A			
Bactoshield CHG2%	☐ N/A			
Sure-clens	☐ N/A			
Mineral Oil	☐ N/A			
Betadine	☐ N/A			
0.9% NaCl	☐ N/A			
Gentamicin	☐ N/A			
Bacitracin	☐ N/A			
Other:				
Other:				
Other:				

Sterilized Equipment Information

Item		ID #	Load Number	Chemical Indicator		Exp. Date
Dermatome	☐ N/A			☐ Passed	☐ Failed	
Bone Set	☐ N/A			☐ Passed	☐ Failed	
Other:				☐ Passed	☐ Failed	
Other:				☐ Passed	☐ Failed	
Other:				☐ Passed	☐ Failed	

Coordinator Initials: _____ Date: _____

Coordinator's Notes

Date/Time	Comments

Coordinator Initials: _____ Date: _____

U.S. Tissue & Cell

USTC-West division
675 Arapeen Drive, Suite 102• Salt Lake City, Utah 84108• 866-255-0034• Fax (801) 583-0957

SKIN PROCUREMENT SUPPLY AND REAGENT LOG

Supply Information

Item		Manufacturer	Lot Number	Exp. Date
SST Gel Vacutainer (yellow, tiger)	☐ N/A			
K_3EDTA Vacutaner (purple)	☐ N/A			
ACD (yellow)	☐ N/A			
Vacutainer (red)	☐ N/A			
Skin Recovery Pack	☐ N/A			
Other:				
Other:				

Solution/Reagent Information

Item		Manufacturer	Lot Number	Exp. Date
RPMI 1640	☐ N/A			
Bactoshield CHG2%	☐ N/A			
Sur-clens	☐ N/A			
Gentamicin	☐ N/A			
Other:				
Other:				

Team Leader Signature:_____ **Date:** _____/_____/_____

RET-005 Rev:00 Effective: 9/20/04 **Donor ID Number:** _____

U.S. Tissue & Cell

TISSUE DONOR PROCUREMENT REPORT

Donor Name: _____

MRN: _____

**This document must be completed and left with the procurement facility*

Recovery Information

Location of Procurement: _____

Room: _____ Facility Contact: _____

Arrival Date: ____/____/____ Time: _____ End Time: _____

Team Members: _____

_____

The following tissue were recovered by U.S. Tissue and Cell:

☐ Skin Grafts

☐ Musculoskeletal:

☐ R Iliac Crest	☐ R Fibula	☐ R Fascia Lata
☐ L Iliac Crest	☐ L Fibula	☐ L Fascia Lata
☐ R Femur	☐ R Patellar Tendon	☐ R Humerus
☐ L Femur	☐ L Patellar Tendon	☐ L Humerus
☐ R Tibia	☐ R Achilles Tendon	☐ Other:_____
☐ L Tibia	☐ L Achilles Tendon	☐ Other:

Funeral Home Information

Funeral Home Name: _____

Phone Number: _____ Contact: _____

Comments: _____

_____

_____

Reconstruction Information

Donor body reconstructed?

☐ Yes ☐ No If "No" explain: _____

_____

☐ Prosthetics used (**CAUTION:** Metal Screws) ☐ Viscerock used Femoral artery intact: ☐ Yes ☐ No

U.S. Tissue and Cell Contact

USTC Contact: Tammy Brown (801) 746-3936

Recovery Team Leader and Phone Number: _____

Coordinator Initials: _____ Date: _____

RET-002 Rev: 02 Effective: 1/30/04

1

U.S. Tissue & Cell

ALLOGRAFT SKIN PROCESSING WORKSHEET

Donor #:_____ **Processing Date#:**____/____/____

Processing Information

☐ Cryopreserved Skin Processing ☐ Fresh Skin Processing

Processing Technician #1:_____

Processing Room #: _____

Room cleaned pre-processing: Date: ____/____/____ Time: _____

Processing Start: Date: ____/____/____ Time: _____

Processing Finish: Date: ____/____/____ Time: _____

Room cleaned post-processing Date: ____/____/____ Time: _____

Total time elapsed un-refrigerated: _____minutes

Skin Graft Analysis

Debris or Hair Present ☐ Yes ☐ No Percentage of Grafts with insufficient dermis _____%

Total centimeters processed _____cm2 Estimated discard _____cm2

Comments: _____

_____

_____

Processing Supply/Reagent Information

Item		Quantity	Manufacturer	Lot Number	Exp. Date
Bowls	☐ N/A				
Gauze	☐ N/A				
Gloves	☐ N/A				
Gowns	☐ N/A				
Knife blades	☐ N/A				
Table Covers	☐ N/A				
Dermacarrier	☐ N/A				
Custom Pack	☐ N/A				

Item		Quantity	Manufacturer	Lot Number	Exp. Date
RPMI 1640	☐ N/A				
0.9% NaCl	☐ N/A				
Gentamicin	☐ N/A				
15% Glycerin/LR	☐ N/A				
Other	☐ N/A				

Item		ID #	Load Number	Chemical Indicator	Exp. Date
Cutting Board	☐ N/A			☐ Passed ☐ Failed	
Instrument Pack	☐ N/A			☐ Passed ☐ Failed	
Mesher	☐ N/A			☐ Passed ☐ Failed	
Tissue Packages	☐ N/A			☐ Passed ☐ Failed	
Other	☐ N/A			☐ Passed ☐ Failed	

Tissue Bank Specialist: _____ Date: _____

U.S. Tissue & Cell

ALLOGRAFT SKIN REVIEW FOR TRANSPLANT

Donor Number:_____ **Date of Procurement:** ____/____/____

Preliminary Procurement Cultures

Tissue	Preliminary Microbiology Results	Date	Initials
Anterior Leg ☐ N/A			
Posterior Leg ☐ N/A			
Back ☐ N/A			
Abdomen ☐ N/A			

Final Procurement Cultures

Tissue	Final Microbiology Results	Date	Initials
Anterior Leg ☐ N/A			
Posterior Leg ☐ N/A			
Back ☐ N/A			
Abdomen ☐ N/A			

Fresh Processing Tissue Cultures

Tissue	Final Microbiology Results	Date	Initials
Anterior Leg ☐ N/A			
Posterior Leg ☐ N/A			
Back ☐ N/A			
Abdomen ☐ N/A			

Cryopreserved Processing Tissue Cultures

Tissue	Final Microbiology Results	Date	Initials
Anterior Leg ☐ N/A			
Posterior Leg ☐ N/A			
Back ☐ N/A			
Abdomen ☐ N/A			

Comments: _____

_____

_____

_____

RELEASE FOR:

☐ **Clinical Transplant** ☐ **Clinical Transplant and Research** ☐ **Research Only** ☐ **Discard**

Administrative Approval *(check required signers)*

☐_____ ____/____/____ ☐_____ ____/____/____

Technical Director or Designee **Date** **Medical Director or Designee** **Date**

PRO-003 Rev:03 Effective: 4/30/04

U.S. Tissue and Cell
675 Arapeen Drive, Suite 102
Salt Lake City, Utah 84108
801-583-0907

ADVERSE REACTIONS

In order to provide high quality allograft tissue, it is essential that we be informed of adverse reaction, allograft and/or package defects, and any problems. Please complete this form and immediately forward it to U.S. Tissue and Cell. The adverse reaction reported will be investigated, and you will be notified of the results. We greatly appreciate your cooperation.

Reaction Date: ____/____/____

Allograft Recipient: _____

Medical Record Number (MRN): _____

Hospital/Facility: _____

Address: _____

City: _____ State: _____ Zip: _____ Telephone #: _____

Allograft Tissue Identification Number(s): _____

Procedure Performed: _____

_____

Detailed Description of Reaction/Problem: _____

_____

_____

Physician Name (Type or Print): _____

Physician or Designee's Signature: _____

U.S. Tissue and Cell
675 Arapeen Drive, Suite 102
Salt Lake City, Utah 84108
801-583-0907

ADVERSE REACTIONS

In order to provide high quality allograft tissue, it is essential that we be informed of adverse reaction, allograft and/or package defects, and any problems. Please complete this form and immediately forward it to U.S. Tissue and Cell. The adverse reaction reported will be investigated, and you will be notified of the results. We greatly appreciate your cooperation.

Reaction Date: ____/____/____

Allograft Recipient: _____

Medical Record Number (MRN): _____

Hospital/Facility: _____

Address: _____

City: _____ State: _____ Zip: _____ Telephone #: _____

Allograft Tissue Identification Number(s): _____

Procedure Performed: _____

_____

Detailed Description of Reaction/Problem: _____

_____

_____

Physician Name (Type or Print): _____

Physician or Designee's Signature: _____

Allograft Skin Package Insert

DESCRIPTION:

Human skin allograft was prepared from the skin of a cadaveric donor. The tissue was recovered within 15 hours, or within 24 hours of death if the body was refrigerated. Prior to recovery, the skin was cleansed with antimicrobial solutions and lubricated with sterile Shur-Clens (20% Poloxamer 188). The average thickness of this skin allograft is approximately 0.010-0.015 inches. The shape is an irregular rectangle and the surface area is indicated on the label.

The donor from whom this allograft was derived has been tested and found negative for antibodies to human immunodeficiency virus (anti-HIV 1 and 2), hepatitis B surface antigen (HbsAg), hepatitis B core antibody (HBc Ab), hepatitis C antibody (anti-HCV), human T-lymphotrophic virus type I and II antibody (anti HTLV 1 and 2), and rapid plasma reagin (RPR) or serological tests for syphilis (STS), using FDA-licensed test kits by a CLIA certified lab. Laboratories performing infectious disease testing include the following; Laboratory at Bonfils, ARUP, Cincinnati Children's Hospital, New Jersey Organ and Tissue Sharing Network, Viromed Laboratories, University of Iowa Hospital, and Lifenet .

The donor was selected based on medical history, social history, and physical examination criteria which meet the Standards of the American Association of Tissue Banks (AATB)[1,2], United States Public Health Service (USPHS)[3], and the Federal Food and Drug Administration (FDA)[4]. Donor suitability determined by the U.S. Tissue and Cell Medical Directors.

At the time of recovery and processing, a representative sample of this skin allograft was microbiologically tested and found to be free from pathogenic microorganisms. The skin allograft may contain certain normal flora that is identifiable and considered to be nonpathogenic of low virulence such as those commonly found on the skin surfaces.

INDICATIONS AND USAGE:

Human skin allograft may be used for temporary coverage of epithelial surface defects due to third degree burn or other cause, in highly selected circumstances after careful review of the availability and desirability of using skin autograft. Surgeons using human skin allograft should possess the training and skills necessary for use.

CONTRAINDICATIONS:

The human skin allograft should **not** be used if the expiration date has been exceeded, container in which the product is stored is damaged, container is not labeled, or the product has not been stored at the recommended temperature. No other absolute contraindications are known to exist. However, **small amounts of gentamicin and/or penicillin antibiotics may be present** and caution should be exercised if the patient is allergic to these antibiotics. A relative contraindication would include the presence of gross infection in the host bed where the graft is applied.

SIDE EFFECTS AND HAZARD:

Alloimmunization of the recipient to donor histocompatibility antigens may be a consequence of human skin allograft transplantation. Human skin allograft is for temporary use only and should be removed soon enough to prevent an immune reaction which may be detrimental to future grafting. Autologous grafts should be used whenever possible. Side effects and hazards should be considered and weighed against the limitations of alternative graft material. Bacterial infection at the site of grafting may occur[5]. U.S. Tissue and Cell utilizes strict donor screening procedures to avoid the ollection of tissues from donors who may carry infectious agents. Despite rigorous donor screening and laboratory testing, this tissue may transmit infectious agents. Any transmission of disease that is suspected to be caused by the tissue allograft must be reported promptly to U.S. Tissue and Cell. U.S. Tissue and Cell will supply an Adverse Reaction Form to report any tissue adverse reactions.

GENERAL INSTRUCTIONS:

The following general instructions pertain to the use of human skin allograft:

CAUTION: This tissue allograft must not be used under the following circumstances:

1. The container in which the skin allograft is stored is damaged.
2. The expiration date has been exceeded.
3. The container is not labeled or the information on the label is obliterated or defaced.
4. The tissue has not been stored at the recommended temperature (Fresh: 2-10°C. Cryopreserved: -70 to -150°C.).

Hospitals must maintain records so that infections associated with human skin allograft can be linked with specific lot numbers of the specific allograft (MMWR 1989; 38:43). Please retain a copy of the Skin Allograft Transplant Record for your records.

Fatal transplantation complications: If a disease transmission complication of tissue allograft use is confirmed to be fatal, it should be reported to the state health department, the hospital tissue storage service, and U.S. Tissue and Cell.

This allograft is intended for single patient use only.
This allograft is restricted for use by a physician, podiatrist, or dentist.

DOSAGE AND APPLICATION PROCEDURE:

1. The amount of skin allograft needed is based on the condition and size of the epithelial defect.
2. Preparation of the host bed is important and it should be devoid of gross infection.
3. Using aseptic technique, the skin allograft should be applied with the dermal side of the allograft applied to the host bed.
4. The allograft should be flattened and applied in a manner to prevent displacement (i.e., steri-strips, surgical staples, or suture).
5. Following application to the patient, record the following information in the hospital tissue storage service record, and the patient's medical record: allograft description, unique identification number, whether the graft was cultured prior to use, date and time of implantation, and other relevant information.

TISSUE TRACKING:

It is the responsibility of the user surgeon to complete recipient records for the purpose of tracking tissue post transplant. Complete the enclosed *TRANSPLANT RECORD* in detail and return as indicated. If allograft is not used for any reason after opening packaging, complete the enclosed *TRANSPLANT RECORD* in detail, noting the method of disposal, and return as indicated.

INSTRUCTIONS FOR PREPARING FRESH HUMAN SKIN ALLOGRAFT:

Grafts have been retrieved under aseptic technique. The tissue was quarantined and placed in antibiotics (Gentamicin 10 mg.).

The grafts are stored in RPMI 1640 w/ 2.05 mM L-Glutamine cell nutrient. The grafts may be stored for up to 14 days after the date of procurement at temperatures between 2-°C. as long as the cell nutrient is changed every 48 to 72 hours. Human skin allograft has been sealed in a FDA Class II Device package to aid in preventing bacterial contamination up to the time of expiration.

1. It is recommended that the package be thoroughly inspected prior to opening.
2. If the skin allograft is packaged in the peel package, opening is accomplished by grasping both sides of the peel pouch and aseptically passing the graft to the scrub nurse or surgical assistant
3. If the skin allograft is packaged in a rigid container with a lid, opening is accomplished by unscrewing the cap to the container and aseptically pouring the graft and media into a bowl on the sterile field.
4. Rinse the skin allograft into room temperature saline or Lactated Ringers solution.
5. A representative sample may be sent for microbiological testing at this point.
6. Antibiotics may be added to the rinse solution at the physician's request.
7. Unbreached packages or containers of fresh human allograft skin may be stored between 0-10°C until the expiration date has been reached.
8. The human skin allograft may be warmed to body temperature immediately before use, but should not be kept above 10° C for more than 2 hours, total.

INSTRUCTIONS FOR PREPARING CRYOPRESERVED HUMAN SKIN ALLOGRAFT:

Grafts have been retrieved under aseptic technique. The tissue was quarantined and placed in antibiotics (Gentamicin 10 mg).

The Grafts are processed aseptically. Grafts are rinsed 3 times, cut, measured, and either meshed (1 to 1), or not-meshed. The grafts are placed between gauze, folded and placed into a cryo-foil package with 5 cc's of cryo-protectant (15% glycerin in Lactated Ringers, USP); antibiotics are added to the cryo-protectant (Penicillin and/or Gentamicin). The packages are sealed and the tissue is frozen using control-rate freezing to a temperature of -70 to -90°C. The cryo-preserved allograft skin should be stored at temperatures between -70° to -130°C.

1. To thaw the skin allograft while still in package, place package directly into room temperature water or normal saline.
2. The package should be wiped dry before opening to avoid contamination of the sterile field.
3. Opening is accomplished by grasping each side of the peel pouch and aseptically passing the allograft to the scrub nurse or surgical assistant.
4. Rinse the skin allograft into room temperature saline or Lactated Ringers solution.
5. A representative sample may be sent for microbiological testing at this point.
6. Antibiotics may be added to the rinse solution at the physicians request.
7. After thawing, unbreached packages may be stored between 0-10°C. for 1 week. Once opened, skin should be placed in a sterile container containing either cell nutrient or Lactated Ringers solution, and refrigerated between 2-10°C. for up to 24 hours.
8. Human skin allograft may be warmed to body temperature immediately before use, but should not be kept above 10° C. for more than 2 hours, total.

REFERENCES:

1. Standards for Tissue Banking; Arlington, VA: American Association of Tissue Banks AATB), 2001.
2. Technical Manual for Tissue Banking; Arlington, VA: American Association of Tissue Banks
3. (AATB), 1993.
4. United States Public Health Service.
5. Federal Food and Drug Administration (FDA): Federal Register (Vol. 58, No. 238, pp. 65514-65521), CFR 1270, 2001
6. United States Pharmacopoeia (USP) 71
7. Code of Federal Regulations (CFR) 610.12

Distributed by: U.S. Tissue and Cell, 675 Arapeen Drive, Suite # 102, Salt Lake City, UT 84108 (866-255-0034)

Document #: DIS-011 Rev: 05 Effective: 12/10/2004

10.04.03

U.S. Tissue & Cell
675 Arapeen Drive, Suite 102
Salt Lake City, Utah 84108
Phone: 801-583-0907
Fax: 801-583-0957

SKIN ALLOGRAFT TRANSPLANT RECORD

Hospital # or SSN of Recipient: _____

Not required if the above area has been stamped.

Name of Recipient: _____

Date of Birth: _____ Age: _____ Sex: _____

Date Implanted : _____

Site of Application: _____

Diagnosis Related to Transplant: [ ] Burns [ ] Other: _____

Procedure Requiring Tissue: [ ] Wound Debridement [ ] Other: _____

Hospital Using Tissue: _____

Physician Responsible: _____

All tissue has been retrieved and processed using aseptic technique as described by the Association of Operating Room Nurses (AORN) standards.

_____ Fresh Allograft Skin is stored in RMPI 1640 Media at a temperature between 2°C and 10°C.

_____ Cryopreserved Allograft Skin using control rate freezing in 15% glycerin and Lactated Ringers is stored at a temperature between -70°C and -130°C.

Serial #	Pkg. #	Serial #	Pkg. #	Serial #	Pkg. #

Please complete the information requested. Retain the yellow copy for your records, pink copy for recipient's chart, and return the original copy to U.S. Tissue & Cell. This transplant form is an important part of our transplant records. This form should be completed for each recipient. Please type or print legibly.

Comments about the tissue (i.e., problems, suggested improvements, etc.):

_____

_____

Person completing this form: _____ Title: _____

TI-001/43956

別添資料２

Skinbank Network System

メインシステム取扱説明書

Ver 1.0　　2006/02/03

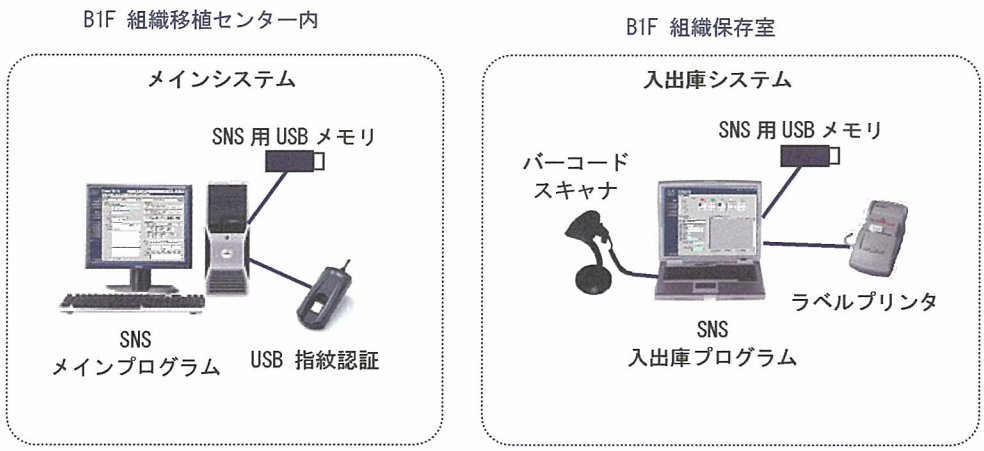
1. はじめに

1.1 システム概要

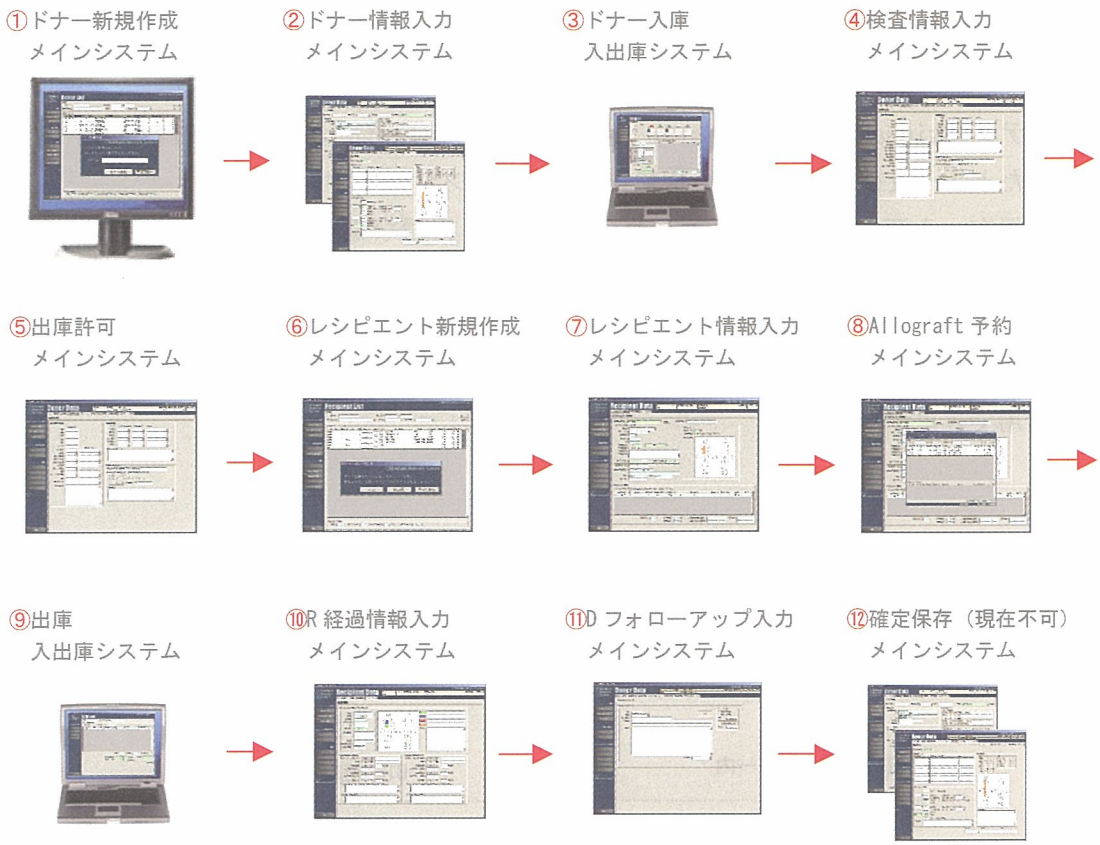
本システム(Skinbank Network System　以下 SNS)は、組織移植センター（杏林大学内）で、発生したドナー及びレシピエント情報を管理するシステムです。
組織の保存、入庫、出庫情報を管理することにより円滑な業務を行うことを目的としています。

検索を行うことで、都道府県別にドナー件数などを表示することができるので、統計処理にも活用できます。

1.2 SNS 構成図



1.3 情報入力の流れ



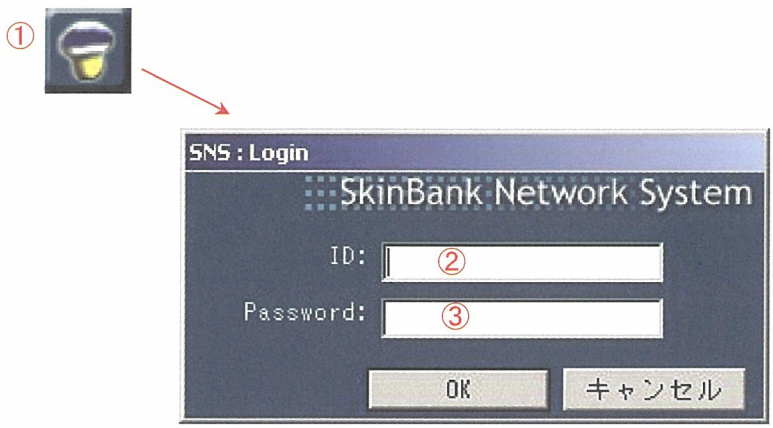
〈操作手順〉

① ドナーの新規作成（メインシステム）。
② ドナー情報入力（メインシステム）。
③ ドナー入庫（入出庫システム）。
④ 検査情報入力（メインシステム）。
⑤ 出庫許可（メインシステム）。
⑥ レシピエント新規作成（メインシステム）。
⑦ レシピエント情報入力（メインシステム）。
⑧ Allograft 予約（メインシステム）。
⑨ 出庫（入出庫システム）。
⑩ レシピエント経過情報入力（メインシステム）。
⑪ ドナーフォローアップ入力（メインシステム）。
⑫ 確定保存（メインシステム）。＊現在使用不可（2006/02/03 現在）

2. SNS の起動、終了

2.1 SNS 起動

SNS を起動し、ログインします。



〈操作手順〉

① デスクトップ上の SNS のアイコンをダブルクリック。 ログイン画面の表示。

② 「ID」を入力。

③ 「パスワード」を入力。

注）SNS 用 USB メモリがないと起動できません。

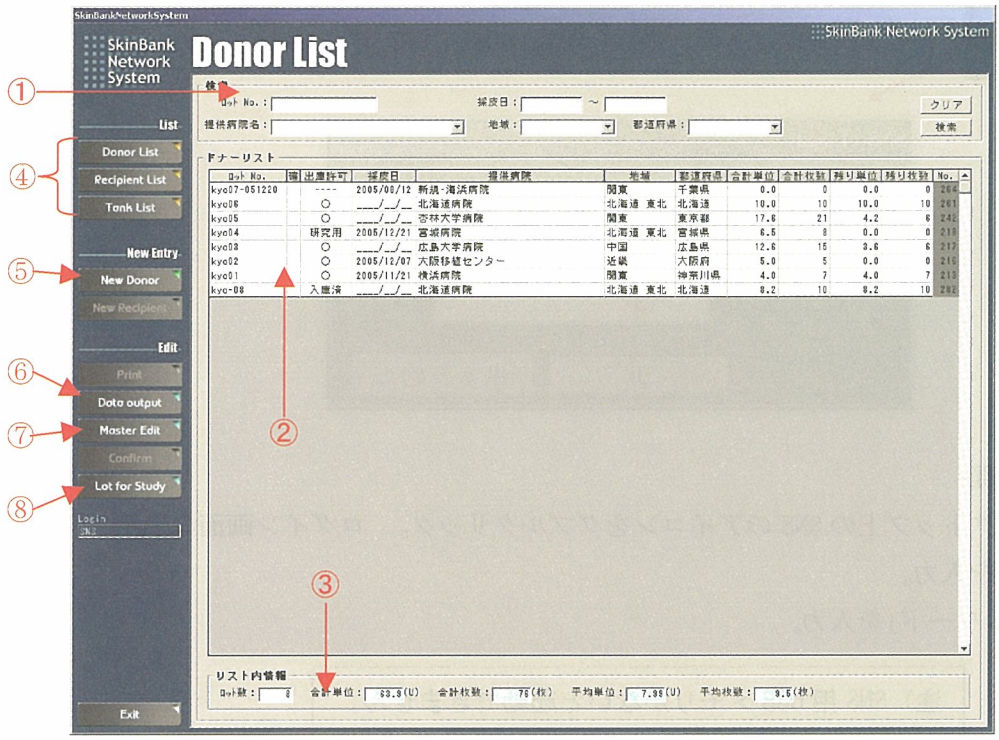
2.2 SNS 終了

画面左下の Exit ボタンをクリックし、SNS を終了します。

3. ドナー作成

3.1 ドナーのリスト表示、検索

ドナーのリスト表示、検索を実行します。



〈説明〉

① 検索項目。「ﾛｯﾄ No.」、「採皮日」の範囲、「提供病院名」、「地域」、「都道府県」の項目で検索できる。全ドナーを表示する場合、検索条件を全部空欄にして「検索」ボタンをクリック。

② 検索した結果がリストに表示される。デフォルトでは全てのリストが表示される。リストをダブルクリックするとドナーの編集ができる。項目名をクリックするとソートをかけてリストを表示できる。

③ リストに表示されている情報の簡易統計が表示される。

④ 各リストを表示する。

⑤ 新規ドナーを作成する。→3.2 参照

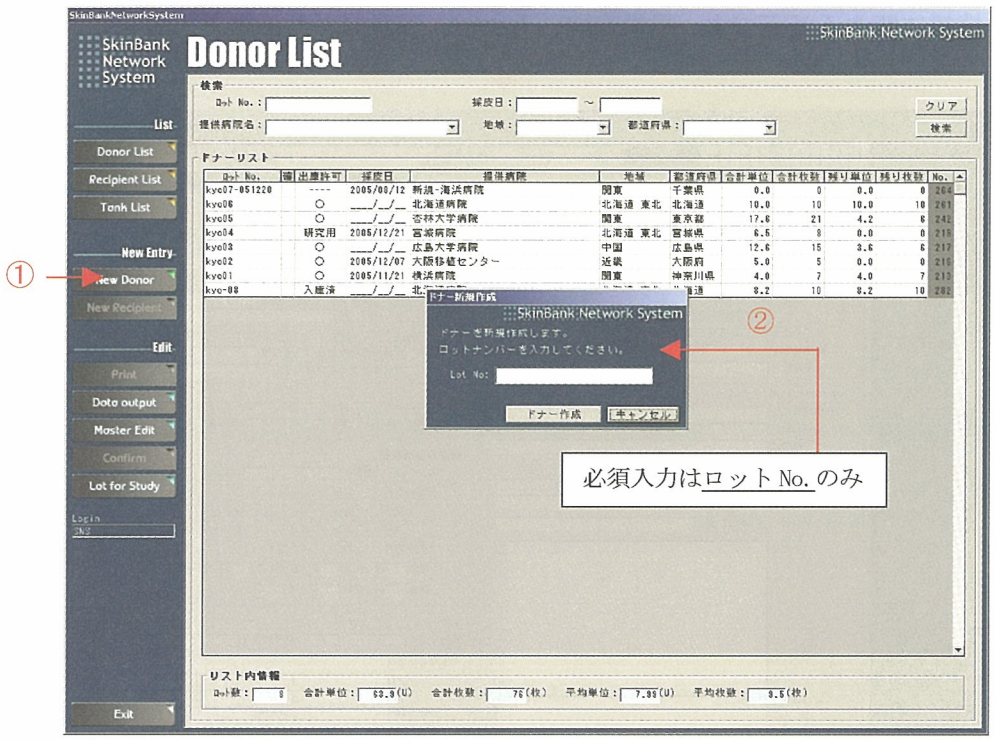
⑥ 入出庫の準備のため、データを USB キーに転送する。→3.5 参照

⑦ スタッフ、施設の登録を行う。→7. 参照

⑧ 研究用ロットの登録、編集を行う。→5. 参照

3.2 ドナーの新規作成

ドナーを新規作成します。



〈説明〉

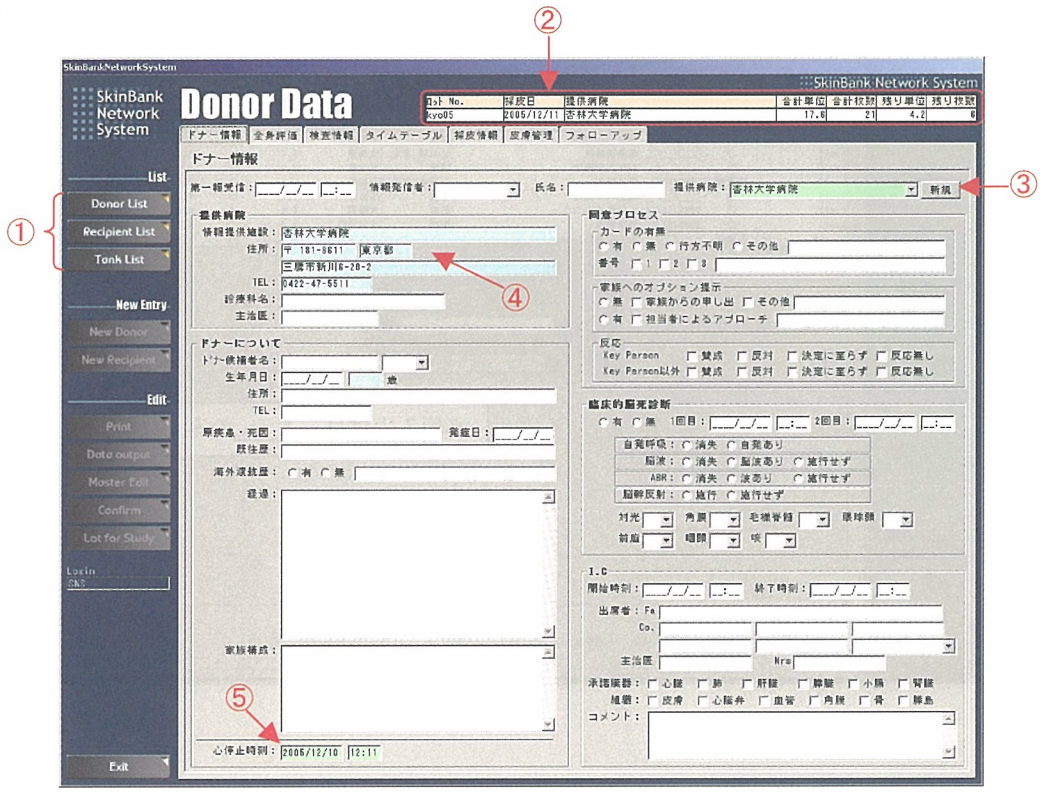
① New Donor ボタンをクリックすると新規ドナーのロット No. の入力ウィンドウが開く。すでに同 No があった場合その No では登録できない。

② ロット No. のみを入力し新規ドナーを作成する。ドナーを作成するとドナー情報の入力画面に移動する。

3.3 ドナーデータの入力

3.3.1 ドナー情報

ドナー情報に関する画面です。提供病院、ドナー、同意プロセス等を入力します。



〈説明〉

① 各リストに戻る。

② 開いているドナーのロットNoや提供病院などの基本情報を表示。

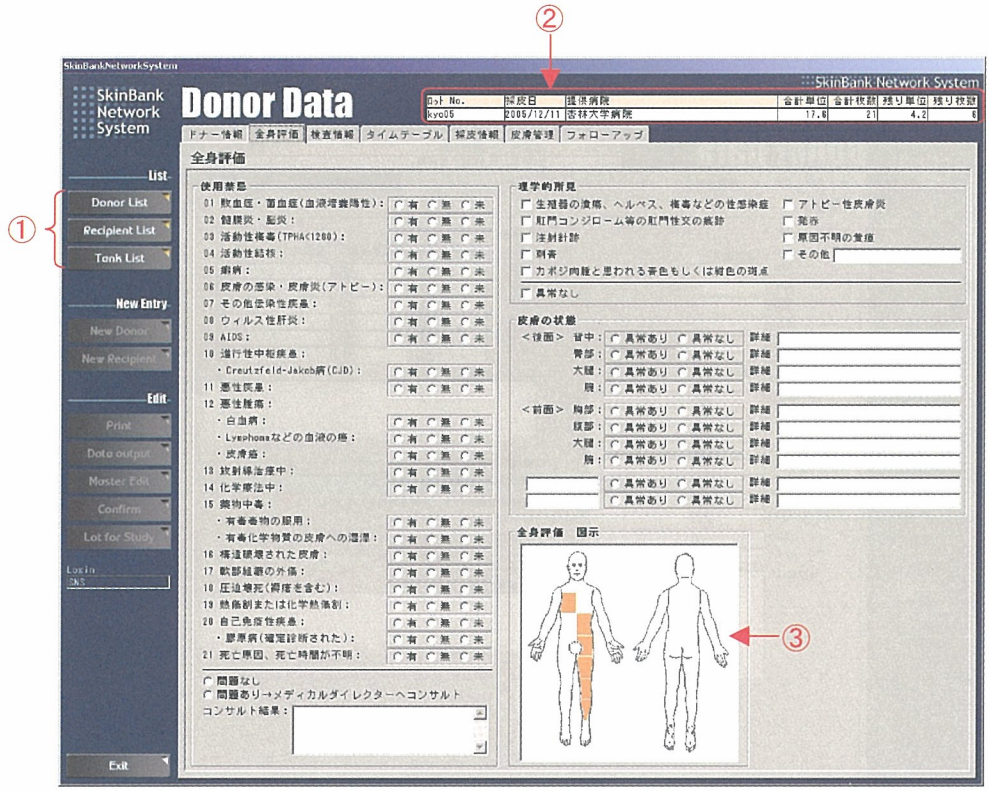
③ 提供病院をリストから選択。もしリストにない場合は「新規」ボタンから施設を登録する。→7.1参照

④ 登録された施設の情報が自動的に表示される。

⑤ 心停止時刻（重要項目）。皮膚管理タブの「採皮までの時間」項目に反映される。→3.3.8参照

3.3.2 全身評価

全身評価に関する画面です。使用禁忌、理学的所見、皮膚の状態等を入力します。



〈説明〉

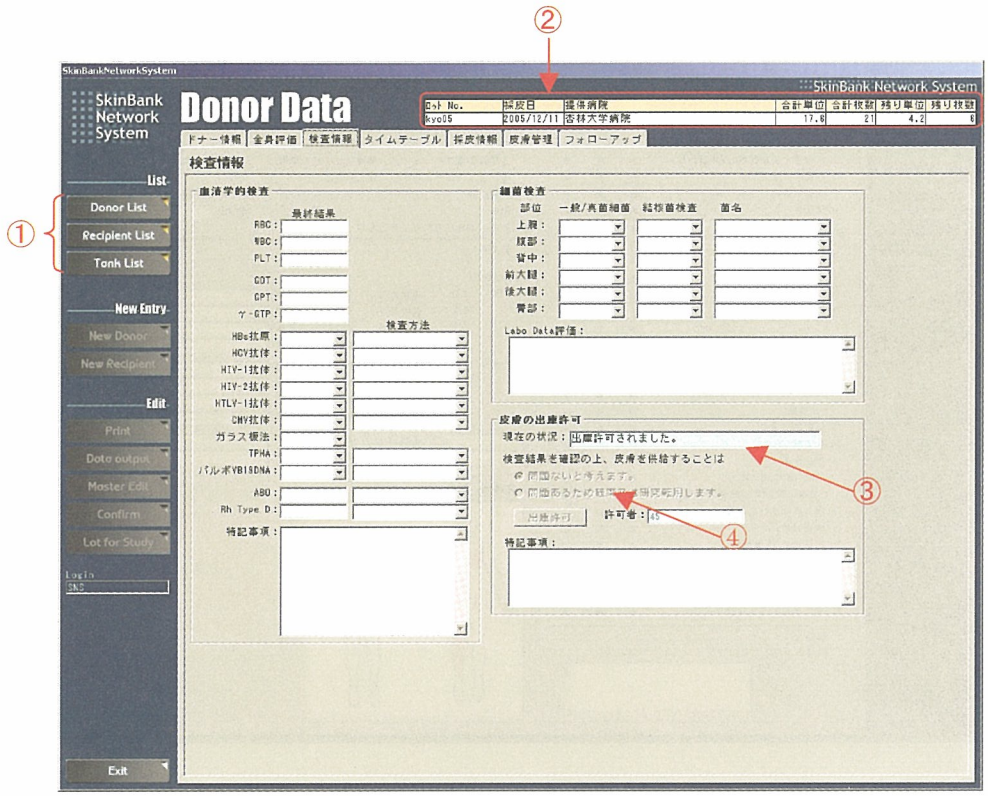
① 各リストに戻る。

② 開いているドナーのロット No や提供病院などの基本情報を表示。

③ 「全身評価　図示」では、部位をダブルクリックすることで色を変えて表示できる。

3.3.3 検査情報

検査情報に関する画面です。血清学的検査、細菌検査などを行います。また、皮膚の出荷許可もここで行います。



〈説明〉

① 各リストに戻る。

② 開いているドナーのロットNoや提供病院などの基本情報を表示。

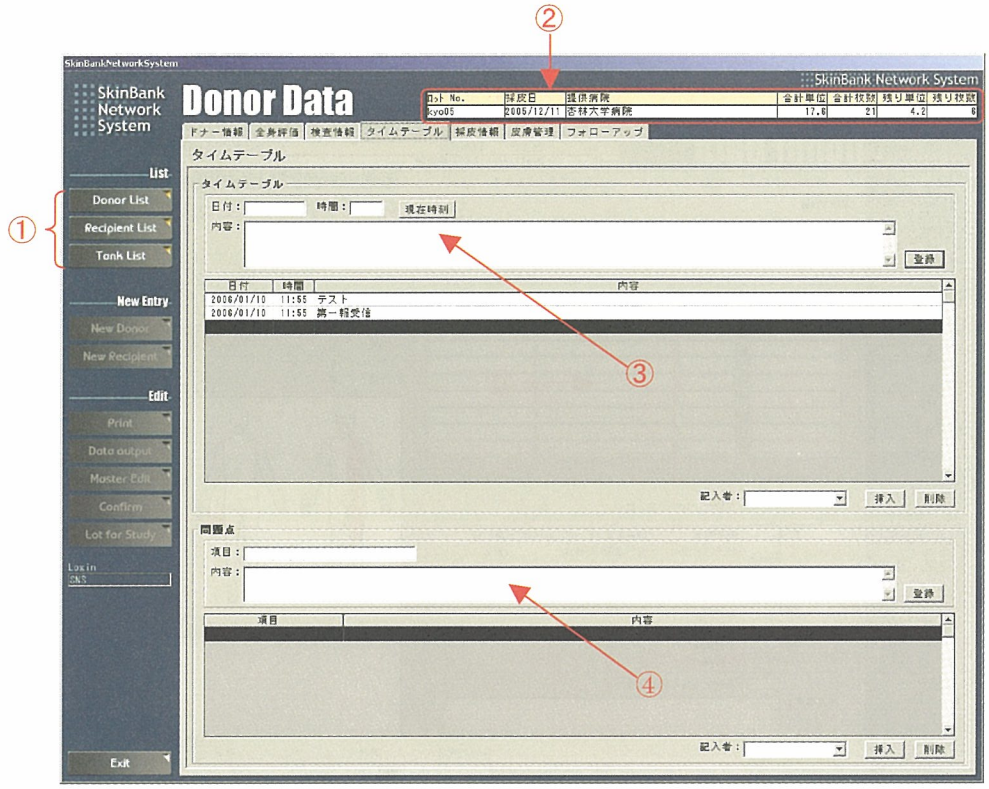
③ 皮膚の状況を表示。

- まだ皮膚が入庫されていません。（ドナーが作成された状態）
- 皮膚が入庫されています。（入庫されたが出庫許可が出ていない状態）
- 出庫許可されました。（出庫の許可が出た状態）
- 研究用に出庫できます。（研究用に出庫許可が出た状態）

④ 皮膚が入庫されている状態のときに入力でき、出庫の許可を出す。

3.3.4 タイムテーブル

タイムテーブルに関する画面です。全体的なタイムテーブル、問題点を入力します。



〈説明〉

① 各リストに戻る。

② 開いているドナーのロットNoや提供病院などの基本情報を表示。

③ タイムテーブルの入力フレーム。 現在時刻 ボタンをクリックすると「日付」、「時間」の項目に自動的に現在の時刻が入力される。内容を入力し 登録 ボタンをクリックするとその内容がリストに反映される。リストを選択して、挿入、削除ができる。

④ 問題点の入力フレーム。「項目」、「内容」を入力し 登録 ボタンをクリックするとその内容がリストに反映される。リストを選択して、挿入、削除ができる。