



Queensland  
Government

# Skin Allograft Consent

Facility: .....

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex:  M  F  I

## A. Does the patient have capacity?

Yes → **GO TO section B**     No → **COMPLETE section A**

- i. a) Is the patient aged under 18 years?  
 Yes (document parent / guardian name below)  
 No → **GO TO ii**

You must adhere to the Advance Health Directive (AHD) or the consent obtained from a substitute decision-maker.

- ii. a) Does the patient have an AHD that is applicable to the procedure, treatment or investigation?  
 Yes     No → **GO TO iii**  
 b) If yes, has the AHD been sighted and a copy in the medical record?  
 Yes     No → **GO TO iii**

- iii. a) Substitute decision-maker (select one only):  
 Attorney(s) for health matters under an Enduring Power of Attorney or AHD  
 Tribunal-appointed guardian  
 Statutory Health Attorney  
 If none of these, the Office of the Public Guardian must provide consent (ph: 1300 653 187)

Name of substitute decision-maker(s) or parent / guardian:

Signature of substitute decision-maker(s) or parent / guardian:

Relationship to the patient (e.g. substitute decision-maker or parent / guardian)

Date:     Phone number:

## B. Does the patient need Interpreter / cultural services?

- i. a) Is a language interpretation service required?  
 Yes     No → **GO TO ii**  
 b) If yes, is a qualified Interpreter present?  
 Yes (complete section K)     No     N/A
- ii. a) Is a cultural support person required?  
 Yes     No → **GO TO section C**  
 b) If yes, is a cultural support person present?  
 Yes     No     N/A

## C. Condition and treatment

The Doctor / Clinician has explained that I have the following condition (Doctor / Clinician to document in patient's words):

This condition requires a procedure (Doctor / Clinician to document, include site and / or side where relevant to the procedure):

**The following will be performed:**  
 The wound will be prepared by surgically removing tissue not expected to live. A Skin Allograft will then be applied as a biologic dressing to help promote wound healing. Further procedures may be required to replace Skin Allograft(s) with a skin graft(s).

## D. Risks and complications of a Skin Allograft

There are risks and complications with this procedure. They include but are not limited to the following.

- Common risks and complications include:**
- **infections** can occur, requiring antibiotics and further treatment;
  - **bleeding** could occur and may require a return to the operating room;
  - bleeding is more common if you have been taking **blood thinning drugs** such as warfarin, aspirin, clopidogrel (Plavix, Iscover, Coplavix), prasugrel (Effient), dipyridamole (Persantin or Asasantin), ticagrelor (Brilinta), ticlopidine (Tilodene), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary / alternative medicines such as fish oil;
  - small areas of the **lung can collapse**, increasing the risk of **chest infection**. This may need antibiotics and physiotherapy;
  - increased risk of wound infection, chest infection, heart and lung complications, and blood clot in the leg or lungs for **people who are obese**.

- Uncommon risks and complications include:**
- **heart attack or stroke** could occur due to the strain on the heart;
  - **blood clot** in the leg causing pain and swelling. In rare cases, part of the clot may break off and go to the lungs;
  - the **duration of skin allografts** may only last seven to ten days before the body rejects them.

- Rare risks and complications include:**
- the Skin Allograft has the potential to **transmit disease-producing organisms (e.g. bacteria, viruses, or similar)**. To minimise this risk the Queensland Skin Bank has screening procedures to avoid the collection of tissue which may carry disease-producing organisms;
  - **allergic reactions** to the **antibiotics** used to process the skin are possible, especially if there is a history of antibiotic allergies;
  - **death** as a result of this procedure is often dependent on the severity of the injury. If you have additional questions, please ask your doctor / clinician.

## E. Specific risks for you in having this procedure

(Doctor / Clinician to document in space provided. Continue in Medical Record if necessary)

## F. Risks of not having this procedure

(Doctor / Clinician to document in space provided. Continue in Medical Record if necessary)

## G. Alternative procedure, treatment or investigation options

(Doctor / Clinician to document in space provided. Continue in Medical Record if necessary)

DO NOT WRITE IN THIS BINDING MARGIN

v1.00 - 11/2016



SW9449

SKIN ALLOGRAFT CONSENT



# Skin Allograft Consent

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex:  M  F  I

## H. Anaesthetic

This procedure may require an anaesthetic (*doctor / clinician to document type of anaesthetic discussed*)

## I. Anticoagulant / Antiplatelet checklist

Information to discuss with your doctor about blood thinning drugs:

**Aspirin**  Yes  No

**Antiplatelet agents**  YES  No

Clopidogrel, Prasugrel, Ticagrelor, Dipyridamole, Other.

If the procedure is elective, can the antiplatelet be withheld and the patient maintained on aspirin alone for 7 days prior?  Yes  NO

Date Authorising doctor / clinician ordered antiplatelet ceased / to be ceased:

**Warfarin / Dabigatran / Rivaroxaban / Apixaban / Heparins / Other new anticoagulants**  YES  No

If elective procedure, can all anticoagulation be ceased before the procedure?  Yes  No

Where there has been changes (i.e. ceased, withheld) to the above drugs, is there a management plan documented in the patient's medical record?  Yes  No

**J. Patient / Substitute decision-maker consent**

## J. Patient / Substitute decision-maker consent

- I acknowledge the doctor / clinician has explained:
- my / the patient's medical condition and the proposed procedure / treatment / investigation may require and include additional treatment if the doctor/clinician finds something unexpected. I understand the risks and benefits, including the risks specific to me;
  - my / the patient's requirement for anaesthetic for this procedure / treatment / investigation - I understand the risks associated with anaesthetic, including the risks specific to me (see Anaesthetic information sheet);
  - my / the patient has alternative procedure / treatment / investigation options;
  - my / the patient's prognosis, and the risks of not having the procedure / treatment / investigation;
  - no guarantee has been made that the procedure / treatment / investigation will improve my / the patient's condition even though it has been carried out with due professional care;
  - my / the patient's procedure / treatment / investigation may include a blood transfusion;
  - my / the patient's tissues / blood may be removed and be used for diagnosis / management of my condition, stored and disposed of sensitively by the hospital;
  - if an immediate life-threatening event happens during my / the patient's procedure / treatment / investigation, I / the patient will be treated based on my discussions with the doctor / clinician or Acute Resuscitation Plan;
  - a doctor other than the consultant / specialist may conduct the procedure / treatment / investigation. I understand this could be a doctor undergoing further training. All surgical trainees are supervised according to relevant professional body guidelines;
  - I / the patient was able to ask questions and raise concerns with the doctor / clinician about my / the patient's condition, the proposed procedure / treatment and its risks, and my / the patient's treatment options. My questions and concerns have been discussed and answered to my satisfaction;
  - I / the patient understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with a doctor / clinician;
  - I / the patient understand image(s) or video footage may be recorded as part of and during my procedure and that these image(s) or video(s) will assist the doctor / clinician to provide appropriate treatment.

On the basis of the above statements, I consent to having this procedure.

Name of patient:

Signature:  Date:

I consent to:

Name of patient having procedure:

Name of substitute decision-maker:

Signature:  Date:

I have received the following information sheet(s):

- 'About your Anaesthetic'
- 'Skin Allograft'
- 'Blood and Blood Products Transfusion'

## K. Interpreter's statement

I have:

- Provided a sight translation
- Translated as per clinician explanation in:

Patient's language:

of this consent form and assisted in the provision of any verbal and written information given to the patient / substitute decision-maker by the doctor / clinician.

Name of patient:

Language of patient:

Name of Interpreter service:

Name of Interpreter:

Interpreter's signature:  Date:

## L. Doctor / Clinician / Delegate statement

**Information for doctor / clinician / delegate:**

The information contained within this form is not, and is not intended to be, a substitute for direct communication between the doctor / clinician / delegate and the patient / substitute decision-maker regarding the medical procedure, treatment or investigation described in this form. I have explained to the patient all the content in this patient consent form and I am of the opinion that the patient / substitute decision-maker has understood the information.

Name of doctor / clinician / delegate:

Designation:

Signature:  Date:



Give this patient information sheet to the patient or substitute decision-maker(s) to read carefully and allow time to ask any questions about the procedure.

### 1. What is this procedure and how will it help me?

A Skin Allograft is prepared from the skin of a human organ donor within 15 hours of death, or within 24 hours of death if the body was refrigerated. The removed skin is disinfected with antibiotics and frozen until used. The donor from whom this Skin Allograft was derived has been tested and found negative for communicable diseases (i.e. for *Hepatitis B virus*, *Human Immunodeficiency Virus (HIV1 and HIV2)*, *Hepatitis C virus*, *Human T-Lymphotropic viruses (HTLV1 and HTLV2)* and *Syphilis by TGA approved tests*). The donor was selected using a medical history and physical examination criteria (i.e. this is based on the American Association of Tissue Banks Standards for Tissue Banking, the American Red Cross Tissue Services, and Department of Health (Commonwealth of Australia) therapeutic goods orders).

The Skin Allograft has been tested for bacterial contamination. The samples indicate that this skin allograft does not have any growth, or if there are organisms present, they are considered to be of low infective risk such as those commonly found on skin surfaces.

Skin Allograft is used as a biologic dressing to assist in wound healing often to prepare the wound to increase the chances of healing, reduce pain, protect from infection and increase the likelihood of the success of subsequent skin graft/s and reconstructive procedure/s. An outcome from this procedure is the body's immune system may recognise an allograft as being foreign, and it may reject the graft in 1 to 3 weeks.

### 2. My anaesthetic

This procedure will require an anaesthetic. For more information about the anaesthetic and the risks involved please refer to the anaesthetic information sheet that has been provided to you. Discuss any concerns with your clinician.

If you have not been given an anaesthetic sheet, ask for one.

### 3. What are the specific risks of this procedure?

There are risks and complications with this procedure. They include but are not limited to the following.

#### Common risks and complications include:

- infections can occur, requiring antibiotics and further treatment;
- bleeding could occur and may require a return to the operating room;

- bleeding is more common if you have been taking blood thinning drugs such as warfarin, aspirin, clopidogrel (Plavix, Iscover, Coplavix), prasugrel (Effient), dipyridamole (Persantin or Asasantin), ticagrelor (Brilinta), ticlopidine (Tilodene), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary/alternative medicines such as fish oil;
- small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy;
- increased risk of wound infection, chest infection, heart and lung complications, and blood clot in the leg or lungs for people who are obese.

#### Uncommon risks and complications include:

- heart attack or stroke could occur due to the strain on the heart;
- blood clot in the leg causing pain and swelling. In rare cases, part of the clot may break off and go to the lungs;
- the duration of skin allografts may only last seven to ten days before the body rejects them.

#### Rare risks and complications include:

- the Skin Allograft has the potential to transmit disease-producing organisms (e.g. bacteria, viruses, or similar). To minimise this risk the Queensland Skin Bank has screening procedures to avoid the collection of tissue which may carry disease-producing organisms. A sample of tissue may be taken for therapeutic purposes or for other medical or scientific purposes;
- allergic reactions to the antibiotics used to process the skin are possible, especially if there is a history of antibiotic allergies;
- death as a result of this procedure is often dependent on the severity of the injury. If you have additional questions, please ask your doctor/clinician.

### 4. What are the risks specific to me?

There may also be risks specific to your individual condition and circumstances. Please discuss these with your clinician and ensure they are written on the consent form before you sign it.

