INSTRUCTIONS

This is an informed-consent document that has been prepared to inform you of skin graft surgery, its risks, as well as alternative treatments.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for surgery as proposed by your plastic surgeon and agreed upon by you.

GENERAL INFORMATION

Skin graft surgery is frequently performed by plastic surgeons by using skin taken from one area of the body to restore skin coverage in other area(s). Skin grafts help wounds heal that otherwise would not heal adequately. Skin grafts are useful in situations where there is adequate subcutaneous tissues present to provide support and blood supply for the skin graft.

Skin grafts are generally classified as to the thickness of the skin that is being grafted from one part of the body to some other region. A "split-thickness" skin graft does not comprise the entire thickness of skin. The donor area where the split-thickness graft is taken can heal on its own. Large areas of the body can be used for split-thickness skin grafts. The "full thickness" skin graft is different as it involves the full thickness of skin and deeper tissues. Full-thickness grafts tend to be used for specific wound coverage applications when thicker skin is needed. The donor area for the full thickness graft is limited in size as full-thickness skin graft donor sites cannot be used more than one time.

Skin grafts are an effective means of assisting wound healing when there has been a loss of skin due to conditions that involve disease, injuries including burns, or surgical removal of tumors. Some wounds may be too complex to heal without other more involved reconstructive techniques. In some situations, surgical procedure(s) and other treatments (dressing changes and hydrotherapy) may be needed to prepare a wound for a skin graft.

ALTERNATIVE TREATMENTS

Alternative forms of care consist of not undergoing surgery. Some minor wounds may heal without surgery. In other situations, different forms of treatment such as the transfer of skin and other composite pieces of tissue may be preferable to skin grafts. Microsurgical tissue transfer may be necessary in situations when ordinary surgical techniques cannot provide for satisfactory tissue to cover a complex wound. Risks and potential complications are associated with alternative surgical forms of treatment. Although wounds can heal spontaneously, there may be increased risk of unsatisfactory result, scarring, and functional impairment.

RISKS OF SKIN GRAFT SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand all possible consequences of skin graft surgery.

<u>Bleeding-</u> It is possible, though unusual, to experience a bleeding episode during or after surgery. Intraoperative blood transfusions may be required. Should post-operative bleeding occur, it may require an emergency treatment to drain the accumulated blood or blood transfusion. Do not take any aspirin or anti-inflammatory medications for ten days before or after surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. Hematoma can occur at any time following injury. If blood transfusions are necessary to treat blood loss, there is the risk of blood-related infections such as hepatitis and HIV (AIDS). Heparin medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

<u>Infection-</u> Infections after skin graft surgery may occur. There is the possibility of skin graft failure or scarring from an infection. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary.

<u>Inability to Heal</u>- Conditions that involve disease, injuries including burns, or surgical removal of tumors can produce severe wounds. Skin grafts require adequate blood supply for survival. Areas of the body where there is inadequate blood supply due to injury, disease states, or the effect of radiation therapy, may not be capable of providing adequate blood supply for skin graft survival. Skin grafts are also vulnerable to loss in disease situations where there is a propensity for chronic swelling or vascular insufficiency disorders. Some wounds may be of the extent and severity that skin grafts cannot produce closure of the wound and healing. More involved reconstructive surgical procedures may be necessary.

<u>Scarring</u>- All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different color than the surrounding skin tone. Scar appearance may also vary within the same scar. Special compressive garments may be needed to help control scarring. In some cases scars may require surgical revision or treatment.

Skin Sensation- Diminished (or loss) of skin sensation in the donor location for the graft as well as the location where the graft is placed may occur and not totally resolve after skin graft surgery. Skin grafts generally do not regain normal skin sensation. Injuries may occur secondary to this lack of sensation if the skin graft is subjected to excessive heat, cold, or physical force. Skin grafts placed in areas of decreased sensation are prone to injury and loss. Care must be given to avoid injury to these areas or complications may occur.

Skin Contour Irregularities - Contour irregularities and depressions may occur after skin graft surgery. Visible and palpable wrinkling of skin can occur. If a skin graft has been processed in a graft meshing device, it may heal with a pattern. Residual skin irregularities at the ends of the incisions or "dog ears" are always a possibility and may require additional surgery. This may improve with time, or it can be surgically corrected.

<u>Delayed Healing</u>- Wound disruption or delayed wound healing is possible. Scarring and inadequate healing may occur in the location where the skin graft is taken for transfer to other parts of the body. Healing of the donor area may take unacceptably long periods of time. The donor area once healed may be prone to abrasions. The skin graft may heal abnormally or slowly. Some areas of skin may die, requiring frequent dressing changes or further surgery to remove the non-healed tissue. **Smokers have a greater risk of skin loss and wound healing complications.**

<u>Skin Discoloration / Swelling-</u> Some bruising and swelling normally occurs following surgery. Skin grafts and the skin graft donor location can undergo changes in color. It is possible to have these areas be either darker or lighter than surrounding skin. These changes can be permanent.

<u>Skin Sensitivity-</u> Itching is a common complaint in both the skin graft donor location and the recipient location. Graft abrasion may occur from scratching. Additionally, these areas may have exaggerated responses to hot or cold temperatures. Usually this resolves during healing, but it may be chronic.

<u>Inability to Restore Function</u>- In some situations, skin grafts cannot restore the normal function of intact skin or undamaged deeper structures. Although it may be possible to produce healing with a skin graft, there can be a loss of function. Additional treatment and surgery may be necessary.

<u>Surgical Anesthesia</u>- Both local and general anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

<u>Damage to Deeper Structures</u>- There is the potential for injury to deeper structures including nerves, blood vessels, muscles, and lungs (pneumothorax) during any surgical procedure. The potential for this

to occur varies according to where on the body surgery is being performed. Injury to deeper structures may be temporary or permanent.

<u>Allergic Reactions-</u> In rare cases, local allergies to tape, suture materials and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur to drugs used during surgery and prescription medications. Allergic reactions may require additional treatment.

Skin Cancer in Skin Grafts- Skin cancer can rarely occur in skin grafts.

<u>Pain-</u> You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after surgery. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or from other causes after skin graft surgery.

<u>Buried Surgical Staples / Sutures</u>- Sutures and staples used to hold skin grafts in place can potentially become buried under the skin during healing. Sutures may spontaneously poke through the skin, become visible or produce irritation that requires removal. Additional surgery may be necessary to remove buried staples and sutures.

<u>Lacks of Graft Durability-</u> Skin grafts do not have the normal padding and durability of normal, undamaged skin. Skin grafts lack the normal ability of skin to resist ordinary abrasions and injuries.

Shock- In rare circumstances, your surgical procedure can cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

<u>Unsatisfactory Result</u>- Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. There is the possibility of a poor result from skin graft surgery. This would include risks such as unacceptable visible deformities, loss of function, poor healing, wound disruption, skin and soft tissue loss, chronic pain and loss of sensation. There may be unacceptable cosmetic deformities from skin grafts placed on visible portions of the body or in the skin graft donor areas. Abnormal color of skin graft and graft origin location may occur. It may be necessary to perform additional surgery to improve your results.

Cardiac and Pulmonary Complications- Surgery, especially longer procedures, may be associated with the formation of, or increase in, blood clots in the venous system. Pulmonary complications may occur secondarily to both blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary and fat emboli can be life-threatening or fatal in some circumstances. Air travel, inactivity and other conditions may increase the incidence of blood clots traveling to the lungs causing a major blood clot that may result in death. It is important to discuss with your physician any past history of blood clots or swollen legs that may contribute to this condition. Cardiac complications are a risk with any surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

ADDITIONAL ADVISORIES

Female Patient Information- It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you believe you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

<u>Mental Health Disorders and Surgery-</u> It is important that all patients seeking to undergo surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery and often are stressful.

Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of surgery, effects on mental health cannot be accurately predicted.

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray) Patients who are currently smoking, use tobacco products, or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying, delayed healing, and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smoking may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication. Please indicate your current status regarding these items below: ______ I am a non-smoker and do not use nicotine products. I understand the risk of second-hand smoke exposure causing surgical complications. _____ I am a smoker or use tobacco / nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired.

<u>Medications</u>- There are many adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions, and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

PATIENT COMPLIANCE

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the skin graft is <u>not</u> subjected to excessive force, swelling, abrasion, or motion during the time of healing or graft loss may occur. Skin graft donor locations are similarly vulnerable to injury during the healing process. Protective dressings and drains should <u>not</u> be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent rehabilitation. You may be advised to wear compressive garments to control both swelling and scarring following skin graft surgery. Personal and vocational activity needs to be restricted. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

ADDITIONAL SURGERY NECESSARY

Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are particularly associated with skin graft surgery. Other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied on the results that may be obtained.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical operations or any complications that might occur from surgery. Please carefully review your health insurance subscriber information pamphlet. **Most insurance plans exclude coverage for secondary or revisionary surgery.**

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your surgeon, the cost of surgical supplies, anesthesia, laboratory tests, and possible outpatient hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revision surgery will also be your responsibility. In signing the consent for this surgery/procedure, you acknowledge that your have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including no surgery. The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed-consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the current state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize DR. ADAMSON and such assistants as may be selected to perform the following procedure or treatment:

SKIN GRAFT SURGERY

I have received the following information sheet:

INFORMED CONSENT - SKIN GRAFT SURGERY

- 2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
- 3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
- 4. I acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.
- 5. I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
- 6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
- 7. I consent to the disposal of any tissue, medical devices or body parts which may be removed.
- 8. I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
- 9. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
- 10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
- 11. I realize that not having the operation is an option.
- 12. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
 - a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
 - b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
 - c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

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I CONSENT TO TH	HE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS
(1-12). I AM SATIS	SFIED WITH THE EXPLANATION.
Patient or Person A	Authorized to Sign for Patient