EXPERIMENTAL SUBJECT'S BILL OF RIGHTS
Medical Research Studies

The rights below are the rights of every person who is asked to be in a medical research study. As an experimental subject, you have the following rights:

1) To be told what the study is trying to determine.

2) To be told what will happen to you and whether any of the procedures, drugs, or devices is different from what would be used in standard practice.

3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to you for research purposes.

4) To be told if you can expect any benefit from participating and, if so, what the benefit might be.

5) To be told the other choices you have and how they may be better or worse than being in the study.

6) To be allowed to ask any questions concerning the study, both before agreeing to be involved and during the course of the study.

7) To be told what sort of medical treatment is available if any complications arise.

8) To refuse to participate or to change your mind about participating after the study is started. This decision will not affect your right to receive the care you would receive if you were not in the study.

9) To receive a copy of the signed and dated consent form.

10) To be free of pressure when considering whether you wish to agree to be in the study.

If you have other questions, please ask the researcher or research assistant. In addition, you may contact the Institutional Review Board, which is concerned with protecting volunteers in research projects. You may reach the IRB office by calling (916) 703-9151, from 8:00 a.m. to 5:00 p.m., Monday through Friday, or by writing to the Institutional Review Board, CTSC Bldg., Suite 1400, Rm. 1429, 2921 Stockton Blvd., Sacramento, California 95817.

_____ _____

Signature of Subject or Legal Representative

Date

UNIVERSITY OF CALIFORNIA, DAVIS
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Investigators' Names: **Michael S. Wong, MD**
Department: **Surgery**

STUDY TITLE: **A Prospective, Randomized-Controlled Trial Evaluating Incisional Negative Pressure Wound Therapy in Patients Undergoing Panniculectomy in Preparation of Renal Transplant**

INTRODUCTION

This is a research study. Research studies only include subjects who choose to participate. As a study participant you have the right to know about the procedures that will be used in this research study so that you can make the decision whether or not to participate. The information presented here is to make you better informed so that you may give or withhold your consent to participate in this research study. Please take your time to make your decision and discuss it with your family and friends.

You are being asked to take part in this study because you may be high-risk for the development of wound healing complications associated with your panniculectomy. You must be 18 years of age or older. In order to participate in this study, it will be necessary to give your written consent.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine how well standard wound closure compared to standard wound closure and incisional negative pressure wound therapy performs in regards to wound healing complications, pain and scarring. Incisional negative pressure therapy (INPWT) has previously been shown to decrease wound healing complications in certain patient populations. We have found a group of patients, those who have panniculectomies in preparation for renal transplant, experience significantly higher rates of wound healing complications. We believe the best way to demonstrate benefits of incisional negative pressure wound therapy will be in this group of patients known to have significantly higher rates of wound complications. This study will compare 1) the rate of wound healing complications between the two groups, 2) the time to drain removal as well as hematoma and seroma formation between the two groups and 3) the scar quality, amount of postoperative pain and quality of life experienced between the two groups. This is a randomized study, meaning that patients will be randomly assigned to the control or test groups. Neither you nor your surgeon will pick which group you are assigned to. You must be willing to have either closure method performed to participate in this study.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 50 people will take part in this study at UC Davis Medical Center.

BEFORE YOU BEGIN THE STUDY

Study Visit 1: Screening

You will need to have a screening visit as part of your first surgeon meeting to determine if you qualify for the research study. The screening visit will take approximately ten (10) to fifteen (15) minutes. You will be asked questions about your medical history. Based on the information obtained from the screening visit, your surgeon will determine your eligibility.

If you are eligible, you will be provided two surveys to complete. The first survey will be a scale for you to rate the current level of pain or discomfort in your abdomen. This survey will ask you about the pain in your abdomen while undergoing multiple activities, such as coughing or sitting up.

The second survey is called the Medical Outcomes Study Short Form SF36. It will ask you several questions that relate to your overall happiness and ability to perform basic duties. This survey is intended to grade your ability to return to the level of activity you had before surgery.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you decide to participate in this study, you will be asked to do the following:

Study Visit 2 (Day 0): Surgery – panniculectomy with incisional negative pressure wound therapy for the TEST group; standard skin closure for the CONTROL group

If you continue to qualify for this study, you will be randomized into one of the two study groups during your panniculectomy procedure. Randomization means you will be randomly assigned to a treatment based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in either group. If you are assigned to the test group, you will have the incisional negative pressure wound therapy device placed over your wound along with the vacuum canister attached (about the size of a small wallet). If you are assigned to the control group, you will have the standard of care wound closure (both groups receive the same type of skin closure).

Pictures will be taken when deemed appropriate during your surgery and/or during your recovery. No identification traits or otherwise recognizable features will be captured; only the surgical site will be photographed for record only. Pictures are essential to any research study, not only to document successes, but to document complications and ensure they are reported in as much detail as possible. Your consent in this study acknowledges and allows for these pictures.

After surgery, your recovery will follow your surgeon's orders. Both study groups will receive the same after surgery care. You will be released from the hospital based on your individual condition, regardless of which study group you were part of.

Study Visits 3 through Discharge (Day 1 to Discharge): Post-operative assessment for pain

The third day after surgery you will be provided a survey identical to the pain survey completed before surgery. The survey will be a scale for you to rate the level of pain or discomfort in your abdomen. This survey will ask you about the pain in your abdomen while undergoing multiple activities, such as coughing or sitting up.

This survey will be given to you every day you are in the hospital starting the third day after surgery or you will be asked to record it while you are at home.

Study Visit 4 (Hospital Discharge): Post-operative assessments for pain and activity

The day you leave the hospital, you will be provided the scale for pain and the SF-36.

You will also be asked to provide a mailing address to contact you. we will not provide this address to anyone outside of the study. We may contact you through the mail after you leave the hospital (defined below) to check your progress.

Study Visit 5 (Weeks 1-3 post-op): Clinical assessment

You will be scheduled to return to your surgeon's office on multiple occasions between 7 and 60 days after your surgery. The study doctor will evaluate the surgical area. You will be interviewed about any problems that you may have had since the previous visit and you will be provided the pain survey and SF-36. If you are in the study group, the device will be removed on the 7th day after your surgery. You will be asked to follow up weekly until all subcutaneous drains are removed (this is a separate device that is standard of care for the procedure, and will be removed when output levels are deemed low enough. Drains will be placed and removed in this manner regardless of whether you choose to participate in this study). These visits will be part of your regular follow-up after surgery.

Study Visit 6 (Weeks 4-6 post-op): Pain Survey, SF-36

During a clinic visit or through the mail, the questionnaires will be completed between 28 and 32 days (6 weeks) after your surgery.

The forms will be the pain survey, and the SF-36. Your honesty and thoughtfulness are extremely important when completing these forms.

Study Visit 7 (Month 3 post-op): Pain Survey, SF-36
During a clinic visit or through the mail, the questionnaires will be completed between 77 and 93 days (3 months) after your operation. Your honesty and thoughtfulness are extremely important.

You will be asked to follow up in clinic at or just before 3 months postoperatively so that your surgeon can evaluate you for clearance for transplantation.

Study Visit 8 (Month 6 post-op): Pain Survey, SF-36, and Scar Quality Scale assessment.

During a clinic visit or through the mail, the questionnaires will be completed between 175 and 185 days (6 months) after your surgery. Your honesty and thoughtfulness are extremely important.

At this time, you will also be scheduled for a clinic visit to allow for scar evaluation. This is a routine clinic visit to allow your surgeon to objectively evaluate your scar quality using the Vancouver Scar Scale.

The following procedures are part of regular care and may be done even if you do not join the study: 1) blood tests checking blood count and chemistries, 2) any other tests deemed necessary for your medical care.

The following procedures are NOT PART OF REGULAR CARE AND WILL ONLY BE DONE IF YOU JOIN THE STUDY: The Pain Survey, SF-36

Another way to find out what will happen to me during the study is to read the chart/table below.

Visit Number	Days After Surgery	Description	Location	Pain Survey	SF-36	Clinical Assessment	Adverse Events
1	--	Screening	Clinic	x	x	x	
2	0	Operation	Hospital			x	
3	varies	Hospitalization	Hospital	x	x	x	
4	varies	Discharge	Hospital	x	x	x	
5	7-23	3 weeks	Clinic	x	x	x	
6	40-44	6 weeks	Clinic	x	x	x	x
7	88-93	3 months	Clinic	x	x	x	x
8	175-185	6 months	Clinic	x	x	x	x

HOW LONG WILL I BE IN THE STUDY?

You will be asked to participate for 6 months after your surgery. After you are finished with your surgery and discharged home, the Investigator will ask you to visit the office for follow-up exams every week until all drains are removed following your surgery. You may be mailed surveys (Pain and SF-36) o complete at approximately 6 weeks, 3 and 6 months following your surgery or we will collect the surveys at a clinic visit. Regardless of whether or not you participate in the study, you will be asked to return to clinic at or just prior to 3 months after your surgery to be evaluated for clearance for transplantation.

CAN I STOP BEING IN THE STUDY?

Yes. You can decide to stop at any time. If you wish to withdraw from the study, please notify your surgeon. Your decision to withdraw will not prevent you from receiving any further treatment required for your care. You may also end your authorization to obtain health information that could identify you by providing written notice to your surgeon. If you end your authorization, no new health information that can identify you will be gathered from you or your existing medical records. However, information that has already been collected cannot be removed from the study records.

Additionally, your surgeon has the right to remove you from this study without your consent due to unforeseeable events. Some of these events may include:

1. Revision surgery that alters the closure in any manner,
2. Lost to follow-up (no return communication from you),
3. Unforeseeable circumstances that remove your eligibility to participate.

YOUR REMOVAL FROM THIS STUDY WILL NOT PREVENT YOU FROM RECEIVING FURTHER TREATMENT.

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

You may have side effects while on this study. Everyone taking part in the study will be watched carefully for any side effects. However, the Investigator does not know all the side effects that may happen. Side effects may be mild or very serious. The following side effects or risks may be possible as a result of participation in this study:

Problems may result from the surgery, or drugs used during surgery such as anesthetics. Your surgeon and hospital will provide you with all of the common and uncommon risks associated with your particular operation. The exact duration of any complication cannot be pre-determined, and may be irreversible. The risk of experiencing these complications is unlikely to be different should you choose not to participate in the study.

In rare instances, you may have an adverse reaction to the adhesive used in the negative pressure device. If this is the case the device will be removed.

You should talk to your study Investigator about any side effects that you have while taking part in the study.

Risks and side effects related to the incisional negative pressure device we are studying include:

Unlikely

- Device leakage
- Allergic reaction to adhesive

Women of Childbearing Potential
All women of childbearing potential will have a urine pregnancy test performed. If you are pregnant or breast feeding you may not participate in this research project because of the very unlikely but not impossible potential harm to the fetus/ developing child or nursing infant. If you are a female of childbearing potential, a method of birth control acceptable to you and your study doctor must be used throughout the study. Acceptable forms of birth control include oral contraceptive pills, intrauterine devices, birth control patches, vaginal rings, Depo-Provera, or a history of bilateral tubal ligation are considered acceptable forms of birth control. If you become pregnant during the study, the study doctor will follow the course of your pregnancy and delivery, as well as the condition of the newborn.

There is no risk to the partner of a male patient that is or may become pregnant during the course of this study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You may not benefit from taking part in this research. It is possible that you may benefit with better healing of the wound after the operation. It is also possible that your outcome may be the same or worse than the control. The information we get from this study may benefit the science community and other patients by advancing the current knowledge of wound closure in high risk patients. This knowledge may also allow other surgeons to improve the way they treat their patients.

We will tell you about new information or changes in the study that may affect your health or willingness to continue in the study.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Your alternative is not to take part in this study. If you choose not to take part in this study, your future care will not be affected. Your wound will be closed according to standard of care and you will be cared for in standard fashion. You will not be required to complete any surveys while in the hospital, in follow-up clinic or through the mail.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

We do our absolute best to ensure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law.

If information from the study is published or presented at scientific meetings, your name and other personal information WILL NOT be used. By signing this consent, you release the rights to the use of any pictures taken throughout the course of the study. These pictures will be de-identified and used only for the purpose of reporting our experience.

All records and data collected during this study will be maintained by your surgeon and will not be furnished to anyone who is not affiliated with this research project without your written consent, per the Health Insurance Portability and Accountability Act (HIPAA). Your identity will be masked and you will be assigned a unique numerical identification code. Any and all images made will be of non-identifiable surgical sites only. Medical data collected throughout the study will be supplied to regulated federal agencies. The Institutional Review Board also has the authority to review this research and your medical records.

Because of the need to release information to these and other parties, absolute confidentiality cannot be guaranteed. However, the collection and submission of the medical information will be accomplished with strict adherence to professional standards of confidentiality.

Study records collected throughout the study will be maintained for at least three years, or until all data analysis and publications have been completed. After this period, all medical data, including individual responses to survey questions, will be destroyed.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

If you are injured as a direct result of research procedures, you will receive reasonably necessary medical treatment at no cost. The University of California does not provide any other form of compensation for injury. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

It is important that you promptly tell the person in charge of the research if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may call the IRB Administration at (916) 703-9151 or email at IRBAdmin@ucdmc.ucdavis.edu.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no additional charge for you to participate in this study. However, you will be responsible for all costs for the underlying panniculectomy. The study surgeon may tell you of the expected costs prior to each procedure being performed. It is suggested that you talk to your surgeon about the costs associated with your procedure and contact your insurance carrier (or other) to determine its policy on payment.

WILL I BE COMPENSATED FOR BEING IN THIS STUDY?

There is no monetary compensation available to you for your participation in this study.
The additional care and monitoring of your progress, however, may identify problems (perhaps unrelated to the device) that can be treated in a more timely and effective manner.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or willingness to continue in the study.

DOES THE RESEARCHER HAVE A FINANCIAL INTEREST IN THIS RESEARCH STUDY?

The investigator does not have a financial interest in this research.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have questions, please ask us. You can talk to the Investigator about any questions or concerns you have about this study at:

The Plastic Surgery Office Phone: (916) 734-2130, Monday – Friday, 8:00 am – 5:30 pm

The Plastic Surgery Service Pager: (916) 816-4852 can be reached 24 hours a day

For questions about your rights while taking part in this study call the IRB Administration at (916) 703-9151 or write to IRB Administration, CTSC Building, Suite 1400, Room 1429, 2921 Stockton Blvd., Sacramento, CA 95817. The IRB Administration will inform the Institutional Review Board which is a group of people who review the research to protect your rights. The IRB Administration has also developed a web site designed to make you familiar with your rights. The web site discusses your basic rights as a research participant, an explanation of the informed consent process, the basic requirement that written consent be in a language understandable to you, and suggested sample questions to ask the research investigator regarding your participation in the study. This web site can be accessed at: www.research.ucdavis.edu/IRBAdmin.

My signature below will indicate that I have decided to participate in this study as a research subject. I have read and understand the information above. I understand that I will be given a signed and dated copy of this consent form and the Bill of Rights.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	