Informed Consent:
A Prospective Study of Port Site Pain Following Percutaneous Externally-Assembled Laparoscopic Donor Nephrectomy

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LOMA LINDA UNIVERSITY
HEALTH

INFORMED CONSENT

TITLE: **A PROSPECTIVE STUDY OF PORT SITE PAIN FOLLOWING PERCUTANEOUS EXTERNALLY-ASSEMBLED LAPAROSCOPIC DONOR NEPHRECTOMY**

PRINCIPAL INVESTIGATOR:
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1. WHY ARE WE DOING THIS STUDY?

The purpose of the study is to determine if use of additional small instruments ("percutaneous externally-assembled laparoscopy," or "PEAL") during kidney donation results in additional pain to the patient. You are invited to participate in this research study because you are over the age of 18 and are undergoing kidney donation (donor nephrectomy). Approximately 100 subjects will participate in this study at Loma Linda University Medical Center. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by United States law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

2. HOW WILL YOU BE INVOLVED?

Participation in this study involves the following:
You will undergo donor nephrectomy using PEAL instruments provided by Teleflex Inc. Both preoperatively and postoperatively, your pain level will be assessed. Postoperatively, you will be asked to rate which of your incisions is the most painful. Additional data will be collected including the amount of pain medication you used, when you used it, and details of your postoperative recovery will be tracked.

3. WHAT ARE THE REASONABLY FORESEEABLE RISKS OR DISCOMFORTS YOU MIGHT HAVE?

The committee at Loma Linda University that reviews human studies (Institutional Review Board) has determined that participating in this study will expose you to risk similar to routine care, but participating in the study will add small amount of risk compared to conventional laparoscopic donor nephrectomy. These include but are not limited to bleeding, pain, infection, damage to nearby structures, need for further surgeries/treatments, bowel injury, renal insufficiency, blood clot, stroke, heart attack, and death.

4. WILL THERE BE ANY BENEFIT TO YOU OR OTHERS?

You may benefit if, as expected, the use of these instruments makes this surgery easier to perform. Knowledge from this study may contribute to the development of advanced surgical techniques in the future.

5. WHAT ARE YOUR RIGHTS AS A SUBJECT?

Participation in this study is voluntary. Your decision whether or not to participate or withdraw at any time from the study will not affect your ongoing medical care/relationship to your doctors and will not involve any penalty or loss of benefits to which you are otherwise entitled. You may get a second opinion about your decision to be in this study from another doctor at your own cost. Likewise, your study doctor may withdraw you from the study for any reason without your agreement or may stop the study entirely.

6. WHAT OTHER CHOICES DO YOU HAVE?

You may decide not to participate in this study. If you do not participate in the study this decision will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are entitled. Your doctor will discuss all other available options for treatment and will answer any questions that you have.

7. HOW WILL INFORMATION ABOUT YOU BE KEPT CONFIDENTIAL?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. You will not be identified by name in any publications describing the results of this study. All information collected will be stored in a locked office and data stored electronically will be password protected and stored in a secure storage location, such as the hospital secured server.

Your rights regarding permission to use your health information are described on the attached "Authorization for Use of Protected Health Information" form.

8. WHAT COSTS ARE INVOLVED?

The cost of the use of these specialized instruments will be billed to you and/or your insurance as part of a normal procedure. You/ your insurance company will be billed for routine clinical care.

9. WILL YOU BE PAID TO PARTICIPATE IN THIS STUDY?

You will not be paid to participate in this research study.

10. WHO DO I CALL IF I AM INJURED AS A RESULT OF BEING IN THIS STUDY?

Your study doctors will be monitoring your condition throughout the study, and precautions will be taken to minimize the risks to you from participating. If you are injured or become ill while taking part in this study:

- If the situation is a medical emergency **call 911** or go to the nearest emergency room. Then, notify the study doctor as soon as you can.
- For a non-emergency injury or illness, notify your study doctor as soon as you can.
- To contact Dr. Duane Baldwin regular business hours, dial 909-558-4196. After hours, call 909-558-4000 and ask for the urologist on call, and identify yourself as a subject in this study.

Appropriate medical treatment will be made available to you. However, you and your insurance company will be billed at the usual charge for the treatment of any research-related injuries, illnesses, or complications. You might still be asked to pay whatever your insurance does not pay.

Also, no funds have been set aside, nor any plans made to compensate you for time lost for work, disability, pain or other discomforts resulting from your participation in this research.

By participating in the study, you do not give up any of your legal rights.

11. WHO DO YOU CALL IF YOU HAVE QUESTIONS?

If you wish to contact an impartial third party not associated with this study regarding any questions about your rights or to report a complaint you may have about the study, you may contact the Office of Patient Relations, Loma Linda University Medical Center, Loma Linda, CA 92354, phone (909) 558-4647, e-mail patientrelations@llu.edu for information and assistance.

12. SUBJECT'S STATEMENT OF CONSENT

- I have read the contents of this consent form, which is in English, a language that I read and understand. I have listened to the verbal explanation given by the investigator.
- My questions concerning this study have been answered to my satisfaction.
- I have received a copy of the California Experimental Subject's Bill of Rights and have had these rights explained to me.
- Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities.
- I may call Dr. Duane Baldwin during routine office hours at (909) 558-4196 or during non-office hours at (909) 558-4000 and ask for the urologist on call if I have additional questions or concerns.
- I understand that if I am enrolled in an in-patient study, my primary care physician may be notified of my participation for proper coordination of care.
- I hereby give voluntary consent to participate in this study.

I understand I will be given a copy of this consent form after signing it.

Signature of Subject	Printed Name of Subject
Date	

13. INVESTIGATOR'S STATEMENT

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with a copy of the California Experimental Subject's Bill of Rights, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

Signature of Investigator	Printed Name of Investigator
Date	