Lahey Hospital & Medical Center

LAHEY CLINIC, INC.
DIVISION OF RESEARCH
Research Consent Form (DR-2)

Principal Investigator: Jeffrey Tiger, MD **Tel: (781) 744-8348**

Protocol Title: PROSPECTIVE RANDOMIZED CLINICAL TRIAL COMPARING OUTCOMES OF SECONDARY INTENTION WOUND CARE METHODS

INTRODUCTION

You are being asked to participate in this clinical trial because you have a wound after skin surgery that is healing on its own without stitches. In order to decide whether or not you should participate in this study, you should know enough about the risks and benefits of the study. This process is known as informed consent.

This consent form gives you detailed information about a clinical trial, which is a type of research study. You may discuss this treatment with your health care team. Your doctor will answer any questions you may have.

Your participation in this clinical trial is voluntary and your refusal to participate will not affect any medical care or benefit to which you would otherwise be entitled. If you decide to participate, you will be provided with a copy of this signed informed consent form. You will be told of any significant new findings during the course of this study and you are free to withdraw your consent and discontinue participation at any time.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You may use the NCT# **03880331** identification number to locate the trial on the ClinicalTrials.gov web site

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine if debridement improves healing time for wounds that are left open to heal on their own without stitches (secondary intention wounds). “Debridement” is the removal of damaged tissue from the open wound. This may be done by cleaning the wound with a clean washcloth, gauze or a sharp surgical instrument.

Background: Leaving wounds open to heal without stitches is an established method of allowing post-surgical wounds to heal. Previous studies have shown that more frequent debridement of wounds that have stopped healing and not improved for several months may improve healing rates. However, the effect of debridement on new wounds that are continuing to heal, although they may be healing slowly, is not as clear. Furthermore, frequent and/or aggressive debridement of post-surgical wounds may be inconvenient and/or uncomfortable for patients.

Given this uncertainty, some medical providers prefer post-operative wounds to be aggressively debrided and some prefer wounds to be minimally debrided; and in fact, both methods are currently used at Lahey Hospital & Medical Center. While both methods lead to good healing outcomes, it is unclear if there are any differences in the rate of healing of post-surgical wounds or the degree of patient satisfaction with their scars when wounds are treated with one method compared to the other. This is because there have been no previous research studies comparing these two methods. That is the purpose of this study.

HOW LONG WILL I BE IN THE STUDY?

The total time for the treatment part of the study is approximately 4 months. You will be followed until your wound completely heals.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 40 patients will participate in this study at the Lahey Hospital & Medical Center and its affiliates as applicable.

WHAT IS INVOLVED IN THE STUDY?

In order to participate in this study you must have undergone a Mohs skin surgery procedure under the care of your dermatologist as part of your routine care.

DURING THE STUDY:

At your first visit, after you sign this informed consent form, we will review your medical records to obtain demographic information (age, sex, and race) and past medical history. We will also be measuring and recording the width, length, and depth of your wound before starting study treatment and at each study visit.

Before starting treatment, you will be randomly assigned to one of two treatment groups (often referred to as a "treatment arm"). Randomized means that you are assigned to a treatment group (or arm) by chance (similar to a flip of a coin). You will be assigned to receive either the aggressive debridement method or the minimal debridement method.

1) Aggressive Debridement Method:
This method involves frequent debridement by you, the nurse, and/or the doctor. At home, you will remove the bandage, clean the wound with mild soap and water, scrub the surface of the wound with a clean washcloth aggressively in order to clean off crust and debris and until you see a small amount of pinpoint bleeding. You will return to the clinic weekly for evaluation and treatment of your wound until your wound is healed. Photographs of your wound will be taken at each of these visits.

2) Minimal debridement Method:
This method involves no debridement by you, the nurse, or the doctor. Exceptions include removing of any dried scab. You will return every 2 weeks for evaluation and treatment of your wound until your wound is healed. Photographs of your wound will be taken at each of these visits. In between visits at weekly intervals, you will be contacted by the study staff by phone to evaluate whether your wound is healing appropriately.

Additional instructions

- You will be provided with detailed instructions and guidelines to help determine whether healing has taken place. If you have any questions or have any difficulty determining how your wound is healing call Dr. Tiger at 781-744-8348.
- When the wound is completely healed, we will ask you to fill out a brief questionnaire (Patient Scar Assessment Questionnaire) to tell us how you feel about the scar, a final photograph will be taken to be evaluated on the cosmetic appearance of your wound, and the final size and depth of the wound will be measured. The final photograph of the healed wound will be evaluated by a blinded investigator outside of Lahey Hospital & Medical Center. A blinded investigator is a term used to describe an investigator who is unaware of which treatment the participant is receiving. This photograph will be zoomed in to only show the scar, and will not be labeled with personally-identifiable information.
- If your wound is not healed by week 16, you will be withdrawn from the treatment part of the study however, we will continue to collect data on how your wound is healing. You will continue to receive care by your doctor until your wound is completely healed. Your doctor will evaluate and determine how your wound should be treated going forward if your wound is not healed by week 16. Your doctor may decide to change the care you are receiving.

WHAT ARE THE FORESEEABLE RISKS AND SIDE EFFECTS TO THIS STUDY?

You may experience risks and side effects from the routine (non-research) care (tests or procedures) you receive during this study. You would be exposed to these risks and potential side effects whether you were in this study or not. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects.

You may have side effects while on the study. In particular, since this study is comparing two methods of treating post-surgical wounds, it is possible that one treatment method is significantly more effective than another. By participating in this study, there is the risk that you are randomized to the less effective treatment method which may delay your wound healing. It is also possible that one group of patients may have more side effects than the other. For example, patients in the aggressive debridement group may experience more bleeding, pain, and scarring than the minimal debridement group.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

Taking part in this study may or may not make your health better. While your doctor hopes that this study regimen will be useful in better understanding wound healing, there is no proof of this yet. Information learned about the treatment(s) used in this study may help doctors learn more about treating patients with the same condition in the future. Your study doctor will tell you about new information or changes.

WHAT OTHER OPTIONS ARE THERE?

Your participation in this study is completely voluntary. You do not need to participate in this research study to receive wound care after your skin surgery. Both aggressive debridement and minimal debridement are accepted methods of post-operative care for wounds.

Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers. You may also wish to discuss this matter with a relative, a friend, or another doctor.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY? CAN I STOP BEING IN THE STUDY?

Taking part in this study is your choice. If you take part in this study you can stop at any time. Talk with your doctor before you decide to stop. It is important to tell your doctor if you are thinking about stopping, so any risks from your treatment can be evaluated. Your doctor will also want to discuss what kind of follow-up care and testing would be most helpful for you. Your doctor may stop your participation in the study at any time if he believes it is in your best interest; for example, if you do not follow the study rules; if you experience serious side effects; If you and your doctor decide to end your study treatment, we will continue to follow your progress and continue to collect data about your progress.

If you decide to withdraw your consent to participate in the study, no new data about you will be collected for study purposes unless the data concerns an adverse event (a bad side effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that has already been collected for study purposes, and any new information about an adverse event related to the study, will be reviewed by study doctor.

Your decision not to participate or to stop participation in the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Lahey Hospital & Medical Center and its affiliates. If you do decide to withdraw your consent to participate in the study, we ask that you contact Dr. Jeffrey Tiger in writing to let him know that you are withdrawing consent to participate in the study. The mailing address is Dr. Jeffrey Tiger, Lahey Hospital & Medical Center, 67 South Bedford Street, Burlington, MA 01803

If you are an employee of Lahey Hospital & Medical Center or any of its affiliated entities and do not wish to participate in the research study or wish to withdraw after signing this form, there will be no prejudice against you or influence on your employment status.

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 ARE THE COSTS?

There are no added costs to participate in this study. The routine costs are the same as that you would incur during normal treatment of your condition. You will be responsible for your regular health insurance premiums, deductibles and co-payments. You will be responsible for all transportation costs you incur in obtaining medical treatment related to your participation in this study.

WILL I BE PAID FOR PARTICIPATING IN THE STUDY?

You will not be compensated, either directly or indirectly, for joining this study.

WHAT ABOUT INJURIES RELATED TO THIS RESEARCH?

All forms of medical treatment whether routine or experimental involve some risk of injury. There may be risk associated with this study that we do not know about. In spite of all precautions, you might develop medical complications from being in this study. Immediate medically necessary treatment is available to you if you are injured as a result of this study.

If you sustain any injury during the course of the research or experience any side effect to a study procedure, please contact Dr. Jeffrey Tiger at 781-744-8348.

If such complications arise, the study doctor will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for medical or other injury related costs.

Lahey Hospital & Medical Center, including its affiliates, will not pay for the costs associated with any medical services or any other services received by you resulting from any illnesses, injuries, or any other adverse effects that you may experience as a result of your participation in this study.

You do not give up any rights to seek payment for personal injury by signing this form.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Federal law requires Lahey Hospital & Medical Center, its affiliates, and its doctors and staff to protect the privacy of your health information. “Protected health information” comes from your past, present and future medical record as well as from study-related tests, clinic visits, procedures, interviews, and/or questionnaires. If you choose to enroll in this research study, your protected health information will be used and shared with others.

While every reasonable effort is made to protect the confidentiality of your health information, it may be used by and/or disclosed (released) to

- Other Lahey Hospital & Medical Center and affiliated clinicians and staff involved in this study,
- The Lahey Clinic, Inc. Institutional Review Board,
- Doctors, researchers, and healthcare professionals taking part in this research at other institutions,
- Other colleagues and offices at Lahey Hospital & Medical Center and affiliated entities that deal with research oversight, billing or quality assurance,
- Hospital accrediting agencies,
- People or groups that Lahey Hospital & Medical Center and affiliates hire to do work for us, such as data storage companies, insurers, and lawyers,
- Federal and state agencies (such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS), or other US or International government bodies that oversee research,
- Public health and safety authorities.

Some of the above mentioned people or groups who receive your health information may not need to follow the same privacy rules that we follow. They may share your information with others without your permission, if permitted by the laws governing them.

The results of this research may be published in scientific books or journals or presented at medical meetings. Your identity will not be revealed in these publications or presentations.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, to keep the integrity of some research studies, you may or you may not have immediate access to your research related health information depending upon the design of the study until it is complete. At the conclusion of the research study and at your request, you will again have access to your health information.

By signing this document, you authorize colleagues at Lahey Hospital & Medical Center and its affiliates to use or share your health information that identifies you for this research study as described above. This authorization does not have an expiration date.

YOUR PRIVACY RIGHTS

You have the right not to sign this form allowing us to use and share your health information for research. However, if you do not sign this form, you may not take part in this research study.

You have the right to withdraw your permission allowing us to use and share your health information for research at any time. Even if you withdraw your permission, Lahey Hospital & Medical Center and its affiliate's doctors and staff may still use or share health information they have already collected about you as needed to keep the integrity of the study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. If you want to withdraw your permission, you must do so by writing to Dr. Jeffrey Tiger, Lahey Hospital & Medical Center, 41 Mall Road, Burlington, MA 01805. Once you withdraw your permission, you may no longer take part in the study.

HOW LONG ARE THE STUDY RESULTS KEPT?

Because research is an ongoing process, there is no set date on which we will destroy your protected health information. There is also no set date on which we will stop using or sharing this information.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions concerning this study, the availability of medical care, or if you have experienced a research-related illness, injury, or emergency, contact Dr. Jeffrey Tiger at 781-744-8348.This study has been reviewed and approved by the Lahey Clinic, Inc. Institutional Review Board. If you have any questions about your rights as a research subject, you may contact the Office of Research Administration at (781) 744-8027.

Principal Investigator: Jeffrey Tiger, MD ☐ **Check here if this is Re-Consent**

Protocol Title: PROSPECTIVE RANDOMIZED CLINICAL TRIAL COMPARING OUTCOMES OF SECONDARY INTENTION WOUND CARE METHODS

STATEMENT OF PARTICIPANT or LEGALLY AUTHORIZED REPRESENTATIVE:

My signature on this consent form means the following:

- I have read (or had read to me) each page of this consent form and I have had enough time to think about participating in this study.
- I have been informed of the procedures to be followed in this study, including a description of those which are investigational and I have been told of the possible discomforts, risks, benefits and costs to be expected as well as the appropriate alternative treatments and that unforeseen effects may occur.
- I have been given the chance to ask questions about the study. All my questions have been answered to my satisfaction and I know that I may contact the investigator if I have additional questions about the study.
- If I wish additional information or believe I have been harmed by this study, I may contact the Chairman of the Institutional Review Board: **Sarkis H. Soukiasian, M.D.** c/o Research Administration, 41 Mall Road, Burlington, MA 01805 or call 781-744-8027.
- I consent to participate in this research study and agree to allow my health information to be used and shared as described in this consent form.

_____ _____ _____**AM / PM**

Signature of Participant – or – Legally Authorized Representative **Date** **Time**

_____

Print Name of Legally Authorized Representative **if signed above**

Check relationship: ☐ Next of Kin ☐ Health Care Proxy ☐ Durable Power of Attorney ☐ Court Appointed Guardian

PERSON OBTAINING PARTICIPANT'S CONSENT

My signature on this consent form means the following:

- This research study has been explained to the study subject and he/she agreed to participate.
- The subject has had an opportunity to ask questions which have been answered to the subject's satisfaction.
- The subject, or legally authorized representative, has been given a copy of this consent form.

_____ _____ _____**AM / PM**

Signature of Person Obtaining Consent **Date** **Time**

_____

Print Name of Person Obtaining Consent

ICF DISTRIBUTION: *(1) Copy to Participant (2) Signed Original & Text Pages- Medical Record (3) Copy to Participant Research Binder*

Patient Name and MRN: