INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH

Scar appearance after hydrocolloid dressing versus petrolatum ointment: a randomized control trial

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IRB #15768

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change the way we do things.

This consent and authorization will give you information about this study to help you decide whether you want to participate. It is your choice whether you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate the differences in cosmetic outcomes when a post-operative wound after dermatologic surgery is treated with conventional petrolatum ointment dressing compared to hydrocolloid dressing. There is a lack of evidence about wound care dressings after dermatologic surgery. Historically, conventional petrolatum daily dressings have consisted of layered ointments and nonadherent, absorbent, contouring, or compressive dressings. Many of these dressings require time-consuming daily changes and topical emollient reapplication. More recently, innovative dressings such as silicone gels, collagen films, and hydrocolloids have been suggested to be beneficial in wound healing because of their antimicrobial properties, insulation, and impermeability. In our study we will use hydrocolloid dressing for post-operative wound and compare its cosmetic outcome with petrolatum dressing.

We are asking if you want to be in this study because you have been diagnosed with a skin cancer or other skin condition that requires surgical intervention. Your dermatologist or provider have confirmed your diagnosis with biopsy and pathology report and referred you to our office for surgical treatment of your skin condition.

The study is being conducted by **Syril Keena Que, MD, MPH** at the Indiana University School of Medicine.

WHAT WILL HAPPEN DURING THE STUDY?

- After post-operative closure of the wounds, You will be randomized (like flipping a coin) to have your wound covered with either hydrocolloid for one week, or with petrolatum ointment dressing. The petrolatum ointment will need to be re-applied daily.
- There are no additional study visits outside the clinic visit(s) required after your skin surgery.
- One week after surgery, you will be contacted by study staff to complete two 1 – 2 minute questionnaires. The purpose of these questionnaires is to evaluate the scar appearance after 1 week of using the dressing as well as to assess surgical site infection. You will be provided with this questionnaire

to view the day of surgery. Study staff will also request you to send a picture of your wounds so that it can be assessed by the clinician. You will also have the option to email your picture if you prefer.

- You will be contacted at two other time points, 1 month and 3 months after surgery. You will be requested to send your picture at these time points.
- The study team will collect limited data from your medical records, as it pertains to this study. Any clinical data about you will be de-identified during analysis of the study data.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

Risks related to hydrocolloid or petrolatum dressing are limited. Both are commonly used to cover wounds after surgery in medical settings. You will be monitored to ensure minimal risk is presented through the total study duration. However, some of the risks, side effects, and/or discomforts include a risk of bleeding or infection, associated numbness, or discomfort. These are also the same risks you may experience from having any skin surgery. These risks are not expected to be increased by your participation in this study.

You may be uncomfortable while answering the survey questions. While competing the survey, you can skip any questions that make you uncomfortable or that you do not want to answer.

There is a risk someone outside the study team could get access to your research or medical information from this study. More information about how we will protect your information to reduce this risk is provided above and below.

WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?

We hope your information will be used for research that will help other people in the future.

WHAT ARE THE OTHER TREATMENT OPTIONS?

There may be other options for covering the post-operative scar with dressing other than petrolatum ointment or hydrocolloid dressing. Other options include silicone gels and collagen films but there is no consensus which dressing have best treatment outcomes.

WILL I BE PAID FOR PARTICIPATION?

You will not be paid for participating in this study.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

HOW WILL MY INFORMATION BE USED?

The study team will collect information about you from your medical records. This information, some of which may identify you, may be used for research-related purposes. This may include gathering information about your post-operative wound after dermatologic surgery to include in the research data, or to inspect and/or copy your research records for quality assurance and data analysis.

The information released and used for this research will include, medical history and treatment documents, medications, laboratory/ diagnostic tests, pathology reports, radiology records, operative notes, consultations, and diagnostic imaging reports. If you agree to participate, you authorize the following to disclose your medical record information:

- Indiana University Health

- Indiana University Health Physicians

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US governments or agencies as required by law
- Data safety monitoring boards and others authorized to monitor the conduct of the study
- State or Federal agencies with research oversight responsibilities, including but not limited to:
    - The United States Food and Drug Administration (FDA)

Information collected for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. 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.

HOW WILL MY INFORMATION BE PROTECTED?

Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the researcher, Syril Keena Que, MD, MPH at (608) 618-2678.

In the event of an emergency, you may contact Dr. Que at this same number.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program at 800-696-2949 or at irb@iu.edu.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with treating doctor or hospital providing care. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled.

If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying Dr. Syril K. Que at ques@iu.edu. If you withdraw your authorization, you will

not be able to continue in this study. However, even if you cancel this authorization, the research team and/or research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

PARTICIPANT'S CONSENT AND AUTHORIZATION

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

Participant's Printed Name: _____

Participant's Signature: _____**Date:** _____

Participant's Address: _____

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____**Date:** _____