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Wake Forest School of Medicine

Department of Dermatology

Improving Disease Severity in Alopecia Areata, Polymorphous Light Eruption, and Psoriasis Patients with Lumiton Technology

Informed Consent Form to Participate in Research

Joseph Jorizzo MD and Steven R. Feldman, MD, PhD Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to. To identify whether use of fabric made from the Lumiton® yarn improves clinical severity in patients with psoriasis, alopecia areata (AA), and polymorphous light eruption (PMLE). You are invited to be in this study because you are an adult over the age of 18 with a diagnosis of psoriasis, AA, or PMLE. Your participation in this research will involve two in office visits over a 12-week period.

The risk of harm of discomfort is not expected to be more than a daily life of routine physical or psychological exam or test. There is the possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. This is not a treatment study. Your alternative is to not participate in this study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is the Principal Investigator Joseph Jorizzo MD. If you have questions, suggestions, or concerns regarding this study or if you want to withdraw from the study his contact information is:

Joseph Jorizzo, MD [redacted]

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific

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knowledge that may help other people in the future. You are being asked to take part in this study because you are an adult over the age of 18 with a diagnosis of psoriasis, AA, or PMLE with a working knowledge of English. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to identify whether use of fabric made from the Lumiton® yarn improves clinical severity in patients with psoriasis, alopecia areata (AA), and polymorphous light eruption (PMLE).

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to 30 people at Atrium Health Wake Forest Baptist Medical Center.

WHAT IS INVOLVED IN THE STUDY?

Participation in this study involves two in person visits over 12 weeks.

Participants will be provided clothing items made from the Lumiton® yarn and patients will be instructed to wear clothing items made from Lumiton® yarn daily for 12 weeks both indoors and outdoors. Participants with alopecia areata will be given a hat. Participants with polymorphous light eruption will be given a shirt. Participants with psoriasis will be given sleeves to cover their arms. Our proposed study will test whether the clothing material made from Lumiton® yarn improves clinical outcomes in patients with AA, PMLE, and psoriasis.

At both the initial and follow up visit, study staff will take photos of the psoriatic, AA, or PMLE lesions among participants. Participants with psoriasis will complete a Psoriasis Area and Severity Index-75 survey at both visits. Participants with AA will complete a Severity of Alopecia Tool (SALT) survey at both visits.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for 12 weeks

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff. Taking part in this research study may involve providing information that you consider confidential or private.

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Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive direct benefit from participation.

WHAT OTHER CHOICES ARE THERE?

Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

The participant will not assume any costs during this study.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will not be paid for your participation in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Lumiton Wear Healthy Technology®. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**: information on age, gender, ethnicity, location of ksin lesions.**

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

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We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and Atrium Health Facilities; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries, and Lumiton corporation.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs, videotapes, audiotapes or other recorded media which are identify you unless we you're your written authorization.

You can tell Dr. Joseph Jorizzo that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Joseph Jorizzo, MD [redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

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Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Jorizzo at [redacted] or after hours through the hospital operator at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

SIGNATURES

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I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____
Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____
Person Obtaining Consent:_____ Date:_____ Time:_____ am pm