The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: IRB16-1541
Name of Subject: _____

STUDY TITLE: Exploring Microbial Association Dynamics in Cicatricial Alopecia Patients

Doctors Directing Research:	Dr. Jack Gilbert
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	Dr. Crystal Porter
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You are being asked to participate in a research study. A member of the research team will explain what is involved in this study and how it will affect you. This consent form describes the study procedures, the risks and benefits of participation, as well as how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether to participate or not. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form.

WHY IS THIS STUDY BEING DONE?

You are being asked to take part in this study because you may or may not be experiencing hair loss. Some of the people being asked to take part of this study will be those who are seen by a dermatologist. Other people are responding to advertisements for volunteers to participate in this study.

The purpose of this study is to look at the microbiome community of the scalp in people who have hair loss caused by scarring (cicatricial alopecia). A microbiome is the collection of microbes (bacteria, fungus, viruses), their genomes (the biological information needed to build and maintain life), and environmental interactions in a defined space. This study will collect swab samples of the scalp and information about hair care from people on this study. The scalp samples will be studied in the lab to look at the scalp microbiome. Information about the hair care of people on the study will be used with the results from the lab tests.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 600 people will take place in this study at the University of Chicago.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate in this study, you will be asked to read and sign this consent form before any study procedures take place. This consent form will be discussed with you and you will be able to ask any questions you might have.

You will be asked to complete the study questionnaire that asks questions about your age, health, ethnic background, family history, and hair including your hair care routine. This questionnaire will take about 15 minutes to complete.

If you have been asked to participate in this study by your dermatologist, your scalp sample will be collected by the dermatologist. Two swabs will be rubbed on your scalp for 10 seconds and then placed in tubes and sent to Dr. Porter. These tubes will be labeled with a study number and not identifying information such as your name.

If you haven't been asked to be in this study by a dermatologist, then you will be asked to collect the swab samples from your scalp. You will be given a kit that contains the swabs and tubes to be used to collect the samples. You will collect two samples from your scalp, one at an area of hair loss, the second at an area without hair loss. The kit contains detailed instructions. After you collect the samples, you are asked to mail them in the envelope provided along with your completed study questionnaire to Dr. Porter.

You have the option to receive a report based on the results from your tests and share the results with your dermatologist (if applicable). The report will summarize the microbial make-up on your scalp and show how your results compare to the average trend of other de-identified subjects. The report will also show which lifestyle factors affect the microbial make-up based on the questionnaire responses.

Your consent (if applicable), scalp samples and questionnaire will be sent to Dr. Porter who owns Mane Insight. Dr. Porter will use your responses on the questionnaires and the information from the lab tests for the purpose of this study. Dr. Gilbert's lab, which is part of the University of Chicago, will then receive the scalp samples and test the samples in his laboratory. The research staff that works in Dr. Gilbert's laboratory may also see information about you including your name, and the responses to your questionnaires.

Any remaining samples will be stored for future research. The information or samples from this study may be shared with other researchers outside of the University of Chicago for future research. If your information or samples are shared, it will be done in a manner that will not identify you. The data will not contain your name or other identifying information.

For this study, Dr. Porter and Dr. Gilbert and his research team will collect information about you for the purposes of this research. This includes your name, address, email address, telephone number, and responses on the study questionnaire and results from your samples.

HOW LONG WILL I BE IN THE STUDY?

You will be in this study until you provide your sample and complete the questionnaire. Your samples will be kept for future research until they are used up.

Dr. Porter may decide to take you off of the study without your consent if:

- You are unable to meet the requirements of the study;
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

Loss of Confidentiality

Any time information is collected about you; there is a potential risk for loss of confidentiality. Please refer to the 'What About Confidentiality' section for information on what measures will be taken to protect your confidentiality.

There are no risks associated with the collection of scalp samples.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope this study can provide insight into the how the scalp microbiome may be affected by hair care and what the relationship is to alopecia.

WHAT OTHER OPTIONS ARE THERE?

You may choose not to participate.

WHAT ARE THE COSTS?

There will be no costs to you or your insurance company resulting from your participation in this research study. However, you or your insurance company will be responsible for costs related to your usual medical care.

WILL I BE PAID FOR MY PARTICIPATION?

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

WHAT ABOUT CONFIDENTIALITY?

Study records that identify you will be kept confidential. Data will be stored in a locked office, or in password protected computers at the University of Chicago and at Mane Insights, Inc.. Only research staff involved in the study will have access to the data except as specified below. The data collected in this study will be used for the purpose described in this form. The research team includes all of the individuals indicated on this consent form and other personnel involved in this study at the University of Chicago.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Office of Human Research Protections (OHRP). In addition, representatives of the University of Chicago, including the Institutional Review Board, a committee that oversees the research at the University of Chicago, may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

If health information is shared outside the University of Chicago, the same laws that the University of Chicago must obey may not protect your health information.

This consent form will be kept by the research team for at least 6 years. The study results will be kept in your research record and be used by the research team indefinitely. At the time of study completion, information identifying you will be removed from study results.

Data from this study may be used in medical publications or presentations. Your name and other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. If you choose not to participate in this study, your care at the University of Chicago/University of Chicago Medical Center will not be affected. You may choose not to participate at any time during the study. Leaving the study will not affect your care at the University of Chicago/University of Chicago Medical Center.

If you choose to no longer be in the study and you do not want any of your future health information or samples to be used, you must inform Dr. Gilbert in writing at the address on the first page. Dr. Gilbert may still use your information that was collected prior to your written notice.

You will be given a signed and dated copy of this document. This consent form document does not have an expiration date.

Personalized Results

You have the option to receive information about this study based on your personalized data. If you were enrolled on this study by your dermatologist, we can also share a copy of these results with your dermatologist. Please make your selection about your report below.

_____ (initials) _____ (date) Yes, I would like to have my results sent to me via email.
Please use the following email address: _____
Email address (*please write legibly*)

_____ (initials) _____ (date) No, I do not want to receive the results from the study.

_____ (initials) _____ (date) Yes, I would like to have a copy of my results also sent to Dr. Lenzy or Dr. Barbosa (please circle the correct name)

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You have talked with the _____about this study and you had the opportunity to ask questions concerning any and all aspects of the research. Dr. Porter is available to answer any questions you have about this research study or your participation in the study. If you have further questions about the study, you may call Dr. Crystal Porter during business days between the hours of 9:00 a.m. and 5:00 p.m. at 630-225-7462.

If you have any questions concerning your rights as a research study participant, you may contact the Institutional Review Board (IRB), which is concerned with the protection of subjects in research projects. You can contact the IRB in writing at Institutional Review Board (IRB), University of Chicago, McGiffert Hall, 2nd floor, 5751 S. Woodlawn Avenue, Chicago, Illinois 60637 or by phone at (773) 702-6505, office hours are 8:30 am - 5:00 pm, Monday through Friday.

CONSENT

SUBJECT

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

_____ Date: _____
Signature of Subject Time: _____ AM/PM (*circle*)

PERSON OBTAINING CONSENT

I have explained to _____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject.

_____ Date: _____
Signature of Person Obtaining Consent Time: _____ AM/PM (*circle*)