### 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: Name of Subject: Medical History Number:

## STUDY TITLE: **Investigation into the Microbiome of your Home**

Doctors Directing Research: Jack Gilbert, Ph.D and Benjamin Shogan, M.D.

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**9700 S Cass Ave**

**Bldg 202 Rm B363**

**Lemont, 60439, IL.**

Telephone Number: 630.915.2383

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?

**The purpose of this study is to investigate what kind of normal bacteria live on your skin and live in your home and how this changes when you move.** **It is known that normal bacteria live on our skin and on surfaces in our house. But, it is not well understood how these communities of bacteria develop, or how these communities change when people move into a new home. This research is being done to define these bacterial communities, which may generate insights allowing advances in treating medical diseases, advances in ecological theory, and development of better antimicrobial substances.**

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

**About 200 people will take part in this study at the University of Chicago.**

WHAT IS INVOLVED IN THE STUDY?

**During this study, Dr. Gilbert and his research team** **will collect information about you for the purposes of this research. You have been approached to be included in this study because you are moving homes. In this study we will analyze bacteria on different parts of your body, and on different surfaces of your home. If you agree to participate in this study, we will ask you to swab different parts of your body and surfaces of your home every other day for two weeks prior to your move, and then for 4 weeks after your move. Participants will be asked to swab the palm of their dominant hand, their heel-pad (bottom of the foot), and perform a nasal swab for respiratory bacteria. Participants will also be asked to do surface swabs of their internal front door knob, the main bathroom internal door knob, the kitchen top surface, the bedroom and bathroom floors, and the kitchen light switch. You will also be given a device to measure the humidity and temperature of your home, and participants will be asked to record these measurements on a daily basis. Finally, personal information will be collected from you including age, sex, household income, and property size. Prior to enrollment in this study you will participate in a training session for detailed instructions of how to obtain and store the above samples. Prior to starting the study, you will be given a sampling kit, freezer for sample storage, instruction manual, and logbook.**

**A member of the research staff will pickup the swab samples on a weekly basis. Each sample will then be analyzed for which bacteria they contain by looking at the different types of DNA in the sample. Only bacterial DNA (not human DNA) will be analyzed.**

## HOW LONG WILL I BE IN THE STUDY?

**We think you will be in the study for 6 weeks.**

WHAT ARE THE RISKS OF THE STUDY?

**There are no health risks for participation in this study.**

## ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

**If you agree to take part in this study, there will be no direct medical benefit to you. But, we hope the information learned from this study will allow insights into how bacterial communities form which may have implications in agriculture, medical diseases, and antimicrobial substances.**

## WHAT OTHER OPTIONS ARE THERE?

## **Instead of being in this study, 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.

**If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of Chicago Medical Center at no cost to you.  Costs of related non-emergency care for an unanticipated research injury will be covered if that care is provided at the University of Chicago Medical Center.  You must notify Dr. Jack Gilbert as promptly as possible after your injury in order to receive this care.  An injury is “unanticipated” if it is not one of the known effects of a study drug, medical device or procedure.  If you think that you have suffered a research related injury, you must let Dr. Jack Gilbertknow right away.**

WILL I BE PAID FOR MY PARTICIPATION?

You will not be paid for participation.

## WHAT ABOUT CONFIDENTIALITY?

Study records that identify you will be kept confidential. No medical history will be obtained. We will obtain personal information such as a size of your home and household income and analyze the bacteria on your skin and in your home. All information obtained or data generated will be strictly confidential and stored in a password protected computer file and will only be accessed by the research team.The data collected in this study will be used for the purpose described in the form. The research team includes the individuals listed 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 Food and Drug Administration (FDA) andOffice 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 six years. The study results will be kept in your research record and be used by the research team indefinitely.

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 to be used, you must inform Dr. Jack Gilbert in writing at the address on the first page. Dr. Jack Gilbertmay still use your information that was collected prior to your written notice.

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

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You have talked to Dr. Jack Gilbert about this study and you had the opportunity to ask questions concerning any and all aspects of the research. If you have further questions about the study, you may call Dr. Jack Gilbert at 630.915.2383.

If you have any questions concerning your rights in this research study you may contact the Institutional Review Board, which is concerned with the protection of subjects in research projects. You may reach the Committee office between 8:30 am and 5:00 pm, Monday through Friday, by calling (773) 702-6505 or by writing: Institutional Review Board, University of Chicago, 5751 S. Woodlawn Ave., McGiffert Hall, Chicago, Illinois 60637.

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.

Signature of Subject:

Date: Time: AM/PM (Circle)

PERSON OBTAINING CONSENT

I have explained to *insert name of subject/parent/guardian* 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 *[and if appropriate add]* and family.

Signature of Person Obtaining Consent:

Date: Time: AM/PM (Circle)

INVESTIGATOR/PHYSICIAN:

Signature of Investigator/Physician

Date: Time: AM/PM (Circle)