If you are using Epic, you must fax a copy of this signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Comparative evaluation of the migrant microbiome and envirome effects of risk of inflammatory bowel disease.**

Application No.: **NA_00086637**

Sponsor: **Sun Yat-Sen University**

Principal Investigator: **Susan Hutfless PhD**
600 N Wolfe St, Blalock Building 449, Baltimore, MD 21287
Phone: +1 410-502-0194
FAX: +1 410-614-7340

1. What you should know about this study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Please ask questions at any time about anything you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.

2. Why is this research being done?

This research is being done to see if there is a link between environment and the risk of inflammatory bowel disease (IBD).

There are three types of diseases that are called inflammatory bowel disease or IBD. These diseases are called: Crohn's disease, ulcerative colitis and intermediate colitis. Doctors and researchers are trying to know how people get these diseases. We think that the environment around us can be a cause of these diseases.

Here we are trying to study how moving from a region to another can affect these diseases. We are also trying to see how different contacts from the environment around us change the situation.

People who have IBD can join. Other people who are relatives or friends of people who have IBD can also join, but they must not have IBD.

How many people will be in this study?
Around 1,800 individuals will take part of this study over 5 years.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

- We will have some questions about your daily food intake, other behaviors and life history. You can ask to see the questionnaire before you decide to participate.
- We will ask you to give a one-time stool sample in a cup that we will provide.
- We will also ask you to take a one-time sample from your mouth. You will spit in a cup to give us a saliva sample
- We will ask you to give a one-time blood sample. The amount of blood that will be taken is around 1 tablespoon (equivalent to 15 ml or 0.5 ounces).

We will use your stool and saliva to see what bacteria are present in your colon or mouth. We want to study how these bacteria are interacting with each other and how they can affect your chance of getting IBD or events that happen after you are diagnosed with IBD.

The blood samples will be used to measure nutrients and vitamin levels and genetics. We will save blood samples so that we can measure new factors measured from the blood that may be important to IBD in the future.

We will only analyze the genetic material of the different bacteria in the samples you give us. We will not attempt to analyze your personal genetic material under any circumstance. You also have to know that at the moment, we are not able to make conclusions from the results. We can not inform you about the importance of your results and how you will be affected, if you will get the disease or if you have the disease how your treatment will be.

Optional Sample Storage for Future Testing
With your permission, we would like to store samples collected during the study in a freezer for future analysis.

Please sign and date your choice below:

Yes ☐ I agree to have the samples stored for future analysis _____

_____

Signature of Participant Date

No ☐ I DO NOT agree to have the samples stored for future analysis _____

_____

Signature of Participant Date

How long will you be in the study?

Your participation in this study will occur during the visit you are making at this time. We will contact you again to see if you are willing to answer additional questions and provide more samples. We will do this again during the next 24 months. If the preliminary results suggest that we should ask more questions, we will ask you again if you want to participate. You will receive a consent form like this the next time that we contact you.

Future Contact

We would like your permission to contact you about other studies that you may be eligible for in the future.

Please sign and date your choice below:

YES ☐ _____ _____
Signature of Participant Date

NO ☐ _____ _____
Signature of Participant Date

4. What are the risks or discomforts of the study?

This is a minimal risk study. This means that the risk that you might encounter in this study is not greater than any risk that you might have in your daily life or during performance of routine physical examinations or tests.

It is less likely that you will experience any side effect from the stool collection or the blood collection than in normal clinical situations. Taking blood may cause discomfort, bleeding or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

There is the risk that information about you may become known to people outside this study. To protect against this, all samples will be stored with a sample ID that contains the following information: Center Random Identification Number – Diagnosis status – Date – Initials. The random identification number will be allocated to patients on a separate list that will be sorted in a secure location within the Hopkins Homer system in order to secure the identity and the privacy of the participants.

5. Are there benefits to being in the study?

There is no direct benefit to you from being in this study. If you take part in this study, you may help others in the future.

6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

No.

8. Will you be paid if you join this study?

No.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.
- If you leave the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

10. How will your privacy be protected?

Johns Hopkins has rules to protect information about you. Federal and state laws also protect your privacy.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and other details.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Johns Hopkins may see your information. These include people who review research studies, their staff, lawyers, or other Johns Hopkins staff.

People outside of Johns Hopkins may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and companies that sponsor the study.

We cannot do this study without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Hopkins who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this confidentiality.

The use and disclosure of your information has no time limit. You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Study Doctor's/ Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

11. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers. You will be asked to give us a list of other health care providers that you use.

12. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- People from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is +1-=410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

b. What do you do if you have questions about the study?

Call the study doctor/ principal investigator, Dr. Susan Hutfless at +1 410-502-0194. If you wish, you may contact the study doctor/ principal investigator by letter. The address is on page one of this consent form. If you cannot reach the study doctor/ principal investigator or wish to talk to someone else, call the IRB office at +1 410-955-3008.

c. What happens to Data, Blood and Specimens that are collected in the study?

Scientists at Johns Hopkins work to find the causes and cures of disease. The data, blood and specimens collected from you during this study are important to both this study and to future research.

If you join this study:

- You will not own the data, or the blood, or other specimens given by you to the investigators for this research.
- Both Johns Hopkins and any sponsor of this research may study your data and the blood or other specimens collected from you.
- If data, blood, or other specimens are in a form that identifies you, Johns Hopkins may use them for future research only with your consent or IRB approval.
- If data, blood or other specimens are in a form that we believe does not identify you, they may be shared with other academic medical centers, non-profit organizations, corporate sponsors and other commercial companies without your consent or IRB approval.
- You will not own any product or idea created by the researchers working on this study.
- You will not receive any financial benefit from the creation, use or sale of such a product or idea.

d. What are the Organizations that are part of Johns Hopkins?

Johns Hopkins includes the following:

- The Johns Hopkins University
- The Johns Hopkins Hospital
- Johns Hopkins Bayview Medical Center
- Howard County General Hospital
- Johns Hopkins Community Physicians.
- Suburban Hospital
- Sibley Memorial Hospital

13. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS CONSENT FORM

_____

Signature of Participant Date/Time

_____

Signature of Person Obtaining Consent Date/Time

_____

Signature of Witness to Consent Procedures (when consent performed in person) Date/Time

NOTE: **A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC, A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC, A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD.**

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.