UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Immunoprofiling of the blood and intestine and creation of a gut cell atlas

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Study Coordinator:	Michael Kattah MD PhD

This is a clinical research study. Your study doctor(s) Michael Kattah MD PhD, from UCSF Gastroenterology, will explain the study to you.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by Dr. Michael Kattah at UCSF.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends and health care team.

Purpose of the study:

You are being asked to take part in this study because you are an adult with or without inflammatory bowel disease (IBD) who is about to undergo an endoscopic procedure or surgery at UCSF in the near future. IBD affects over 1% of US adults, leading to disability, hospitalization, and surgery. Patients with IBD have damage to the "lining" of their intestine, also known as the intestinal epithelium. The goal of this study is to understand differences in the genes, proteins, bacteria, cells, and other molecules between people with IBD compared to people who do not have IBD.

Study Procedures: If you choose to participate in this study, we will perform a small blood draw, have you fill out a questionnaire, and we will take additional biopsies during your endoscopic procedures. We may also ask you to provide saliva or an oral swab for nucleic acid testing. We may also ask you to submit a fecal sample using a collection kit. You will not need to visit the research site beyond your scheduled procedure, but you will fill out a questionnaire at

clinic visits as well. If you consent to participate, we may access your medical record and/or de-identified samples in the future.

Possible Risks: There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

- Temporary discomfort or bruising from blood draw
- Risk of loss of privacy
- Risks associated with genetic testing

There are also rare but serious risks of participation, like:

- 1 in 5000 risk of bleeding from additional biopsies

We'll tell you about the other risks later in this consent form.

Possible Benefits:

There will be no direct benefit to you from participating in this study.

Your Other Options: You do not have to participate in this study. Your other choices may include:

- Getting treatment or care for your condition without being in a study.
- Taking part in another study.

Please talk to your doctor about your choices before agreeing to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you either have Inflammatory Bowel Disease (IBD), another intestinal disorder, or you can serve as a healthy control, and you are about to undergo an endoscopic procedure or surgery at UCSF in the near future.

Why is this study being done?

The purpose of this study is to understand differences in the genes, proteins, bacteria, cells, and other molecules between people with inflammatory bowel disease (IBD) compared to people who do not have IBD. IBD affects over 1% of US adults, leading to disability, hospitalization, and surgery. Patients with IBD have damage to the "lining" of their intestine, also known as the

intestinal epithelium. We want to understand what genes, proteins, and cells protect the epithelium and prevent inflammation. Through this study, we hope to understand better why some patients develop IBD, and why certain medications work better in some individuals versus others.

Who pays for this study?

This study is funded in part through the Division of Gastroenterology in the Department of Medicine at UCSF, the Burroughs Wellcome Fund, the UCSF ImmunoX program, with pending support from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and additional industry sponsors. These funding sources pay for the conduct of this study, including salary support for the study personnel, including Dr. Kattah.

How many people will take part in this study?

About 480 people will take part in this study. 120 of the enrolled patients will not have IBD, 120 will have a type of IBD called Crohn's Disease, and 120 will have a type of IBD called Ulcerative Colitis, and 120 will have other intestinal disorders.

What will happen if I take part in this research study?

If you agree to take part in this study, you will first sign this informed consent form and personal health information release form before any study-related procedures are performed. **No changes in your medical care will be made as a result of your participation in this study.** You will fill out a brief questionnaire that asks about intestinal symptoms and medical treatment, and will likely take you 5 minutes to complete. During your scheduled endoscopic procedures we will collect a total of up to 20 biopsies from your intestine. These biopsies are 2-3 millimeters in size (smaller than a grain of rice). If you agree, we will also perform a small blood draw. The blood will be drawn by putting a needle into a vein in your arm. This will take about five minutes. Up to five small tubes of blood will be taken (<50 milliliters or equivalent to ~3 tablespoons) at the time of your procedure, but you can decline to participate in the blood draw and agree only to the survey and biopsies if you prefer. If you are having intestine removed as part of a surgical procedure, we would analyze only leftover or surplus tissue that is not needed for diagnostic or patient care purposes. When you return for clinic visits we will ask you to fill out the same brief questionnaire. When you return for future endoscopic procedures recommended by your doctor, we will follow the same protocol above (questionnaire, blood draw, and research biopsies).

We may also ask you to provide saliva (2 milliliters or less than 1 tablespoon) or an oral swab. We may also ask you to submit a small fecal sample using a collection kit.

Aside from the specimen and data collection there will be no further requirements from you. Researchers involved in these studies may contact you again in the future for more information. **When you sign this form you are giving permission for investigators to contact you in the future unless you have notified the investigators that you are withdrawing from the study.** If an event occurs for which we need further information on your medical history, study investigators will analyze information from the medical record.

Study location

All study procedures will be done at UCSF, wherever your procedure has been scheduled.

- **Blood drawing (venipuncture):** A blood sample will be drawn by inserting a needle into a vein in your arm. Each sample will be approximately 10 teaspoons; or a total of about 3 tablespoons will be drawn before your procedures. If you decline the blood draw, you can still participate in the study (biopsy collection and filling out the survey/questionnaire).

How long will I be in the study?

We estimate that your direct participation in the study will take 20-25 minutes of your time during your procedure visits. This includes obtaining informed consent (10 minutes), completion of the questionnaire (5-10 minutes), and biopsy collection (5-10 minutes). Prior to clinic visits, we will ask you to complete the same questionnaire as your procedure visits to monitor your symptoms.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

It is important to tell the study doctor if you are thinking about stopping so any risks can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious.

You should talk to your study doctor about any side effects you experience while taking part in the study.

Risks and side effects related to the survey, blood draw, biopsies, and genetic testing include those which are:

<u>Less Likely</u>

- **Biopsy risks:** You may experience minor bleeding that is usually managed at the time of the procedure.

Rare but serious

- **Biopsy risks:** There is a small risk of perforation, infection, or significant bleeding with endoscopy in general, but the biopsies are unlikely to significantly increase this risk.
- **Survey and data collection risks:** There is a risk of loss of privacy based on data collection, however your medical information and the survey data you provide will be handled as confidentially as possible. Your name will not be used in any published reports or shared with any outside institution.
- **Genetic testing risks:** There is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk. Although your name will not be with the sample, it will have other facts about you such as your IBD status. This is necessary because this information will help us learn if the factors that cause IBD to occur or get worse are related to this information.

- **Blood drawing (venipuncture) risks:** Drawing blood may cause temporary discomfort from the needle stick, bruising, infection, and fainting.

- For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, this study will help doctors learn more about Inflammatory Bowel Disease (IBD) and other intestinal disorders, and it is hoped that this information will help in the treatment of these patients.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Having your procedure without participating in this study.
- Taking part in another study.
- Your care at UCSF will not change based on your participation.
- Please talk to your doctor about your choices before deciding if you will take part in this study.

How will my specimens and information be used?

Researchers will use your specimens and information to conduct this study. Once the study is done using your specimens, we may share them with other researchers at UCSF so they can use them for other studies in the future. We may share de-identified informationwith UCSF researchers, non-UCSF researchers, and industry sponsors. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Genetic Testing: Researchers will use your specimens (for example, blood, tissue, saliva, etc.) to look at all of your DNA (this is called "whole genome sequencing."). DNA contains information that determines things like eye color, height, or disease risk that are passed on from parent to child.

How will my genetic information be shared?

Genetic information (also known as genotype data) and the medical record data (also known as phenotype data) may be shared broadly in a coded form for future genetic research or analysis. We may give certain medical information about you (for example, diagnosis, blood pressure, age if less than 85) to other scientists or companies not at UCSF, including to a controlled access government health research database, but we will not give them your name, address, phone number, or any other identifiable information. Genetic information about you that results from these studies will not be returned to you.

Donating data may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. It is possible that future research could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.

There will be no direct benefit to you from allowing your data to be kept and used for future research. However, we hope we will learn something that will contribute to the advancement of science and understanding of health and disease. If the data or any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits. If you decide later that you do not want your information to be used for future research, you can notify the investigator in writing at: Michael Kattah MD PhD, Assistant Professor of Gastroenterology. UCSF, 1701 Divisadero St, San Francisco, CA 94115. Phone: 415.502.4444; michael.kattah@ucsf.edu. Any remaining data will be destroyed. However, we cannot retract any data has been shared with other researchers.

Research results: There may be times when researchers using your information and/or specimens may learn new information. The researchers may or may not share these results with you, depending on a number of factors. It is possible we discover infections through this research. The methods we use are validated for detecting infections. However, if we think you might have an infection that could affect your care, we will communicate these results to your primary care physician. Your primary care physician can determine if you need dedicated follow-up testing in a certified clinical laboratory.

Commercial Use: Your specimens may be used for commercial use. If this happens, you will not share in any profits.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California

Are there any costs to me for taking part in this study?

No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

Will I be paid for taking part in this study?

You will be paid $50 for participating. We will pay you $50 each time we collect blood samples and biopsies during your procedure visit. You will not be paid for completing the IBD questionnaire at your clinic visits.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. Kattah, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at 415.502.4444.

> **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor(s) Dr. Michael Kattah at 415.502.4444

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

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Consent for storing specimens for research purposes

The information in this section specifically concerns what may happen to your specimens after this study is complete, depending on what you are willing to permit

The biopsy and/or blood specimens that are obtained during this study will be stored in a laboratory at UCSF. With your permission, your specimens may be stored indefinitely at UCSF, even after this study has completed.

The reason for the collection and indefinite storing of samples is to make samples available for use in research for the study of IBD and related disorders after this study is completed. These samples may give scientists valuable research material that can help them to develop new diagnostic tests, treatments and ways to prevent diseases.

If you agree to have your samples stored indefinitely in the central repository at UCSF, you can change your mind up until the end of this study. When study researchers receive written instructions from you, they will destroy your sample and all information that identifies you. When the study ends, we will permanently delete the database that links your unique specimen identifier to your personal information, which means you will not be able to withdraw your sample because no one will know which one yours is.

The researchers responsible for storing your samples will take measures to protect your privacy, although no guarantee of confidentiality can be absolute. Each sample will be given a randomly assigned code number. Scientists may link certain information about you to your specimens such

as your age, sex and data obtained from this study, however any personal information that can be used to identify you will not be retained after the initial study is complete. Scientists storing your samples may share some of this information with other scientists along with your specimens, however this information will not be sufficient to identify you.

You will not receive any direct benefit for allowing your samples to be stored for use in future studies, but your sample may benefit the future health of the community at large or some particular group. Because other researchers will not have access to your identity, neither you nor your physician will get the eventual results of studies that might be done using your sample. It is possible that data from the use of your sample may be used in a research publication. In that event, your name or other identifying information will not be included – this information will not even be available to the researchers.

Any samples that you provide as a participant in this study and allow us to store indefinitely are donations to UCSF for research. You will not have any property rights to the samples, nor will you have any property rights to or be entitled to compensation of any type for any products, data or other items or information that is developed from the samples. If you consent to the use and indefinite storage of your samples for future scientific studies, please initial and date next to the statement below stating you do give permission. If you do not consent to the use of these biological samples for future studies, initial and date next to the line stating you do not give permission.

There is no cost to you or your insurance company for the storage and use of the specimens. Your donation is voluntary, and if you choose not to participate in this portion of the study you can still participate in the rest of the study.

Statement of consent for biopsy specimen storing for future studies

_____ _____ I **do** give permission for my participation in the sample
Initials Date storing part of the study.

_____ _____ I **do not** give permission for my participation in the sample
Initials Date storing part of the study.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____ _____ I give permission for **blood sample** collection
Initials Date

_____ _____ I give permission for **biopsy sample** collection
Initials Date

_____ _____
Date Participant's Signature for Consent

_____ _____
Date Person Obtaining Consent

_____ _____
Date Witness – Only required if the participant is a non-English speaker