STANFORD UNIVERSITY Research Consent Form

Protocol Director: Ellen Casavant

Protocol Title: Identifying Inflammatory Markers in Human Stool Using Mass Spectrometry Proteomics

STANFORD CONSENT FORM TEMPLATE
For MINIMAL RISK Medical Human Subject Research

Please check one of the following:

_____ You are the parent or guardian granting permission for a child in this study.

Print child's name here:

_____

The following information applies to the adult participant or to the child or ward. If the participant is a child or ward, the use of "you" refers to "your child" or "your ward."

****

FOR QUESTIONS ABOUT THE STUDY, CONTACT:

Ellen Casavant
School of Medicine
318 Campus Drive
Clark Center, Room W300
Stanford, CA 94305
Phone: +1 650-723-6121

DESCRIPTION: You are invited to participate in a research study on analyzing stool inflammatory markers using a mass spectrometer. The purpose of the research is to provide proof of principle that this mass spectrometry protocol can accurately detect the presence or absence of gastrointestinal inflammation. You will be asked to collect naturally-passed stool and provide this stool to the hospital in a container and secondary container. No results from this study will be reported to you. Results from this study will possibly be published, but no personal identification or health information will be released ever.

Tissue Sampling for Research

Research using tissues is an important way to try to understand human disease. You have been given this information because the investigators want to include your tissues (stool) in a research project and because they want to save the samples for future research. There are several things you should know before allowing your tissues to be studied.

Your tissues will be stored in a -80 degree Celsius freezer and labeled with a coded random number, which is linked to your personal identification information in a private, secure document that only the project co-ordinator Ellen Casavant, project sponsor Josh Elias, and your physician Dr. KT Park will have access to.

You have the right to refuse to allow your tissues to be studied now or saved for future study. You may withdraw from this study at any time. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not for additional research.

The results of the study of your samples will be used for research purposes only and you will not be told the results of the tests.

_____ I consent to my samples being saved for future research

_____ I do not consent to my samples being saved for future research

RISKS AND BENEFITS: The risks associated with this study are none. The benefits which may reasonably be expected to result from this study are none. We cannot and do not guarantee or promise that you will receive any benefits from this study. Your decision whether or not to participate in this study will not affect your employment/medical care.

TIME INVOLVEMENT: Your participation in this experiment will take approximately one day, or as long as it takes to pass stool and bring the stool specimen to the hospital in a container and secondary container.

PAYMENTS: You will receive no payment for your participation.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.
The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed**.**

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The study is a proof of principle study for a protocol involving diagnosing gastrointestinal inflammation through stool on a mass spectrometer. The only health information used is whether you have a presence of inflammatory markers or not, and this will be conveyed through research publication. No identification information will be given.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study

Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Ellen Casavant318 Campus Drive, 350W, Stanford, CA 94305

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, the presence or absence of inflammatory markers in your stool via this experimental protocol, and

an already existing test for inflammatory markers. I will have knowledge of the patient's name, MRN, DOB, gender when I approach the patient for consent. Patient diagnosis may be obtained before or after consent.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Ellen Casavant
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2025 or when the research project ends, whichever is earlier.

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

CONTACT INFORMATION:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Ellen Casavant. You may contact him/her now or later at (650)-723-6121.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Ellen Casavant (650)-723-6121. You should also contact him/her at any time if you feel you have been hurt by being a part of this study.

The extra copy of this signed and dated consent form is for you to keep.

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator

_____ _____
(If available) Signature of Other Parent or Guardian Date

_____
Authority to Act for Participant

The IRB determined that the permission of one parent is sufficient in accordance with 21 CFR 50.55(3)(e).

_____ _____
Signature of Person Obtaining Consent Date