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PARTICIPATION IN OTHER RESEARCH STUDIES

Are you participating in any other research studies? _____Yes _____No

KEY INFORMATION

- Consent being sought is for research and participation is voluntary and patients may withdraw anytime
- The purpose of this study is to understand how a patient's immune cells, gastrointestinal tract, and gut bacteria predict disease severity and response to medical therapy in inflammatory bowel disease
- Direct participation in the study is expected to last a few minutes to obtain specimens but patients may be followed for several years (data regarding clinical status of IBD will be collected) while under the care of a Stanford IBD physician
- The risks will be similar to standard of care (risk of bleeding, infection, damage to wall of gut, i.e. perforation) and discomfort related to blood draws and endoscopy
- Participation in the study may involve providing blood, stool, and biopsy samples if your physician feels this is necessary for your clinical care
- There may be no immediate benefits in participating in this study. Results from the study may allow physicians to improve their diagnosis and personalize treatment of inflammatory bowel disease

PURPOSE OF RESEARCH

You are invited to participate in a research study of inflammatory bowel disease such as Crohn's disease or ulcerative colitis. We hope to learn what types of immune cells and factors present in the intestines initiate and propagate the inflammation that is characteristic of these diseases and how this differs in people who do not have any inflammatory intestinal diseases. You were selected as a possible participant in this study because you have inflammatory bowel disease or gastrointestinal symptoms for which you are going to have, or already undergone, surgery or an endoscopy and biopsy as part of the diagnosis. You may also have been chosen as a healthy volunteer (control subject).

If you decide to terminate your participation in this study, you should notify Dr. John Gubatan at (650) 736-7311

This research study is looking for 200 people with inflammatory bowel disease and 50 control patients (patients without inflammatory bowel disease and

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healthy patients undergoing screening endoscopies (e.g. colon cancer screening with colonoscopy, Barrett's esophagus screening with EGD) or patients with other gastrointestinal conditions (i.e. Celiac disease, Irritable Bowel Syndrome, etc.)). Enrollment will occur only in the United States at Stanford Hospital. Stanford University expects to enroll 250 research study participants.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

This research protocol to obtain patient samples/information is expected to take only a few minutes for extra blood draw and stool collection (if collected). If undergoing an endoscopy, it will add a few minutes to your endoscopy to take an extra tissue biopsy and collect intestinal fluid. It will not add extra time to your surgery if you are scheduled to undergo one. If your gastroenterology physician decides that you should undergo further endoscopies and biopsies we may ask you again for your permission to take an additional blood sample and biopsy tissue.

PROCEDURES

If you choose to participate, Dr. Stephan Rogalla and her research study staff will pay a brief visit in the clinic or at the endoscopy. These things will occur.

- If you are coming in-person to research visits, you are required to be fully vaccinated—2 doses (1 for Johnson and Johnson), 2 weeks out and to provide proof of your vaccination (e.g., CDC COVID-19 Vaccination Card, e-Health record, etc.) to the researcher prior to study participation. Alternately, you can provide a negative COVID test within 72 hours of your visit.
- We will collect a brief medical history regarding your gastrointestinal symptoms and current treatments
- If you are scheduled for endoscopy, before the endoscopy, we may ask you to collect stool in a cup. The nurse will place an IV into a vein as a part of standard care for the endoscopy. He or she will take a blood sample (2-3 tablespoons) from this IV for the research study. If it is not possible to draw blood from the IV, blood will be obtained by a peripheral

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blood draw with a small needle if you consent. You may be asked to have your blood drawn or stool collected during clinic visits as a part of standard care and extra blood will be collected or stool may be collected for the research study.

- If biopsies are taken during the endoscopy as a part of standard care, your doctor may take extra pieces of the biopsy sample of the gastrointestinal tissue for this research.

Please initial the applicable option

_____ I consent for my biopsy samples to be collected during Endoscopy.

_____ I **do not** consent for my biopsy samples to be collected during Endoscopy.

- If you are undergoing a surgery for removal of all or part of your intestine from your body as a part of standard care. Some part of this removed intestine (surgical tissue sample) may be taken for this research study.
- Your blood and tissue samples (if collected) will be identified by a unique number rather than by your name to maintain your privacy.
- Any samples left over after analysis will be saved for future research

Future Use of Private Information and/or Specimens

Research using private information and/or specimens is an important way to try to understand human disease. You are being given this information because the investigators want to save private information and/or specimens for future research. Your specimens will be stored under a unique identifier. Your name or other public identifiers will not be included with any data shared with other investigators. Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Genetic Testing and Future Research

As part of the analysis on your specimens, the investigators may do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual

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and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

The results of the study of your specimens from this project will be used for research purposes only, and you will not be told the results of the tests.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should contact the protocol director Dr. Stephan Rogalla or Dr. John Gubatan at (650) 736-7311.

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The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are no additional risks, discomforts, and inconveniences associated with any aspect of this research study beyond those associated with the endoscopy procedure. If the blood is taken at the time of your IV placement there will be no additional risk of bruising. The risks of peripheral blood draw are minimal and include mild bruising and soreness. The risk of infection is minimal and no more than a standard blood draw that you would have done in the laboratory for routine blood testing. Increased risk of taking extra biopsies and washing intestinal mucosa is minimal beyond the risk of endoscopic procedure itself.

You should talk with the Protocol Director if you have any questions.

POTENTIAL BENEFITS

You will not benefit directly from participating in this study, however, your participation may contribute to general scientific knowledge about this condition, and may help others in the future. **We cannot and do not guarantee or promise that you will receive any benefits from this study.**

ALTERNATIVES

The alternative to participating in this study is to not participate.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

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You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

CONFIDENTIALITY

Your identity will be kept as confidential as possible as required by law. Your personal health information related to this study may be disclosed as authorized by you. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number**.** De-identified data resulting from your samples (blood, stool, biopsies) may be sent to collaborators outside of Stanford (other academic institutions, industry) for further analysis but we will not be sharing protected health information (PHI) in this scenario.

Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed**.**

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

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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 purpose of this study is to gain information about certain immune cells and inflammatory markers in people with inflammatory disease of the intestines. Studying the cells in your blood, stool, tissue sample from your intestines will give researchers a better understanding about the processes that cause inflammation in the gastrointestinal tract. Hopefully this information will lead to future treatments.

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

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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: Dr. Stephan Rogalla at 300 Pasteur Drive, H0262, MC: 5244 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:

- Laboratory and Pathology Test Results with embedded identifiers
- Clinical Records with embedded identifiers
- Images and Imaging Reports with embedded identifiers
  Demographics with embedded identifiers
  -Names
  -Telephone numbers
  -Address (All geographic subdivisions smaller than a State)
  -Dates more precise than year only, e.g. date of birth or death, date of service, diagnosis, admission
  -Electronic mail addresses
  -Medical record numbers
- Date of endoscopic procedures
  -Any other unique identifying number, characteristic, or code excepting only study-specific coded 'identifiers' (study IDs).

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 Dr. Stephan Rogalla
- 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?

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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
- Genentech, Inc.

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 June 30th, 2065 or when the research project ends, whichever is earlier.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

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FINANCIAL CONSIDERATIONS

Payment
You will not be paid to participate in this research study.

Costs
If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. You will also be responsible for any co-payments and/or deductibles as required by your insurance. Participation in this study is not a substitute for health insurance.

Sponsor
Genentech, Inc is providing financial support and/or material for this study.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

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, Dr. Stephan Rogalla or Dr. John Gubatan. You may contact them now or later at (650) 736-7311.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Stephan Rogalla or Dr. John Gubatan at (650) 736-7311.

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, 1705 El Camino Real, Palo Alto, CA 94306.

Alternate Contact: If you cannot reach the Protocol Director, please contact Dr. John Gubatan at (650) 736-7311.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;

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- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you? *(Please put a checkmark)* ☐ Yes ☐ No

Signing your name means you agree to be in this study and that you were given a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____

Signature of Witness Date

_____

Print Name of Witness

(e.g., staff, translator/interpreter or family member)

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  - *The non-English speaking participant/LAR does not sign the English consent.*
  - *The non-English speaking participant/LAR should not sign the HIPAA participant line*
  - *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*