NCT# 04054908

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICPATE IN RESEARCH

Study Title: CC# 174527: GO: Gut Microbiome and Oral Fluoropyrimidine Study in Patients with Colorectal Cancer

Principal Investigator:	Wesley Kidder, MD Assistant Professor University of California, San Francisco [redacted]

This is a request for participation in medical research. The researcher, Wesley Kidder, MD or one of his associates from the Helen Diller Family Comprehensive Cancer Center will explain this study to you. If you have any questions, you may ask the study doctor.

Medical research includes only people who choose to take part. 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 the researchers.

You are being asked to participate in this study because you have been diagnosed with colon or rectal cancer and are receiving cancer care at UCSF. During the course of your treatment, researchers will be collecting stool samples and dietary information to help better understand the effects of chemotherapy on the gut microbiome.

Why is this research being done?

The purpose of this study is to help to better understand the changes that occur in the gut bacteria of patients with colon and rectal cancer as they are treated with oral chemotherapy drugs, either capecitabine (Xeloda) or TAS-102 (Lonsurf), both in a class of drugs called fluoropyrimidines. Currently the impact of these drugs on the composition of bacteria living in the gut, also referred to as the gut microbiome, is largely an understudied area with mostly preliminary data. This pilot study will not only help us learn more about these changes, both how the diversity of bacterial species and the relative abundance of different species change during treatment, but also if collecting and analyzing stool is a feasible way to evaluate these changes. Participation in this study will not impact the treatment of your cancer.

This study is being funded by the Helen Diller Family Comprehensive Cancer Center and funding from the National Cancer Institute.

How many people will take part in this research?

Approximately 60 people will be asked to take part in this research at UCSF, Kaiser, and Washington Hospital. Researchers at UCSF, Kaiser, and Washington Hospital will continue to participate until the research has been concluded.

What will happen if I agree to participate?

- **Baseline survey:** You will be asked to complete an online survey of your long-term diet and food intake. Additional information about your baseline bowel habits, past antibiotic use and use of any supplements or probiotics will also be collected. A paper option will be available if preferred. The survey will take approximately one hour to complete.

- **Medical record review**: Investigators will review your medical records, to gather information about your cancer (including things like your diagnosis, your age, and prior therapies) in an attempt to correlate your cancer status with the results of the tests that are performed on your specimens in the laboratory. For this purpose, your medical records will be reviewed for up to 5 years.

- **Collection of stool:** You will be asked to collect a stool sample at a number of time points during your treatment with an oral fluoropyrimidine (either capecitabine or TAS-102). Two collection methods will be used to collect stool samples throughout the study including: 1) FOBT (Fecal Occult Blood Test) card and 2) Stool scoop. Specimens will be collected by participants at designated time points and returned via mail to the investigators in a pre-addressed, stamped envelope supplied by the study team. All required collection materials and instructions regarding collection methods, safe handling of specimens and submission of specimens will be provided. Stool specimens will be collected at the following time-points:

    - Screening or enrollment visit: As a part of the baseline assessment of your gut bacteria, you will be asked to submit two stool specimens, one by each collection method (FOBT and stool scoop).
    - Cycle 1 on Day 1, 3 and at the midpoint of the cycle: FOBT card only
    - Cycle 2 Day 1: FOBT card only
    - Cycle 3 Day 1: FOBT and stool scoop
    - You may be asked to collect additional samples with FOBT cards if you experience side effects thought to be due to your regular treatment
    - Two weeks after stopping either capecitabine or TAS-102: FOBT card only

  Any stool samples remaining after the study's analysis will be stored and retained for future research. Your withdrawal of consent for this banking can be done at any time and the remaining specimens will be destroyed.

- **Dietary Records:** Dietary factors may alter the gut microbiome. Along with the collection of stool, you will also be asked to complete a dietary record at four time points during your treatment. An online survey tool will be used to collect information about all your food intake over 72 hours. If you are having trouble with the online version, a paper option will be available. Completion of the record will be at the same time points as the collection of stool. The diet records take 20-30 minutes a day to complete.

How long will I be in the study?

You will remain in the study as long as you are taking the oral fluoropyrimidine chemotherapy (either capecitabine or TAS-102). Two weeks after stopping treatment with one of these agents, you will be asked to submit one additional stool specimen and complete a dietary record.

What risks are involved with participating in this study?

- **Stool collection**: During stool collection contamination of skin with feces may occur. Instructions on handwashing techniques and disposal of soiled collection implements will be provided to minimize risk. Disposable plastic gloves will also be made available.

- **Confidentiality**: Participating may involve a loss of privacy, but information about you will be handled as confidentially as possible. The UCSF Investigators and Study Coordinators involved in this study will gather and store your information in a secure database; all your collected samples will be assigned a unique code by the study investigators and will then be processed without knowledge of your identity. Only the UCSF investigator has access to the records that link this coded ID number to you. Only relevant UCSF study personnel will have access to this database. The UCSF Institutional Review Board and other University of California personnel also may see information about you during routine auditing processes. Your name will not be used in any published reports from research performed using your specimen.

  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. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record.

  There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. In some cases, this information could be used to make it harder for you to get or keep a job. There are laws against misuse of genetic information, but they may not give full protection. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

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

It is important that you tell your study doctor, Wesley Kidder or one of his associates if you feel that you have been injured because of taking part in this study. You may tell the doctor in person, or you may call him [redacted].

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, depending on a number of factors. The University does 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 the benefits of participating in the study?

There will be no direct benefit to you from participation. We hope we will learn something that will contribute to the advancement of science and understanding of health and disease.

What financial issues should I consider before agreeing to participate?

You will not be paid for participating in the study. 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.

What alternatives do I have?

You can choose not to participate in this study.

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. 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.

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 the researchers about any questions or concerns you have about this study. Contact the researcher, Wesley Kidder, MD or his associates [redacted] or the assigned clinical research coordinator.

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. 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

Wesley Kidder, MD
University of California, San Francisco
[redacted]

and we will not use your stool and health information in any future research. Please let Dr. Kidder know if you would like any remaining identifiable stool specimens destroyed if they are no longer needed for your care. However, if any research has already been done using portions of your specimens and health information, the data will be kept and analyzed as part of those research studies.

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OPTIONAL RESEARCH PARTICIPATION

This section of the informed consent is about optional future contact of participants in the main study. You can still be in the main study even if you say "no" to allowing optional future contact.

Future Contact

We want to know if we may contact you in the future to see if you are interested in participating in other research studies.

If you agree and we contact you to tell you about a study, you have no obligation to actually participate in any study. You can decide when you are told about the study if you want to receive more information about the study. There would be a new consent process for that study.

If at any time you decide you no longer want to be contacted about future studies, please let us know [redacted].

Making Your Choice

Please read the sentences below and think about your choice. After reading the sentence, please put your initials in the "Yes" or "No" box. If you have any questions, please talk to your doctor or nurse, or call our research review board at 415-476-1814.

No matter what you decide to do, it will not affect your care or your participation in the main study.

1. **Someone may contact me in the future to ask me questions about my health status.**

YES	NO

2. **Someone may contact me in the future about new research studies that I may be eligible for at UCSF.**

YES	NO

3. **Someone may contact my next-of-kin and/or emergency contact if I cannot be reached.**

YES	NO

CONSENT

You will be given copies of this consent form, the privacy (HIPAA) 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.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent