Text Document, Supplemental Digital Content 1: Recruitment Letters

Randomized Controlled Trial of Personalized Colorectal Cancer Risk Assessment vs. Education To Promote Screening Uptake

**Short Title:** Colorectal cancer risk assessment vs. education

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HIPAA Authorization Form



HIPAA Authorization Form

**\*FOR QUESTIONS ABOUT THE STUDY, CONTACT:**

Dr. Uri Ladabaum, 900 Blake Wilbur MC 5355, Palo Alto, CA 94304, (650)736-5555

**\*DESCRIPTION:** You are invited to participate in a research study on attitudes towards colorectal cancer screening. The purpose of this study is to characterize whether receiving information about colorectal cancer influences an individual’s likelihood of undergoing colorectal cancer screening. You will be asked to answer a series of survey questions before and after receiving some information regarding colorectal cancer. You might also receive a phone call in 6 months and one year to assess your colorectal cancer screening status.

**\*RISKS AND BENEFITS:** There are no foreseeable risks associated with this study. The benefits which may reasonably be expected to result from this study include gaining more knowledge about colorectal cancer screening. 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 15-30 minutes.

**\*PAYMENTS:** You will receive no reimbursement as 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**.**

You have the right to refuse to answer particular questions.

**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 authorization. If you you agree to participate in the study, 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 providing authorization.

**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 characterize whether receiving information about colorectal cancer influences an individual’s likelihood of undergoing colorectal cancer screening. As part of the study, you will be asked to complete a series of brief survey questions regarding your attitudes towards colorectal cancer screening. Some of these questions will involve your health information, but this information will not be linked to your identity. We plan to publish the results of this study when complete.

**Do I have to give my authorization?**

Yes, you will need to provide verbal authorization. Giving authorization is not a condition for receiving any medical care outside the study.

**If I give authorization, 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: Dr. Uri Ladabaum, 900 Blake Wilbur MC 5355, Palo Alto, CA 94304

**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, your weight and height, your diet, your medications, your physical activity level, your smoking history, personal history of cancer, family history of cancer, and personal risk of developing colorectal cancer.

**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. Uri Ladabaum
* The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
* Research Staff: Dr. Timothy Yen, Dr. Sang-Ick Chang, Helene Jernick, Mary Christensen

**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
* The Associate Dean of the Stanford Primary Care Clinics

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, 2050 or when the research project ends, whichever is earlier.

**WITHDRAWAL FROM STUDY**

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 study is cancelled.
	+ Other administrative reasons.
	+ Unanticipated circumstances.

**\*Contact Information:**

**\***Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about thisresearch study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Uri Ladabaum. You may contact him now or later at (650)736-5555.

**\***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.

Alternate Contact: If you cannot reach the Protocol Director, please contact Dr. Timothy Yen by paging 12849 through the Stanford page operator at 650-723-4000.

**EXPERIMENTAL SUBJECTS 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;
* 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.

Opt-out consent letter

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September 28th, 2016

To our Stanford Health Care Primary Care patients,

I am writing to let you know about a research study being conducted by my colleagues Dr. Uri Ladabaum, Professor of Medicine in the Division of Gastroenterology, and Dr. Timothy Yen, a resident in our Department of Medicine. Dr. Ladabaum leads the Division of Gastroenterology Gastrointestinal Cancer Prevention Program. The study is about screening for colorectal cancer. Your primary care provider may have reached out to you regarding this subject in the past. As you may know, colorectal cancer is the third leading cause of cancer death in both men and women. However, when it is found at an early stage, it is a potentially curable disease. Screening for colorectal cancer using colonoscopy, sigmoidoscopy, or fecal occult blood test—to name a few—allows us to detect these early signs of cancer. The study will involve receiving information about colorectal cancer and completing a short questionnaire to be administered over the phone by Dr. Yen.

The attached document, known as a “HIPAA authorization form” (stands for “Health Insurance Portability and Accountability Act”, a federal health privacy law that establishes national standards for the use and disclosure of patient health information) gives more information about the study, as well as the rights and protections for research volunteers.

If you are current with your colorectal cancer screening, we apologize in advance for the bother. If you do not want to be approached further to consider being a part of this study, please let Dr. Yen know by sending an email to \*\*\*@stanford.edu, or by filling out the section below and sending this letter back to Uri Ladabaum, M.D., 300 Pasteur Drive, Alway Building, Room M211, Stanford, CA 94305. If you would consider participating, you do not need to do anything further at this time. Drs. Ladabaum and Yen will allow a few weeks for patients to reply if they do not want to be approached, and then they will begin reaching out to patients to consider participating.

Sincerely,

Sang-ick Chang, MD, MPH

Clinical Professor of Medicine

Associate Dean for Primary Care

Stanford University School of Medicine

Regarding: Colorectal cancer screening study. Please do not contact me further about this study.

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_