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Consent Form

Official Study Title:

Comparative Effectiveness Pilot Trial of Mailed Cologuard Outreach to Mailed FIT Outreach

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University of California, San Diego
Consent Form

Optimal early colorectal cancer screening initiation:
Pilot Trial

Introduction
Our research team is asking for your consent to join a research study. Here is a summary of important information for you:

- Joining the study is your choice. You can talk with other people (like family, friends or doctors) about your choice.
- If you join, you can still change your mind later.
- If you do not join, we will not punish or be upset with you
- Your choice will not change your health care.
- You do not have to join even if the person inviting you is on your health care team.
- Please ask questions and tell us your concerns at any time.

The study goal is to learn about colorectal cancer screening in people ages 45-49. The research team wants to learn how to make screening easier to get. They will use this information to help more people get screened. Joining this study may or may not benefit you directly. It may give new knowledge that could help other people in the future.

If you agree to participate in this study, you will be assigned by chance to one of two mailed invitations to complete colorectal cancer screening: either mailed fecal immunochemical test or mailed Cologuard test. These tests are intended to be completed at home. The invite will include screening information, a screening test kit, and a guide to complete and return the test.

Colorectal cancer screening is recommended for people ages 45-75. The two colorectal cancer screening tests are both standard tests. The study is testing if use of Cologuard increases screening use compared to the fecal immunochemical test.

The most common possible study risk is loss of privacy or personal information. This is also the most serious risk. We will limit this by collecting little personal information and keeping your records secure.

More information about this research is below. A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time. Please feel free to ask questions at any time.

Why were you asked to participate? How were you chosen? How many people are in the study?
You were asked because you are a patient at University of California San Diego Health System. Our records show you are not up to date with colorectal cancer screening. However, you are eligible for screening based on new guidelines. You were selected by chance to participate. The study will have about 100 participants.

What will happen to you in this study? Which procedures are standard and which are experimental?
If you agree to be in this study,

1. You will be assigned by chance to receive one of two mailed invites to complete colorectal cancer screening, either with a fecal immunochemical test or Cologuard test. Both colorectal cancer screening tests are standard tests that can be completed at home. The type of test is the study's experiment.
    a. Each mailed invitation includes screening information, a screening test kit and a guide and return box with paid postage to complete and return the test.
        i. If you are assigned to the mailed Cologuard arm, a test order that includes your name, medical record number, date of birth, sex, address, phone number, and health insurance information will be provided to Exact Sciences, who will mail you the Cologuard test and process the results.
        ii. If you are assigned to the mailed FIT arm, your name, address and phone number will be collected to facilitate mailed FIT outreach.
2. After you complete and return your test, you will be sent a letter with the results.
3. If your test is normal, you will be mailed a letter with your results and a reminder of when to get screened next. Your primary care provider will also be mailed a letter about your normal results.
4. If your test is abnormal, you will be mailed a letter with your results. You will also receive directions about follow-up testing. Your primary care provider will also be mailed a letter about your abnormal test results.

How much time will the study take? How long will the study last?
It will take up to 30 minutes to complete the colorectal cancer screening test. If you do not finish the test, you will be contacted within the next month to complete the test. The test result will be mailed to you. If the test is abnormal, your mailed results will explain what the results mean and how to schedule follow-up testing. For most participants, the study period will last 1 month. For those with abnormal results, the study may last up to a year to finish follow-up tests. The whole study will last one year.

What are the risks from being in the study?
The primary risk of the study is loss of privacy. We will limit this by protecting your data and who can see it. You may also feel uncomfortable, upset or nervous completing the screening test. There is also a very small risk you might be responsible for costs of the colorectal cancer screening test not otherwise covered by your insurance plan. Since this is a research study, there may be some risks that we don't know about yet. If we find any new risks, you will be notified.

What is the alternative to participating in this study?
You can decide not to participate in this study.

What benefits can you expect?
It is not certain you will benefit from being in this study. By participating, you may learn more about colorectal cancer screening. You may also learn if you are at risk of colorectal cancer. However, you do not have to be in this study to get screened. You can contact your primary care provider to get screened.

Your participation might help someone else. The research team will learn from this study to improve colorectal cancer screening use in future patients.

What if you change your mind about participating?

You may refuse to participate or stop at any time without penalty or loss of health benefits. If you change your mind, you can call Dr. Joshua Demb at (858) 552-8585 (ext. 2272) to be removed from the study. You will be told if any new information is found that might change your mind about being in the study.

Can you be taken out of the study without your consent?
You may be taken out of the study if you do not follow the directions given by the study team.

Will you be paid for participating in this study?
You will not receive payment for being in the study.

Will you need to pay to participate in this study?
Your insurance will be billed for costs of the screening test. Both screening tests are covered as essential health benefits under the Affordable Care Act, which means the costs of the tests are covered as part of your health insurance plan. In very rare cases, your insurance plan will not cover the full costs of the test, resulting in a bill for the uncovered costs.

What if you are injured as a result of being in this study?
If you are injured from being in this study, the University of California will provide the medical care you need to treat those injuries. The University will not give any other form of payment if you are injured. You can call the Office of IRB Administration (OIA) at 858-246-4777 if you have questions about being a participant or to report study-related problems.

What about your privacy?
Research records will be kept private in locked files or on password-protected computers. Only approved research team members will be able to access the records. Information that could identify you will not be included when reporting our study results.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the research team cannot release or use personal or medical information to identify you in any potential lawsuit unless you give consent to do so. Your research records cannot be shared except in the following cases:

1) There is a federal, state or local law that requires disclosure. This includes reporting child or elder abuse, or intent to hurt yourself or others.
2) You consent to release of this information, such as for medical care.
3) For other research studies covered by federal law protecting research participants

The Certificate of Confidentiality does not prevent you from choosing to release information about yourself or being in this project. If you want the research records to be released to people not on the research team, such as a doctor or insurer, you must provide consent.

Under California law, we must report information about abuse of a child, family member or elder. If any person on the research team is given this information, he or she may need to report it.

Will you receive any results from being in this study?
Participants will be notified of any significant findings that may affect their willingness to continue participating in this study.

What are my rights when providing electronic consent?
California law provides specific rights when you are asked to provide electronic consent:

- You have the right to obtain a copy of the consent document in a non-electronic format.

- You have the right to provide consent in a non-electronic format.
- If you change your mind about electronic consent, you have the right to request your electronic consent to be withdrawn and you can then provide consent in a non-electronic format; however, a copy of your electronic consent will be maintained for regulatory purposes. If you wish to withdraw your electronic consent, please tell the study team.

This agreement for electronic consent applies only to your consent to participate in this research study.

Who can you call if you have questions?
If you have other questions or research-related problems, call Dr. Joshua Demb at (858) 552-8585 (ext. 2272).

You may also call the Office of IRB Administration (OIA) at 858-246-4777 to ask about your rights as a research subject or to report research-related problems.

Experimental Participant's Bill of Rights

Every individual asked to participate in a research study has the right to be:

1. Informed about the nature and purpose of the study.

2. Provided an explanation of the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. Given a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. Informed about any benefits that would reasonably be expected from the participation in the study, if applicable.

5. Informed about of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. Told of the types of medical treatment, if any, available if complications should arise.

7. Provided an opportunity to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. Informed that individuals can refuse to participate in the research study. Participation is voluntary. Research participants may refuse to answer any question or discontinue their involvement at any time without penalty or loss of benefits to which they might otherwise be entitled. Their decision will not affect their right to receive the care they would receive if they were not in the experiment.

9. Provided a copy of this form.

10. Given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study, contact Dr. Joshua Demb at (858) 552-8585 (ext. 2272).

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research participant, please contact:
UC San Diego Office of IRB Administration at irb@ucsd.edu or 858-246-4777