Study Title: A Patient-centered Intervention Using Technology to Reduce Colorectal Cancer Disparities in Primary Care

NCT#: NCT03407417

Document: Waiver of Documentation of Informed Consent

Date of IRB Approval: 10/30/2023

R01
IRB 201702765
English Phase 1 Recruitment and informed consent V.14
Phase 1 Recruitment message (E-mail / MyUFHealth)

Subject line: (SEE "English Invitation subject lines V.2")

Dear Ms./Mr. <X>,

Good news! You are one of a select group of patients at UF Health invited to try our new virtual health assistant named ALEX. ALEX is free and provides important health information from the comfort of your own home.

After you meet ALEX, you will be invited to answer questions about your experience as part of a research study. You could receive up to $45 in e-gift cards for your time.

What to Do:

- **Click this link [link to HIPAA compliant secure local server] to meet ALEX.**
- Spend about 20 minutes with ALEX and complete some questions.

Study Eligibility:

- Aged **45-73**
- **No recent colonoscopy (last 10 years) or home stool test (FIT last year, Cologuard last 3 years)**

Click the link below or copy/paste it into your browser to meet ALEX. Your appointment with ALEX will launch in a different window.

When you click the link, please read the consent form. If you consent to being part of the study, you'll be asked to complete questions to receive your e-gift card.

Participation is voluntary. If you choose not to participate, it will not affect your normal healthcare.

Please click this link or copy/paste it into your browser to participate:
<link to HIPAA compliant secure local server>.

If you have questions, please e-mail <NAME> (<E-MAIL>) or call <NUMBER>. Our hours are 8:00 a.m. to 4:30 p.m., Monday through Friday.

Sincerely,
<NAME>

To opt-out of this study, please fill out this form:
https://ufl.qualtrics.com/jfe/form/SV_eW1rS7d07rmxy1T.

R01
IRB 201702765
English Phase 1 Recruitment and informed consent V.14

Consent Form

A patient-centered intervention using virtual technology to reduce colorectal cancer disparities in primary care

We are asking you to be in a research study.

- **You do not have to be in the study.**
- **If you say yes, you can quit the study at any time.**
- **Your medical care will not change in any way if you say no.**

Why are you doing this research study?

We want to learn more about how to help people get screened for cancer at the right time. This study will help us learn whether patients find an online/mobile application helpful for getting screened.

What happens if I agree to be in the study?

If you say yes, you will complete an online study. Participating in the study implies that you have read the information in this form and consent to take part in the research. If you received this information via email or MyUFHealth (formerly known as MyChart), it will remain in your account for future reference.

The study has 3 parts. All can be completed on your home computer or smart phone. You can receive an e-gift card for each part for which you answer follow-up questions for a maximum total of $45.00.

- Part 1 of the study can be completed now. You will receive information about screening and complete questions.
- Part 2 of the study will only be sent to you after 1 month of being invited to Part 1 but not completing both the intervention and survey or completing Part 1 but not screening for colorectal cancer. You will receive an email link. You may be given more information about cancer screening. You will be asked follow- up questions.
- Part 3 of the study will be sent to you 12 months after completing Part 1 or Part 2.

What kinds of questions will I answer?

- The questions will ask about your diet, general health, and opinions about healthcare. There are no right or wrong answers to these questions. You can skip any question you do not want to answer.

How long will the study take?

Part 1 or 2 will take between 20-40 minutes. Part 3 will take about 20 minutes.

What happens if I do not agree to be in the study?

Nothing. This study is voluntary. The care you get from your healthcare provider will not change.

What happens if I say yes, but change my mind later?

You can stop being in the study at any time. The care you get from your healthcare provider will not change.

Who will see my answers?

Your participation in this research is confidential. That means that the only people allowed to see your answers will be the people who work directly with the study team. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

R01
IRB 201702765
English Phase 1 Recruitment and informed consent V.14
A description of this study is available on http://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 website at any time.

Will it cost me anything to be in the study?

No, there will be no cost to you to see the information or request the test. If you are concerned about whether your insurance will cover the cost of analyzing the test results, please contact your healthcare provider.

Nearly all health insurance plans cover the cost of colon cancer screening and there may be other cost- free options for you to screen if you do not have insurance.

Will being in this study help me in any way?

Participating in this study may help you understand new and easier ways of being screened for colon cancer. However, you do not need to participate in the study to be screened for colon cancer. You can also be screened by talking to your healthcare provider.

How will I be paid for my time?

You can receive a maximum of $45.00 in e-gift cards for participating in the study. We will give you a $30.00 e-gift card for completing Part 1. You will receive a $10.00 e-gift card if you are eligible for and complete Part 2. You will also receive a $5 e-gift card for completing Part 3 of the study.

Your payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (RPP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment, contact the study coordinator.

Could this study be bad for me?

The purpose of this study is to help you protect your health by providing information about how to get screened. However, if you participate in this study, there is a small chance that:

- If you use the app while driving or operating heavy machinery, it could result in injury or loss of life.
- The questions may make you uncomfortable.
- Someone may find out that you were in the study and learn something about you that you did not want them to know. However, we will do our best to protect your privacy. Information that identifies you will be taken off our data as soon as possible and your information will be protected the same way as other UF Health websites.

Privacy Authorization: UF and Shands will be allowed to collect, use and/or give out your medical information, but only to:

a. Other researchers whose research is approved by an Institutional Review Board (IRB).
b. The sponsor of a study, the Food and Drug Administration, the Department of Health and Human Services, the Office of Human Research Protections or other Government agencies

What if I have questions?

If you have comments or questions about the study, please contact the UF principal investigator, Dr. Benjamin Lok at 352-214-9829. If you have questions about your rights as a research participant or feel that you have been harmed by being in this study, please call the office in charge of monitoring research at 352-273-9600.