NCT05746195

# UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
# CONSENT TO PARTICIPATE IN A RESEARCH STUDY

## CC #224523: Optimization of Adaptive Text Messages for Cancer Survivors II (OATS II)



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| Principal Investigator: | Erin L. Van Blarigan, ScD<br>Associate Professor<br>University of California, San Francisco<br>UCSF Box 0560<br>[redacted]<br>San Francisco, CA 94143<br>Phone: [redacted]<br>E-mail: [redacted] |



This is a clinical research study. The study's Principal Investigator, Dr. Erin Van Blarigan, or one of her associates from the University of California, San Francisco (UCSF) Helen Diller Family Comprehensive Cancer Center or Zuckerberg San Francisco General (ZSFG) Hospital can answer any questions you may have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to decide about participating. You can discuss your decision with your family, friends, and health care team. If you have any questions, you may ask a member of the study team.

## STUDY SUMMARY

**Introduction:** We are asking you to consider taking part in a research study being led by Dr. Erin Van Blarigan at UCSF. The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team also can explain the study to you and answer any questions you have.

**Purpose of the study:** You are being asked to participate in this study because you are an adult colorectal cancer survivor. The purpose of this study is to learn if mobile phone text messages can be used to help colorectal cancer survivors eat more whole grain foods and less refined grain foods.

**Overview of Study Activities:** If you choose to participate, you will be in the study for about 12 weeks. The main study activities include:

- **Text messages:** You will receive text messages about nutrition for 12 weeks. Each day, you will be asked to respond to a text message that asks whether you ate whole grains the day before, and if so, how many times. It is important for the study that you answer this question each day. The number of messages you

receive each day will vary; usually, you will receive 1-2 text messages per day. You can stop the text messages at any time.

- **Interviews:** If you do not respond to the text messages for 7 days, you may be asked to do a 10-to-15-minute phone interview, so we can learn more about why you did not respond to the text messages. Some people also will be asked to do a 15-to-30-minute optional exit interview by phone at the end of the study.
- **Surveys**: You will be asked to complete a set of surveys at the start and end of the study. The surveys take about 45-90 minutes to complete and can be done online or on paper.
- **Medical record review**: We may review your medical record to confirm information, such as date of diagnosis and treatment history.

In return for your time and effort, you will be paid up to $85 in the form of gift cards for participating in this study.

**Possible Risks:** There are risks to taking part in a research study. Please talk to your doctor about your choices before deciding if you will take part in this study.

Some of the most likely risks of participation in this study include digestive changes**.** If you change the types of foods that you eat because of being in this study, it could result in digestive side effects for some people, such as:

- Loose/watery stools or increased urgency to have bowel movements (diarrhea)
- Decreased frequency of bowel movements (constipation)
- Passing gad (flatulence)
- Bloating

You will receive tips on how to lessen or avoid digestive changes due to increased whole grain and fiber intake as part of the study.

We will tell you more about these risks and the risks of taking part in the study later in this consent form.

**Possible Benefits**: There will be no direct benefit to you from participating in this study. However, we hope we will learn something that will lead to improvements in cancer survivorship care and nutrition programs.

**Your Other Options:** You do not have to participate in this study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

# ADDITIONAL DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about the study.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

## Why is this study being done?

**Purpose of the study:** You are being asked to participate in this study because you are an adult colorectal cancer survivor. The purpose of this study is to learn if mobile phone text messages can be used to help colorectal cancer survivors eat more whole grain foods and less refined grain foods.

This study is funded by the National Cancer Institute.

## How many people will take part in this study?

About 60 people will take part in this study.

## What will happen if I take part in this research study?

You may be invited to complete (or you already may have completed) a brief screening survey either by phone or online, or your medical records may be reviewed, to determine if you can be in the study. If it is determined that you can be in the study, and you choose to continue, this is what will happen next:

- **Medical record review:** Your medical records may be reviewed to collect information about your medical history and current medical condition (such as your cancer diagnosis, stage, and treatments).
- **Surveys at the beginning of the study:** You will be asked to complete surveys, which take about 45-90 minutes to complete. The surveys will ask you about your demographic characteristics and background (date of birth, gender, race, ethnicity, etc.), any symptoms you may be experiencing, and usual diet (the types of foods you eat and how often you eat them). They will also ask you about your beliefs, social support, and experiences around food and nutrition.

  The surveys are designed to be completed online. You will be emailed a secure link to complete your personal surveys. If you are not able to complete them online, you can request paper copies of the surveys. We will mail these to you with an addressed, prepaid return envelope.

  You will receive a $25 gift card if you complete the surveys at the beginning of the study. See the section, *"Will I be paid for taking part in this study?"* for more information.

- **Mobile Phone Text Messages:** You will receive text messages about nutrition to your mobile phone for 12 weeks. The number of messages you receive each day will vary. On most days, you will receive 1 to 2 text messages per day.

  Each day, you will be sent a text message that asks whether you ate any whole grain foods the day before. If you answer yes, you will be asked how many of your meals included whole grains on the prior day. It is important for the study that you answer these questions every day. The text messages you receive may change based on your answers.

  We estimate that it will take no more than 5 minutes to read and respond to the text messages each day.

- **Non-response interview:** If you do not respond to the text messages for 7 or more days, you may be called and asked to do a short interview. During the interview, the researcher will ask you questions, so we can learn more about why you did not respond to the text messages. The interview will take approximately 10-15 minutes and will be done by phone or Zoom. If it is done by phone, the researcher will make a sound recording of your conversation. If the interview is conducted by Zoom, video also will be recorded because of how recording works for this platform; however, the video will be deleted after collection. The sound will be saved so the study team can accurately document your responses. The study team will keep your responses for up to 2 years after all participants complete the study.

**After completing the main part of the study:**

At the end of the study (after receiving text messages for 12 weeks), you will be asked to complete surveys and participate in an optional interview, as described below:

- **Surveys at the end of the study:** You will be asked to complete surveys, which take about 45-90 minutes to complete. The surveys will ask about your usual diet and any symptoms you may be experiencing. They also will ask about your beliefs, social support, and experiences around food and nutrition; and the acceptability, appropriateness, feasibility, and usability of the text message program. The surveys may be completed online, or you can request paper copies of the surveys, as described under the section, *"Surveys at the beginning of the study."*

  You will receive a $35 gift card if you complete the surveys at the end of the study. See the section, *"Will I be paid for taking part in this study?"* for more information.

- **Medical record review:** Your medical records may be reviewed to collect information about your current condition and symptoms you may be experiencing.

**Throughout your participation in the study:**

**Contact:** You may be contacted by text, phone, or email with reminders to complete study tasks, such as the questionnaires.

**Study location:** All study procedures will be done by phone (text messages, interview), computer or other internet device (digital questionnaires), or Zoom (interview).

## How long will I be in the study?

You will be in the study for about 12 weeks.

## Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study investigator if you are thinking about stopping or decide to stop.

If you withdraw from the study, any data we have already collected from you will remain part of the study records. After you withdraw, the researchers may still get information from your medical records if it is relevant to the study. You must tell the study team you do not want this information to be collected when you withdraw, otherwise it will be collected.

Also, the study investigator may stop you from taking part in this study at any time if she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

## What side effects or risks can I expect from being in the study?

- **Digestive changes:** If you change the types of foods that you eat because of being in this study, it could result in digestive side effects for some people. These may include:
  - Loose/watery stools or increased urgency to have bowel movements (diarrhea)
  - Decreased frequency of bowel movements (constipation)
  - Passing gad (flatulence)
  - Bloating

  You will receive tips on how to lessen or avoid digestive changes due to increased whole grain and fiber intake as part of the study.
- **Risks from interviews and surveys:** Some of the survey or interview questions may make you uncomfortable or upset. You are free to decline to answer any questions you do not wish to answer or to leave the interview at any time.
- **Confidentiality risks:** Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. See below sections *"How will my information be used?"* and *"How will information about me be kept private?"* for more information.

## Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, we hope we will learn something that will lead to improvements in cancer survivorship care and nutrition programs.

## What other choices do I have if I do not take part in this study?

You do not have to participate in this study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

## How will my information be used?

Researchers will use your information to conduct this study. This information will not be put in your health record. The research will not change the care you receive.

Once the study is done using your information, we may use the de-identified information collected for future research studies or share it with other researchers so they can use it for other studies in the future. We may share certain medical information about you (for example, diagnosis, treatment history, age) with other researchers at UCSF and outside of UCSF, including an unrestricted or controlled-access government health research database. However, we will not give researchers outside of UCSF your name, address, telephone number, or any other information that might be able to identify you. We cannot guarantee that this will prevent future researchers from determining who you are. Your information will be kept indefinitely. Results from future research will not be returned to you, will not be put in your medical record, and will not change the care you receive. These results may be published, but your information will not be reported individually.

Donating data may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

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,

Dr. Erin Van Blarigan
University of California, San Francisco
UCSF Box 0560
[redacted]
San Francisco, CA 94143
[redacted]

and any remaining data will be destroyed. However, we cannot retract any data that have already been shared with other researchers.

**Commercial Use:** If your 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.

## How will information about me be kept private?

We will do our best to make sure that information gathered about you for this study is kept private, but we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Some information from your medical records may be collected and used for this study. If you have a University of California, San Francisco (UCSF) or Zuckerberg San Francisco General Hospital (ZSFGH) medical record, your signed consent form may be added to your medical record. Therefore, people involved with your future care and insurance may become aware of your participation. Information gathered directly from you by the researchers will be part of your research records and will not be added to your medical record.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California
- Representatives of the Office of Human Research Protections (OHRP)
- Representatives of Zuckerberg San Francisco General Hospital

The HealthySMS/Twilio platform will be used to send you text messages. Your phone number will be securely shared (using commercial-grade encryption) with Twilio only for the purpose of sending you text messages for the study.

**Certificate of Confidentiality:** This research is covered by a Certificate of Confidentiality. It prevents State and Federal courts, legislatures, and administrative agencies from requiring researchers to reveal information (by subpoena/court order or otherwise) about research participants.

The Certificate DOES NOT:

- stop legally required reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.
- stop a sponsoring United States federal or state government agency from reviewing research records to monitor or evaluate programs.
- stop disclosures required by the federal Food and Drug Administration (FDA).
- prevent your information from being used for other research if that is allowed by federal regulations.

The Certificate does not stop you:

- from releasing information about your involvement in this research
- from having access to your medical record information

## Are there any costs to me for taking part in this study?

You will be responsible for any text messaging, Internet, and data charges for your personal cell phone/smartphone or computer/tablet related to participating in this study.

## Will I be paid for taking part in this study?

In return for your time and effort, you will paid up to $85 in the form of gift cards for taking part in this study:

- You will receive a $25 gift card if you complete the surveys at the beginning of the study.
- You will receive a $35 gift card if you complete the surveys at the end of the study.
- You will receive a $25 gift card if you complete the optional end-of-study interview. See the *"Optional Study Participation"* section at the end of this consent form for additional information about the optional end-of-study interview.

The gift cards will be sent electronically or mailed to you. You will need to provide an email or mailing address where the gift card(s) can be sent. It may take up to 6 weeks to receive each gift card.

## Will I be reimbursed if I pay expenses related to my participation in this study?

You will not be reimbursed for expenses if you take part 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. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

## Who can answer my questions about the study?

You can talk to the study investigator about any questions, concerns, or complaints you have about this study. Contact the study investigator, Dr. Erin Van Blarigan, [redacted].

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.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

[redacted]

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# OPTIONAL RESEARCH PARTICIPATION

## Optional End-of-Study Interview

We want to know if we may ask you to participate in a short interview at the end of the study to give the researcher feedback about your experience in the study. If you agree, the interview will be conducted after receiving text messages for 12 weeks. The researcher will ask you questions about your experience in the study.

The interview will take approximately 15 to 30 minutes and will be done by phone or Zoom. If it is done by phone, the researcher will make a sound recording of your conversation. If the interview is conducted by Zoom, video also will also be recorded, because of how recording works for this platform; however, the video will be deleted after collection. The sound will be saved so the study team can accurately document your responses. The study team will keep your responses for up to 2 years after all participants complete the study.

Participating in the end-of-study interview is optional. It is your choice if you want to take part in the end-of-study interview. No matter what you decide to do, it will not affect your care or your participation in the main study.

### Will I be paid for taking part in the optional interview?

In return for your time and effort, you will receive a $25 gift card if you complete the optional end-of-study interview. The gift cards will be sent electronically or mailed to you. You will need to provide an email or mailing address where the gift card can be sent. It may take up to 6 weeks to receive each gift card.

### What risks can I expect from taking part in the optional interview?

- Some of the interview questions may make you uncomfortable or upset. You are free to decline to answer any questions you do not wish to answer or to leave the interview at any time.
- Confidentiality risks: Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. See prior sections *"How will my information be used?"* and *"How will information about me be kept private?"* for more information.

## 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 participate in any study. You can decide when you are told about the study if you want to receive more information. 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 by emailing [redacted] or leaving a voicemail [redacted]

## Making Your Choice

Please read the sentences below and mark your choice in the "Yes" or "No" boxes. 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 about taking part in the optional end-of-study interview:

| | |
|---|---|
| ***YES*** | ***NO*** |

2. Someone may contact me about taking part in more research in the future:

| | |
|---|---|
| ***YES*** | ***NO*** |

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## CONSENT

You have been given a copy of this consent form 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 |
| | _____ |
| | Participant's Name (Printed) |