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

Study Title	CC# 24806: Addressing the Nutritional Needs of Cancer Survivors with Nutrition Insecurity
Principal Investigators (People in charge of this study)	*Sorbarikor Piawah MD, MPH* *Telephone:* [redacted] *E-mail:* [redacted] *Erin Van Blarigan, ScD* *Telephone:* [redacted] *E-mail:* [redacted]
Study Coordinator	*Banaz Shwan*
Study Contact Information	[redacted]

Clinicaltrials.gov National Clinical Trial (NCT) Number	*NCT06602999*

1. Why have I been given this document?

To see if you are interested in taking part in a research study. A research study is a planned project done to learn more about a topic.

2. Do I need to take part in this research study?

No. Taking part in research is voluntary. If you don't want to take part, there will be no penalty and you will not lose your current benefits. The Principal Investigator, or another member of the study team, will explain the study to you. Please ask questions. Take your time deciding if you want to be in this study. You can talk with your health care team, your family, and friends before deciding.

3. This section describes key information to consider about this study.

3.1 Why is this study being done?

This study wants to see if providing Instacart vouchers for groceries is helpful for cancer survivors. The study also wants to see if it can help participants make healthier food choices. Instacart is a company that purchases and delivers your groceries to your door.

3.2 How long would I be in this study? How many study visits are there?

You would be in this study for about 2 months. This study is conducted virtually (over the phone or computer).

3.3 What are the procedures with the most risk in this study?

The procedures with the most risk in this study are:

- A change in diet.

You may experience diarrhea (loose stools), constipation (hard stools), flatulence (gas), and bloating. These side effects can happen if you change your usual diet. The side effects should improve as your body adjusts.

3.4 What risks and discomforts are most severe? What risks and discomforts are most common?

- Diarrhea
- Constipation
- Flatulence
- Bloating

We will tell you more about risks and discomforts later in this form.

3.5 Are there benefits to taking part in this study?

You may or may not benefit from participating in the study. The information learned from this study may help others in the future.

3.6 What are my other options if I don’t want to take part in this study?

You may be able to take part in another study if one is available.

4. How many people will take part in this study?

About 45 people will take part in this study at UCSF.

5. Who is paying for this study?

This study is being paid for by the National Cancer Institute through the Upstream Research Center.

6. Do any UCSF researchers of this study have financial interests that I should know about?

No.

7. What are the research procedures of this study?

Baseline (Start of Study)

- The study team may ask you about your medical history.
- You will be asked to fill out a questionnaire that asks about your demographic information, such as your marital status, who lives in your home, your daily responsibilities, level of education, and your household income.
- You will be asked to fill out a questionnaire that asks you about your eating habits from the past month.
- You will be asked to fill out a questionnaire that asks about how often you and your family are able to eat.
- You will be asked to fill out a questionnaire that asks about your recent health, such as any changes to your medication and any symptoms you have been experiencing.
- You will be asked to fill out a questionnaire about your access to the internet and a credit or debit card. You may also be asked about any foods you cannot eat.

Weeks 1-4

- The study team will give you a booklet that gives you information about nutrition for cancer survivors. You will be asked to review it and try to follow the guidelines.
- Instacart Fresh Funds or Care Carts for grocery deliveries.
    - Fresh Funds are a digital coupon code that can be added to the Instacart application on your phone or through the Instacart website. Only foods that fall under the nutrition plan for cancer survivors may be purchased using the Fresh Funds. You will receive $200.00 in Fresh Funds for each family member living in your house. The funds must be used within 4 weeks. You will be asked to log in to Instacart at least once during the 4-week study period to order groceries for your home. If you select foods that are not eligible for Fresh Funds, your credit card or debit card will be charged. If your cart total is more than the amount of the Fresh Funds, you will have to pay for the difference.
    - If you don't have internet access or are not able to create an Instacart account (for example, if you don't have a credit or debit card), a study team member can order food and send it to your home using Instacart's "Care Cart" system. The value of the Care Cart groceries are the same as the Fresh Funds (up to $200.00 for each family member in your house that must be used in the 4-week study period). A trained member of the study team will select the foods for the Care Cart.
- Nutrition navigation phone calls. A Nutrition Navigator is a member of the study team trained to help you follow cancer survivor nutrition guidelines and order groceries on Instacart. They can also help answer any questions about the study. They will call you once a week to check in with you.
    - The Nutrition Navigator will also ask about any side effects you may be having from your diet changes.

End of Study

- You will be asked to fill out questionnaires about your recent health and your diet and access to food during the study period.

- You will be asked to fill out a questionnaire about the usefulness of the study. The questions will ask you whether Instacart, the nutrition booklet, and the Nutrition Navigator were easy to use and useful for your daily life.
- You will be asked to participate in an interview that lasts about 30 minutes. The study team will ask you questions about your experiences in this study. The interview will be over the phone or Zoom (a video conferencing software). The interview will be recorded. The recording will be sent to a company called Transcription Wing.
    - Transcription Wing (TranscriptionWing.com) will transcribe your interview recording for analysis. Recordings may include limited personal health information (PHI) if mentioned during your interview. For example, the recording may include your first name and mention your cancer diagnosis. The audio recordings will be shared with Transcription Wing only for the purpose of transcribing the audio. Transcription Wing follows data protection policies that meet HIPAA guidelines. Their privacy policy is linked here: https://www.transcriptionwing.com/privacy-policy/

If you receive Fresh Funds

To use the Instacart Fresh Funds, you must create an Instacart account. You must register an account with your name, email address, phone number, mailing address, and a valid credit or debit card number. UCSF will share the Fresh Fund codes with you to use on Instacart. Your redemption of a Fresh Fund code will identify you to Instacart as a participant in this study. Instacart will have access to the information you used to register your account. In addition, Instacart will ask your permission to share your shopping data. This will apply to the orders where you used Fresh Funds. Your shopping data for orders using Fresh Funds will be shared with UCSF for research purposes. Instacart may use the data it collects when you use the Instacart Platform. For example, the Instacart Shopper may contact you to ask about your grocery order and delivery. Please review Instacart's privacy policy and terms and conditions linked below:
Privacy Policy: https://www.instacart.com/privacy
Terms and Conditions: https://www.instacart.com/terms

If you receive food via Care Carts

If you receive food via Care Carts, you do not have to create an Instacart account. UCSF will share information about you with Instacart. This is to schedule the food

delivery. The information shared includes your name, phone number, and mailing address. Instacart may contact you via phone or text message about your grocery deliveries to confirm the delivery time.

7.1 Where do the procedures happen?

The Nutrition Navigator will contact you over your phone or with Zoom.

The questionnaires will be given to you over the Internet through RedCap (a web-based application for surveys). If you can't use RedCap, the surveys will be mailed to your home, and you will be instructed to mail it back to the study team (the study team will provide paid postage).

The Interview will take place over the phone or through Zoom.

7.2 Will clinically relevant research results be shared with me?

No.

8. What are the risks of this study?

You may experience diarrhea (loose stools), constipation (hard stools), flatulence (gas), and bloating. These side effects can happen if you change the food you eat. The side effects should improve as your body adjusts.

Answering the questions on the questionnaires may make you feel embarrassed or uncomfortable. You are free to skip any of the questions or stop participating in this study at any time.

9. Will I be paid if I take part in this study?

In return for your time and effort, you will be given a $25 gift card for completing the questionnaires at the end of the study. You will be given another $25 gift card once you complete the interview at the end of the study.

10. Will I be reimbursed for expenses if I take part in this study?

This study does not involve any expenses to research participants.

11. How will my information be used?

UCSF researchers will use your information to do this study. Once the study is done, we may use your information for other research studies in the future. We may share it with other researchers to be used in their studies. We will not share your name or other information that could identify you. We cannot promise that this will prevent future researchers from figuring out who you are. We will not ask you for additional permission to share this de-identified information.

12. How will information about me be kept confidential?

If you take part in this study, there may be some loss of privacy. We will do our best to make sure information about you is kept confidential. 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.

12.1 Who may review my research information?

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 University of California
- Representatives of Stanford University
- Representatives of the National Institutes of Health

12.2 Certificate of Confidentiality

This study has something called a Certificate of Confidentiality. This helps keep your information private. Researchers can't be forced to share your information with others like courts or law enforcement.

There are some things that the certificate does not stop:

- Reporting abuse of children or elders, or if you or someone else is in danger.
- Reporting of certain diseases.
- Groups (like those listed in 12.1) from checking the research records to make sure the study is going okay.
- Agencies from getting information if they need it for safety reasons.
- Your information from being used in other research if it follows the rules.

The certificate doesn't stop you from:

- Talking about being in this research study.
- Looking at your own medical records.

13. Does this study involve testing of diseases and conditions that must be reported to the public health department?

No, this study does not involve testing for reportable diseases and conditions.

14. What happens if I am injured or feel harmed because I took part in this study?

It is important to tell the Principal Investigator if you feel you have been injured or harmed because you took part in this study. The contact information for this person is on the first page of this form.

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

There will be no costs to you for being in this study.

16. Can I stop being in the study if I want to?

Yes. You can decide to stop at any time. If you are thinking about stopping, tell the study team so they can discuss any risks of stopping with you.

If you stop being in the study, any data we have already collected will remain part of the study records.

17. Can I be removed from the study by the Principal Investigator?

Yes. The Principal Investigators may stop you from taking part in this study at any time. This could happen without your permission. It could be because it is in your best interest, if you did not follow the study rules, or the study has been stopped.

18. What are my rights if I take part in this study?

You may choose to take part or not to take part in this study. It's your choice. 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. Leaving the study will not affect your medical care. You can still get your medical care from our institution. We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

19. Who can answer my questions about this study?

You can contact the study team with any questions, concerns, or complaints you have about this study. The contact information is on the first page of this form.

UCSF has an office that can answer questions about your rights as a research participant. This office is called the Institutional Review Board (IRB). The IRB is available to talk about any problems or concerns you have about the study. The UCSF IRB's phone number is 415-476-1814.

19.1 Where can I get more information about this study?

A description of this clinical trial will be 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.

The National Clinical Trial (NCT) number for this study will be listed on the first page of this form. If the NCT number is not yet available, the study team will give it to you when it is available.

20. Consent

You will be given a copy of this form to keep.

You will also be given the Experimental Subject's Bill of Rights to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to say “No” to this study now or at any point without penalty.

If you wish to take part in this study, please sign below.

Date	Participant's Signature for Consent

Date	Person Obtaining Consent

If you consent to participate, we will mail a study booklet to you at the start of the program. Please provide your mailing address below:

Street Address (including apartment/unit number):

City: State: Zip Code: