Cover Page for Consent Form

Official Study Title:	Multi-Level Trial of a Workplace Sales Ban of Sugary Beverages and Brief Motivational Counseling Intervention on Adiposity
NCT Number:	NCT ID not yet Assigned.
Document Date:	July 10, 2023

Title of the Study: The Sweet Study

CONSENT PART 1: EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As someone who is being asked to participate in a research study you have the following rights:

1. To be informed about the nature and purpose of the study.
2. To be informed about the study procedures and what drugs or devices will be involved.
3. To be informed about the risks and discomforts that are reasonably expected from the study.
4. To be informed about the benefits that are reasonably expected from the study.
5. To be informed about other options and how they might be better or worse than being in the study.
6. To be informed what medical treatment, if any, is available if complications arise.
7. To be able to ask any questions about the study and the procedures.
8. To refuse to be in study, or withdraw from the study at any time, without any change to benefits or medical care you would receive if you were not in the study.
9. To be given a copy of the signed and dated written consent form.
10. To be allowed decide whether or not to participate free from force, fraud, deceit, duress, coercion, or undue influence.

If you have questions regarding a research study, the researcher or his/her assistant will be glad to answer them. You may also seek information from the Sutter Health Institutional Review Board, established for the protection of volunteers in research projects, by calling (855) 771-7498 or by writing: Sutter Health Institutional Review Board Office, 2121 N. California Blvd, Suite 310, Walnut Creek, CA 94596.

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You are being asked to decide whether or not to participate in a research study. This section is to give you key information to help you decide. More detailed information is given in the main consent that follows this section.

The person in charge of this study, who is referred to as the principal investigator, is Jamey M. Schmidt, RD. Please ask Jamey M. Schmidt or the research staff if you have questions. If you have questions about the study later, Jamey M. Schmidt can be contacted at 415-600-1182. Your decision is up to you: If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

A. WHAT IS THE PURPOSE OF THIS STUDY?

You have been asked to participate in this study because you are a full-time employee at a participating Sutter Health affiliate, and you drink sugar-sweetened beverages, such as sodas and pre-sweetened coffees and teas. The purpose of this study is to gather information about your food and beverage choices and to study how employers can support healthy choices through changes in the workplace environment. These changes may include the types of beverages sold in your workplace and a session of health coaching.

B. HOW LONG WILL I BE IN THIS STUDY?

Your participation in the study will last approximately 18 months.

C. WHAT ARE THE MAIN STUDY PROCEDURES

The hospital where you work may be randomly assigned to remove sugar sweetened beverages from the cafeteria, vending machines and vendors on the hospital campus, or will be a control hospital where no changes will happen.

If you are in this study, you will be randomly assigned to either the brief health coaching (intervention) or control (no intervention). All study procedures will happen either at the hospital where you work or at your home, either online or via telephone.

You will be asked to answer questions about your health and lifestyle at enrollment, and 6 months and 12 months after enrollment is complete at your hospital. At these times, you will complete online questionnaires, and you will measure your waist circumference. You will also be asked to measure your height and weight on a standard research scale at your workplace. At

two times during the study, you will have blood drawn in a lab at your workplace. If you are randomly selected to receive the brief health coaching, you will also have one brief phone or online session with a trained study coach and two short follow-up visits. At six timepoints (enrollment, 1, 2, and 3 months after enrollment, and at 6 and 12 months), you will receive a text message in the morning and evening on four days during a week.

D. STUDY RISKS AND DISCOMFORTS

There are few risks associated with participation in this study. These include physical risks related to blood draws, inconvenience, and possible emotional discomfort from answering questionnaires, and loss of privacy and confidentiality of protected personal information. These risks are described in detail in this consent form, part 3.

E. STUDY BENEFITS

We cannot guarantee that you will benefit from this study. However potential benefits are improvement in your overall health, and an improvement in your knowledge about the impact beverage choices can have on your health. It is also hoped that the information gained from the study will help guide the future of workplace health and wellness programs.

F. STUDY ALTERNATIVES

This is not a treatment study. Your alternative is non-participation.

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CONSENT PART 3: STUDY DETAILS

Principal Investigator: Jamey M. Schmidt, RD
Address: 2351 Clay Street, San Francisco, CA 94115
Phone: 415-600-1182

Sutter Health Affiliate or Entity: California Pacific Medical Center
Study Sponsor: National Institute of Diabetes and Digestive and Kidney Diseases

A. HOW MANY PEOPLE WILL PARTICIPATE?

About 700 participants will take part in this study at hospitals throughout Sutter Health.

B. HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last approximately 18 months. Your eligibility to participate for the entire 18 months will be based on the completion of the enrollment procedures described below.

Completing all of the questionnaires should take about 1½ hours or less total. Text messages should take 1-5 minutes each. Due to different wait times at each Sutter Health affiliate or Sutter Health Foundation blood draw station, it is unclear how long you may need to wait for the blood draw at the beginning and end of the study. If you are randomly assigned to receive a brief health coaching session, this will take about 30-minutes total by phone or online, with two short follow-up calls (about five minutes each).

C. WHAT WILL HAPPEN TO ME DURING THIS STUDY?

Most of this study will be conducted remotely with the exception of the two blood draws, measuring your height at enrollment, and measuring your weight three times. This means that we will be communicating with you via phone, text, email, and regular mail. You will not have in-person visits with study personnel. Instead, the study team will be communicating with you remotely (email, text, and/or phone) to remind you to complete study activities at specific timepoints: enrollment, 6-months and 12-months after enrollment is completed.

Your study information will be collected using REDCap and the ASA24. REDCap is an online data collection tool approved by Sutter Health Privacy and Information Security for this study. The ASA24 is an on-line tool developed by the National Institutes of Health for recording what you ate and drank the day before. All links you receive will be specific to you and only you. They will be sent to you by a study team member.

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Assigning Participants to the Health Coaching or Control

After completing the enrollment study procedures described in detail below (questionnaires, height, weight, waist, ASA24, and fasting blood draw) you will be assigned randomly (like a flip of a coin) to participate in either brief health coaching or a control group. If you are randomly assigned to the health coaching group, you will be asked to participate in a brief health coaching session through an online video or via telephone with a trained health coach about how to improve your nutrition through changes in the beverages you drink. You will also receive two follow-up calls to see how you are doing with your goals. If you are assigned to the control group, you will not receive the coaching session.

Visit Procedures (Enrollment, 6-Month and 12-Month)

After signing the informed consent, you will be sent a secure REDCap link via email, unique to you, which you will use to enter information for this study.

Demographics and Medical History:

You will be asked for basic information about yourself and your medical history, including some medications you currently take. You will also be asked about where you work, how many hours and what shift you typically work. You will enter this information into REDCap. This information will be updated at each timepoint (each time you answer the other questionnaires explained below).

Weight:

You will be asked to weigh yourself on a scale at your workplace. You will be asked to record your weight from that scale in REDCap.

Height:

You will be asked to measure your height yourself using the measurement tool attached to the scale at your workplace. You will be asked to record your height in REDCap.

Waist Circumference:

We will mail you a tape measure with instructions on how to accurately measure your waist. You will be asked to record your waist circumference in REDCap.

Questionnaires:

You will be asked to complete questionnaires in REDCap about beverages you typically consume, your lifestyle, and how you are feeling, including questions about any feelings of depression. These questionnaires will take about 15 minutes to complete at each timepoint.

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24-Hour Recall (Automated Self-Administered 24-hour Dietary Assessment Tool (ASA24))

Three times during the study, an email and/or text messages will be sent to you asking you to complete a survey of what you ate and drank over the past 24-hours. The email or text will include the website link for the ASA24 as well as a username and password to securely enter your information. This will take you 20-30 minutes to complete each time. The ASA24 does not collect any personally identifiable information, however the IP address for the computer you use to complete the assessment may be automatically logged by the ASA24 system.

Text Messages

You will also be sent a REDCap link to your smartphone two times a day (morning and evening) for 4 days during a one-week period at the following timepoints: enrollment, 1, 2, and 3 months after enrollment is complete, then at 6 and 12 months, to seek information about how you are feeling.

Text messaging is not secure, which means that other people might be able see text messages that are intended to be private.

We will use reasonable means to protect the privacy and security of text messages sent and received. However, we cannot guarantee the privacy and security of text messaging.

You can stop participating in texting at any time. To stop participating, reply STOP to the text message, or call 415-600-5848.

Fasting Blood Draw (enrollment and 12-Month only):

You will be asked to go to your hospital campus or Sutter Medical Foundation laboratory and have fasting blood samples drawn at the beginning and end of the study. This means you will be asked to not eat or drink anything, except water, 8 hours prior to having the blood draw. These blood tests will measure your metabolic health and include blood sugar, insulin, cholesterol, and triglycerides. No more than 50 mL (less than 3 ½ tablespoons) will be drawn at each timepoint.

We will share the results of these blood tests with you using My Health Online (MHO). If you are not already signed-up to receive MHO notifications, you will need to sign-up if you want to be able to see your results. If you should have any questions or concerns about out-of-range results, please seek the guidance of your primary care provider.

Brief Health Coaching:

If you are randomized to receive health coaching, you will be contacted by a study team member to arrange a 20-30 minute online or telephone session with a trained study coach. Your coach will talk with you about sugar-sweetened beverages and provide personalized guidance on any health risks or benefits specific to you. Your coach will help you set goals and may provide additional educational materials to help you reach these goals. Your coach will follow up with two very brief phone calls, one week and one month later, to see how you are doing and answer any questions. Some of the calls may be audio-recorded by the research team for quality

assurance. If your call is selected to be recorded, we will inform you prior to starting the session. These recordings will not be shared with anyone outside of the Sutter research team. If you feel uncomfortable having your session recorded, please inform the coach and your session will not be recorded.

Employment/Medical Record Review:

If you receive health care at Sutter, we will collect some health information from your medical records. While the study team (study doctor, clinical research coordinators, data steward, and the Investigator) will have access to your entire Sutter EHR (electronic health record), we will only collect limited information from your medical record, such as most recent height, weight, medical history, medication list, bloodwork results and medical care for weight-related health problems. We will collect this information for the year prior to your enrollment, during the study, and for up to 5 years after. Only members of the research study team described above will access your medical records for the purposes of gathering this data.

We will also receive aggregate (combined) information on health plan use, looking at the year prior to your enrollment, during the study, and for up to 5 years after, to see if the changes in food and beverages offered in the workplace have a positive impact on employee health and wellness. This information will be collected by a representative of SutterSelect (Sutter Health's medical plan) and sent to the research team. The information sent to the research team will be in aggregate form only—this means that all data will be combined and will NOT include any personally identifying information or any information about your individual health plan utilization or claims.

D. WHAT ARE THE RISKS OF THIS STUDY?

Questionnaires

You may find the questions asked in the questionnaires to be difficult or embarrassing to answer. You will be asked some personal questions, for example, about how you are feeling, including questions about stress, food and beverage cravings, and depression. If you feel uncomfortable answering or do not know the answer of any of the questions asked, you do not have to answer them. If your answers on the questionnaires show signs of severe depression a study team member will contact you with information about Sutter Health's employee assistance program (EAP) for support.

Loss of Confidentiality

The risk of loss of confidentiality is very small because there are data security measures in place to keep your identity and results confidential. However, there is a very small chance that someone could access your research information or learn of your participation in this study.

Blood Draw

Side effects associated with blood draws may include infection, bruising, redness, discomfort, pain, or bleeding at the needle puncture site. You may feel dizzy, or you may faint.

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Employment/Medical Record Review:
The study team will have access to your medical records as part of your participation in this study. None of your individual medical record information will be shared outside of the CPMC Research Institute staff or stored in your employment record, and it will not have any impact on your employment at Sutter.

E. WILL MY INFORMATION BE KEPT CONFIDENTIAL?

For purposes of this study, we will collect and record information that personally identifies you. We will do our best keep this information confidential to the extent permitted by law. However, we cannot guarantee total confidentiality. Your personal information may be viewed by the study staff and others assisting, funding, or regulating the research. Groups that may have access to your personal information include government regulatory agencies, the study sponsor, and the Sutter Health Institutional Review Board (a committee that reviews and approves research studies).

Your name will not appear on any of your research data. Your information will be assigned a unique study number. Your name, address, phone number, and other identifying information will never appear on any study documents. All research data will be stored in a password-protected database on the Sutter secure network, and any identifying information like your name, birthdate, address, phone number, will only be available to study researchers and study staff at the CPMC Research Institute (CPMCRI); CPMCRI is the research department within CPMC. Your individual data collected as part of this research study is not accessible to anyone but the study researchers and coordinators. Your supervisors, managers, or other employees within Sutter will never be able to see your individual data collected as part of this study. Identifying information will not be sent outside Sutter Health. Your research records, without any personal information included, will be shared securely with researchers who are also working on this study at University of California, San Francisco.

An authorization describing what health information about you from the study may be used and to whom it will be disclosed will be provided to you. Federal and state law requires that patients must give authorization for use of their protected health information in order to participate in this research study. Please refer to Section L, "Patient Authorization for the Use and Disclosure of Protected Health Information for Research," of this form.

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.

F. IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to

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be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

G. WILL I BE PAID FOR PARTICIPATING?

Because you are an employee of Sutter Health, you cannot be paid for your participation. However, we can provide you with a gift. You will receive a $50 gift upon completion of all questionnaires, ASA 24, weight, and waist circumference at enrollment, 6 months, and end of study visit, and you will receive a $50 gift upon completion of each blood draw at enrollment and end of study. In addition, you will receive a $10 gift when you complete the weekly text messages. Upon completion of all study activities, you will receive approximately $310 value of gifts.

Gifts will be sent remotely to your email, for example, using a gift code, from a vendor like Amazon.

H. WHO IS FUNDING THIS STUDY?

The National Institute of Diabetes and Digestive and Kidney Diseases is funding this research study. This means that the principal investigator at California Pacific Medical Center Research Institute is receiving payments from the National Institutes of Health to support the activities that are required to conduct the study.

I. WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs from participating in this study.

J. WILL I RECEIVE NEW INFORMATION ABOUT THE STUDY WHILE PARTICIPATING?

During the study, you will be informed of any new information that might cause you to change your mind about continuing to be in the study. If appropriate, you may be asked to renew your consent to be in the study.

K. WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, or to report an injury from the research, please contact: Jamey M. Schmidt at 415-600-1182.

Should you have any questions about your rights as a research participant, you may call the Sutter Health Institutional Review Board, which is concerned with protection of volunteers in research projects, at (855) 771-7498 or by writing: Sutter Health Institutional Review Board Office, 2121 N. California Blvd, Suite 310, Walnut Creek, CA 94596.

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L. AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION FOR RESEARCH PURPOSES

Because information about you and your health is personal and private, it cannot be used in this research study without your written permission. If you sign this form, it will provide written permission to allow the use and disclosure of your information for this research study. This form also describes the different ways that we will share your information. Please read it carefully before signing. The health information that you agree to share will be solely used for the purpose of the research study named above.

What information can be used or disclosed for the study?

- Billing records
- Biological samples with or without information that could identify you (e.g. name)
- Consultation reports
- Data gathered from questionnaires and interviews
- History & physical
- Medical history
- Medication lists
- Numbers or codes that will identify you
- Physician orders
- Progress notes
- Results of laboratory, pathology and/or radiology tests

I specifically authorize release of the following information:

☐ HIV test results ___ (initial) ☐ Alcohol and Substance abuse ___ (initial)
☐ Mental Health ___ (initial) ☐ Genetic testing ___ (initial)

Note: Researchers will not receive any HIV/AIDS test results unless you initial here but your medical record may include general information about your HIV status.

Who can use or share health information for this research study?

- Sutter Health and Sutter Health affiliates (including but not limited to Hospitals, Medical Foundations, Surgery Centers and other outpatient care providers)

- Others with the authority to oversee the research.
- The Principal Investigator and the research team for the research described in the study's Informed Consent Form.
- The Institutional Review Board responsible for this study.
- Individuals providing care during the research.
- Your providers or consulting doctors that are treating you.
- The research study sponsor and any entity contracted by or affiliated with the sponsor to provide services related to the research study, such as an organization hired to manage study conduct or other study related business.
- Others required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, Department of Health and Human Services, or government agencies in other countries National Cancer Institute ASA24 online data capture system (IP address only)
- Researchers working on this study at University of California, San Francisco (UCSF)

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 permission expire?

Unless revoked, this authorization will expire when the research ends and all the required study monitoring is over.

Do I have to sign this authorization form?

No, you are not required to sign this document. However, you will not be able to participate in this research study if you do not sign the document. It will not affect your ability to receive treatment that is unrelated to this study.

Will my ability to have access or copies of my medical record be limited during the study?

This research will not limit your ability to have access or copies of your medical record during this study.

If I sign, can I revoke or withdraw from the research later?

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You can cancel your permission at any time. You may revoke your authorization at any time by writing to the Principal Investigator at the address listed at the top of this informed consent and authorization form. If you cancel your permission, you will no longer be in the research study. Information already collected and disclosed about you, however, may continue to be used to the extent the law allows (e.g., as necessary to maintain the integrity of the research). Also, if the law requires it, the sponsor and government agencies may be authorized to look at your medical records to review the quality or safety of the study.

SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this consent form, including a copy of the Subject's Experimental Bill of Rights, and the Authorization for the Use and Disclosure of Protected Health Information for Research.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH AND THE USE AND DISCLOSURE OF MY HEALTH INFORMATION AS DESCRIBED ABOVE.

In order to receive study communication, questionnaires, information and/or gifts, I agree to be contacted by phone, text, email, and mail.

Phone/text (standard rates apply):
Email:
Address:

Print Subject Name:	Date:
Subject Signature:	