Cover Page for Protocol Summary Form

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SUTTER HEALTH
INSTITUTIONAL REVIEW BOARD

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Project Title: Multi-Level Trial of a Workplace Sales Ban of Sugary Beverages and Brief Motivational Counseling Intervention on Adiposity. The Sweet Study

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PART I: General Study Information

► Is there a **separate protocol document** (for example, an external study sponsor has supplied the protocol) that explains the study purpose, background/significance, inclusion/exclusion criteria, and data analysis/methods?

☐ **Yes**	→	**Include protocol document with IRB application and skip to Part II.***
☒ **No**	→	**Complete Part I and the rest of the form.**

** In some cases, parts of the sponsor protocol will NOT be implemented at your site (for example, if the sponsor protocol allows for enrollment of minors but you will only be enrolling adults; or if the protocol is phase 1/2 but you will only be implementing the phase 2 part). If this is the case or there are other planned deviations from the sponsor protocol, please explain in the space provided in [Part IV: Other Comments] of this form.*

► ***Note: If completing the below (Part I: General Study Information #1-7), please delete guidelines (in italics) when submitting your protocol to IRB.***

1. STUDY AIM/PURPOSE:

"Liquid sugar" in the form of sugar-sweetened beverages (SSBs, e.g., sodas, sports drinks, "fruit" drinks, bottled teas, coffees) has emerged as a dietary risk factor with potent harmful effects on metabolic health.[1-3] SSBs are the largest single source of added sugars in the American diet, and have disproportionate metabolic health impacts on lower-income and ethnic-minority Americans.[4,5] We propose a double-randomized controlled trial of a multilevel workplace intervention that combines an employer-sponsored sales ban on SSBs with brief counseling to support reduced consumption.

After decades of research, it is clear that there is no single "magic bullet" for obesity prevention. However, bundled interventions that combine incremental changes in food environments with targeted behavioral interventions motivating healthier food choices show great promise.[6] The workplace provides an efficient venue to intervene. Rising obesity- and diabetes-related healthcare costs

incentivize employers to invest in prevention if workplace interventions are found to be effective, efficient, and scalable.

Health systems and schools are increasingly adopting SSB sales bans, wherein employers stop selling SSBs in all cafeterias and vending outlets and replace them with healthier options. Employer-based brief counseling interventions, despite being low-cost and efficacious for alcohol and tobacco reduction, have received limited attention as an approach to reduce SSB consumption.[7-10] **A multilevel intervention** may be the most effective because it combines a counseling intervention that increases motivation to reduce or quit SSBs with a sales ban that removes environmental triggers and cues. In our pilot study of 214 heavy SSB drinkers followed for 10 months,[11] a workplace sales ban on its own reduced waist circumference by 2.1 cm. The sales ban alone also led to an 8.2 oz/day decline in SSB consumption which correlated with increased insulin sensitivity. However, employees who received brief counseling, in addition to exposure to the sales ban, experienced more pronounced declines in SSB consumption.[11] And employees with strong SSB cravings benefitted more from the multilevel intervention, drinking 16.7 oz/day less than comparable controls.[12]

To assess the effectiveness of this multilevel intervention, called the workplace *Metabolic Health Improvement Program (MHIP)*, we will conduct a double-randomized trial in partnership with the clinical trials division of a large Northern California-based academic healthcare system, Sutter Health (*N*=700 employees on *N*=16 hospital campuses). We will first cluster-randomize 8 Sutter Health hospital campuses to the SSB sales ban condition and 8 campuses to serve as controls (no sales ban). Across these 16 campuses, we will further randomize heavy-SSB-consuming employees (>30 oz/week) to receive a brief SSB counseling intervention delivered remotely or to a control condition.[11,12] The **primary outcomes** are central obesity (e.g., waist circumference) and change in serum insulin sensitivity (homeostatic model assessment [HOMA] ratio). **Secondary outcomes** include changes in SSB consumption, Body Mass Index (BMI), and lab values to include: lipid profile, triglycerides, triglyceride:HDL ratio, uric acid, ApoA, ApoB, lactate, ALT/AST, GGT, fasting glucose, fasting insulin, HbA1c. We will assess dietary composition remotely using the Automated Self-Administered 24-hour (ASA-24) at baseline, 6 and 12 months, and waist circumference remotely with empirically validated instructions and a standardized tape measure provided to participants. We will collect blood samples in the workplace labs at baseline and 12 months. All analyses will consider compensatory changes in at-home SSB intake, calories from sugar, and total calories. Aims are:

Aim 1: *How well does each intervention work alone?* We will assess the independent effects of the brief counseling intervention and workplace SSB sales ban on changes in primary and secondary outcomes. We will compare outcomes across employees exposed to the brief intervention only (*n*=175), SSB sales ban only (*n*=175), and no intervention (*n*=175). *We hypothesize that the brief counseling intervention and sales ban will each independently decrease waist circumference and HOMA relative to no intervention. Those at high risk (baseline BMI >25, ethnic-minority, and lower-occupational status) will benefit more from the interventions.*

Aim 2: *Does a multilevel intervention work better?* We will assess the effects of combining a brief intervention and SSB sales ban on outcomes. We will compare outcomes for participants exposed to the multilevel intervention (*n*=175) to those who receive the: (a) brief intervention only (*n*=175), (b)

sales ban only (*n*=175), and (c) no intervention (*n*=175). *We hypothesize that the combined intervention will have a greater effect on outcomes than the brief intervention or sales ban alone. Higher-risk employees (see Aim 1) will benefit more from the multilevel intervention than their lower-risk counterparts.*

Aim 3: *(Exploratory): How does the intervention work?* We will test whether changes in SSB cravings mediate the effects of the multilevel intervention on outcomes. The multilevel intervention seeks to increase motivation to reduce SSB intake while reducing environmental cues to drink SSBs. *We hypothesize that the multilevel intervention will lead to the greatest reductions in cravings for SSBs, and cravings will mediate its effects on outcomes. We will explore mediation across high-risk groups (see Aim 1).*

2. BACKGROUND:

Obesity and type 2 diabetes are pressing health concerns, particularly for lower-income and ethnic minority employees. Obesity rates are at an all-time high and disparities persist: 49.6% of adult African Americans are currently obese and 44.8% of Latinos, compared to 42.2% of non-Hispanic whites.[13] Diabetes rates have nearly doubled since 2000.[14] Employers face disproportionately rising obesity-related healthcare costs alongside productivity losses.[15] Obesity is major concern for occupational safety, particularly for physically active nurses, manual workers and technicians at heightened risk for injury.[15,16]

Sugar-sweetened beverages (SSBs) are a key target for obesity prevention. SSBs lack nutrition and are the largest contributor of added sugars in the American diet.[17-19] Sugar from beverages is rapidly digested, promoting hyperinsulinemia and insulin resistance.[1] Recent metanalyses establish dose-response relationships between SSB consumption and obesity, abdominal adiposity, hypertension and diabetes.[20,21] Systematic reviews find that an increase of one SSB serving per day increases the risk of obesity by 12%,[21] diabetes by 18%,[20] coronary heart disease by 17%,[1] and hypertension by 8%.[22] Among the working-age population, SSBs are the top dietary factor associated with cardiometabolic mortality.[2] Adults gain from one-half to one pound annually for every 8 oz of SSBs in the diet.[23] Despite these known health harms, reducing SSB consumption is difficult because sugar is highly palatable and triggers dopaminergic craving.[24]

The workplace is an ideal place to site obesity prevention programs but to expand access, we need to "lower the bar" for participation. Adults spend most of their waking hours in the workplace, providing an efficient place and mechanism to intervene in obesity. Yet currently, American workplaces contribute to the problem. Foods and beverages purchased in the workplace are generally higher in added sugars than those available at home,[25-27] with SSBs purchased the most.[28] Common obesity interventions involving extended coaching in diet and fitness can be effective for weight loss.[29-32] But they disproportionately benefit employees with more flexible time and resources, thus selecting for higher status, more motivated, employees.[33,34] This reinforces health disparities[35-37] and undercuts the employer's return on investment.[33]

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Pilot Study of Multilevel Intervention: Published in *JAMA Internal Medicine*, the pilot study examined the effectiveness of a brief SSB motivational counseling intervention in the context of a workplace sales ban in 214 UCSF employees (with a retention rate of 94% after 10 months).[11] The sample was drawn from a larger online survey of a representative sample of 2556 UCSF employees (see immediately below), where the baseline occurred 3 months prior to implementation of a sales ban. Employees who reported heavy consumption of SSBs on the baseline survey were randomized to receive the brief counseling intervention or the control condition (sales ban only). All participated in anthropometric and fasting blood draws prior to the sales ban and 10 months after. Across both the multilevel and sales-ban only conditions, study participants experienced a 2.1 cm reduction in waist circumference, as well as decreases in uric acid and HDL cholesterol. Regression analyses, controlling for baseline BMI, insulin sensitivity (HOMA) and gender, found that this reduction in SSB consumption predicted a statistically significant reduction in HOMA. Those exposed to the multilevel intervention reported more pronounced reductions in SSB intake than the sales ban only group (25.4 oz vs. 8.2 oz, $p < .001$). Moreover, those with a >25 baseline BMI benefitted most and also experienced statistically significant reductions in lipids (total and LDL cholesterol, and ApobB*).*[11] *This pilot study was underpowered and lacked a non-intervention control group, which the proposed study will address. Still, it demonstrates our ability to administer the brief counseling intervention and suggests that the multilevel intervention has a beneficial impact on metabolic health, particularly for people with a BMI >25.*

Online Data Collection Evaluating UCSF Sales Ban: Observational data from an online survey of 2556 UCSF employees suggests that higher-risk demographic groups could disproportionately respond to the proposed intervention. Sample retention in this online study was 89% at the 12-month follow-up. Ethnic minority employees were twice more likely to report heavy consumption at baseline. Latinos experienced a more pronounced decline following the sales ban than Whites (by -3.7oz/day, $p<.007$). The lowest occupation stratum (service/manual workers) experienced a 30% reduction in consumption compared to 13% in the highest occupational group (academic medicine faculty) ($p<.0001$). *While limited by an observational approach, this study supports our proposed analyses by ethnic minority and lower occupational status, and speaks to our capacity for online data collection with good retention.*

Pilot Study of SSB Craving as a Mechanism: A published analysis of the UCSF pilot data found variable responses to the interventions for those with stronger SSB cravings (+1 SD above sample mean at baseline).[12] Individuals with weaker (-1 SD) SSB cravings reduced their SSB consumption, on average, by 12.8 oz/day ($p=.02$) more than individuals with stronger SSB cravings. However, among those with stronger cravings, those randomized to the multilevel intervention had significantly greater reductions in daily consumption (-19.21 oz/day vs. -2.49 oz/day, $p<.001$), a difference of 16.72 oz/day. *This study informs analyses proposed under Aim 3 by suggesting that employees with stronger SSB cravings may need the added motivational boost of brief counseling to achieve benefits on a par with others.*

Current Controlled Trial of Workplace Sales Ban in Sutter Health: In partnership with Sutter Health, we are currently completing a fully powered controlled trial of workplace SSB sales bans across 8 hospital campuses (5 intervention sites and 3 controls, $N=657$ employees), funded by the Laura and John Arnold Foundation. Retention was 88% at 6 months and 78% at 12 (during the COVID-19 pandemic). Collection of anthropometrics for this controlled trial was interrupted by the pandemic, but we continue to collect dietary assessments and other data using an online format. At 6-months post-sales ban, there is a

statistically significant mean reduction of 4.2 oz/day in SSB consumption in employees at intervention sites versus controls (p<.04), including a 2.7 oz/day reduction in SSBs consumed while at work (p <0.02). *This study is not cluster-randomized nor does it consider serum biomarkers for metabolic disease, which the proposed study will address. However, it demonstrates a successful collaboration with Sutter Health, and shows the feasibility of the proposed recruitment and remote data collection efforts.*

3. SIGNIFICANCE:

The proposed study tests a scalable, efficient approach for obesity prevention in the workplace. Following recent trials demonstrating the effectiveness of online obesity counseling using nonmedical providers, we test a remote counseling intervention delivered by trained health coaches.[38,39] The SSB sales ban is a food environment intervention that is easily adopted through changes in procurement policy and that promotes health equity by impacting the workforce as a whole.

Across all aims of the proposed study, we will assess the heterogeneity of intervention effects across higher-risk employee groups from ethnic minority backgrounds, lower occupational status and >25 baseline BMI. A recognized limitation of this study is that our disparities analyses will be confined to people in the workforce. If the interventions tested here prove effective, however, future studies can test them in other congregate settings that touch populations outside the labor market (e.g., in criminal justice settings, community colleges).

Brief SSB counseling interventions are promising but underutilized for obesity prevention. Brief interventions are short (~15 minute) counseling sessions that use motivational interviewing to offer advice and set goals to modify health behaviors. They are the standard of care for tobacco and alcohol prevention, with diverse applications in primary care,[7] emergency rooms,[8] and trauma centers,[9] and are effective when delivered by nonmedical providers (e.g., probation officers,[10] college counselors[40]). Despite this track record, brief interventions have not been widely deployed in obesity prevention. Our literature review found only four smaller-scale studies examining the effectiveness of brief motivational interventions for SSB reduction.[41-44] All found that telephone or online brief counseling, with booster contacts using text messages or mobile apps, produce significant declines in SSB consumption and/or BMI. *Under Aim 1, we will conduct the first fully powered trial of brief counseling for SSB reduction in the context of a large employer.*

Workplace SSB sales bans have promise for obesity prevention, but studies are limited. A sales ban entails the removal of SSBs from all workplace sales outlets, replacing them with non-sugary beverage options while still allowing employees to bring SSBs from home. Informed by behavioral economics, sales bans are designed to "nudge" employees towards healthier options,[44,45] while reducing the environmental cues and triggers that drive hedonic consumption.[46] There is robust prior research demonstrating that workplace sales bans on tobacco lead to declines in consumption and broader normative shifts.[48-52] Thus, a growing number of health systems, health departments, city governments, schools and universities have launched SSB sales bans.[53] [54-58] But evaluations are limited with as yet no published controlled trials.[59-61] In an observational study of 2556 employees, we found that a sales ban resulted in an average decline in employee SSB consumption of 1.5 oz/day.[12] In a subsequent microsimulation analysis, we estimated that SSB sales bans could save employers about $300,000 per 10,000 employees over 10 years in healthcare savings and productivity gains.[62] *Our proposed Aim 1*

analyses will contribute new knowledge by testing the effectiveness of sales bans using anthropometrics and blood biomarkers in the first fully-powered randomized controlled trial.

Our preliminary studies suggest that brief SSB counseling interventions and workplace sales bans could be potentially synergistic with respects to obesity prevention: The proposed trial leverages multiple levels of the socioecological model in mutually-reinforcing ways.[63] While the sales ban intends to reduce availability, and the environmental cues associated with SSBs in the workplace, the brief intervention provides employees with a motivational boost to cut down or quit. In our UCSF pilot study of heavy SSB drinkers, all were exposed to a sales ban and half were randomized to a brief motivational counseling intervention. We found that the combined effects led to reductions in SSB consumption of 24 oz/day compared to an 8 oz/day reduction for employees exposed to the sales ban alone (see "Preliminary Studies").[11,12] This pilot study, however, was not fully powered or able to test the brief intervention in the absence of a sales ban. *Under Aim 2, we will pursue the hypothesis that reduced SSB availability and cues under a sales ban, combined with the motivational boost of a brief intervention, will optimize outcomes.*

Exploring mechanisms of change. The NIH Common Fund is spearheading the Science of Behavior Change (SoBC) Initiative to urge scientists to explore the mechanisms of action in behavior change interventions, thus promoting the cumulative advancement of science.[64] The SoBC model (see Figure 2 below) allows scientists to systematically explore the "how and why" behind changes in obesogenic behaviors, thus contributing to the development of blueprints for more effective obesity prevention. Our pilot study found that employees who reported drinking SSBs due to strong cravings did not benefit from the sales ban alone.[12] But if those who received the brief intervention reduced their consumption by over 19 oz/day. SSB cravings could, therefore, be a mechanism on the critical pathway leading from the multilevel intervention to changes in central obesity (see "Preliminary Studies"). *If the multilevel intervention proves to be effective, mediation analyses proposed under Aim 3 will help shed light on why. If not effective, they will help us to build future interventions that are more effective.*

Public health impact: If effective, the proposed employer-sponsored multilevel intervention will offer an efficient, scalable strategy for preventing obesity in millions of American working adults. This study will also contribute to science on mechanisms of change in obesity prevention and inform the design of interventions that exploit synergies between individual behavior change strategies and food environment policies.

4. METHODS:

(4a) General Study Design:

This is a prospective, double-randomized study in which 16-Sutter Health affiliate hospital campuses will be cluster randomized to control (no SSB sales ban) vs. intervention (removal of SSBs). Across these 16 campuses, we will enroll 700 employees and then randomize those who self-report consuming >30 oz of SSB per week to receive a brief counseling intervention or control (no intervention).

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(4b) Procedures:

Cluster Randomization of 16 Sutter Health Affiliates
Sutter Health affiliates will be eligible to participate in the study who meet the criteria: 1) the affiliate has not participated in a SSB intervention; 2) the affiliate is not in a county that has instituted a SSB sales tax. Affiliates will be stratified by their location (urban vs. rural) and number of employees and will be randomly assigned using a computer program to be assigned to either control or intervention. Sutter Health leadership (James Conforti and Conrad Vial, MD) have signed a letter of support to conduct this study.

Sites randomized to the SSB will eliminate sugar-sweetened beverages from the cafeterias, vending machines, Walgreens, vendors, and from patient care areas. Sutter Health has already implemented Healthy Beverage Initiatives (HBI) at Alta Bates, Palo Alto Medical Foundation (PAMF) and all CPMC campuses.

Study Procedure	Description	Baseline	6 Months	12 Months
Informed Consent	Procedures Described Below	X		
Demographics	Self-reported gender, ethnicity, household income, education, work location, hours, shifts	X	X	X
Medical History	Self-reported concurrent medications and general medical history with an emphasis on diabetes	X	X	X
Height	Measured using a stadiometer on a standardized scale at a semi-private location on the affiliate campus.	X		
Weight	Obtained on a standardized scale at a semi-private location on the affiliate campus.	X	X	X
Waist Circumference	A tape measure with instructions will be provided to the participant to measure at the designated timepoints.	X	X	X
Fasting Blood Draw	The collection will include: complete metabolic and lipid panel, uric acid, ApoB, GGT, glucose, insulin, HbA1c. These are biomarkers that are risk factors for poor metabolic health, diabetes, and cardiovascular disease	X		X
BevQ	This questionnaire seeks to quantify the frequency, type and volume of beverages consumed at work and home.	X	X	X

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ASA 24	This is a web-based, 24-hour dietary recall tool developed by the National Cancer Institute	X	X	X
Stanford Leisure Time Scale (L-CAT)	This is a scale that measures physical activity.	X	X	X
*PROMIS4a Depression	Assesses the presence and severity of symptoms of depression.	X	X	X
Beverage Craving Questionnaire (FCQ-T-R)	Assesses the following: 1) preoccupation with sweetened beverages; 2) loss of control; 3) positive outcome expectancy; 4) emotional cravings	X		
Reward Based Eating Drive (RED-13)	Assesses three aspects of drive to eat: 1) loss of control; 2) lack of satiety; 3) preoccupation with food	X	X	X
Perceived Stress Scale	This is a widely used questionnaire to assess stress levels. It evaluates the degree to which an individual has perceived life as unpredictable, uncontrollable, and overloading over the previous month.	X	X	X
Copenhagen Burnout Inventory (CBI)	This six-item inventory measures personal burnout experienced by participants.	x	x	x
Self-Efficacy	These questions are used to determine if an individual exhibits intention to reduce SSB consumption.	X	X	X
Science of Behavior Change Texts Parent Grant	Assesses craving, psychological stress, consumption and self-efficacy (two texts/day x four days/week)	X	X	X
Science of Behavior Change Texts Supplemental Grant	Assesses craving, psychological stress, consumption and self-efficacy (two texts/day x four days/week)	Additional texts will be sent at the following time periods: 1, 2, and 3 months after SSB intervention.		
EPIC EMR	Lab results from the blood draw will be extracted from EPIC utilizing the resources of the Center for Health Services Research (CHSR). Limited data from the medical record will be extracted by CHSR that looks at metabolic health.	X		X
Incentive Gift		X	X	X

***Patient-Reported Outcomes Measurement Information System (PROMIS)**: We have selected a self-report measures of depression which are person-centered which all study participants will be asked to complete. We will investigate the possible correlation between SSB consumption, general health and depression as well as change over time between the intervention and control campuses. Subjects who report high levels of depression will be provided with contact information to Sutter Health's Employee Assistance Program (EAP). No documentation will be placed in the subject's medical or employment record.

REDCap will be set-up with a notification alerting the CRCs when the depression scores result with severe depression. When the participant completes their questionnaires, the Clinical Research Coordinators will review the depression questionnaire. If a participant scores a severe depression (score, a phone call will be made to the participant using a script. A form has been created and will be used as documentation. This includes a script for leaving a message and for a live call. During a live call only, the Clinical Research Coordinator will inform the participant of their high score and will with the phone number to Sutter Health's EAP.

Demographics: Including gender, ethnicity, primary work location, occupational status, income, and usual number of worked shifts each week will be recorded via REDCap.

Medical History: Concurrent medications and general medical history will be obtained directly from study participants with an emphasis on metabolic history such as diabetes. Data will be recorded via REDCap

Height, weight, and waist circumference measurements: Subjects will be asked to record their self-reported height in REDCap. Height and weight will be measured using a standard scale with an attached stadiometer in a semi-private location at the affiliate and record their weight and height in REDCap. A tape measure and instructions on measuring waist will be sent to the participant's home. They will record the measurement in REDCap.

Fasting Blood Draw: A fasting blood draw will take place at the draw station of the local affiliate. Labs will be drawn at baseline and at 12-months. The panels will be comprised of metabolic and lipid panels that pertain to metabolic syndrome. Labs will be accessible to participants using My Health Online.

Medical Record: Medical record data will be requested for the Sutter EHR (Epic) over a seven-year period (to include one year prior to enrollment, the 12-month study period and for five years thereafter). Data collection will include metabolic parameters related to obesity, such as: lipid panels, glucose, insulin, liver panels, height, weight, and past and prospective history. Medical records data collection will include medication history, progress reports, discharge summaries, and other data allowing us to look at the long-term impact of metabolic health in this population.

Depression: We will investigate the possible correlation between SSB consumption, general health and depression as well as change over time between the intervention and control campuses.

Benefits: In cooperation with SutterSelect, we will obtain aggregate claim information for subjects at the intervention and control campuses. The aim of this data is to evaluate differences in health plan costs between the two groups. No individual health claims information will be collected. The data access form will review the security and privacy controls to ensure protections are in place. This data will be collected one year prior to enrollment, the 12-month study period and five years after.

Questionnaires: Subjects will complete all questionnaires remotely using a secure instance of REDCap.

BEVQ: BEVQ is a food frequency questionnaire measuring specific beverage items. We will use an adapted version of the BEV-Q field tested in the UCSF studies that captures beverage consumption while in the workplace and while not at work. The questions ask the type and frequency of consuming specific types of beverages on a typical day: regular/non-diet soda, diet soda, 100% fruit juice, fruit drinks (lemonade, smoothies), sports or energy drinks, sweetened coffee or tea drinks (Arizona iced tea, Frappucinos), and water. Participants also report how much (in ounces) they consume of each beverage each time over a limited, one week, recall period. Daily intake can be calculated for each beverage type by multiplying the frequency and serving size

The Automated Self-Administered 24-hour Dietary Assessment Tool (ASA24): The ASA24 is a free, web-based tool that enables multiple, automatically coded, self-administered 24-hour diet recalls and/or single or multi-day food records. ASA24 was developed by the National Cancer Institutes. Participants will be asked to complete one 24-hour recall at enrollment, 6 and 12 months using a link and password sent to them.

The Stanford Leisure-Time Categorical Item (L-CAT): The L-CAT is a questionnaire asking participants to rank their activity level from inactive to very active. This tool has been validated and can detect statistical differences when used over time.

Patient-Reported Outcomes Measurement Information System (PROMIS) Depression: The PROMIS Depression 4-item questionnaire banks assess self-reported negative mood (sadness, guilt), views of self (self-criticism, worthlessness), and social cognition (loneliness, interpersonal alienation), as well as decreased positive affect and engagement (loss of interest, meaning, and purpose). The depression short forms are universal rather than disease specific. All assess depression over the past seven days. If they score in the severe range the Clinical Research Coordinators will contact the participant and will provide them with the EAP contact information and will encourage them to call EAP.

Food Craving Questionnaire-Trait, Reduced (FCQ-T-r): The 15-item FCQ-T-R assesses (1) preoccupation with SSB (i.e., obsessive thought about food and eating), (2) loss of control (i.e.,

difficulty regulating eating behavior when exposed to food cues), (3) positive outcome expectancy (i.e., believing eating to be positively reinforcing), and (4) emotional craving (i.e., tending to crave food when experiencing negative emotion).

Reward Based Eating Drive (Red-13): The 13-item RED assesses three aspects of drive to eat (loss of control, lack of satiety, and preoccupation with food). Items are answered on a Likert scale from 0 (Strongly Disagree) to 5 (Strongly Agree). Example items include "I feel out of control in the presence of delicious food" and "When I start eating, I just can't seem to stop."

Copenhagen Burnout Inventory (CBI): The 6-item portion of the CBI assess personal burnout as is a state of prolonged physical and psychological exhaustion. Participants quantity the frequency of physical and emotional fatigue, as well as their susceptibility to illness, from on a six-point scale from “Always” to “Never”. Formulated in a way that all human beings can answer it (regardless of job status), the measure was validated through the PUMA study.

Participant Randomization

Upon completion of five enrollment measurements (questionnaires, height/weight, waist, ASA24, and blood draw) participants will be randomly assigned to either a control group, or a group receiving a brief, remote motivational intervention, known as the Metabolic Health Improvement Plan (MHIP). Participants are randomized by a REDCap randomization module, using stratified random sampling by location. Those randomized to intervention will be contacted as described below.

SSB Brief Motivational Counseling Intervention- The Health Improvement Program

Participants randomly assigned to the health improvement program and will be contacted to participate in an education session with a trained coach via phone or video conference. The session led by a trained coach will describe the amount of sugar ingested in SSBs per week and will then proceed to provide personal guidance on health risks and the benefits of reducing sugar intake. Next, the coach will engage the participant in achievable, gradual goals to reduce SSB consumption reviewing and providing education materials. This will include discussing substitution beverages and preferred alternatives. Coaches will provide tools to the participate to increase self-efficacy and mediate the impact of stress, and cravings. The brief counseling session ends with the coach providing education materials including recordings relevant to the discussion, which can include topics of stress reduction and mindfulness. Depending on the participant, the brief intervention will take between 15 and 25 minutes to complete.

The coach will make two, 5-minute booster telephone calls within 4-6 weeks of the initial call. The first will be about two weeks after the initial session and the second call will be about two weeks later. The coach will revisit goals and obstacles and determine compliance to the educational materials.

Elissa Epel, PhD and Rachel Radin, PhD will supervise the training of Sutter Health externs/interns who are seeking hours towards their graduate education. Interns will meet the following minimum requirements: psychologist trainees enrolled in a masters-level or doctoral-level American Psychology Association accredited graduate program, with a minimum of 1 year of prior supervised clinical/clinical

research experience, interest in Motivational Intervention and/or health psychology, and ability to commit to 6 months of this practicum opportunity. Training sessions will include mock sessions until coaches are comfortable and proficient with the intervention. To assure a high degree of fidelity with the registered intervention protocol, 20% of counseling sessions will be recorded and reviewed by Dr. Radin. During these observations, she will record any breeches with protocol and other guidance using a standard checklist. Checklist data will be collated during analysis to capture an overall assessment of fidelity in implementation of the clinical protocol.

Dr. Radin and the externs will be onboarded at Sutter Health to work on this project using one of two methods:

Method 1: Dr. Radin and the externs will be onboarded as a volunteer. Dr. Radin will lead the training and will review the coaching sessions.
Method 2: Dr. Radin and the externs will be onboarded as paid interns.

To communicate with the participants, the externs/interns will utilize a Sutter Health TEAMS or ZOOM approved for PHI use. It is preferred that either method will have recording capabilities. In the event they do not, a Sutter Health approved encrypted audio recorder will be used.

Recordings will be saved in a folder on a Sutter Health drive only accessible by research team members.

SSB Cravings and Stress Text Based Data Collection

Using the Ecological Momentary Assessment (EMA) approach, cravings will be measured by study participants using smart phones. Using the REDCap platform, participants will receive a short set of questions at the following timepoints: baseline, 1, 2, and 3 months after SSB intervention starts at randomized affiliates, and 6 and 12-months. Two texts will be sent each day (morning and evening) four of the seven days of the week. Participants will be asked to quickly record the following: cravings (if any) for sugar sweetened beverages, psychological stress, consumption, and psychological stress. The primary target for this exploratory analysis is cravings for SSBs but we will also have access to information on whether or not subjects consumed SSBs in response to the craving. Each text should take one to-five minutes each. The content of the text is as follows:

- Introductory text at the start of each assessment period (Sunday afternoon) shall read:
    - *Greetings Sweet Study Participant – this week, we'll text you 4 clickable links in the morning and 4 in the evening on Tues, Thurs, Fri, and Sat. Each link will take 1-5 minutes to complete – Short and Sweet! The week after you finish the surveys, we'll email you a $10 gift code. Please complete at least 6 of the 8 texts in order to receive a gift code.*

Each day, the texts will be labeled as morning Sweet text 1, 2, 3, 4 and evening Sweet text 1, 2, 3, 4.

Location (asked in evening)

Today, were you physically working at your Sutter Health workplace?

- Yes
- No

Can define a sugary drink here.

Craving Battery – Evening – Supplement and Parent

1. Today, did you crave a sugary drink? Yes / No

· *If No, skip #2 and #3*
· *If Yes: Move on to #2.*

2. At its most severe point, how strong was your craving for a sugary drink today?

Sliding bar, slider starting at middle or optimally nowhere and it gets placed when the respondent touches the screen, if starting in the middle then movement of bar required to advance to next question

**For #3, make these checkboxes, with the first two non-exclusive, and the "no" exclusive*

3. Did you drink anything in response to ANY of these cravings?

- *Yes, a sugary drink*
- *Yes, water, a sugar-free drink, or a drink with no added sugar*
- *No*

Psychological Stress Battery - Evening – Supplement and Parent

What was your overall mood like during the day?

1. *I felt stressed, anxious, overwhelmed.*
2. *I felt joyful, glad, happy.*
3. *I felt in control, coping well, on top of things.*
4. *I felt sad, downhearted, unhappy.*

Scale:
0 = Not at all
1 = A little bit
2 = Somewhat
3 = Moderately
4 =Extremely

Consumption Battery – Evening, last item administered – Supplement

1. Thinking back on how much sugary drinks you had **today**, which is most true for you:

Response options: Assessment 1 (baseline)
- I drank less than I usually do
- I drank about as much as I usually do
- I drank more than I usually do

Response options: Assessment 2 and beyond
(1-month post-Ban and all further assessments)

- I drank less than I usually did before the Sweet study
- I drank about as much as I usually did before the Sweet study
- I drank more than I usually did before the Sweet study

Self-Efficacy Battery – Morning
If going to work:
1) How sure are you that you will avoid drinking sugary drinks today while at your Sutter Health workplace?

Not sure at all ---------- Extremely sure

Sliding bar, slider starting at middle or optimally nowhere and it gets placed when the respondent touches the screen, if starting in the middle then movement of bar required to advance to next question

□ Don't know
□ I don't plan to go to my Sutter Health workplace today

2) How sure are you that you will avoid drinking sugary drinks today while **not** at your Sutter Health Workplace?
[1] Not sure at all
[2]
[3] Somewhat sure
[4]
[5] Extremely sure
□ I do not drink sugary drinks
□ Don't know

Blood Draw
The orders for the blood draw will be signed off by Nisha S. Patel, MD the study physician. Results will be sent to patients via My Health Online. The study participants will be asked to review out of range labs with their primary care physician

(4c) Methods of Data Analysis:

Analysis Plan for Aim 1: *How well does each intervention work alone?* We will assess the independent effects of the brief counseling intervention and workplace SSB sales ban on changes in primary and secondary outcomes.

Introduction: Aim 1 analyses will compare primary and secondary outcomes for employees exposed to the brief intervention only, the SSB sales ban only, and no intervention. Our operative hypothesis is that both the brief counseling intervention and sales ban will independently decrease HOMA and waist circumference relative to no intervention. Of four smaller studies testing the effects of brief SSB

counseling interventions, all found decreases in SSB consumption and BMI.[41-44] A pilot study and current trial by this team found that workplace sales bans reduce SSB consumption, waist circumference and some blood biomarkers for metabolic disease.[11]

Analyses for all aims will also consider the hypothesis that those at highest risk for obesity and metabolic disease will benefit more from the interventions**.** This is justified by our pilot study showing that employees with a baseline BMI <25 benefitted most from the sales ban and brief intervention.[11] Preliminary studies (described above) suggest that ethnic minority and lower occupational status employees may experience disproportionate reductions in SSB consumption following an employer sales ban.

Analyses for all aims will also consider the possibility that study participants exposed to the interventions could compensate for reduced SSB consumption during work hours by increasing their consumption of SSBs at home, or by increasing calories from sugary foods or in the total diet.[107,108] In our evaluation of the UCSF sales ban, we observed no compensatory at-home SSB consumption but rather, spillover effects of the intervention: After 12 months of exposure to a sales ban, the average SSB intake of heavy drinkers not only declined at work but also by 40% at home (by 9.3 oz/day) (data unpublished).

Research Design for Aim 1: The main analysis will focus on ANOVA and regression modeling to determine the independent effects of each intervention on primary and secondary outcomes.

Key Measures for Aim 1: As described in section C3d above: HOMA, waist circumference, abdominal adiposity, SSB consumption, insulin sensitivity, BMI, lipid profile, triglycerides, triglycerides:HDL ratio, liver function, glucose control, demographics, risk factors/disparities, and intervention assignment.

Analytic Plan: We will analyze Aim 1 using all data collected at the baseline, 6- and 12-month time points. First, we will use ANOVA to compare group means and determine whether there is a significant main effect for each intervention (the sales ban and the brief intervention). Based on theory and our previous studies, we know that baseline risk factors and demographics are likely relevant to the impact of these interventions; those at greater baseline risk tend to benefit more from the interventions. Therefore, each dependent variable will also be examined using a linear regression model, which allows us to observe the main effects of these factors. For example, the model predicting HOMA change would include assignment to the sales ban condition (coded as 0/1), assignment to the brief intervention condition (coded as 0/1), baseline HOMA, baseline SSB consumption, baseline BMI, race/ethnicity, and sex. Subsequent models can consider baseline BMI > 25, ethnicity and job classification. The procedure for analyzing each outcome would be the same, but with each primary and secondary outcome substituted for HOMA in turn.

For SSB consumption, we will examine at-work consumption, at-home consumption, and total consumption as separate outcomes to thoroughly investigate the impact of the interventions across work and home environments. We will similarly check for potential compensatory consumption in sugar from calories and total calories for participants in the intervention conditions relative to controls. If ASA-24-based total calories or calories from sugar disproportionately increase in the intervention groups, this suggests a compensatory effect.

Although we believe our strategy of cluster randomization and controlling for individual differences that can vary regionally (such as ethnic distribution) is sufficient, we will also analyze the effects of the brief intervention via an exploratory mixed regression model, with individuals nested within sites, to see if study site was an important factor. If it is, we will consider mixed models where possible.

Power Calculations: Power calculations are based on changes observed in the pilot study and response rates from the current Sutter Health trial. Calculations are conservative, based on 80% retention of participants after 12 months. With an initial N of 700 drawn from 16 Sutter Health sites randomly assigned to the sales ban and control conditions, and with participants within those sites randomly assigned to brief intervention/no brief intervention conditions, 80% retention would result in an overall N of 550 at 12 months. This results in approximately 138 in each of four experimental conditions: brief intervention + sales ban, the brief intervention only, sales ban only, and no intervention. Power analysis for a full factorial design conducted with the BDEsize[109] package within R[110] indicates that with 80% power and an alpha level of .05, we will be able to detect effect sizes as small as .08 for the effect of each intervention on each outcome.

Anticipated Problems and Alternative Approaches: One potential problem is attrition, particularly biased attrition. We have calculated the sample to allow for up to 20% attrition; this is a conservative number based on our current Sutter Health data. In the UCSF pilot, which took place entirely pre-pandemic, we achieved a 94.4% response rate for blood draws. The existing study team has experience with the challenges of retaining a sample of health care workers during a challenging time and can use the same techniques (e.g., email and phone outreach) to reduce attrition here. We will conduct statistical tests to determine if attrition is biased on baseline risk levels, demographic factors (including regional differences), or study condition.

As with all self-report data, the survey data on SSB consumption could be biased, perhaps particularly for intervention participants who want to self-present improvement. However, the anthropometric and blood measures are objective and should show a consistent pattern with the SSB changes. Standard data cleaning procedures should reveal any extreme cases of self-representation bias. For SSB consumption data, we have also established a convention in previous studies of pruning outliers that are more than 4 SD away from the mean to reduce error from participants who may have responded inaccurately.

We have several primary and secondary outcomes. To avoid bias from multiple statistical tests, we will closely examine patterns of data. Many of the biomarkers are related, for example, as are the anthropometric measurements. Thus, it will be apparent whether or not each result is consistent with the overall pattern of health impacts.

Expected Outcomes: We expect statistically significant main effects for both study condition variables in the ANOVA analysis, specifically that the means for each of the three groups exposed to the sales ban and/or brief interventions will demonstrate more improvement (reduction in HOMA, abdominal adiposity, blood lipids, SSB consumption, BMI, etc.) than those in the group receiving neither intervention. We also anticipate statistically significant coefficients for each study condition variable in the regression analysis that again indicates that those interventions are linked to better outcomes. This would indicate that each intervention has an effect.

Analysis Plan for Aim 2: *Does a multilevel intervention work better?* We will assess the multilevel effects of combining a brief intervention and SSB sales ban on outcomes.

Introduction: The goal of Aim 2 is to test the hypothesis that the combined intervention will have a greater effect on outcomes than the brief intervention or sales ban alone. This is justified by our pilot study findings that employees benefitted most from the multilevel intervention (see Figure 1)[11] and by

the socioecological model which argues that obesity prevention should address multiple levels of intervention at once.[99]

Research Design for Aim 2: The analysis will use ANOVA and regression models similar to those above, but with the key addition of an interaction term for the two interventions, allowing us to explore the possibility that they work better in combination than separately.

Key Measures for Aim 2. Measures are the same as those described above under Aim 1.

Analytic Plan for Aim 2: Having established the main effects of each intervention under Aim 1, our analyses for Aim 2 focus on the interaction between them. Specifically, we anticipate that the combined intervention will have an effect above and beyond the simple additive effects of the two interventions. This analysis will require replicating the ANOVA and regression models used for Aim 1 with the addition to each of an interaction term for the two interventions. For example, the model predicting HOMA change will include assignment to the sales ban condition (coded as 0/1), assignment to the brief intervention condition (coded as 0/1), the interaction term for the two conditions (sales ban*brief intervention), baseline HOMA, baseline SSB consumption, baseline BMI, race/ethnicity, job classification (if sample size allows, as above), and sex. The procedure for analyzing each outcome is the same, but with each primary and secondary outcome substituted for HOMA in turn. This time, the main variable of interest will be the interaction term. We will graph and deconstruct each significant interaction term to determine the details of the interaction.

Power Calculations: As with Aim 1 above, power calculations are based on findings from the UCSF pilot and retention rates from the Sutter pilot. We will have 175 participants in each of the following groups. With 80% retention, this allows a final N of 550, with approximately 138 in each of the four experimental conditions. Power analysis for a full factorial design conducted with the BDEsize[109] package within R[110] indicates that at 80% power and an alpha level of .05 we will be able to detect effect sizes as small as .12 for the interaction between the two interventions.

Anticipated Problems and Alternative Approaches: As with Aim 1, attrition and self-report bias are the primary potential issues we anticipate; handling of each is described above.

Expected Outcomes: We anticipate a significant interaction term, and more specifically, that the effect of the sales ban and brief intervention together will be stronger than each is individually. Participants assigned to the brief intervention and working at sites with a sales ban would thus demonstrate the greatest amount of change, and more change than one would expect if the effect of the two conditions were simply additive.

Analysis Plan for Aim 3: *(Exploratory): How does the intervention work?* We will test whether changes in SSB craving mediate the effects of the multilevel intervention on outcomes.

Introduction: The goal of this analysis is to examine SSB craving as a mediator in the relationship between the multilevel intervention and primary and secondary health outcomes. This is justified by our pilot study analysis showing that employees with a high level of baseline craving benefited more from the multilevel intervention than comparable employees exposed to the sales ban alone.[12] This study is designed to test the mediation model for the sales ban and brief intervention separately, helping us to understand the "active ingredients" in the multilevel intervention. We can also explore differential benefits for members of high-risk groups.

Research Design for Aim 3: This exploratory analysis will estimate mixed effects using logistic regression models. In contrast to some approaches toward mediation analysis (e.g.,[111-114]), ours will

simultaneously test all paths, including indirect effects through the mediator,[112-114] regardless of the presence of a statistically significant total intervention effect.[114] Available measures allow us to examine the extent that changes in SSB cravings and SSB consumption after cravings mediate the effects of the multilevel intervention on outcomes.

Key Measures for Aim 3: In addition to measures described above, this aim incorporates text message-based EMA data that captures SSB cravings in the context of day-to-day life.

Analytic Plan for Aim 3: Participants will respond to a question asking if they experienced a craving for SSBs as *yes* or *no*. We will use this SSB craving variable (M), along with group assignment (X), to predict 12-month SSB consumption (Y). This simultaneous mediation model will comprise, first, a mixed effects logistic regression model (Path A in Figure 2 above, from X to M). This model will include random effects for day nested within study period, nested within person for each of the possible reports per day (morning, afternoon, evening, and "any other time not previously reported"). The dependent variable will be the dichotomous primary outcomes reflecting the experience of a craving or whether a craving was acted upon. Model covariates (fixed effects) include time of day, study period, randomization group, and the interaction of study period by randomization group. This will allow us to estimate the odds of having a craving or indulging in one at 6- and 12-months compared to baseline, separately for each experimental arm, as well as allowing for direct comparisons between study arms at each time point.

A second component of the model is a mixed effects linear regression model (Path B in Figure 2 above, from M to Y) that links a change in cravings between baseline and the 6-month follow up (measured as the change in the proportion of responses in which subjects reported cravings) to SSB consumption and HOMA at 12 months. We will perform this mediation model first without covariates[115] and then will perform it with other predictors of SSB consumption (e.g., demographics, high-risk group) as in Aim 1. This analysis will allow us to estimate the proportions of variance in SSB consumption at 12 months that are related to changes in SSB craving experiences.

The relationship between the interventions and SSB consumption without the inclusion of craving (Path C) will have already been established in the analyses for Aims 1 and 2, so lastly, we will examine Path C' (interventions predicting consumption and waist change with the inclusion of the craving mediator). This will necessitate a model similar to those used in Aims 1 and 2, but with the addition of craving change and an interaction term for intervention*craving change.

Anticipated problems and Alternative Approaches: This is an exploratory analysis, and thus may not be able to detect very small mediation effects. However, based on our pilot analysis with a much smaller sample, we do not anticipate this will be an issue. The same caveats about retention and self-report bias described in the Aim 1 analysis plan also apply here.

Expected Outcomes: We anticipate that participants in the multilevel intervention group will have a greater reduction in cravings than those in the sales ban or brief intervention groups alone and no intervention groups. We also anticipate that a greater reduction in cravings will be associated with greater reduction in SSB consumption and HOMA at 12 months.

(4d) Subject Selection:

Inclusion Criteria:

1. Full-time employee who works on campus at one of the 16 Sutter Health participating sites.
2. English speaking.

3. Reports drinking ≥3 SSBs/week.
4. Agrees to having two fasting blood draws.

Exclusion Criteria:

1. Pregnant

5. RISKS/DISCOMFORTS

Blood Draw: there is a risk of pain, bruising, and/or infection at the needle stick site. This is minimal risk.

Confidentiality: there is a risk of loss of confidentiality which is minimal. Controls are in place as described in the data access plan to collect data in Sutter Health applications.

6. ALTERNATIVES

Employees can choose not to participate.

7. BIBLIOGRAPHY:

See Attached: Literature Cited

PART II: Subject Recruitment and Consent

► Does your study **involve recruiting, obtaining consent or any other kind of subject intervention/interaction?** (This means research-related activity that involves *any* contact with participants, even a minimal intervention such as an anonymous survey.)

☒ **Yes**	→	***Complete all of [Part II: Subject Recruitment and Consent] below ("1. Recruitment" and "2. Consent").***
☐ **No***	→	***Skip [Part II: Subject Recruitment and Consent] and go to [Part III: Waiver of Informed Consent].*** * Answer "no" and skip to [PART III: Waiver of Informed Consent] if your study involves ONLY data collection without consent or without any other interaction with study participants.

1. RECRUITMENT

A. Please indicate your prospective subject pool (check all that apply):

☐ Patients from Sutter Health investigators' own medical practice at Sutter

☐ Patients from Sutter Health entities but outside investigators' own medical practice

☒ Sutter Health workforce members
☐ Sutter Health physicians
☐ Non- Sutter Health Patients
☐ Other (please explain):

B. What method(s) will be used to identify potential participants for the study (check all that apply)?
☐ Patient clinic visit
☐ Physician/provider (non-investigator) referral
☐ Database search. If checked, please answer the following:
(i) Please identify all databases(s) that will be used (e.g., EPIC):
(ii) Who will be conducting the data search (e.g., PI, CRC, data steward?):
☐ Patient (or other potential participant) response to advertisement/solicitation. If checked, please indicate type of solicitation (check all that apply):
☐ MyHealthOnline (MHO) message
☒ Email (other than via MHO)
☒ Advertisement (flyers, radio/TV/social media, sponsor or other study website)
☒ Other (please explain): see below

C. **Recruitment Procedures**: After potential participants are identified (via methods explained under B above), what will be the procedures for making initial contact to follow-up and initiate further recruitment and consent? Please provide a narrative of all procedures, in chronological, step-by-step fashion (starting with how potential subjects' contact information will be obtained and used). For each step, identify the individuals involved in these procedures by role (e.g., PI, Sub-I(s), investigators' regular clinical staff, research institute or research center staff, etc.). If non-Sutter Health personnel or entity will be involved, please be sure to make that explicit in your narrative.

Direct Mail to Employees Home
An IRB-approved letter will be sent from the Sutter Health mailroom to employees who work at each participating affiliate.

The flyer and all content described below will include a description of the study, phone number, email, and QR code an employee can use to seek additional information about participation.

Emails to Employees Using Distribution Lists
IRB-approved content will be sent from hospital leadership approved Distribution Lists.

Flyers Distributed in Affiliates
IRB-approved flyers and screen savers will be distributed to departments including the cafeteria.

Electronic Content
IRB-approved screen savers and content will be used to submit to affiliate and Sutter Health newsletters.

General Management Meetings and Town Halls
IRB-approved content will be used to present the study in different forums throughout each affiliate.

All methods of recruitment will be managed by a Clinical Research Coordinators employed by CPMCRI. QR code inquires will go directly to a recruitment instance of REDCap. Employees will answer questions to determine if they qualify and if so, they will provide an email if they would like to consent for the study. Contact information will be provided at all timepoints allowing an employee to seek additional information from a study team member.

D. Please describe any other recruitment methods or information you think is relevant to recruitment that has not been described above. If none, please put n/a: n/a

IMPORTANT ►
► *All recruitment materials (e.g., newspaper advertisements, flyers, posted signs, MHO messages) must be submitted for IRB approval prior to use.*
► *Any use or sharing of PHI for recruitment purposes without patient authorization prior to consent requires an IRB-approved HIPAA waiver, unless access to the PHI is limited to those who are already in a treatment relationship with the patient. To apply for a HIPAA waiver, please complete Section 4 of the Data Access Plan form.*

2. CONSENT

A. Will a signed informed consent form be obtained prior to study participation from study subjects or their legal representative?

☒ **Yes**	→	***Go to next question (B) and complete rest of this section (B-F)***
☐ **No**	→	***Skip rest of Part II; go to Part III.***

B. Who will be conducting the informed consent process? Please list all individuals by role (e.g., PI, Sub-I(s), investigators' regular clinical staff, research staff, etc.):

Informed consent will be conducted remotely using REDCap

C. Consent Process:
Describe the general procedures for obtaining consent, including the timing of obtaining consent (e.g., generally how much time will patients have to decide to participate?) and how subjects' comprehension of the study will be ensured. If electronic, video, telephonic, or other remote (not in-person) methods will be used, please include in your description:

Interested employees will seek information using multiple methods.

1. Employees may use their personal phone and scan the QR code. When they scan the QR code, they will be asked inclusion/exclusion criteria. If they qualify using this method, they will be asked to provide an email address so we may send an electronic consent via REDCap. If employees have any questions and concerns at any timepoint, they may contact the study team via email or phone number provided to seek additional information.
2. Employees may send an email or call the study team seeking to determine if they qualify. If so, the study team will email/call the employee and provide information about the study and review the inclusion/exclusion criteria. Upon meeting criteria, the study team will ask if the employee would like to be consented and if so, the employee will provide an email and the study team will send a consent via REDCap.

Prior to initiation of any study activities the completed informed consent document will be reviewed and verified by the study team. REDCap consent has been set up so that participants cannot submit unless a signature and date and all other fields are complete. We encourage all participants to call the listed phone number with any questions, concerns or clarification requests. Compliance and monitoring will be documented in REDCap.

D. Do you plan to enroll non-English speaking subjects?

Yes ☐ No ☒ Unknown at this time ☐

If yes:

(i) Which languages(s) other than English do you expect?

(ii) Please confirm you will use certified interpreters/translators and describe your plan for obtaining consent from these subjects (e.g., using translated versions of the IRB-approved consent form or short-form method?):

IMPORTANT ► *Full consent form should be translated into the participant's language whenever possible—particularly in the context of studies that involve investigational drugs and/or devices.* *Federal regulators and SHIRB discourage routine use of the short form method and you are advised to limit use of this mechanism to circumstances where translating the full consent form into the subject's language of fluency substantially impedes the ability to obtain a time-sensitive enrollment. For more information see SHIRB Guidance on Short Forms, accessible in IRBNet. Translated consents must be submitted to SHIRB for approval prior to use, along with the translator's certificate.*

E. Are minors eligible to be enrolled in the study at your site? Yes ☐ No ☒

If yes: Please explain the consent process for this population and whether a separate assent form will be used for this population:

F. Do you anticipate obtaining consent from legally authorized representatives (LAR)? Yes ☐ No ☒

If yes: please explain why and what procedures will be followed to determine when a subject does not have capacity for consent and when the use of an LAR is appropriate:

IMPORTANT ► *If planning on obtaining consent from an LAR, please consult the SHIRB Guidance on Surrogate Consent, accessible in IRBNet.*

Protocol Summary Form

PART III: Waiver of Informed Consent

IMPORTANT ► All studies please answer #1 below, and additional questions if applicable

1. Are you requesting a waiver of informed consent for any portion of your study? Please check the boxes below that are applicable to your study and follow directions as indicated:

☐ **Requesting waiver of obtaining a signed informed consent form. However, participants will be informed about the study and convey their consent verbally or in other ways (sometimes called "implicit consent" - for example, by taking a survey after reading an information sheet).** ⇨ **Complete #2 of this Part below.**
☐ **Requesting waiver of informed consent and participants will not be informed about the study. Informed consent will not be obtained, either written, verbal, or in any other way.** ⇨ **Complete #3 of this Part below.**
☒ **Neither of the above applies. The study will be obtaining a signed informed consent form from all study participants.** ⇨ **Skip the rest of this section and go to [Part IV: Other Comments].**

2. Request for waiver of obtaining signed informed consent form (also known as waiver of documentation of consent):

A. By regulations, an IRB may approve a waiver of signed consent form only if ONE of the following scenarios applies. Please check which of these applies to your research *(if neither applies to your research, please submit written consent form with IRB application)*:

☐ The consent form would be the only record linking the subject to the research and the principal risk would be potential harm resulting from a breach of confidentiality.

☐ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

B. If only verbal (or other type of non-written) consent is obtained, the IRB requires an information sheet to be given to potential participants describing the study and key information, *unless there are special circumstances justifying no information sheet*. Will you be using an information sheet?

Yes ☐ Please be sure to submit information sheet with your IRB application.
No ☐ **Please explain the reason(s) justifying no information sheet**:

3. **Informed consent will not be obtained, either written, verbal, or any other way. Requesting waiver of informed consent.** Please answer the following:

By regulations, an IRB may approve a waiver of consent only it if the research could not practicably be carried out without the waiver. Please explain why this criterion is met (that is, explain why the research would **NOT** be feasible if you were required to get consent (either written or verbal) from participants:

PART IV: Other Comments

If you have any comments about the study and/or clarifications to information submitted above that you would like the IRB to know about, please describe here.

NOTE: If you are submitting a separate sponsor protocol, please use this space to explain any parts of the protocol that will NOT be implemented at your site or other pertinent deviations (for example, if the sponsor protocol allows for enrollment of minors but you will only be enrolling adults; or if the protocol is phase 1/2 but you will only be implementing the phase 2 part).

If no other comments, please put n/a:
This study is a collaboration with UCSF. UCSF personnel are involved in study design, training of interns, and the analysis of de-identified data.
Laura Schmidt, PhD- Laura is a co-PI of the prime grant. She has oversite of the study and works closely with the team to ensure the methods and data collection are in alignment with the statistical analysis.
Laurie Jacobs, PhD- Laurie Jacobs participates in developing the data collection plan. She will review all of the de-identified data, send queries to CPMCRI team members. She will clean and code the data and run statistical analyses of the entire data set.
Elissa Epel, PhD is a co-PI of the grant. She has oversite of the study and is the leader of the motivational intervention.

Depression
The study team is using the PROMIS questionnaires for depression. Since the PROMIS depression does not have a question for suicidal ideation, the team would prefer to provide high scoring (severe) individuals with the contact number for EAP.

SUTTER HEALTH
INSTITUTIONAL REVIEW BOARD

Protocol Summary Form

NOTE: *CVs for all investigators must be submitted in IRBNet with your application unless previously submitted for an already approved SHIRB study. Depending on the nature of the study, upon review the IRB may request additional information on the investigator's background and qualifications to perform study procedures.*