



coupons for healthy intake
using variable economic strategies

Manual of Operational Procedures



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A randomized 312-subject behavioral intervention trial of effectiveness and cost-effectiveness of different food vouchers in a low-income population.

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STUDY OVERVIEW

Study Title

CHIVES: *A randomized 312-subject behavioral intervention trial of effectiveness and cost-effectiveness of different food vouchers in a low-income population.*

Aims

Primary Aim: Compare the effectiveness of alternative strategies for delivering food vouchers to low-income populations, as measured by consumption of fruits and vegetables. The alternative strategies are weekly versus monthly receipt of vouchers (with the same total monthly monetary value), and targeted (to fruits and vegetables) versus untargeted (eligible for any food purchase) vouchers.

Secondary Aim: Compare the cost-effectiveness of alternative food voucher delivery strategies for low-income populations.

Design

Design: This study is a randomized 312-subject behavioral intervention trial of effectiveness and cost-effectiveness of different food voucher assignments in a low-income population of adults ages 21 years and older. Participants will be randomly assigned to 6 months of one of four food voucher assignments.

Outcomes

Primary Outcome Measure:

- Individual self-reported change in fruit and vegetable intake (measured in cup-equivalents) at Month 6 of study participation, as compared to Month 0. Participant fruit and vegetable intake will be evaluated by two verbal 24-hour dietary recall assessments conducted over the phone with a diet assessor at each data collection time point (Month 0/Baseline, Month 6, and Month 12).

Secondary Outcome Measures:

- Individual self-reported change in fruit and vegetable intake (measured in cup-equivalents) at Month 12 of their study participation, as compared to Month 0. This measurement will reflect on fruit and vegetable intake 6 months after their final use of food vouchers, to determine maintenance of behavior change after cessation of food voucher receipt.
- Healthy Eating Index and Alternative Healthy Eating Index scores at Months 6 and 12, calculated from the 24-hour dietary recall data.
- Change in monthly food consumption cycle of overall consumption, comparing total calories and fruit and vegetable consumption in Week 4 versus Week 1 of Months 6 and 12, as compared to Month 0.
- Voucher utilization rate at Month 6. The percent of vouchers utilized by participants in each study arm will be calculated.

Other Outcome Measures:

- Voucher ease of use, assessed through of a verbal 20-minute survey conducted over the phone with a diet assessor at Month 6. Survey asks whether vouchers were easy to use and allow for free-text response of why or why not vouchers were easy to use.
- Fruit and vegetable acquisition, attitudes, and consumption, also assessed during aforementioned verbal 20-minute survey conducted over the phone with a diet assessor at Months 0, 6, and 12.
- Self-reported height and weight, also assessed during aforementioned verbal 20-minute survey conducted over the phone with a diet assessor at Months 0, 6, and 12.
- Participant food security status, also assessed during aforementioned verbal 20-minute survey conducted over the phone with a diet assessor at Months 0, 6, and 12. Questions include participation in nutritional assistance programs and the 6-item United States Department of Agriculture adult food security scale.

Schedule of Participant Flow & Outcome Measures

Timeframe	Month 0, \leq 4 th Week	Month 0, 4 th Week	Month 1, 1 st Week	Month 6, 1 st Week	Month 6, 4 th Week	Month 12, 1 st Week	Month 12, 4 th Week
	<i>Recruitment, Orientation, Consent, & Screening</i>	<i>Baseline Data Collection</i>	<i>Data Collection, Initiation of Voucher Utilization</i>	<i>End of Intervention Data Collection, Final Month of Voucher Utilization</i>	<i>End of Intervention Data Collection, Final Month of Voucher Utilization</i>	<i>6-month Follow Up Data Collection after final Voucher Utilization</i>	<i>6-month Follow Up Data Collection after final Voucher Utilization</i>
Participant Perspective	<ul style="list-style-type: none"> Recruited to participate in CHIVES Sign up for orientation Attend orientation, give informed consent to participate, & complete screening survey 	<ul style="list-style-type: none"> Deemed eligible to participate & contacted for baseline data collection Before voucher receipt & randomization Complete two 24-hour dietary recalls & baseline survey over the phone 	<ul style="list-style-type: none"> Receive randomized voucher assignment Receive in mail 1st month of vouchers after completing two 24-hour dietary recalls over the phone 	<ul style="list-style-type: none"> Use vouchers for final month in trial Complete two 24-hour dietary recalls & Month 6 survey over the phone 	<ul style="list-style-type: none"> Use vouchers for final month in trial Complete two 24-hour dietary recalls & Month 6 survey (if not already completed during 1st Week) over the phone Receive \$20 incentive for Month 6 data completion 	<ul style="list-style-type: none"> No vouchers used for past 6 months Complete two 24-hour dietary recalls & Month 12 survey over the phone 	<ul style="list-style-type: none"> No vouchers used for past 6 months Complete two 24-hour dietary recalls & Month 12 survey (if not already completed during 1st Week) over the phone Receive \$20 incentive for Month 12 data completion Final involvement in study participation
Evaluation Measures	<p>Two 24-hour dietary recalls (ideally one weekday + one weekend)</p> <p>F&V acquisition, attitudes, and consumption survey questions</p> <p>Participation in nutrition assistance programs survey questions (WIC/SNAP/EatSF)</p> <p>Participant food security status survey questions</p> <p>Self-reported height & weight, pregnancy / lactation status</p>	<p>Two 24-hour dietary recalls (ideally one weekday + one weekend)</p>	<p>Two 24-hour dietary recalls (ideally one weekday + one weekend)</p> <p>F&V acquisition, attitudes, and consumption survey questions*</p> <p>Participation in nutrition assistance programs survey questions (WIC/SNAP/EatSF) *</p> <p>Participant food security status survey questions*</p> <p>Self-reported height & weight, pregnancy / lactation status*</p> <p>Voucher ease of use survey questions*</p>	<p>Two 24-hour dietary recalls (ideally one weekday + one weekend)</p> <p>F&V acquisition, attitudes, and consumption survey questions*</p> <p>Participation in nutrition assistance programs survey questions (WIC/SNAP/EatSF) *</p> <p>Participant food security status survey questions*</p> <p>Self-reported height & weight, pregnancy / lactation status*</p> <p>Voucher ease of use survey questions*</p>	<p>Two 24-hour dietary recalls (ideally one weekday + one weekend)</p> <p>F&V acquisition, attitudes, and consumption survey questions*</p> <p>Participation in nutrition assistance programs survey questions (WIC/SNAP/EatSF) *</p> <p>Participant food security status survey questions*</p> <p>Self-reported height & weight, pregnancy / lactation status*</p> <p>Voucher ease of use survey questions*</p>	<p>Two 24-hour dietary recalls (ideally one weekday + one weekend)</p> <p>F&V acquisition, attitudes, and consumption survey questions*</p> <p>Participation in nutrition assistance programs survey questions (WIC/SNAP/EatSF) *</p> <p>Participant food security status survey questions*</p> <p>Self-reported height & weight, pregnancy / lactation status*</p>	<p>Two 24-hour dietary recalls (ideally one weekday + one weekend)</p> <p>F&V acquisition, attitudes, and consumption survey questions*</p> <p>Participation in nutrition assistance programs survey questions (WIC/SNAP/EatSF) *</p> <p>Participant food security status survey questions*</p> <p>Self-reported height & weight, pregnancy / lactation status*</p>

Sample Size, Covariate-Adaptive Randomization, and Population

Sample Size: We aim to have 312 total participants in this trial, with 78 participants assigned to each of the four intervention arms. Participants will be divided into six cohorts, with a goal of enrolling approximately 52 participants per cohort. We anticipate an 8% attrition rate, or plan for approximately 25 enrolled participants to be lost to follow up, or drop out of study, which would leave 288 participants with complete data for analysis.

Covariate-Adaptive Randomization: We will use covariate-adaptive randomization to place participants into their randomly assigned intervention arm by the following factors:

- Age
- Sex
- Race
- Ethnicity
- Income category
- Current Supplemental Nutrition Assistance Program (SNAP) / CalFresh participation status

Population: We anticipate that all participants at baseline will be: 21 years of age or older; residents of San Francisco who do not plan to move out of San Francisco within the next 12 months; free of cancer or congestive heart failure; not currently pregnant or breastfeeding; not concurrently participating in any other dietary or nutrition studies that would impact their normal eating patterns; not currently receiving EatSF vouchers; have a household income at $\leq 250\%$ of the federal poverty level; have regular access to a mobile phone with ability to send and receive text messages; and are willing to receive a random assignment to one of the four intervention arms. Although any resident of San Francisco is potentially eligible for the study, we anticipate that most participants will reside in San Francisco's Bayview neighborhood, based on where we plan to recruit for the study.

Interventions and Duration

Intervention arms:

Participants will be randomly assigned to one of the following four intervention arms:

- (1) *Monthly & Untargeted Food Vouchers*. Participants will receive four \$5 food vouchers per month (\$20/month) that are each valid for the entire calendar month. They are able to spend these food vouchers on any CalFresh/SNAP-eligible grocery item.
- (2) *Monthly & Targeted Food Vouchers*. Participants will receive four \$5 food vouchers per month (\$20/month) that are each valid for the entire calendar month. They are able to spend only on fresh and frozen fruits and vegetables with no added sugar or salt.
- (3) *Weekly & Untargeted Food Vouchers*. Participants will receive four \$5 food vouchers per month (\$20/month) that are each valid for a sequential Week* of the calendar month. They are able to spend these food vouchers on any CalFresh/SNAP -eligible grocery item.
- (4) *Weekly & Targeted Food Vouchers*. Participants will receive four \$5 food vouchers per month (\$20/month) that are each valid for a sequential Week* of the calendar month. They are able to spend only on fresh and frozen fruits and vegetables with no added sugar or salt.

Chart of intervention arms:

	Untargeted	Targeted
Monthly	<p><i>Monthly & Untargeted Food Vouchers</i></p> <ul style="list-style-type: none"> - Voucher Timeframe: 4 vouchers / month, each valid for 1 month - Voucher Exchangeable for: any CalFresh/SNAP-eligible grocery item - Voucher value: Each monthly food voucher worth \$5, total of \$20 / month 	<p><i>Monthly & Targeted Food Vouchers</i></p> <ul style="list-style-type: none"> - Voucher Timeframe: 4 vouchers / month, each valid for 1 month - Voucher Exchangeable for: any fresh and frozen fruits and vegetables with no added sugar or salt - Voucher value: Each monthly food voucher worth \$5, total of \$20 / month
Weekly	<p><i>Weekly & Untargeted Food Vouchers</i></p> <ul style="list-style-type: none"> - Voucher Timeframe: 4 vouchers / month, each valid for a sequential Week* - Voucher Exchangeable for: any CalFresh/SNAP-eligible grocery item - Voucher value: Each weekly food voucher worth \$5, total of \$20 / month 	<p><i>Weekly & Targeted Food Vouchers</i></p> <ul style="list-style-type: none"> - Voucher Timeframe: 4 vouchers / month, each valid for a sequential Week* - Voucher Exchangeable for: any fresh and frozen fruits and vegetables with no added sugar or salt - Voucher value: Each weekly food voucher worth \$5, total of \$20 / month

* Because most months are not exactly $7 \times 4 = 28$ days, we will label vouchers to clarify the exact dates over which a weekly voucher is valid. To ensure we consistently track the monthly food consumption cycle, Week 1 and Week 4 will always be 7 days. Then Weeks 2 and 3 will be split evenly among the remaining days.

Duration:

Each eligible candidate who chooses and consents to participate in the study will partake in the intervention for a total of 6 months. During this 6-month timeframe, each participant will receive and utilize food vouchers on a monthly basis and participate in specified data collection time points. All participants, regardless of whether they complete the 6-month intervention will also be asked to participate in a follow-up data collection period at 12 months after baseline, or 6 months after their participation in the intervention has ended (i.e., they have not received food vouchers for 6 months).

STUDY TEAM ROSTER

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- Contact Principal Investigator;
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- Aim 2: will oversee model design, programming and validation for cost-effectiveness analysis.

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Main responsibilities & roles:

- Logistics Principal Investigator;
- Aim 1: oversee voucher distribution and retention of vendors for the trial;
- Aim 2: inform modeling of impact of healthy eating on cardiovascular disease disparities for cost-effectiveness analysis

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Main responsibilities & roles:

- Aim 1: contribute staff, expertise, and supervision to ensure accurate and successful completion of dietary recalls and their analysis

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Main responsibilities & roles:

- Aim 1: will integrate economic and food environment data into the cost-effectiveness analysis for national projections

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- Aim 1: inform trial design and conduct; assist in recruitment, randomization, and retention strategy development and execution;
- Aim 2: inform cost-effectiveness analysis components

PROTOCOL CONTRIBUTOR *

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** In addition to Principal Investigators, the study coordinator was also a primary protocol contributor.*

PARTICIPATING STUDY SITES

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1 **STUDY AIMS**

Overall, this study tackles a stubborn scientific issue—the design and implementation of effective and cost-effective interventions for healthy eating among low-income populations—to reduce cardiovascular disease disparities.

1.1 Primary Aim: Determine the most effective food voucher design for significantly increasing participant consumption of fruits and vegetables by testing whether weekly vouchers are more effective than monthly vouchers, and whether targeted vouchers are more effective than untargeted vouchers.

Our benchmark for effectiveness will be to double the daily consumption of fruits and vegetables among our low-income participants at Month 6—from 0.7 to 1.4 cup-equivalents—meeting the Healthy People 2020 goal for fruit and vegetable consumption. Secondary end-points include metrics of overall dietary quality assessed through 24-hour dietary recalls at Months 0, 6 and 12 (6 months after vouchers end); and voucher utilization. Assessment months include Week 1 and Week 4 dietary recalls of a given month—testing the hypothesis that frequent vouchers smooth the monthly food consumption cycle. This improves upon trials where theorized mediators were rarely tested *a priori* with sufficient power. Additional surveys at Months 0, 6, and 12 will detect other moderators and mediators of effectiveness (food insecurity, CalFresh/SNAP participation, ease of voucher use, and fruit and vegetable attitudes) for future intervention refinement.

1.2 Secondary Aim: Calculate the cost-effectiveness of voucher programs.

Interventions that support healthy dietary intake reduce population-level cardiovascular disease disparities over the course of decades. Hence, the full benefits of such interventions are not possible to directly observe through time-limited trials. The lack of clarity about whether vouchers are cost-effective over the long term has hindered their wider adoption, according to a recent Institute of Medicine review. To address this gap, we will follow recent National Institutes of Health policy statements and apply an innovative, validated microsimulation modeling approach—a systems science method to integrate trial results with comprehensive data on the effect of dietary changes on cardiovascular disease outcomes and associated healthcare costs over the life course. We will estimate the cost-effectiveness of vouchers, identifying which voucher delivery strategies (monthly, weekly, untargeted, targeted) most cost-effectively reduce socioeconomic disparities in cardiovascular disease.

2 BACKGROUND AND RATIONALE

2.1 Background – how cardiovascular disease affects society.

This study tackles a stubborn scientific issue—how to design and implement cost-effective interventions to support healthy eating among low-income populations—in an effort to reduce cardiovascular disease disparities between low- and higher-income Americans. According to the Centers for Disease Control & Prevention, over 610,000 Americans die of heart disease every year, making heart disease responsible for approximately one in every four deaths. Cardiovascular disease is the leading cause of death for American men and women.

2.2 Study Rationale – how the CHIVES study tackles cardiovascular disease disparities.

Unhealthy diets are a key contributor to socioeconomic disparities in cardiovascular disease. Improving diets, particularly through increased fruit and vegetable (F&V) consumption, significantly reduces the risk of hypertension, obesity, type II diabetes, myocardial infarction, and stroke. Disparities in healthy diets are related to the accessibility and affordability of F&Vs. Yet federal food programs that aim to increase the accessibility and affordability of F&Vs among low-income Americans have been hindered by the food consumption cycle associated with poverty: the tendency to over-consume calorie-dense foods shortly after receiving funds at the beginning of each month, draining the budget for F&V purchases, or for all food purchases, by month's end. This food consumption cycle persists even if healthy foods are affordable and accessible.

Our study will inform the design of these existing federal food assistance programs in which 1 in every 7 Americans are enrolled. Such nutrition programs are currently under federal review. According to the Institute of Medicine, new research is needed to guide decisions about which program delivery strategies (e.g., weekly versus monthly, targeted versus untargeted) are most effective for improving dietary intake among program participants. Already, the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) and Senior Farmer's Market Nutrition Program have started providing monthly, targeted F&V vouchers, which significantly increased F&V consumption; however, maintenance of F&V consumption at 6 months was lowest (bordering on non-significance, $p=0.05$) among participants subject to continued food consumption cycling. These vouchers were never compared to weekly or untargeted vouchers. Additionally, many cities are starting to fund voucher programs that apply to supermarkets and corner stores, not just farmer's markets. A recent systematic review found that extant studies did not evaluate how such programs could address the food consumption cycle, or differential effects of targeted versus untargeted funding (given that substitution between food groups may critically affect the impact of targeted funds). Our study will address these major gaps in the literature using our two-by-two factorial study design and comprehensive 24-hour dietary recalls validated among low-literacy, community-dwelling populations.

To improve healthy eating interventions, we will directly address the food consumption cycle. Our preliminary data suggest that interventions helping low-income individuals transition from extreme cycles of consumption to more stable consumption patterns can improve overall dietary quality. The interventions utilize an emerging theory about dietary behavior: that providing funds for food in smaller installments (i.e., weekly) distributed throughout the month will smooth the food consumption cycle and improve healthy eating—counteracting the tendency to respond to lump sum, once-monthly funding installments by purchasing calorie-dense foods immediately

after funds are received. Consistent with our preliminary data, the theory implies that nutrition programs could use smaller, more frequent funding installments to reduce disparities in healthy eating. The theory also suggests that funds targeted toward specific healthy foods (e.g., F&Vs) will improve diets more than untargeted funds, despite the inconvenience of utilizing targeted funds. Our test of both hypotheses derived from this theory is of potentially high impact and timely, as 1 in 7 Americans are enrolled in nutrition programs that currently use monthly, untargeted funding approaches.

We will test these hypotheses in a real-world setting by comparing alternative approaches for delivering food purchasing vouchers. We have established the infrastructure to provide vouchers accepted by all major food stores, including supermarkets, corner stores, and farmer's markets in three San Francisco neighborhoods. We have successfully tested the voucher system among 250 low-income participants in a pilot study whose preliminary results support the theory. Leveraging this innovative and unique infrastructure, we will implement this randomized trial with a two-by-two factorial design, comparing \$20 of vouchers valid for one month to four \$5 vouchers each valid for a sequential week of the month (testing lump-sum versus distributed funding), and comparing vouchers restricted to F&V purchases to vouchers redeemable for any food (testing targeted versus untargeted funding). Low-income adults ($N=312$ with income $\leq 250\%$ federal poverty level) recruited through our community partners will be randomized to one of four 6-month voucher interventions balanced on time and attention from study staff: monthly untargeted, monthly targeted, weekly untargeted, or weekly targeted vouchers. Participants will be assessed for the primary outcome measure through efficient verbal 24-hour dietary recalls validated among low-literacy populations and verbal surveys to assess other moderators and mediators.

No known or potential risks are anticipated while the participant partakes in the 6-month intervention period. After the 6-month intervention period, participants may experience difficulty purchasing the same foods as during the intervention, as they will no longer receive the extra \$20 per month for foodstuffs.

3 STUDY DESIGN

Study Design. The CHIVES study is a two-by-two factorial design that randomly assigns participants to one of four food voucher assignments (monthly untargeted, monthly targeted, weekly untargeted, or weekly targeted). Diet assessors who are primary data collectors will be blinded to participant voucher assignment, as well as the study statistician and the study director. Only the participants and the study coordinator will not be blinded to participant voucher assignment. Study staff who are blinded will not be unblinded for any reason.

Outcomes.

Outcomes

Primary Outcome Measure:

- Individual self-reported change in fruit and vegetable intake (measured in cup-equivalents) at Month 6 of study participation, as compared to Month 0. Participant fruit and vegetable intake will be evaluated by two verbal 24-hour dietary recall assessments conducted over the phone with a diet assessor at each data collection time point (Month 0/Baseline, Month 6, and Month 12).

Secondary Outcome Measures:

- Individual self-reported change in fruit and vegetable intake (measured in cup-equivalents) at Month 12 of their study participation, as compared to Month 0. This measurement will reflect on fruit and vegetable intake 6 months after their final use of food vouchers, to determine maintenance of behavior change after cessation of food voucher receipt.
- Healthy Eating Index and Alternative Healthy Eating Index scores at Months 6 and 12, calculated from the 24-hour dietary recall data.
- Change in monthly food consumption cycle of overall consumption, comparing total calories and fruit and vegetable consumption in Week 4 versus Week 1 of Months 6 and 12, as compared to Month 0.
- Voucher utilization rate at Month 6. The percent of vouchers utilized by participants in each study arm will be calculated.

Other Outcome Measures:

- Voucher ease of use, assessed through of a verbal 20-minute survey conducted over the phone with a diet assessor at Month 6. Survey asks whether vouchers were easy to use and allow for free-text response of why or why not vouchers were easy to use.
- Fruit and vegetable acquisition, attitudes, and consumption, also assessed during aforementioned verbal 20-minute survey conducted over the phone with a diet assessor at Months 0, 6, and 12.
- Self-reported height and weight, also assessed during aforementioned verbal 20-minute survey conducted over the phone with a diet assessor at Months 0, 6, and 12. Participant food security status, also assessed during aforementioned verbal 20-minute survey conducted over the phone with a diet assessor at Months 0, 6, and 12. Questions include participation in nutritional assistance programs and the 6-item United States Department of Agriculture adult food security scale.

Study Population. We anticipate that all participants at baseline will be: 21 years of age or older; residents of San Francisco who do not plan to move out of San Francisco within the next 12 months; free of cancer or congestive heart failure; not currently pregnant or breastfeeding; not concurrently participating in any other dietary or nutrition studies that would impact their normal eating patterns; not currently receiving EatSF vouchers; have a household income at $\leq 250\%$ of the federal poverty level; have regular access to a mobile phone with ability to send and receive text messages; and are willing to receive a random assignment to one of the four intervention arms. Although any resident of San Francisco is potentially eligible for the study, we anticipate that most participants will reside in San Francisco's Bayview neighborhood, based on where we plan to recruit for the study.

Sample Size. We aim to have 312 total participants in this trial, with 78 participants assigned to each of the four intervention arms. Participants will be divided into six cohorts, with a goal of enrolling approximately 52 participants per cohort. We anticipate an 8% attrition rate, or plan for approximately 25 enrolled participants to be lost to follow up or drop out of study, which would leave 288 participants with complete data for analysis.

The study director calculated a 265-participant sample size minimum using G*Power software, aiming for a sample size that would give us 90% statistical power to detect two main effects (weekly versus monthly, targeted versus untargeted), and their interaction (F-test using ANCOVA with baseline F&V intake as the main covariate), assuming a moderate Cohen's $d = 1.4$ effect size. Thus, taking into account up to a 15% participant attrition rate, we aim to enroll 312 participants so that we have sufficient statistical power for our analyses.

In sum, for optimal statistical power ($\geq 90\%$), our goal will be to recruit 312 participants. For a less ideal statistical power ($\geq 80\%$), we will aim to recruit at the very minimum 236 participants.

Intervention arms. Participants will be randomly assigned to one of the following four intervention arms:

- (1) *Monthly & Untargeted Food Vouchers.* Participants will receive four \$5 food vouchers per month (\$20/month) that are each valid for the entire calendar month. They are able to spend these food vouchers on any CalFresh/SNAP-eligible grocery item.
- (2) *Monthly & Targeted Food Vouchers.* Participants will receive four \$5 food vouchers per month (\$20/month) that are each valid for the entire calendar month. They are able to spend only on fresh and frozen fruits and vegetables with no added sugar or salt.
- (3) *Weekly & Untargeted Food Vouchers.* Participants will receive four \$5 food vouchers per month (\$20/month) that are each valid for a sequential Week* of the calendar month. They are able to spend these food vouchers on any CalFresh/SNAP-eligible grocery item.
- (4) *Weekly & Targeted Food Vouchers.* Participants will receive four \$5 food vouchers per month (\$20/month) that are each valid for a sequential Week* of the calendar month. They are able to spend only on fresh and frozen fruits and vegetables with no added sugar or salt.

Chart of intervention arms:

	Untargeted	Targeted
Monthly	<p><i>Monthly & Untargeted Food Vouchers</i></p> <ul style="list-style-type: none"> - Voucher Timeframe: 4 vouchers / month, each valid for 1 month - Voucher Exchangeable for: any CalFresh/SNAP-eligible grocery item - Voucher value: Each monthly food voucher worth \$5, total of \$20 / month 	<p><i>Monthly & Targeted Food Vouchers</i></p> <ul style="list-style-type: none"> - Voucher Timeframe: 4 vouchers / month, each valid for 1 month - Voucher Exchangeable for: any fresh and frozen fruits and vegetables with no added sugar or salt - Voucher value: Each monthly food voucher worth \$5, total of \$20 / month
Weekly	<p><i>Weekly & Untargeted Food Vouchers</i></p> <ul style="list-style-type: none"> - Voucher Timeframe: 4 vouchers / month, each valid for a sequential Week* - Voucher Exchangeable for: any CalFresh/SNAP-eligible grocery item - Voucher value: Each weekly food voucher worth \$5, total of \$20 / month 	<p><i>Weekly & Targeted Food Vouchers</i></p> <ul style="list-style-type: none"> - Voucher Timeframe: 4 vouchers / month, each valid for a sequential Week* - Voucher Exchangeable for: any fresh and frozen fruits and vegetables with no added sugar or salt - Voucher value: Each weekly food voucher worth \$5, total of \$20 / month

* *Because most months are not exactly $7 \times 4 = 28$ days, we will label vouchers to clarify the exact dates over which a weekly voucher is valid. To ensure we consistently track the monthly food consumption cycle, Week 1 and Week 4 will always be 7 days. Then Weeks 2 and 3 will be split evenly among the remaining days.*

Study location. This study is taking place in a community setting. Participants and participating vendors will be recruited from the Bayview area – a southeastern neighborhood of San Francisco, California. The study office will also be located in the Bayview neighborhood at 1485 Bayshore Boulevard, a central location for residents. While participants are permitted to be residentially located outside of the Bayview neighborhood, they must have a primary address from the city of San Francisco, and all will be required to redeem food vouchers at one of the local participating Bayview, SoMa, or Tenderloin vendor locations.

Approximate duration of enrollment period and follow-up. Each eligible candidate who chooses and consents to participate in the study will partake in the intervention for a total of 6 months. During this 6-month timeframe, each participant will receive and utilize food vouchers on a monthly basis and participate in specified data collection time points. All participants, regardless of whether they complete the 6-month intervention will also be asked to participate in a follow-up data collection period at 12 months after baseline, or 6 months after their participation in the intervention has ended (i.e., they have not received food vouchers for 6 months).

Recruitment and enrollment for the study as a whole will begin in December 2016 and last through approximately July 2017. However, a small pilot trial of $N=5$ participants will begin in late October 2016 to allow our team to become aware of and work through any issues that arise before the official study starts a few months later. The intervention period will begin in January 2017, in which data collection and voucher distribution will begin in the fourth calendar week of the month. We will aim to enroll six distinct cohorts, each consisting of 52 participants per month starting in January 2017, until the final goal of 312 participants is reached in June 2017. Each cohort of participants will be enrolled in the study for a total of 12 months, the first 6 months of which they will actively participate in the intervention and receive food vouchers, and the final 6 months of which they will no longer be in the intervention and no longer receive food vouchers, but will be asked to complete one final round of data collection at 12 months for follow up.

Description of intervention and administration. The intervention primarily entails participant's utilization of assigned food vouchers throughout their six months of study participation. Study staff will mail food vouchers to participants at the end of each of the six months to spend for the following month. Participants will then be expected to spend their four monthly food vouchers at approved vendors within the timeframe they are valid. During the sixth month of the intervention period, diet assessors will contact each participant to complete the Month 6 data collection.

Randomization. Once participants have consented, taken screening survey, been deemed eligible, and completed first part of Baseline/Month 0 assessment (two 24-hour dietary recalls and baseline survey), participants will be randomly assigned by covariate-adaptive randomization to one of the four voucher group assignments through a statistical minimization process based on the baseline survey data stored in our online database management program REDCap. The study statistician will generate these randomized group assignments for each participant, which he will be uploaded into REDCap. Each participant will then automatically have a group assignment visible under their REDCap profile page (Groups 1 through 4). The study coordinator will have the key for which study group (monthly/weekly and untargeted/targeted) corresponds with each group

number. This will remain concealed from the statistician and staff during the intervention. Staff will only see that participant are assigned to Groups 1, 2, 3, or 4.

Blinding. The study coordinator will be unblinded to participant voucher assignment because she will translate which group number represents which voucher group when preparing to mail vouchers. Since participants have to know which voucher assignment they receive in order to participate in the program, they will not be blinded either. However, diet assessors who collect data at each time point will be blinded to participant voucher assignment, as will the study statistician and study director, to prevent any bias or predisposition to a certain outcome. Study staff who are blinded will not be unblinded for any reason.

Covariate-adaptive randomization. We will randomize participants into their assigned intervention arm by balancing across the following factors in each cohort of 52 participants:

- Age
- Sex
- Race
- Ethnicity
- Income category
- Current Supplemental Nutrition Assistance Program (SNAP) / CalFresh participation status

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

The study director has chosen the following inclusion and exclusion criteria in order to select for a reasonably representative sample of the populations and are characteristics that will allow for sufficient generalizability.

4.1 Inclusion Criteria. Participants must meet all of the following inclusion criteria to participate in this study; each participant must:

- Be age 21 years or older;
- Have self-reported household income $\leq 250\%$ of the federal poverty level;
- Have regular access to a mobile phone with ability to send and receive text messages;
- Understand English sufficiently to provide informed consent;
- Be a resident of the City of San Francisco as defined by official municipal boundaries;
- Be willing to be randomized to one of four food voucher assignments.

4.2 Exclusion Criteria. All candidates who meet any of the exclusion criteria at baseline will be excluded from study participation. If candidates are found to meet any of the exclusion criteria at the Month 6 or Month 12 surveys but not at the Month 0 survey, they will be included in the intent-to-treat analysis but a robustness check will be performed with their exclusion. Any candidate will be excluded at baseline if he/she is found to:

- Currently be participating in any other dietary or nutrition studies that would impact their normal eating patterns;
- Currently receiving EatSF vouchers;
- Currently have diagnosed cancer or congestive heart failure;
- Be planning to move out of San Francisco in the next year;
- Currently pregnant or breastfeeding.

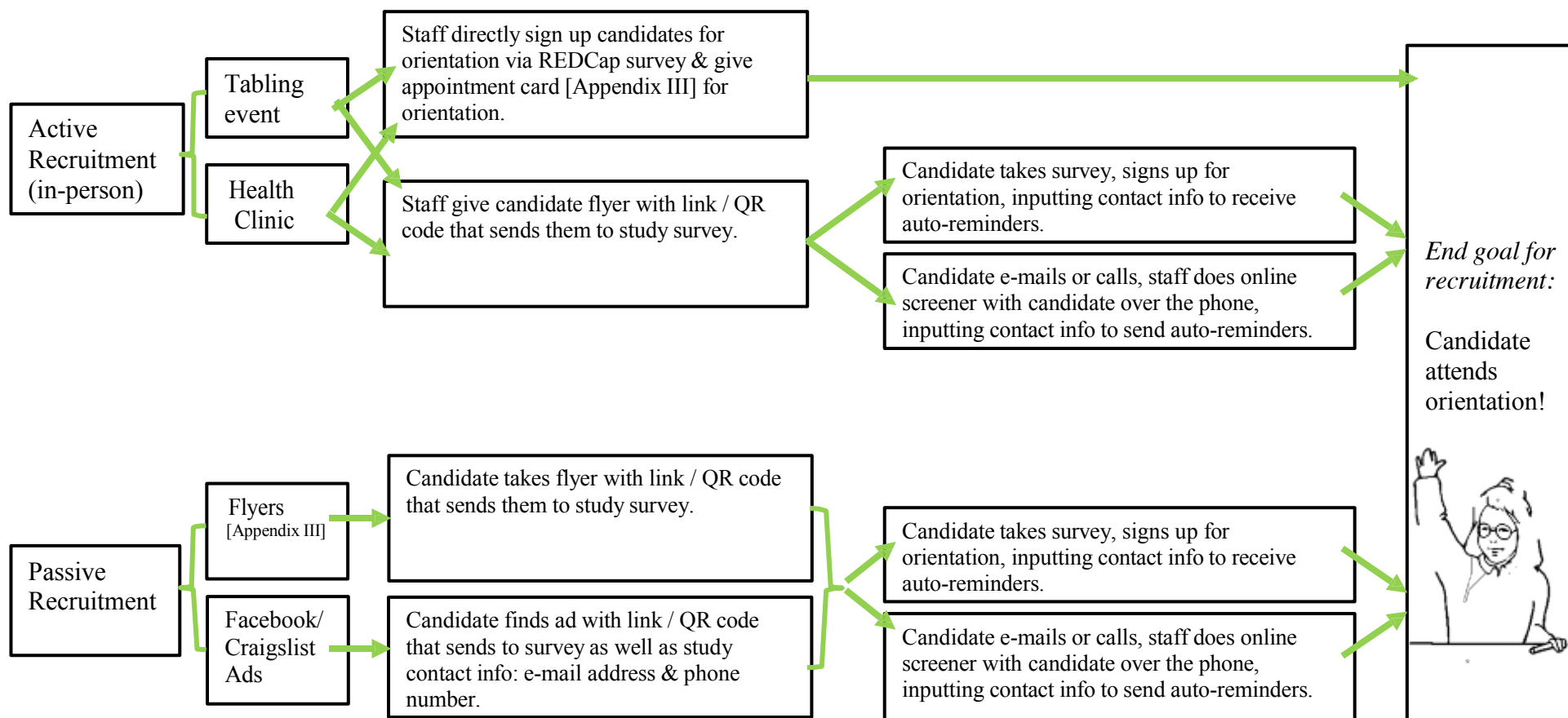
4.3 Study Enrollment Procedures

Recruitment strategy. As this is a community-based intervention, we aim to recruit participants where they most frequent within the Bayview neighborhood and plan to use a variety of strategies to recruit potential study participants. Our planned recruitment strategy includes the following:

- *“Tabling” at important community places & events.* Have two to three study staff standing at a table with banner, flyers, and study information that invites questions and candidates to sign up for orientation.
 - Table at frequented local grocery stores;
 - Table at local health clinics;
 - Table at 3rd on 3rd community event – community block party on 3rd Street every third Friday of the month (10/21/2016, 11/18/2016, 12/16/2016, 1/20/2017, 2/17/2017, 3/17/2017, 4/21/2017, 5/19/2017, 6/16/2017, 7/21/2017).
- *Posting flyers at frequented community places.* Use simple, attention-grabbing flyers with pull-off tabs with study survey link as well as Quick Response (QR) code to study survey [Appendix III].

- Local grocery stores & corner stores;
- Local health clinics;
- YMCA;
- Local community pool;
- City College San Francisco on Oakdale Avenue;
- Bayview Library;
- Faith-based organizations;
- SF Food Bank & food pantries;
- Laundromats.
- *Posting Facebook & Craigslist advertisements.* Create simple, attention-grabbing advertisements for targeted demographic on Facebook, and under “gigs” and/or “volunteer” section of Craigslist on a weekly basis.
- *Partnering with community advocates.* Announce study, pass out flyers at community meetings (BMAGIC & Bayview HealZone), and ask for feedback, support, and/or recruitment ideas every third Tuesday of the month (12/20/2016, 1/17/2017, 2/21/2017, 3/21/2017, 4/18/2017, 5/16/2017, 6/20/2017, 7/18/2017).

Recruitment flow. Once candidates are either actively recruited through a tabling event or community partner, or they read about the study through flyer or advertisement, they will:



From recruitment to orientation. Orientations will be in a group format with 10 to 15 study candidates and last approximately 60 minutes. The purpose of the orientation will be to relay to candidates a clear understanding of what the study entails, the benefits and risks of participating, the possibility of being randomized into any one of four food voucher assignment groups, and what would be expected of them should they choose to participate. The study coordinator and/or study staff will lead the orientations using the visual aid of a PowerPoint presentation as well as a study expectations handout [Appendix VII] and Food Amounts Booklet [Appendix VIII] for dietary recalls for each attendee. At the end of the orientation presentation, the study staff who is presenting will lead candidates through consent form and screening survey page by page. Then, candidates will read through and sign the consent, HIPAA, and Personal Health Information forms [Appendix V] and complete a self-administered screening survey [Appendix VI], during which study staff will be available to answer any questions. As each candidate leaves orientation, study staff will review all paperwork to assess for completeness. After orientation, study staff will determine whether orientation attendees are eligible to participate based on their answers to the self-administered screening survey.

Determining participant eligibility & next steps. If study staff determine that candidates meet *all* of the inclusion criteria and do not meet any of the exclusion criteria, study staff will mark them as eligible in REDCap. REDCap will then send an automated text message to inform them they are eligible to participate and that they will begin completing the baseline data collection.

Determining candidate ineligibility & next steps. If study staff determines that any candidate does not meet *all* of the inclusion criteria or meets any of the exclusion criteria, REDCap will send an automated text message to inform them there are not eligible at this time, and to please contact us with any questions. Study staff will not disclose the reason(s) for ineligibility. In addition, if the candidate is not eligible specifically due to being pregnant or currently breastfeeding, study staff will mail any of these ineligible pregnant or breastfeeding candidates a food resources handout [Appendix IX] to ensure she is hooked into available community services (WIC, EatSF, etc.) Additionally, *any* candidate deemed ineligible will be mailed two \$5 EatSF vouchers to thank them for their time, as well as a handout referring them to EatSF website and EatSF project office at San Francisco General Hospital to encourage them to determine whether they are eligible to participate in the EatSF program [Appendix IX]. Because there are a finite number of EatSF vouchers to distribute to ineligible CHIVES candidates, study staff must track each ineligible participant who is mailed EatSF vouchers in the Google Sheet [“Tracking of ineligible participants & EatSF voucher distribution”](#) by REDCap Record ID. No personal health information will be tracked in the Google Sheet. Currently UCSF has budgeted for 75 EatSF vouchers, or enough EatSF vouchers for approximately 37 ineligible candidates.

Ineligible participant count	REDCap Record ID	EatSF Voucher #1 Serial Number	EatSF Voucher #2 Serial Number	Recorded in REDCap?
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“Tracking of ineligible participants & EatSF voucher distribution” Google Sheet

Tracking of eligible participants & ineligible candidates. All candidates who attend orientation and complete screening survey will be recorded in REDCap. If any candidate is deemed ineligible to participate in the study, study staff will record the reason for exclusion in REDCap (*optional reasons*: did not meet inclusion criteria, declined to participate, or specify other reasons for ineligibility). Study staff will mark in REDCap whether any ineligible pregnant or breastfeeding candidate was mailed the appropriate food resources handout [Appendix IX], and whether all other ineligible candidates were mailed two \$5 EatSF vouchers and a handout referring them to EatSF program [Appendix IX]. Any candidate that is deemed eligible to participate will also be tracked in REDCap as they complete baseline data collection, are then randomized, and receive the first month of vouchers.

Change in participation status. If, at any point, participant status should change (e.g., participant chooses to drop out or cannot be reached), study staff will record this in either REDCap Project (CHIVES Screening Candidates or CHIVES Main Project, depending on when the participant drops out) under the “Status” instrument form with a clear reason as to why participant chose to drop out of study. Careful tracking of candidates and participants in study will ensure that the study always conforms with the CONSORT guidelines.

Record ID	13
If participant status changes for ANY REASON after they are told they are eligible to participate in CHIVES (i.e., participant chooses to drop or withdraw from study, or we choose to withdraw them from study), please use this form to record any changes in their status.	
What date did the participant's status in CHIVES change? <small>* must provide value</small>	<input type="text" value="12-09-2016"/> <input type="button" value="Today"/> <input type="button" value="M-D-Y"/>
At what point in the study did this take place? <small>* must provide value</small>	<input type="text" value="Month 1 of intervention"/>
Who made this decision? <small>* must provide value</small>	<input type="text" value="Participant"/>
Why did participant's status change? [Why did they withdraw, or why are we withdrawing them from study?] <small>* must provide value</small>	<input type="checkbox"/> Participant told us they moved out of SF <input checked="" type="checkbox"/> Participant told us they no longer wished to participate <input type="checkbox"/> We received returned mail / vouchers <input type="checkbox"/> We received zero response from participant during data collection periods after multiple attempts to contact them <input type="checkbox"/> Participant demonstrated unacceptable or dangerous behavior with store vendor <input type="checkbox"/> Other
If this participant contacted CHIVES directly to withdraw, are they okay with being contacted for Month 6 or Month 12 data collection? <small>* must provide value</small>	<input type="text" value="No, they no longer wish to be contacted for any rea"/>
Status Notes:	<input type="text"/>

“Status” REDCap instrument

Randomization procedure for assigning an eligible participant to an intervention group. Once eligible participants complete Month 0/Baseline survey data collection over the phone with study staff (and staff have entered, simultaneously with the phone call, the data into REDCap), the study coordinator will notify the statistician, who will run a randomization program using covariates (age, sex, race, ethnicity, income category, and current SNAP / CalFresh participation status). The statistician will perform covariate-adaptive randomization to minimize differences in these covariates among individuals when randomizing participants into each of the four intervention arms, using blinded labels (Group 1, Group 2, Group 3, or Group 4), and will upload the assignments under each participant REDCap record ID number into REDCap. Only the study coordinator will know which group number corresponds to which intervention arm (monthly untargeted, monthly targeted, weekly untargeted, or weekly targeted).

5 STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

Description of intervention and administration. The primary intervention is the participant's utilization of assigned food vouchers throughout the six months of their study participation. From an administrative standpoint, there is no anticipated differential treatment to participants, based on the arm of the intervention to which a participant is assigned. Regardless of which arm of the intervention any given participant is assigned, he/she will go through virtually the same procedures to receive and spend vouchers that any other participant will, with balanced time and attention from study staff across all four intervention groups. Study staff will mail appropriate food vouchers to participants at the end of each of the six months to spend for the following month.

Month 1 of food voucher distribution. The first month of food vouchers will be mailed along with "How to Use Vouchers & List of Store Vendors" Handout [Appendix X] after participants have completed all baseline data collection. Participants will then be expected to spend their four monthly food vouchers at approved Bayview, SoMa, and Tenderloin vendors within the timeframe for which they are valid; these dates will be hand-stamped in the "start date" and "end date" boxes on every food voucher. Study staff will track all mailed food vouchers in REDCap with date, time, staff name, and any relevant comments.

Which month of vouchers were prepared? <small>* must provide value</small>	<input type="radio"/> Month 1 <input type="radio"/> Month 2 <input type="radio"/> Month 3 <input type="radio"/> Month 4 <input type="radio"/> Month 5 <input type="radio"/> Month 6 <input type="radio"/> Other Month
This is the 1st month the participant will receive vouchers.	<input type="radio"/> Yes <input type="radio"/> No
Was the Month 1 handout included in their voucher envelope? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No
This is the 5th month the participant will receive vouchers.	<input type="radio"/> Yes <input type="radio"/> No
Was the Month 5 handout included in their voucher envelope? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No
If other month, please specify: <small>* must provide value</small>	<input type="text"/>
Who prepared this participant's vouchers? <small>* must provide value</small>	<input type="checkbox"/> Carrie <input type="checkbox"/> Lindsay <input type="checkbox"/> Liz <input type="checkbox"/> Mandy <input type="checkbox"/> Melissa <input type="checkbox"/> Sanjay <input type="checkbox"/> Sarah <input type="checkbox"/> Other
When were the vouchers prepared? <small>* must provide value</small>	<input type="text"/> <small>31</small> Today M-D-Y
When were the vouchers mailed? <small>* must provide value</small>	<input type="text"/> <small>31</small> Today M-D-Y

"ADMIN: Mailing Vouchers Monthly" REDCap instrument

Months 2 through 6 of food voucher distribution. For all subsequent intervention months (Month 2 through Month 6), study staff will simply continue to mail one month's worth of vouchers during the last week of the month before which the food vouchers are valid (e.g., study staff will mail out March food vouchers during the last week of February). Study staff will record in REDCap the date, time, staff name, and any relevant comments in regards to all food vouchers that are sent via mail. During Month 5 of the intervention, study staff will include a handout [Appendix XI] for participants, reminding them about the upcoming data collection period and that Month 6 will be their final month of receiving vouchers.

Month 6 data collection. During the sixth and final month of the intervention period, diet assessors will contact each participant to complete the Month 6 data collection pieces (recalls and surveys) during the 1st and 4th Week of that final intervention month. The recalls and surveys will be scheduled according to the participant's indicated availability on screening survey [Appendix VI]. Also, while in theory it would be less participant burden and ensure data completeness to combine the surveys with one of the four dietary recall phone calls, the dietary recalls and surveys may be completed during separate phone calls. Diet assessors will inquire when the participant would like to complete the survey during the first phone call.

Month 12 data collection. After the Month 6, participants will no longer receive any food vouchers, and will not be considered part of the active intervention. However, diet assessors will contact them during the 1st and 4th Weeks of Month 12 from baseline to complete final set of data collection.

5.2 Handling of Study Interventions

Food voucher administration & distribution. Vouchers will be mailed to participants on a monthly basis for six months.

Timing of food voucher preparation.

For cohorts that are beginning the CHIVES Project, i.e., will be receiving Month 1 of vouchers, study staff will prepare their vouchers toward the end of Month 1 Week 1 (ideally on 8th or 9th day of any given month, as Month 1 Week 1 data collection is wrapping up).

For cohorts that are continuing with the CHIVES Project, i.e., will be receiving Months 2 through 6 of vouchers, study staff will prepare their vouchers during Weeks 2 or 3 of each month (ideally between data collection periods). These must be finished and mailed out several days before the end of each month so that participants will receive their vouchers by the 1st of the month at the latest.

Study Coordinator Instructions for Unblinding Food Voucher Assignment:

- 1) During Weeks 2 and 3 of each month, the study coordinator will download the “Mailing Vouchers” REDCap report from CHIVES Main Project with the following information: first name, last name, street address, apartment number, city, state, zip code, CHIVES ID, blinded food voucher assignment (Group 1, 2, 3, or 4), and cohort into a .csv file.

first_name	last_name	street_address	apt_number	city	state	zipcode	chives_id	randomize_group	elig_cohort
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“Mailing Vouchers” REDCap Report – column headers

- 2) The study coordinator will save this originally downloaded file as: “[Month] Mailing Vouchers with addresses,” for example: “February Mailing Vouchers with addresses.”

- 3) The study coordinator will delete the randomize_group column, convert all ‘1’ values under state column to “CA,” and check that all city values are “San Francisco,” as opposed to “SF” or “SAN Francisco.”

first_name	last_name	street_address	apt_number	city	state	zipcode	chives_id	elig_cohort
Mandy	Test	3367 17th Street		San Francisco	CA	94110	CP1001	1
Mandy	Test2	3367 17th Street		San Francisco	CA	94110	CP1005	1

“[Month] Mailing Vouchers with addresses” saved file to later use for generating address labels

- 4) The study coordinator will sort data by apt_number column. This will put any entries that have an apartment number together at the top of the excel sheet.

record_id	first_name	last_name	street_address	apt_number	city	state	zipcode	chives_id	elig_cohort
10	Mandy	Test2	123 Main Street	313	San Francisco	CA	84096	CP1002	1
9	Mandy	Test	123 Park Place	2-208	San Francisco	CA	94403	CP1001	1
12	Test	Mandy Test	3367 17th Street		San Francisco	CA	94102	CP1003	1
13	Mandy	Test	3367 17th Street		San Francisco	CA	94110	CP1004	1

“[Month] Mailing Vouchers with addresses” file sorted by apt_number.

- 5) The study coordinator will insert a column to the left of the apt_number column and name this column “apt.” The study coordinator will add the word “Apt.” next to only the rows with any value entered for apartment number.

record_id	first_name	last_name	street_address	apt	apt_number	city	state	zipcode	chives_id	elig_cohort
10	Mandy	Test2	123 Main Street	Apt.	313	San Francisco	CA	84096	CP1002	1
9	Mandy	Test	123 Park Place	Apt.	2-208	San Francisco	CA	94403	CP1001	1
12	Test	Mandy Test	3367 17th Street			San Francisco	CA	94102	CP1003	1
13	Mandy	Test	3367 17th Street			San Francisco	CA	94110	CP1004	1

“[Month] Mailing Vouchers with addresses” file with inserted “apt” column and the word “Apt.” next to all entries with anything entered for apartment number.

- 6) The study coordinator will sort the data one final time by chives_id column, so that all participants are in numerical order by their CHIVES ID. The study coordinator will save and close the file, which will later be used to prepare address labels with Avery software.

record_id	first_name	last_name	street_address	apt.	apt_number	city	state	zipcode	chives_id	elig_cohort
9	Mandy	Test	123 Park Place	Apt.	2-208	San Francisco	CA	94403	CP1001	1
10	Mandy	Test2	123 Main Street	Apt.	313	San Francisco	CA	84096	CP1002	1
12	Test	Mandy Test	3367 17th Street			San Francisco	CA	94102	CP1003	1
13	Mandy	Test	3367 17th Street			San Francisco	CA	94110	CP1004	1

“[Month] Mailing Vouchers with addresses” file sorted by chives_id.

- 7) Now the study coordinator will open the original CSV file downloaded from REDCap (in downloads folder) and will delete all columns with contact information (name & address columns), leaving only the chives_id column, the randomize_group, and elig_cohort columns. The study coordinator will then sort the data by group number (randomize_group):

chives_id	randomize_group	elig_cohort
CP1001	1	1
CP1006	1	1
CP1010	2	1
CP1028	2	1
CP1030	2	1
CP1020	3	1
CP1029	3	1
CP1023	4	1
CP1027	4	1
CP1031	4	1

“Mailing Vouchers” REDCap Report – sorted by randomize_group with no contact information.

- 8) The study coordinator will then convert (unblind) the group number to actual voucher assignment (monthly CalFresh, monthly fruits & vegetables, weekly CalFresh, weekly fruits & vegetables), separate each of these food voucher assignment groups onto a different tab within the excel file, and save this as a new file: “[Month] Mailing Vouchers unblinded,” for example, “February Mailing Vouchers unblinded.”

chives_id	randomize_group	elig_cohort
CP1001	1	1
CP1006	1	1

▶ monthly F&V weekly CalFresh weekly F&V monthly CalFresh

chives_id	randomize_group	elig_cohort
CP1010	2	1
CP1028	2	1
CP1030	2	1

▶ monthly F&V weekly CalFresh weekly F&V monthly CalFresh

chives_id	randomize_group	elig_cohort
CP1020	3	1
CP1029	3	1

▶ monthly F&V weekly CalFresh weekly F&V monthly CalFresh

chives_id	randomize_group	elig_cohort
CP1023	4	1
CP1027	4	1
CP1031	4	1

▶ monthly F&V weekly CalFresh weekly F&V monthly CalFresh

Study coordinator’s new excel file “[Month] Mailing Vouchers unblinded” with CHIVES ID, group number, and cohort matched to unblinded voucher assignment, each on a separate tab.

Please note: these are not actual unblinded voucher assignments. This is merely an example.

- 9) The study coordinator will insert a row at the top of each sheet, and write in what each of the four sheets represents (e.g., “Monthly F&V”).

A	B	C	D	E	F
Wrap Text	randomize_group	elig_cohort			
Monthly F&V					
CP1001		1	1		
CP1006		1	1		

monthly F&V weekly CalFresh weekly F&V monthly CalFresh

“[Month] Mailing Vouchers unblinded” file with inserted voucher assignment as header.

- 10) The study coordinator will then delete the randomize_group column from each of the four tabs. The only two columns on each sheet to be printed out are the chives_id column and elig_cohort column.

chives_id	elig_cohort
Monthly F&V	
CP1001	1
CP1006	1

monthly F&V weekly CalFresh weekly F&V monthly CalFresh

“[Month] Mailing Vouchers unblinded” file with only CHIVES ID and cohort columns, ready for print.

- 11) Finally, the study coordinator will print four different lists of all active study participants by unblinded food voucher assignment (monthly CalFresh, monthly fruits & vegetables, weekly CalFresh, weekly fruits & vegetables). Each list will contain all active study participants in one of the food voucher assignments.

Study Staff Instructions for Voucher Preparation:

Next, study staff will divide the blank food vouchers into four different piles by type: monthly fruits & vegetables, weekly CalFresh, weekly fruits & vegetables, and monthly CalFresh. The fruits & vegetables versus CalFresh voucher are distinguished by color: the former are green, and the latter are orange. Study staff will each take one of the four lists of study participants that correspond to the correct food voucher type and proceed to write each CHIVES ID on a total of **four** vouchers in the six boxes under “Participant #.”

handwritten 6-digit study id

food voucher type: untargeted or targeted

stamped start date for which specified food voucher is valid

stamped end date for which specified food voucher is valid

Participant #:

First day to use:

Last day to use:

Vendor:

VALID FOR: Any fresh or frozen fruits and vegetables (including pre-packaged). No added sugar or salt.

VÁLIDO PARA: Cualquier frutas y vegetales frescos o congelados (incluyendo preenvasados) sin azúcar o sal.

THE CHIVES PROJECT

EXACT PURCHASE PRICE MUST NOT EXCEED \$5.00

NOT REDEEMABLE FOR CASH

EatSF

For questions please call 1-800-4-CHIVES or email chivesproject@stanford.edu

Customer signature

Date

Sample blank fruit & vegetable food voucher.

Once study staff have hand-written all CHIVES IDs on food vouchers, they will then proceed to stamp the correct dates for which each food voucher is valid.

For monthly food vouchers, the start date will typically be the first day of the month (e.g., APR 01 2017), which will be stamped in the “First day to use” box directly on the food voucher, and the end date will always be the final day of the month (e.g., APR 30 2017), which will be stamped in the “Last day to use” box.

However, for Month 1 of the intervention, the monthly food vouchers will have a start date that is the tenth day of the month (e.g., APR 10 2017). This is to ensure that participants do not start using food vouchers before their baseline data collection that occurs during Week 1 of Month 1 is complete. Refer to charts below for specifics.

For weekly food vouchers, the start date for the 1st voucher will typically be the first day of the month (e.g., APR 01 2017), which will be stamped in the “First day to use” box directly on the food voucher, and the end date will typically be the 7th day of the month (e.g., APR 7 2017), which will be stamped in the “Last day to use” box. The start date for the 4th voucher will always be seven days before the last day of the month (e.g., APR 24 2017) and the end date will always be the final day of the month (e.g., APR 30 2017). The start dates for the 2nd and 3rd vouchers will vary, depending on how many days are in the month (i.e., 28, 30, or 31 days). For a month with 30 days (e.g., April), the 2nd and 3rd vouchers will each last 8 days.

As is with the monthly food vouchers, Month 1 of weekly food vouchers will have a slightly different dating system. The 2nd through 4th vouchers will remain the same. However, the 1st voucher will have a start date that is the tenth day of the month (e.g., APR 10 2017) and end date that is the final day of the month (e.g., APR 30 2017). Once again, we need to ensure that participants do not start using food vouchers before their baseline data collection that occurs during Week 1 of Month 1 is complete. Since we cannot provide food vouchers during Week 1 of Month 1, participants receiving weekly vouchers would not be able to spend their 1st voucher, as it is only valid the first seven days of the month. Therefore, the 1st voucher of Month 1 will be valid for the final three Weeks of the month to allow participants to spend it when it makes most sense for them. Refer to charts below for specifics.

Once all vouchers for the coming month are filled out with CHIVES ID as well as stamped start and end dates, study staff will put all four food vouchers for each participant in an envelope, writing the CHIVES ID *in pencil* on the front of the envelope, where the participant address label will later be placed. If preparing Month 1 vouchers, study staff will include Month 1 Handout [Appendix X]; if preparing Month 5 vouchers, study staff will include Month 5 Handout [Appendix XI]. Study staff will then seal the envelope closed, organize all envelopes numerically by CHIVES ID, and place all envelopes in a single pile, indicating they are ready to be matched with an address label.

Chart of dating for weekly vouchers – Month 1

Remember to include Month 1 Handout [Appendix X] in envelope.

Day of Month	28-day month February	30-day months April, June, September, November	31-day months January, March, May, July, August, October, December
1	Voucher 1: 10th - 28th	Voucher 1: 10th - 30th	Voucher 1: 10th - 31 st
2			
3			
4			
5			
6			
7			
8	Voucher 2: 10th - 14th	Voucher 2: 10th - 15th	Voucher 2: 10th - 16 th
9			
10			
11			
12			
13			
14			
15	Voucher 3: 15th - 21st	Voucher 3: 16th - 23rd	Voucher 3: 17th - 24 th
16			
17			
18			
19			
20			
21			
22	Voucher 4: 22nd - 28th	Voucher 4: 24th - 30th	Voucher 4: 25th - 31 st
23			
24			
25			
26			
27			
28			
29			
30			
31			

Chart of dating for weekly vouchers – Months 2 though 6

Remember to include Month 1 Handout [Appendix XI] in envelope.

Day of Month	28-day month February	30-day months April, June, September, November	31-day months January, March, May, July, August, October, December
1	Voucher 1: 1st - 7 th	Voucher 1: 1st - 7th	Voucher 1: 1st - 7th
2			
3			
4			
5			
6			
7			
8	Voucher 2: 8th - 14 th	Voucher 2: 8th - 15th	Voucher 2: 8th - 16th
9			
10			
11			
12			
13			
14			
15	Voucher 3: 15th - 21st	Voucher 3: 16th - 23rd	Voucher 3: 17th - 24th
16			
17			
18			
19			
20			
21			
22	Voucher 4: 22nd - 28th	Voucher 4: 24th - 30th	Voucher 4: 25th - 31 st
23			
24			
25			
26			
27			
28			
29			
30			
31			

Chart of dating for monthly vouchers – Month 1

Remember to include Month 1 Handout [Appendix X] in envelope.

Day of Month	28-day month February	30-day months April, June, September, November	31-day months January, March, May, July, August, October, December
1	Vouchers 1-4: 10th - 28th	Vouchers 1-4: 10 th - 30th	Vouchers 1-4: 10th - 31 st
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29	n/a		
30	n/a		
31	n/a	n/a	

Chart of dating for monthly vouchers – Months 2 through 6

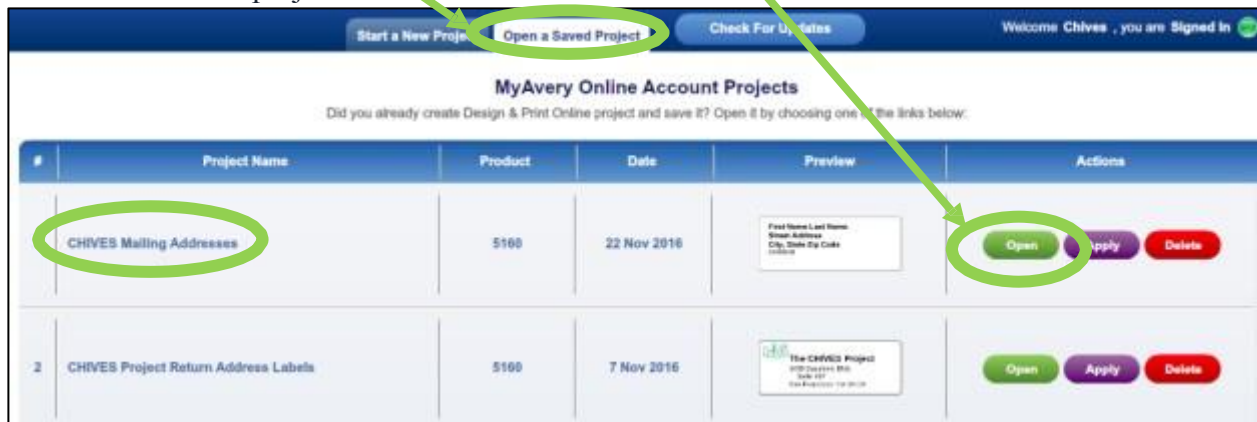
Remember to include Month 5 Handout [Appendix XI] in envelope.

Day of Month	28-day month February	30-day months April, June, September, November	31-day months January, March, May, July, August, October, December
1	Vouchers 1-4: 1st - 28th	Vouchers 1-4: 1st - 30th	Vouchers 1-4: 1st - 31st
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29	n/a		
30	n/a		
31	n/a	n/a	

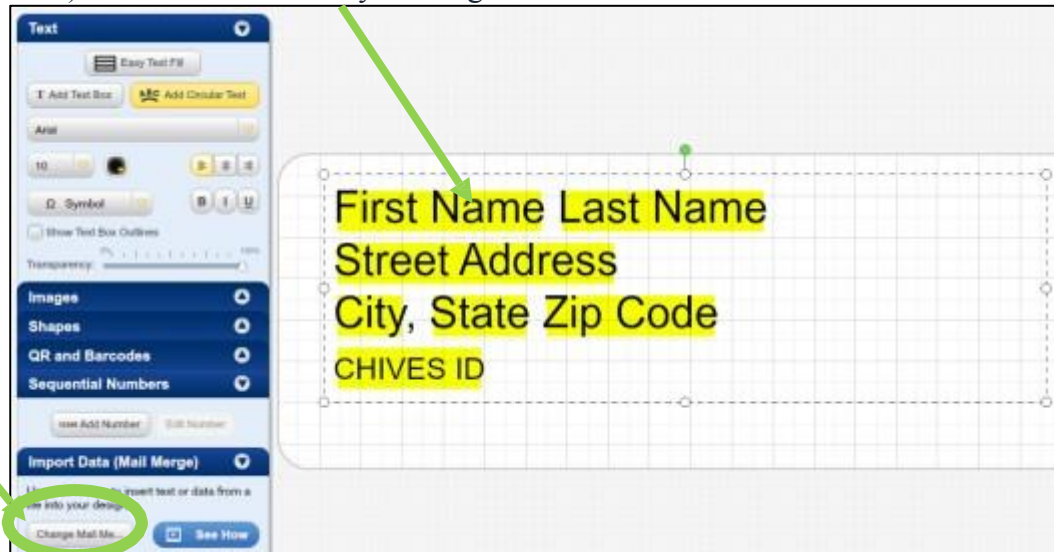
Study Staff Instructions for Printing Address Labels:

Study staff, or study coordinator, will then print sheets of address labels for all active participants. The address labels will be printed using the Avery Design & Print software system (login: chivesproject@stanford.edu, password: ChivesProject1485):

- 1) Click “Open a Saved Project” tab. Then click “Open” under “CHIVES Mailing Addresses” project.

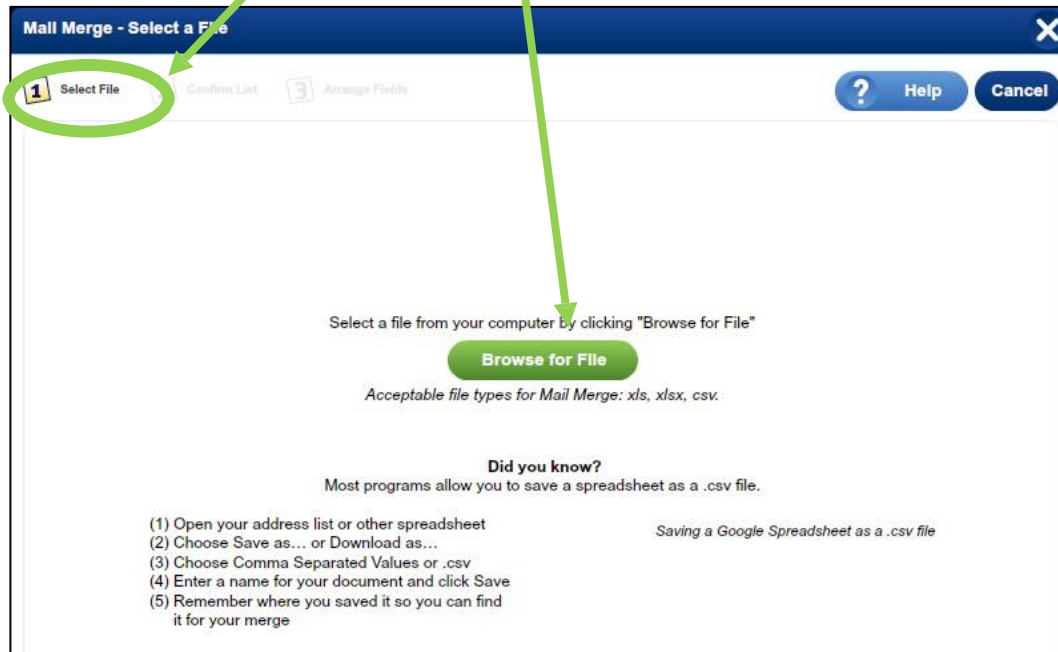


- 2) Select the text box by clicking on text.

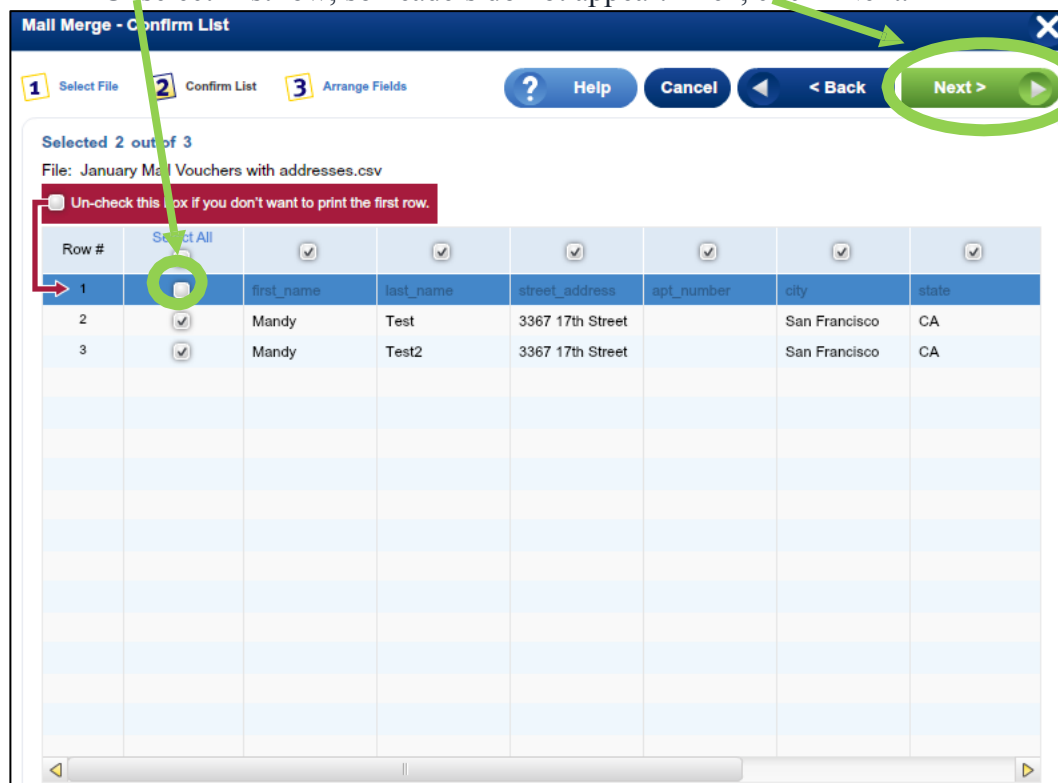


- 3) Under “Import Data” tab on left, click “Change Mail Merge.”

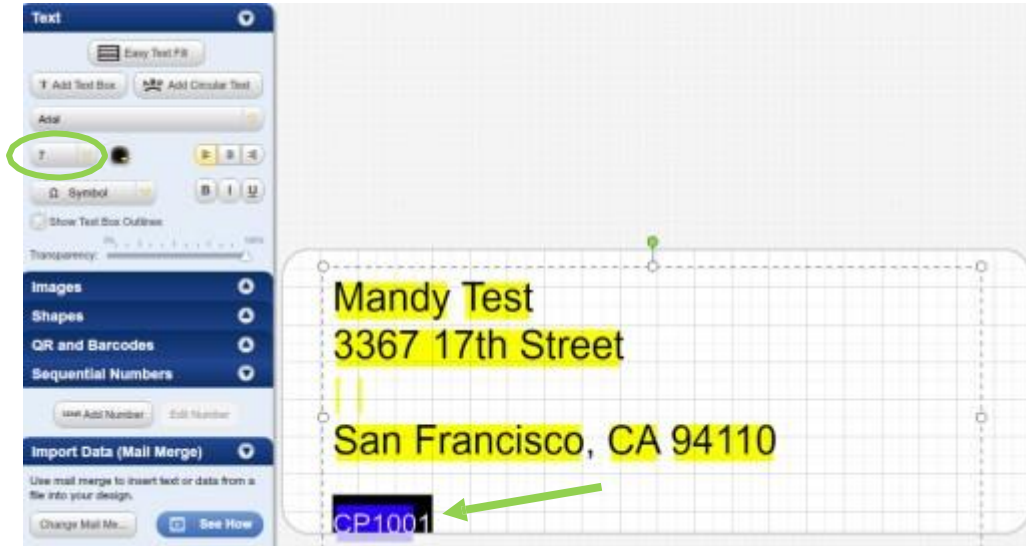
4) Then click “Select File,” and browse for “[Month] Mailing Vouchers with addresses” file.



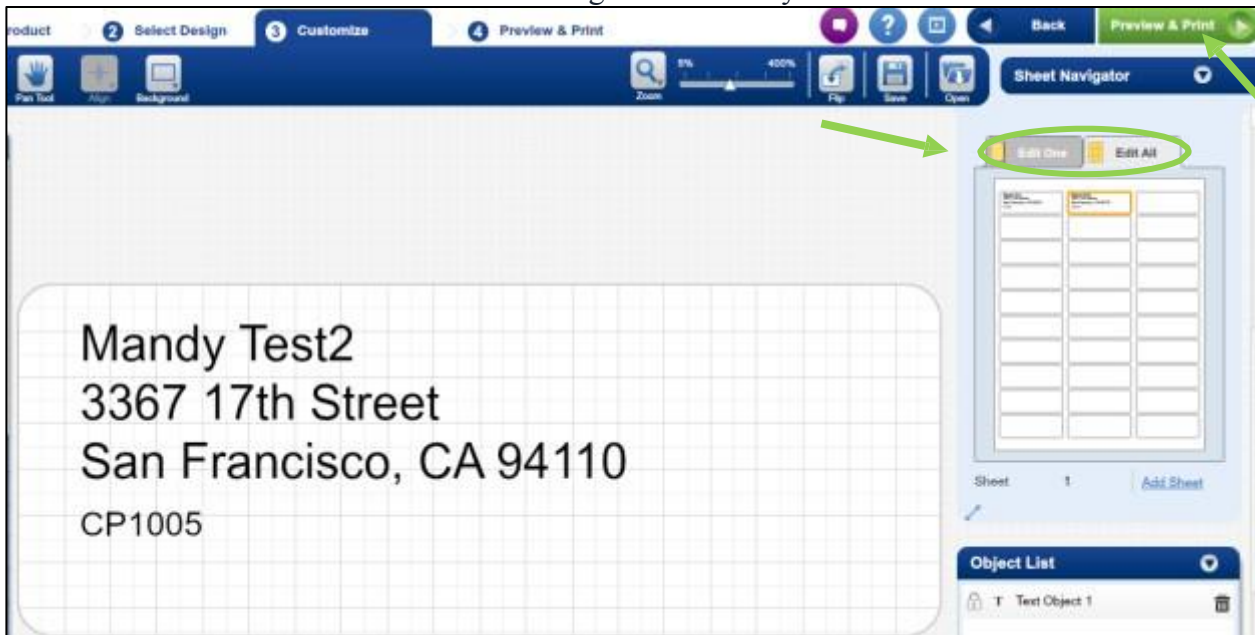
5) The file will upload with all the data in the needed fields to print address labels. Unselect first row, so headers do not appear. Then, click “Next.”



- 8) On the next screen, highlight the CHIVES ID field and make it 7-point font, so that it is easier to white out.

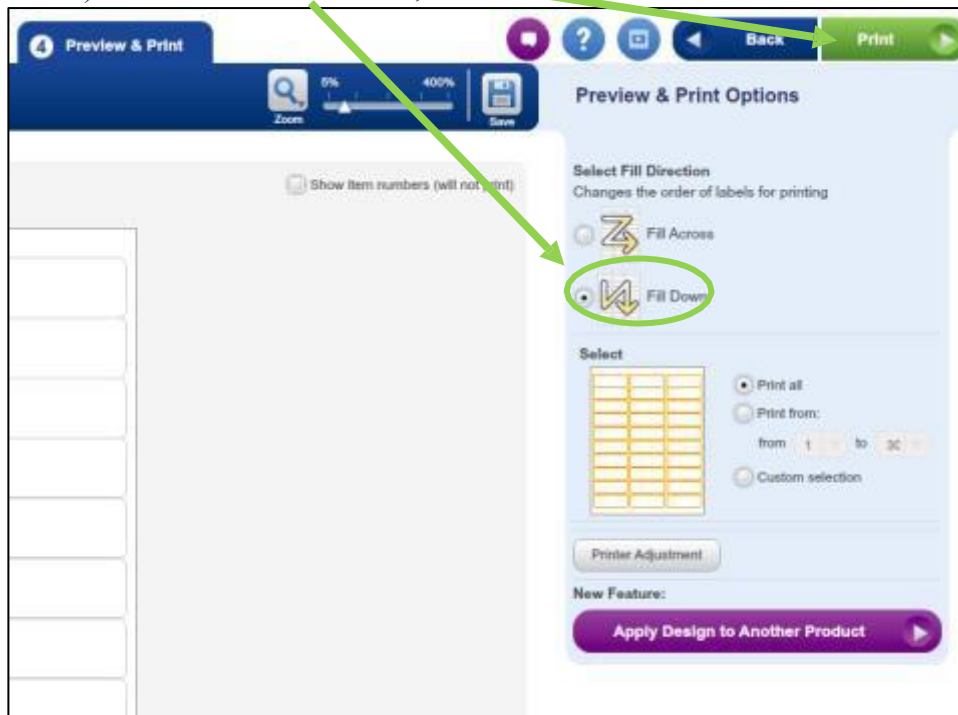


- 9) Look through a few labels to make sure they are centered correctly for each participant. Make special note to look through any addresses with apartment field. Choose either “Edit One” or “Edit All” to make changes as necessary.



- 10) Click “Review & Print” when finished editing.

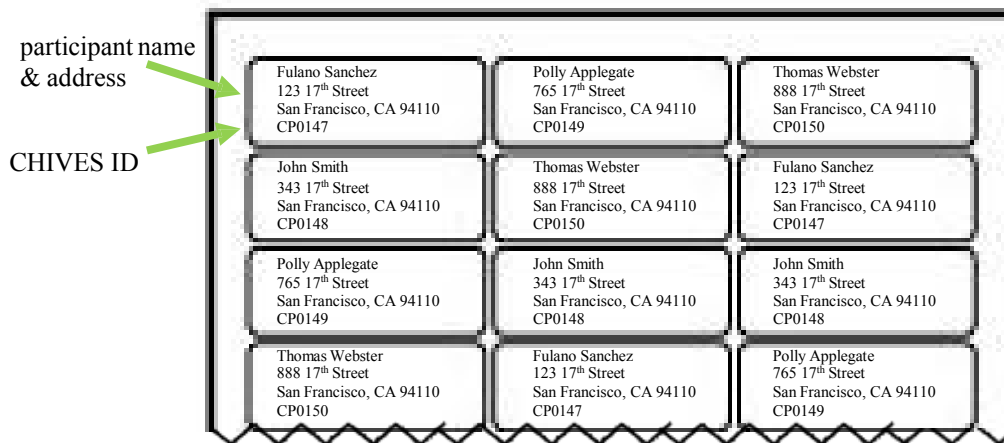
11) Click “Fill Down.” Then, “Print.”



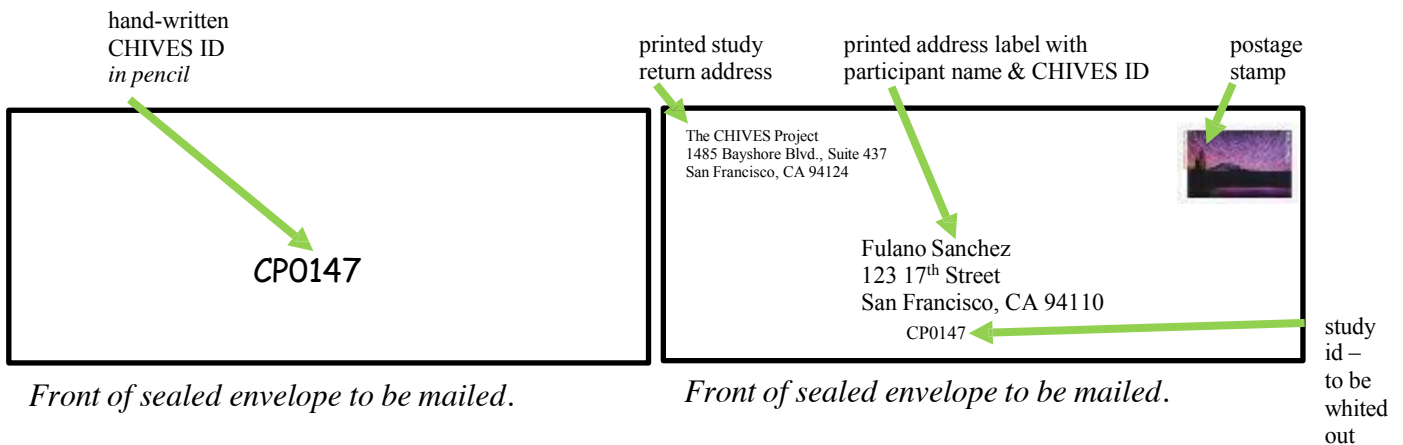
12) Open Tray 1 in printer and add necessary number of label sheets to Tray 1 in printer, with labels facing down. Then, click print!

Each label will have the participant name, address, and in small font below, the participant's corresponding identification number (CHIVES ID). The address labels will be printed numerically by CHIVES ID. Study staff will match participant address label to envelope with corresponding CHIVES ID, covering up the hand-written CHIVES ID previously written on the envelope, and simultaneously place both a CHIVES Project return address label and a postage stamp on each envelope, if envelope does not already have these adhered. Study staff will use white out to cover up the participant's CHIVES ID on the mailing label.

For each mailed set of vouchers, study staff will note in REDCap the date and time of mailed vouchers, the staff name, and any relevant comments under each participant profile. Once study staff complete all preparation for mailed vouchers, a designated staff member will place all envelopes in United States Postal Service mailbox located immediately outside the office building for outgoing mail no later than the 3rd day prior to the end of the month.



Printed Avery address labels.



5.3 Concomitant Interventions

5.3.1 Allowed Interventions

Participants are allowed to be concurrently enrolled in the CalFresh (also known as the Supplemental Nutrition Assistance Program, or SNAP). Participants, or members in their household, are also allowed to be concurrently enrolled in WIC. Participants may receive food from their local food bank.

5.3.2 Required Interventions

Since this study is a community effectiveness intervention, participants will be included in the data analysis regardless of how many vouchers they redeem during the 6-month intervention period. Therefore, participants are only required to complete the Month 0/Baseline dietary recalls to receive vouchers and be included in data analysis.

5.3.3 Prohibited Interventions

Candidates will not initially be allowed in the study if they report in the screening survey that they are currently participating in any other dietary or nutrition studies that would impact their normal eating patterns, or if they are currently receiving EatSF vouchers.

5.4 Adherence Assessment

Adherence to study intervention will be defined as participants who have redeemed 80% of their food vouchers. All participants will be included in the final analysis, but those who have meet this adherence criteria will be included in a special sensitivity analysis.

6 STUDY PROCEDURES

The Schedule of Participant Flow & Outcome Measures in Section 6.1 includes all study evaluations. This is primarily intended for study staff, but a simplified version of this will be shared in a handout with potential study participants in orientation [Appendix VII] to set up their expectations for their required involvement in the study, should they choose to participate.

6.1 Schedule of Participant Flow & Outcome Measures

Timeframe	Month 0, ≤ 4 th Week	Month 0, 4 th Week	Month 1, 1 st Week	Month 6, 1 st Week	Month 6, 4 th Week	Month 12, 1 st Week	Month 12, 4 th Week
	<i>Recruitment, Orientation, Consent, & Screening</i>	<i>Baseline Data Collection</i>	<i>Data Collection, Initiation of Voucher Utilization</i>	<i>End of Intervention Data Collection, Final Month of Voucher Utilization</i>	<i>End of Intervention Data Collection, Final Month of Voucher Utilization</i>	<i>6-month Follow Up Data Collection after final Voucher Utilization</i>	<i>6-month Follow Up Data Collection after final Voucher Utilization</i>
Participant Perspective	<ul style="list-style-type: none"> Recruited to participate in CHIVES Sign up for orientation Attend orientation, give informed consent to participate, & complete screening survey 	<ul style="list-style-type: none"> Deemed eligible to participate & contacted for baseline data collection Before voucher receipt & randomization Complete two 24-hour dietary recalls & baseline survey over the phone 	<ul style="list-style-type: none"> Receive randomized voucher assignment Receive in mail 1st month of vouchers after completing two 24-hour dietary recalls over the phone 	<ul style="list-style-type: none"> Use vouchers for final month in trial Complete two 24-hour dietary recalls & Month 6 survey over the phone 	<ul style="list-style-type: none"> Use vouchers for final month in trial Complete two 24-hour dietary recalls & Month 6 survey (if not already completed during 1st Week) over the phone Receive \$20 incentive for Month 6 data completion 	<ul style="list-style-type: none"> No vouchers used for past 6 months Complete two 24-hour dietary recalls & Month 12 survey over the phone 	<ul style="list-style-type: none"> No vouchers used for past 6 months Complete two 24-hour dietary recalls & Month 12 survey (if not already completed during 1st Week) over the phone Receive \$20 incentive for Month 12 data completion Final involvement in study participation
Evaluation Measures	Two 24-hour dietary recalls (ideally one weekday + one weekend)	Two 24-hour dietary recalls (ideally one weekday + one weekend)	Two 24-hour dietary recalls (ideally one weekday + one weekend)	Two 24-hour dietary recalls (ideally one weekday + one weekend)	Two 24-hour dietary recalls (ideally one weekday + one weekend)	Two 24-hour dietary recalls (ideally one weekday + one weekend)	Two 24-hour dietary recalls (ideally one weekday + one weekend)
	F&V acquisition, attitudes, and consumption survey questions		F&V acquisition, attitudes, and consumption survey questions*	F&V acquisition, attitudes, and consumption survey questions*	F&V acquisition, attitudes, and consumption survey questions*	F&V acquisition, attitudes, and consumption survey questions*	F&V acquisition, attitudes, and consumption survey questions*
	Participation in nutrition assistance programs survey questions (WIC/SNAP/EatSF)		Participation in nutrition assistance programs survey questions (WIC/SNAP/EatSF) *	Participation in nutrition assistance programs survey questions (WIC/SNAP/EatSF) *	Participation in nutrition assistance programs survey questions (WIC/SNAP/EatSF) *	Participation in nutrition assistance programs survey questions (WIC/SNAP/EatSF) *	Participation in nutrition assistance programs survey questions (WIC/SNAP/EatSF) *
	Participant food security status survey questions		Participant food security status survey questions*	Participant food security status survey questions*	Participant food security status survey questions*	Participant food security status survey questions*	Participant food security status survey questions*
	Self-reported height & weight, pregnancy / lactation status		Self-reported height & weight, pregnancy / lactation status*	Self-reported height & weight, pregnancy / lactation status*	Self-reported height & weight, pregnancy / lactation status*	Self-reported height & weight, pregnancy / lactation status*	Self-reported height & weight, pregnancy / lactation status*
			Voucher ease of use survey questions*	Voucher ease of use survey questions*	Voucher ease of use survey questions*	Voucher ease of use survey questions*	

* Surveys administered during Months 6 & 12 may be completed during 1st or 4th Week of either month, whichever more convenient for participant. Only one set of surveys at Months 6 & 12 need to be completed.

6.2 Description of Evaluations

24-hour dietary recalls. The dietary recall method was previously tested among low-income populations in both independent studies and in our own prior trials. The method has good internal consistency (Cronbach's alpha >0.80) and high correspondence among individuals ≤250% FPL to the lengthier Automated Multi-Pass Method used in the National Health and Nutrition Examination Survey, and to intake estimates obtained via doubly-labeled water.

Briefly, the method includes distinct passes to obtain a participant's food intake during the previous 24 hours, including foods obtained at home and away from home, and including bartered, foraged, food pantry, and other non-purchased items. Participants will receive a standard 2-dimensional paper copy of the Food Amounts Booklet [Appendix VIII] during the orientation session to enhance estimating portion sizes during each dietary recall. The diet assessors are blinded to the participant's intervention arm and are skilled in guiding dietary recalls among diverse participants in a non-judgmental, comprehensive manner.

As in prior trials, quality control/lead diet assessor Sarah Farzinkhou will provide 20 hours of standardized staff training for diet assessors via written manuals and protocols, case studies, and role play to cover content such as recall procedures; techniques to support participants and gather recalls in a non-judgmental manner; provide tailored feedback and problem-solving skills; and engage in facilitation techniques such as active listening.

The diet assessor will collect data from the participant using a standardized verbal protocol and enter the data into the Nutrition Data System for Research (NDSR, University of Minnesota), a computer-based software application developed at the University of Minnesota Nutrition Coordinating Center (NCC). NDSR records foods using standardized codes to match comprehensive nutrient databases.

Dietary recalls will be collected in a standardized fashion using a multiple-pass interview approach consisting of five steps to ensure completeness and accuracy. First, diet assessors will ask participants to list all foods and beverages consumed in the previous 24 hours (i.e., midnight to midnight). Second, the diet assessor will review the list with the participant. Third, the diet assessor will collect detailed information about each reported food and beverage (e.g., method of preparation and amount consumed). Fourth, the diet assessor will probe for commonly forgotten foods and beverages. Fifth, the diet assessor reviews the information for completeness, correctness, and marks each recall as a typical or atypical day.

Throughout each recall, the NDSR software searches for foods and brand name products by name and will prompt the diet assessors with requests for additional detailed information. The NCC Food and Nutrient Database serves as the source of food composition information in NDSR. This database includes over 18,000 foods including 8,000 brand name products. Ingredients and preparation methods allow for more than 160,000 food variants. Values for 165 nutrients, nutrient ratios, and other food components were generated by the database. The USDA Nutrient Data Laboratory is the primary source for nutrient composition for the database. These values are supplemented by food manufacturers' information and data available in the scientific literature. Diet assessors will apply standardized, published imputation procedures to minimize

missing values. The diet assessors will enter recipes for homemade and restaurant items not included in the software.

In addition to using NDSR to specifically capture foods and beverages consumed, diet assessors will also record in REDCap whether each completed recall was a weekday or weekend day, when each recall was completed (date and time), and who completed each recall. Also, each diet assessor will be prompted in REDCap to ask participants at each recall a 2-item food security survey in order to later correlate any abnormal food days (i.e., days of especially low caloric intake) with possible food insecurity [Appendix XIV]. If any dietary recall day is deemed to be abnormal (typically, and daily intake of ≤ 600 calories, but determined on a case-by-case basis by diet assessor), the diet assessor will attempt to complete a third dietary recall within the given data collection period. Diet assessors will also record any third recalls in REDCap and ask the 2-item food security survey at end of recall.

In general, diet assessors will complete a total of twelve recalls per participant, two recalls at each of six timepoints:

- (1) Month 0/Week 4 (baseline – before randomization, before voucher use);
- (2) Month 1/Week 1 (baseline – after randomization, before voucher use);
- (3) Month 6/Week 1 (follow up – during final month of voucher use and intervention);
- (4) Month 6/Week 4 (follow up – during final month of voucher use and intervention);
- (5) Month 12/Week 1 (follow up – no voucher use for prior 6 months);
- (6) Month 12/Week 4 (follow up – no voucher use for prior 6 months).

Two dietary recalls (one weekday and one weekend day) will be done during Week 1, which reflect the first seven consecutive days of the month, and two during Week 4, which reflect the last seven consecutive days, of the assessment months. Ideally one weekday (recall of a Monday through Friday) and one weekend day (recall of a Saturday or Sunday) will be collected for each timepoint. However, we will alternatively accept two weekdays or two weekend days. In the worst-case scenario, we will also accept one weekday recall only or weekend day recall only.

Also, while recalls are technically to reflect the first or last seven days of the month, recalls may include up to first or last *eight* consecutive days of the assessment month to allow for a 1-day buffer period. This would mean Week 1 recalls take place the 2nd through the 9th of any given month in order to reflect the first eight consecutive days of the month. And, Week 4 recalls take place the 22nd through the 1st for 28-day months, the 24th through the 1st for 30-day months, and the 25th through the 1st for 31-day months. For clarification as to when dietary recalls take place each month, please refer to the graphics below:

28-day month
(e.g., February 2017)

			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	1			

30-day months
(e.g., April 2017)

						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	1					

31-day months
(e.g., May 2017)

	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31	1		

When dietary recalls take place each month.

KEY

	Week 1 recalls
	Week 4 recalls

Diet assessors will attempt recalls during time periods in which the participants have specified they are likely available. (In the orientation screening survey, participants will mark all 2 to 3-hour time blocks during which they are available each day of the week. These will be recorded in REDCap and transferred to a shared diet assessor dietary recall calendar). We are hopeful with these “semi-scheduled” recalls that diet assessors will not have to call participants multiple times in order to complete each required dietary recall.

However, we know that some participants will need to be called repeatedly in order to complete the two dietary recalls required for each week during data collection window at each timepoint. Diet assessors will attempt to call participants a total of seven times during each 8-day period (“Week 1” – reflects first eight consecutive days of the assessment month, or “Week 4” – reflects last eight consecutive days of the assessment month). Diet assessors will not attempt to call more than once per day, unless they hear back from a participant via text message, or a call that they are available later that same day. For each time diet assessors attempt to call participants and do not reach them, they will leave a scripted voicemail and follow up with a quick scripted text message [Appendix XV] to see when participants might be available for the call. Diet assessors will record each attempt in the shared diet assessor dietary recall calendar, and make any pertinent participant notes in REDCap.

Overall, this dietary recall plan minimizes the number of recalls required to capture intra-person variation in diet between weekdays and weekends, while simultaneously capturing the monthly food consumption cycle among participants (the key hypothesized mediator for the lump sum/monthly versus distributed/weekly voucher effect). The method limits participant fatigue, even in low-literacy, low-income populations; fewer than 10% of participants cited the recalls as detracting from completion of a prior trial. To ensure adequate follow-up and data completion at Months 6 and 12, a \$20 gift card to a popular local store will be mailed following the final Week 4 recalls of Months 6 and 12. The same recall protocol will be utilized for Months 0, 6 and 12, except the \$20 gift card given only at Months 6 and 12.

The 24-hour dietary recalls are the most critical evaluation measure as data obtained from these will be used to assess the primary outcome measure and two of the three secondary outcome measures.

Participant surveys. Diet assessors will verbally administer the participant surveys over the phone, preventing literacy-based biases, consistent with recent Institute of Medicine recommendations. These 20-minute surveys [Appendix XIII] will be conducted at Months 0, 6, and 12. At each data collection time point, diet assessors will assess which phone call would be most convenient for participant to answer the additional 20-minute survey. The baseline survey may be administered during either of the two phone calls for dietary recalls during Week 4 of Month 0. The Month 6 and Month 12 surveys may be administered during one of any of the four phone calls for Month 6 and Month 12.

The participant survey will cover attitudes and preferences regarding the food vouchers and F&Vs generally, shopping patterns, food expenditures, household environment, participation in nutrition assistance programs, food insecurity, and self-reported height and weight, pregnancy and lactation status. Survey measures [Appendix XII] were chosen over alternatives due to brevity, good internal consistency (Cronbach's $\alpha > 0.8$), high construct and criterion validity both in English and Spanish versions among low-literacy and low-income adults, and because participants in our pilot feasibility study indicated excellent comprehension of the questions during post-pilot focus groups. The only difference in survey questions between Month 0/Baseline, Month 6, and Month 12 survey will be an additional four questions at Month 6 to assess voucher usability.

Vendor surveys. The Bayview, SoMa, and Tenderloin vendors are highly enthusiastic about their participation because it offers positive advertising, additional foot traffic, and financial support for turnover of perishable products. Memorandums of Understanding (MOUs) were signed by every vendor and EatSF program staff before the EatSF pilot study began.

Study staff will present the updated EatSF and CHIVES Project MOU [Appendix XVI] to all participating CHIVES vendors during Month 0 (January 2017) through in-person meetings to read and sign two copies of the MOU, as well as provide updated training materials for store staff on how to accept CHIVES vouchers [Appendix XVIII]. The vendor will keep one signed copy for their own records, and the CHIVES study coordinator will keep the other copy of each signed MOU in the study office. The updated MOU outlines that participating vendors agree to study staff visiting vendors on a monthly basis to: (i) gather any feedback, resolve any issues or confusion, and hear about any misuse; (ii) routinely assess product pricing (to ensure prices do not increase in response to the intervention); and (iii) assess the available quality, quantity, and variety of F&Vs. Finally, the MOU will state that the participating vendors agree to participate in a post-intervention vendor survey [Appendix XVII].

Study staff will visit participating vendors after the final intervention month for the last cohort (estimated to be early 2018), to conduct the post-intervention survey as an in-person interview. The survey questions will be modeled on a United States Department of Agriculture survey of retailers participating in a prior subsidy program, which assesses: (i) whether vendors have any difficulties with the voucher system and whether those difficulties are at the point of sale, at the point of reimbursement, and/or when answering questions to customers about the vouchers; (ii) what if any activities were used by vendors to promote F&Vs during the voucher trial period; (iii) what if any activities they had engaged in to sell more F&Vs; and (iv) a free text entry to elicit what changes vendors would propose to the voucher system in future iterations. Study staff

will continue to visit vendors until all survey interviews are completed. [*Note*: at larger stores, such as Foods Co and Safeway, the EatSF contact will be interviewed, as opposed to the store owner or general manager in the small stores.]

6.2.1 Screening Evaluation

Consenting Procedure

When candidates visit the online recruitment survey via REDCap during recruitment, they will fill out a pre-screening survey with a Waiver of Documentation [Appendix IV] that gives a general overview of the study, and is something they must agree to in order to continue with the pre-screening questions. This is the candidate's first form of acknowledgement of being in a study.

When candidates agree to the Waiver of Documentation form, they agree to answer pre-screening questions and potentially share contact information, if they are eligible based on pre-screening questions. If they are deemed eligible based on their answers to the pre-screening questions, they will then be asked to share contact information and sign up for an orientation date.

If they attend the orientation session for which they signed up, they will read and sign a single informed consent form that describes both the screening and study procedures during the orientation session [Appendix V].

The study director, the study coordinator, and/or the study staff will review the major components of the consent, page by page, in the group orientation with the visual aid of a PowerPoint presentation. The candidate will then have time to individually review consent in detail, ask any questions to available staff members, and sign once they fully understand the components of the consent form.

As candidates are leaving orientation, study staff will collect consent forms, answer any additional questions, and ensure the consent form was signed and dated correctly.

Signed consent forms will be organized alphabetically by last name in a secure folder locked in the study coordinator's file cabinet.

Screening

All candidates who have signed the consent form during orientation will then be invited to complete the 16-item self-administered screening survey [Appendix VI]. This brief survey captures whether each candidate meets all enrollment criteria (inclusion and exclusion criteria), and captures availability for phone survey and food recalls.

The screening survey must be dated within two months of baseline data collection. If more than two months have passed since the candidate attended orientation and completed the screening survey, study staff must administer an additional screening survey over the phone to ensure the candidate is still eligible to participate.

6.2.2 Baseline Assessments, Randomization, and Enrollment

Baseline Assessments (4th Week of Month 0)

For participants who have successfully been screened for eligibility and are consented into the study, baseline assessments are executed so that we can measure against these at Months 6 and 12 to calculate study outcomes. They also ensure that the groups are balanced with respect to baseline characteristics.

The baseline assessments during 4th Week of Month 0 will include:

- Two 24-hour dietary recalls (1 weekday + 1 weekend day)
- One 20-minute baseline survey [Appendix XIII]

Randomization

During Week 4 of Month 0 for each cohort, study coordinator will daily run a report in REDCap that shows how many participants have completed all Month 0 data collection (two 24-hour dietary recalls and survey) over the phone with diet assessors. Once study coordinator identifies that the minimum of 48 participants has been reached, or it is the first day of Month 1 (i.e., Week 4 of Month 0 data collection will cease by end of day), the study coordinator will inform the study statistician that it is time to run the code to match all eligible participants to a randomization assignment. The study statistician will download all de-identified information needed for covariate-adaptive randomization (age, sex, race, ethnicity, income category, and current SNAP / CalFresh participation status) from REDCap.

The statistician will run the randomization code, and will perform covariate-adaptive randomization to minimize differences in these covariates among individuals when randomizing participants into each of the four intervention arms, using blinded labels (Group 1, Group 2, Group 3, or Group 4). The study statistician will generate these randomized group assignments for each participant. Upon generating the randomized group assignments, the study statistician will inform the study coordinator of completion. The study coordinator will then go into the Randomization Check-Data Push report in REDCap, which has been automatically prepopulated with randomized group assignments, and manually click on the first participant ID, open JOE'S FORM: Randomization, click the check box by Randomization Check and save the record. The study coordinator will do this for every participant being randomized. This will then transfer the randomization data from the CHIVES Screening Project to the CHIVES Main Project. Each participant will then automatically have a group assignment visible under their REDCap profile page (Groups 1 through 4), and at that point, each participant will be considered as having received a randomization allocation.

Once participants are randomized into their group assignments, an automated text message will be sent from REDCap to inform participants of their randomization assignment. All relevant dates (Month 0/Baseline data collection completion dates, and randomization date) will be recorded in REDCap.

Enrollment

A participant will be officially enrolled in the study once they are randomized into one of the four group assignments. This will typically happen between the 4th Week

of Month 0 and the 1st Week of Month 1.

The official randomization date in the participant record will automatically be recorded in REDCap. This will help to ensure that not too much time (more than two months) has lapsed since the participant attended orientation, signed the consent form, and completed the screening survey.

Baseline Assessments (1st Week of Month 1)

Once the participant is randomized into one of the four intervention arms, diet assessors will complete the baseline data collection during the 1st Week of Month 1: two 24-hour dietary recalls (1 weekday + 1 weekend day).

Chart of Baseline Assessments, Randomization, and Enrollment.

Month 0	Month 0 – 4th Week	Between Month 0 & Month 1	Month 1 – 1st Week
- Participant attends orientation	- Baseline/Month 0 data collection (two 24-hour dietary recalls + baseline survey)	- Randomization & Enrollment - REDCap sends out an automated text message to inform participant of their randomization allocation, or food voucher assignment	- Baseline/Month 1 data collection (two 24-hour dietary recalls) - Participants receive food vouchers via mail once all remaining data collection is complete

6.2.3 Follow-up Visits

During the 6-month intervention period, participants will receive food vouchers via mail. They are not required to return to the study office during the intervention. Beyond receiving food vouchers and spending them during specified timeframes, the study requires no other commitments from participants during the 6-month intervention period.

Participants will complete the end of intervention data collection during 1st and 4th Weeks of Month 6, according to evaluation schedule. Diet assessors will call the participant a total of four times to complete two separate 24-hour dietary recalls during both 1st and 4th Weeks and the 20-minute participant survey during any of the four phone calls. If the participant desires, the 20-minute survey can also be conducted during a separate phone call. For completion of Month 6 data collection, participants will receive a \$20 gift card to compensate them for their time and to ensure optimal participant retention. To remind participants of upcoming data collection and \$20 incentive, study staff will mail out a reminder handout [Appendix XI] along with Month 5 vouchers.

6.2.4 Completion/Final Evaluation

Six months after the intervention period has ended, or Month 12 from Month 0/Baseline, diet assessors will contact participants to complete final data collection during 1st and 4th Weeks of Month 12. Again, diet assessors will call the participant a total of four times to complete two separate 24-hour dietary recalls during both 1st and 4th Weeks and the 20-minute participant survey during any of the four phone calls. For completion of Month 12 data collection, participants will receive a \$20 gift card to compensate them for their time and to ensure optimal participant retention.

For participants who did not complete the full 6-month intervention (e.g., they stopped picking up vouchers), diet assessors will still attempt to contact them to complete the final Month 12 data collection.

7 SAFETY ASSESSMENTS

Participant safety will be monitored once an individual is enrolled in the study, primarily through feedback, complaints, and concerns from participants and vendors. During orientation, participants will be encouraged to share any feedback, complaints, and concerns about their participation or voucher use via phone call, e-mail, or by visiting the study office. Study staff will directly elicit feedback from vendors during regular monthly vendor visits. Due to the nature of this study and the low-risk intervention, we do not have any safety concerns or anticipate any adverse events or serious adverse events. There are no plans for compensation if any adverse event or serious adverse event occurs.

The possible foreseeable risks associated with this study are:

- The inconvenience of maintaining a consistent mailing address to receive vouchers once per month for six months.
- The inconvenience of remembering to use the vouchers when you shop for food.
- The time and inconvenience of answering surveys and describing everything that you ate.
- The psychological discomfort of talking about whether it was difficult for you to obtain nutritious food or enough food.
- The small possibility of communicable disease from F&V purchased with vouchers. This is a general risk in the population consuming F&Vs, which is not unduly elevated because of participation in the voucher study.

Any study staff that are made aware of safety concerns and/or adverse events will immediately report these to the study coordinator and/or study director. The study director will record any adverse events on the adverse event form and communicate this to the Data Safety Monitoring Board as well as the two approving Institutional Review Boards within 48 hours.

8 INTERVENTION DISCONTINUATION, WITHDRAWAL & MODIFICATION

Intervention discontinuation. We do not foresee discontinuing any participants. However, the only foreseeable reasons for which the study coordinator or study director will discontinue a participant's intervention are:

- If the participant has acted in a violent or inappropriate manner to study staff or any vendors;
- If participant moves from San Francisco area, is unable to receive food vouchers via mail, and/or spend vouchers at specified vendors;
- If participant no longer has regular access to a mobile phone and is unable to complete data collection.

Study withdrawal. We anticipate that the majority of participants will be able to complete the intervention, due to its inherent low-risk nature. However, participants may withdraw their participation in the study at any time.

If for any reason a participant chooses to withdraw their participation and stop receiving vouchers and participate in subsequent data collection, he/she must contact study staff who will detail this in his/her REDCap file. Due to the nature of the study, participants will not be able to temporarily withdraw and rejoin the study. If a participant decides to withdraw from the study, this decision will be effective permanently. When any participant decides to withdraw from the study, study staff will record this in either REDCap Project (CHIVES Screening Candidates or CHIVES Main Project, depending on when the participant drops out) under the "Status" instrument form with a clear reason as to why participant chose to drop out of study. For voluntary withdrawals, study staff will inquire whether participant would allow contact for Month 6 and Month 12 data collections, which study staff will note in REDCap file to ensure study staff follows up with subsequent data collection, according to recorded answer.

If any participant chooses to withdraw due to safety reasons or adverse events, this will be recorded in REDCap and communicated to the study director immediately. The study director will record this in the adverse event form and communicate this to the Data Safety Monitoring Board as well as the two approving Institutional Review Boards within 48 hours. There are no plans for compensation if any adverse event or serious adverse event occurs.

Study modification. We have decided not to modify the intervention mid-study in any way.

9 STATISTICAL CONSIDERATIONS

9.1 General Design Issues

This study tests two hypotheses: that increasing the frequency of food assistance (weekly versus monthly), but not the overall amount of assistance, and targeting assistance toward healthy fruits and vegetables increases dietary quality in a manner that can cost-effectively reduce cardiovascular disease disparities.

Thus, we have chosen a two-by-two factorial study design that randomly assigns participants to one of four food voucher assignments (monthly untargeted, monthly targeted, weekly untargeted, or weekly targeted) to test the two hypotheses.

9.2 Sample Size and Randomization

We aim to have 312 total participants in this trial. We anticipate an 8% attrition rate, or plan for approximately 25 enrolled participants to be lost to follow up or drop out of study, which would leave 288 participants with complete data for analysis.

The study director calculated a 265-participant sample size minimum using G*Power software, aiming for a sample size that would give us 90% statistical power to detect two main effects (weekly versus monthly, targeted versus untargeted), and their interaction (F-test using ANCOVA with baseline F&V intake as the main covariate), assuming a moderate Cohen's $d = 0.4$ effect size. Thus, taking into account up to a 15% participant attrition rate, we aim to enroll 312 participants so that we have sufficient statistical power for our analyses.

In sum, for optimal statistical power ($\geq 90\%$), our goal will be to recruit 312 participants. For a less ideal statistical power ($\geq 80\%$), we will aim to recruit at the very minimum 236 participants.

9.3 Interim analyses and Stopping Rules

There will be no interim analyses conducted. Thus, no stopping rules are in place. We do not foresee stopping the trial.

9.4 Outcomes

9.4.1 Primary outcome

- Individual self-reported change in fruit and vegetable intake (measured in cup-equivalents) at Month 6 of study participation, as compared to Month 0. Participant fruit and vegetable intake will be evaluated by two verbal 24-hour dietary recall assessments conducted over the phone with a diet assessor at each data collection time point (Month 0/Baseline, Month 6, and Month 12).

9.4.2 Secondary outcomes

- Individual self-reported change in fruit and vegetable intake (measured in cup-equivalents) at Month 12 of their study participation, as compared to Month 0. This measurement will reflect on fruit and vegetable intake 6 months after their final use of food vouchers, to determine maintenance of behavior change after cessation of food

- voucher receipt.
- Healthy Eating Index and Alternative Healthy Eating Index scores at Months 6 and 12, calculated from the 24-hour dietary recall data.
 - Change in monthly food consumption cycle of overall consumption, comparing total calories and fruit and vegetable consumption in Week 4 versus Week 1 of Months 6 and 12, as compared to Month 0.
 - Voucher utilization rate at Month 6. The percent of vouchers utilized by participants in each study arm will be calculated.

9.4.3 Other outcomes

- Voucher ease of use, assessed through of a verbal 20-minute survey conducted over the phone with a diet assessor at Month 6. Survey asks whether vouchers were easy to use and allow for free-text response of why or why not vouchers were easy to use.
- Fruit and vegetable acquisition, attitudes, and consumption, also assessed during aforementioned verbal 20-minute survey conducted over the phone with a diet assessor at Months 0, 6, and 12.
- Self-reported height and weight, also assessed during aforementioned verbal 20-minute survey conducted over the phone with a diet assessor at Months 0, 6, and 12.
- Participant food security status, also assessed during aforementioned verbal 20-minute survey conducted over the phone with a diet assessor at Months 0, 6, and 12. Questions include participation in nutritional assistance programs and the 6-item United States Department of Agriculture adult food security scale.

9.5 Statistical Analyses

Our trial is powered for a standard ANCOVA to test the mean effects of both axes (frequency and targeting) and their mediators on the primary outcome of F&V consumption at Month 6, as well as to test the interaction between frequency and targeting of vouchers. To explicitly test the mediator of the consumption cycle on the effectiveness of the weekly versus monthly vouchers, we will test the significance of the interaction between voucher frequency assignment (weekly or monthly) and the ratio of Week 4 to Week 1 F&V intake and total calorie intake at Month 6 relative to Month 0. To explicitly test the mediator of ease of use on the effectiveness of the targeted versus untargeted vouchers, we will test the significance of the interaction between differences in ease of use of vouchers between groups (from the survey) and change in F&V intake between Month 0 and Month 6.

We aim for power ($1 - \beta$) of 0.80 with a two-tailed significance threshold α set to 0.01 (Bonferroni corrected for five tests: two main effects, their interaction, and two mediators). We aim to detect a minimum effect size of Cohen's $d=0.44$ between weekly and monthly vouchers based on the 95% lower bound effect size observed in our pilot study; this is smaller than the minimum effect size of $d=0.71$ between targeted and untargeted vouchers estimated in a comparison of recipients of targeted F&V vouchers to propensity score matched recipients of a general grocery purchasing discount, or the $d=0.76$ in the direct targeted versus untargeted voucher study in the United Kingdom. Using the lowest (more conservative) effect size, we calculated power with a conservative 15% attrition rate over the study period, requiring $N=288$ people ($n=72$ people per intervention condition; G*Power software v. 3.1). Strengths of the ANCOVA approach include the ability to isolate the impact of the mediators while correcting for

within-person time-invariant confounders (i.e., accounting for the fact that different individuals start from different F&V intake levels and exhibit different responsiveness to the same incentive). In a secondary analysis, we will assess the extent to which healthy eating habits are maintained after the voucher period ends by comparing mean effects at Month 6 to those of Month 12, which requires less power. We will conduct an intent-to-treat analysis under the conservative assumption that those lost to follow-up had no change in intake; in sensitivity analyses, we will use a well-established multiple imputation technique for missing data, which fills in missing values in multiple variables iteratively using chained equations (a sequence of univariate imputation methods with conditional specification that accommodates arbitrary missing-value patterns).

In further statistical analyses, we will explore other mediators of effectiveness captured in our survey (e.g., food security), and moderators of gender and race/ethnicity consistent with the NIH Policy on the Inclusion of Women and Minorities in Clinical Research (n.b., the policy does not require high statistical power for each subgroup). We will also perform subgroup analyses by SNAP status, to identify the impact of the vouchers independent of, versus in addition to, existing food support program dollars.

Vendor survey data will be summarized using descriptive statistics of survey responses to inform future intervention refinement, with free-text comments classified into categories related to willingness to participate, ease of participation, and suggestions for improvement.

10 DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms. Below is a brief description of each data collection form, how information about each participant will be collected and by whom.

Pre-screening survey. This survey asks candidates some basic inclusion and exclusion criteria, how they found out about the study, their contact information, and what orientation date works best for them to attend. Candidates complete this survey themselves online either through their mobile device or computer. Data entered here goes directly into REDCap [Appendix IV].

Screening survey. This survey is given to candidates during orientation and asks candidates a few additional eligibility criteria, information needed for balancing into randomization groups, their contact information, and availability for data collection phone calls. Candidates complete this survey themselves during orientation with pen and paper. Immediately after orientation, study staff will transcribe all answers from paper survey directly into REDCap. Once done, they will store all paper copies of screening survey in locked filing cabinet in study office [Appendix VI].

Month 0, Month 6, and Main Surveys. These surveys capture whether the participant understood how to use vouchers, general feelings and attitudes about fruits and vegetables, availability of fruits and vegetables in the home, participation in food assistance programs, 6-item food security questions, height and weight, and pregnancy and breastfeeding status. Study staff will verbally ask participants these questions over the phone as a part of Month 0 / Baseline, Month 6, and Month 12 data collection forms. Study staff ask questions directly from REDCap, and enter answers in real-time into REDCap database [Appendix XIII].

24-hour Dietary Recalls. These recalls capture all the food and beverages a participant consumed in the previous 24-hour period. Study staff will verbally conduct these recalls with participants over the phone, simultaneously entering data into NDSR, using NDSR protocols [Appendix XIV].

10.2 Data Management

Data from orientation sessions will be collected via paper form and subsequently typed into the REDCap data management system. NDSR diet data will be collected via telephone interview and directly typed into the NDSR data collection system. NDSR reports will be stored on a secure server. Key variables for the statistical analysis will be extracted from these securely stored NDSR reports. NDSR report 9 contains the variables necessary to compute cup equivalents of fruits and vegetables, the main study outcome. Specifically, servings of the 7 NDSR food groups that count as fruits and the 10 NDSR food groups that count as vegetables will be summed and divided by 2 as report 9 displays servings (equal to half cup equivalents). The derivation of the main study outcome will be executed in R version 3.3.2.

Our study statistician will calculate the Healthy Eating Index 2010, or the most updated Healthy Eating Index score at the time of analysis, from the relevant NDSR reports using R. The R code he creates and uses will be made publicly accessible via the Stanford Digital Repository (sdr.stanford.edu) concurrent with publication.

10.3 Quality Assurance

- 10.3.1 *Training.* As in prior trials, quality control/lead diet assessor Sarah Farzinkhou will provide 20 hours of standardized staff training for diet assessors via written manuals and protocols, case studies, and role play to cover content such as recall procedures; techniques to support participants and gather recalls in a non-judgmental manner; provide tailored feedback and problem-solving skills; and engage in facilitation techniques such as active listening. Also, study coordinator Mandy Carroll will review REDCap thoroughly will study staff to familiarize them with data collection instruments and have study staff run two mini-pilots (one with participants and one with each other) to practice using all data collection instruments.
- 10.3.2 *Quality Control Committee.* The study director Sanjay Basu, quality control & lead diet assessor Sarah Farzinkhou, and study coordinator Mandy Carroll make up the quality control committee. Sarah will monitor the NDSR database and Mandy will monitor the REDCap data entry. Sanjay will serve as support in both of these projects.
- 10.3.3 *Metrics.* The study statistician will review the full dataset for outliers, both in diet data generated by NDSR dietary recalls and in survey responses. The individual parameters to define outliers for each nutrient or food category will be determined upon analysis.
- 10.3.4 *Protocol Deviations.* No protocol deviations are anticipated. The study coordinator is here to ensure compliance to trial protocol. However, if study coordinator or study staff identifies any deviations in the protocol, they will notify the study director immediately. The study director and study coordinator will review and document any changes together.
- 10.3.5 *Monitoring.* Study coordinator will regularly be monitoring participant flow and data entry through the REDCap database throughout the study. Before any participant is randomized and enrolled in the study, the study coordinator will use the REDCap instrument “ADMIN: Ready to be Randomized” to go through individual candidate files to ensure that the consent form was properly signed and dated, the screening survey was filled out, both dietary recalls have been completed, and the Month 0 and Main Surveys have been completed.

ADMIN: Ready to be Randomized

Editing existing Record ID 16 Mandy Test

Record ID 16

Check box if ALL forms have been checked & eligibility confirmed:

- Consent/HIPAA/PHI
- Screening survey
- M0 Recall 1
- M0 Recall 2
- M0 & Main Surveys

Have the above forms been checked & completed?
* must provide value

Randomization Notes:

Form Status

Complete? Incomplete

“ADMIN: Ready to be Randomized” REDCap instrument

To monitor dietary recalls, the lead diet assessor will conduct a quality check after data collection at each data collection time point (Baseline/Month 0, Month 6, and Month 12). This includes an in-depth review of both individual and composite reports for completeness and errors.

Finally, there will be weekly full team meetings to encourage regular communication, and allow for any issues around monitoring to be discussed.

- 10.4 Data sharing.** Only study director and study statistician will have access to final trial dataset. Per NIH rules, the de-identified data will be disclosable to third parties. Furthermore, anyone who desires access to full trial protocol, participant-level dataset, and/or statistical code will be able to access via National Heart, Lung, and Blood Institute repository after peer-reviewed publication.

11 PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This IRB protocol [IRB approval letters: Appendix I & II] and the informed consent document [Appendix V] and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight of the study.

11.2 Informed Consent Forms

Prior to attending orientation, candidates will fill out a pre-screening survey with a Waiver of Documentation sheet that gives a general overview of the study, and is something they must agree to in order to continue with the pre-screening questions [Appendix IV]. Candidates who attend orientation will be competent in the English language and able to complete the consent form independently. There is a single informed consent form that describes both the screening and study procedures [Appendix V].

The study director, the study coordinator, and/or the study staff will review the major components of the consent, page by page, in the group orientation with the visual aid of a PowerPoint presentation. The candidate will then have time to individually review consent in detail, ask any questions to available staff members, and sign once they fully understand the components of the consent form.

As candidates are leaving orientation, study staff will collect consent forms, answer any additional questions, and ensure the consent form was signed and dated correctly. Study staff will record all signed and dated consent forms in REDCap after orientation, and then organize alphabetically by last name in a secure folder locked in the study coordinator's secure file cabinet.

11.3 Participant Confidentiality

As much as possible, any data, forms, survey responses, and other records that contain participant information, will be identified only by a participant identification number (CHIVES ID). Any data, forms, survey responses, and other records that must leave the study office will be identified only by a CHIVES ID to maintain confidentiality. All physical records with patient health information, along with all blank food vouchers will be kept in a locked file cabinet. All computer entry and networking programs (mostly NDSR and REDCap) will be done using CHIVES IDs / REDCap Record ID. Information will not be released without written permission of the participant, except as necessary for monitoring by Institutional Review Board or the National Institutes of Health.

11.4 Study Discontinuation

The study may be discontinued at any time by the Institutional Review Board, the National Institutes of Health, or other government agencies as part of their duties to ensure that research participants are protected.

12 ETHICAL CONSIDERATIONS

All study candidates and participants will be treated equally and with utmost respect, in accordance with principles outlined in the Declaration of Helsinki. All participants will have the right to make informed decisions regarding their participation in the study. No minors or people who are not capable of giving informed consent will be recruited for the study.

13 COMMITTEES

The committee overseeing the trial is the Data Safety Monitoring Board, which consists of Jason Block from Harvard University, Arjumand Siddiqi from University of North Carolina, and Kristina Lewis from Wake Forest University, all of whom are independent from the study sponsor and have no competing interests. The study director will update them immediately with any adverse events and quarterly, otherwise. More details are available in the Data Safety and Monitoring Protocol [Appendix XIX].

13.1 Study Contributors – Main Roles and Responsibilities

None of the investigators, co-investigators, or study staff have any financial or other competing interests.

Co-Principal Investigators

Sanjay Basu, MD, PhD *Stanford University*

Main role: Contact Principal Investigator

Main responsibilities:

- Aim 1: will oversee recruitment, retention and assessment for the trial;
- Aim 2: will oversee model design, programming and validation for cost-effectiveness analysis.

Hilary Seligman, MD, MAS *University of California San Francisco*

Main role: Logistics Principal Investigator

Main responsibilities:

- Aim 1: oversee voucher distribution and retention of vendors for the trial;
- Aim 2: inform modeling of impact of healthy eating on cardiovascular disease disparities for cost-effectiveness analysis

Co-Investigators:

Christopher Gardner, PhD *Stanford University*

Main responsibility:

- Aim 1: contribute staff, expertise, and supervision to ensure accurate and successful completion of dietary recalls and their analysis

Matthew Harding, PhD *University of California, Irvine*

Main responsibility:

- Aim 1: will integrate economic and food environment data into the cost-effectiveness analysis for national projections

Justin White, PhD *University of California San Francisco*

Main responsibilities:

- Aim 1: inform trial design and conduct; assist in recruitment, randomization, and retention strategy development and execution;
- Aim 2: inform cost-effectiveness analysis components

13.2 Steering Committee

The steering committee is made up of the co-principal investigators – Sanjay Basu, MD, PhD and Hilary Seligman, MD, MAS as well as the study coordinators – Mandy Carroll, MPH, RD and Melissa Akers, MPH, CPH.

13.3 Data Management Team

The data management team is made up of the co-principal investigators – Sanjay Basu, MD, PhD and Hilary Seligman, MD, MAS; the study coordinators – Mandy Carroll, MPH, RD and Melissa Akers, MPH, CPH; and the diet assessment team – Sarah Farzinkhou, MPH (lead diet assessor), Carrie McKinley, Lindsay Durand, RD, and Elizabeth Zanley, RD.

14 PUBLICATION OF RESEARCH FINDINGS

Publication of the results of this trial will be governed by the policies and procedures developed under the Co-Principal Investigator agreement submitted with the original R01 grant for this proposal (see National Institutes of Health Data Sharing Policy). Who is eligible for authorship in this trial is based on International Committee of Medical Journal Editors criteria.

Study director and/or study coordinator will communicate trial results to participants by community meeting. Study director will communicate trial results to professionals and interest groups via peer-reviewed publication. Also, study director will post trial results on clinicaltrials.gov, per SPIRIT guidelines.

Anyone who desires access to full trial protocol, participant-level dataset, and/or statistical code will be able to access via National Heart, Lung, and Blood Institute repository after peer-reviewed publication.

15 APPENDICES

I. Stanford University Institutional Review Board Approval Letter

STANFORD UNIVERSITY

Stanford, CA 94305 [Mail Code 5579]

David D Oakes, M.D.

(650) 723-5215

CHAIR, PANEL ON MEDICAL HUMAN SUBJECTS

Certification of Human Subjects Approvals

Date: May 21, 2019

To: Christopher D Gardner, PhD, Medicine - Med/Stanford Prevention Research Center
Mandy Murphy Carroll MA, Jennifer L. Robinson MA

From: David D Oakes, M.D., Administrative Panel on Human Subjects in Medical Research

eProtocol Title: Designing Food Voucher Programs to Reduce Disparities in Healthy Diets

eProtocol #: 36763

IRB 8 (Registration #: 6208)

The IRB approved human subjects involvement in your research project on 05/21/2019. **'Prior to subject recruitment and enrollment, if this is: a Cancer-related study, you must obtain Cancer Center Scientific Review Committee (SRC) approval; a CTRU study, you must obtain CTRU approval; a VA study, you must obtain VA R and D Committee approval; and if a contract is involved, it must be signed.'**

The expiration date of this approval is 02/28/2020 at Midnight. If this research is to continue beyond that date, it is your responsibility to submit a Continuing Review application in eProtocol. Research activities must be reviewed and re-approved on or before midnight of the expiration date. The approval period may be less than one year if so determined by the IRB. Proposed changes to approved research must be reviewed and approved prospectively by the IRB. No changes may be initiated without prior approval by the IRB, except where necessary to eliminate apparent immediate hazards to subjects. (Any such exceptions must be reported to the IRB within 10 working days.) Unanticipated problems involving risks to participants or others and other events or information, as defined and listed in the Report Form, must be submitted promptly to the IRB. (See Events and Information that Require Prompt Reporting to the IRB at <http://humansubjects.stanford.edu>.) Upon completion, you must report to the IRB within 30 days.

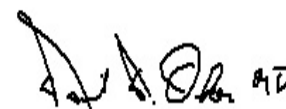
Please remember that all data, including all signed consent form documents, must be retained for a minimum of three years past the completion of this research. Additional requirements may be imposed by your funding agency, your department, HIPAA, or other entities. (See Policy 1.9 on Retention of and Access to Research Data at <http://doresearch.stanford.edu/policies/research-policy-handbook>)

This institution is in compliance with requirements for protection of human subjects, including 45 CFR 46, 21 CFR 50 and 56, and 38 CFR 16.

Includes: Personnel changes. Sanjay Basu, MD, PhD has left Stanford and Christopher Gardner, PhD has assumed PI role on the project. NIH approved this change in PI.

Waiver of Individual Authorization for recruitment under 45 CFR 164.512(i)(2)(ii)(A),(B),(C), pursuant to information provided in the HIPAA section of the protocol application.

Alteration of HIPAA Authorization under 45 CFR 164.512(i)(2)(ii), pursuant to information provided in the HIPAA section of the protocol application.



David D Oakes, M.D., Chair

Approval Period: 05/21/2019 - 02/28/2020

Review Type: EXPEDITED - MODIFICATION

Funding: NIH / NHLBI - Grant: 1R01 HL132814-01, SPO: 121890

Expedited Under Category: 7

Assurance #: FWA00000935 (SU)

II. University of California San Francisco Institutional Review Board Approval Letter



University of California
San Francisco

**Human Research Protection Program
Institutional Review Board (IRB)**

Expedited Review Approval

Principal Investigator

Hilary K Seligman M.D.,

Type of Submission: Submission Correction for Continuing Review Submission Form
Study Title: Coupons for Healthy Intake using Varied Economic Strategies (Designing Food Voucher Programs to Reduce Disparities in Healthy Diets)

IRB #: 15-17957

Reference #: 245983

Committee of Record: San Francisco General Hospital Panel

Study Risk Assignment: Minimal

Approval Date: 03/18/2019

Expiration Date: 03/17/2020

This submission was eligible for expedited review as:

Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Data analysis phase:

This study is in data analysis and involves no greater than minimal risk for the population being studied.

IRB Comments:

All changes to a study must receive UCSF IRB approval before they are implemented. Follow the [modification request](#) instructions. The only exception to the requirement for prior UCSF IRB review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). In such cases, report the actions taken by following these [instructions](#).

Expiration Notice: The iRIS system will generate an email notification eight weeks prior to the expiration of this study's approval. However, it is your responsibility to ensure that an application for [continuing review](#) approval has been submitted by the required time. In addition, you are required to submit a [study closeout report](#) at the completion of the project.

Documents Reviewed and Approved with this Submission (includes all versions – final approved versions are labeled ‘Approved’ in the Outcome column):

Other Study Documents

Study Document			
Title	Version #	Version Date	Outcome
Vendor	Version 1.0	03/30/2016	Approved
Consent Form	Version 1.0	03/30/2016	Approved
Stanford IRB Approval	Version 1.0	03/15/2016	Approved
Protection of Human Subjects Section of NIH Grant	Version 1.0	03/07/2016	Approved
Participant questionnaire	Version 1.0	03/07/2016	Approved
Vendor questionnaire	Version 1.0	03/07/2016	Approved
Study flyer	Version 1.0	03/07/2016	Approved

For a list of all currently approved documents, follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to UCSF IRB approval and follow all applicable VA and other federal requirements. The UCSF IRB [website](#) has more information.

III. Recruitment Flyers & Recruitment Appointment Card



DO YOU HAVE A HARD TIME AFFORDING HEALTHY FOODS?

CHIVES Project can help!

If you are interested:

- You will receive \$20 worth of vouchers to purchase foods each month for 6 months.
- You will be asked to complete phone surveys about the foods you eat.
- Visit the website to see if you qualify:

is.gd/chivesproject

Your participation is voluntary. Participant's rights questions, contact 1-866-680-2906.

Enrolling CHIVES participants through July 2017.

FOR MORE INFORMATION:



CHIVES Food Voucher Project
visit: is.gd/chivesproject

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visit: is.gd/chivesproject

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DO YOU HAVE A HARD TIME AFFORDING HEALTHY FOODS?

The CHIVES Project can help!

If you are interested:

- You will receive \$20 worth of vouchers to purchase foods each month for 6 months.
- You will be asked to complete phone surveys about the foods you eat.
- Visit the website to see if you qualify: is.gd/chivesproject

FOR MORE INFORMATION: visit the website is.gd/chivesproject 

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FOR MORE INFORMATION: visit the website is.gd/chivesproject 

Your participation is voluntary. Participant's rights questions, contact 1-866-680-2906.

****Enrolling CHIVES participants through July 2017.****

IV. Waiver of Documentation & Pre-Screening Survey

More information about the CHIVES Project

DESCRIPTION:

You are invited to participate in a research study on how food vouchers affect people's nutrition. First, you will be asked to attend an orientation to give you more information about the research study. If you choose to participate and if you are eligible, you will be asked to use food vouchers at local stores to purchase some of your groceries. You will also be asked to participate in approximately 12 phone calls over the course of the next year to provide information on what you eat and other information about your food preferences and habits.

TIME INVOLVEMENT:

Your participation will take approximately 10 hours over the next year.

RISKS AND BENEFITS:

There are no anticipated major risks for you participating in this study, except for the inconvenience of having to use your food vouchers while buying groceries, and possible discomfort talking about some personal information over the phone. The benefits for participating in this study are receiving an additional \$20 monthly to spend on groceries, which may positively influence your eating behaviors.

PAYMENTS:

In addition to the \$20 food vouchers you will receive the first six months, you will also receive one \$20 gift certificate for completing the final 4 phone calls after participating in the study 6 months, and an additional \$20 gift certificate for completing the final 4 phone calls at 12 months.

SUBJECT'S RIGHTS:

If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. The alternative is not to participate.

CONTACT INFORMATION:

If you have any questions, concerns, or complaints about this research, its procedures, risks and benefits, contact the Protocol Director, Sanjay Basu at (844) 4-CHIVES, or (844) 424-4837. If you want to talk to someone separate from the research team about a concern or complaint or your rights as a possible research subject, feel free to contact the Stanford Institutional Review Board (IRB) at (650) 723-5234 or toll free at (866) 680-2906.

If you agree to participate in this research, please click to box below that states you agree to share your contact information, and sign up for an orientation session in a following screen.

After reading the above information, do you agree to provide your contact information, and sign up for an orientation?

- Yes
 No

Sorry to hear that. We will miss working with you.

Thanks for checking out the CHIVES Project!

Thank you for your interest in the CHIVES Project!**Please answer the next few questions to see if you are likely to be eligible to participate in the CHIVES Project.**

- Are you 21 years or older? Yes
 No
- Do you have regular access to a cell phone? Yes
 No
- Are you able to send & receive text messages with your cell phone? Yes
 No
- Are you a resident of San Francisco? Yes
 No
- Are you planning to move out of San Francisco in the next year? Yes
 No
- Are you currently participating in any nutrition study or trial? Yes
 No
- Are you currently participating in the EatSF voucher program? Yes
 No
(Answer "yes" only if you have received an EatSF voucher in the past 4 weeks.)
- Are you currently pregnant? Yes
 No
- Are you currently breastfeeding? Yes
 No
- Do you currently have cancer? Yes
 No
- Do you currently have heart failure or congestive heart failure? Yes
 No
- How did you hear about the CHIVES Project?
 Community event
 Craigslist ad
 Facebook
 Flyer
 My church
 My health clinic
 My local grocery store
 Word of mouth
 Other
- Please let us know which community event.
- Please let us know where you saw the flyer.
- Please let us know at which church you heard about the CHIVES Project.

Please let us know which health clinic.

- Arthur H. Coleman Medical Center, Bayview Hunters Point Clinic
- Silver Avenue Family Health Center
- Southeast Health Center
- Other Health Clinic

At which health clinic did you hear about the CHIVES Project?

Please let us know in which grocery store you heard about the CHIVES Project.

- Duc Loi's Pantry
- Foods Co (on Folsom)
- Foods Co (on Williams)
- Friendly's Market
- Heart of the City Farmer's Market
- Lee's Market
- Palou Market
- Safeway
- Super Save
- Other Grocery Store

At which grocery store did you hear about the CHIVES Project?

Please let us know how you found out about the CHIVES Project.

Great!

It looks like you are likely able to participate in the CHIVES Project.*

Please fill out you contact information below, and which date works best for you to attend an orientation session on the CHIVES Project.

***Please note: One reason you may not qualify is if your annual income is too high. The study will be limited to people with an income of less than 250% of the federal poverty level. For 1 person, this means an annual income of**

First Name

Last Name

Preferred Name / Nickname

E-mail Address

Cell Phone

Are you able to send & receive text messages with this cell phone?

- Yes
 No

Additional Phone Number

What is this additional phone number?

- Home phone number
 Workphone number
 Different cell phone
 Other phone

Please provide us with a secure mailing address. If you wish to participate, and you are eligible, we will send the food vouchers to this address.

Please note: This cannot be a P.O. Box.

Street Address

Apartment number

City

State

- CA

Zip Code

Orientation Sessions

WHERE: 1485 Bayshore Blvd., San Francisco 94124
in Conference Room 230 (to the left of the reception desk).

WHAT: You will learn more about CHIVES Project, sign a consent form, and take a paper survey that will assess your annual income and gather a little more personal information.

HOW LONG: The orientation sessions last about 60 minutes.

Please select which date & time work best for you.

Which orientation works best for you to attend?

- Tuesday, 1/10/2017 at 11am
- Tuesday, 1/10/2017 at 2pm
- Tuesday, 1/10/2017 at 5:30pm
- Wednesday, 1/11/2017 at 11am
- Wednesday, 1/11/2017 at 2pm
- Wednesday, 1/11/2017 at 5:30pm
- Thursday, 1/12/2017 at 11am
- Thursday, 1/12/2017 at 2pm
- Thursday, 1/12/2017 at 5:30pm
- Friday, 1/13/2017 at 11am
- Friday, 1/13/2017 at 2pm
- Tuesday, 1/17/2017 at 11am
- Tuesday, 1/17/2017 at 2pm
- Tuesday, 1/17/2017 at 5:30pm
- Wednesday, 1/18/2017 at 11am
- Wednesday, 1/18/2017 at 2pm
- Wednesday, 1/18/2017 at 5:30pm
- Thursday, 1/19/2017 at 11am
- Thursday, 1/19/2017 at 2pm
- Thursday, 1/19/2017 at 5:30pm
- Friday, 1/20/2017 at 11am
- Friday, 1/20/2017 at 2pm
- Friday, 1/20/2017 at 5:30pm
- Thursday, 2/9/2017 at 11am
- Thursday, 2/9/2017 at 2pm
- Thursday, 2/9/2017 at 5:30pm
- Friday, 2/10/2017 at 11am
- Friday, 2/10/2017 at 2pm
- Friday, 2/10/2017 at 5:30pm
- Monday, 2/13/2017 at 11am
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- Tuesday, 2/14/2017 at 5:30pm
- Wednesday, 2/15/2017 at 11am
- Wednesday, 2/15/2017 at 2pm
- Wednesday, 2/15/2017 at 5:30pm
- Thursday, 2/16/2017 at 11am
- Thursday, 2/16/2017 at 2pm
- Thursday, 2/16/2017 at 5:30pm
- Friday, 2/17/2017 at 11am
- Friday, 2/17/2017 at 2pm
- Friday, 2/17/2017 at 5:30pm
- Tuesday, 2/21/2017 at 11am
- Tuesday, 2/21/2017 at 2pm
- Tuesday, 2/21/2017 at 5:30pm
- Thursday, 3/9/2017 at 11am
- Thursday, 3/9/2017 at 2pm
- Thursday, 3/9/2017 at 5:30pm
- Friday, 3/10/2017 at 11am
- Friday, 3/10/2017 at 2pm
- Friday, 3/10/2017 at 5:30pm
- Monday, 3/13/2017 at 11am
- Monday, 3/13/2017 at 2pm
- Monday, 3/13/2017 at 5:30pm
- Tuesday, 3/14/2017 at 11am
- Tuesday, 3/14/2017 at 2pm
- Tuesday, 3/14/2017 at 5:30pm
- Wednesday, 3/15/2017 at 11am
- Wednesday, 3/15/2017 at 2pm
- Wednesday, 3/15/2017 at 5:30pm
- Thursday, 3/16/2017 at 11am
- Thursday, 3/16/2017 at 2pm
- Thursday, 3/16/2017 at 5:30pm
- Friday, 3/17/2017 at 11am
- Friday, 3/17/2017 at 2pm
- Friday, 3/17/2017 at 5:30pm
- Tuesday, 3/21/2017 at 11am
- Tuesday, 3/21/2017 at 2pm

Tuesday, 3/21/2017 at 5:30pm

Other

(Please write down for which orientation date & time you signed up. You will receive a text message reminder one day before the orientation.)

This is the Bayshore Business Center, or the Comcast Building, where the orientation will be held. This is next door to the U-Haul facilities on Bayshore Blvd.



Family & Friends

Finally, do you have any friends or family members who do NOT live with you that would be interested in participating in the CHIVES Project?

- Yes
- No

Please pass along our contact information and invite them to participate!

Not eligible at this time!

I'm sorry, it looks like you are not eligible to participate in the CHIVES Project at this time.

Please call us at (844) 4-CHIVES or (844) 424-4837, or e-mail us at chivesproject@stanford.edu with questions.

Thank you!

V. Participant Consent Form

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Sanjay Basu

Protocol Title: Designing Food Voucher Programs to Reduce Disparities in Healthy Diets

FOR QUESTIONS ABOUT THE STUDY, CONTACT: Sanjay Basu at (844) 4-CHIVES or (844) 424-4837.

DESCRIPTION: You are invited to participate in a research study on whether vouchers for food help to improve your nutrition. You will be asked to:

- **Receive vouchers via mail** every month, for six months. You will be randomly assigned to receive a particular type of voucher; randomly means like flipping a coin or like rolling a dice. Each month, you will either receive four vouchers. The vouchers will either last for one week, or for a month. Your vouchers will either allow you to buy fruits and vegetables, or to buy any CalFresh approved foods (any food or beverage, except hot or prepared foods, vitamins or supplements, or alcohol).
- **Use the vouchers** as permitted, to help you purchase food at stores that accept the vouchers.
- **Complete three surveys about your nutrition.** A research study staff member will call you to tell us about how easy or hard it was to use the voucher, how much you enjoy and are able to eat fruits and vegetables, and how hard it is to find money to pay for food. Each survey takes about **20 minutes** to finish, and will be completed **once when you enter the study, a second time in 6 months, and a third and final time 1 year from now.** Therefore, it will take about an hour of your time over the course of the next year to complete these surveys.
- **Tell us what you eat.** A research study staff member will call you to give us a list of everything you ate the day before the telephone call. This is called a "food recall", and takes about **30 minutes** to finish. It will be conducted **four times when you enter the study, another four times 6 months from now, and another four times 1 year from now.** Therefore, it will take about six hours of your time over the course of the next year to complete these food recalls.

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.

RISKS AND BENEFITS:

The risks associated with this study are:

- The inconvenience of remembering to use the vouchers when you shop for food.
- The time and inconvenience of answering surveys and describing everything that you ate.
- The psychological discomfort of talking about whether it was difficult for you to obtain nutritious food or enough food.

The benefits which may reasonably be expected to result from this study are:

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Sanjay Basu

Protocol Title: Designing Food Voucher Programs to Reduce Disparities in Healthy Diets

- You may experience benefits to your nutrition by being able to purchase more food and healthier foods.
- You may experience less difficulty affording foods because of the vouchers.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

TIME INVOLVEMENT: Your participation in this experiment will take approximately 10 hours of your time over the next year.

FINANCIAL CONSIDERATIONS

PAYMENTS: You will receive \$20 in the form of \$5 food vouchers each month for six months. In addition, after you complete the survey and food recall 6 months from your enrollment, you will receive one \$20 gift card. After you complete the survey and food recall 1 year from your enrollment, you will receive another \$20 gift card.

COSTS: You will need to receive and send about 10 text messages as a part of this study over the next year. Your message rates may apply. In other words, when you use receive and send text message services with CHIVES Project, the cost to you is whatever your wireless provider charges you to send and receive text messages. If you have an unlimited text messaging plan, then you don't have to worry, as this will not apply to you.

PARTICIPANT'S RIGHTS

If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed.

You have the right to refuse to answer particular questions.

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Sanjay Basu

Protocol Title: Designing Food Voucher Programs to Reduce Disparities in Healthy Diets

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to determine what type of voucher to help people purchase food is most likely to improve nutrition. To answer this question, information about what you eat will be collected, and statistics about how everyone in the study eats will be published in a scientific journal. Information in some form will be submitted to the National Institutes of Health, which is sponsoring the study.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related vouchers to help purchase food.

Signing the form is not a condition for receiving any medical care outside the study.

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

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Sanjay Basu, Medical School Office Building X322, 1265 Welch Road, Stanford CA 94305-5411

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Sanjay Basu

Protocol Title: Designing Food Voucher Programs to Reduce Disparities in Healthy Diets

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, your name; your telephone number; your stress address, city, county and zip code; your electronic mail addresses; your height; your weight; whether you currently have cancer; and whether you currently have congestive heart failure.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Sanjay Basu
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The National Institutes of Health
- The Food and Drug Administration

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 authorization expire?

Your authorization for the use and/or disclosure of your health information will end on February 28, 2030 or when the research project ends, whichever is earlier.

Signature of Adult Participant

Date

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Sanjay Basu

Protocol Title: Designing Food Voucher Programs to Reduce Disparities in Healthy Diets

WITHDRAWAL FROM STUDY

The Protocol Director may also withdraw you from the study and stop you from receiving the research-related vouchers, without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

CONTACT INFORMATION:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Sanjay Basu. You may contact him now or later at (844) 4-CHIVES, or (844) 424-4837.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at (866) 680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

The extra copy of this signed and dated consent form is for you to keep.

Signature of Adult Participant

Date

Signature of Person Obtaining Consent

Date

Signature of Person Obtaining Consent

Date

Print Name of Person Obtaining Consent

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Sanjay Basu

Protocol Title: Designing Food Voucher Programs to Reduce Disparities in Healthy Diets

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

Signature of Witness

Date

Print Name of Witness

(e.g., staff, translator/interpreter, family member, or other person who speaks both English and the participant's language)

- Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.
- The English consent form ("summary form"):
 - Must be signed by the witness AND the Person Obtaining Consent (POC).
 - The non-English speaking participant/LAR does not sign the English consent.
 - The non-English speaking participant/LAR should not sign the HIPAA participant line
 - if the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.

VI. Self-Administered Screening Surveys (English & Spanish) – for orientation

CHIVES Screening Survey

NAME:

Do you prefer a Spanish form? If so, please tell a study staff member now that you would like a Spanish version of this form.

The purpose of this screening survey is to see if you meet the criteria for taking part in our research study of how food vouchers affect how many vegetables, fruits, and other foods you eat. This survey will take approximately 10 minutes. You may choose not to answer these questions. You also may choose to stop participating in this survey at any time; if you want to stop, please do so and notify the study staff present at the orientation session.

The answers and information that you provide during this survey will be kept as confidential as possible as required by law. It is possible that the Food and Drug Administration, and other federal and state authorities, may inspect this record.

You can choose if you want or do not want to take part in this research screening procedure – it is up to you. If you choose not to answer the questions or stop answering them at any time, there will be no penalty, and you will not lose any benefits to which you otherwise would be entitled.

The risk to taking part in this survey is very small. The screening survey is not designed to ask you for sensitive personal information, but it is possible that some people may feel uncomfortable answering these questions. If that is the case, please stop and inform the study staff that you wish to stop. If you qualify to take part in the study and are interested in taking part, then study staff will keep your name and information; this will be kept confidential, but there is a small risk that people outside of the study staff could learn this information. If you are not interested in the study, then study staff will destroy all the answers and personal information you've provided.

The benefit to you of taking part in this survey is that you will find out whether you can take part in the study of how food vouchers affect how many vegetables, fruits, and other foods you eat. This study involves receiving vouchers to help you purchase food over the next six months, and looks at how different kinds of food vouchers affect people's nutrition intake.

If you do not want to answer these questions, you have other choices. You can talk to your doctor about nutrition. You may also want to do nothing.

You will not be paid for answering questions in this survey since it is only to see whether you qualify to take part in the study.

If you have any questions, concerns, or complaints about this interview, contact CHIVES study staff at 844-4CHIVES (844-424-4837). If you want to talk to someone separate from the study staff about a concern, complaint, or your rights as a possible research subject, please contact the Stanford Institutional Review Board (IRB) to speak to an informed person who is separate from the study staff at 650-723-5244, or toll-free at 866-680-2906. Also, please call the Stanford IRB at these numbers if you cannot reach the study staff.

**** PLEASE CONTINUE TO NEXT PAGE. ****

CHIVES Screening Survey

Survey Questions

Please fill out the following questions to determine whether you are eligible to participate in the study. You may leave any questions blank that you prefer not to state, but it may exclude you from the study.

Full Name: _

Preferred Name: _

Mailing Address: _

E-mail Address: _ *(not required)*

1. What is your age in years?

_ years

2. What is your gender?

_ Male

_ Female

_ Other

3. What is the highest grade or year of school you **completed**?

_ Never attended school or only attended kindergarten

_ Grades 1 through 8 (Elementary or Middle school)

_ Grades 9 through 11 (Some high school)

_ Grade 12 or GED (High school graduate)

_ College 1 year to 3 years (Some college or technical school)

_ College 4 years or more (College graduate)

_ Other, please define: _

**** PLEASE CONTINUE TO NEXT PAGE. ****

CHIVES Screening Survey

NAME:

4. What race(s) do you consider yourself? (Check all that apply).

- American Indian / Alaskan Native
- Asian
- Black / African American
- Native Hawaiian / Pacific Islander
- White
- Don't Know / Unknown
- Other, please define: _

5. Do you consider yourself Hispanic or Latino?

- Yes
- No

6. What is your best estimate of your household's monthly income before taxes, last year (2016)?

\$ (monthly income in 2016)

7. How many people, including you, lived in your household in 2016?

A household includes all people (adults and children) who live with you most of the year and are related to you by birth, marriage, or adoption.

_ people

**** PLEASE CONTINUE TO NEXT PAGE. ****

CHIVES Screening Survey

NAME: _

8. Are you willing to be randomly assigned (like flipping a coin) to receive a food voucher that could be valid for a week, or for a whole month?

- Yes

- No

9. Are you willing to be randomly assigned (like flipping a coin) to receive food vouchers that could be valid for only fruits and vegetables, or food vouchers that could be valid for any type of food, excluding alcoholic beverages, vitamins, hot food, or food eaten in the store?

- Yes

- No

10. Are you **currently** participating in the CalFresh program, also known as EBT, SNAP, or Food Stamps?

- Yes

- No

11. Is someone in your household, other than you, **currently** participating in the CalFresh program, also known as EBT, SNAP, or Food Stamps?

- Yes

- No

- Don't know

**** PLEASE CONTINUE TO NEXT PAGE. ****

CHIVES Screening Survey

NAME:

12. Do you have a reliable address where you can receive mail safely?

- Yes

- No

13. Are you interested in participating in this study, and would you like to be contacted for next steps?

- Yes

- No

If you marked "**No**" to Question 13 above, please inform a study staff member now that you would like this survey to be destroyed.

If you marked "**Yes**" to Question 13 above, please fill out your phone number(s) and table on the next page:

**** PLEASE CONTINUE TO NEXT PAGE. ****

CHIVES Screening Survey

NAME: _

14. If you are eligible to participate in the CHIVES project, we will call you during the next two weeks to complete 4 food recalls and 1 survey over the phone.

What are the best phones numbers to reach you?

Cell Phone: _

Additional Phone: _

Is this additional phone number your:

_ Home _ Work _ Different Cell _ Other

15. This study will require that receive and respond to multiple text messages (approximately 10) over the next year. Are you okay with this?

_ Yes

_ No

16. What are generally good times to call you? Please mark an "X" in **all boxes** that show a good time to call you for each day of the week.

	Mondays	Tuesdays	Wednesdays	Thursdays	Fridays	Saturdays	Sundays
8am-10am <i>(early morning)</i>							
10am-12pm <i>(late morning)</i>							
12pm-2pm <i>(lunch hour)</i>							
2pm-4pm <i>(mid-day)</i>							
4pm-6pm <i>(evening)</i>							
6pm-8pm <i>(night)</i>							

** End of survey. Thank you! **

Encuesta de elegibilidad para participar en el ensayo clínico CHIVES*

NOMBRE:

Por la presente encuesta se busca determinar si el encuestado (usted) reúne todos los requisitos para participar en este estudio de investigación cuyo objetivo es determinar la correlación entre el uso de los cupones para comida (food vouchers) y el consumo de verduras, frutas y otros alimentos. Esta encuesta le llevará aproximadamente 10 minutos. Podrá dejar preguntas sin responder. También podrá dejar de participar en el estudio en cualquier momento; si decide hacerlo, haga el favor de notificar a los responsables del estudio quienes estarán presentes en la sesión de orientación de hoy por la noche.

Las respuestas e información que usted proporcione en esta encuesta se mantendrán confidenciales en la medida posible según lo exige la ley. La Administración de Medicamentos y Alimentos, y otras agencias federales y estatales, podrían tener acceso a este registro.

Está en libertad de elegir si desea o no participar en este proceso de preselección para su participación en este estudio —la decisión es suya. Si opta por no responder a las preguntas, o por dejar de contestarlas, no se le penalizará, ni se le revocará ninguno de los beneficios a los que tiene derecho.

El riesgo de participar en esta encuesta es muy bajo, ya que se ha diseñado de forma que no incluya información personal de índole delicada, aunque es posible que algunas personas se sientan incómodas de responder algunas de las preguntas. De ser así, por favor deje de contestar las preguntas, e informe al personal del estudio que ya no desea continuar. Si le interesa participar en este estudio, y califica, nuestro personal conservará su nombre e información personal, los cuales se mantendrán confidenciales. Aun así, hay un pequeño riesgo de que personas ajenas al estudio pudieran tener acceso a su información. Si, por otro lado, una vez que ha completado la encuesta usted decide que no le interesa participar en el estudio, el personal destruirá todo el material con sus respuestas e información personal.

El beneficio de participar en esta encuesta es que le permitirá saber si califica para participar en el estudio sobre la correlación entre el uso de los cupones para comida y el consumo de verduras, frutas y otros alimentos. Por medio de este estudio, que examina el efecto de los diferentes cupones para comida en la nutrición de las personas que los reciben, se le darán cupones para asistirle en la compra de alimentos durante los seis meses próximos.

Si no desea responder estas preguntas, se le darán otras alternativas entre las que se cuentan el que usted decida hablar con su médico sobre la nutrición o que simplemente decida no hacer nada nuevo.

No se le remunerará por responder las preguntas en esta encuesta por la que solo se busca determinar si usted califica para participar en este estudio.

**** CONTINÚA EN LA PÁGINA SIGUIENTE. ****

* La palabra CHIVES es un acrónimo que proviene de: Coupons for Healthy Eating Using Variable Economic Strategies (Cupones para comer de manera saludable mediante estrategias económicas variables).

Encuesta de elegibilidad para participar en el ensayo clínico CHIVES*

Si tiene alguna pregunta, inquietud, o queja sobre esta entrevista, llame al 844-4CHIVES (844-424-4837) para ponerse en contacto con el personal del estudio CHIVES. Si, por otro lado, prefiere contactarse con una persona no involucrada directamente en el estudio sobre algo que le preocupa, o si tuviera alguna queja, o quisiera informarse sobre sus derechos como sujeto de investigación, llame al Consejo de Revisión Institucional de Stanford (IRB, por sus siglas en inglés) al 650-723-5244 ó al 866-680-2906 (línea telefónica gratuita), para hablar con una persona informada e independiente del estudio. También llame al Consejo de Revisión Institucional de Stanford a cualquiera de los números telefónicos anteriores si no puede comunicarse con el personal del estudio.

Preguntas de la encuesta

Responda las preguntas a continuación para determinar si califica para participar en el estudio de investigación. Puede dejar en blanco cualquier pregunta que prefiera no responder; aunque esto lo podría descalificar para participar en el estudio.

Nombre completo: _____

Nombre por el que prefiere que lo llamen: _____

Dirección: _____

Dirección de correo electrónico: _____ *(no es obligatorio)*

1. ¿Cuántos años tiene?

_____ años

2. ¿Con qué género se identifica?

_____ masculino

_____ femenino

_____ otro

**** CONTINÚA EN LA PÁGINA SIGUIENTE. ****

Encuesta de elegibilidad para participar en el ensayo clínico CHIVES*

NOMBRE:

3. ¿Hasta qué grado (**terminado**) llegó en la escuela?

- nunca fui a la escuela o sólo llegué al jardín de niños
- del primero al octavo grados (primaria o secundaria)
- del noveno al onceavo grados (algo de preparatoria)
- doceavo grado o terminé la preparatoria (recibí el GED)
- asistí a la universidad de 1 a 3 años
(alguna experiencia universitaria o de escuela técnica)
- 4 años o más de estudios universitarios (recibí mi licenciatura)
- otra, por favor explique: _

4. Favor de indicar su raza (marque todas las opciones que correspondan).

- nativo de América del Norte / nativo de Alaska
- asiático
- negro / afroamericano
- nativo de Hawái / de las islas pacíficas
- blanco
- no lo sé / se desconoce
- otra, por favor explique: _

5. ¿Se considera hispano o latino?

- Sí
- No

**** CONTINÚA EN LA PÁGINA SIGUIENTE. ****

Encuesta de elegibilidad para participar en el ensayo clínico CHIVES*

NOMBRE:

6. ¿Cuál es la mejor estimación de su ingreso familiar mensual antes de impuestos el año anterior (2016)?

\$ (ingreso mensual in 2016)

7. ¿Cuántas personas, incluyéndolo a usted, vivieron en su hogar en 2016? Aquí se incluyen todas las personas (adultos y niños) que viven con usted la mayor parte del año y que están emparentados con usted por nacimiento, matrimonio o adopción.

- personas

8. ¿Estaría usted dispuesto a que se le seleccionara al azar (como se hace al tirar una moneda al aire) para recibir un vale de despensa que podría ser válido por una semana o un mes entero?

- Sí

- No

9. ¿Estaría usted dispuesto a que se le seleccionara al azar (como se hace al tirar una moneda al aire) para recibir cupones para comida que fueran válidos sólo para comprar frutas y verduras, o cupones para comida que se podrían usar para comprar toda clase de alimentos, excepto bebidas alcohólicas, vitaminas, alimentos calientes o que se comen en la misma tienda?

- Sí

- No

10. ¿Participa **actualmente** en el programa CalFresh, también conocido como EBT, SNAP o estampillas para comida (Food Stamps)?

- Sí

- No

**** CONTINÚA EN LA PÁGINA SIGUIENTE. ****

Encuesta de elegibilidad para participar en el ensayo clínico CHIVES*

NOMBRE:

11. ¿Alguien en su hogar, que no sea usted, **actualmente** participa en el programa CalFresh, también conocido como EBT, SNAP o estampillas para comida?

- Sí
- No
- No sé

12. ¿Tiene usted una dirección confiable donde recibir correo de forma segura?

- Sí
- No

13. ¿Le interesaría participar en este estudio, y quisiera que le contactáramos para dar el paso siguiente?

- Sí
- No

Si respondió «**no**» a la pregunta anterior N°13, ahora es cuando debe informar a un encargado de este estudio que quiere que se destruya la encuesta.

Si respondió «**sí**» a la pregunta anterior N°13, anote su(s) número(s) de teléfono y marque el mejor día y hora para contactarlo en la tabla a continuación.

**** CONTINÚA EN LA PÁGINA SIGUIENTE. ****

Encuesta de elegibilidad para participar en el ensayo clínico CHIVES*

NOMBRE: _

14. Si usted es elegible para participar en el proyecto CHIVES, le llamaremos en el curso de las próximas dos semanas para completar 4 repasos de comida y 1 encuesta por teléfono.

¿Cuáles son los mejores números de teléfono para contactarlo?

Teléfono celular: _

Teléfono adicional: _

El teléfono adicional es el número de mi:

_ Casa _ Trabajo _ Otro celular _ Otra

15. El estudio requiere que usted reciba y mande varios mensajes de texto (aproximadamente 10) en el curso del próximo año. ¿Usted estará de acuerdo?

_ Sí

_ No

16. ¿Cuándo es mejor llamarle? Por favor marque con una «X» **todos los cuadros** que le resulten convenientes para cada día de la semana.

	lunes	martes	miércoles	jueves	viernes	sábados	domingos
8:00 – 10:00 <i>(temprano por la mañana)</i>							
10:00 – 12:00 <i>(a media mañana)</i>							
12:00 – 14:00 <i>(a la hora de almuerzo)</i>							
14:00 – 16:00 <i>(temprano por la tarde)</i>							
16:00 – 18:00 <i>(en la noche, temprano)</i>							
18:00 – 20:00 <i>(en la noche)</i>							

** Fin de la encuesta. ¡Gracias! **

VII. Participant Handout – *Expectations, Guidelines, & Timeline* – for orientation

What to expect

as a CHIVES Project participant

General Expectations & Guidelines:

- **Complete all phone calls.** All phone calls specified in the timeline on the back must be completed at each time point.
- **Inform us of changes.** Please inform us immediately if there are any changes in your contact information, especially your mailing address and phone number.
- **Look out for your vouchers.** Vouchers will be mailed at the beginning of every month for the next 6 months. We cannot replace vouchers for any reason.
- **No EatSF vouchers for the next year.** You cannot receive EatSF vouchers for the next 12 months (only our CHIVES project vouchers).
- **Be in touch.** Let us know if you have a problem using a voucher – we'll talk to the store manager & fix it!

Questions?

Please contact our study coordinator: Mandy Carroll

E-mail: chivesproject@stanford.edu

Call: (844) 4-CHIVES, or (844) 424-4837

Food Recall Team Expectations:

- **12 dietary recalls throughout the next year.** Our team will call you to complete 4 food recalls at each data collection time period: (1) January / February 2017, (2) July 2017, and (3) January 2018.
- **3 surveys throughout the next year.** This 20-minute survey will happen during one of the two food recalls at each data collection time period.
- **Communicate your schedule.** If you will be out of town during any data collection period, please let us know in advance. We will try our best to work with you.
- **Food Amounts Booklet.** During data collection, it is important to have this booklet available at all times. Without it, we are unable to complete your dietary recall.
- **Return our phone calls.** If unavailable when we call, please return our phone call or text message on the same day, and let us know when is a good time to call.

Questions? Please contact our lead: Sarah Farzinkhou

E-mail: chivesproject@stanford.edu

Call: (844) 4-CHIVES, or (844) 424-4837

Timeline: a year in the life of a CHIVES Project participant

60-minute Orientation:

- Sign study consent form
- Complete screening survey



1485

Receive a text message:

- We will send a text to let you know if you are eligible to participate in CHIVES.
- Please text back to let us know you received the text.



30-minute Food Recalls

- 2 total food recalls



20-minute Survey:

- food preferences
- participation in food assistance programs
- food availability



Receive a text message:

- We will send a text to let you know which vouchers you will receive for the next 6 months.
- Please text back to let us know you received the text.



30-minute Food Recalls

- 2 total food recalls



Receive vouchers:

- After completing all four food recalls, we will mail 1st month of vouchers to the mailing address you gave us.



Receive vouchers:

- We will continue to mail you vouchers for the next 5 months.
- If your address changes, please let us know ASAP!
- We cannot give you new vouchers, and we cannot replace your vouchers for any reason.



30-minute Food Recalls

- 4 total food recalls
- 2 food recalls during the 1st week of July
- 2 food recalls during the 4th week of July



20-minute Survey:

- food preferences
- participation in food assistance programs
- food availability



30-minute Food Recalls

- 4 total food recalls
- 2 food recalls during the 1st week of July
- 2 food recalls during the 4th week of July



20-minute Survey:

- food preferences
- participation in food assistance programs
- food availability



January 2017

February 2017 – 1st Week

March – July 2017

July 2017

January 2018

Key for Timeline

1485 = 1485 Bayshore Blvd. #230
San Francisco 94124



= receive text message



= receive phone call



= receive mail

VIII. Food Amounts Booklet for Dietary Recalls – for orientation

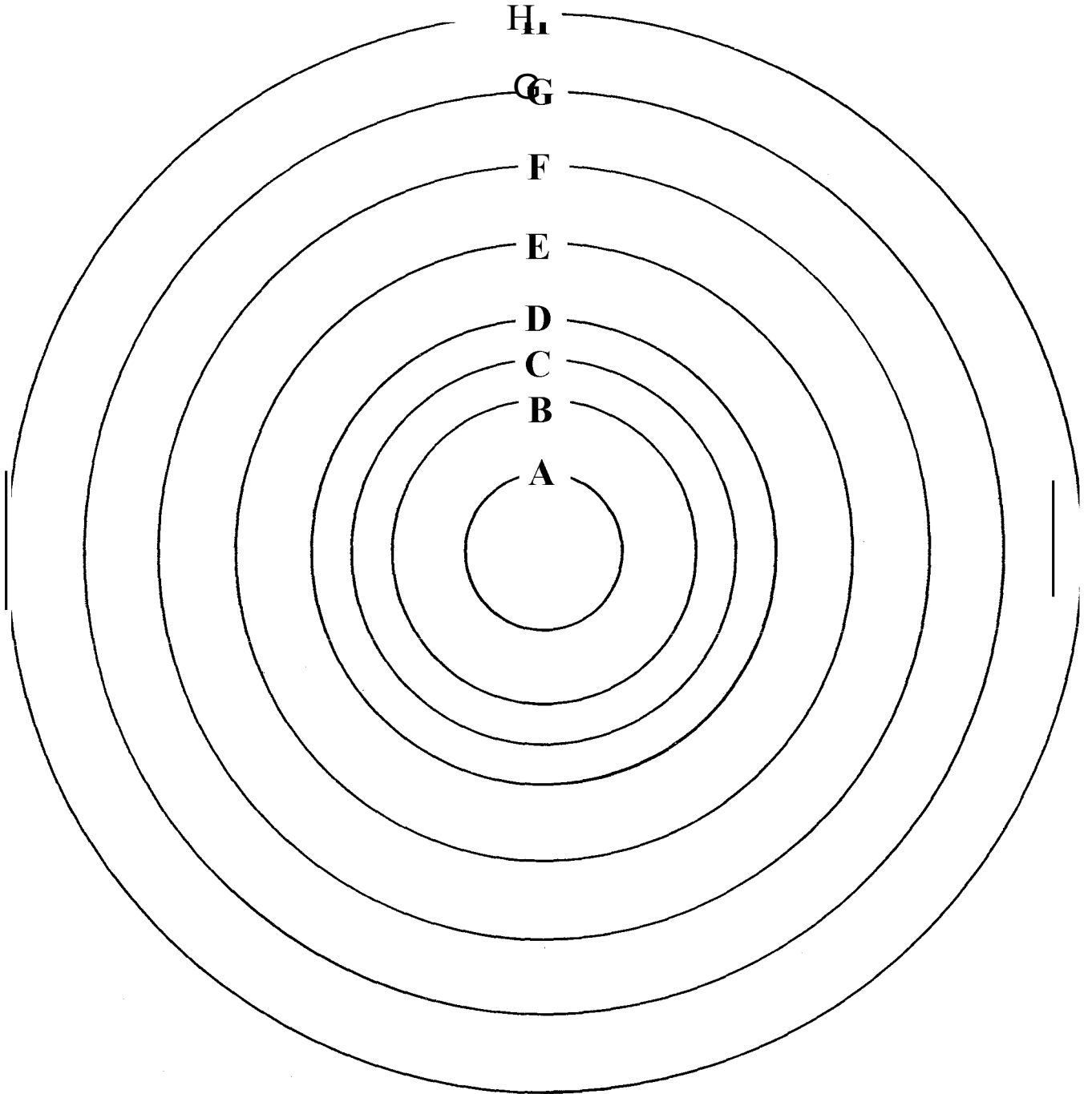
Food

Amounts

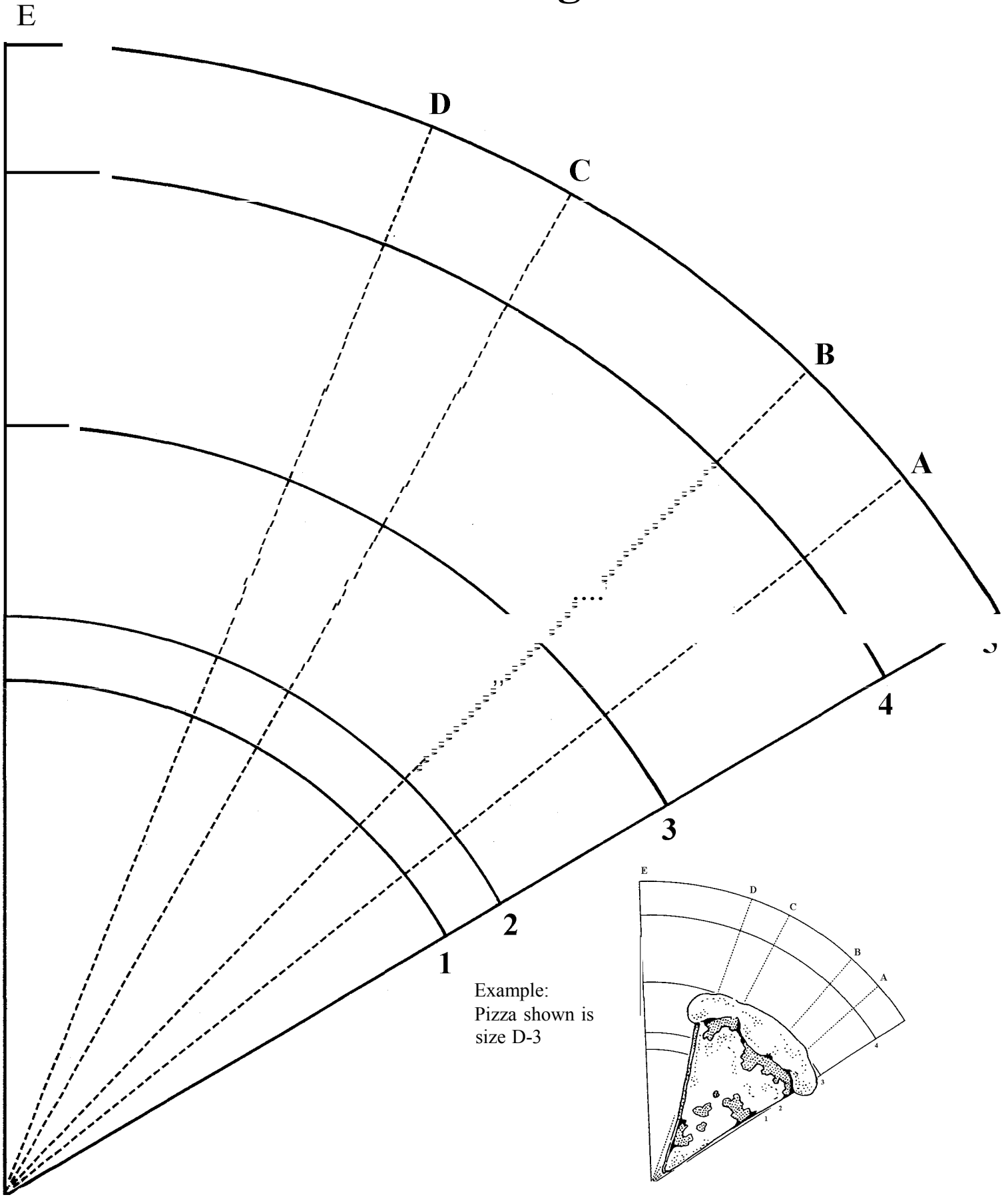
Booklet

Please, keep this near your phone.

Circles

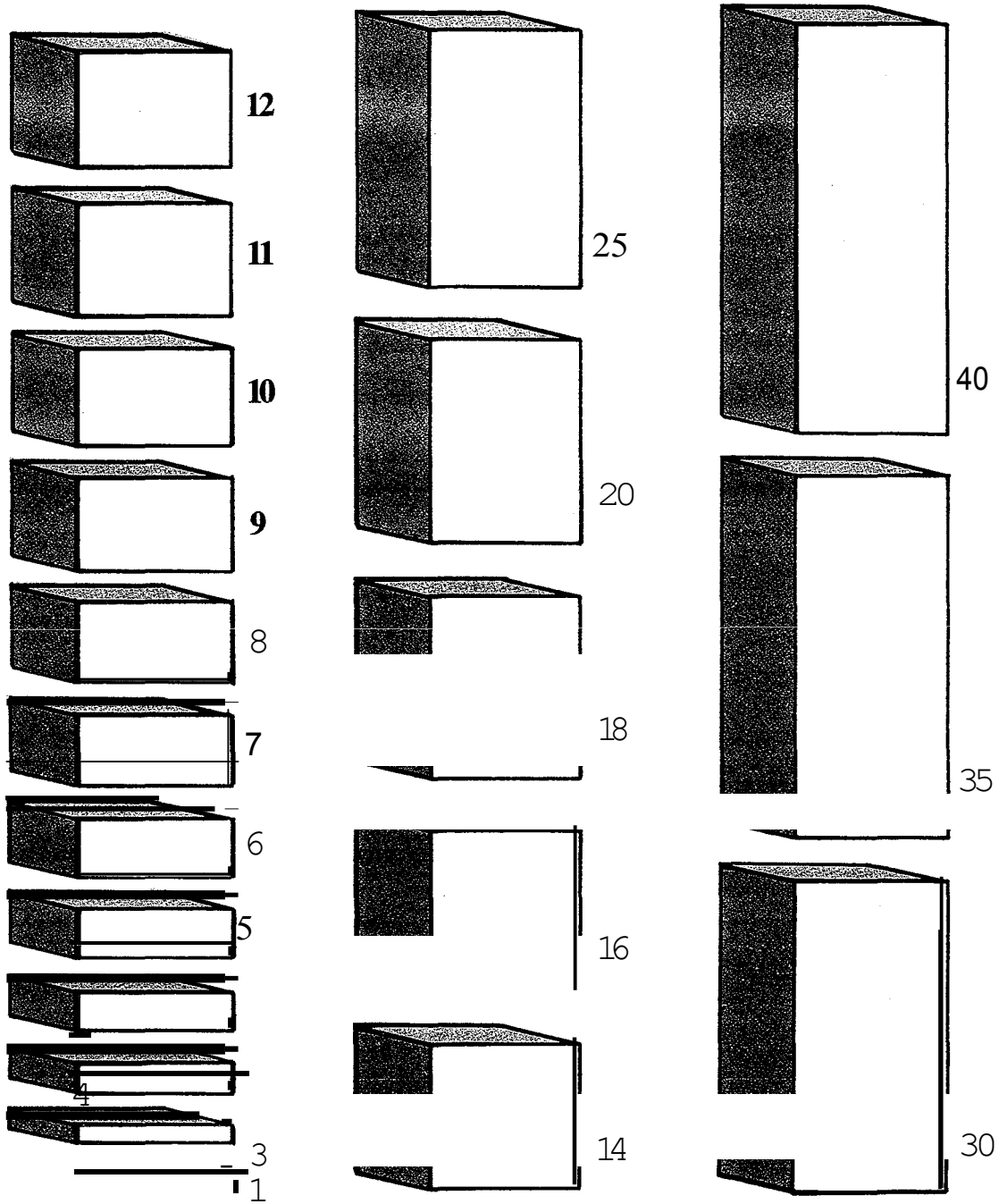


Wedges

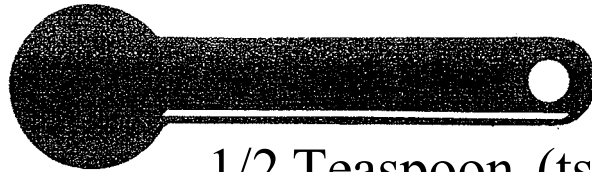


Example:
Pizza shown is
size D-3

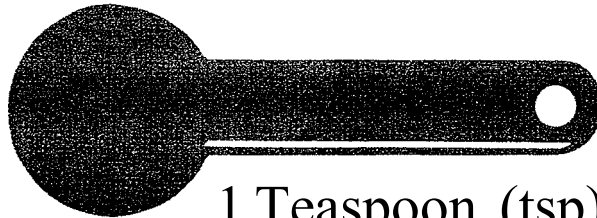
Thickness



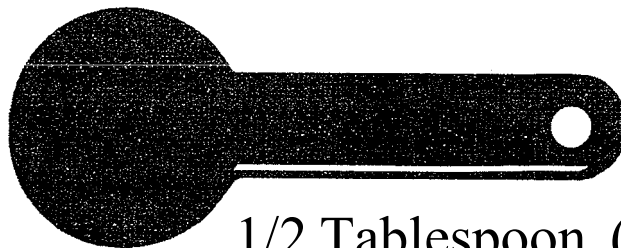
Measuring Spoons



1/2 Teaspoon (tsp)



1 Teaspoon (tsp)



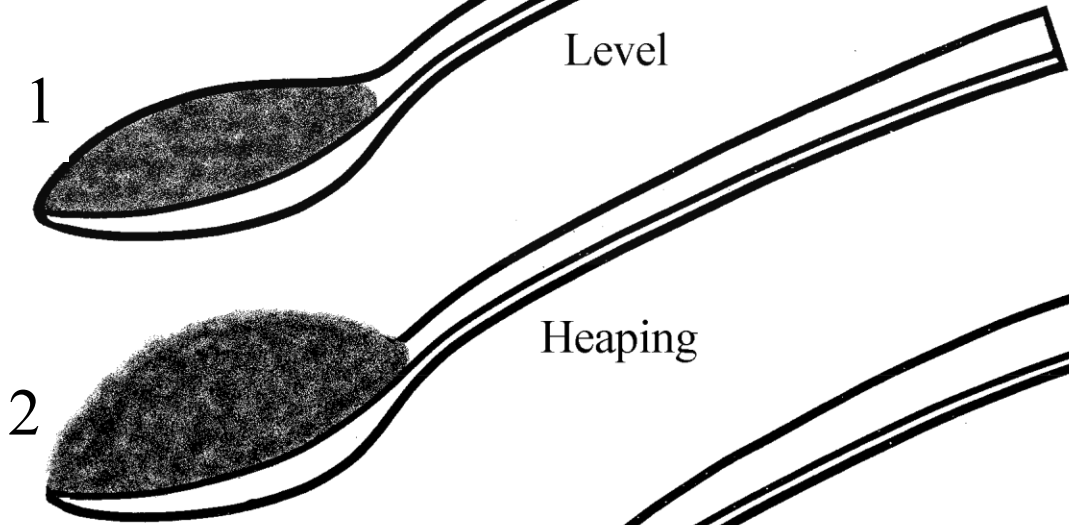
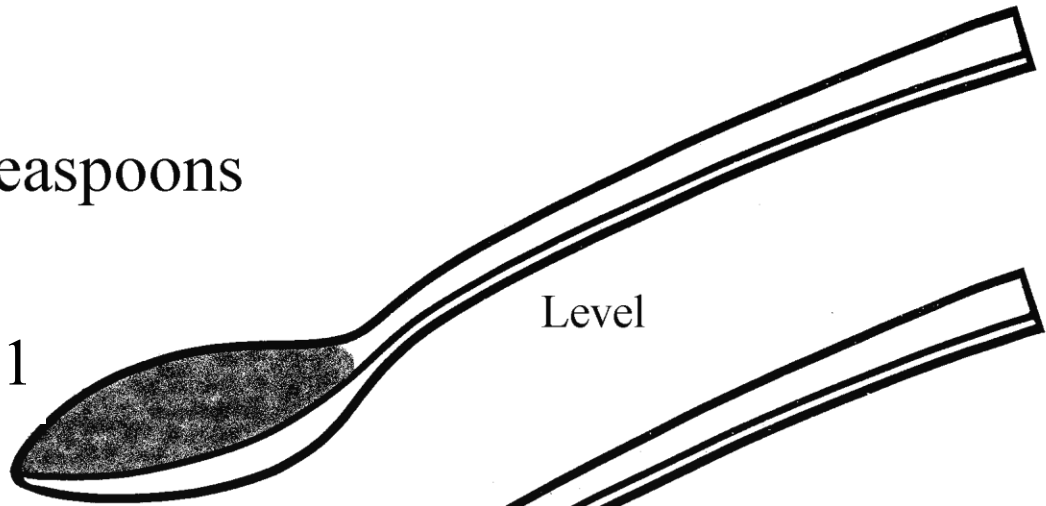
1/2 Tablespoon (Tbsp)



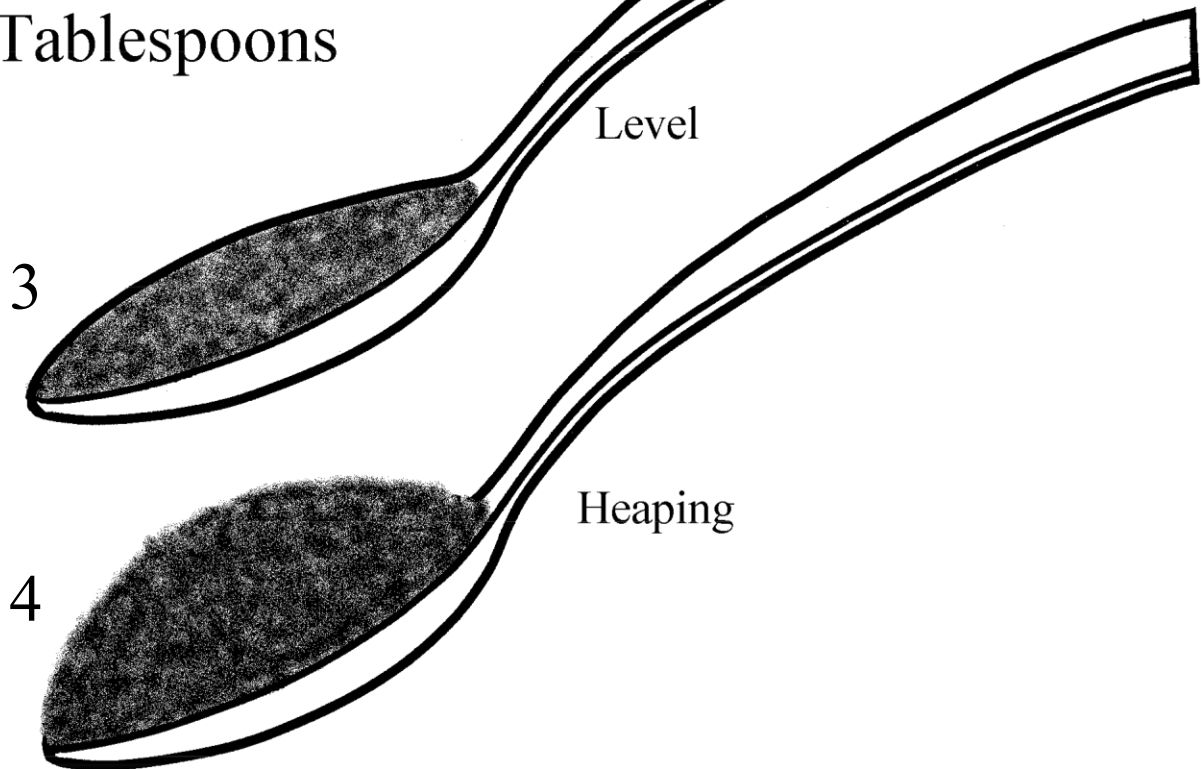
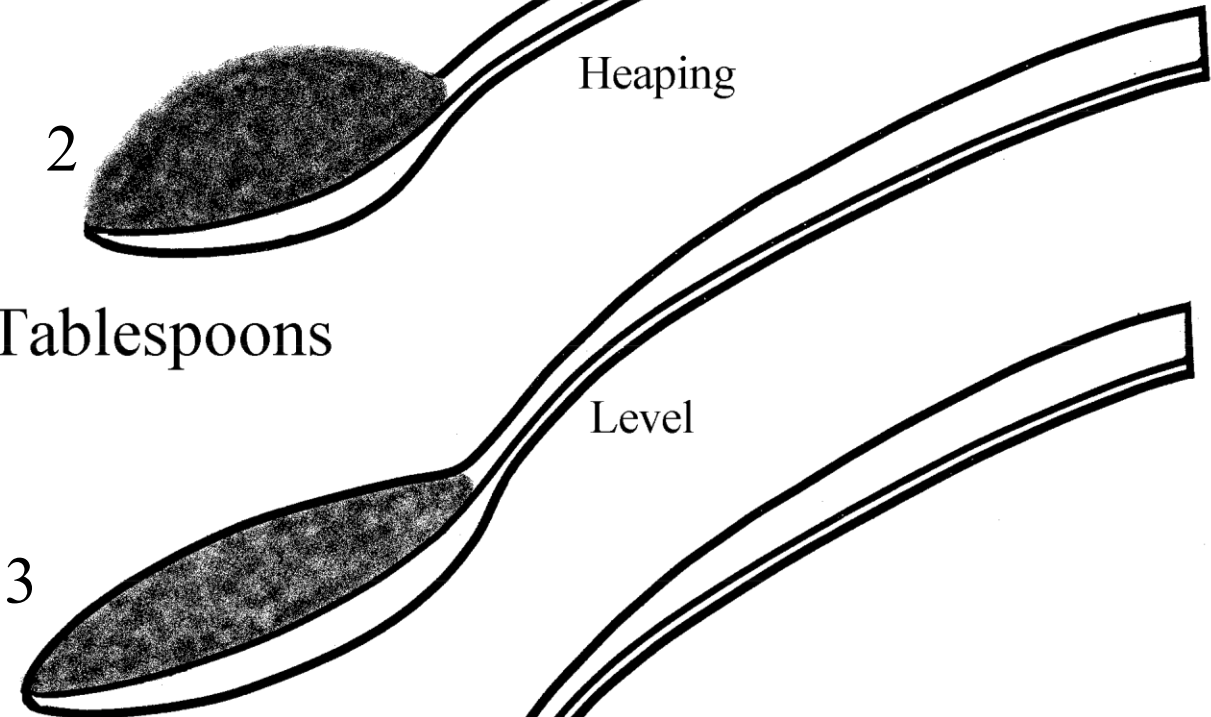
1 Tablespoon (Tbsp)

Eating and Serving Spoons

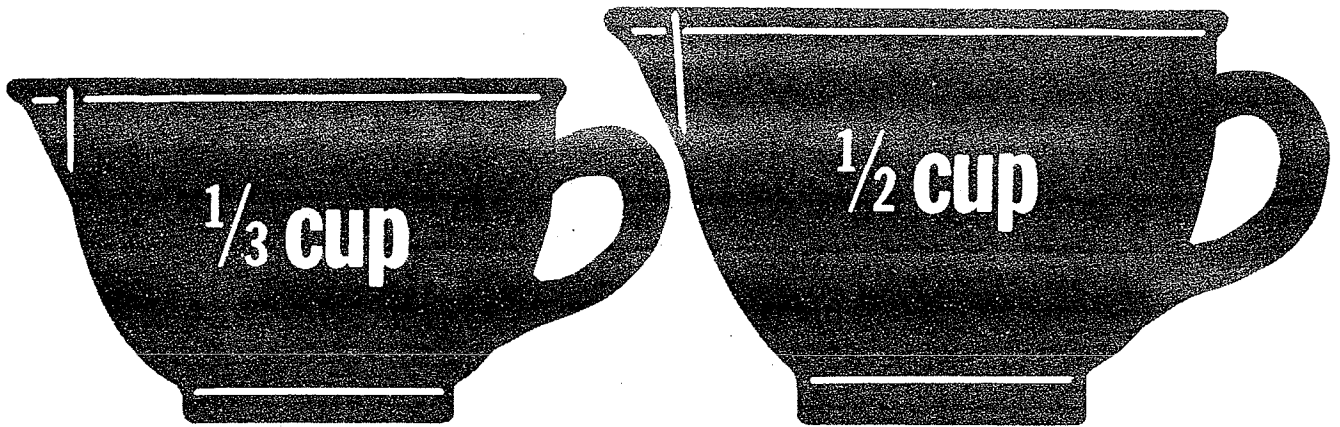
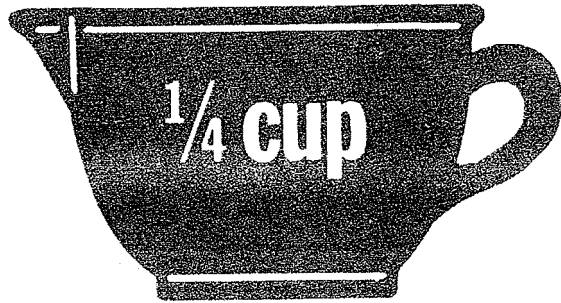
Teaspoons



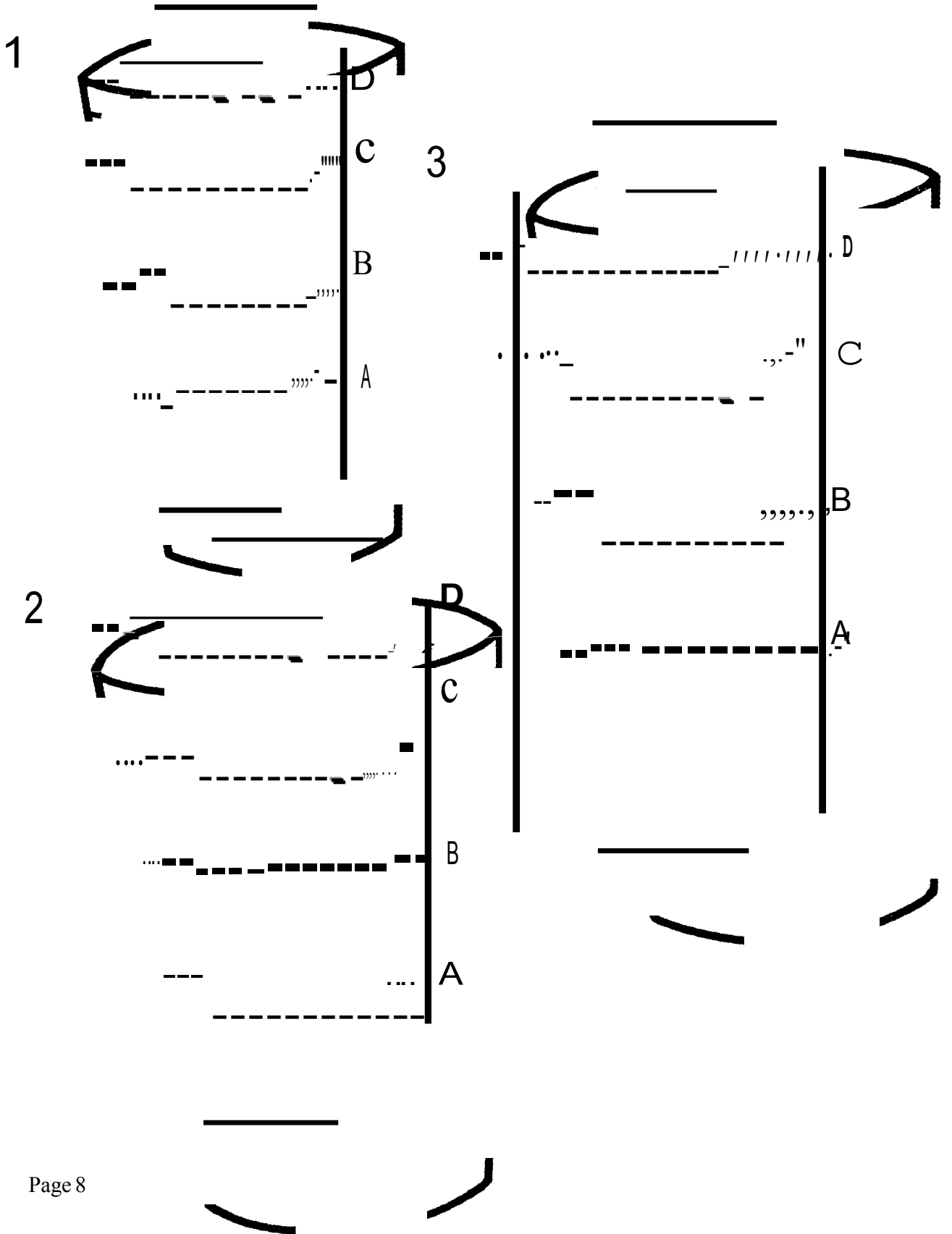
Tablespoons



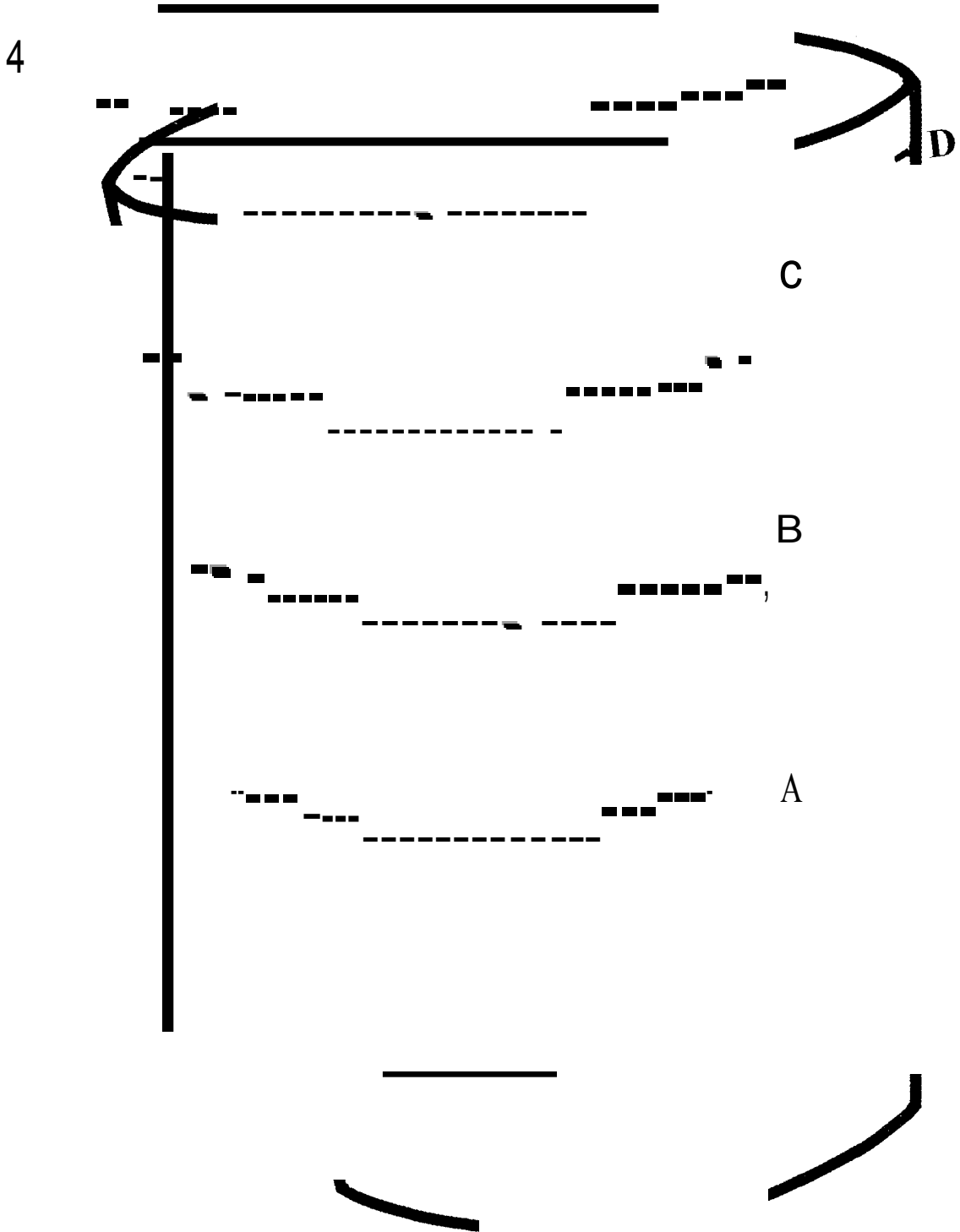
Measuring Cups



Glasses

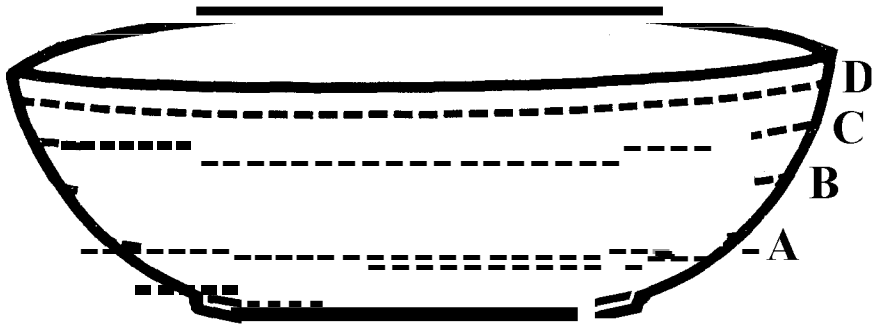


Glasses

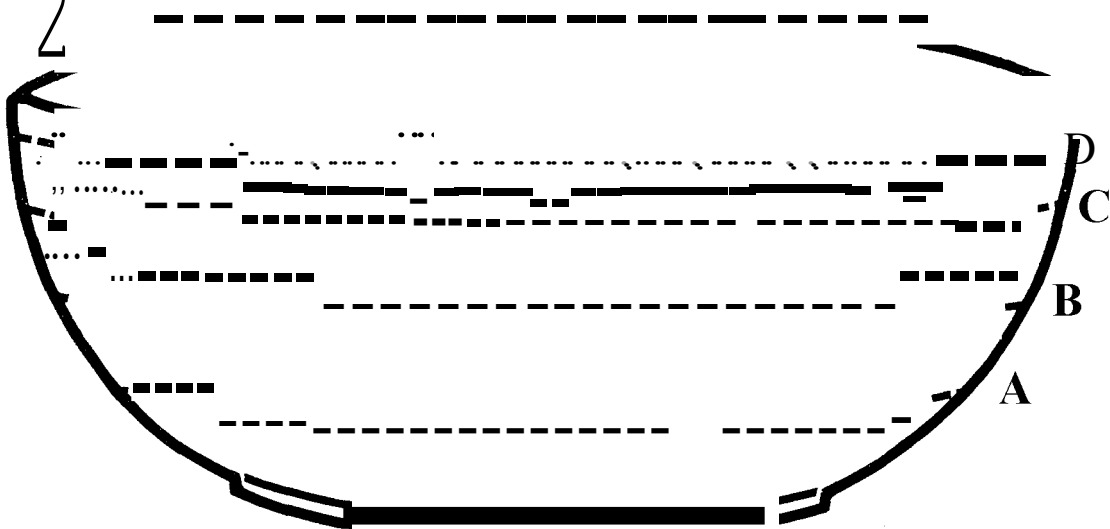


Bowls

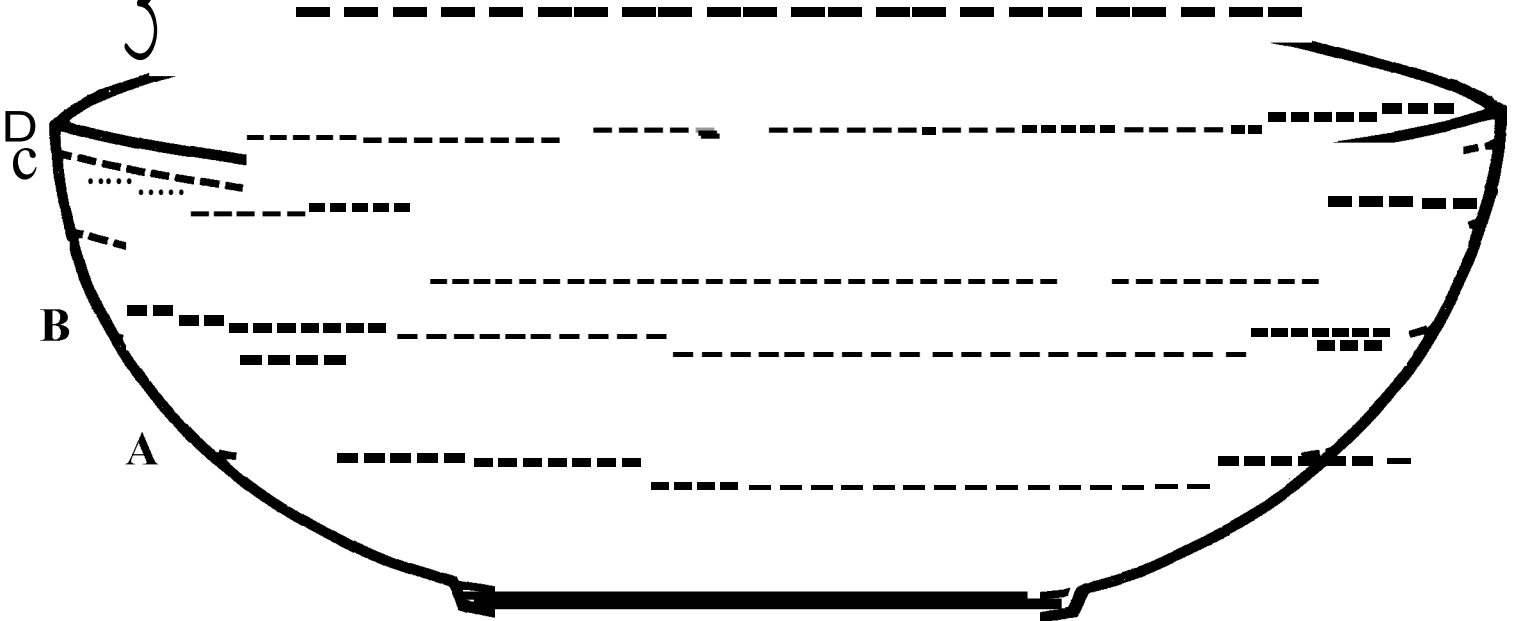
1



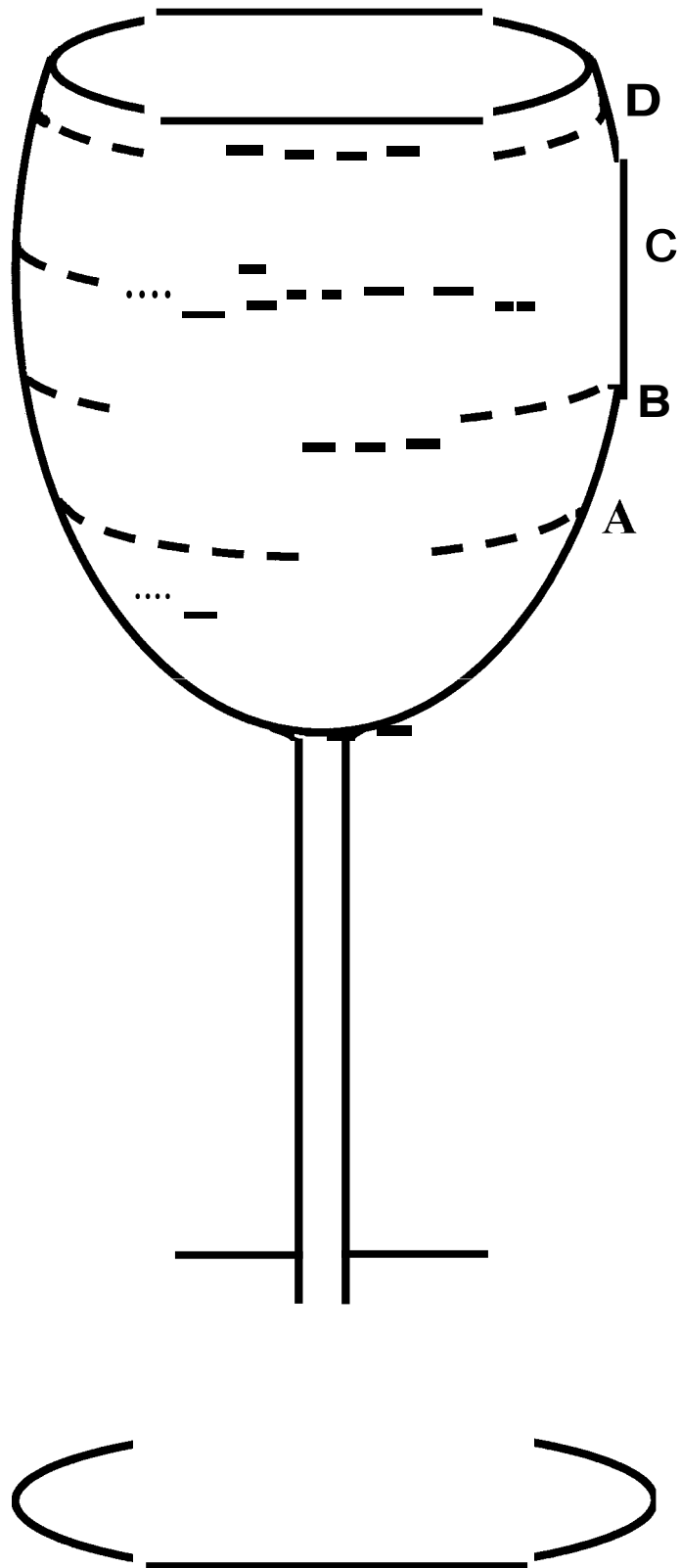
2



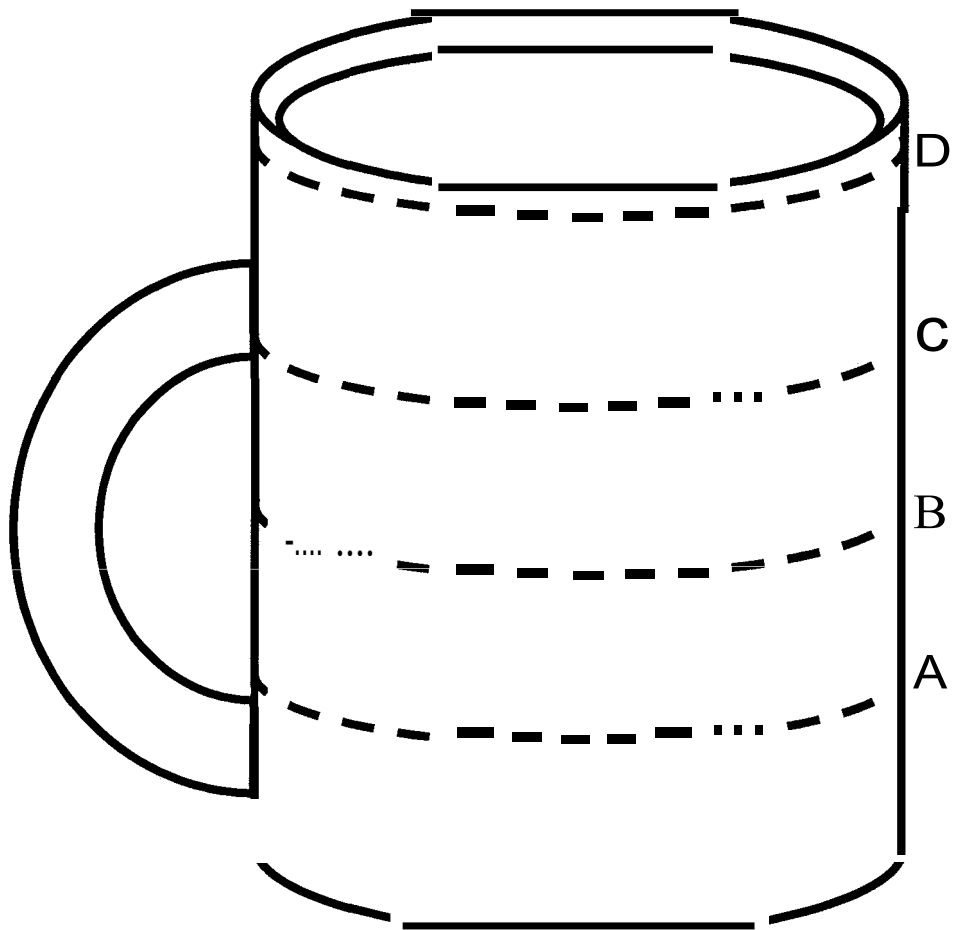
3



Wine Glass

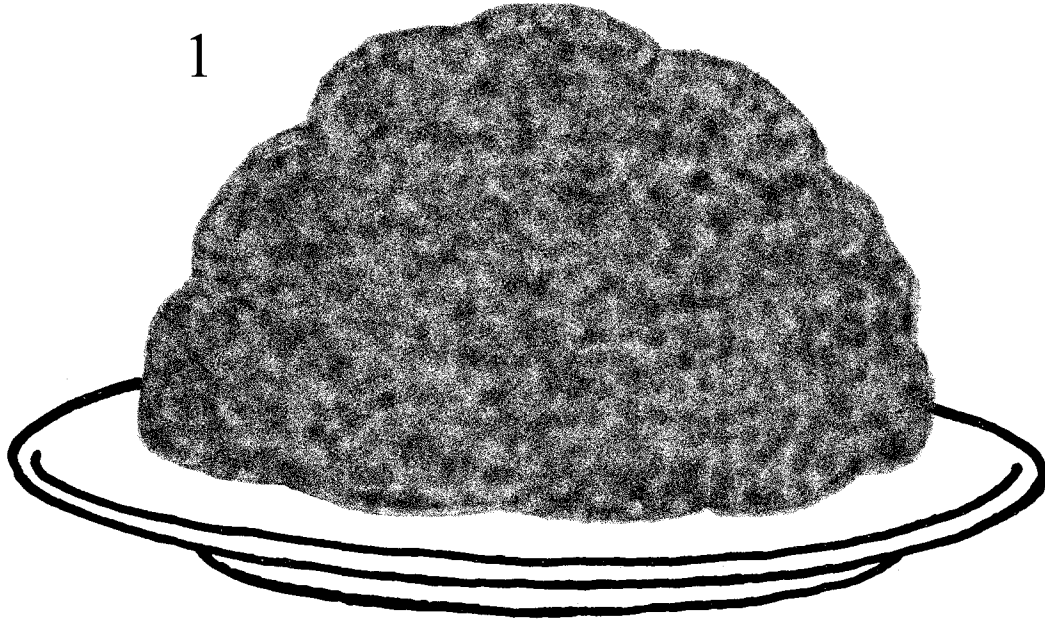


I fug

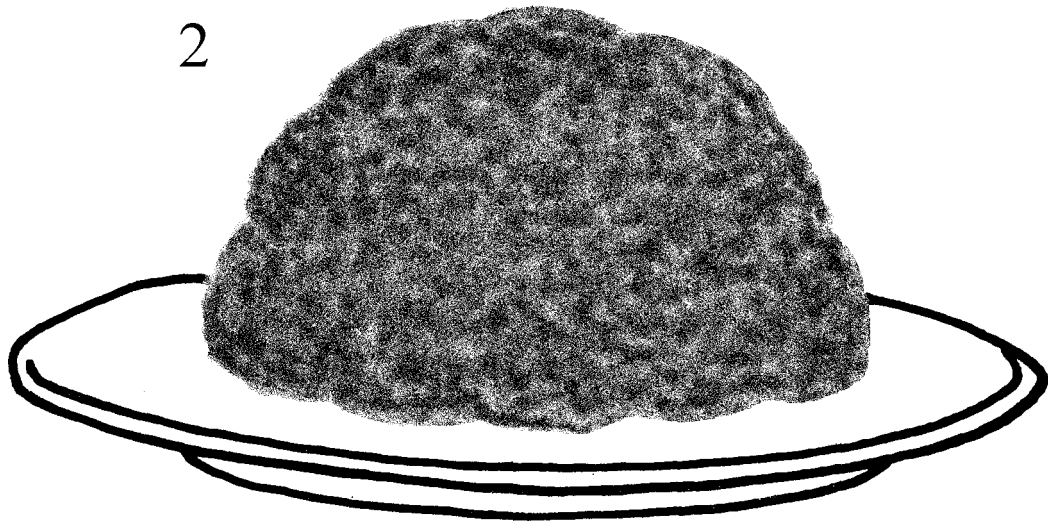


Mounds

1

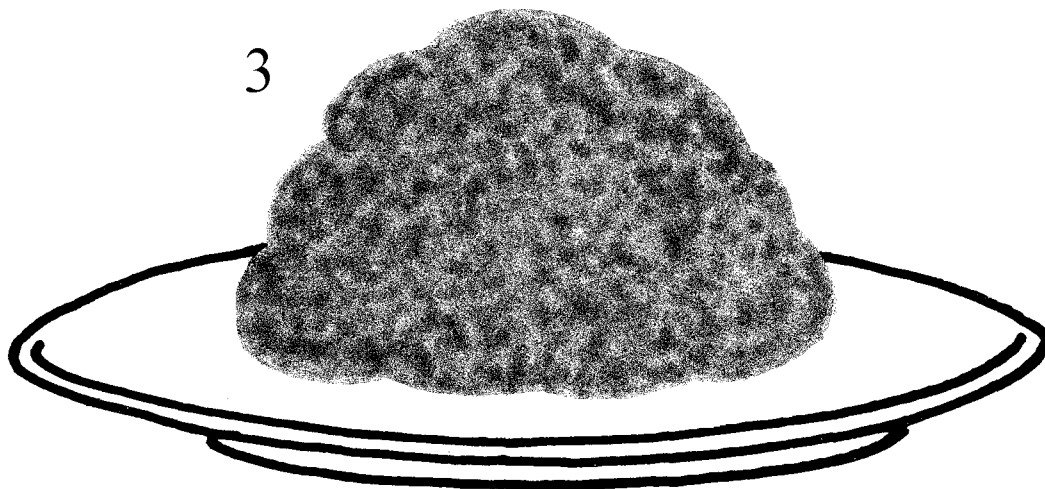


2

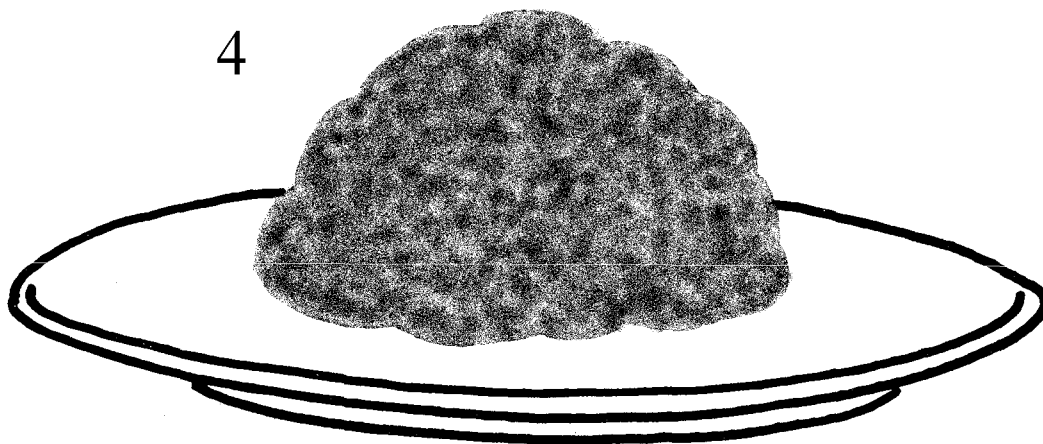


Mounds

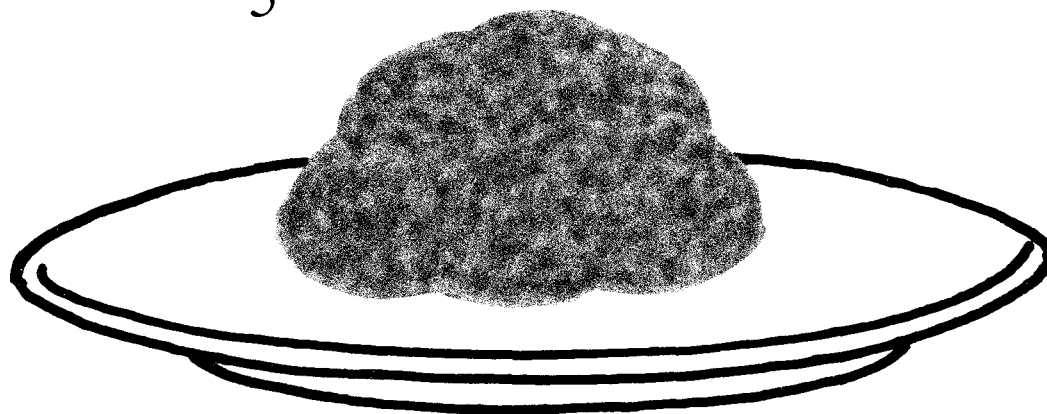
3



4

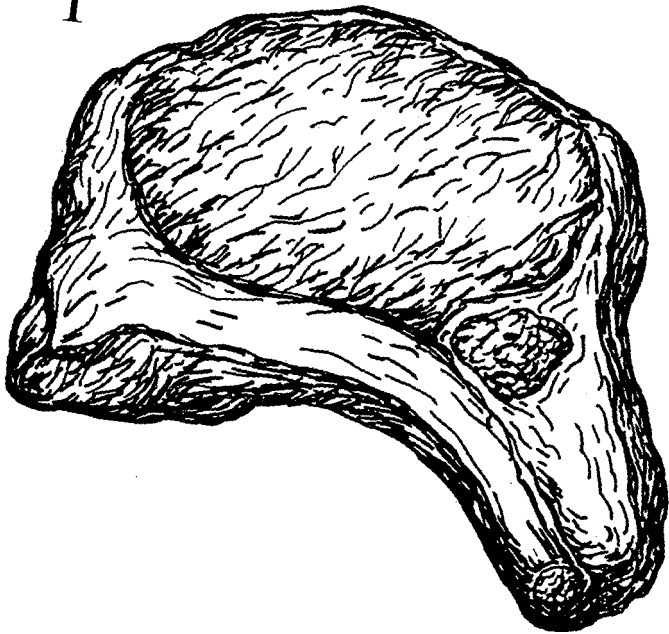


5

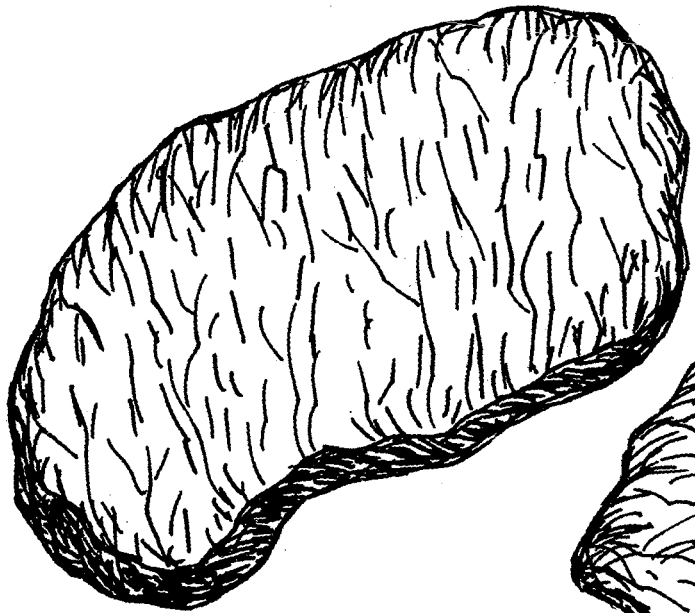


Meats

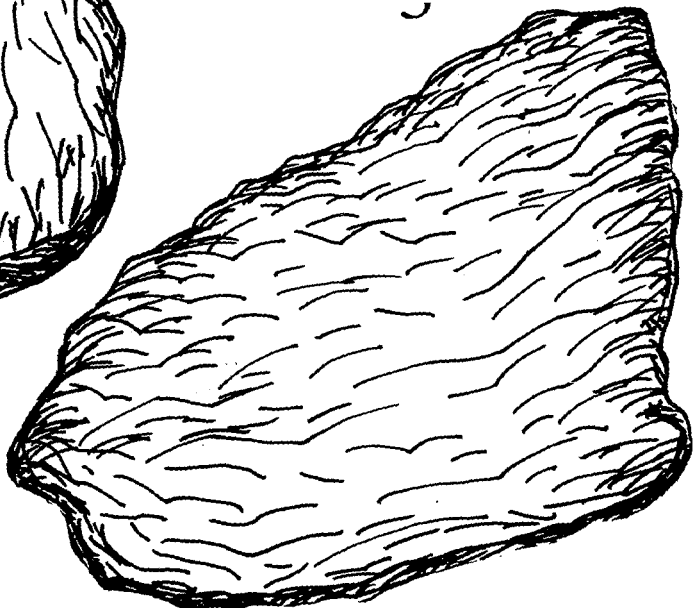
1



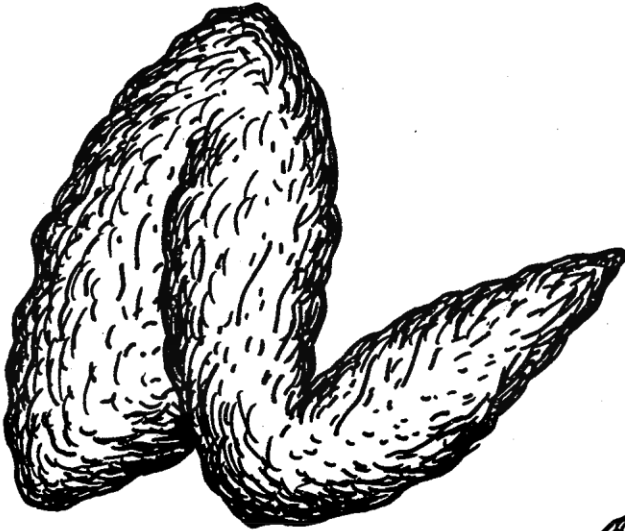
2



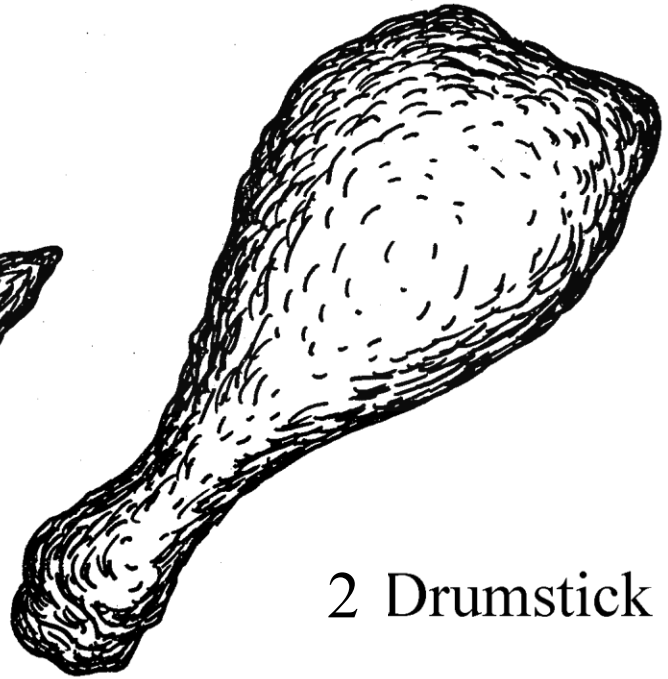
3



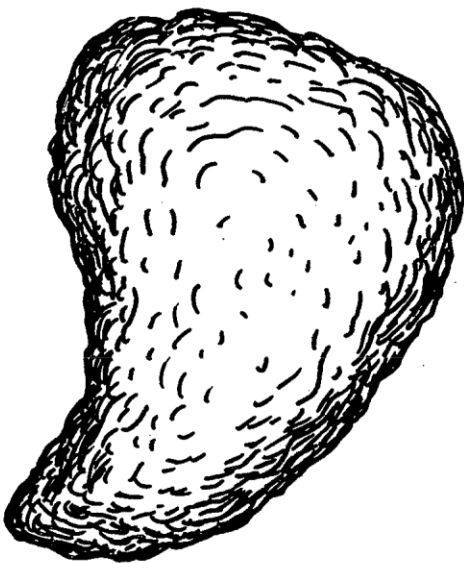
Chicken



1 Wing



2 Drumstick



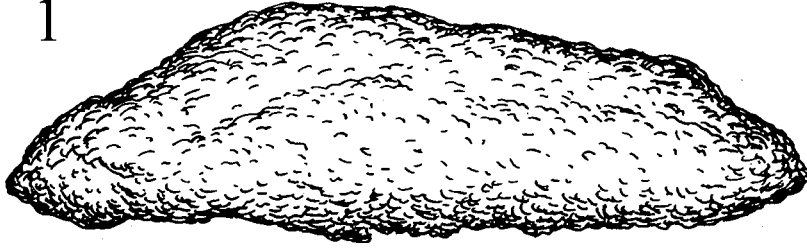
3 Thigh



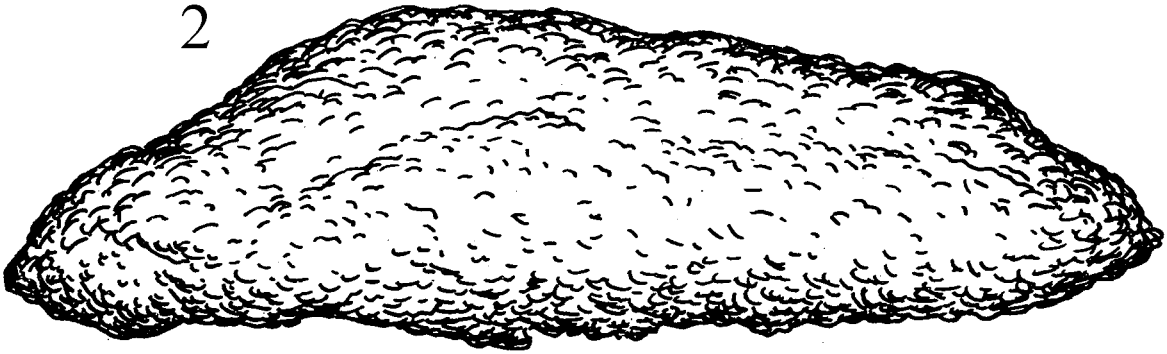
4 Breast

Fish

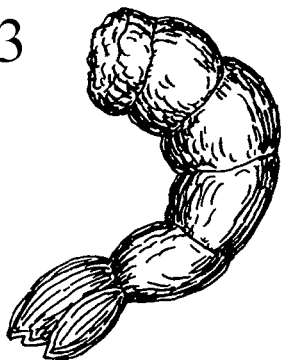
1



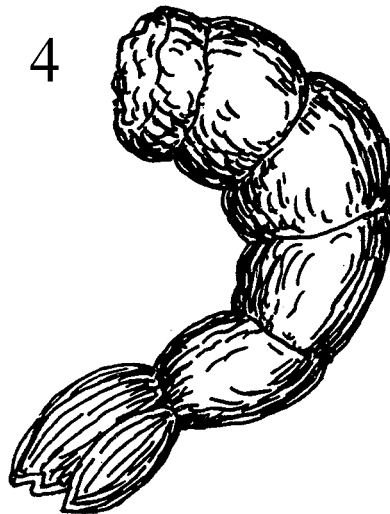
2



3



4



Adapted from: Van Horn LV, Stumbo P, Moag-Stahlberg A, Obarzanek E, Hartmuller VW, Farris RP, Kimm SY, Frederick M, Snetselaar L, Liu K. The Dietary Intervention Study in Children (DISC): dietary assessment methods for 8- to 10-year-olds. *J Am Diet Assoc.* 1993 Dec;93(12):1396-403.
Modified by Alejandra Valencia, Mary Stevens, Nutrition Coordinating Center, University of Minnesota for the Hispanic Community Health Study, Study of Latinos, 2007.

IX. Food Resources Handout – for all
ineligible candidates

EatSF Program Referral Handout – for all
ineligible candidates

Pantries that give away free groceries or produce

Citywide

Bayview TLC Family Resource Center. 1601 LANE ST (at Quesada, in Bayview YMCA). 415-822-9404. Call M-F 9am-4pm for one-time-only emergency food box for any SF resident with photo ID showing SF address. **Closed Oct 3-4, Nov 24-25, Dec 26.** ☺

Food Locator. Visit <sfmfoodbank.org/get-food> to find a neighborhood pantry where you can apply for weekly groceries. See **Note** at right.

***Project Open Hand.** 730 POLK (near Ellis). 415-447-2326 or 800-551-6325 (toll-free). For SF residents with critical illness (including HIV, AIDS, or breast cancer), or recovering from trauma or major surgery. **Call Tu-Sa 9am-4pm** for interview appt. If accepted, pick up food Tues 9am-4pm or Wed-Sat 11am-4pm. They'll need your physician's signature on application; plus proof of medical insurance, income, & address; & photo ID. **Closed Nov 24-26, Dec 26; limited hours Dec 24.** ☺

***S.F. Rescue Mission.** 140 TURK (bet. Taylor & Jones). Apply **Wed 12-12:30pm** to pick up food Thurs 12-12:30pm. Photo ID required. ☺

Supplemental Food Program. CALL 211 (OR 1-800-273-6222) for signup info. Low-income Bay Area seniors age 60+ can register for a monthly 35-lb box of dry & canned goods (proof of age, residency & income required).

211. CALL 211 (OR 1-800-273-6222). Any SF resident can call 211 for a referral to a food pantry in their zip code. (However, 211 pantry information may be incomplete or unreliable.) ☺

Neighborhood pantries

***Note:** All neighborhood pantries listed below require advance registration. Bring photo ID & proof of SF address to any pantry during the hours listed. Your application will be screened by the Food Bank. If you qualify, they'll assign you to a nearby pantry where you may pick up food weekly.*

Bayview/Hunters Point/Visitacion

Bayview TLC Family Resource Center. 1601 LANE ST (at Quesada, in Bayview YMCA). 415-822-9404. See **Note** above. Apply in person **Mon Tu Wed Fri 10am-3pm.** Serving mostly zip code 94124. Call M-F 9am-4pm for one-time-only emergency food box for any SF resident with photo ID showing SF address. **Closed Oct 3-4, Nov 24-25, Dec 26.** ☺

Our Lady of Lourdes. 410 HAWES (at Innes). 415-559-2637. See **Note** above. Apply in person **Sat 9:30-10am (except 1st Sat of the month).** Serving mostly zip code 94124. English, Cantonese, Mandarin, Spanish. **Closed Nov 26; Dec 24, 31.** ☺

***United Council of Human Services.** 2111 JENNINGS (at VanDyke). 415-671-1100 (M-Th 9am-5pm). See **Note** above. Apply in person **Wed 8am.** Serving mostly zip code 94124. ☺

Mission/Potrero/Castro

Salvation Army, Mission. 1156 VALENCIA (bet. 22nd & 23rd Sts). 415-648-0260. See **Note** above. **Call M-Th 9am-11am** for interview appointment. Serving mostly zip code 94107, 94110, 94114, or 94131. English, Spanish. **Closed Nov 24-25; Dec 9, 16, 26.** ☺

St. Aidan's. 101 GOLDMINE DR (at Diamond Heights Blvd). See **Note** above. Apply in person **Fri 1-2pm.**

Serving mostly zip code 94131. **Closed Nov 25; may close Dec 23, 30.** ☺

Women's Building. 3543 18TH ST. (bet. Valencia & Guerrero). 415-431-1180 ext. 11 (M-F 10am-5pm, W 10am-7pm). See **Note** at left. For immigrant SF residents. Apply in person **Mon 9:30-11am, 1-5pm; TuThFri 1-5pm; Wed 1-7pm.** English, Cantonese, Spanish. **Closed Dec 26.** ☺

Ocean View/Sunset/R ichmond

OMI Senior Ctr (Catholic Charities CYO). 65 BEVERLY (at Shields). 415-334-5550. See **Note** above. For seniors 60+ & disabled adults, with proof. Apply in person for weekly pantry **Mon Tu Wed Fri 8:30am-2pm.** Apply in person for monthly food box **9am-12pm fourth Mon of the month** (Oct 24, Nov 28, Dec 27; closed Dec 26). Serving mostly zip code 94112, 94127, or 94132. English, Cantonese, Mandarin, Spanish, Tagalog, Vietnamese. **Closed Nov 24-25, Dec 23, 26.** ☺

Tenderloin/Chinatown/SoMa

Salvation Army Chinatown. 1450 POWELL (near Broadway). 415-781-7002. See **Note** above. **Call M-F 11am-4:30pm** for interview appointment. Serving mostly zip code 94108, 94109, 94111, 94123, 94129, 94130, 94133, or 94158. English, Cantonese, Mandarin. **Closed Nov 24-25; Dec 9, 16, 26.** ☺

Salvation Army Kroc Center. 240 TURK (near Jones). 415-345-3414. See **Note** above. Apply in person **Fri 7:30am.** Serving mostly zip code 94102, 94103, or 94115. ID required. English, Cantonese, Khmer. **Closed Nov 24-25; Dec 9, 16, 26.** ☺

* indicates important changes since July-September 2016

We'd like your corrections, comments, or additions for our next update. Please call 415-648-3222, or email free@freeprintshop.org. Up-to-the-minute charts available at <http://freeprintshop.org>

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Pantries that give away free groceries &/or produce

Other ways to get free groceries

Note: All neighborhood pantries listed below require advance registration. **How to register:** Bring photo ID & proof of SF address to any pantry during the hours listed below. Your application will be screened by the Food Bank. If you qualify, they'll assign you to a nearby pantry where you may pick up food weekly.

Treasure Island

Treasure Island Homeless Development Initiative. 850 AVENUE I ON TREASURE ISLAND (at 9th St, in the Shipshape Building). 415-986-4810. For Treasure Island residents only; ID & lease required at signup. Apply **Tues 2:30pm**. ☺

Tenderloin/Chinatown/SoMa cont.

Salvation Army South of Market. 360 4TH ST. (nr. Folsom). 415-777-2677. See **Note** above. Call M-F 9am-5pm for interview appt or apply in person **Fri 8am-3pm**. Serving mostly zip code 94103, 94105, or 94107. English, Cantonese, & Mandarin. **Closed Nov 24-25; Dec 9, 16, 26.** ☺

Youth With A Mission. 357 ELLIS (near Jones). 415-885-6543. See **Note** above. Apply in person **Thur 3pm**. Serving zip code 94102. **Closed Nov 24, Dec 22.** ☺

Western Addition/Haight

***Booker T. Washington Community Service Ctr.** 1100 DIVISADERO (btw Turk & Eddy). 415-928-6596. See **Note** above. Apply in person **Thurs 10-11am**. Serving mostly zip code 94115 or 94117. ☺

Jones Memorial United Methodist Church. 1975 POST (at Steiner). See **Note** above. Apply in person **Sat 10:30am**. Serving mostly zip code 94102, 94109, or 94115. **Closed Oct 1; Nov 5, 26; Dec 24, 31.** ☺

Korean American Senior Service. 745 BUCHANAN (at Grove). 415-255-9371. See **Note** above. Apply in person **Fri 9:30-10:30am**. Serving mostly zip code 94102, 94115, 94117, or 94118. ☺

St. Andrew Missionary Baptist Church. 2565 POST (near Baker). See **Note** above. Apply **Wed 10am**. **Closed Nov 23, Dec 28.** ☺

Food Stamps (CalFresh). 1235 MISSION (btw. 8th & 9th Sts.) or 1440 HARRISON (btw. 10th & 11th). 855-355-5757 (toll-free) for info in English, Cantonese, Mandarin, Russian, Spanish, Tagalog, or Vietnamese. Food vouchers for low-income California residents. You can check eligibility & apply online at <mybenefitsCalWIN.org>, or apply in person **M-F 8am-5pm**. It's best to get there early (8-10am), fill out an application, & turn it in. You'll get an appointment for that day or for a few days later. Bring ID, Green Card (if you're an immigrant), & proof of your rent, expenses, & income. If approved before 4pm, you may get your card that day; otherwise you may pick it up later or have it mailed to you within 2 weeks. Individuals can get up to \$194 worth of food stamps per month (most individuals get less; most families get more). The amount you get depends on income and how much you pay for shelter (and for out-of-pocket medical costs if you're over 60 or disabled). People with SSI/SSP cannot get food stamps. People with resources (house, car, bank account, etc.) or SSD but limited income can still get food stamps, & so can homeless people. **Closed Oct 11; Nov 11, 24, 25; Dec 26.** ☺

WIC. CALL 415-575-5788 (**M-F 8am-12pm, 1-5pm**) or 415-621-7574 (**M-F 8:30am-5pm**). Food vouchers for children under 5. Pregnant or postpartum women, or guardians of children under 5 years, call for appointment to sign up in 1 of 6 locations. Bring ID, proof of income (check stubs, Medi-Cal card), & address (California ID/utility bill/piece of mail). WIC offers food vouchers, info & support for breastfeeding, & nutrition counseling. You can use vouchers at WIC-authorized grocery stores for produce, whole grains, beans (or peanut butter), cereal, eggs, milk, yogurt, cheese, juice, iron-fortified formula & baby food. **Closed Oct 10, 19, 25; Nov 11, 24-25; Dec 16, 23, 26.** ☺

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Thank you for attending the recent CHIVES Project orientation session.
Enclosed are two \$5 EatSF vouchers to thank you for your time!



Since you are not eligible for CHIVES Project at this time,
we would like to refer you to the EatSF program.

For more information about EatSF:

- 1) Visit their website: eatsfvoucher.org
- OR-
- 2) Call their project offices: 415) 206-4947



See reverse for more information on whether you would be eligible!

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See reverse for more information on whether you would be eligible!

AM I ELIGIBLE for EatSF?

To be eligible for EatSF, you must be at least 18 years of age, live in the Tenderloin, SOMA, or Bayview neighborhoods, and meet at least one of the following criteria:

1. You are currently receiving Supplemental Security Income (SSI), Supplemental Security Income Pending (SSIP), or Social Security Disability Income (SSDI).
2. You are an adult with obesity (BMI greater than 30) or are living with pre-diabetes, diabetes, high blood pressure, heart failure, HIV, hepatitis C, or tuberculosis.

IMPORTANT: All participants for EatSF are enrolled through a participating community-based organization. Organizations are located in the Tenderloin, SOMA, and Bayview and include clinics, social service organizations, and Single Room Occupancy (SRO) buildings. Check to see whether your doctor, case manager, housing site, or social service provider participates in the EatSF program.

AM I ELIGIBLE for EatSF?

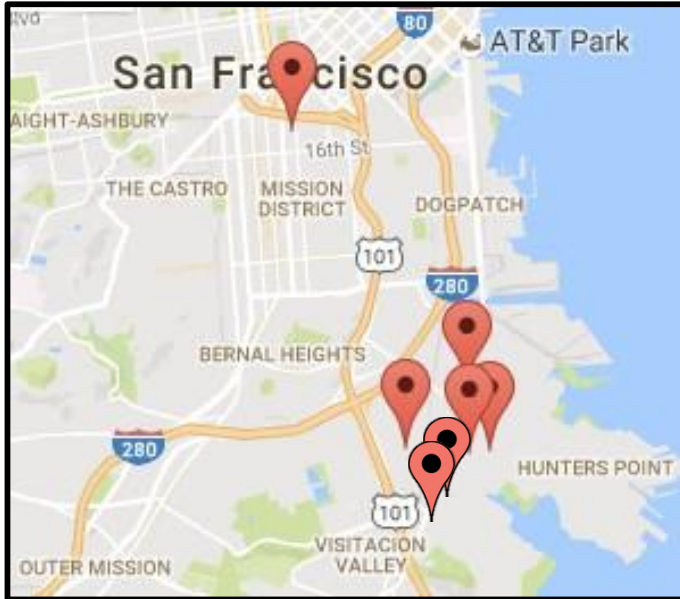
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X. Participant Handout - *How to Use Vouchers & List of Store Vendors* – to be mailed with Month 1 Vouchers

Where to spend your CHIVES vouchers:



Bayview Store Locations

Duc Loi's Pantry – coming soon!

5900 3rd St. (at Carroll St.)
(415) 551-1772

Foods Co

1800 Folsom St. (at 14th St.)
(415) 558-9137

Foods Co

345 Williams Ave.
(415) 330-1870

Friendly's Market

1499 Thomas St. (at Keith St.)
(415) 822-8321

Lee's Market

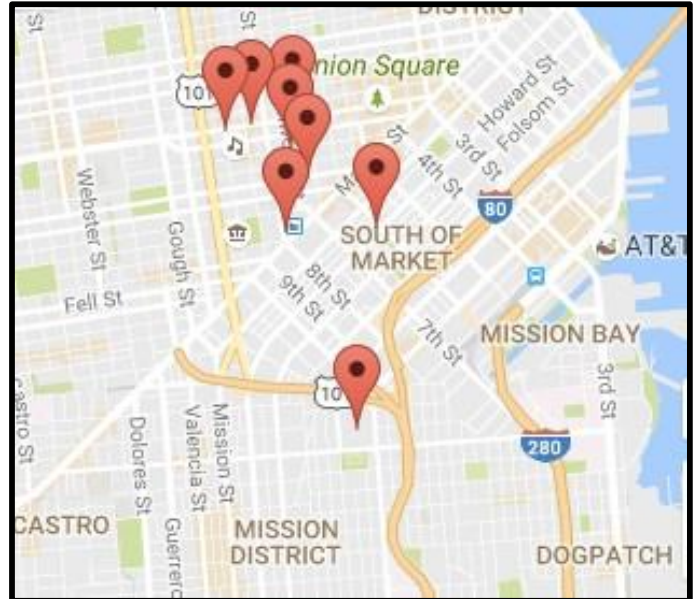
1397 Revere St. (at Jennings St.)
(415) 822-2818

Palou Market

4919 3rd St. (at Palou St.)
(415) 822-8074

Super Save

4517 3rd St. (at LaSalle)
(415) 282-3722



Tenderloin & SoMa Store Locations

Amigo's Market

500 Ellis Street (at Leavenworth)
(415) 674-4145

California Produce

986 Polk St (at Geary St.)
(415) 345-1700

City Supermarket

669 Geary St. (between Jones & Leavenworth)
(415) 474-2126

Heart of the City Farmers Market

UN Plaza, 1182 Market St. (between 7th St. & 8th St.,
above Civic Center BART station)
(415) 558-9455

Mid-City Market

868 Geary St. (between Larkin & Hyde)
(415) 474-1568

Radman's Produce Market

201 Turk Street (at Jones)
(415) 674-4437

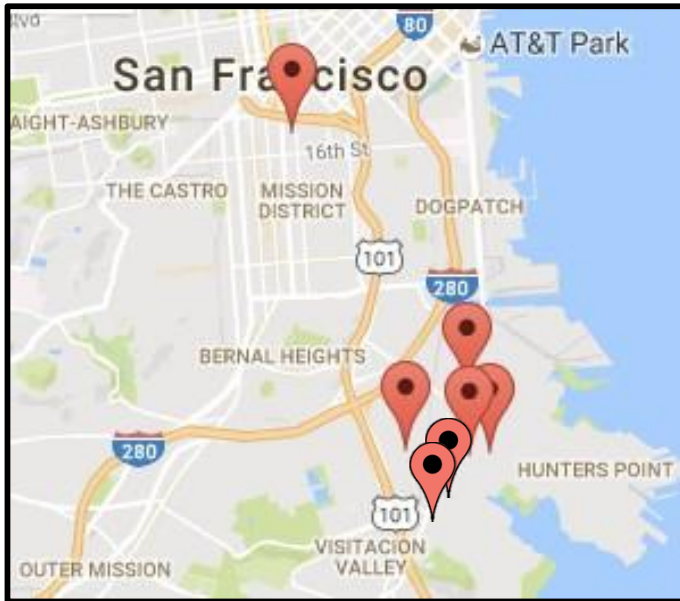
Safeway

2300 16th St. (at Potrero St.)
(415) 575-1120

SOMA Market

1000 Howard St. (between 5th St. & 6th St.)
(415) 553-6333

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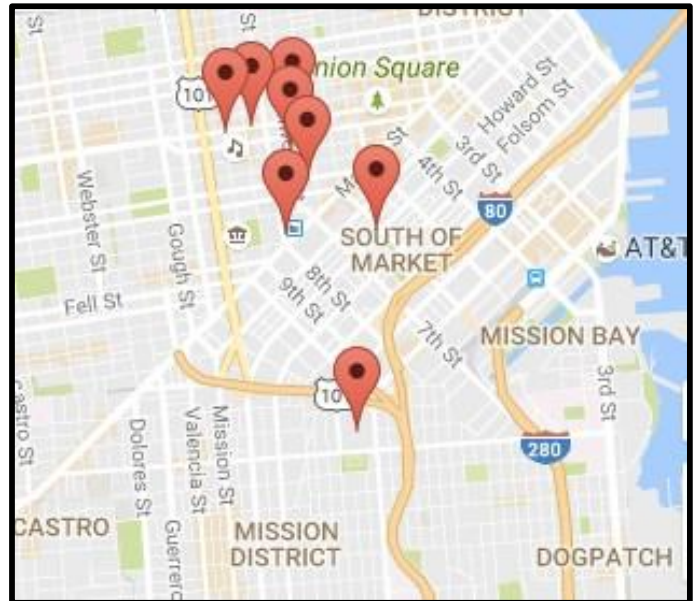
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(415) 553-6333

Using your CHIVES Vouchers

What to look for on your CHIVES vouchers:

Valid for box:
only fruits & vegetables

First day to use box

Last day to use box

CHIVES Project Logo

You will sign here when you purchase

Participant #:

First day to use: MAY 1 2017

Last day to use: MAY 31 2017

Vendor:

VALID FOR: Any fresh or frozen fruits and vegetables (including pre-packaged). No added sugar or salt.

VÁLIDO PARA: Cualquier frutas y vegetales frescos o congelados (incluyendo empacados) sin azúcar o sal.

THE CHIVES PROJECT

EXACT PURCHASE PRICE MUST NOT EXCEED \$5.00

NOT REDEEMABLE FOR CASH

EatsSF

Customer signature

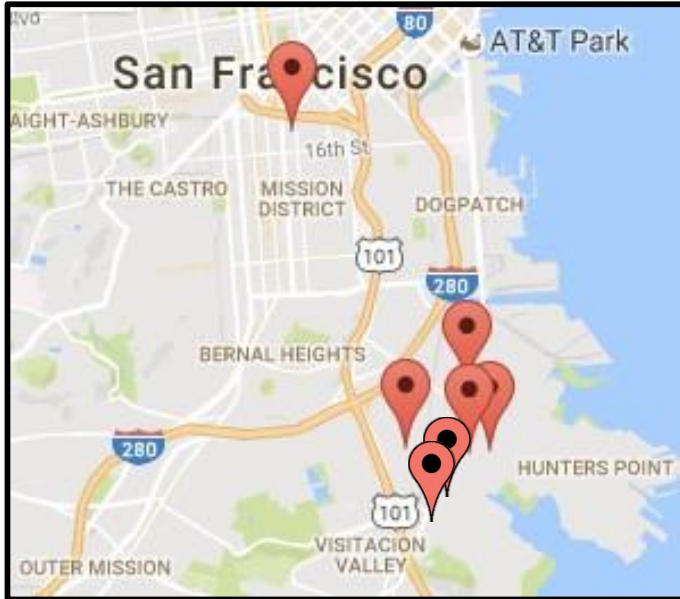
Date

For questions please call 1-844-4-CHIVES (1-844-424-4837) or email chivesproject@stanford.edu

How to use your CHIVES vouchers:

1. **Timeframe.** Use your vouchers within the month timeframe for which they are valid. You have a total of four vouchers for each month, which you are able to use at any time during the month.
2. **Foods to purchase.** Your vouchers may be used to purchase any fresh or frozen fruits and vegetables, including those that are pre-packaged without sugar or salt. Organic is allowed.
3. **Dollar amount.** Each voucher is worth \$5.
 - If you spend over \$5, you may use your own cash, credit card, debit card, or CalFresh/EBT card to pay the balance.
 - If you spend under \$5, you will not receive any change.
4. **Where to spend.** Please see the list of stores on the back to know which stores accept CHIVES vouchers.
5. **Questions, concerns, complaints.** Please contact us at any time if you have any questions, concerns, or complaints whatsoever.
We are here for you!
 - **E-mail us:** chivesproject@stanford.edu
 - **Call us:** (844) 4-CHIVES, or (844) 424-4837

Where to spend your CHIVES vouchers:



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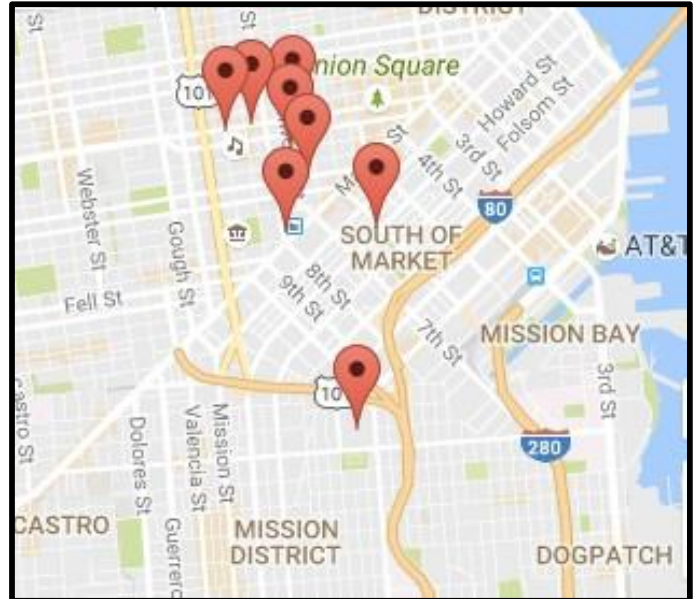
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XI. Participant Handout – *Reminder for Month 6 Data Collection & Incentives* – to be mailed with Month 5 Vouchers

Reminder: [m6] is your final month of receiving CHIVES vouchers.

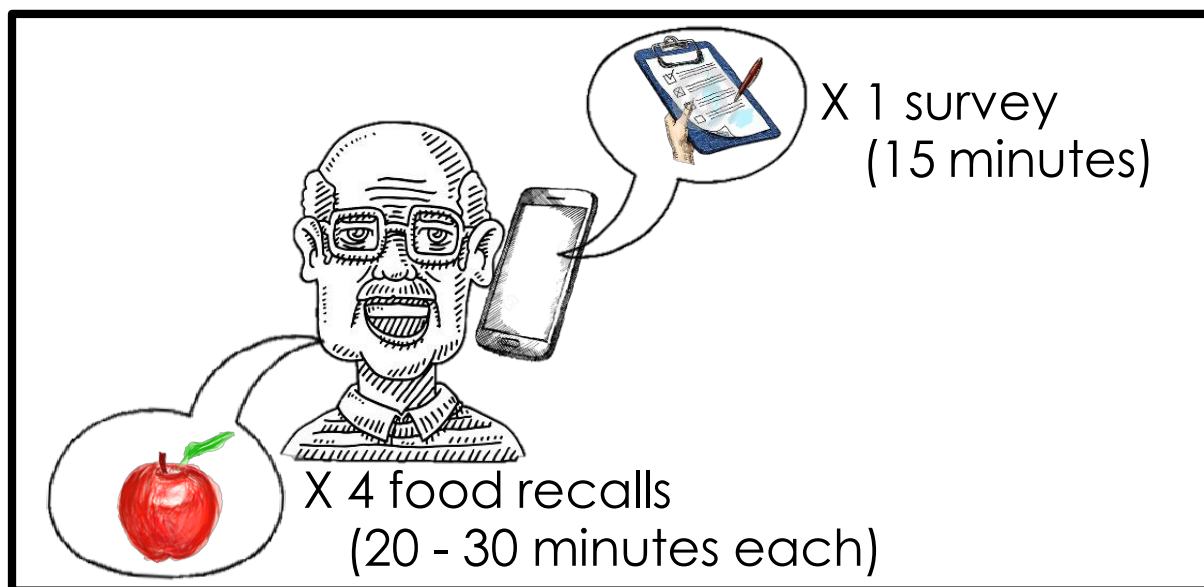
What to expect in [m6]:

During the first week of [m6], our team will call you to complete:

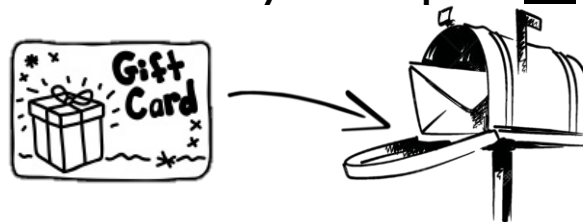
- 2 food recalls
- 1 survey

During the last week of [m6], our team will call you to complete:

- 2 more food recalls



Thank you! To thank you for your time & effort, we will send you a \$20 gift card in the mail **when you complete all of these phone calls.**



Contact us: Please contact us immediately if your phone number has changed. Also, please contact us with any questions!

E-mail us: chivesproject@stanford.edu

Call us: (844) 4-CHIVES or (844) 424-4837

XII. Participant Survey Measures

Participant survey measures.

Construct	Theoretical Justification	Metrics (on 5-point Likert scales from 1 “not at all” to 5 “extremely”)	Sources
Ease of use	Hypothesized mediator for the targeted versus untargeted voucher effect	3 items such as “how hard was it to decide what to spend the voucher on?”	Healthy incentives pilot study
Food preferences and beliefs	Preferences as potential moderator of effect	3 items such as “I enjoy trying new vegetables”	Satter inventory
Barriers to the consumption of F&Vs and to grocery shopping	Barriers as potential moderator of effect	4 items such as “It is hard to eat vegetables because it is difficult to know how to prepare them”	WIC Participant Characteristics Survey
Household food environment	Household environment as potential moderator of effect	2 items such as “Have fruits available at home”	CDC Flexible Consumer Behavior scale (used in NHANES)
Food insecurity	Scarcity theory: insecurity as potential moderator or mediator of effect	6 items such as “In the last 6 months, did you cut the size of meals or skip meals because there wasn’t enough money for food?”	CDC Household Food Security Survey Module, Short-form (used in NHANES)

XIII. Month 0/Baseline Survey, Month 6 Survey, and Main Survey

MO Survey

Record ID

First, I'm going to ask you about our voucher program. Please answer yes or no.

You recently completed an orientation session about how the vouchers work. Do you understand how to use the vouchers? Yes No

I'm sorry to hear that. I will ask our study coordinator to call you to answer your questions about the program.

Let me ask you a few more questions.

Great. I'm glad you understood how to use them.

Let me ask you a few more questions.

NOTE to ASSESSORS:

Now move onto main survey.

For study coordinator to follow up with misunderstanding of vouchers.

Contacted for follow up? Yes

When contacted for follow up?

Month 0 Survey Notes

M6 Survey

Please complete the survey below.

Thank you!

First, I'm going to ask you a few questions about our voucher program. For these questions, please answer yes or no.

You have been in our voucher program for several months. Do you feel you understood how to use the vouchers? Yes No

The participant answered "yes."

SAY: "What made it easier to understand how to use the vouchers?"

The participant answered "no."

SAY: "I'm sorry to hear that. What was the reason that you didn't understand how to use the vouchers?"

Was it easy to decide which foods you are allowed to spend the voucher on? Yes No

The participant answered "no."

SAY: "I'm sorry to hear that. What was the reason why it was hard to know which foods you can spend the vouchers on?"

Did you have any trouble using the vouchers at any stores; that is, did any cashiers or store employees give you a hard time or not allow you to use the vouchers? Yes No

The participant answered "yes."

I'm sorry to hear that. Would you please tell me the name and location of the store, and what happened?

Of the food purchased using your vouchers, was some of it also shared with other people in your household? It's absolutely okay to share it' we just want to know how people use their vouchers. Yes No

NOTE to ASSESSORS:

Now move onto main survey.

M6 Survey Notes:

Main Survey

Record ID

PLEASE SAY:

"Thanks for taking the time to complete this survey today. Once we complete this survey, we won't have to do this again anytime soon. We will only have to complete the remaining food recalls.

So, the other phone calls we'll have should be shorter.

Okay, I'm going to start by asking you a few questions about how you feel about food in general, and specifically about fruits and vegetables. I'm going to read several statements that people have said about food. After each statement please tell me whether you agree or disagree with each statement, or that you are not sure."

I enjoy trying new foods.

- Agree
- Disagree
- Not sure

I enjoy trying new fruits.

- Agree
- Disagree
- Not sure

I enjoy trying new vegetables.

- Agree
- Disagree
- Not sure

I eat enough fruits to keep me healthy.

- Agree
- Disagree
- Not sure

I eat enough vegetables to keep me healthy.

- Agree
- Disagree
- Not sure

I often encourage my family or friends to eat fruits and vegetables.

- Agree
- Disagree
- Not sure

PLEASE SAY:

"Next I'm going to ask you some questions about how easy or hard it is for you to eat fruits and vegetables. I'm going to read several statements that people have said about fruits and vegetables. After each statement please tell me whether you agree or disagree with each statement, or that you are not sure."

It's hard for me to eat more vegetables because I don't know how to prepare them.

- Agree
- Disagree
- Not sure

It's hard for me to eat more vegetables because they are hard to find where I shop for food.

- Agree
- Disagree
- Not sure

It's hard for me to eat more fruits because they are hard to find where I shop for food.

- Agree
- Disagree
- Not sure

I don't eat fruits and vegetables as much as I like to because they cost too much.

- Agree
- Disagree
- Not sure

I don't eat fruits and vegetables as much as I like to because they often spoil before I get a chance to eat them.

- Agree
 Disagree
 Not sure

I don't eat fruits and vegetables because I don't like them.

- Agree
 Disagree
 Not sure

I don't eat fruits and vegetables as much as I like to because my family doesn't like them.

- Agree
 Disagree
 Not sure

It is hard to shop for fruits and vegetables because I live far away from a store that sells them.

- Agree
 Disagree
 Not sure

It is hard to shop for fruits and vegetables because I don't have a car or other transportation to a store that sells them.

- Agree
 Disagree
 Not sure

PLEASE SAY:

"Now I am going to ask you some questions about the food you have in your home."

How often do you have fruit in your home? This includes fresh, dried, canned, and frozen fruit.

- All the time Sometimes
 Never

Do you have them available all the time, sometimes, or never?

How often do you have vegetables available at home? This includes fresh, dried, canned, and frozen vegetables.

- All the time Sometimes
 Never

Do you have them available all the time, sometimes, or never?

PLEASE SAY:

"The next questions are about whether you participate in any other programs that help you buy food."

Are you currently participating in WIC, that is, the Women, Infants, and Children program?

- Yes No

Is someone in your household, other than you, currently participating in WIC?

- Yes No Don't Know
 Refused

Who is participating in WIC?

- Myself, I am pregnant
 Myself, I am breastfeeding
 An infant (0 - 12 months)
 A child (1 - 5 years) My partner, who is pregnant or breastfeeding
 Other; define in RedCap
 Don't know Refused

Who is participating in WIC?

- An infant (0 - 12 months)
 A child (1 - 5 years) My partner, who is pregnant or breastfeeding
 Other; define in RedCap
 Don't know Refused

Besides this CHIVES program, are you currently participating in the EatSF voucher program?

- Yes No

Is someone in your household, other than you, currently participating in the EatSF voucher program?

- Yes No Don't Know
 Refused

Who is participating in the EatSF voucher program?

Please specify who:

Are you currently receiving benefits from CalFresh, EBT, or SNAP, formerly know as the Food Stamp Program?

- Yes No

Is someone in your household, other than you, currently receiving benefits from CalFresh, EBT, or SNAP, formerly known as the Food Stamp Program?

- Yes No Don't Know
 Refused

Who is participating in CalFresh, EBT, or SNAP, formerly know as the Food Stamp Program?

Please specify who:

Do you have any children in your household?

- Yes No

Are any children in your household currently receiving a free or reduced-price school breakfast or school lunch?

- Yes No Don't Know
 Refused

PLEASE SAY:

"Next, I'm going to read you several statements that people have made about their food situation. For these statements, please tell me whether the statement was often true, sometimes true, or never true for you or your household in the last 12 months-that is, since last [name of current month]."

The first statement is, "The food that (I/we) bought just didn't last, and (I/we) didn't have money to get more."

- Often true
 Sometimes true
 Never true

Was that often, sometimes, or never true for (you or your household) in the last 12 months?

"(I/we) couldn't afford to eat balanced meals."

- Often true
 Sometimes true
 Never true

Was that often, sometimes, or never true for (you or your household) in the last 12 months?

In the last 12 months, since last [name of current month], did you (or other adults in your household) ever cut the size of your meals or skip meals because there wasn't enough money for food?

- Yes
 No

How often did this happen-almost every month, some months but not every month, or in only 1 or 2 months?

- Almost every month
 Some months but not every month
 Only 1 or 2 months

In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money for food?

- Yes
 No

In the last 12 months, were you ever hungry but didn't eat because there wasn't enough money for food?

- Yes
 No

PLEASE SAY:

"Finally, I'm going to ask a few questions about you, including your height and weight.

Your answers are completely confidential and will never be tied to your name. We only ask this information to get an overall snapshot of CHIVES participants as an average. No individual's height or weight is ever looked at."

How tall are you without shoes, in feet and inches?

- Knows height, enter in next question
 Doesn't know Refused

What is participant's height in inches?

(Please write participant height in inches only. Remember that 1 foot equals 12 inches. 5' = 60" ; 6" = 72")

How much do you weigh without clothes or shoes, in pounds?

- Knows weight, enter in next question
 Doesn't know Refused

What is participant's weight in pounds?

Are you currently pregnant?

- Yes No Don't Know
 Refused

Are you currently breastfeeding?

- Yes No Refused

PLEASE SAY:

"This is the end of our survey.

I greatly appreciate the time you have taken. Now that this survey is complete, we will only have to complete the remaining food recalls together. These food recalls should be shorter phone calls.

If you have any questions about this study, please contact the study coordinator at 844-4CHIVES, 844-424-4837.

Thank you and have a great day."

Main Survey Notes:

Surveys completed?

- Yes
 No

When were the surveys completed?

- Week 1, Recall 1
 Week 1, Recall 2
 Week 4, Recall 1
 Week 4, Recall 2
 Separate phone call

If during a separate call, when?

By whom?

- Carrie
 Lindsay
 Liz
 Mandy
 Sarah
 Other

Other assessor, please specify name:

XIV. 24-Hour Dietary Recall REDCap Form and 2-item food security questions

Recall 1

Record ID

NOTE to ASSESSORS:

First complete Recall 1 using NDSR.

Please remind participants NOT to reveal their voucher assignment with you throughout the phone call.

Once you conclude the recall, please complete the rest of this form.

NOTE to ASSESSORS:

After you complete Recall 1, please end phone call with the following two food security questions.

SAY: "Finally, I'm going to read you two statements that people have made about their food situation. Your answers are completely confidential and will never be tied to your name. We only ask this information to get an overall snapshot of CHIVES participants as an average.

For these statements, please tell me whether the statement was often true, sometimes true, or never true for you or your household in the LAST WEEK."

The first statement is: "We worried whether (my/our) food would run out before (I/we) got money to buy more."

- Often true
- Sometimes true
- Never true

Was that often true, sometimes true, or never true for (you/your household) in the last week?

"The food that (I/we) bought just didn't last and (I/we) didn't have money to get more."

- Often true
- Sometimes true
- Never true

Was that often true, sometimes true, or never true for (you/your household) in the last week?

Recall 1 completed?

- Yes
- No

Was Recall 1 a weekday or weekend day?

- Weekday
- Weekend day

When was Recall 1 completed?

By whom?

- Carrie
- Lindsay
- Liz
- Mandy
- Sarah
- Other

Other assessor, please specify name:

Recall 1 Notes:

XV. Dietary Recall Script for text messages, voicemails, and e-mails



Shared E-mail Account Basic Response

Hi [candidate name],

Thank you for your e-mail and your interest!

Please take a short survey online (via your phone or computer) [here](https://is.gd.chivesproject) to see if you qualify, or visit:
<https://is.gd.chivesproject>

If you are eligible to participate, the survey will ask you to sign up for an orientation session in [month] for more information and next steps about the study.

Let us know if you have any further questions.

Take Care,
The CHIVES Project Team



Orientation Reminder Mass Text

Hello from the CHIVES Project! This is a reminder that you have signed up for an orientation session tomorrow, [day of the week], [date] at [time].

The orientation is at 1485 Bayshore Blvd., San Francisco in Conference Room 230 (to the left of the reception desk). This is in the Comcast Building, next to U-Haul facilities.

Will you be able to attend?

If participant confirms:

Great! We look forward to seeing you tomorrow. Please call us at (844) 424-4837 with any questions.

If participant needs to reschedule:

Sorry to hear that. Please call us at (844) 424-4837 or e-mail us at chivesproject@stanford.edu to reschedule as soon as you are able.



Data Collection Initiation Text

Hi. This is [your name] from the CHIVES project. When would be a good time to call you and complete a food recall?

Data Collection Confirmation Text

Hi. This is [your name] from the CHIVES project. We have a food recall scheduled for [date] at [time]. I just wanted to check if this time still works for you?

If participant confirms:

Great! I look forward to our call (*tomorrow*).

If participant needs to reschedule:

That's okay. When would be a better time to reach you?



Data Collection Voicemail

Baseline Voicemail:

Hello, this is [your name] calling from the CHIVES project to do one of your food recalls. If you get this message you can call or text me back at [your phone number]. Please remember in order to receive your food vouchers you need to complete 4 food recalls. Thank you!

Baseline Text after leaving voicemail or if voicemail issues:

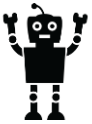
Hi. This is [your name] from the CHIVES project. When would be a good time to reach you? Please remember you need to do all 4 recalls to receive your vouchers.

6-month and 12-month Voicemail:

Hello, this is [your name] calling from the CHIVES project to do one of your food recalls. If you get this message you can call or text me back at [your phone number]. Please remember that after you complete 4 food recalls you will receive a \$20 gift card. Thank you!

6-month and 12-month Text after leaving voicemail or if voicemail issues:

Hi. This is [your name] from the CHIVES project. When would be a good time to reach you? Please remember that after you complete 4 food recalls you will receive a \$20 gift card. Thank you!



Robot Voicemail or Different/Unintelligible name

Baseline:

Hello this message is for (participant name). Hello, this is [your name] calling from the CHIVES project to do one of your food recalls. If you get this message you can call or text me back at [your phone number]. Please remember in order to receive your food vouchers you need to complete 4 food recalls. Thank you!

6-month and 12-month Text after leaving voicemail or if voicemail issues:

Hello this message is for [participant name]. This is [your name] calling from the CHIVES project to do one of your food recalls. If you get this message you can call or text me back at [your phone number]. Please remember that after you complete 4 food recalls you will receive a \$20 gift card. Thank you!



Data Collection Sample Email

Subject Line: CHIVES Food Voucher Project

Hello [participant name],

My name is [your name] and I am contacting you from the CHIVES food voucher project. You attended our orientation on [orientation date] at [time] where we talked about our new food voucher project.

After you complete 4 food recalls and one phone survey you will receive food vouchers for the next 6 months. I tried to contact you via text and phone calls over the last few days, but have not received a response. If you could please update me with a number I can reach you at, that would be great!

Hope to hear from you soon,
[your name]

XVI. Vendor Memorandum of Understanding



EatSF & The CHIVES Project: Food Voucher

Vendor Agreement

This letter of agreement marks the beginning of a partnership between the EatSF Fruit and Vegetable Voucher Program (referred to as EatSF), the CHIVES Project, and [XXXX] (referred to as [XXXX]).

BACKGROUND

EatSF: EatSF is a free fruit and vegetable voucher program for low-income San Francisco residents. Vouchers are distributed from clinics and community-based organizations to households that meet certain criteria. Vouchers can be used for fresh or frozen fruits, vegetables, and herbs (including pre-packaged). EatSF vouchers can be redeemed at selected stores and farmer's markets.

The CHIVES Project: The CHIVES Project is a collaboration between UCSF and Stanford University. The CHIVES Project is a research study that is evaluating the EatSF Program, which will be working with approximately 315 San Francisco residents from January 2017 through December 2018. The CHIVES Project is also a free food voucher program for low-income San Francisco residents, however, vouchers are distributed via mail directly to participants from the CHIVES Project office in Bayview. Participants will be assigned to receive one of two kinds of vouchers throughout their 6 months of participation: (i) Participants will be assigned to received vouchers that can be used for fresh or frozen fruits, vegetables, and herbs (including pre-packaged), identical to the EatSF vouchers, *or* (ii) Participants will be assigned to receive vouchers than can be used for any CalFresh-eligible (EBT / SNAP / Food Stamp-eligible) food items – any food or beverage, except for alcoholic beverages, vitamins / supplements, hot food, or prepared food eaten in the store. The CHIVES Project vouchers can be redeemed at the same selected stores and farmer's markets as EatSF vouchers.

[XXXX] Market: [XXXX] Market is a store located in the [Bayview] district of San Francisco. [XXXX] collaborates with Healthy Southeast and has shown a commitment to selling healthy groceries to the [Bayview] community.

AGREEMENT

EatSF, the CHIVES Project, and [XXXX] enter in to this agreement in good faith to assist eligible clients with healthy eating and access to free fruits and vegetables, and other food items. [XXXX] agrees to accept EatSF and CHIVES Project vouchers for eligible fresh and frozen fruits and vegetables, *or* CalFresh-eligible (EBT / SNAP / Food Stamp-eligible) food items, depending on the type of food voucher. EatSF and the CHIVES Project agree to reimburse [XXXX] for the value of the voucher plus a convenience fee. The following section outlines the distinct responsibilities of the partners:

RESPONSIBILITIES OF THE PARTNERS

Agreed upon practices. [XXXX] agrees to:

1. Accept (i) EatSF fruit and vegetable vouchers, (ii) CHIVES Project fruit and vegetable vouchers, (iii) *and/or* CHIVES Project CalFresh-eligible (EBT / SNAP / Food Stamp-eligible) vouchers, in exchange for either eligible fresh or frozen fruits and vegetables, *or* CalFresh-eligible (EBT / SNAP / Food Stamp-eligible) food items, depending on the type of food voucher, up to the dollar value listed on the voucher (\$5);
2. Train staff in the appropriate use of the vouchers;
3. Take reasonable precautions to avoid voucher fraud;
4. Follow the guidelines and restrictions of the EatSF program and the CHIVES Project to ensure proper use of the vouchers by EatSF and CHIVES Project participants (customers) and vendor staff;
5. Allow EatSF / CHIVES Project staff to visit store on a monthly basis to: (i) gather any feedback, resolve any issues or confusion, and hear about any misuse; (ii) routinely assess product pricing (to ensure prices do not increase in response to the intervention); and (iii) assess the available quality, quantity, and variety of fruits and vegetables;
6. Secure EatSF and CHIVES Project vouchers in a safe place to avoid theft;
7. Ensure the participant signs the voucher at the time of purchase (and not before);
8. Send completed vouchers to EatSF for reimbursement at the following address:
 - a. EatSF Voucher Program
P.O. Box 410330
San Francisco, CA 94941
9. Participate in a 15-minute verbal post-intervention vendor survey, conducted by EatSF / CHIVES Project staff sometime in late 2018.



EatSF & The CHIVES Project: Food Voucher

Vendor Agreement

Prohibited practices. [XXXX] agrees to:

1. NOT give change or any cash back to customers (EatSF or CHIVES Project participants) for EatSF or CHIVES Project vouchers;
2. NOT accept EatSF or CHIVES Project vouchers before the first day to use or after the last day to use as stated on each voucher;
3. NOT buy or sell an EatSF or CHIVES Project vouchers for cash;
4. NOT sell in exchange for a EatSF voucher or CHIVES Project fruit and vegetable voucher any food items that are not eligible, including processed foods, meats, canned goods, dried goods, dairy products, alcoholic beverages, tobacco products or any other non-EatSF item;
5. NOT sell in exchange for a CHIVES Project CalFresh-eligible food items vouchers any food or beverages that are not eligible, including alcoholic beverages, vitamins / supplements, hot food, or food eaten in the store;
6. NOT redeem EatSF or CHIVES Project vouchers in whole or in part for cash, rain checks, other items of value, or as a credit on accounts;
7. NOT charge participants (or their proxies) prices that are higher than prices charged to other customers;
8. NOT provide cash for returned food items originally purchased with EatSF or CHIVES Project vouchers;
9. NOT exchange EatSF or CHIVES Project vouchers for any other certificate or product.

Agreed upon practices. EatSF Program agrees to:

1. Administer the EatSF program and CHIVES Project, and communicate to participants the eligible stores and farmer's markets where EatSF and CHIVES Project vouchers can be used;
2. Reimburse [XXXX] for EatSF or CHIVES Project vouchers redeemed at their store at [street address] San Francisco, CA. EatSF and the CHIVES Project will:
 - a. Make payment to the vendor for the actual retail costs for EatSF and CHIVES Project vouchers accepted and redeemed (not to exceed \$5.00 per voucher);
 - b. Pay an additional convenience fee to vendor of \$0.25 per voucher redeemed at their store
 - c. EatSF will make every effort to reimburse the vendor within two weeks of receipt of vouchers.
 - i. Note that vouchers that are incomplete may require additional processing time.
3. Provide self-addressed, stamped envelopes for mailing back of vouchers;
4. Offer support and training to [XXXX] staff;
5. Supply promotional and other information materials;
6. Be the main contact for EatSF and CHIVES Project questions, concerns, general customer service requests and other information

PROCEDURE

The vendor packet outline the general guidelines for partnership with the EatSF program and CHIVES Project.

DURATION

The term of this agreement will cover the period of January 2017 through July 2018 with the option to extend the term. Either party may cancel this agreement with a 15-day notice.



EatSF & The CHIVES Project: Food Voucher

Vendor Agreement

APPROVED BY:

Hilary Seligman, MD, MAS
EatSF Director
UCSF's Center for Vulnerable Populations at San Francisco General Hospital & Trauma Center

Date

Signature

Date

Name: _

Title: __

Organization: __

Both EatSF and [XXXX] are to retain signed copies of this Memorandum of Understanding for their records.

XVII. Vendor Surveys

STANFORD UNIVERSITY

Protocol Director: Sanjay Basu

Protocol Title: Designing Food Voucher Programs to Reduce Disparities in Healthy Diets

NOTE TO RESEARCH STAFF

This questionnaire is to be administered in person to managers of all vendors participating in the voucher program. Only the participant ID should be entered on this form, and all paper copies are to be kept in the locked drawer at the study office when not in use for data entry.

Please note that all managers of vendors will have completed an informed consent form as part of their enrollment if they agreed to participate in the survey. Surveys should only be sent to those managers with a documented informed consent form and participant ID.

Participant ID:



STUDY

STANFORD UNIVERSITY

Protocol Director: Sanjay Basu

Protocol Title: Designing Food Voucher Programs to Reduce Disparities in Healthy Diets

INTRODUCTION

Thank you for participating in our study of how well food vouchers help improve nutrition among low-income households in San Francisco.

As part of the study, we wish to ask you questions about how our program could improve. Please complete the attached survey and place it in the included self-addressed stamped envelope by December 31, 2018. This survey is completely voluntary.

If you have any questions about this study, or about anything else, you can contact me at 415-881-7030, or the Stanford IRB at 650-723-2480 or toll free at 1-866-680-2906. Have a good day and I look forward to talking with you later.

Participant ID:



STUDY

STANFORD UNIVERSITY

Protocol Director: Sanjay Basu

Protocol Title: Designing Food Voucher Programs to Reduce Disparities in Healthy Diets

We want to know your experience with the voucher program and how voucher programs might improve in the future. Please answer all questions to the best of your ability.

V1. Do you or your cashiers or other store employees have difficulty accepting any vouchers, to your knowledge?

- YES
 NO

If you answered “yes”, please explain the difficulty in the space below. Include where the difficulty(ies) happened, e.g., “at the cashier’s stand”, and why, e.g., “the cashier did not know what the voucher was”. You can write your answer in any language and we will have it translated.

Participant ID:



STANFORD UNIVERSITY

Protocol Director: Sanjay Basu

Protocol Title: Designing Food Voucher Programs to Reduce Disparities in Healthy Diets

V2. Did you have any difficulty receiving prompt and correct reimbursements for the vouchers you redeemed?

- YES
- NO

If you answered “yes”, please explain the difficulty in the space below. You can write your answer in any language and we will have it translated.

Participant ID:



STANFORD UNIVERSITY

Protocol Director: Sanjay Basu

Protocol Title: Designing Food Voucher Programs to Reduce Disparities in Healthy Diets

V3. Did you promote or advertise fruits and vegetables during the period of the voucher study, from January 1, 2017 through December 31, 2017?

- YES
- NO

If you answered “yes”, please explain how you promoted fruits and vegetables (e.g., “a mailer” or “in-store advertising”). You can write your answer in any language and we will have it translated.

Participant ID:



STUDY

STANFORD UNIVERSITY

Protocol Director: Sanjay Basu

Protocol Title: Designing Food Voucher Programs to Reduce Disparities in Healthy Diets

V4. Do you think you sold more fruits and vegetables than usual because of the voucher program?

- YES
- NO

V5. What changes or suggestions would you have for improving the voucher program in the future? Please answer in the space below. You can write your answer in any language and we will have it translated.

Participant ID:



STANFORD UNIVERSITY

Protocol Director: Sanjay Basu

Protocol Title: Designing Food Voucher Programs to Reduce Disparities in Healthy Diets

This completes all of our questions. We greatly appreciate the time you have taken to participate in our study. If you have any questions about this study, or about anything else, you can contact me or the study director, Sanjay Basu, at 415-881-7030, or the Stanford IRB at 650-723-2480 or toll free at 1-866-680-2906.

Thank you and have a great day.

Participant ID:



STUDY

XVIII. Vendor Handout – “cheat sheet” for store staff on how to accept CHIVES vouchers

XIX. Data Safety and Monitoring Protocol

Food Vouchers Project
(NHLBI R01 HL132814)

Data Safety Monitoring Board (DSMB) Report
Sanjay Basu, MD, PhD, Principal Investigator
Hilary Seligman, MA, MAS, Principal Investigator

July 15, 2016, 12pm Pacific Standard Time

-
- I. Welcome and introductions
 - II. Review DSMB charter
 - III. Review project protocol and proposed modifications
 - IV. Review DSMP and proposed data report templates for subsequent DSMB meetings
 - V. Executive Session of DSMB
 - VI. Review of recommendations that result from 7/15/2016 meeting
-

II. Data and Safety Monitoring Board Charter

The Data and Safety Monitoring Board (DSMB) will provide oversight to the project with respect to issues of project progress, data quality, and participant safety. The project consists of a 2x2 factorial design intervention trial followed by a cost-effectiveness analysis. Although the project does not involve greater than minimal risk, the PI assembled a DSMB as the intervention trial meets criteria for a Phase III clinical trial. The DSMB will convene the initial meeting via conference call on Friday, July 15th, 2016.

The DSMB consists of three experts not affiliated with the project: Jason Block, Harvard; Kristina Lewis, Wake Forest; and Arjumand Siddiqi, University of Toronto. These members have expertise in epidemiology, nutrition, randomized intervention trials, and community-based participatory research among vulnerable and low-income populations. These three experts comprise the voting members of the DSMB.

One of the PIs (Sanjay Basu) and designated staff are responsible for preparing and presenting masked data reports for the DSMB meetings. The Study Statistician (Joe Rigdon) is responsible for preparing unmasked data reports for the voting members of the DSMB. Dr. Basu will provide overall guidance on the project's a priori statistical analyses and report to the DSMB on issues related to participant safety. Only the voting members of the DSMB and the designated Study Statistician (Joe Rigdon) will have access to unmasked outcome data.

The DSMB will have the following charges:

- At the initial meeting, the DSMB will review the project protocol with regard to recruitment, randomization, intervention implementation, retention, data management and quality control, statistical analysis plans, and participant safety. The DSMB will review proposed modifications and identify any additional needed modifications.
- At the initial meeting, the DSMB will decide on meeting frequency, expected to be at least annual, and identify the relevant data parameters and report format for subsequent meetings. The DSMB will develop any stopping rules for the project with a primary consideration based on participant safety.
- At subsequent meetings, the DSMB will review data relating to recruitment including ethnic/racial minority inclusion, randomization, intervention adherence, retention, data management and quality control, statistical analyses, intervention effects, and participant safety including review of adverse events.
- Over the project, the DSMB will request any needed additional data relevant to safety issues, inform PI Basu of any safety problems by phone and via written report, and make overall recommendations to the PI concerning the safety of continuing the project.
- Following each meeting, the DSMB will send written reports to the PI that summarize any key concerns brought up by the DSMB.