Effectiveness and Implementation of a Research Tested Mobile Produce Market Designed to Improve Diet in Underserved Communities

Complete Research Protocol (HRP-503)

Protocol Number: 1144594

National Clinical Trial (NCT) Identified Number: NCT04246593

Principal Investigator: Lucia Leone, PhD

Sponsor: University at Buffalo, State University of New York

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University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Complete Research Protocol (HRP-503)

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Template Instructions

Sections that do not apply:

- *In several sections, the addition of checkboxes for **Not Applicable** have been added to the template as responses.*
    - *If an N/A checkbox is present, select the appropriate justification from the list.*
    - *If an N/A checkbox is not present, or if none of the existing checkboxes apply to your study, you must write in your own justification.*
- *In addition:*
    - *For research where the only study procedures are records/chart review: Sections 19, 20, 22, 23, 24, 25, 31, and 32 do not apply.*
    - *For exempt research: Sections 31 and 32 do not apply.*

Studies with multiple participant groups:

- *If this study involves multiple participant groups (e.g. parents and children), provide information in applicable sections for each participant group. Clearly label responses when they differ. For example:*

Response:

Intervention Group:

Control Group:

Formatting:

- *Do not remove template instructions or section headings when they do not apply to your study.*

If you are pasting information from other documents using the "Merge Formatting" Paste option will maintain the formatting of the response boxes.

Amendments:

- *When making modifications or revisions to this and other documents, use the **Track Changes** function in Microsoft Word.*
- *Update the version date or number **on Page 3.***

PROTOCOL TITLE:

Include the full protocol title.

Response:

Effectiveness and Implementation of a Research Tested Mobile Produce Market Designed to Improve Diet in Underserved Communities

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response: Lucia Leone, PhD
Community Health and Health Behavior
(716) 829-6953
lucialeo@buffalo.edu

VERSION:

Include the version date or number.

Response: 4-13-2022 Version #7

GRANT APPLICABILITY:

Indicate whether this protocol is funded by a grant (e.g. NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.

NOTE: This question does not apply to studies funded by a sponsor contract.

Include a copy of the grant proposal with your submission.

Response:

This study NIH funding and internal UB funding (Blue Skye). This IRB protocol pertains to Aim 2 of NIH funding and the Blue Skye Funding

RESEARCH REPOSITORY:

Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.

Response: A locked file cabinet in room 324 Kimball Tower, UB South Campus. The room is within the Department of Community Health and Health Behavior. Only the PI and project coordinator will have a key that can access the room and cabinet.

1.0 Objectives

1.1 Describe the purpose, specific aims, or objectives of this research.

Response:

Aim 2 from NIH Grant: Use a Hybrid Type 1 design to simultaneously measure program effectiveness and implementation at sites randomized to implement a Mobile Markey for 1 year versus a planning condition

2a. Measure MM effectiveness at improving the following outcomes between baseline and 1-year follow-up:

1.) self-reported diet measured via two 24-hour dietary recalls

2.) BMI based on in-person height and weight measurements

3.) an objective indicator of fruit and vegetable (F&V) consumption (dermal carotenoids measured via finger scan)

4.) Social Cognitive Theory diet-related constructs including self-efficacy and food environment.

Sub-study (Funded by UB) Aim

The goal of this research is to understand:

1. Why do residents of underserved communities choose not to participate in food access programs
2. What can food access programs do improve their reach to the most vulnerable members of the community

1.2 State the hypotheses to be tested, if applicable.

NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

Response:

We hypothesize that by making F&V available in underserved communities and increasing nutrition/cooking knowledge and skills, the VV program will help participants increase their F&V consumption.

2.0 Scientific Endpoints

2.1 Describe the scientific endpoint(s), the main result or occurrence under study.

NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should ***not*** *be a date.*

Response:

Determine the impact of a mobile market (MM), the Veggie Van (VV), on lower-income (LI) communities using a randomized controlled study design and intent-to-treat analysis, by measuring:

a) Reported consumption of F&V at baseline, and 12 months

b) Body Mass Index (BMI) at baseline and 12 months

c) Dermal Carotenoids using a finger scan technology called the "Veggie Meter" at baseline and 12 months

d) Psychosocial measures (self-efficacy, perceptions of access to fruits and vegetables, shopping behavior and attitudes) at baseline and 12 months

3.0 Background

3.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.

Response: Consumption of F&V is an important dietary component of disease prevention. Adults who consume fewer foods high in saturated fat, sodium, and sugar in favor of fresh F&V are less likely to develop heart disease, diabetes, certain types of cancer, and are more likely to sustain a healthy weight (1). However, in the United States, substantial socioeconomic disparities exist in the prevalence of chronic disease, and lower rates of healthy behaviors among LI Americans are significant contributors (2, 3). Some studies indicate that limited access to fresh F&V and healthy foods coupled with a higher prevalence of fast food outlets in LI neighborhoods are partially responsible for poor diets among residents (4); however, the research is mixed. Randomized controlled trials evaluating changes in the food environment are needed to better understand the relationship between food access and diet. An intervention study conducted in North Carolina at 12 community sites reported that those that regularly frequented a Veggie Van over 6 months increased their intake of fruit and vegetables by 1 cup greater than those who did not utilize the Veggie Van. This study will assess the effectiveness and sustainability of a MM program, Veggie Van, to coordinate, distribute, and sell affordable F&V in LI communities and food deserts in the Northeast, Midwest, and Southeastern regions of the United States. It will contribute to the literature describing the impact of the food environment on individual dietary behaviors. In addition, we will assess implementation measures to determine standards for successful and sustainable MMs. This data will be used to refine a VV toolkit for future MM efforts.

We will test the effectiveness of the VV model across multiple organizations and sites to understand what factors are associated with dietary change and sustainability.

3.2 Include complete citations or references.

Response:

(1) Whitney E, Rolfes SR. Understanding nutrition: Nelson Education; 2012.

(2) Wang X, Ouyang Y, Liu J, Zhu M, Zhao G, Bao W, Hu FB. Fruit and vegetable consumption and mortality from all causes, cardiovascular disease, and cancer: systematic review and dose-response meta-analysis of prospective cohort studies. BMJ : British Medical Journal. 2014;349. doi: 10.1136/bmj.g4490.
(3) National Center for Chronic Disease P, Health P. The Power of Prevention: Chronic Disease... the public health challenge of the 21st century. Atlanta, GA: Centers for Disease Control and Prevention, 2009 Contract No.: Report.
(4) Maddock J. The relationship between obesity and the prevalence of fast food restaurants: State-level analysis. American Journal of Health Promotion. 2004;19(2):137.

4.0 Study Design

4.1 Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational).

Response: This Veggie Van effectiveness and implementation study, funded by the NIH, will be overseen by Drs. Leone, Dr. Ammerman, Co-Investigator, Dr. Samina Raja, Co-Investigator, and Dr. Laurene Tumiel-Berhalter, Co-Investigator. This study will be coordinated by project coordinators and staff at UB and UNC.

For Aim 2 of the study, all study related procedures will be carried out by UB staff.

Aim 2: After 9 qualified organizations* have been identified among applicants, we will randomize proposed MM sites (33 total across all partner organizations), to an intervention (MM program implementation) or comparison condition (extended planning). Randomization will be stratified within each organization so that each organization will have 2 intervention and 2 comparison sites. One organization will have 5 sites. The 5th site will allow for more thorough testing of protocol procedures. This ensures that study groups will be balanced at the organizational level. The condition for which each proposed MM location was selected will be communicated at the time of award. Organizations will communicate to intervention sites that they want to open a MM at that location within the next year. Organizations will communicate to comparison sites that they want to work with them on a food systems planning process to determine if a MM program is the right fit for their location. At the end of the year-long planning process with comparison sites, the organization and proposed MM site will decide together how to proceed (start a MM, apply for grant funding for a different project; etc.).

Both arms will undergo community engagement efforts that serve to both identify potential research participants and engage them in the planning for a MM. Intervention sites will work with a community advisory committee to develop an engagement plan to raise community awareness of the forthcoming MM. Comparison sites will work with a community advisory committee to engage community members in a food access planning process.

Both intervention and comparison sites will distribute sign-up forms as part of the community engagement process. UB staff will identify from the sign-upforms those interested in participating in the study. Consent will be obtained via phone. Phone surveys and in-person data collection will then be completed.

- Baseline and 12 month Follow-Up Survey will include dietary–related psychosocial measures (self-efficacy to purchase, prepare, and eat fresh F&V), shopping behavior and attitudes, process measures, and demographics. At follow-up they will also answer qualitative questions related to program implementation. These surveys will be administered over the phone and collected using REDCAP. Questions assessing changes in food behavior due to COVID will also be assessed at baseline and follow-up.
- Our main individual-level outcome, change in F&V intake at 12 months, will be measured through four 24-hour recalls (2 at baseline and 2 at 12 months) which will be administered over the phone by trained interviewers. One recall at each time point will be from a weekday and the other from a weekend day. Recalls will be collected using the Nutrition Data Systems for Research (NDSR) computer-based software application. A participant will receive The Food Amounts Booklet via mail after the baseline survey to have as a visual reference for the 24-hour recalls.
- In addition to survey data, body mass index (BMI) and dermal carotenoids will be measured at in-person data collection events at baseline and 12 months.
    - Dermal carotenoids will be measured using a finger scan technology called the "Veggie Meter" which is thought to be a valid indicator of dietary carotenoid consumption.
    - BMI will be calculated from height and weight.

We are aware that there is the potential that a comparison participant may be exposed to the intervention. In previous work, this only occurred in 1 out of nearly 100 control participants.

*(update 1-7-2020: The 9 organizations that have been selected include: 1. Massachusetts Avenue Project (Buffalo, NY), 2. Urban Fruits and Veggies (Buffalo, NY), 3. Local Matters (Columbus, OH), 4. The Bulb (Charlotte, NC; 5. Mobile Oasis (Greensboro, NC); 6. Nuestras Raices (Holyoke, MA); 7. Family Residences and Essential Enterprises, Inc. (Long Island, NY); 8. Community Food Initiatives (Athens, OH); 9. Feast Down East (Wilmington, NC).

5.0 Local Number of Subjects

5.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.

Response:

Aim 2: We plan to recruit at least 30 participants at each of the 33 proposed sites (990 total).

Sub-study: We are looking to recruit an additional 50 individuals from across all sites.

5.2 If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e. your screen failure rate).

Response: The majority of recruitment will take place over a 2-month community engagement process at each site. During this 2-month process, we anticipate screening at least 100 individuals per site in order to reach our target of 30 participants per site.

- Screen 100 participants per site (3,300 total)
- Enroll at least 30 per site (990 total). If there is a lot of interest at a particular site, we may enroll up to 40 participants at a given site. Our target of 990 participant total for the study will be maintained.

5.3 Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response: While we need 6 organizations (24 sites) to achieve the desired power of at least 80%, we will work with 9 organizations (33 sites) across the north, mid, and south east region to recruit 990 participants. We expect participant attrition to be no more than 30% based on previous work, so we will plan to recruit about 30 participants per site over a 2-month process through community engagement efforts Participants may also be recruited at their first visit to the MM which would clearly show an intent to shop at the MM (i.e. engage with the intervention) or during community events at the planning sites

6.0 Inclusion and Exclusion Criteria

*6.1 Describe the criteria that define who will be **included** in your final study sample.*

NOTE: This may be done in bullet point fashion.

Response: Individuals will be eligible to participate in the main study if they are:

- at least 18 years old, speak English or Spanish
- the primary grocery shopper for their household
- interested in using a mobile market if it were to come to their community
- either frequent the proposed MM site regularly or live near by

Individuals will be recruited to the sub-study if they are:

- at least 18 years old and speak English
- the primary grocery shopper for their household
- NOT interested in using a mobile market if it were to come to their community

*6.2 Describe the criteria that define who will be **excluded** from your final study sample.*

NOTE: This may be done in bullet point fashion.

Response: Individuals will be excluded if they do not meet the above inclusion criteria. They will be excluded if they are planning to leave the area or stop using the proposed MM site (intervention participants) within the next year.

6.3 Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.

NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.

Response: N/A

☐ Adults unable to consent

☐ Individuals who are not yet adults (infants, children, teenagers)

☐ Pregnant women

☐ Prisoners

6.4 Indicate whether you will include non-English speaking individuals in your study. ***Provide justification if you will exclude non-English speaking individuals.***

In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may ***not*** *be routinely excluded from research as a matter of convenience.*

In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.

Response:

We will not exclude non-English speaking individuals. We will include non-English speaking individuals and make appropriate modifications to survey materials and the data collection protocol to accommodate an individual's primary language.

7.0 Vulnerable Populations

If the research involves special populations that are considered vulnerable, ***describe the safeguards included to protect their rights and welfare.***

NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.

*7.1 For research that involves **pregnant women,** safeguards include:*
NOTE CHECKLIST: Pregnant Women (HRP-412)

Response:

☒ **N/A**: This research does not involve pregnant women.

*7.2 For research that involves **neonates of uncertain viability or non-viable neonates,** safeguards include:*
NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)

Response:

☒ **N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

*7.3 For research that involves **prisoners**, safeguards include:*
NOTE CHECKLIST: Prisoners (HRP-415)

Response:

☒ **N/A:** This research does not involve prisoners.

*7.4 For research that involves **persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")**, safeguards include:*
NOTE CHECKLIST: Children (HRP-416)

Response:

☒ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

*7.5 For research that involves **cognitively impaired adults**, safeguards include:*
NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)

Response:

☒ **N/A:** This research does not involve cognitively impaired adults.

*7.6 Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. **Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.***

Response:

8.0 Eligibility Screening

*8.1 Describe **screening procedures** for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.*

Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaire).

Response: Partner organizations (1. Massachusetts Avenue Project (Buffalo, NY), 2. Urban Fruits and Veggies (Buffalo, NY), 3. Local Matters (Columbus, OH), 4. The Bulb (Charlotte, NC; 5. Mobile Oasis (Greensboro, NC); 6. Nuestras Raices (Holyoke, MA); 7. Family Residences and Essential Enterprises, Inc. (Long Island, NY); 8. Community Food Initiatives (Athens, OH); 9. Feast Down East (Wilmington, NC).) will assist with community engagement and distribute interest forms. The interest form is distributed and collected by partner organizations to determine if community members are interested in having a mobile market at their community site. The interest form is also used to determine if the community member is interested in learning more about the veggie van study. The interest forms will be shared with both the partner organization and the UB research team. A UB research team member will identify from the interest forms those interested in participating in the study and will contact via phone to determine eligibility.

A set of screening questions will be asked of them (See Recruitment and Screening Scripts). If a participant's responses to the screening questions indicate not eligible, participant will be thanked for his/her time. A record of the number of screen failures will be kept but no direct data about participants. Supported by the University at Buffalo, REDCap (Research Electronic Data Capture), a secure web application for building and managing databases, will be used as part of screening efforts to: 1) track participant recruitment and 2) collect survey data for those who screen eligible.

☐ **N/A:** There is no screening as part of this protocol.

9.0 Recruitment Methods

☐ **N/A:** This is a records review only, and subjects will not be recruited. NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections.

9.1 Describe when, where, and how potential subjects will be recruited.

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g. searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.).

Response:

At both intervention and comparison sites, community engagement activities will assist with participant recruitment over a 2-month period. Partner organizations, site

leaders, and advisory committee members will assist with identifying people who are interested in having more healthy food options in their community. Information will be collected from potential participants using an Interest Form. Respondents can indicate whether or not they would like to be contacted about the research study. A research assistant from the UB research team will contact interested individuals to confirm eligibility, obtain verbal consent, complete baseline survey data collection, and schedule the baseline in-person data collection session at the community site.

An in-person data collection will be schedule at each community site. Members of UB's research team will attend and train two or more members of the Partner organizations staff and/or community advisory committee to recruit participants and collect in-person data. A community friendly version of the CITI human subjects training which the UB Institutional Review Board has approved will be utilized. Individuals from the 9 Partner Organizations that are CITI trained will be added to the IRB as external members as they come on board and before the in-person data collection event. These external community members will not have access to REDcap; instead they will collect any study information via paper (see Phase 2 Interest Form) and provide to UB research team.

We will invite individuals that have already been screened and consented over the phone as well as individuals who have completed interest forms but are not yet consented to attend in-person data collection events. These events will be open to anyone who uses the community site and additional participants may be screened for eligibility, consented (by UB staff only), and complete in-person data collection.

If all 30 planned participants have not completed data collection at the events, trained staff/advisory committee members will continue to recruit participants utilizing Phase 2 Interest Form for up to one month or until 30 participants have been achieved. Partner organization staff members that completed CITI training and in-person data collection training with UB staff will ask interested individuals to complete a Phase 2 Interest Form that contains a brief series of demographic questions and can check off a box if they are interested in participating in the study. The following measurements can also be collected, but remain property of the partner agency until the individual consents to research with the UB research team over the phone.

- Height and Weight measurements
- Veggie Meter measurements

For the sub-study: Participants will be asked to complete the baseline and the follow-up survey, but will not complete any 24-hour recalls or in-person data collection. They will be asked to complete an additional semi-structured phone interview to learn more about why they do not plan to use a mobile market program.

9.2 Describe how you will protect the privacy interests of prospective subjects during the recruitment process.

NOTE: Privacy refers to an individual's right to control access to him or herself.

Response: Privacy of potential participants is protected because the participant controls his own response to recruitment materials.

9.3 Identify any materials that will be used to recruit subjects.

NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.

For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.

Response:

- Flyers will be posted at sites as part of community engagement efforts.
- Interest forms (English and Spanish Versions) will be disseminated at community sites during the recruitment process. Interest forms will be available digitally via Google Forms through a link displayed on the paper interest form.
- A Veggie Van study FAQs sheet will be attached to interest forms for respondents to take with them to review.
- Recruitment and Screening Script will be utilized to screen interested community members.

10.0 Procedures Involved

*10.1 Provide a description of **all research procedures or activities** being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response.

Response:

Once a subject is screened and determined to be eligible, UB researchers will consent participant via phone. Phone surveys and in-person data collection will then be completed. If 30 participants have not been recruited at a site, the study moves into

Phase 2: community members will fill out a Phase 2 Interest form, the partner organization will collect in-person data. UB researchers will reach out to those interested in the study, and consent via phone and then complete phone surveys.

	Phase 1	IN-PERSON DATA COLLECTION	Phase 2
Recruitment and Screening	Interest Form: Property of partner organization. Shared with UB. UB will enter data in REDCap and only contact those who indicate interest in participating in research.		Phase 2 Interest Form: Property of partner organization. Shared with UB. UB will enter data in REDCap and only contact those who indicate interest in participating in research.
Consent	UB research team reach out to those indicating interest in study		UB research team reach out to those indicating interest in study. UB research team may consent in person.
Phone Surveys	UB Research complete phone surveys		UB research team complete phone surveys
24 Diet recalls	UB research team administer 24-hour diet recall phone calls		Not completed at Baseline; completed at 12-month follow-up
In-person data collection	UB research team schedule participants for in-person data collection event at community site. UB research team with assistance of CITI trained partner staff will collect in-person data (height, weight, veggie meter)		CITI trained partner staff collect in-person data (height, weight, veggie meter). This data only shared with UB if participant indicates interest in study and is consented to be part of study (see above).

Veggie Van Study Information Sheet and Verbal Consent Script:

Once screened, determined to be eligible and still interested in the study, the Study Information Sheet will be read to the participant explaining their involvement in the study. If still interested, the Verbal Consent Script will be read and the participant will be asked if they are interested in providing consent at that time, or would like to instead receive a copy of the Study Information Sheet and provide consent at a later date. If it's the latter, the Study Information Sheet will be sent to the participant either via REDCap link via email or via postal mail. The Study Information Sheet will be sent to participants who agree to provide consent at any point via REDCap link via email or via postal mail. Participants will be asked if they would like to stay on the phone and complete the baseline survey or if they would like to schedule for another time.

During Phase 2, a Phase 2 Veggie Van Information Sheet will be read to the participant. See Veggie Van Info Sheet PHASE 2.

Both the PHASE 1 and PHASE 2 Veggie Van Information Sheets (attached) include information about voluntary participation in additional survey(s)/interview(s) outside the scope of the Veggie Van Study described here. Adjacent studies will recruit participants from the Veggie Van Study based on qualifying responses to Veggie Van Surveys and will be submitted for individual review by the IRB (e.g, IRB ID 00006217). Participation in an adjacent study is optional, includes incentive(s), and will not impact eligibility or enrollment in the Veggie Van Study described here. Consent for possible future contact about these additional metrics will be gathered during the above-described consent process.

Current participants who are deemed eligible to participate in an adjacent study will be reconsented via telephone call, either during their next applicable Veggie Van Study metric (see 11.0 Study Timelines) or during a separate call updating their consent. See attached Reconsent Script For Additional Metrics.

BASELINE

- The Baseline Survey will include dietary–related psychosocial measures (self-efficacy to purchase, prepare, and eat fresh F&V), shopping behavior and attitudes, process measures, and demographics.
- Two 24-hour recalls will be administered over the phone by trained interviewers. One recall will be from a weekday and the other from a weekend day. Recalls will be collected using the Nutrition Data Systems for Research (NDSR) computer-based software application. A participant will receive The Food Amounts Booklet via mail after the Baseline Survey to have as a visual reference for the 24-hour recalls. Phase 2 participants will only complete the 2, 24-hour recall during the 12-month follow up period.
- Participants will be scheduled for an in-person data collection session at the site. Body mass index (BMI) and dermal carotenoids will be measured: Phase 2 participants will have this data collected by CITI trained partner organization staff; after providing consent to be in the study, they will allow the partner organization to provide this information to UB researchers.
    - Dermal carotenoids will be measured using a finger scan technology called the "Veggie Meter" which is thought to be a valid indicator of dietary carotenoid consumption. We will ask participants to clean their hands with an alcohol wipe before inserting the left index finger into the machine. The participant's finger will be scanned 3 times and the average value will be used in this analysis. Scans take about 3 seconds each
    - BMI will be calculated from height and weight.

12 Month Follow-Up

One-year post Baseline data collection, participants will be contacted to schedule and complete:

- Follow-up Survey (same as baseline survey). They will also answer qualitative questions related to program implementation.
- Two 24-hour recalls. Phase 2 participants will be administered the 24-hour recalls.
- In-person data collection to collect Body mass index (BMI) and dermal carotenoids

Sub-study: Baseline: Same survey as described above. In addition, a semi-structured interview will last 30-40 minutes and will take place within 2 months of the baseline survey. The follow-up survey will take place at 12-month follow-up as described above.

10.2 Describe what data will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response:

- Dietary recalls will be used to collect our main individual-level outcome, cups/day of F&V. Secondary dietary outcomes which can be calculated from this data include total calories per day, percent of total calories from F&V and percent of total calories from added sugars.
- Height and weight will be obtained to calculate BMI.
- Dermal carotenoids, a valid indicator of changes in skin carotenoids in response to dietary carotenoid consumption, will be measured using the Veggie Meter.
- Psychosocial measures such as self-efficacy, perceived access to F&V, shopping behavior and attitudes will be assessed using surveys administered at baseline and 12 months. Demographics will be also assessed in the survey at baseline.

Sub-study:

Semi-structured qualitative interviews will collect options on shopping, programs to increase fruit and vegetable consumption and the mobile market organization.

10.3 List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form).

Include copies of these documents with your submission.

Response:

- **Fruit and Veggie Intake** (Baseline and Follow-up): The 24-hour dietary recalls will be collected using the Nutrition Data Systems for Research (NDSR) 24-hour recall survey (see: *NDSR 24-hour Recall Phone Script).* Participants will refer to The Food Amounts Booklet as a visual reference.
- **Anthropometrics (height and weight)** Weight will be measured using a SECA 876 digital scale and height measured to the nearest 1/8 inch using a SECA

stadiometer. Data will be collected and either directly entered by UB researcher into REDCap or recorded first on the *Veggie Van Baseline and 12-month Data Collection Form* and subsequently entered into REDCap.

- **Dermal Carotenoids** A finger scan technology, called the "Veggie Meter," relies on pressure mediated Raman Spectroscopy (RS) will be used as a non-invasive, objective marker of carotenoid consumption in participants. Data will be collected and either directly entered by UB researcher into REDCap or recorded first on the *Veggie Van Baseline and 12-month Data Collection Form* and subsequently entered into REDCap.
- **Baseline and Follow-Up Surveys see attached:**
    - Veggie Van Baseline 12 month Survey Phone Script
    - VEGGIEVANBaselineSurvey_8.27.19 (REDCap .pdf print-out)

All survey data will be collected by a UB Researcher via phone and entered directly into REDCap.

Sub Study: Semi-structured interview guide attached.

10.4 Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records).

Response: N/A

*10.5 Indicate whether or not **individual** subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe how these will be shared.*

Response: Individual subject results will not be shared with subjects

*10.6 Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

Response: Study results will be shared via peer-reviewed journal publications and conferences

11.0 Study Timelines

11.1 Describe the anticipated duration needed to enroll all study subjects.

Response: Through community engagement efforts, we anticipate being able to recruit the majority of needed participants during the 2-month community engagement phase for each site. Recruitment will span a total of two years to enroll all 990 subjects at the 33 sites. In the event that we are not able to reach 30 participants at a given site, and additional month will allow partner organizations to continue recruitment efforts.

11.2 Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.

Response: The study will span over 12 months and will include 2 data collection time-points: baseline and at 12 months. Participants will be contacted approximately 8 times (4 times at baseline, 4 times at 12 months) to complete:

1. Screening/verbal consent (20 Minutes) & Baseline Survey (25 Minutes) (some participants may want to do survey during a separate call)

2. Baseline 24-hour recall call (30 Minutes)

3. Baseline 24-hour recall call (30 Minutes)

4. Baseline in-person data collection height/weight, dermal carotenoids (15 Minutes)

5. Follow-up Survey (25 Minutes)

6. Follow-up 24-hour recall call (30 Minutes)

7. Follow-up 24-hour recall call (30 Minutes)

8. Follow-Up in-person data collection height/weight, dermal carotenoids (15 Minutes)

Total participation for the study is expected to be approximately 4 hours. Phase 2 participants will complete 24-hour recalls during 12-month follow up only. Phase 2 participants that are currently enrolled in the study will be reconsented at follow-up to inform them that they are eligible to complete follow-up diet recalls and can earn an additional incentive for completing.

Sub-study: Baseline: Same survey as described above. In addition, a semi-structured interview will last 30-40 minutes and will take place within 2 months of the baseline survey. The follow-up survey will take place at 12-month follow-up as described above.

11.3 Describe the estimated duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed).

Response: The expected study duration is 5 years.

12.0 Setting

12.1 Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.

NOTE: Examples of acceptable response may be: "A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software," "The angiogram suite at Buffalo General Medical Center, a fully accredited tertiary care institution within New York State with badge access," or, "Community Center meeting hall."

Response: Data collection will be completed over the phone (surveys, 24-hour dietary recall) with a trained interviewer and in a private location (height/weight and dermal carotenoid measurements) at the community site from which they were recruited.

12.2 For research conducted outside of UB and its affiliates, describe:

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure*

NOTE: This question is referring to UB affiliated research taking place outside UB, i.e. research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.

Response: In the various VV sites throughout the Northeast, Midwest, and Southeastern regions, the setting will be similar (i.e. churches, community centers, housing; etc). Data collection will be completed over the phone (surveys, 24-hour dietary recall) with a trained interviewer and in a private location (height/weight and dermal carotenoid measurements) at the community site from which they were recruited.

☐ **N/A:** This study is not conducted outside of UB or its affiliates.

13.0 Community-Based Participatory Research

13.1 Describe involvement of the community in the design and conduct of the research.

NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

Response:

☒ **N/A:** This study does not utilize CBPR.

13.2 Describe the composition and involvement of a community advisory board.

Response:

At both the intervention and comparison sites, engagement will focus on involving community members in food access program planning and research. We anticipate each organization will create one or more community advisory committees to oversee their food access work. At intervention sites, these advisory committees will focus on planning for a MM program. At comparison sites, engagement efforts will be more generally centered on food access and understanding what types of programs would be most acceptable.

☐ **N/A:** This study does not have a community advisory board.

14.0 Resources and Qualifications

*14.1 Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the research. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles.

Response: The Principal Investigator on this study is Dr. Lucia Leone. She holds a Ph.D. in Nutrition Intervention and Policy from the University of North Carolina at Chapel Hill. Her pre and postdoctoral training focused on cancer prevention and control and cancer health disparities. All of her research has been focused on developing community or organization-based interventions which are designed with an eye toward dissemination and implementation by community organizations. As a postdoctoral fellow, she worked with community partners to run a randomized controlled trial of Veggie Van. In order to conduct this research, there was a close relationship between the program team at Community Nutrition Partnership, a non-profit organization delivering the intervention, the research team, and other community-based organizations which serve as host partners for the mobile market. She co-founded the Community Nutrition Partnership, and has significant experience with the business aspects of running a food access program which will allow her to provide technical assistance to other organizations running this program across the country.

She has been conducting formative research in Buffalo related to developing new food access programs. She has conducted over 14 focus groups and 30 key-informant interviews with organizations working in food access to inform the development of a healthy corner store initiative and to translate the mobile market program to a new setting. This qualitative work will be instrumental in informing the current effectiveness trial. This project will also benefit greatly from the mentorship and experience of Drs. Ammerman, Raja, and Tumiel-Berhalter who together have extensive expertise in food policy, local food systems, and community engagement. Dr. Ammerman was Dr. Leone's postdoctoral advisor and co-investigator on previous Veggie Van work. Drs. Raja and Tumiel-Berhalter both serve as part of Dr. Leone's current mentorship team at UB. In addition, Dr. Raja leads an interdisciplinary initiative on Built Environment, Health Behaviors, and Health Outcomes which led to Dr. Leone's hiring at UB. Together, these collaborations and my previous experience developing, running and evaluating mobile market programs put Dr. Leone in an excellent position to run this research study.

The project coordinator holds a master's degree in clinical psychology and has 8+ years of experience working on research projects, and is UB and CITI trained.

The graduate research assistant is pursuing her doctoral degree in community health and will be thoroughly trained on the protocol, and have completed UB and CITI training.

Describe other resources available to conduct the research.

14.2 Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.

NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.

Response: Dr. Leone will devote 30% of her time to this study, Ms. Vermont (project coordinator) will dedicate 100% of her time to this study. The community engagement specialist will devote 50% of her time to this study. The Graduate Research Assistant will devote 20 hours/week to this study. We also plan to hire to additional graduate student assistants to dedicate 10 hours/week to this study.

14.3 Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.

NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression.

Response: N/A

14.4 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Response: All persons assisting with the research will have current training in UB's Good Research Procedures course and CITI training. The project coordinator will be trained by the PI on all aspects of the research. The project coordinator will train the data collectors using provided protocols.

All research personnel will be adequately informed about the protocol, research procedures, and their duties and functions through individual training provided by the Principal Investigator and project coordinator. All team members will receive appropriate training on maintaining confidentiality and protecting human subjects. Study staff will be assigned duties that are best suited to their qualifications. The Principal Investigator and project coordinator will provide direct oversight of the research staff to ensure proper conduct of research and the protection of subjects' rights and welfare.

Two individuals from each of the 9 Partner Organizations will also be trained in UB's Good Research Procedures course and CITI training. These individuals will be added as external members to the IRB as they come on board. They will only be involved

with helping to recruit and collect in-person data collection (height, weight, veggie meter). When the in-person data is collected, it will be property of the partner organization. Once the participant consents to be in the study, only then will the in-person data be shared with UB research team. The partner organization staff will not have access to REDCap; instead they will collect this information via paper and hand over directly to UB Research Team (See Phase 2 Interest Form).

15.0 Other Approvals

15.1 Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety).

Response:

☒ **N/A:** This study does not require any other approvals.

16.0 Provisions to Protect the Privacy Interests of Subjects

16.1 Describe how you will protect subjects' privacy interests during the course of this research.

NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

Examples of appropriate responses include: "participant only meets with a study coordinator in a classroom setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."

Response: Conducted over the phone, the consent process and data collection will take place in a private room on the UB campus in Kimball Tower. The PI (Lucia Leone), coordinator (Leah Vermont), graduate assistant (Christina Kasprzak), and student data collectors (to be named) will be entering data into REDCap. Only the research team will have access to the survey data. In some cases if internet access is not available and a paper copy of the survey is needed, the UB research assistant will keep those copies secure until in Buffalo where they will be entered directly in REDCap and the paper copy will be destroyed. Any paper copies of data that are kept while waiting to be entered will be kept in a locked filing cabinet in a locked office (Kimball 816).

Height, weight, and dermal carotenoid data will be collected in a private room at the community site with only the participant and research team members present during measurement.

When completing surveys over the phone, the UB research assistant will be in a private room and will remind the subject that all information discussed over the phone will be kept confidential. The research assistant will ask the subject to go to a closed or private area in their home while they answer survey questions. Participants will be informed at the start a survey that they can skip any questions that they are not comfortable with. Survey responses and data collection measures will not be shared with anyone at the communities where the MM will take place nor will they be shared with partners who are implementing the MM program. Only the research team will have access to identifiable data.

16.2 Indicate how the research team is permitted to access any sources of information about the subjects.

NOTE: Examples of appropriate responses include: school permission for review of records, consent of the subject, HIPAA waiver. This question ***does apply*** *to records reviews.*

Response: After the consent process, the participant controls the research team's access to the survey data and feedback provided during the program (intervention only) information because it is directly provided by the participant.

During the consent process over the phone, , a study team member will detail all of the elements of informed consent. If the individual decides to participate in the study, they will verbally agree to participate. Consent of the subject will grant permission to the affiliated research team to view information collected during the study.

17.0 Data Management and Analysis

17.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

Response:

Data Management:

- This study will utilize UB's REDCap (Research Electronic Data Capture) service, a software toolset and workflow methodology for electronic collection and management of clinical and research data, to collect and store data. REDCap provides a secure, web-based application that provides an intuitive data manipulation interface, custom reporting capabilities, audit trail functionality, real-time data monitoring/querying of participant records, and variations of data exporting/importing. REDCap has multiple data export options to common statistical packages (SPSS, SAS, Stata, R/S-Plus). REDCap data collection projects rely on a study-specific data dictionary defined in an iterative self-documenting process. The project specific data dictionary is defined by the research team. As part of the data dictionary development process, individual fields can be denoted as identifiers. When exporting a de-identified dataset, these variables are omitted. Additionally, the data export tool allows for the shifting/removal of dates. All web-based information transmission is encrypted. The data is all stored on a UB private, firewall protected network. All users are given individual user ids and passwords and their access is restricted on a role-specific basis.

- Data collected from participants will be entered by UB researchers into RedCap including: Baseline and 12-month height, weight, dermal carotenoid values, survey data.
- PI (Lucia Leone), coordinator (Leah Vermont), graduate assistant (Christina Kasprzak), and student data collectors (to be named) will be entering data into REDCap.
- Data will be stored in REDCap, and then extracted into a statistical package for analysis. Extracted data will be stored on the PI's UB School of Public Health and Health Professions encrypted drive .

Data Analysis

Aim 2: In this cluster-randomized study, our primary outcome is change in F&V intake (cups/day) at 12 months using the 24 hour recall, thus, we will compare the difference in mean changes in F&V between intervention and comparison group participants. Our primary analysis will test the hypothesis under the intent-to-treat principle using a Generalized Linear Mixed Model (GLMM) that will account for the correlation induced by the clustering of participants within sites. The GLMM (see below) will include a random intercept for sites (β_0) fixed effects for the baseline value of the primary outcome (β_1) and the intervention (β_2) to test if the differences in mean changes in primary outcomes is zero where β_0 is the fixed intercept and e is error.

$$Changein\,\mathrm{Pr}imaryOutome_{9m} = \beta_0 + \beta_1\,\mathrm{Pr}imaryOutcome_{baseline} + \beta_2 Intervention + b_0 + e$$

Including the baseline values score as a covariate in an analysis of covariance (ANCOVA, in our case a GLLM ANCOVA) is known to be a more powerful test than a group comparison of baseline to post-intervention change. In order to further explore the intervention effect, we will fit FLMMs that (1) adjust for baseline covariates of interest; (2) adjust for baseline variables distributed differently between intervention groups; (3) test interaction terms between treatment group and other covariates; and (4) complete sub-group analyses. Specifically, we will look at differences in changes of F&V consumption, perceived access and self-efficacy by intervention usage. Additionally, if we see correlations between changes in F&V consumption, self-efficacy, intervention usage and/or perceived access at 12 months, we will conduct analyses to determine if these changes mediate the intervention effect. In addition, we will expand the regression models by including interaction terms to examine the heterogeneity of intervention and the role of moderators such as organizations or community types.

17.2 If applicable, provide a power analysis.

NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.

Response: Based on our initial cluster RCT, we estimate the intra-class correlation (ICC) for change in F&V intake to be 0.08 (SD 2.7). We expect the MM program to increase the F&V intake by at least 1 cup/day (effect size of approximately 0.4). Using one-sided tests of significance at p=0.05, an ICC=0.08, and cluster size=21 participants per site, 12 sites per group will provide at least 90% power to detect the anticipated change in F&V consumption. To account for possible attrition or extended delays on the part of the organization, we will over-recruit. While we need 6 organizations (24 MM sites) to achieve the desired power, we will recruit 9organizations (33 sites). We expect participant attrition to be no more than 30% based on previous work, so we will plan to recruit about 30 participants per site.

17.3 Describe any procedures that will be used for quality control of collected data.

Response: Research staff will be adequately trained in proper data collection. Collected data will be reviewed by the project coordinator to ensure completeness and accuracy.

18.0 Confidentiality

A. Confidentiality of Study Data

Describe the local procedures for maintenance of confidentiality of ***study data and any records that will be reviewed for data collection****.*

18.1 A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) ***and*** *electronic files.*

Response:

Data collected via surveys will be entered directly into a web-based REDCap survey. Only the research team will have access to the survey data

The REDCap database is hosted at the University at Buffalo School of Medicine, Office of Medical Computing. REDCap data projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by members of the research team. In terms of regulatory compliance, REDCap can be fully personalized to meet individual project's need for collecting and storing participant data.

. In some cases, if internet access is not available and a paper copy of the survey is needed those copies will be stored in a locked file cabinet. A locked file cabinet in room 814 Kimball Tower, UB South Campus. The room is within the Department of Community Health and Health Behavior. Only the PI and project coordinator will have a key that can access the room and cabinet.

The only personally identifying information from study participants will be their names, addresses, e-mail addresses, and phone numbers so that we can contact them

for follow-up surveys and incentive payment. This data will be stored directly in REDCap. Each subject will receive an identification number which will be used to designate their data. Personal contact information will be stored separately from survey data. Any files linking this information will be password protected and will be permanently deleted as soon as the data collection is completed and payment has been received. Data files prepared for analysis will not include any identifiers.

18.2 A. How long will the data be stored?

Response: Any other paper data collection tools will be destroyed after the data has been analyzed. De-identified electronic data will be retained indefinitely.

18.3 A. Who will have access to the data?

Response: Only the research team members responsible for data collection will have access to identifiable information. All team members will receive appropriate training on maintaining confidentiality and protecting human subject.

18.4 A. Who is responsible for receipt or transmission of the data?

Response: The Principal Investigator and project coordinator are responsible for receipt and transmission of the data.

18.5 A. How will the data be transported?

Response: Electronic and paper survey data collected by UB research team at community sites will be collected via password protected tablets and kept in secure files for transport back to Buffalo to be stored in a locked filing cabinet (Kimball 324). The data will stay in the possession of the UB research team at all times.

B. Confidentiality of Study Specimens

*Describe the local procedures for maintenance of confidentiality of **study specimens**.*

☒ **N/A:** No specimens will be collected or analyzed in this research.
(Skip to Section 19.0)

18.6 B. Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable.

Response:

18.7 B. How long will the specimens be stored?

Response:

18.8 B. Who will have access to the specimens?

Response:

18.9 B. Who is responsible for receipt or transmission of the specimens?

Response:

18.10 B. How will the specimens be transported?

Response:

19.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include: exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.

19.1 Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Response: This is a low risk study. We do not anticipate any harm to the participants. We are confident that the procedures outlined will limit any risk or breach of confidentiality. In the rare event that an adverse event occurs, study staff has the responsibility of reporting it to the PI within 24 hours. In turn, the PI will be responsible for reporting all adverse events in accordance with the policy of the UB IRB. Because of this low risk status, the data safety monitoring plan (DSMP) will focus on close monitoring by the principal investigator (PI) in conjunction with a safety officer, along with prompt reporting of excessive adverse events and any serious adverse events to the NIH and to the IRB at the University at Buffalo.

Because of this study's low risk status, the data safety monitoring plan for this study will focus on close monitoring by the principal PI along with prompt reporting of excessive adverse events and any serious adverse events to the IRB.

19.2 Describe what data are reviewed, including safety data, untoward events, and efficacy data.

Response: Recruitment, drop-out, and missing data will be reviewed. Anything affecting statistical power will also be reviewed.

19.3 Describe any safety endpoints.

Response: As we do not anticipate this study having any higher risk than normal participation in exercise we do not have any safety endpoints.

19.4 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response: Safety information will be collected at study visits and telephone calls with participants if necessary.

19.5 Describe the frequency of safety data collection.

Response: Study visits and telephone calls with participants occur at baseline and 12 month follow-up. Participants will be provided contact information for the study project coordinator as well as the Institutional Review Board in the event that they need to report a complaint or concern at any point in the study.

19.6 Describe who will review the safety data.

Response: A safety officer will be appointed who does not have a scientific, financial, or other conflict of interest related to the study and is not a collaborator or association of the principle investigator.

19.7 Describe the frequency or periodicity of review of cumulative safety data.

Response: Data will be reviewed quarterly to assess safety.

19.8 Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Response: We do not anticipate this study to be higher risk; therefore, we will not be analyzing safety data.

19.9 Describe any conditions that trigger an immediate suspension of the research.

Response: We do not anticipate this study to be higher risk; therefore, we do not require conditions that will trigger immediate suspension of the study.

20.0 Withdrawal of Subjects

☐ **N/A:** This study is not enrolling subjects. This section does not apply.

*20.1 Describe **anticipated** circumstances under which subjects may be withdrawn from the research without their consent.*

Response: In the event [site] withdraws from the study, participants may no longer be able to participate in the study and as a result will not be eligible for future incentives. If this occurs, the Veggie Van Study team will contact participants about the change in their enrollment status.

20.2 Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.

Response:

20.3 Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response: If a participant decides to leave the study, already collected data may not be removed from the study database unless they request that their data be destroyed.

21.0 Risks to Subjects

21.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

Response: As with all research, there are risks associated with participation in this study. However, we consider the risks to be modest and acceptable. Breach of confidentiality is the primary risk associated with this study. Another potential risk of this study is embarrassment if participants indicate that they are unable to afford healthy food for their family.

21.2 Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.

Response: Participants' privacy will be ensured by performing data collection (in-person and over the phone) in private areas. The research team will make every effort to keep participant's data private. The only personally identifying information from study participants will be their names, addresses, e-mail addresses, and phone numbers so that we can contact them for follow-up surveys and incentive payment. Each subject will receive an identification number which will be used to designate their data. Personal contact information will be stored separately from survey data. Any files linking this information will be password protected and will be permanently deleted as soon as the data collection is completed and payment has been received. Data files prepared for analysis will not include any identifiers. Only the research team members responsible for data collection will have access to identifiable information. All team members will receive appropriate training on maintaining confidentiality and protecting human subject.

Regarding potential embarrassment, participants will be instructed that they can skip any questions that they are not comfortable with.

*21.3 If applicable, indicate **which procedures** may have risks to the subjects that are currently unforeseeable.*

Response: We will measure weight using a SECA 876 digital scale and height using a SECA stadiometer. We will measure dermal carotenoids using a finger scan technology called the "Veggie Meter." These procedures are considered non-invasive and we do not anticipate any risks to the subjects.

21.4 If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.

Response: N/A

21.5 If applicable, describe risks to others who are not subjects.

Response: N/A

22.0 Potential Benefits to Subjects

22.1 Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.

*NOTE: Compensation **cannot** be stated as a benefit.*

Response: Participants who utilize the VV program may have better access to fruits and vegetables as well as nutrition and cooking education and potentially improve their diets. By participating in the evaluation, they can help improve the program so it better serves them and their community.

23.0 Compensation for Research-Related Injury

☒ **N/A:** The research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

*23.1 **If the research procedures carry a risk of research related injury,** describe the available compensation to subjects in the event that such injury should occur.*

Response:

23.2 Provide a copy of contract language, if any, relevant to compensation for research related injury.

*NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with **different language regarding research related injury**, you must modify your response here and submit an amendment to the IRB for review and approval.*

Response:

24.0 Economic Burden to Subjects

24.1 Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking.

Response: N/A

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

25.0 Compensation for Participation

25.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.

Response: Gift cards will either be mailed to participants specified mailing address or sent electronically via email for surveys. Gift cards may be handed directly to participants by UB Researchers during in-person data collection.

- Baseline Survey (phone) $15
- Baseline 24-Hour Recall (phone x2) $15
- Baseline In-person data collection $15
- Follow-Up Survey (phone) $15
- Follow-Up -Hour Recall (phone x2) $15
- Follow-Up In-person data collection $15

- Total compensation for completing all study benchmarks (baseline and 12 months) is up to $90.

- Phase 2 participants will not complete baseline 24-hour recalls and therefore will receive $75 total. Phase 2 respondents that are already enrolled in the study will be re-consented at follow-up data collection (during their follow-up survey call) to inform them of the change to their incentive schedule caused by adding diet recalls at follow-up. Phase 2 respondents can receive one of the two following combinations of incentives based on when they are recruited;

Recruited prior to in-person event:

- $15 at baseline
- $15 at in-person data collection
- $15 at follow-up survey

- $15 for both diet recalls
- $15 for in-person data collection (follow-up)

Recruited after in-person event (unable to do in-person data collection at baseline):

- $15 at baseline
- $15 at follow-up survey
- $15 at follow-up first diet recall
- $15 at follow-up second diet recall
- $15 at in-person data collection (follow-up)

For the sub-study:

- Baseline Survey (phone) $15
- Semi-structured Interview (phone) $15
- Follow-Up Survey (phone) $15

Total compensation for all benchmarks would be $45

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

☐ **N/A:** There is no compensation for participation. This section does not apply.

26.0 Consent Process

26.1 Indicate whether you will be obtaining consent.

NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study. Consent documentation is addressed in Section 27.0.

☒ ***Yes*** *(If yes, Provide responses to each question in this Section)*
☐ ***No*** *(If no, Skip to Section 27.0)*

26.2 Describe where the consent process will take place. Include steps to maximize subjects' privacy.

Response: The consent process will take place over the phone, in a private room in Kimball Tower. Participants will be asked if they are in a place they feel comfortable answering questions.

26.3 Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.

NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See "SOP: Informed Consent Process for Research (HRP-090)" Sections 5.5 and 5.6.

Response: All participants will have the option to review recruitment information prior to consenting. Once screened, determined to be eligible and still interested in the study, the Study Information Sheet will be read to the participant explaining their involvement in the study. If still interested, the Verbal Consent Script will be read and the participant will be asked if they are interested in providing verbal consent at that time or would like to instead receive a copy of the Study Information Sheet and provide consent at a later date. If it's the latter, the Study Information Sheet will be sent to the participant either via REDCap link via email or via postal mail to provide additional time to review. The UB researcher will ask the participant if they have any questions or need any part of the study explained in more detail.

26.4 Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.

Response: When study staff contacts participants over the phone for surveys, they will ask if they have any questions regarding the study and remind the participant that their participation is voluntary.

26.5 Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:

- *The role of the individuals listed in the application who are involved in the consent process*
- *The time that will be devoted to the consent discussion*
- *Steps that will be taken to minimize the possibility of coercion or undue influence*
- *Steps that will be taken to ensure the subjects' understanding*

Response:

☒ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)."

Non-English Speaking Subjects

☐ **N/A:** This study will not enroll Non-English speaking subjects. *(Skip to Section 26.8)*

26.6 Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

NOTE: The response to this Section should correspond with your response to Section 6.4 of this protocol.

Response: Spanish

26.7 If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

NOTE: Guidance is provided on "SOP: Informed Consent Process for Research (HRP-090)."

Response: We will modify the consent form to be written in a language understandable to the subject/representative (Spanish). If needed, we will obtain the services of an interpreter fluent in both English and the language understood by the subject/representative (Spanish). The interpreter may be a member of the research team, or a family member, or friend of the subject/representative. We will read the consent document (or have the interpreter read the translated consent document) with the subject/representative. We are not currently enrolling Spanish speakers and a modification will be submitted to the IRB before we do so.

Cognitively Impaired Adults

☒ **N/A**: This study will not enroll cognitively impaired adults.
(Skip to Section 26.9)

26.8 Describe the process to determine whether an individual is capable of consent.

Response:

Adults Unable to Consent

☒ **N/A**: This study will not enroll adults unable to consent.
(*Skip to Section 26.13)*

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 26.9 and 26.10) ***and, where possible, assent of the individual should also be solicited*** *(Sections 26.11 and 26.12).*

26.9 Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" for research in New York State.

NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.

Response:

☐ We have reviewed and will be following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

26.10 ***For research conducted outside of New York State****, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

26.11 Describe the process for ***assent of the adults****:*

- *Indicate whether assent will be obtained from all, some, or none of the subjects. If some, indicate which adults will be required to assent and which will not.*

Response:

- *If assent will not be obtained from some or all subjects, provide an explanation of why not.*

Response:

26.12 Describe whether ***assent of the adult*** *subjects will be documented and the process to document assent.*

NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the "Template Consent Document (HRP-502)" Signature Block for Assent of Adults who are Legally Unable to Consent.

Response:

Subjects who are not yet Adults (Infants, Children, and Teenagers)

☒ **N/A**: This study will not enroll subjects who are not yet adults. *(Skip to Section 27.0)*

26.13 Describe the criteria that will be used to determine ***whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research*** *under the applicable law of the jurisdiction in which the research will be conducted* ***(e.g., individuals under the age of 18 years)****. For research conducted in NYS, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

NOTE: Examples of acceptable responses include: verification via electronic medical record, driver's license or state-issued ID, screening questionnaire.

Response:

26.14 ***For research conducted outside of New York State****, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

26.15 Describe whether parental permission will be obtained from:

Response:

☐ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

☐ Parent permission will not be obtained. A waiver of parent permission is being requested.

NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the "CHECKLIST: Children (HRP-416)."

26.16 Describe whether permission will be obtained from individuals ***other than parents****, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual's authority to consent to the child's general medical care.*

Response:

26.17 Indicate whether assent will be obtained from all, some, or none of the ***children****. If assent will be obtained from some children, indicate which children will be required to assent.*

Response:

26.18 When assent of children is obtained, describe how it will be documented.

Response:

27.0 Waiver or Alteration of Consent Process

Consent will not be obtained, required information will not be disclosed, or the research involves deception.

☐ **N/A:** A waiver or alteration of consent is not being requested.

27.1 If the research involves a waiver or alteration of the consent process, please review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.

NOTE: For records review studies, the first set of criteria on the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" applies.

Response:

This study should be eligible for exemption of the written informed consent requirement. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Prior to the interview, obtaining verbal consent, instead of written signed consent, will not adversely affect the rights and welfare of subjects, as subjects will still be informed about details of the study via the information sheet that requires no signature and a general statement describes the overall purpose of the study.

The study could not practicably be carried out without this waiver because the anonymous survey is via telephone.

Participants will not be provided with additional information after the responses are put through because it is not needed such a low risk study.

27.2 If the research involves a waiver of the consent process for planned emergency research, please review the "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response:

28.0 Process to Document Consent

☒ **N/A:** A Waiver of Consent is being requested.
(Skip to Section 29.0)

28.1 Indicate whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not or if there are any exceptions, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.

NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as 'verbal consent.' Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.

📎 *If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. consent script or Information Sheet).*

Response:

Once screened, determined to be eligible and still interested in the study, the Study Information Sheet will be read to the participant explaining their involvement in the study. If still interested, the Verbal Consent Script will be read and the participant will be asked if they are interested in providing consent at that time, or would like to instead receive a copy of the Study Information Sheet and provide consent at a later date. If it's the latter, the Study Information Sheet will be sent to the participant either via REDCap link via email or via postal mail. When participant verbalizes that they consent to be a part of the study, the UB Researcher will document in REDCap by checking a box that indicates participant verbalized consent. The Study Information Sheet will be sent either via mail or email to the participant following the consent process to keep for their records.

☐ We will be following "SOP: Written Documentation of Consent" (HRP-091).

29.0 Multi-Site Research (Multisite/Multicenter Only)

☒ **N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

*29.1 If this is a multi-site study **where you are the lead investigator**, describe the processes to ensure communication among sites, such as:*

- *All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*

- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Response:

29.2 Describe the method for communicating to engaged participating sites:

- *Problems*
- *Interim results*
- *Study closure*

Response:

29.3 Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites.

Response:

29.4 If this is a multicenter study for which UB will serve as the IRB of record, and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.

Response:

30.0 Banking Data or Specimens for Future Use

☒ **N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

*30.1 If data or specimens will be banked (stored) for **future use, that is, use or research outside of the scope of the present protocol**, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.*

NOTE: Your response here must be consistent with your response at the "What happens if I say yes, I want to be in this research?" Section of the Template Consent Document (HRP-502).

Response:

30.2 List the data to be stored or associated with each specimen.

Response:

30.3 Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Response:

31.0 Drugs or Devices

☒ **N/A:** This study does not involve drugs or devices. This section does not apply.

31.1 If the research involves drugs or devices, list and describe all drugs and devices used in the research, the purpose of their use, and their regulatory approval status.

Response:

31.2 Describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

Response:

If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

31.3 Identify the holder of the IND/IDE/Abbreviated IDE.

Response:

31.4 Explain procedures followed to comply with FDA sponsor requirements for the following:

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

Response:

32.0 Humanitarian Use Devices

☒ **N/A:** This study does not involve humanitarian use devices. This does not apply.

32.1 For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

Response:

32.2 For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.

Response: