

Official Title:	Adapting the Veggie Van Mobile Market Intervention to Address Disparities in Nutrition Security Among College Students
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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.*
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- *In addition:*
 - *For research where the only study procedures are records/chart review: Sections 6, 21, 22, 24, 25, 26 and 27 do not apply.*
 - *For exempt research: Section 6 may not apply. Section 6.1 will still apply if there is a study intervention.*

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 Example

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:

Adapting the Veggie Van mobile market intervention to address disparities in nutrition security among college students

PRINCIPAL INVESTIGATOR:

Name

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Response:

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VERSION NUMBER/DATE:

Include the version number and date of this protocol.

Response:

Version 6 5/20/2026

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	7/13/2023	Updated section 23 regarding the risk of feelings of shame and embarrassment due to food insecurity.	No
2	4/5/2024	PI updated (see section 16)	No
3	7/11/2024	Increased the number of participants (section 7) and extended the timeline to recruit more participants (section 13). Sections 8 and 11 were updated to clarify the timeline.	No
4	8/12/2024	Update UB Students' Nutrition Security Survey to deploy in Qualtrics. (See sections 12.1, 18.1, 19.1, and 20) Substitute the 2021 'Behavioral Risk Factor Surveillance System' FV module with the 'Produce Prescription Projects' FV module, add questions about the utilization of available food resources on campus, such as the Blue	No

		Table and the UB Veggie Van, and add the ‘Childhood Unpredictability and Socioeconomic Status’ questionnaire. (See section 12.12)	
5	3/20/2025	Updated UB Students' Nutrition Security Survey to include new available food resources on campus, such as UB Food Stand and other food access initiatives. (See sections 5.0, 12.2, and survey’s attachment) Included Aim 4 to the current study “Identify adaptations to the Campus VV necessary for increasing program feasibility, acceptability and usage in a college setting.” To achieve it, we have included focus groups with students, and semi-structured interviews with internal and external stakeholders. (See sections 2, 6, 7, 8, 9.6, 10, 11, 12, 13, 14, 18, 19, 27, 28, 30)	No
6	5/30/2026	Updated UB Students' Nutrition Security Survey to eliminate questions about ‘Childhood Socioeconomic Status and Childhood Unpredictability’, and UB Farm Stand since that resource is no longer available (See section 12.2)	No

FUNDING:

Indicate any funding for this proposal. This should match the Funding Sources page in Click IRB.

Response:

School of Public Health and Health Professions Pilot Funding Program

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 protocol is funded by a grant provided by UB's School of Public Health and Health Professions Pilot Funding Program and the National Institute of Minority Health Disparities. This research covers all aims of the grants:

Aim 1: estimate the prevalence of food insecurity among UB students using a campus-wide survey.

Aim 2: determine the impact of a pilot campus-based Veggie Van intervention on the diet, food/nutrition security, food access, and SNAP enrollment of postsecondary students.

Aim 3: identify adaptations to the Campus VV necessary for increasing program feasibility, acceptability, and usage in a college setting.

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:

Location: In a protected online folder that only the research team can access in the Community Health Interventions Lab within UB Box.

Address: <https://buffalo.app.box.com/>

Department: N/A

1.0 Study Summary

Study Title	Adapting the Veggie Van (VV) mobile market intervention to address disparities in nutrition security among college students
Study Design	Cross-sectional study
Primary Objective	To adapt the Veggie Van—an evidence-based mobile market influencing access and consumption of healthy food in underserved communities—to a campus setting.
Secondary Objective(s)	<ul style="list-style-type: none">• To conduct a needs assessment to understand the nutrition security rates and determinants among UB students using mixed methods.• To receive feedback from a Student Advisory Board to adapt the VV to a campus setting.• To pilot test the adapted UB VV using a quasi-experimental pretest-posttest design with 155 UB undergraduate students.
Research Intervention(s)/ Investigational Agent(s)	The present study will adapt the VV model—an evidence-based mobile market intervention supported by over ten years of research in efficacy, effectiveness, and implementation—to a college campus setting
IND/IDE #	
Study Population	UB graduate and undergraduate students
Sample Size	<ul style="list-style-type: none">• 2,147 undergraduate and 1,087 graduate students to participate in a campus-wide survey

	<ul style="list-style-type: none"> • 20 undergraduate students to participate in in-depth interviews or until saturation • 6 students participating in Student Advisory Board • 155 undergraduate students participating in the Campus Veggie Van pilot • 32 undergraduate students participating in pilot evaluation focus groups • 20 stakeholders participating in pilot evaluation semi-structured interviews.
Study Duration for individual participants	<ul style="list-style-type: none"> • In-depth interview participation will take approximately 1 hour. • The campus online survey will take approximately 15-20 minutes. • The Student Advisory Board will participate in 6 meetings lasting approximately 1 hour each. • Participation in the pilot intervention will last 26 weeks throughout the school year. • Each pilot evaluation focus group will last 75 minutes. • Stakeholder interviews will last between 30 to 60 minutes.
Study Specific Abbreviations/ Definitions	UB = University at Buffalo Veggie Van = VV NS = Nutrition Security FS = Food Security FV = Fruits and vegetables SNAP = Supplemental Nutrition Assistance Program

2.0 Objectives*

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

Response:

To adapt the Veggie Van —an evidence-based mobile market influencing access and consumption of healthy food in underserved communities— to a campus setting.

Aim 1: To conduct a needs assessment to understand the nutrition security rates and determinants among UB students using mixed methods.

Aim 2: To receive feedback from a Student Advisory Board to adapt the VV to a campus setting.

Aim 3: To pilot test the adapted UB VV using a quasi-experimental pretest-posttest design with 155 UB undergraduate students.

Aim 4: To identify adaptations to the Campus VV necessary for increasing program feasibility, acceptability and usage in a college setting.

2.2 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 FV available in a campus setting, providing incentives, and increasing food utilization skills, the adapted Campus VV will help students increase their FV consumption and nutrition security indicators.

3.0 Scientific Endpoints*

3.1 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:

- a) FV consumption
- b) Nutrition security

4.0 Background*

4.1 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:

Food insecurity experienced by students attending postsecondary institutions in the US deepens health disparities since it threatens the educational attainment of financial aid recipients,¹⁻⁵ lower-income,⁶ first-generation,^{5, 7} and racial/ethnic minority students^{1, 3-5, 8-12}—groups more likely to experience higher rates of food insecurity due to historical patterns of discrimination.¹³ Students are food insecure when they do not have access at all times to enough food for an active and healthy life.¹⁴ One out of ten US households reported experiencing food insecurity in 2021;¹⁵ however, this rate is two to eight times higher among post-secondary students.¹⁶ The changing demographics of post-secondary students in the US, including students from lower-income households, first-generation students, and racial/ethnic minority groups, combined with increasing tuition and related costs, may contribute to this increased prevalence of food insecurity.⁴⁻⁶ A survey of nearly 86,000 post-secondary students found sizable racial and ethnic disparities in post-secondary food access: 59% of American Indian or Alaskan Native students, 58% of Black or African American students, and 50% of Hispanic or Latinx students reported experiencing food insecurity, whereas 39% of white students were food insecure.⁷ Beyond the known negative impacts on physical health,⁸ post-secondary students experiencing food insecurity are more likely to

experience depression⁵ and have a lower likelihood of graduating, with these associations being more pronounced among first-generation students.⁶

There is a dearth of strategies designed to address nutrition insecurity among college students. Previous solutions to nutrition insecurity on US campuses have primarily focused on modifying the behavior of individuals through educational messages.¹⁷⁻²⁰ However, there is a lack of research on multicomponent interventions to address nutrition security in general, particularly on college campuses and for students at risk of experiencing it.²¹ College food pantries were the first and remain the most common intervention to address food insecurity in postsecondary institutions.⁴ However, they are considered short-term emergency relief,^{4,10} do not support healthy diets,²² and stigma around the use of campus food pantries leads to shame, embarrassment, and fear of judgment.^{11, 12, 23, 24} New interventions for students at risk of nutrition insecurity are needed as the population of college students continues to diversify.

Another contributor to nutrition insecurity among college students is that many are not eligible for food assistance SNAP, and those who are eligible may not know how to access it.²⁵ While legislation currently proposes expanding SNAP eligibility by including attending college as a form of qualification considered equal to work,⁹ there will still be a need to increase awareness of eligibility requirements among students. To address these gaps in the literature, this research will adapt the VV evidence-based produce mobile market to address nutrition insecurity on college campuses and test the inclusion of SNAP application assistance to support the enrollment of eligible students.

Moreover, nutrition security on college campuses is not well understood. In postsecondary institutions, food insecurity has been measured using the United States Department of Agriculture (USDA) Food Security Survey Module, which categorizes individuals as food insecure when at times, they cannot acquire adequate food because they have insufficient money and other resources for food.²⁶ However, the measure captures only the availability and affordability pillars of nutrition security and leaves behind the utilization and stability pillars, including the ability to consume a diet consistent with the US Dietary Guidelines for Americans.²⁷ Therefore, there is growing consensus among researchers and policymakers to transition from food security towards nutrition security, which includes having equitable and stable availability, access, affordability, and utilization of foods that promote well-being and prevent and treat disease.²⁸ There were no validated measures of nutrition security until recently.^{29, 30} Still, these instruments do not assess other aspects of nutrition security, such as certainty, safety, nutrient adequacy, and cultural acceptability of food.³¹⁻³⁴ Unfortunately, few qualitative studies on nutrition security in college settings exist.^{11, 23, 24, 35} To fill this gap, this research will use a mixed-methods approach to assess college students' nutrition security status and the barriers and enablers to achieve it.

This study responds to the National Strategy on Hunger and Nutrition call to provide healthy foods and promote nutrition security to create healthier college campus environments by showcasing best practices and examples from the field.³⁶ Our study transitions from a narrow food security approach towards a

comprehensive nutrition security one, addressing structural barriers to healthy eating to achieve nutrition and health equity and advance research, practice, and policy.³⁷ It recognizes that there is no nutrition security and health equity without promoting and facilitating the consumption of fruits and vegetables among vulnerable students. Fruit and vegetable (FV) consumption is an essential component of a healthy diet,³⁸ associated with lower disease burden³⁹ since it is inversely related to chronic disease and all-cause mortality risk.⁴⁰ It is well documented that US college students do not meet the recommended five or more FV daily servings.⁴¹ Unfortunately, persistent structural inequities that produce multiple barriers have contributed to low FV consumption among individuals who report low income or belong to a racial and/or ethnic minority group.⁴²⁻⁴⁴

Moreover, our study indicates a shift from the current food pantry approach to an evidence-based model that honors students' choices and dignity. The Campus VV will be available to the whole university community and involve students in a solution that works for them through a needs assessment process, establishing a student advisory board. Moreover, our study signals a change in how we think about who needs food assistance by recognizing that the demographics of postsecondary students have shifted significantly and that campuses need to adapt to ensure that all students can succeed. Since the current solutions for this nationwide problem are short-term and assistance-based, we want to provide an adaptable model that targets the needs of students facing nutrition insecurity and provides consistent access to and support of healthy eating to reduce nutrition insecurity and related health, social, and educational impacts (e.g., depression, and lower graduation rates).

4.2 *Include complete citations or references.*

Response:

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5.0 Study Design*

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

Response:

In-depth interviews: qualitative

We will use in-depth qualitative interviews to determine the barriers that impede UB students from consuming FV and achieving nutrition security.

Student advisory board: qualitative

To inform the adaptation of the VV to a campus setting, we will set up a Student Advisory Board of at least six students.

UB Students' Nutrition Security Survey: cross-sectional observational design.

We will assess UB students' FV consumption and nutrition security status using a cross-sectional online campus-wide survey.

Pilot VV evaluation: a pre-post non-randomized intervention study.

The adapted VV intervention will be piloted on campus during the school year (26 weeks). While the campus VV intervention will be available to everyone on campus, we will recruit food-insecure students to participate in the pilot study.

We will use a quasi-experimental pretest-posttest design comparing the FV consumption and the nutrition security pillars measures.

Pilot VV evaluation student focus groups: qualitative

We will complement the third aim by shedding light on adaptations to the VV model necessary for increasing program feasibility, acceptability, and usage on a college campus, employing student focus groups.

Pilot evaluation stakeholder semi-structured interviews: qualitative

To elucidate how the Campus VV intervention needs to be adapted for a college setting we will conduct stakeholder semi-structured interviews to identify changes in the intervention's structure, content, or delivery methods for broader implementation.

6.0 Study Intervention/Investigational Agent

6.1 Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.

Response: For the UB VV pilot, the intervention will be an adaptation of the VV model—an evidence-based mobile market intervention supported by over ten years of research in efficacy, effectiveness, and implementation—to a college campus setting. Mobile markets are like farmers' markets on wheels that travel to underserved communities, sell high-quality, reduced-cost produce and other healthy foods, and engage community members in healthy food behaviors. The VV model addresses the five components of nutrition security: availability, accessibility, affordability, stability, and utilization. VVs (i.e., mobile market interventions following the VV model) increase the availability and accessibility of high-quality produce and other healthy foods by traveling to communities with limited access and partnering with organizations already serving that community. VVs ensure affordability through incentives or unique pricing structures and provide stability by visiting each community weekly and operating year-round. The VV model promotes utilization by offering food and cooking education to develop nutrition knowledge and culinary skills. The VV model employs theory-based strategies, including produce bundles based on behavioral economic principles of default bias and pricing and promotion to increase purchasing of fruits and vegetables.

The results of the in-depth interviews, the Student Advisory Board meetings, student focus groups, and stakeholder interviews will inform the pilot Campus VV adaptations. The Campus VV intervention will be available to the whole UB community and named UB Veggie Van. Study participants will receive a weekly \$5 FV incentive similar to that provided by many state and federal programs and used at mobile markets to increase FV consumption. The intervention will start with a marketing campaign and kick-off event to entice students to attend the VV. Every week, the intervention coordinator and student volunteers will set up a market at the chosen locations (at least one on North Campus and one on South Campus) for approximately two hours. SNAP application assistance and education are planned adaptation components. We will provide the following

services to students: conduct outreach to improve SNAP awareness, prescreen applicants, explain exemptions so students know whether they qualify, help students complete the application form, help with verification documents, and provide guidance on what to expect in interviews with SNAP staff.

6.2 *Drug/Device Handling: If the research involves drugs or device, 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.*

- *If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.*

Response:

N/A

6.3 *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:*

- *Identify the holder of the IND/IDE/Abbreviated IDE.*
- *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

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

Response:

N/A

7.0 Local Number of Subjects

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

Response:

In-depth interviews: We plan to conduct in-depth interviews with undergraduate students until saturation (we estimate approx. 40).

Student advisory board: We will recruit six students across UB undergraduate programs.

Campus online survey: We plan to survey 2,147 undergraduate and 1,087 graduate students.

Pilot VV evaluation: We plan to enroll 223 students across UB undergraduate programs.

Focus groups: We are looking to conduct 4 focus groups with 8 students each (32 participants). These groups will be categorized as follows: undergraduate students, graduate students, international students, and staff/volunteers.

Stakeholders' semi-structured interviews: We plan to conduct interviews with 20 key stakeholders, including 10 from the University at Buffalo and 10 college administrators from other schools interested in implementing a Campus Veggie Van.

At UB, our stakeholders will include:

- The Assistant Director of Partnerships and Outreach (Community Health Interventions)
- UB Veggie Van Coordinator and student staff
- Deans of Student Affairs
- Campus Life Directors
- Staff from offices such as Health Promotion, Sustainability, and Diversity & Inclusion
- Campus Food Pantry coordinators

For other schools, we plan to interview stakeholders in similar roles, as well as faculty involved in nutrition, public health, or community engagement.

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

Response: We will recruit students during Summer 2023 and Summer 2024. We expect to contact for screening between 10 to 15% of the UB students' population (according to UB's survey response rates and previous campus-wide surveys). UB currently has 32,332 enrolled students (21,467 undergraduate and 10,865 graduate), meaning Aim 1 has the potential to screen 3,233-4,850 undergraduate students and 2,147-3,220 graduate students.

7.3 *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:

In-depth interviews: we aim to interview approximately 40 students experiencing food insecurity. According to UB's internal data, the food insecurity

rate among the student population is 53%, which means that with a 10% response rate, we might be able to recruit 1,714 to 2,570 students.

Advisory board: we will recruit from in-depth interviews participants and a list of Pell Grant recipients.

UB Students' Nutrition Security Survey: we aim to survey 2,147 undergraduate and 1,087 graduate students to achieve a statistically representative sample of students (95% confidence level and a 5% margin of error). This allows for ample representation since the 750 students are 1.4% of UB students.

Pilot VV evaluation: we aim to recruit 223 undergraduate students experiencing food insecurity. Since 53% of UB undergraduate students experience food insecurity, there are 17,136 students eligible to participate; we need to recruit 0.9% of those potential subjects.

Focus groups: we will recruit from the lists of students who participated in the previous study activities.

Stakeholders' semi-structured interviews: We will recruit 10 stakeholders (not students) who are UB administrative staff involved in food access/wellness initiatives. The other 10 stakeholders will be interested stakeholders from other campuses interested in implementing the Campus Veggie Van.

8.0 Inclusion and Exclusion Criteria*

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

NOTE: This may be done in bullet point fashion.

Response:

In-depth interviews: Students will be eligible if they are undergraduate students that attended UB during Spring 23 (to be recruited Summer 23) or Spring 2024 (to be recruited Summer 24), experienced food insecurity during the past semester, are older than 18, and are fluent in English.

Student advisory board: Students will be eligible to participate if they are undergraduate students that attended UB during the last Spring semester, will Attend UB during the following academic year), experienced food insecurity during the past semester, are older than 18, and are fluent in English.

Students will be eligible to participate in the **UB Students' Nutrition Security Survey** if they attended UB last semester, are at least 18 years old, and fluent in English.

Pilot VV evaluation: Students will be eligible to participate if they attended UB the last Spring semester and will be attending UB the following academic year, experienced food insecurity during the previous semester, are older than 18 years old, are fluent in English, and are interested in using the UB VV

Focus groups: We will recruit students who have previously participated in UB Veggie Van-related research activities and have expressed interest in receiving information about participation in future research through the UB Student's Nutrition Security Survey.

Stakeholders' semi-structured interviews: Interviewees will be eligible to participate if they are UB stakeholders that participated in the implementation of Campus Veggie Van and/or are involved in nutrition security efforts around campus. Stakeholders outside UB would-be scholars or staff involved in nutrition security efforts on their own campuses and who are interested in implementing a Campus Veggie Van.

8.2 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 did not attend UB during the previous Spring semester and will not attend UB the following academic year.

8.3 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

8.4 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: College students are required to demonstrate English proficiency before admission. We do not expect to find non-English speaking students. The same applies to the stakeholders, who are campus professors or staff.

9.0 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.

9.1 For research that involves **pregnant women**, safeguards include:

NOTE CHECKLIST: Pregnant Women (HRP-412)

Response:

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

9.2 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.

9.3 For research that involves **prisoners**, safeguards include:

NOTE CHECKLIST: Prisoners (HRP-415)

Response:

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

9.4 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").

9.5 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.

9.6 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:

This study will include students. We will ensure voluntary participation by recruiting with general email announcements, postings, or sign-up flyers and recruitment by research team members with no relationship to students. Also, recruitment materials will make clear that students are not required to participate to fulfill course requirements.

We will protect the privacy interests of students by conducting in-depth interviews via Zoom in a place and at a time when the student will be alone and/or comfortable participating in the interview. The UB Students' Nutrition Security Survey will be administered by web and mobile application so the students can complete the survey at a place and time of their convenience. Also, the Student Advisory Board will be conducted by the Community Health Interventions Lab research assistants; no instructor will participate in the recruitment process nor will attend the meetings.

The confidentiality of research participants' personal information will be protected by anonymizing their data. It will not be accessible to parents, teachers, or others not directly involved in the research.

Student participants will be free to withdraw from participation at any point in a study without penalty, and recruitment and consent materials will have this information. Students who withdraw from the study will still be compensated for participation. Incentives will be prorated and earned as the study and not contingent upon the student's completion.

10.0 When recruiting UB employees who implemented the UB Veggie Van or other schools' employees interested in implementing a campus Veggie Van for stakeholder interviews, we will ensure that all communications highlight that participation is entirely voluntary, and declining or withdrawing participation will have no negative consequences. The informed consent process will explain the study's purpose, procedures, risks, and benefits, ensuring participants fully understand their involvement and have the opportunity to ask questions. To prevent coercion, recruitment messaging will remain

neutral, avoiding any implication that participation could impact employment status, performance evaluations, or professional relationships. While direct outreach will be used, we will ensure that invitations are extended in a non-pressuring manner, giving individuals the freedom to decline without discomfort. Confidentiality will be prioritized by anonymizing data in reports and securely storing all collected information with restricted access. While recording interviews, participants will be informed about how the recordings will be used, who will have access, and when they will be destroyed.**Eligibility Screening***

*10.1 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:

Students who respond to study recruitment materials will be asked to complete an online screener or an interest form. Screeners and interest forms will ask for the eligibility criteria and the willingness to participate in the interviews. If a participant's responses to the screening questions indicate not eligible, the 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. For focus groups, we included questions in the Nutrition Security Survey and screeners regarding Campus Veggie Van usage. Students who indicate that they have used the Campus Veggie Van in a screening form will be eligible to participate.

To determine eligibility for UB stakeholder interviews, we will ask among UB Staff (involved in wellness/food access initiatives) their willingness to participate through an email invitation or phone call. If they agree to participate, their contact and availability data will be kept in a spreadsheet for scheduling the interview.

To determine eligibility for stakeholders from other universities interested in implementing Campus VV, we will start by identifying key individuals such as administrators, faculty, student wellness staff, and campus food security leaders. We will leverage colleges-wide networks, professional associations, and existing collaborations to spread awareness. We will contact these individuals indicating the program's purpose, benefits, and expected commitment, using personalized emails, virtual presentations, phone calls and social media outreach. We will engage universities' offices focused on student wellness and sustainability to help identify potential partners. If these stakeholders agree to participate

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

11.0 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.

11.1 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:

- **In-depth interviews:** UB's Office of Institutional Analysis will provide an email list of students eligible for Federal Pell Grants (Pell Grants are awarded to undergraduate students who display exceptional financial need, a significant food insecurity risk factor). Recruitment emails will be sent to these students from a study email with an online screener. Eligible participants will be contacted via email/SMS and invited to schedule an interview. Before the start of the interview, the interviewer will ask if the student read the Information Sheet, if they have any questions, and if they consent to participate in the interview.
- **Student advisory board:** The research team will contact students who indicated their interest in participating in the in-depth interviews and other UB VV-related activities. These students have already been screened through the methods described above. We will also contact Pell Grant recipients and send advertisements through physical flyers and university-wide announcements (I.e., UB now). Eligible participants will be contacted via email/SMS and invited to participate in the Student Advisory Board. Information and consent materials will be reviewed with them during the first meeting.
- **UB Students' Nutrition Security Survey:** UB's Office of Institutional Analysis will provide a list of emails from undergraduate and graduate students who attended UB during the last Spring semester. During the first four weeks of the Fall semester, at least four recruitment emails over the course of a month will be sent from the study email to undergraduate and graduate students who attended UB during the last Spring semester. Reminders about the survey may also be shared in university-wide announcements (I.e., UB now) or school/department-specific listservs. The emails will have an invitation to participate, a link to the survey, and an information sheet attached. The survey links will be personalized to prevent duplicate responses. After entering the survey link, students will view an online consent script. If students consent to participate, they will be directed to

three screening questions to ascertain their compliance with the eligibility criteria. Students who meet the criteria will be directed to complete the survey. As an incentive, eight \$50 gift cards will be offered to students who complete the survey.

- **Pilot VV evaluation:** As we recruit Pell grant recipients for the Student Advisory Board, we will recruit students to participate in the VV pilot. The emails will have an invitation to participate, a link to an interest form, and an information sheet attached. The interest form will ask for the eligibility criteria, students' food security status, and their desire to participate in the pilot study. If participants are eligible and interested, they will be asked to provide their contact information so the research team can contact them to obtain consent. Also, we will send advertisements through physical flyers, and university-wide announcements (I.e., UB now). If all planned participants have not been recruited before the UB VV launch, the research team will continue to recruit during the first two weeks of the mobile market operation. First, we will have a Kick-off event to entice students to come to the UB VV and have their dermal carotenoids tested. Second, students can indicate their interest in participating through an interest form. The event and the UB VV will be open to the UB community.
- **Focus groups:** Email invitations will be sent to students who may have completed the Nutrition Security Survey, have used the UB VV, and have provided permission to be contacted for further research participation opportunities. Information and consent materials will be reviewed with them during the focus group.
- **Stakeholders' semi-structured interviews:** recruitment will target both internal and external stakeholders involved in food security, nutrition initiatives, and student wellness. Internal UB stakeholders will include Campus Veggie Van implementers, student wellness staff, faculty members involved in food access programs, and campus administrators. External stakeholders will consist of faculty, administrators, student wellness staff, and leaders of food security programs at other institutions interested in implementing a Veggie Van on their campus. Potential participants will be contacted via personalized email invitations or phone calls, outlining the purpose of the study, expected time commitment, and the voluntary nature of participation. Professional networks and partnerships within universities, faculty connections, and institutional offices focused on student wellness, sustainability, and food security will be leveraged to identify and recruit interviewees. Recruitment will also include short virtual presentations at relevant meetings or conferences, direct phone calls and follow-ups to confirm participation. Institutional leadership, including deans, department heads, and program directors, may also be engaged to introduce the study and encourage participation among their teams. Where applicable, professional recognition or small compensation may be offered as an incentive for participation.

11.2 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:

Potential participants will receive an "Information Sheet" as an attachment in emails containing the study and consent information for each aim of the study. If participants are interested, they can access a link that will take them to the screeners, interest forms, and/or survey. Their introduction reminds students that their participation is voluntary and that their responses will be kept confidential since non-personally identifiable information will be associated with their answers in any data reports. They will also be asked if they agree that the study's purpose was thoroughly explained; they are 18 and consent to participate. Participation in the survey's raffle is optional; if students want to participate, they will have to provide their contact information in a separate form that will not be matched to their survey answers. Any files with identifying information (name, phone number, email address) will be permanently deleted/destroyed as soon as the data collection and incentives phase is completed.

All email correspondence will be done through UB email by trained research staff. Group emails will be sent as blind copies to ensure that students' contact information is available to others and that responses are not seen by unintended recipients. If the research staff contacts an interested party, all Zoom and phone calls to discuss eligibility and study details will be conducted by trained research staff in a private office in Kimball Tower or remotely. The research staff will remind the participants that all information discussed over the phone will be kept confidential.

The privacy of potential participants is protected because the participant controls their own responses to recruitment materials.

11.3 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:

- Emails will contain links to the screeners/surveys and an attached Info Sheet.
- Flyers will be posted on the North and South campuses.
- Social media ads will be posted in UB now, University Communications, and UB's social media accounts.
- Screeners, or interest forms, will be used for each aim according to what has been described in Section 11.

- The UB Students' Nutrition Security Survey will have a consent form and a screening form before the actual survey is displayed.

12.0 Procedures Involved*

12.1 *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:

In-depth interviews

Once a subject is screened and determined to be eligible, the research team will schedule a Zoom interview with the participant via phone, SMS, or email. During the interview, the Study Information Sheet will be read to the participants to explain their involvement in the study. If still interested, the Verbal Consent Script will be read. The participant will be asked if they are interested in providing consent at that time or would like instead to receive a copy of the Study Information Sheet and provide consent later. If it is the latter, the Study Information Sheet will be sent to the participant's email. Participants will be asked if they would like to complete the interview or if they would like to schedule for another time.

In-depth interviews (30-60 minutes) with undergraduate students who report experiencing food insecurity in the survey will be conducted via Zoom. The interviews will be conducted by a single trained interviewer using an interview guide with open-ended questions. Questions will focus on the participants' enablers and barriers to nutrition security and FV consumption and their perspectives on a campus mobile market.

Student Advisory Board

To inform the adaptation of the VV to a campus setting, we will set up a Student Advisory Board of at least six students. Students will initially be recruited from among interested food insecure students who complete the qualitative interviews and Pell Grant recipients, but later may include participants in the pilot intervention or VV customers. Student Advisory Board members will meet up to 6 times over six months during the intervention adaptation, delivery, and evaluation. They will receive a \$

30 incentive per meeting. Campus administration and other stakeholders will be invited to join planning meetings and/or will be consulted as needed to ensure intervention feasibility on campus.

UB Students' Nutrition Security Survey

After recruitment materials have been deployed, a confidential online survey will be available for four weeks through a Qualtrics link. The survey will have 69 questions that might take 15 to 20 minutes to complete. At the end of the survey, participants will be directed to a second form to indicate if they wish to participate in the further aims of the study and provide contact information. A third form will be available for participants wishing to participate in the raffle and willing to provide their contact information.

Pilot VV evaluation

Baseline data collection includes the completion of the UB Students' Nutrition Security Survey (if it has not been already completed) and the reading of dermal carotenoids, which is a finger scan technology, called the “Veggie Meter,” to scan a participant’s finger at baseline and follow-up. 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 three times, and the average value will be used in this analysis. Scans take about 3 seconds each.

The UB VV pilot follow-up survey will be administered to students by e-mail, and they will be asked to come to the market to get a Veggie Meter reading.

Study participants will receive a weekly \$5 FV incentive to buy at the Campus VV. To access their incentive, they will show their UB card, and their incentive will be applied through the point of sales system.

Focus groups: Once students are screened and determined eligible, they will receive an email invitation with details about the study and a consent information sheet. Focus groups will be conducted in person. Each session will last approximately 75 minutes and will be facilitated by a trained moderator using a structured discussion guide. The focus groups will explore participants’ experiences with the UB VV, including its acceptability, appropriateness, and feasibility as a food access intervention for students. Key discussion areas will include usage patterns, perceptions of produce quality and affordability, experiences with educational components, and suggestions for improvement. Sessions will be audio-recorded and transcribed for qualitative analysis. To ensure confidentiality, participants will be reminded not to share information discussed in the session and will be assigned a unique ID for data analysis. Participants will receive a gift card incentive for their time.

Stakeholders’ semi-structured interviews: Stakeholder interviews will target internal UB stakeholders (e.g., Veggie Van implementers, student wellness staff, campus administrators) and external campus stakeholders (e.g., faculty, administrators, and campus leaders involved in food access and nutrition initiatives). Once stakeholders express interest, they will receive an email invitation with details about the study, an information sheet, and available time slots. Interviews will be conducted via Zoom, in person, or phone call at the participant’s convenience and will last 60 minutes.

A trained interviewer will follow a semi-structured guide to explore how the Campus Veggie Van model can be adapted and implemented at their institution, including perceptions of acceptability, appropriateness, feasibility, and interest in participating in a cluster-randomized trial. Internal stakeholders will also be asked about the feasibility and sustainability of the Veggie Van at UB. Interviews will be audio-recorded and transcribed for qualitative analysis. To ensure confidentiality, transcripts will be de-identified, and all data will be securely stored. Participants will receive a small incentive or professional recognition for their time.

12.2 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:

In-depth interviews – *July to September* – We will ask how students define nutrition insecurity. The interview guide will be based on a conceptual model of nutrition insecurity adapted for college students. It will include questions about the students' nutrition insecurity risk factors, food acquisition and coping strategies, perceived barriers and facilitators to access food, nutrition environment. Also, we will explore students' perspectives on how to adapt the VV to ensure student acceptability and usage.

Student Advisory Board – *August to January* – No personal data will be collected from the Student Advisory Board members. Instead, we will solicit their opinions and feedback on the VV adaptation to UB. The focus is to receive their input on the UB Veggie Van. Data will be collected in a qualitative manner over ~1-hour meetings (five meetings total). The sessions will be audio-recorded.

UB Students' Nutrition Security Survey – *Last week of August and first three weeks of September* – We will combine the USDA Food Security Survey Module, which assesses accessibility and affordability, with a new suite of measures that complement the Food Security measure to help capture the remaining pillars of nutrition security (availability, utilization, and stability).

- **Availability** will be assessed with the Perceived Limited Availability Measure. Three items assess perceived limited availability at food stores. The types of food include “quality fruits and vegetables,” “food we liked,” and “foods that were good for our health and well-being.” We have incorporated questions designed to evaluate students' awareness of and engagement with existing nutrition security programs on campus, including Blue Table and UB Veggie Van.
- **Accessibility and Affordability** will be assessed using the 10-item USDA Adult Food Security Survey Module adapted to examine the past semester's intake. USDA's scoring system adds affirmative responses: 0, high food security; 1-2, marginal food security; 3-5, low food security; and 6-10, very-low food security.

- **Barriers to utilization** will be assessed with Calloway et al. 2023 measure that considers individuals' barriers to using food they have access to produce healthful meals. Eight items assess tangible and intangible barriers to preparing healthful meals from the food a person can access.
- **Utilization**
 - FV consumption will be assessed using the Gretchen Swanson Center for Nutrition 'Produce Prescription Projects' 2022 FV module.
 - The Nutrition Security, Healthfulness Choice, and Dietary Choice Measures assess factors associated with the ability of an individual to obtain foods that meet their nutritional and health needs, and dietary preferences, without resource limitations or worry.
 - Health status will be measured using the subscales of general health, emotional well-being, and social functioning of the SF-36 Health Survey. We will adapt this scale to a college student context.
- **Stability** will be assessed with the Food Insecurity Stability measure. It evaluates the temporal state of an individual's chronic, seasonal, intra-monthly, and intermittent food insecurity.
- We will obtain participant students' **sociodemographic information** from the Office of Institutional Analysis. The information will be linked to a client ID. The same client ID is also linked to the emails in the recruitment lists. The information will include age, gender, race/ethnicity, marital status, dependent children, student status (including the year in school), whether they are international students, enrolment status, financial aid receipt, employment status, and residency (on-campus v. off-campus). The consent form will ask participants if they agree to share their demographic information with the Community Health Interventions lab to assess how their survey answers are affected by their demographic information.
 - We will add questions to the survey, so the students can report having a car, SNAP enrollment, and participation in food pantries and on-campus meal plans.

We will assess the **Use of Campus Food Security Resources**, including questions about students' awareness, usage, barriers, and perceptions of UB Veggie Van, and Blue Table Food Pantry. We will evaluate awareness and engagement, including reasons for non-use. The survey will also identify barriers such as scheduling conflicts. **UB Veggie Van Pilot: Baseline** – *From the last two weeks of August to the first week of September* - UB Students' Nutrition Security Survey will serve as the student baseline for the pilot study. To avoid duplicates, the pilot study consent form (Information Sheet) asks for the student's permission to use the survey data as a baseline and to link it to the other pilot baseline and follow-up measures. The student's e-mail (contact information) will allow us to identify their survey ID, which will be linked to the pilot participant ID.

Baseline measures will also include ‘Skin Carotenoids,’ which will be measured using a noninvasive finger scan technology called the "Veggie Meter," which relies on pressure-mediated reflection spectroscopy. Skin carotenoid measurements correlate positively and significantly with blood carotenoids and reported FV intake. Associations between skin and plasma carotenoids and between skin carotenoids and self-reported FV intake do not vary substantially by race or ethnicity. Each participant's finger will be scanned three times for the proposed study, and the average value will be used in this analysis. Scans take about 3 seconds each. Intra-individual variation of the triplicate measurements using a skin carotenoids scanner was 5.2% in a prior study.

UB Veggie Van Pilot: Follow-up – *First two weeks of December* – The UB VV pilot follow-up survey will use the same FV consumption, nutrition security, and SNAP enrollment measures focusing on students' experiences during the past academic year. We will measure follow-up skin carotenoids and include process measures, including receipt and usage of newsletters, frequency of interaction with cooking demonstrations or SNAP assistance, and usage of recipes and educational materials distributed at UB VV. Intervention Dosage will be measured as the number of visits to the VV over the intervention period, total FV spending, and amount of purchasing incentives redeemed. As all customers need to give their name at check-out, these will be automatically tracked by the Farmers Register point-of-sale system and linked to individual study participants via a study ID.

Focus groups: The focus groups will collect qualitative data on students' experiences, perceptions, and suggestions related to the Campus Veggie Van (CVV). The discussions will explore students' usage patterns, barriers to access, affordability perceptions, produce quality, educational components, and potential improvements to the CVV. Specifically, data will include insights on acceptability (student comfort and perceptions), appropriateness (alignment with student needs and schedules), and feasibility (barriers to sustained participation). Focus group sessions will be audio-recorded and transcribed verbatim. Transcripts will be de-identified, and no personally identifiable information will be retained. Field notes and participant observations made by the moderator will also be collected to supplement the transcripts.

Stakeholders' semi-structured interviews: Stakeholder interviews will generate qualitative data on the implementation and scalability of the CVV model within UB and across US campuses. The interviews will cover stakeholders' perspectives on the acceptability, appropriateness, and feasibility of the intervention, including its alignment with student wellness initiatives, logistical challenges, required institutional support, and potential for sustainability. For external stakeholders, additional data will be collected on barriers to implementation and interest in participating in future collaborations. Interviews will be audio-recorded, transcribed verbatim, and de-identified. Additional documentation, such as notes from stakeholder discussions or supplementary materials provided by participants, may also be collected for context.

12.3 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:

- Nutrition security barriers and enablers interview guide
- Student Advisory Board Moderator Guide
- UB students Nutrition Security Survey
- UB VV pilot follow-up survey
- Dermal carotenoids. A finger scan technology, called the “Veggie Meter” will be used as a non-invasive, objective marker of FV consumption in participants.
- UB VV Student Focus Groups – Moderator GuideUB VV Internal Stakeholder Focus Groups – Interview Guide
- UB VV External Stakeholder Focus Groups – Interview Guide

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

Response: UB’s Office of Institutional Analysis will provide us with student recruitment email lists and demographic information from the UB Students' Nutrition Security Survey participants.

12.5 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. Only the “Veggie Meter” results will be shared with students right after measurement at baseline and follow-up. The research team performing the measurement will indicate the result and provide a Veggie Meter FAQ Sheet that explains the score.

12.6 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. We will also share results with campus stakeholders.

The Student Advisory Board meetings will follow a focus group format, and follow-up decisions because of previous meetings will be shared with the whole group. In addition, Student Advisory Board results will be shared with other mobile market stakeholders (i.e., UB administrative staff involved in the UB

Veggie Van implementation). Results will be discussed concerning the adaptation of UB Veggie Van.

13.0 Study Timelines*

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

Response:

In-depth interviews: We anticipate being able to recruit the students for in-depth interviews between July and August 2023 and July-September 2024.

Student Advisory Board: We expect to recruit all students between July and August.

UB Students' Nutrition Security Survey: We expect to recruit most needed participants during the first four weeks of survey deployment.

UB VV pilot: We anticipate recruiting most needed participants in August of 2023 and August of 2024. If we cannot reach the recruitment goal, we will recruit during the first two weeks of the Campus VV launch.

Focus groups: Recruitment will take place throughout April. Focus groups will be conducted during April and early May, ensuring timely data collection while accommodating participants' schedules.

Stakeholders' semi-structured interviews: Recruitment will occur during Spring And Summer semesters, targeting both internal UB stakeholders and external stakeholders. Interviews will be conducted on a rolling basis throughout this period, allowing flexibility to accommodate stakeholders' availability.

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

Response:

1. One in-depth interview (30-60 min) completed between July and August
2. One UB Students' Nutrition Security Survey (15-20 min) completed between the last week of August and the first 3 weeks of September
3. 5 Student Advisory Board meetings between July and December (50 min each, 250 min total)
4. The Veggie Van pilot study to be conducted during the throughout the academic years (starting in the Fall semester):
 - 1 baseline skin carotenoids measurement completed during the last week of August or the first 2 weeks of September (5 min)
 - 1 UB VV pilot follow-up survey completed during the first two weeks of December (15-20 min)

- 1 Follow up Skin Carotenoids measurement completed during the first two weeks of December (5 min)

5. Focus Group should last approximately 75 min

6. Semistructured interviews should last approximately 60 mins

If a student participates in all activities, the total participation for the study is expected to be 5.3-7.5 hours. However, participants will only participate in the activities they were recruited for and consented to participate.

13.3 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 12 months, including data analysis, written reports, and academic publications.

14.0 Setting

14.1 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:

Survey forms (UB students Nutrition Security Survey and UB VV pilot follow-up survey) will be completed on subjects' mobile phones, tablets, or personal computers.

Interviews will be completed through Zoom with a trained interviewer and in a private location.

Skin carotenoids will be collected in the Campus VV locations.

Advisory board meetings will be conducted in UBs conference rooms at North and South Campus or via Zoom (depending on availability).

Focus Groups will be conducted in person in a classroom that accommodates at least 8 students.

Stakeholder interviews will be conducted in person, by phone or Zoom (depending on availability).

14.2 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:

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

15.0 Community-Based Participatory Research

15.1 *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: There is no previous involvement from the UB students' community in the development of the study protocol; however, the Student Advisory Board, contemplated in this protocol, will provide feedback about the planning activities and adaptation of the UB Veggie Van.

☐ N/A: This study does not utilize CBPR.

15.2 *Describe the composition and involvement of a community advisory board.*

Response:

Engagement will focus on involving students experiencing food insecurity in adapting the VV Model to a campus setting. Participants will focus on planning for a UB mobile market.

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

16.0 Resources and Qualifications

16.1 *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:

Dr. Lucia Leone is the principal investigator. She holds a Ph.D. in Nutrition Intervention and Policy from the University of North Carolina at Chapel Hill. Her research has focused on developing community or organization-based interventions designed with an eye toward dissemination and implementation by community organizations. She is currently a PI on a 7-year NCI funded-study to test the effectiveness and implementation of the Veggie Van, a mobile produce market designed to increase access to fresh local produce in lower-income and underserved communities in 32 communities (up to 1,000 individuals) in the eastern US. Since 2010, she has been working on research that has moved the Veggie Van model from a pilot study to efficacy research to effectiveness and implementation. Related to this work, she directs the Veggie Van Training Center, which was developed to support practitioners in using evidence-based methods to develop sustainable food access programs, like mobile produce markets. We have also received funding from multiple sources, including an extension on our current Veggie Van grant, to test new implementation models for the Veggie Van model. However, the Veggie Van model has only been tested to increase fruit and vegetable consumption in urban community settings. The present study will inform the development of College Campus solutions. We will build upon our previous work to adapt the Veggie Van to a campus setting to address food insecurity among underrepresented students on campus.

Angelica Tutasi-Lozada is a student researcher who holds an MPH from Columbia University and a bachelor's degree in food science from Universidad San Francisco de Quito in Ecuador. Her predoctoral training is focused on food access interventions and dissemination and implementation science. As a Community Health Interventions Lab member, she has collected and analyzed mix-methods data about shopping, eating, and cooking during the Covid-19 pandemic. Also, she has conducted mixed methods work on looking at the impact of a fruit and vegetable incentive program at mobile markets on food insecurity among seniors. Her previous work has informed the development of the current study.

The graduate research assistants will be thoroughly trained on the protocol and will be UB and CITI trained.

Describe other resources available to conduct the research.

16.2 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 dedicate 10% of her time to this study. Angelica Tutasi-Lozada Will devote 75% of her time to this study

16.3 *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

16.4 *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 research personnel will be adequately informed about the protocol, research procedures, and duties and functions by the principal Investigator. All persons assisting with the research will have current training in UB's Good Research Procedures course and applicable CITI training. 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 student researcher will receive appropriate training on maintaining confidentiality and protecting human subjects. The Principal Investigator will ensure proper research conduct and protect the subjects' rights and welfare.

17.0 Other Approvals

17.1 *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:

We will sign a data-sharing agreement with UB's Office of Institutional Analysis to obtain the student recruitment email lists and demographic information from the UB Students' Nutrition Security Survey participants.

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

18.0 Provisions to Protect the Privacy Interests of Subjects

18.1 *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:

In-depth interviews

When completing interviews with Zoom, the research assistant will be in a private room and will remind the subject that all information discussed will be kept confidential. During the interview, the research assistant will ask the subject to go to a closed or private area. At the start of an interview, participants will be informed that they can skip any questions they are uncomfortable with. Only the research team will have access to identifiable data.

UB Students' Nutrition Security Survey

The consent process and survey will be conducted on personally owned electronic devices (owned by the participants) by entering data directly into web-based Qualtrics survey forms. Only the research team will have access to the survey data.

At the start of a survey, participants will be informed that their personal identification and contact data will not be linked to their survey answers. Also, they can skip any questions they are uncomfortable with. Only the research team will have access to identifiable data collected for further research or incentives, which will be deleted as soon as the study finishes.

Student advisory board

Student Advisory Board members will be informed before the onset of the meeting that they may refuse to provide feedback or answer any questions they do not feel comfortable answering. Committee members will be asked to use their judgment to share personal information within the group and to keep the items discussed during the meetings private. We will not ask committee members to share personal information during a meeting but instead will ask them to provide feedback on the adaptation of UB Veggie Van.

UB VV pilot

The consent process will be conducted over the phone or in person. Data will be collected through students' personally owned electronic devices by entering data directly into web-based REDcap survey forms. 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. Data will be entered directly into a web-based REDcap survey. Only the research team will have access to the survey data. In some cases, if internet access is unavailable and a paper recording of the measurement is needed, the UB research assistant will keep those copies secure in Buffalo, where they will be kept in a locked filing cabinet in a locked office (Kimball 324).

Focus groups: To protect the privacy of student participants, all focus groups will be conducted in a private and quiet location on campus. Participants will be informed that while confidentiality cannot be fully guaranteed in a group setting, they are encouraged to respect the privacy of others by not sharing what is discussed outside the session. Each participant will be assigned a unique study ID, and no personally identifiable information (e.g., names, student ID numbers) will be collected in the transcripts. Audio recordings will be stored on a secure, password-protected server, and upon transcription, all recordings will be permanently deleted. Any direct quotes used in publications or reports will be de-identified to prevent identification of individual participants.

Stakeholders' semi-structured interviews: Stakeholder interviews will be conducted in private locations, either via Zoom, phone call, or in-person settings, ensuring that discussions remain confidential. Participants will be assigned a unique study ID, and their names or affiliations will not be linked to their responses in any transcripts or reports. Audio recordings will be securely stored on a password-protected server, and transcripts will be de-identified. Stakeholders will be informed that their participation is voluntary and that their responses will remain confidential. Any direct quotes used in reports or publications will be presented in a way that prevents attribution to a specific individual or institution.

18.2 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:

For in-depth interviews, surveys, pilot study activities, focus groups/stakeholder interviews, participants can access the study and consent data during the screening and recruitment procedures. If the individual decides to participate in the study, they will indicate so in the consent section. The subject's consent will grant the affiliated research team permission to view information collected during the data collection procedures. After the consent process, the participant controls the research team's access to the data because the participant directly provides it.

For the student advisory board, the research team will have access to participants' phone and e-mail contact information to schedule advisory board meetings.

19.0 Data Management and Analysis*

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

Response:

Data management

Quantitative data

This study will utilize UB's REDCap (Research Electronic Data Capture) service, a software toolset and workflow methodology for the electronic collection and management of clinical and research data to collect and store data. REDCap provides a secure, web-based application with an intuitive data manipulation interface, custom reporting capabilities, audit trail functionality, real-time data monitoring/querying of participant records, and data exporting/importing variations. 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 research team defines the project-specific data dictionary. Individual fields can be denoted as identifiers in the data dictionary development process. When exporting a de-identified dataset, these variables are omitted.

We will also use Qualtrics, which is an online survey platform renowned for its advanced features and capabilities in survey creation, distribution, and analysis. Its user-friendly interface, robust data collection, and rigorous security measures contribute to effectiveness in gathering and analyzing survey data.

Both services provide data export tools that allow for the shifting/removal of dates. All web-based information transmission is encrypted. The data from both platforms 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 REDCap surveys include screeners, , and the UB VV pilot follow-up survey. Data from dermal carotenoids will be entered by the research team into REDCap. Qualtrics will be used for the UB Students' Nutrition Security Survey

Data will be stored in REDCap and Qualtrics (respectively), and then extracted into a statistical package for analysis. Extracted data will be stored on the encrypted drive of PI's UB School of Public Health and Health Professions.

Qualitative data

Audio recordings from interviews, Student Advisory board meetings, student focus groups, and stakeholder semi-structured interviews will be transcribed. Once transcripts have been checked for quality against audio recordings, audio recordings (and video, if any) from Zoom and in-person focus group sessions will be destroyed. Only the research team will have access to the transcripts. 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 any follow-up questions and for issuing incentive payments. Personal contact information will be stored in the REDCap profile of each participant, separately from interview and/or advisory board data, and will be used to issue incentives for participation.

Data analysis

In-depth interviews - In-depth analysis of interview transcripts will increase the understanding of the barriers and facilitators that impede UB students from achieving nutrition security. Transcripts and analytical summaries will be coded and analyzed using Atlas.ti software. A codebook will be created using the conceptual model and supplemented with themes that emerged during two phases of data analysis. Finally, illustrative quotes in the transcripts will be selected to reflect key themes and provide evidence of results.

UB Students' Nutrition Security Survey – A descriptive analysis will summarize sociodemographic characteristics and the outcomes of interest. Bivariate associations will be assessed using Pearson's chi-square tests for categorical variables and ANOVA for continuous variables. The relationships between the sociodemographic characteristics with food security, perceived food access, perceived food environment, and FV intake will be examined using multivariate logistic regression models. Models' fitness will be assessed using the Hosmer–Lemeshow goodness-of-fit test, and multicollinearity will be examined using the variance inflation factor (VIF) of all explanatory variables. Students with missing values for items used to calculate the dependent variable, any independent variables included in the models, or reported implausible values would be excluded from the analyses.

Student advisory board – Our qualitative analysis will be purely descriptive. After each meeting, a summary of the discussion and decisions will be used to document our intervention development process. The Student Advisory Board will review findings from the pilot and focus groups to determine the next steps for adaptation and make plans for any changes to the VV as it continues its operation into the Spring 2025 semester and beyond.

UB VV Pilot – Our objective is to describe the extent to which participation in a Campus VV program—with the dosage measured as the number of VV visits, total FV purchasing, and amount of incentives redeemed—is associated with changes in FV consumption (including skin carotenoids), nutrition security measures, and SNAP enrollment status. We will use descriptive statistics to characterize the sample and paired t-tests to compare baseline and follow-up outcomes, regardless of dosage. In addition, linear regression models will inspect mean changes in the outcomes of interest as a function of sociodemographic and UB VV dose covariates. Given that unmeasured confounding associated with higher intervention participation may contribute to greater change in the outcomes of interest over time, we will use a dose propensity score approach. Dose propensity scores allow for a simulation of the average number of visits, purchasing, or redemptions expected from two otherwise similar participants. To control for confounding, dosage propensity scores will be evaluated based on covariates known to be associated with nutrition security, which includes age, gender, race/ethnicity, marital status, having dependents, student status (year in school), international student status, enrollment status, receipt of financial aid, employment status, residency (on or off-campus), car ownership, and participation in food pantries and on-campus meal plans. Then we will employ linear regression models to estimate the dose propensity-adjusted correlation

between the independent variables and the average changes in the targeted outcomes. By doing so, we can compare shifts in these outcomes in conjunction with anticipated and actual program dosage metrics.

Focus groups and Stakeholders' semi-structured interviews: All data collected from the focus groups and stakeholder semi-structured interviews will be securely stored and managed to ensure confidentiality and data integrity. Focus groups and interviews will be audio-recorded using a secure digital recorder or Zoom's built-in recording function. Upon completion, recordings will be transferred to a secure, password-protected server and deleted after transcription. Transcripts will be de-identified by removing any personally identifiable information, such as names, job titles, or affiliations, and each participant will be assigned a unique study ID. All data files, including transcripts and field notes, will be stored on an encrypted and password-protected university server, with access restricted to approved study personnel. De-identified transcripts will be securely retained for five years after study completion, after which they will be permanently deleted in accordance with institutional policies.

A qualitative thematic analysis approach will be used to examine focus group and interview data. Transcripts will be coded using both deductive and inductive coding frameworks to identify themes related to the acceptability, appropriateness, feasibility, and sustainability of the Campus Veggie Van. Atlas ti will be used to organize and systematically analyze the data. For stakeholder interviews, responses from internal and external stakeholders will be compared to assess differences in implementation feasibility, institutional support needs, and scalability considerations across different campuses. Findings will be synthesized into key themes to inform program modifications, recommendations for scaling the intervention, and potential policy implications. Results from both the focus groups and stakeholder interviews will be used to guide improvements to the Campus Veggie Van model, support adaptation efforts, and inform future implementation research.

19.2 *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:

For the UB Students' Nutrition Security Survey, to achieve a statistically representative sample of students (95% confidence level and a 5% margin of error), we must survey at least 378 undergraduate and 372 graduate students. From a previous survey involving UB students, we expect a 15% response rate; thus, we expect to recruit 3,220 undergraduates and 1,630 graduate students, allowing for ample representativeness.

Since this is a pilot study, we will not conduct a power analysis for the UB VV pilot. Instead, the sample size will be based on practical considerations. Bearing in mind the Nutrition Security Survey power calculation (we need to recruit at least 378 undergraduate and 372 graduate students), that 53% of UB students might be food insecure, and that our previous efficacy trial had a 39% overall recruitment rate among individuals with food access barriers, we would expect to recruit 155 students.

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

Response: The research staff will be adequately trained in proper data collection. The student researcher will review the collected data to ensure completeness and accuracy.

20.0 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.*

*20.1 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:

Quantitative data

The REDCap and Qualtrics databases are hosted at the University at Buffalo School of Medicine, Office of Medical Computing. REDCap data projects and Qualtrics forms rely on a comprehensive study-specific data dictionary defined in an iterative self-documenting process by research team members. Regarding regulatory compliance, REDCap and Qualtrics can be fully personalized to meet individual projects' collecting and storing participant data needs.

The participants will enter data collected via Qualtrics and REDCap forms. Only the research team will have access to the survey data. The only personally identifying information from study participants will be their names, e-mail addresses, and phone numbers so that we can contact them for further research and incentive payment. Each subject will have a client identification number (provided by the Office of Institutional Analysis) which will be used to designate their data.

Personal contact information will be stored separately from survey data. There will be no files linking this information. Personal contact data will be password protected and permanently deleted once the data collection is completed and

payment has been received. Data files prepared for analysis will not include any identifiers.

Qualitative data

Data collected will be recorded, and the recordings will be uploaded promptly upon the completion of the interview or advisory board meeting to a secure shared drive housed and managed by the SPPHP IT at UB – Department of Community Health and Health Behavior. If a handheld audio recorder is used for in-person interviews or advisory board meetings, the recordings will be transferred to a laptop computer promptly upon completion of the focus group session, where they will then be uploaded to the secure shared drive and deleted from the audio recorder. No data will be stored on the recording device after the completion of the interview or advisory board meeting. The recordings will be transcribed into Microsoft Word documents, with all identifiable information removed and saved to the same shared drive. Once transcripts have been checked for quality against audio recordings, audio recordings (and video, if any) from Zoom and in-person interviews or advisory board meetings will be destroyed. Only the research team can access the interview or advisory board meeting transcripts. 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 any follow-up questions and for issuing incentive payments. Personal contact information will be stored in the REDCap profile of each participant, separately from the interview or advisory board meeting, and will be used to issue incentives for participation. Data files prepared for analysis will not include any identifiers.

20.2 A. How long will the data be stored?

Response: Consent forms will be retained for at least three years. Personal contact information will be destroyed once data collection is completed and incentives have been received. Audio recordings from Zoom and in-person sessions will be deleted after data checking. De-identified data and transcripts will be retained indefinitely.

20.3 A. Who will have access to the data?

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

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

Response: The Principal Investigator, student researcher, and Graduate Research Assistants are responsible for the receipt and transmission of the data.

20.5 A. How will the data be transported?

Response: Data will be collected in Web-based REDCap forms and a Qualtrics form. Audio recordings will be collected through Zoom or a recording device.

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 21.0)

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

Response:

20.7 B. How long will the specimens be stored?

Response:

20.8 B. Who will have access to the specimens?

Response:

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

Response:

20.10 B. How will the specimens be transported?

Response:

21.0 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.*

21.1 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.

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

Response: Recruitment, opt-out, and missing data will be reviewed.

21.3 Describe any safety endpoints.

Response: We consider this to be a low-risk study; therefore, we do not have any safety endpoints.

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

Response: We consider this to be a low-risk study; therefore, we do not plan to collect safety information.

21.5 Describe the frequency of safety data collection.

Response: N/A

21.6 Describe who will review the safety data.

Response: N/A

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

Response: N/A

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

Response: N/A

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

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

22.0 Withdrawal of Subjects*

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

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

Response: We do not anticipate needing to withdraw subjects from the study unless they leave UB throughout the course of the study. Subjects may request to withdraw their information at any point.

22.2 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: N/A

22.3 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.

23.0 Risks to Subjects*

23.1 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 feelings of shame and embarrassment if participants disclose their food insecurity situation. Previous qualitative studies have identified this phenomenon, attributing it to peers becoming aware of students' food situation and the fear of being judged. However, it is important to recognize that the experience of shame and embarrassment can vary among individuals and their unique circumstances. One limitation of previous studies is the lack of comprehensive documentation regarding the prevalence of food insecurity in the specific campuses where they were conducted. In contrast, this study benefits from UB's data, which reveals that food insecurity is a pervasive issue affecting a significant proportion of the student population. Specifically, during the Fall of 2022, 53% of students experienced food insecurity. This data highlights the significance of the problem and underscores the fact that students facing food insecurity are not alone in their struggle. The present study aims to raise awareness about food insecurity on campus and facilitate solutions for the entire student community, regardless of whether their experience of food insecurity is temporary or long-lasting. By shedding light on the issue's prevalence and promoting a collective approach, the study seeks to foster a sense of solidarity and understanding among participants.

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

Response: The research team will make every effort to keep participants' data private. The only personally identifying information from study participants will be their names, e-mail addresses, and phone numbers so that we can contact them

for further research 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 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 subjects.

To mitigate the potential distress associated with disclosing food insecurity, the study's protocol includes the abovementioned measures to ensure participant confidentiality. Furthermore, it is important to note that the mobile market will be accessible to all university community members, ensuring inclusivity and removing the requirement for students to disclose their food insecurity status to utilize its services. These safeguards are designed to alleviate concerns and instill confidence in participants, minimizing the risk of prolonged negative consequences.

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

Response: We do not anticipate any risks to the subjects.

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

Response: N/A

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

Response: N/A

24.0 Potential Benefits to Subjects*

24.1 *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 use the UB VV program may have better access to FV as well as nutrition and cooking education and potentially improve their nutrition security. For participants that do not participate in UB VV, they will provide valuable information about nutrition insecurity on college campuses. By participating in the in-depth interviews and advisory board, they can help improve the program to serve them and their community better.

25.0 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.

25.1 *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:

25.2 *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:

26.0 Economic Burden to Subjects

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

NOTE: *Some examples include transportation or parking.*

Response: Students in the pilot evaluation have the option to purchase food at Veggie Van, though this is not required. We anticipate that the cost of food will be lower than at the average supermarket, so participants may save money.

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

27.0 Compensation for Participation

27.1 *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 addresses or sent electronically via email for surveys.

- UB Students' Nutrition Security Survey: We will provide research incentives using a raffle of 8 \$50 gift cards.
- In-depth interviews with food insecure students: \$25 per interview
- Advisory Board: \$30/meeting
- UB VV pilot follow-up surveys: \$15/person
- Focus Groups: \$30/person
- Stakeholder Interviews: \$50/person

- ☐ **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.

28.0 Consent Process

28.1 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 29.0.

- ☒ **Yes** (If yes, Provide responses to each question in this Section)
- ☐ **No** (If no, Skip to Section 29.0)

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

Response: In all stages, participants will have the option to review consent information and ask questions prior to participating

In-depth interviews

The invitation to participate in the interviews will lead interested individuals to a screener. If the interested individuals are eligible, we will contact the participants via email. In this email, we will send them the 'Information Sheet' and ask if they would like to schedule the interview. Before starting the interview, the interviewer will ask the participant if they have any questions or need any part of the study explained in more detail. Participants will be asked to verbally agree to study participation before starting the interview (see Interview script).

UB Students' Nutrition Security Survey

All participants will receive 4 emails over the course of a month inviting them to participate in the survey. The email will provide access to a screener. If eligible, students will be directed to the 'Information Sheet' where they will be asked about their agreement to participate and invited to contact the Community Health Interventions Lab if they have further questions. Students will be informed that completion of the survey indicates their consent to participate in the survey.

Student Advisory Board

Participants will receive a phone call describing the study and asking for their availability to schedule an advisory board meeting. During the first meeting, after receiving a verbal description of the study prior to starting the meeting, participants will be asked if they have any questions or need time to consider participating before being scheduled to participate in the upcoming meetings.

UB VV pilot

The invitation to participate in the UB VV Pilot will lead interested individuals to a screener. If the interested individuals are eligible, we will contact the

participants via email. In this email, we will send them the 'Information Sheet'. If eligible participants want to participate, they can call/email/text questions or go directly to fill out the UB Students' Nutrition Security Survey.

Focus groups: Participants will receive the consent information sheet via email before the focus group and will have the opportunity to review it and ask questions before the session begins. The consent information will also be reviewed verbally at the beginning of the session. Prior to starting the focus group, all participants will be informed that participation in the focus group indicates consent to participate in research. In-person focus groups will be conducted in private locations on campus, such as conference rooms or designated study spaces, to ensure confidentiality. To maximize privacy, participants will be reminded not to disclose any identifying information during the discussion, and moderators will reinforce group confidentiality norms at the beginning of the session.

Stakeholders' semi-structured interviews: The consent process will occur prior to the interview, either through an email containing the consent information sheet or verbally at the start of the interview. Prior to starting the interview, all participants will be informed that participation in the interview indicates consent to participate in research. Interviews will be conducted in private locations, either via Zoom, phone call, or in person, ensuring a confidential setting. Participants will be encouraged to ask any questions before the interview begins. To further protect privacy, interviewees will be assured that their responses will be de-identified and that any direct quotes used in reports or publications will not be linked to their name or institution.

28.3 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:

- 1) Students will receive an email or find a flyer describing the corresponding study aim and inviting them to access the survey/screeners. The emails will have the corresponding Information Sheets attached.
- 2) After reading a description of the study before starting the survey/screeners, participants will be given the Community Health Interventions Lab contact if they have any questions. They can access the screeners/survey at any time during the recruitment period.

28.4 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 for data collection, they will ask if they have any questions regarding the study and remind the participant that their participation is voluntary.

In the case of surveys, participants will be reminded that they can skip any question at any time. At the end of the survey, we will ask permission to contact them again for further research. Before the survey, we will remind them that their agreement to move forward indicates their consent to participate in the research and that they can end participation at any time.

In the case of interviews or Student Advisory Board meetings, participants will be reminded that they can leave the interview session or meeting at any time. Following the interview/meeting, we will ask permission to contact them again if we have follow-up questions. Before each interaction, we will remind them that their agreement to move forward indicates their consent to participate in the research and that they can end participation at any time.

28.5 Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." Pay particular attention to Sections 5.4-5.9. 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 28.8)

28.6 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 8.4 of this protocol.

Response:

28.7 *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, how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study, and any process to ensure ongoing consent. 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:

Cognitively Impaired Adults

☒ **N/A:** This study will not enroll cognitively impaired adults.
(Skip to Section 28.9)

28.8 *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 28.13)

*When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 28.9 and 28.10) **and, where possible, assent of the individual should also be solicited** (Sections 28.11 and 28.12).*

28.9 *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)."

28.10 ***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:

28.11 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:

28.12 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 29.0)

28.13 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:

28.14 **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:

28.15 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)."

28.16 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:

28.17 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:

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

Response:

29.0 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.

29.1 *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 the written informed consent requirement exemption. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is usually required outside of the research context.

Prior to the interviews or focus groups, 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 be conducted practically without this waiver because the surveys (UB students Nutrition Security Survey and UB VV pilot follow-up survey) are online (web or mobile), the interviews will be performed via Zoom, and the advisory board may meet via Zoom.

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

29.2 *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:

30.0 Process to Document Consent

☒ N/A: A Waiver of Consent is being requested.
(Skip to Section 31.0)

30.1 *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:

In-depth interviews

Once screened, determined to be eligible, and still interested in the interview, the Information Sheet, which includes consent information, will be emailed to the participants explaining their involvement in the interview. If still interested, they will be asked to schedule an interview. Before starting the interview, when a participant verbalizes that they consent to participate in the interview, the interviewer will document in REDCap by checking a box that indicates the participant verbalized consent.

UB Students' Nutrition Security Survey

Consent information included in the Information Sheet will be available to participants as a form after completing the screener (if they are eligible). Before starting the interview, participants will have to check a box indicating that they have read the Information Sheet and that they consent to participate in the survey. Students will be informed that completion of the survey indicates their consent to participate in a research study.

Student Advisory Board

Once screened, determined to be eligible, and still interested in the student advisory board, the Information Sheet, which includes consent information, will be emailed to the participants explaining their involvement in the board. If still interested, they will receive an email/SMS asking about their availability to schedule an advisory board meeting. During the first meeting, after receiving a verbal description of the study prior to starting the meeting, participants will be asked if they have any questions or need time to consider participating before being scheduled to participate in the upcoming meetings.

UB VV pilot

Consent information included in the Information Sheet will be available to participants by email after completing the screener (if they are eligible). We will ask them to reply indicating that they have read the Information Sheet and indicating their consent to participate in the UB VV pilot. Eligible interested individuals will be invited to call/email/text questions. Confirmation of participation will be emailed to participants. We will attach the Information Sheet

for their records. The confirmation email will include instructions to complete baseline and follow-up measurements and how to use the fresh produce incentives in the UB VV mobile market.

Focus groups: Once screened, determined to be eligible, and still interested in the focus group, the Information Sheet, which includes consent information, will be emailed to the participants explaining their involvement in the focus group. A scheduling email will be sent to confirm participation. During the meeting, after receiving a verbal description of the study prior to starting the meeting, participants will be asked if they have any questions or need time to consider participating.

Stakeholders' semi-structured interviews: Once screened, determined to be eligible, and still interested in the interview, the Information Sheet, which includes consent information, will be emailed to the participants explaining their involvement in the interview. They will also receive a booking link so they can schedule the interview according to their preferences. During the interview, after receiving a verbal description of the study prior to starting the meeting, participants will be asked if they have any questions or need time to consider participating.

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

31.0 Multi-Site Research (Multisite/Multicenter Only)*

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

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

Response:

*31.2 If this is a multi-site study **where you are the lead Investigator**, describe the processes to ensure communication among sites, such as the following.*

- *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 in accordance with applicable federal regulations and local laws.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Response:

31.3 *Describe the method for communicating to engaged participating sites.*

- *Problems (inclusive of reportable events)*
- *Interim results*
- *Study closure*

Response:

31.4 *If this is a multicenter study **where you are a participating site/investigator**, describe the local procedures for maintenance of confidentiality.*

- *Where and how data or specimens will be stored locally?*
- *How long the data or specimens will be stored locally?*
- *Who will have access to the data or specimens locally?*
- *Who is responsible for receipt or transmission of the data or specimens locally?*
- *How data and specimens will be transported locally?*

Response:

31.5 *If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described elsewhere in the protocol.*

- *Describe when, where, and how potential subjects will be recruited.*
- *Describe the methods that will be used to identify potential subjects.*
- *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*

Response:

32.0 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.

32.1 *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:

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

Response:

32.3 *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: