Official Title:	Implementation of Innovative Food Prescription Programs in Older Adults
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Complete Research Protocol (HRP-503)

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Template Instructions

Sections that do not apply:

- *In several sections, the addition of checkboxes for **Not Applicable** have been added to the template as responses.*
    - *If an N/A checkbox is present, select the appropriate justification from the list.*
    - *If an N/A checkbox is not present, or if none of the existing checkboxes apply to your study, you must write in your own justification.*
- *In addition:*
    - *For research where the only study procedures are records/chart review: Sections 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: Implementation of Innovative Food Prescription Programs in Older Adults

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response: We have two PIs.

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VERSION NUMBER/DATE:

Include the version number and date of this protocol.

Response:

Version 4.0

12/20/2024 (Version approved as Continuing Review 2/4/2025)

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	3/11/24	Parts part: 8.1, 11.1, 28.5 – clarify consent process, Spanish language	Yes
2	7/19/24	Edits to language on attached information sheets including eligibility criteria and recruitment processes. Additionally, attaching new study documents for intervention specific surveys.	No
3	8/26/24	Edits to the attached baseline (follow-up) survey. Edits to the clinical screening and	Yes

		recruitment processes to identify eligible participants for recruitment, including clinical partners reviewing patient record Z codes to identify additional eligible participants. Adding "clinical partners" to include other clinics (i.e. UBMD) outside ECMC that may refer participants to our study dependent on participant enrollment from ECMC. Updated eligibility criteria to exclude patients with severe food allergies from recruitment, and edits to the attached recruitment scripts to include updated eligibility criteria.	
4	12/20/2024	First, we're adding a follow-up survey and uploading a participant interview guide. Updating the study team with a new member joining the study.	No

FUNDING:

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

Response: American Heart Association

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: Grant funding for American Heart Association's Food is Medicine project. This protocol covers aims 1 and 2 of the grant proposal.

AHA Award Number: 24FIM1266996

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: All documentation will be kept in the School of Public Health and Health Professions Box drive. Only study staff will have access to the folders specific to this study.

1.0 Study Summary

Study Title	Implementation of Innovative Food Prescription Programs in Older Adults
Study Design	3 arm RCT with mixed methods evaluation
Primary Objective	Understand how we can increase usage of food prescription programs in older adults
Secondary Objective(s)	Determine which type of food prescription is more effective
Research Intervention(s)/ Investigational Agent(s)	Food prescription programs
IND/IDE #	
Study Population	Food prescription program participants
Sample Size	75
Study Duration for individual participants	3 months
Study Specific Abbreviations/ Definitions	FIM = Food is Medicine F/V = Fruits and vegetables ECMC= Erie County Medical Center UBMD=UBMD Physician's Group

2.0 Objectives*

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

Response: To understand how novel attributes of food prescription programs including default delivery and customization can improve food prescription utilization rates.

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 both food prescription intervention arms will have higher redemption than the usual care control arm.

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: Food prescription program utilization as measured through prescription redemption as well as F/V intake, nutrition security, and self-efficacy for preparing healthy meals.

Redemption is defined as the weekly usage of the food prescription by the participant.

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 is associated with poor diet and higher rates of chronic disease. FV consumption is an important component of disease prevention and adults who consume more fresh produce are less likely to develop heart disease, diabetes, certain types of cancer, and are more likely to sustain a healthy weight.[3,4,5,6] FI rates are higher among adults living with chronic diseases including diabetes, hypertension, coronary heart disease and congestive heart failure.[7] FI is also associated with higher health care utilization and costs including more emergency room visits and hospitalizations.[2] Considering that the older adult population is continuing to increase in the U.S.[8] and that FI in older adults continues to rise[9], there is an urgent need to develop FI interventions for this population.[10,1,8]

Food prescriptions can address food insecurity and help prevent and manage disease. Medically tailored meals are often designed to serve patients with severe/chronic illness or physical limitations and typically provide all the calories a patient needs daily, while medically tailored groceries and produce prescriptions (referred to jointly as food prescription programs) have often been implemented as supplemental food programs.[11] A systematic review concluded that food prescriptions may improve FV consumption and reduce food insecurity, but that more studies with stronger designs are needed.[12] Nevertheless, the few studies of produce prescriptions that included comparison groups have shown improvements in FV consumption and food security.[13,14] In a previous small produce prescription delivery program at a different clinic at Erie County Medical Center (ECMC), a clinical partner for this study, approximately 3 cups/day of produce was provided to participants and those who completed the program increased their intake by 2.68 cups suggesting that produce prescriptions may be more additive rather than replacing current FV already in the diet (unpublished data). *To our knowledge, there currently is no published research examining comparative effectiveness of different food prescription programs.*

Food prescription redemptions remain a consistent challenge to program effectiveness. In a recent systematic review of food prescription program, five studies reported usage of food voucher redemption rates ranging from 34.5% to 59% with between 63% and 73% of participants redeeming vouchers at least once and between 9% and 18% of participants redeeming all their vouchers[12]. Barriers to participation were found at the individual level (cooking skills and tools) and the program level (access to farmers' markets, produce quality, lack of employee training on voucher redemption, poor communication with participants, and technological issues)[12]. Another study found inability to choose desired vegetables or not having enough to share with children or other families were barriers.[15] Success was mixed when programs attempted to address transportation issues by facilitating free transportation to farmers' markets or working with mobile markets.[16,17] *Our formative research mirrors national findings indicating that low program utilization is the result of both patient and program-level barriers including stigma, transportation, and poor food literacy.*

Food insecurity in older adults with chronic disease poses extra challenges. Older adults have higher rates of chronic disease than the rest of the population; two thirds of this population have multiple chronic conditions. The addition of FI may lead to worsened health status due to the seriousness of their health conditions.[18] One study in older adults found that a food delivery program with a clinical-community partnership improved FI but had poor survey follow-up to see significance in health measures.[19] *There is a large gap as to how to best implement food prescriptions in the older adult population.*

FIM could benefit from an implementation science perspective. The 2022 Food is Medicine Action Plan authored by the Center for Health Law and Policy Innovation at Harvard Law School highlighted the need to understand which programs are effective, if they will be used by patients, how those programs work, and what happens when participants bring food home[11]. There is also scant research on how produce prescriptions affect current FV purchases or what is an appropriate prescription size. Another recent study focused on facilitators and barriers to food prescription programs in health care settings and highlighted the need to understand all facets of a program to improve implementation.[20]

Preliminary Studies and Partnerships

While the FIM field is extremely new, we have been working for the past two years to develop linkages both locally and nationwide to inform best practices for implementation of FIM programs.

Piloting Home-Delivered Produce Prescriptions with a Federally Qualified Healthcare Center (FQHC) partner. We received a small grant in Fall 2023 to conduct process evaluation, surveys and/or focus groups with produce prescription program participants who redeem vouchers at a mobile produce market or through a pilot home delivery program with customization (N=25) to improve prescription redemption. While it is still early in the pilot, in the first three weeks, we have had 74.6% of participants confirm receipt of their deliveries. Qualitative findings and implementation data from this study will help refine the proposed intervention arms.

Implementation of Food Prescription Programs. Dr. Leone and Dr. Tirabassi (Co-PIs) are leading a project to understand the implementation of existing food prescription program nationwide as part of the Food Security Working Group within the CDC-funded Nutrition & Obesity Policy Research and Evaluation Network (NOPREN); we are conducting surveys and follow-up interviews with high usage food prescription programs across the country. Emergent data from this nationwide research will be used to identify best practices in implementation and will be used to inform the current study.

Experience Administering and Tracking Fruit and Vegetable Incentive Programs. Dr. Leone's team has led several mobile market-based produce incentive programs which are administered similarly to the current produce prescription programs. Our team created a point-of-sale integrated incentive that removes the need for vouchers and cards thus reducing stigma when redeeming benefits (like produce prescriptions) at mobile markets (see Facilities). We also developed a back-end system (Farmers Manager Market Reporter) to allow the research team access to study participant purchasing data. Using this data, we can track how often produce prescriptions are redeemed and what participants purchase using their prescriptions. The current study will use the Market Reporter to track produce prescription redemption in the usual care arm.

Evaluation of Meal Kits to improve diet and cooking skills. Dr. Leone is a Co-I on the evaluation of the *Healthy Options Cooking at Home* program, a 4-week cooking skills program delivered remotely to lower-income families (unpublished data). The program provides one recipe/meal kit each week, paired with an instructional video from a local

chef who created the recipe with a registered dietitian. An evaluation was conducted with participants from four cohorts (N=473). Most (84%) of participants reported being very or extremely satisfied with the program and 65% of respondents reporting repeating the meals at 6-months. Among participants who completed all 3 surveys (n=161), there were improvements post-program and at 6-months in reported ease of preparing healthful foods (p=0.002), self-efficacy for preparing healthy food on a budget (p<0.001) and higher servings of vegetables. *These findings suggest that a meal-kit program with cooking instruction is acceptable to participants and can improve cooking skills longer-term, but we still need to understand program usage*. For the current study, we plan to test expanding this program to three meals/week and examine program usage over 3 months.

Older Adult Perspective in Research Studies. Dr. Stoll (Co-I) has years of experience conducting community-based participatory research with Elder Voices, who focus on the needs of older adults in healthcare research. Elder Voices is an active group of older adults that have guided study designs, created educational material, and developed dissemination strategies. We will dedicate significant planning time (Aim 1) in our study to help design the intervention with them so it will resonate with the target population, as they are key stakeholders in this realm. Previous research has highlighted the need for stakeholders to be included in all produce prescription program design and implementation.[20] Using this group to design the intervention can also reduce unnecessary program costs spent on ineffective or unacceptable designs within this population.

Partnerships with Community Organizations for a Pragmatic Efficacy Trial. The development of this research mirrors the proposed structure of the Medicaid 1115 waiver demonstration project in NY for FIM programs. As is currently proposed, Medicaid FIM programs will be implemented through community-based organizations with a Social Care Network will serve as a linkage between healthcare partners prescribing the FIM program to their patients and the community-organizations that will fulfill the program delivery. In this study, the research team will play the Social Care Network role. Patients will be identified in partnership with our healthcare partners, ECMC and other Buffalo-based clinics dependent on enrollment from ECMC (i.e., UBMD), which are located in an urban setting designated as a Medically Underserved Area/Population defined by the Health Resources and Services Administration. ECMC medical campus is located on the east side of Buffalo, New York, where approximately 30% of the population lives below the poverty level and is predominately African American. ECMC has three primary care clinics and most adult patients have at least two chronic diseases, such as hypertension, obesity, or diabetes (Table 1).

Table 1. Characteristics of ECMC patients across primary care clinics

ECMC Clinic	Total Patients	Underrepresented Minority Patients	Patients Age 65+	Chronic Conditions per Patient
EFHC	9,352	7,789	1,964	2.72
GFHC	5,920	4,931	1,243	2.18
IMC	8,753	7,291	1,838	2.38

Dr. Tirabassi has clinical courtesy privileges as a physician and was previously a primary care provider at the ECMC Family Health Clinic (EFHC). ECMC has an official research collaboration with the University at Buffalo (UB) Primary Care Research Institute in which Drs. Tirabassi and Stoll reside. ECMC has previously partnered with FreshFix, a local food delivery company that focuses on NY products, to offer home delivery of produce to patients. FreshFix is working with our team on the above-mentioned FQHC pilot, having delivered meal kits for the Healthy Options Cooking at Home program.

Massachusetts Avenue Project, a mobile produce market, and FreshFix have a long history of partnering with the research team to conduct research related to mobile markets and food delivery to increase access to and consumption of healthy foods in Western NY (see letters of support). *In summary, ECMC, FreshFix, and Massachusetts Avenue Project have all previously partnered with our research team across various projects and they are excited to support this project to increase the usage of fresh FV in participants.*

4.2 Include complete citations or references.

Response:

1. NCOA. Get the Facts on Food Insecurity and Older Adults. 2022. https://www.ncoa.org/article/what-is-food-insecurity-get-the-facts
2. Hager K, Cudhea FP, Wong JB, et al. Association of National Expansion of Insurance Coverage of Medically Tailored Meals With Estimated Hospitalizations and Health Care Expenditures in the US. *JAMA Netw Open*. Oct 3 2022;5(10):e2236898. Doi:10.1001/jamanetworkopen.2022.36898
3. Aune D, Giovannucci E, Boffetta P, et al. Fruit and vegetable intake and the risk of cardiovascular disease, total cancer and all-cause mortality-a systematic review and dose-response meta-analysis of prospective studies. *Int J Epidemiol*. Jun 1 2017;46(3):1029-1056. Doi:10.1093/ije/dyw319
4. Nour M, Lutze SA, Grech A, Allman-Farinelli M. The Relationship between Vegetable Intake and Weight Outcomes: A Systematic Review of Cohort Studies. *Nutrients*. Nov 2 2018;10(11)doi:10.3390/nu10111626
5. Lee-Kwan SH, Moore LV, Blanck HM, Harris DM, Galuska D. Disparities in State-Specific Adult Fruit and Vegetable Consumption – United States, 2015. *MMWR Morb Mortal Wkly Rep*. Nov 17 2017;66(45):1241-1247. Doi:10.15585/mmwr.mm6645a1
6. Whitney E RS. *Understanding Nutrition*. Nelson Education; 2012.
7. Berkowitz SA, Berkowitz TSZ, Meigs JB, Wexler DJ. Trends in food insecurity for adults with cardiometabolic disease in the United States: 2005-2012. *PloS One*. 2017;12(6):e0179172. Doi:10.1371/journal.pone.0179172
8. Ziliak JP GC. *State of Senior Hunger in 2021*. 2023:1-33.
9. Household Food Security in the United States in 2022 (U.S. Department of Agriculture) (2023).
10. Lee JS. Food insecurity and healthcare costs: research strategies using local, state, and national data sources for older adults. *Adv Nutr*. Jan 1 2013;4(1):42-50. Doi:10.3945/an.112.003194
11. Downer S CE, Kummer C. . *Food is Medicine Research Action Plan*. 2022:1-121. https://www.aspeninstitute.org/wp-content/uploads/2022/01/Food-is-Medicine-Action-Plan-Final_012722.pdf
12. Little M, Rosa E, Heasley C, Asif A, Dodd W, Richter A. Promoting Healthy Food Access and Nutrition in Primary Care: A Systematic Scoping Review of Food Prescription Programs. *American journal of health promotion : AJHP*. Mar 2022;36(3):518-536. Doi:10.1177/08901171211056584

13. Bryce R, WolfsonBryce JA, CohenBryce A, et al. A pilot randomized controlled trial of a fruit and vegetable prescription program at a federally qualified health center in low income uncontrolled diabetics. *Prev Med Rep*. Sep 2021;23:101410. Doi:10.1016/j.pmedr.2021.101410
14. Watt TT, Appel L, Lopez V, Flores B, Lawhon B. A Primary Care-Based Early Childhood Nutrition Intervention: Evaluation of a Pilot Program Serving Low-Income Hispanic Women. *J Racial Ethn Health Disparities*. Dec 2015;2(4):537-47. Doi:10.1007/s40615-015-0102-2
15. Cohen DA, Estrada EL, Montes M, et al. Food prescription pilots: feasibility, acceptability and affordability of improving diet through menu planning and grocery delivery. *J Hum Nutr Diet*. Aug 2023;36(4):1556-1563. doi:10.1111/jhn.13142
16. Schlosser AV, Smith S, Joshi K, Thornton A, Trapl ES, Bolen S. "You Guys Really Care About Me...": a Qualitative Exploration of a Produce Prescription Program in Safety Net Clinics. *J Gen Intern Med*. Nov 2019;34(11):2567-2574. doi:10.1007/s11606-019-05326-7
17. DeWit EL, Meissen-Sebelius EM, Shook RP, et al. Beyond clinical food prescriptions and mobile markets: parent views on the role of a healthcare institution in increasing healthy eating in food insecure families. *Nutr J*. Sep 9 2020;19(1):94. doi:10.1186/s12937-020-00616-x
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19. Zimmer RP, Moore JB, Yang M, et al. Strategies and Lessons Learned from a Home Delivery Food Prescription Program for Older Adults. *J Nutr Gerontol Geriatr*. Apr-Jun 2022;41(3):217-234. doi:10.1080/21551197.2022.2084204
20. Auvinen A, Simock M, Moran A. Integrating Produce Prescriptions into the Healthcare System: Perspectives from Key Stakeholders. *International Journal of Environmental Research and Public Health*. 2022;19(17):11010. doi:10.3390/ijerph191711010

5.0 Study Design*

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

Response: This is a three-arm randomized controlled trial with a mixed methods evaluation. Each participant will be randomized to one of the three study arms. Each intervention will give a participant free food (21 servings of fruits and vegetables) weekly for 12 weeks.

The usual care arm (Mobile Market) is receiving access to a mobile market-based produce prescription which can be redeemed at over 10 locations in the city to choose fresh F/V.

The first intervention arm (Produce Prescription) will have a fully customizable box of fresh F/V delivered to their home.

The second intervention arm (Meal Kit) will be a meal kit delivery box where a participant can choose from 6-9 options weekly. A meal kit includes the F/V and other food and food products needed to complete the meal.

We anticipate that this study will be exempt given that it involves participants choosing food they would like to have delivered to them.

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:

This is a 3 arm RCT testing food prescription progams:

Mobile Market Produce Prescription Program (Usual Care Control) participants will receive a weekly credit to purchase produce boxes from any of the 10+ mobile market locations run by Massachusetts Avenue Project in the city of Buffalo. Participants can use their credits to shop at the market and purchase any produce items they would like. These credits will automatically be added to their account each week using Farmer's Register Point-of Sale software and will not carry-over; thus, participants must "use it or lose it."

Produce Prescription Delivery Program (Intervention Arm 1) participants will receive weekly home deliveries of fresh FV delivered by study partner FreshFix. At enrollment, participants will select a default box type based on their household size with the option of either a standard box or a diabetic friendly box (featuring FV with a lower glycemic index). Produce box contents will change weekly and participants will have the ability to customize their produce selections each week through the online ordering platform, however if they do nothing, they will receive a default box.

Healthy Meal Kit Delivery (Intervention Arm 2) participants will select a default meal kit preference at enrollment based on their household size and dietary preferences or medical conditions. Options will include vegetarian, diabetic-friendly, and gluten-free. Participants will automatically receive the ingredients to make 3 meals/week based on their preference or can select from 6-9 options available through the online ordering platform. Participants cannot, however, pick and choose ingredients within meal kits. These meal kits will be designed by our team to optimize incorporation of FV and prepared and delivered by study partner FreshFix.

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:*

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

Response: 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: We expect that 75 participants will be enrolled across the three arms, so 25 in each arm.

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 work with the three primary care clinics at ECMC to identify potential participants and anticipate utilizing their population health lists to minimize screen failure. We will extend our recruitment to additional primary care clinics (i.e., UBMD) if we are unable to recruit 75 participants from ECMC referrals.

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: Among existing ECMC patients, they have identified over 200 that meet eligibility criteria. We plan to recruit approximately 25% of them (50) at the start of the study and pull the data again as time goes on when we need more participants. Partnering with additional clinics outside of the ECMC system will provide additional participants as needed.

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:

Eligible participants are patients aged 65 and older receiving care at a partner primary care clinic who screen positive for FI through an existing two question screener that all patients receive at their annual visit. This screener asks patients if "in the last 12 months, did you ever, eat less than you felt you should because there wasn't enough money for food" and "do you have access to fresh fruits and vegetables within two miles of your residence." Patients who answer in the affirmative to either question will be eligible for the study. Clinical partners will also review Z codes related to food and nutrition security within their patient charts to identify additional eligible patients. The UB research team will screen patients for eligibility criteria which include: being 65 or older, can store food and prepare meals in their home, are the primary grocery shoppers of the household, have no severe food allergies, and receive care through a clinical partner (i.e., ECMC, UBMD). If the potential participant is not the primary grocery shopper, their spouse or caregiver may be recruited provided they meet the eligibility criteria outlined below.

The spouse or caregiver must meet the age criteria of 65 or older for participation. If the spouse or caregiver is under 65 years old, the UB research team will inquire whether they also perform meal preparation duties. If affirmative, they are not eligible for participation. Additionally, participants must be able to store food and prepare meals in their home and must not have any severe food allergies.

Our clinical partners (i.e., ECMC, UBMD) will be directly looking at the EMR and identifying potential participants for the study, not the UB research team, so we have filled out the HRP-611 form "Request for Limited Waiver of the Authorization for Use of Individually Identifiable Health Information for Study Recruitment" form. It is attached in the submission.

*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: Patients deemed medically unstable by partner clinicians will be excluded.

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:

☐ Adults unable to consent

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

☐ Pregnant women

☐ Prisoners

8.3 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: Our team has research team members who can speak both English and Spanish. Although we expect this population to be primarily English speaking, if we find that an individual, we are attempting to recruit is primarily a Spanish speaker, we will administer consent and surveys to them in Spanish. In this case, the survey will be translated into Spanish and submitted to the IRB prior to use.

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: N/A

10.0 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: Our clinical partners (i.e., ECMC, UBMD) will create an initial list of potential participants that meet eligibility criteria. These potential participants will receive a letter from their healthcare provider (i.e., ECMC, UBMD) indicating that they are eligible for a food prescription and encouraging them to participate in the FIM program and associated research study. This mailing will also include the study information sheet (see attached). All potential participants will have the option to opt out of being contacted by UB. (see opt-out letter attached). After the opt-out period, contact information for those who do not opt-out will be provided to the study team. Healthcare providers and staff in our

partner clinics will also identify potential participants in the clinical setting. If a provider/staff identifies an older adult that is food insecure through the clinic, they will provide them with the program flyer (see AHA Flyer) and instruct them to call the study number if they are interested. They will be screened for eligibility and enrolled using the same process described for participants recruited through the opt out letter modality.

☐ **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: After the UB team receives the list of potential participants for the study, the participants will be randomized to one of the intervention arms. Next, the UB team will contact participants via phone to recruit them for the study arm they were randomized to. The study team member will follow the phone recruitment/consent script (attached) and share information about the program and the expectations of the study. If they agree to participate, they will complete a verbal consent through the information sheet (attached). We have now created three intervention specific scripts to use in that recruitment/consent call to reflect which program they are in.

Because the participants will be randomized prior to consent, we also have created three different HRP-502 consent forms that will explain that they have been randomized and that they are now part of their distinct program. Each one of the three consent forms (all attached and labeled) is attached and explains how they will receive their food prescription more clearly. They will receive their HRP-502 consent form with their initial mailed packet with the study information. (They will have already been consented verbally in the recruitment/consent call as detailed above, but we want to ensure they have the HRP-502 form to review before they begin their program).

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: Our research team is CITI trained and will contact each participant through a phone call during recruitment. All personal data will be kept in REDCAP to minimize any security breaches.

11.2 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: The recruitment script for the phone is attached.

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:

Once recruited, participants will be asked to complete a baseline survey. This survey may be completed during the initial recruitment phone call or may be scheduled for a future date. Participants will be informed that completing the survey indicated consent to participate in the research. Next, participants will receive a packet in the mail detailing study activities (weekly surveys) and how to redeem their food prescriptions (how to place their food orders, where to visit the mobile market). Next, they will complete a phone call with a patient navigator to orient them to the study arm to which they were randomized and troubleshoot any issues they may have redeeming their prescriptions. During this call, participants will be assessed to determine if they need cooking supplies to be able to use the food provided. We have budgeted to provide these materials to those who need them.

Once the program starts, participants will redeem their prescriptions as follows:

Mobile Market Produce Prescription Program (Usual Care Control) participants will receive a weekly credit to purchase produce boxes from any of the 10+ mobile market locations run by Massachusetts Avenue Project in the city of Buffalo. Participants can use their credits to shop at the market and purchase any produce items they would like. These credits will automatically be added to their account each week using Farmer's Register Point-of Sale software (See Facilities) and will not carry-over; thus, participants must "use it or lose it."

Produce Prescription Delivery Program (Intervention Arm 1) participants will receive weekly home deliveries of fresh FV. At enrollment, participants will select a default box type based on their household size with the option of either a standard box or a diabetic friendly box (featuring FV with a lower glycemic index). Produce box contents will

change weekly and participants will have the ability to customize their produce selections each week through the online ordering platform, however if they do nothing, they will receive a default box.

Healthy Meal Kit Delivery (Intervention Arm 2) participants will select a default meal kit preference at enrollment based on their household size and dietary preferences or medical conditions. Options will include vegetarian, diabetic-friendly, and gluten-free. Participants will automatically receive the ingredients to make 3 meals/week based on their preference or can select from 6-9 options available through the online ordering platform. They cannot, however, pick and choose ingredients within meal kits. These meal kits will be designed with adietician to optimize incorporation of FV.

In both intervention arms, participants will receive weekly communications (text and/or email) with links to suggested recipes and food education. In addition, they will receive reminders from the food delivery partner as to when their orders can be customized, when the cut-off time for customization is approaching, and delivery reminders. Participants who have difficulty placing orders online can choose to receive the default box or order by phone. Each week, intervention participants will receive a weekly text message (process) survey on the evening of delivery day (Wednesday or Thursday). The text messages will ask participants to confirm delivery receipt and collect usage of food delivered the previous week. The weekly survey (see attached) will also ask participants about any barriers they are facing to prescription redemption, food usage, or study participation.

If a participant does not respond to the survey and/or login to the ordering website (or call the patient navigator) by Sunday evening, they will receive a call on Monday reminding them of the importance of completing the text survey and troubleshooting any issues. Participants who express challenges with the website or problems with the food they receive will also be contacted to troubleshoot issues. If participants do not have any contact with the study team for 2 weeks (no response to text surveys or e-mails, no online login, or no phone calls), their deliveries will be discontinued until they reinitiate contact. Usual care arm participants will also receive weekly text message surveys asking if they went to the market and how much food they used.

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:

- Participant data: name, contact information (phone, email, address), demographics
- Baseline and 3-month phone surveys: F/V consumption, nutrition security measures, diet-related psychosocial constructs
- Weekly text message surveys: food prescription usage

- Food prescription program utilization measured through: program interest, program enrollment, redemption
- Qualitative data from select group of participants that will be asked to participate in a phone survey or in person focus group at the conclusion of the study.

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:

- Baseline/Three Month phone survey
- Weekly text surveys
- Focus group moderators guide
- Participant 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:

The population health screener is a part of the participant's electronic medical record. Our clinical partners will utilize this screener and Z codes related to food and nutrition security within patient medical records to identify potential participants, but data from this screener will not be shared with the UB research team.

*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: We do not anticipate this happening, but we can share the individual data with the subject's primary care physician at ECMC (or additional clinical partners) at the request of the participant. For example, if they want to let their physician know about certain foods or meals that they utilized during the study, we could pass it along to their physician. Additionally, we will ask participants during their baseline survey if they would like us to share with their clinician that they are participating in this study (see 'Baseline/Three Month phone survey').

*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 with community partners to improve their food prescription programs.

13.0 Study Timelines*

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

Response: Participants will be enrolled over 4 months.

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: Each participant will be in the study for 3 months between enrollment, the intervention, and follow-up.

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 study will take 18 months time.

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: Baseline/three month surveys will take place over the phone. Weekly surveys will be through text or phone call. These all will be conducted by the research team in private UB offices. Select people may be asked to be interviewed by phone or be part of an in person focus group at the end of the study.

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: We will develop a community advisory board of older adults to help inform the research. Freshfix will help administer the food prescription programs and will provide input on this evaluation.

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

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

Response: We will develop a community advisory board of older adults to help inform the research to aid in how to best implement the project in older adults. They will be recruited from a local community center.

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:

A Co- Principal Investigator on this study is Dr. Jill Tirabassi who holds an MD from Upstate Medical University and an MPH from the University of Massachusetts Amherst. Her clinical training has been in family medicine, sports medicine, and preventive medicine and public health. She is finishing up a K12 grant in implementation science, focusing on mixed methods evaluation of lifestyle medicine related projects. She is currently the project manager of a CDC NOPREN study looking at food prescription programs as well as pilot studies of food prescription projects under Dr. Leone's mentorship.

The other Co- Principal Investigator on this study is Dr. Lucia Leone. She holds a Ph.D. in Nutrition Intervention and Policy from the University of North Carolina at Chapel Hill. Her pre and postdoctoral training focused on cancer prevention and control and cancer health disparities. Her research has been focused on developing community or organization-based interventions which are designed with an eye toward dissemination and implementation by community organizations. As a postdoctoral fellow, she worked with community partners to run a randomized controlled trial of Veggie Van. In order to conduct this research, there was a close relationship between the program team at Community Nutrition Partnership, a non-profit organization delivering the intervention, the research

team, and other community-based organizations which serve as host partners for the mobile market. She co-founded the Community Nutrition Partnership, and has significant experience with the business aspects of running a food access program. She has been conducting formative research in Buffalo related to developing new food access programs. She has conducted over 14 focus groups and 30 key-informant interviews with organizations working in food access to inform the development of a healthy corner store initiative and to translate the mobile market program to a new setting.

Jennifer Stoll PhD is a Co-I and research faculty of PCRI in the Department of Family Medicine and is part of the Team Alice team looking at research in older adults. She will interface with the older adult advisory board and think about how to improve food prescription programs in older adults.

Anne Lally (Mathiebe), PhD is the Assistant Director of Research and Evaluation in the Community Health Interventions lab and has extensive experience with qualitative research.

Alicia Claudio, MPH has been a research coordinator in Dr. Leone's lab for over 4 years and has experience with survey and focus group administration.

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 is dedicating 15% of her time

Dr. Tirabassi is dedicating 20% of her time

Dr. Stoll is dedicating 10% of her time

Dr. Lally (Mathiebe) will dedicate 25% of her time.

Alicia Claudio will dedicate 50% of her time.

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: Participants in this research suffer from food insecurity and will have access to food prescriptions in this intervention. If any medical or psychological issues arise due to the research, we will work with their treatment team at our clinical partners (i.e., ECMC, UBMD).

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 persons assisting with the research will have current training in UB's Good Research Procedures course and applicable CITI training. The project coordinator will be trained by the PIs on all aspects of the research. The project coordinator will train any additional research assistants using provided protocols.

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: The partners for whom we are conducting this evaluation will approve all data collection tools prior to usage.

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:

Surveys will be conducted through phone calls or texts and the participant will be remined that they are free to refuse to answer any questions that they do not feel comfortable answering.

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: We will not access any participant electronic medical records directly, as we will have our clinical partners' population health team review their records to identify eligible participants for us to contact.

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:

Survey Data – Descriptive analysis and quantitative analyses will be conducted using SAS 9.4. Outcomes will be analyzed using mixed effect logistic regression for dichotomous outcomes (i.e., interest, enrollment) and ANCOVA for

continuous outcomes. For dietary intake and related psychosocial constructs, mixed models will allow for covarying baseline values and covariates and as well as help address missing data and allow for an intent-to-treat approach.

Audio recordings of the focus groups/phone interviews will be transcribed then checked for accuracy. Focus analysis will be completed using ATLAS.ti 9 qualitative analysis software. First, we will complete a round of deductive coding which consists of identifying and grouping together all discussion related to a particular focus group topic (e.g., food sources, cooking). Next, an inductive process will be used to uncover themes within each topic. We will combine similar themes and count their frequency. Summaries of each topic, noting common themes across organizations, will be created.

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: Power for this study is based on our **primary outcome of food prescription redemption**. In order to detect a difference in usage of 45% using a chi-square (w=0.426 at p=0.05 and 80% power) between either intervention arm and the usual care arm, we will need 54 participants (18 per arm). This assumes a redemption rate of 30% for usual care and 75% for delivery. These redemption numbers are conservative compared to published usage rates for usual care (under 18%) and delivery (89%)).

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

Response: Research team will be adequately trained in proper data collection. Collected data will be reviewed by team 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:

Data collected will be uploaded to a secure shared drive housed and managed by the SPPHP IT at UB – Department of Community Health and Health Behavior.

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 payment. Personal contact information will be stored separately from other data. Any files linking this information will be password protected and will be permanently deleted as soon as the data collection is completed and payment has been received. Data files prepared for analysis will not include any identifiers.

20.2 A. How long will the data be stored?

Response: For the duration of the study.

20.3 A. Who will have access to the data?

Response: Only research team members that are responsible for data collection will have access to identifiable information.

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

Response: The PIs, project manager, and the research assistants are responsible for the receipt and transmission of the data.

20.5 A. How will the data be transported?

Response: N/A

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: N/A as this study involves minimal risk.

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

Response: N/A

21.3 Describe any safety endpoints.

Response: N/A

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: N/A

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: N/A

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 the need to withdraw subjects from the study as it is minimal risk. 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: Breach of confidentiality is the primary risk in this study. Others could include being embarrassed or uncomfortable about answering a research question. We consider the risks here to be modest and acceptable.

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

Response: Participants' privacy is of the upmost concern. The research team will make every effort to ensure confidentially and privacy of data. The only personally identifying information from study participants will be their name, mailing address, e-mail address, and phone number so that we can contact them to ensure food delivery and perform data collection. Personal contact information will be stored separately from de-identified focus group/phone interviewdata that

is transcribed. The file linking this information will be password protected and will be permanently deleted as soon as the data collection is completed and payment has been received. Data files prepared for analysis will not include any identifiers. Only the research team members responsible for data collection will have access to identifiable information. All team members will receive appropriate training on maintaining confidentiality and protecting human subject.

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

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

Response: N/A

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

Response: No known risk to an embryo or fetus; minimal risk study

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: The benefit to participants is that they will receive free food and may improve their diet and diet-related health outcomes. These outcomes are highly likely for those who fully participate in the produce prescription program. Therefore, they can help inform other like-minded organizations with best practices for food prescription programs and may learn from the study results as well.

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: Transportation to get to the mobile market site in the control group might be a cost to consider. We hope to get a mobile market site at the ECMC clinic and possible other clinical partners to help mitigate this. However, because this is the standard of care for food prescriptions in Buffalo, and we were required by the grant to have a usual care control group, it will help us understand how our intervention arms may improve food prescription redemption.

☐ **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:

Participants will receive their food prescription for free. However, to receive each weekly box, they need to complete the prior week's short text survey.

Participants will receive $20 via mail or e-mail (depending on their preferences) within 1 week of completing the three-month survey. Interview/Focus group participants will receive $35 after participation.

☐ **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: Consent will take place over the phone during the initial recruitment phone call. Participants will receive the study information sheet (see 'AHA Info Sheet General' in the mail as a component of their initial opt-out letter for recruitment (see 'AHA Opt Out Recrutiment Letter'). Information about the specific intervention arm they will be assigned to will be provided verbally during the recruitment call consent process (see 'AHA Phone Recruitment and Consent Script' labeled for each intervention arm). Those who are eligible and choose to participate after providing verbal consent will receive the HRP-502 Consent document specific to their assigned intervention (see 'HRP-502 Template Consent Document AHA' labeled for each intervention arm) in their orientation packet sent in the mail upon enrollment. Participants will be able to contact the research team with any further questions about the study or to decline participation after their orientation materials are received and reviewed.

Phone calls to participants will take place in private offices at UB and request that a participant be in a private place for the process.

1.1 *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.

1.1 Response: Participants will receive the initial study information sheet with the opt-out letter and will have time to opt-out of having their name shared for recruitment. They will have a second opportunity to consider the study when they receive a recruitment call so they will have ample time to consider their participation. After enrollment but before the start of the intervention, participants will receive orientation materials, including the HRP-502 Consent document specific to their assigned intervention (see 'HRP-502 Template Consent Document AHA' labeled for each intervention arm), in the mail. They will be able to contact the research team with any questions or to remove themselves from the study after review of the HRP-502 document.

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

Response: Participants will be reminded they can stop the study at any time, and specifically each week they could easily choose to stop delivery of their food prescription, as they will be contacted weekly to customize their prescription.

28.3 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)*

28.4 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: The study population is primarily English speaking, but if a Spanish speaking participant is encountered during the recruitment process, the study team member will pause recruitment until a Spanish speaking member of the research team is available to call the participant.

If this situation does occur, the UB team will translate their current recruitment and consent documents into Spanish for IRB approval prior to contacting/enrolling the potential participant.

28.5 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: For Spanish speaking participants, they will receive the study information sheet in Spanish and will be recruited by a Spanish-speaking research assistant.

Cognitively Impaired Adults

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

28.6 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).*

28.7 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)."

28.8 ***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:

28.9 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:

*28.10 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)*

*28.11 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:

*28.12**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:

28.13 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)."

*28.14 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:

*28.15 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:

28.16 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:

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:

Response: This study does not involve procedures for which written documentation of consent is normally required outside of the research context. As such, we will be obtaining verbal consent. The consent script that will be done over a phone call is detailed in the attached 'AHA Phone Recruitment and Consent Script' for each intervention arm.

☐ 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).

NOTE: If the UBIRB has approved this study to bank data and/or specimens for potential future use outside the scope of this research study, any future use or disclosure of the data that is not described within the approved study must be submitted for review to the UBIRB.

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: