University at Buffalo
The State University of New York

CTSI Pilot: Improving Adherence to a Diabetic Diet
NCT 04051008
Study Protocol and Statistical Analysis Plan
Document date: 5-4-2020

Complete Research Protocol (HRP-503)

Table of Contents

Template Instructions

Sections that do not apply:

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

Studies with multiple participant groups:

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

Response 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:

Improving adherence to a diabetic diet with a grocery shopping intervention

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response:

Stephanie Anzman-Frasca, PhD
Pediatrics, Division of Behavioral Medicine
(716) 829-6692
safrasca@buffalo.edu

VERSION NUMBER/DATE:

Include the version number and date of this protocol.

Response 11 – 05/04/2020 (final version)

All changes from the original protocol and Clinicaltrials.gov registration were minimal and are detailed herein.

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	3/28/19	Changes made in response to clarifications requested: unbolded payment on recruitment postcard, removed date from HIPAA form and added detail on how this information is confirmed, unchecked pregnant women in section 6.3, checked box in 7.1, provided further detail on recruitment/social media, indicated waiver of consent requested, with justification, clarified voluntary nature of participating in consent document	Yes
2	4/11/19	Changes made in response to clarifications requested: recommended statement added to consent, formatting of protocol template was checked/updated as requested, NA was added to 6.1 and 6.2, additional details on social media use were added, the term de-identified was changed to coded throughout, requested	Yes

		modifications were made to the HIPAA form, and recruitment postcard was checked/edited as requested.	
3	6/28/19	We have made the following changes: receipts will be collected for the household; modifications to inclusion criteria – participant needs to do 75% of the grocery shopping for household and needs to complete at least 75% of grocery shopping at Wegman's/Tops; changed number of recipes cards provided (3 per week). We also made a few minor additions/changes to questionnaire/interview: asking how long they were in the store shopping; whether they use insulin; how they liked the recipes from the study; whether they follow a special diet; and a question about their liking of several possible recipes. We also modified our food frequency questionnaire (to ask about the past month rather than year given the time frame of our study) and added a receipt form to allow participants to clarify what the items on their receipts are. All of these changes are included in the modification in tracked changes (in this protocol/the relevant attachments).	
4	7/24/19	We made minor changes after internal feasibility testing of the protocol. These include: removing part of our baseline questionnaire (corresponding changes are tracked in the protocol and study script/questionnaire attachments) and minor changes to the script/receipt form to streamline procedures, now asking questions about who the purchased food items are for on the receipt forms rather than the phone interview. We also specify our stratification factors in the protocol. All of these changes are included in the modification in tracked changes (in this protocol/the relevant attachments)	
5	9/16/19	We have changed the consent procedure to include written consent consistent with SOP and full HIPAA authorization after challenges acquiring participant medical information from clinicians. All of these changes are included in this modification in tracked changes (in this protocol/the relevant attachments).	

6	9/30/2019	We have made the following changes: adding pre-diabetes/type II diabetes eligibility criteria to the front of the recruitment materials (flyer, postcard, and Facebook advertisement) to make this criteria more visible for interested individuals; modifying our eligibility script to align with the SOP consent/HIPAA form; expanding recruitment as described herein (collaborating with partners within our department, at Independent Health Foundation, I2B2 and ResearchMatch; adding an additional mode of communication with physicians' offices (fax via eFax.com, to maintain confidentiality because or lab does not have a private fax machine); adding an option for participants to receive study documents via postal mail if that is their preference. We have also made minor changes to eligibility criteria where participants must shop at Tops/Wegmans at least 50% of the time (instead of 75% of the time). A number of interested participants were deemed ineligible solely because of this criterion, leading the study team to review the inclusion criteria and their purposes. While it is important that participants shop at these stores regularly, the selection of the specific cutoff was somewhat arbitrary, and upon revisiting, the study team felt that a cutoff of 50% or more would still capture the majority of the household's shopping and would facilitate greater participation without affecting the rigor of the study. An additional option was added to the screener document to encompass this change in eligibility criteria. We have also added a question to the screener document asking participants if they have recently participated in (or are currently in) any other research studies and to explain the nature of each study. Additionally, we have changed our enrollment procedures to allow participants to self-report and start the study before confirming their diabetes status with a physician. This decision was made because of feasibility concerns; a number of eligible participants have not been able to enroll in the study as a direct result of	

		extended delays in communication between study staff and physician's offices; this change will allow for faster turnover and study progress, while still allowing for the confirmation of diabetes status later in the study. All of these changes are included in the modification in tracked changes (in this protocol/the relevant attachments)	
7	11/5/2019	We have made the following changes: Addition of a joint recruitment postcard and flyer to be used by our study as well as two other studies recruiting similar populations within the Division of Behavioral Medicine (STUDY00002659 and STUDY00003608) so that we may efficiently direct participants to the study that might suit them. We have also created a shared online questionnaire that will be used solely to direct participants to the IRB-approved online screening questionnaire for the aforementioned studies. No personally identifiable information will be collected on this survey; it is completely anonymous. All of these changes are included in the modification in tracked changes (in this protocol/the relevant attachments)	
8	12/10/2019	We have made the following changes: Given the remote nature of this study (all participant contact takes place via phone, email, or postal mail), we have elected to expand our recruitment efforts past the Buffalo area to include the greater Northeastern US, where Tops and Wegmans stores are located. For this reason, we have added an additional question to the screener asking potential participants to input their home zip code; this will help us determine whether the participant is within the specified distance to Tops and/or Wegmans stores, and if they are eligible to receive Instacart delivery services in their area. We have also edited the protocol to specify that recruitment will extend beyond the Buffalo area to include the Northeastern US. All of these changes are included in the modification in tracked changes (in this protocol/the relevant attachments)	

9	02/20/2020	We have made the following changes: We plan to collaborate with the UB contracted media-buying agency Fahlgren Mortine (FM) for study recruitment. FM has created a customized media plan specific to our study objectives, and we have developed a new recruitment material for digital display advertising. This has been adapted from previously approved material to better suit a digital display platform, and a user-friendly vanity link has been created to direct interested individuals to our screening survey (which remains unchanged). All of these changes are included in the modification in tracked changes (in this protocol/the relevant attachments)	
10	03/12/2020	We have made the following changes to the protocol in response to the COVID-19 pandemic: We will allow study team members to work remotely on UBs secure VPN as a preventative measure to limit person contact. The study team has been instructed to maintain confidentiality as in the lab setting and to perform study tasks in a private space in accordance with laboratory emergency procedures.	
11	05/04/2020	We have made the following changes: We have modified our definition of "at risk for diabetes" after learning that few individuals have a formal prediabetes diagnosis. We are still interested in recruiting individuals with type 2 diabetes and type 2 diabetes risk, but now, instead of defining this as type 2 diabetes or prediabetes diagnosis, we are defining it as type 2 diabetes diagnosis OR at risk for type 2 diabetes based on a diagnosis of prediabetes or meeting criteria for increased risk of developing type 2 diabetes based on the American Diabetes Association Type 2 Diabetes Risk Test (described further herein). This affects the questions we ask on our screening questionnaire and the wording of some of our materials; uploaded attachments have been included and described in the modification submission. We have also extended our study timeline and prepared additional language and measures in response	Yes

		to the COVID19 pandemic; these include tempering the language about in-person grocery shopping for the control group, so that it doesn't feel like it is required if not preferred in the context of COVID-19, and adding changes in daily life, perceived stress and loneliness measures within our baseline and post surveys. Additionally, we added newspapers and periodicals, and the Clinical and Translational Sciences Institute (CTSI) Community Liaison and Buffalo Research Registry (BRR) to our recruitment methods to aid in the recruitment of participants from the greater Buffalo community. We also changed the mention of added sugar to sugar and/or added sugar throughout the protocol, as we do plan to examine at least one of these, but realized in beginning our data entry processes that examination of added sugar in particular may be difficult with the current nutritional software/analysis plan.	

FUNDING:

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

Response:

This research is being funded by the Clinical and Translational Science Institute.

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:

Response: A grant proposal to fund this work was submitted to the CTSI in December 2018 and has been funded with a start date of 4/1/2019 (pending IRB approval). The grant is attached.

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: Child Health and Behavior Lab, Division of Behavioral Medicine

Address: 151 Farber Hall

Department: Pediatrics

1.0 Study Summary

Study Title	Improving adherence to a diabetic diet with a grocery shopping intervention
Study Design	This study has an experimental design. Participants will be randomly assigned to 1 of 2 interventions or a control group in which they will shop in-person as usual. Stratification factors will be sex and diabetes status: diabetic vs. at risk for type 2 diabetes, defined as a diagnosis of prediabetes or meeting criteria for increased risk of developing type 2 diabetes in accordance with the American Diabetes Association Type 2 Diabetes Risk Test. In all groups, recipe cards that follow the evidence-based DASH diet will be provided; recipes correspond to dietary recommendations for patients with type 2 diabetes or at increased risk of developing type 2 diabetes. The *Online* intervention will utilize online grocery shopping (shopping at a local grocery store via Instacart) to promote healthier purchasing, removing visceral factors that can lead to impulse purchases in stores. The *Defaults* intervention will augment this intervention, showing participants a default cart when they log into their accounts. They will be told that their cart has been filled with items that conform to a diet for diabetes prevention, management, and overall health and can be used to make the recipes from the provided recipe cards, and that they may modify it as they like. At baseline, all participants will complete a survey online or via phone and then will grocery shop in-person as usual. Participants will then be randomized and receive further instructions. For the next 3 weeks, they will receive recipe cards and shop in accordance with their assigned study group. The following week (post), they will shop using their preferred mode (in-person or online) and complete a survey again. Household receipt data will be collected throughout

	the study. The baseline period will also serve as a run-in period, and participants who do not comply with study guidelines for baseline procedures (including guidelines for receipt submission) will not be randomized for further participation. Primary analyses will examine intervention effects on grocery purchases, with additional analyses on spending and dietary intake. The study is designed, so that all participant interactions will occur remotely: online, via phone, or through paper mail (study materials may be sent via paper mail if it is the participants preference, and Clincards for participant payment will initially be sent via mail as is standard, using participant addresses as already collected on the consent form).
Primary Objective	The goal of this study is to test novel approaches informed by behavioral economics to promote healthier grocery shopping among adults with type 2 diabetes or at an increased risk of developing type 2 diabetes.
Secondary Objective(s)	The specific aims are: (1) to test effects of Online and Defaults grocery shopping interventions on the grocery purchases of adults with type 2 diabetes or at risk of developing type 2 diabetes and (2) to explore effects of the Online and Defaults interventions on participants' spending during grocery shopping. We will also explore effects on dietary intake.
Research Intervention(s)/ Investigational Agent(s)	There will be two interventions in this study. The first intervention is the *Online* intervention, which will utilize online grocery shopping (shopping at a local grocery store via Instacart) to promote healthier purchasing, removing visceral factors that can lead to impulse purchases in stores. The second intervention, the *Defaults* intervention, will augment the *Online* intervention, showing participants a default cart when they log into their accounts. They will be told that their cart has been filled with items that conform to a diet appropriate for diabetes prevention, management, and overall health and can be used to make the recipes from the provided recipe cards, and that they may modify their carts as they like.
IND/IDE #	
Study Population	Adults diagnosed with type 2 diabetes or at increased risk of developing type 2 diabetes, defined as a diagnosis of prediabetes or meeting criteria for increased risk of developing type 2 diabetes in accordance with the American Diabetes Association Type 2 Diabetes Risk Test
Sample Size	Up to 100

Study Duration for individual participants	An individual subject's participation in the study will take place over about 6 weeks.
Study Specific Abbreviations/ Definitions	

2.0 Objectives*

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

Response:

The goal of this study is to test novel approaches informed by behavioral economics to promote healthier grocery shopping among adults diagnosed with type 2 diabetes or at increased risk of developing type 2 diabetes, defined as a diagnosis of prediabetes or meeting criteria for increased risk of developing type 2 diabetes as determined by the American Diabetes Association Type 2 Diabetes Risk Test. The specific aims are: (1) to test effects of *Online* and *Defaults* grocery shopping interventions on participants' grocery purchases and (2) to explore effects of the *Online* and *Defaults* interventions on participants' spending during grocery shopping.

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:

It is hypothesized that (1a) purchases made by adults in the Defaults group will be lower in calories, carbohydrates, and sugar (total sugar and/or added sugar) and higher in nutritional quality (DASH diet score) at post-test versus other study groups, (1b) adults in the Defaults group will show the greatest increases in nutritional quality versus other study groups, (1c) the Online group will have intermediary results between Defaults and Controls, and (2) there will be no difference in total dollars depicted on receipts across study groups during the intervention period (i.e., the costs of online shopping will be offset by effects of the Online and Default interventions).

3.0 Scientific Endpoints*

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

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

Response:

The primary endpoint is to determine whether there are group differences in grocery purchases among adults randomized to the Online or Defaults interventions or control group. Primary analyses will examine differences in the study groups' grocery purchases, including total calories, carbohydrates, and sugar (total sugar and/or added sugar), and overall nutritional quality of foods and beverages purchased at post-test and throughout the study period.

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:

Millions of deaths are caused by diabetes, and impacts on health expenditures are staggering, with $727 billion spent in 2017. Dietary approaches are recommended for weight control and diabetes prevention and management, but modern environments, characterized by plentiful, unhealthy foods, pose challenges to selecting a healthy diet. Modifications to the food environment can address these barriers by making healthier choices more automatic and reducing the need for self-control.

Behavioral economics offers a framework for modifying the food environment to encourage individuals with diabetes to select foods that align with diabetic diet goals. The standard dietary approach to diabetes involves educating people in a clinical setting but does not prepare them to make purchasing decisions under normal conditions. Decision-making is affected by visceral factors, including hunger and strong emotions, which can lead to impulse purchasing. Rather than expecting humans to behave rationally, behavioral economics aims to make the healthy choice the easy choice. For example, people tend to accept default options rather than requesting alternatives, offering the potential to encourage healthier behaviors by positioning them as automatic defaults.

Such strategies have been applied effectively in many domains (e.g., organ donation; Johnson & Goldstein, 2003) but have seldom been used to promote health during grocery shopping, which is the leading source of sugar-sweetened beverages and nutrient-poor foods (An & Maurer, 2016). One recent study randomized undergraduates to grocery shop online, receiving either: 1) nutrition education, 2) a financial incentive for selecting healthy foods, or 3) a default shopping cart with healthy foods, which they could alter as desired. The default group chose healthier foods than education controls, with no effect of incentives. This study supports the promise of defaults to encourage healthier purchases when grocery shopping and highlights a need for ecologically-valid studies in populations with diet-related diseases. The present study will fill this gap by testing online grocery shopping and defaults as potential mechanisms

to promote adherence to a diabetic diet among adults with diabetes or at risk of developing diabetes.

These strategies have translational significance as they could be incorporated into clinical treatment: e.g., by "prescribing" online grocery shopping if the Online intervention is efficacious, and/or working with dieticians to generate default carts catering to different lifestyles and disseminating this information in clinical settings and/or via partnerships with grocery stores. As such, the proposed interventions have the potential to improve dietary intake, glucose regulation, weight, and medication needs among diabetic patients. The study team has the substantive expertise needed to examine this question, including a history of behavioral economics, diabetes, grocery shopping/retail, and community-based research (e.g., Anzman-Frasca et al., 2018; Epstein & Saelens, 2000; Leone et al., 2018).

4.2 Include complete citations or references.

Response:

American Diabetes Association. (2020). 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes - 2020. *Diabetes Care, 43*(Supplement 1), S14-S31.

An, R., & Maurer, G. (2016). Consumption of sugar-sweetened beverages and discretionary foods among US adults by purchase location. *European Journal of Clinical Nutrition*, *70*, 1396-1400.

Anzman-Frasca, S., Braun, A. C., Ehrenberg, S., Epstein, L. H., Gampp, A., Leone, L. A., … Tauriello, S. (2018). Effects of a randomized intervention promoting healthy children's meals on children's ordering and dietary intake in a quick-service restaurant. *Physiology & Behavior*, *192*, 109-117.

Epstein, L. H., & Saelens, B. E. (2000). Behavioral economics of obesity: Food intake and energy expenditure. In W. K. Bickel & R. E. Vuchinich (Eds.), *Reframing health behavior change with behavioral economics* (pp. 295-314). Mahwah, NJ: Lawrence Erlbaum Associates.

Johnson, E. J., & Goldstein, D. (2003). Do defaults save lives? *Science*, *302*(5649), 1338-1339.

Leone, L. A., Tripicchio, G. L., Haynes-Maslow, L., McGuirt, J., Grady Smith, J. S., Armstrong-Brown, J., … Ammerman, A. (2018). Cluster randomized controlled trial of a mobile market intervention to increase fruit and vegetable intake among adults in lower-income communities in North Carolina. *International Journal of Behavioral Nutrition and Physical Activity, 15*(1), 1-11.

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 study has an experimental design. Participants will be randomly assigned to 1 of 2 interventions or a control group in which they will shop in-person as usual. Stratification factors will be sex and diabetes status: type 2 diabetic vs. at risk for type 2 diabetes, defined as a diagnosis of prediabetes or meeting criteria for increased risk of developing type 2 diabetes as determined by the American Diabetes Association Type 2 Diabetes Risk Test. In all groups, recipe cards that follow the evidence-based DASH diet and correspond to dietary recommendations for diabetic patients will be provided. The *Online* intervention will utilize online grocery shopping (shopping at a local grocery store via Instacart) to promote healthier purchasing, removing visceral factors that can lead to impulse purchases in stores. The *Defaults* intervention will augment this intervention, showing participants a default cart when they log into their accounts. They will be told that their cart has been filled with items that conform to a diet appropriate for diabetes prevention, management, and overall health and can be used to make the recipes from the provided recipe cards, and that they may modify it as they like.

At baseline, all participants will complete a survey online or via phone and then will grocery shop in-person as usual. Participants will then be randomized and receive further instructions. For the next 3 weeks, they will receive recipe cards and shop in accordance with their assigned study group. The following week (post), they will shop using the method of their choice (in-person, online) and complete a survey again. Household receipt data will be collected throughout the study. The baseline period will also serve as a run-in period, and participants who do not comply with study guidelines for baseline procedures (including guidelines for receipt submission) will not be randomized for further participation. Primary analyses will examine intervention effects on grocery purchases, with additional analyses on spending and dietary intake. All participant interactions will occur online or via phone.

6.0 Study Intervention/Investigational Agent

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

Response:

This study does not involve drugs or devices; however, there will be two interventions in this study. The first intervention is the *Online* intervention, which will utilize online grocery shopping (shopping at a local grocery store via Instacart) to promote healthier purchasing, removing visceral factors that can lead to impulse purchases in stores. The second intervention, the Defaults intervention, will augment the *Online* intervention, showing participants a default cart when they log into their accounts. They will be told that their cart has been filled with items that conform to a diet appropriate for diabetes prevention, management, and overall health and can be used to make the recipes from the provided recipe cards, and that they may modify their cart as they like.

6.1 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, this study does not involve drugs or devices.

6.2 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, this study does not involve drugs or devices.

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 will enroll up to 100 adults with type 2 diabetes or at increased risk of developing type 2 diabetes in this study.

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

Response:

Given that approximately 14% of the US population has diabetes, and an estimated 34% of US adults has prediabetes, we anticipate that about 208 adults would need to be screened in order to identify 100 eligible adults.

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:

Participants will be recruited during 2019-2020 from the Northeastern United States via one or more of the following methods. Participants will be recruited via advertisements in print and social media, mailings, newspapers and periodicals, flyers in clinics and other community locations, and attendance at community events and clinics. Prior research by study team members has led to relationships with area clinics that will facilitate recruitment of diabetic patients. With regards to social media, the study will be advertised on our lab's and our Division's Facebook and Twitter pages (UB Child Health and Behavior Lab, UB Division of Behavioral Medicine). The information will also be posted on our lab's website (http://ubhablab.weebly.com/). The attached recruitment advertisement and/or postcard will be uploaded/linked to these sites. These are public pages that potential participants can view (and "like"/follow in the case of Facebook and Twitter) of their own free will. No information will be collected from participants by the researchers via these sites. The potential participants will be able to read the text on the recruitment postcard and decide whether to contact the study team for more information using the contact information provided and/or whether to access and fill out the study screener, with screening information collected on a different platform (e.g. Survey Monkey) and protected as indicated herein.

The study will also utilize the University at Buffalo's Clinical and Translational Sciences Institute (CTSI) for recruitment assistance and consultation. The CTSI's Recruitment and Community Engagement Team provides resources and guidance to link our study with community partners to reach populations of interest. These resources include the Buffalo Research Registry (BRR) and Conventus Research Table. The BRR is a voluntary research registry which can connect researchers to community members who have completed a health profile and are interested in participating in research. These community members have agreed to be contacted about potential research opportunities based on their self-reported information. The BRR's Community Recruitment Liaison (CRL) will complete the process of sorting BRR data to reflect the inclusion and exclusion criteria for the study, and may reach out to potentially eligible participants in the BRR to provide information about the study. The CRL will then provide the study team with the name and contact information of interested participants. No recorded health information will be shared from BRR data.

We will collaborate with the UB contracted media-buying agency Fahlgren Mortine (FM) for the purposes of study recruitment. FM services include media

planning, placement, management of assets, and creative support specific to study objectives. For the purposes of our study, FM will utilize a digital pharmacy network to display recruitment advertisements on digital screens in three pharmacies in Erie and Niagara counties. These advertisements will be adapted from our standard recruitment materials to better suit the digital display platform. This advertisement will be used for print and digital media platforms where limited text is appropriate (e.g. newspaper advertisements, social media). These advertisements will be shown in public spaces that potential participants can view of their own free will. The potential participants will be able to access the link on the advertisement to decide whether to contact the study team for more information and/or whether to access and fill out the study screener, with screening information collected on a different platform and protected (e.g. Survey Monkey) as indicated herein.

We will also utilize ResearchMatch, a not-for-profit, free recruitment initiative that is supported by a National Institutes of Health (NIH) Clinical and Translational Science Award Program grant. ResearchMatch identifies participants from a pool of registered study volunteers that fit within specified demographic filters and will email a de-identified group of eligible participants. ResearchMatch volunteers are individuals who have self-registered their interest to be contacted about participating in research studies that may be a good match for them. Recruitment access to ResearchMatch requires evidence of having IRB approval and only lasts as long as the IRB-study approval. The expiration date of recruitment access will mirror the expiration date of the study. After a researcher has been granted recruitment access, they are able to search for appropriate matches amongst the non-identifiable ResearchMatch volunteer pool by entering the study's criteria into the ResearchMatch search builder. Search criteria will be adults living within 20 miles of a TOPS and/or Wegmans. This process will yield a list of potential matches, and these individuals will be contacted with the IRB-approved recruitment content in an initial recruitment message via a secure ResearchMatch system. These potential matches will then have the option to reply yes, no, or no response.

In addition, we will share study information with individuals from several databases; first, we will access the contact information from a database of potentially interested participants maintained by our department. Our department's centralized database includes hundreds of individuals with prediabetes or type II diabetes who indicated interest but did not participate in prior studies. In addition, there are several similar but smaller databases maintained by individual labs within our department. These labs also conduct studies with type II diabetic and/or prediabetic patients, and maintain a list of individuals who were interested in participating, but did not meet the eligibility criteria for the given study. We plan to collaborate with these labs, sharing information about our study with these potential participants who indicated an interest in hearing about other study opportunities, and also sharing information about these colleagues' studies with individuals who were interested in, but not

eligible for, the present study. Two other IRB-approved studies within the Division of Behavioral Medicine, STUDY00002659 and STUDY00003608, are recruiting pre-diabetic and type II diabetic participants. To minimize the likelihood participants screen for multiple projects in the lab, and in order to efficiently direct participants to the study that might suit them, a shared online (Qualtrics) questionnaire will be used that asks participants questions about their height and weight, diabetes/prediabetes status, if they are taking medications for blood glucose management, hypertension, or high cholesterol, if they are interested in weight loss, if they shop at local grocery stores, and if they are on public assistance. No personally-identifiable information will be collected on this survey; it is completely anonymous and it will only be used to direct participants to the IRB-approved online screening questionnaire for the aforementioned studies. Research staff within the Division of Behavioral Medicine have used the database successfully for multiple years for recruitment purposes, and we feel confident that we can recruit the required number of subjects from this database and our online and community based efforts. Additionally, Dr. Anzman-Frasca has experience conducting research within and recruiting from community settings and has recruited similarly-sized samples within similar time frames.

We will also utilize the I2B2 dashboard, a secure, HIPAA compliant database maintained by the Institute for Healthcare Informatics within the University at Buffalo. In addition, we have previously collaborated with Independent Health Foundation on research, and our colleagues there have indicated their willingness to share information about this study in two ways: 1) with contacts from their database, and 2) via the Brook app. With regard to the latter, our colleagues at Independent Health Foundation are collaborating with Brook (*https://www.brook.health/),* encouraging Independent Health members who are diabetic to download the app to help track and manage their diabetes. Study information can be sent to these individuals via the app. Similar to our outreach via the other methods described above, potential participants who receive study information through these avenues will be able to read the recruitment text and decide whether to contact the study team for more information using the information provided and/or whether to access and fill out the study screener, with screening information collected on a different platform (e.g. Survey Monkey) and protected as indicated herein.

Efforts will be made to recruit low-income individuals (e.g., by mailing recruitment postcards to low-income census tracts of Buffalo and/or connecting with clinic locations in these tracts). Even though we are excluding SNAP/WIC recipients as mentioned above, there are low-income individuals who do not meet eligibility criteria for these programs or who do not sign up for these programs despite eligibility. Participants will provide informed consent prior to participation.

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:

- Must be at least 18 years old
- Must have been diagnosed with prediabetes or type 2 diabetes, or meet criteria for increased risk of developing type 2 diabetes as determined by the American Diabetes Association Type 2 Diabetes Risk Test
    - The American Diabetes Association Type 2 Diabetes Risk Test takes the factors below into account with the following scoring system; a total score of 5 points or higher indicates an increased risk of developing type 2 diabetes

Criteria	**Scoring**
Age	Less than 40 years = 0 points 40-49 years = 1 point 50-59 years = 2 points 60 years and older = 3 points
Gender	Man = 1 point Woman = 0 points
For women: previous or current diagnosis of gestational diabetes	Yes = 1 point No = 0 points
Family history of diabetes	Yes = 1 point No = 0 points
Previous or current diagnosis of high blood pressure	Yes = 1 point No = 0 points
Level of physical activity	Physically active = 0 points Not physically active = 1 point
Weight Status	BMI < 24.9 = 0 points BMI of 24.9 – 29.8 = 1 point BMI of 29.9 – 39.8 = 2 points

	BMI > 39.9 = 3 points

- Must report shopping in-person at Tops and/or Wegmans stores at least weekly, and at least 50% of the grocery shopping for the household must be done at Tops and/or Wegmans
- Must do at least 75% of the grocery shopping for the household
- Must speak English

*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:

We will exclude anyone who:

- Is under 18 years of age
- Has not been diagnosed with prediabetes or type 2 diabetes, or does not meet criteria for increased risk of developing type 2 diabetes as determined by the American Diabetes Association Type 2 Diabetes Risk Test
- Does not report shopping in-person at Tops and/or Wegmans stores at least weekly
- Does not live in a household in which at least 50% of groceries come from Tops and/or Wegmans
- Does not do at least 75% of the grocery shopping for the household
- Does not speak English
- Receives SNAP or WIC benefits (an exclusion criterion for this study due to incompatibility of EBT cards with the Instacart platform at this time)
- Has dietary restrictions or preferences that would not allow them to reasonably partake in the study (i.e. they would not be willing or able to buy/eat many of the staple foods included in default carts/recipe cards)
- Has recently participated, or is currently participating, in studies that may affect shopping habits and/or eating behavior

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:

☐ 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:

We will not include non-English speakers given the pilot nature of the study.

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:

A portion of our sample may be of a lower socioeconomic status, including of a lower level of education. We will take care to ensure we give each potential participant a thorough explanation of the study and what it entails prior to consent, that we answer any questions they may have, and that measures are at an appropriate reading level.

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:

Potential subjects will be screened online or over the phone for eligibility [See attachment – Screener]. If it is determined that they meet all eligibility criteria based on their self-report, the consent document will be provided to the participant, and the participant will have the opportunity to review it and ask

study staff any questions. Then, interested participants will indicate their interest in participating and will complete consent and HIPAA forms consistent with SOP (see attached Consent, HIPAA Form), so that their diabetes/prediabetes diagnosis, or specific health characteristics that increase their risk for developing type 2 diabetes in accordance with the American Diabetes Association Type 2 Diabetes Risk Test, can be confirmed by their physician (and so their mailing address can be obtained for mailing of their Clincard if they are eligible for the study and decide to sign up). Participants will progress to the next phase of the study while study staff seek confirmation of diabetes status with physicians via HIPAA authorizations.

☐ **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:

Participants will be recruited during 2019-2020 from the Northeastern United States via one or more of the following methods. Participants will be recruited via advertisements in print and social media, mailings, newspapers and periodicals, flyers in clinics and other community locations, and attendance at community events and in clinics. Prior research by study team members has led to relationships with area clinics that will facilitate recruitment of diabetic patients. With regards to social media, the study will be advertised on our lab's and our Division's Facebook and Twitter pages (UB Child Health and Behavior Lab, UB Division of Behavioral Medicine). The information will also be posted on our lab's website (http://ubhablab.weebly.com/). The attached recruitment postcard will be uploaded/linked to these sites. These are public pages that potential participants can view (and "like"/follow in the case of Facebook and Twitter) of their own free will. No information will be collected from participants by the researchers via these sites. The potential participants will be able to read the text on the recruitment postcard and decide whether to contact the study team for more information using the contact information provided and/or whether to access and fill out the study screener, with screening information collected on a different platform and protected as indicated herein.

The study will also utilize the University at Buffalo's Clinical and Translational Sciences Institute (CTSI) for recruitment assistance and consultation. The CTSI's Recruitment and Community Engagement Team provides resources and guidance

to link our study with community partners to reach populations of interest. These resources include the Buffalo Research Registry (BRR) and Conventus Research Table. The BRR is a voluntary research registry which can connect researchers to community members who have completed a health profile and are interested in participating in research. These community members have agreed to be contacted about potential research opportunities based on their self-reported information. The BRR's Community Recruitment Liaison (CRL) will complete the process of sorting BRR data to reflect the inclusion and exclusion criteria for the study, and may reach out to potentially eligible participants in the BRR to provide information about the study. The CRL will then provide the study team with the name and contact information of interested participants. No recorded health information will be shared from BRR data.

We will collaborate with the UB contracted media-buying agency Fahlgren Mortine (FM) for the purposes of study recruitment. FM services include media planning, placement, management of assets, and creative support specific to study objectives. For the purposes of our study, FM will utilize a digital pharmacy network to display recruitment advertisements on digital screens in three pharmacies in Erie and Niagara counties. These advertisements will be adapted from our standard recruitment materials to better suit the digital display platform. This advertisement will be used for print and digital media platforms where limited text is appropriate (e.g. newspaper advertisements, social media). These advertisements will be shown in public spaces that potential participants can view of their own free will. The potential participants will be able to access the link on the advertisement to decide whether to contact the study team for more information and/or whether to access and fill out the study screener, with screening information collected on a different platform and protected (e.g. Survey Monkey) as indicated herein.

We will also utilize ResearchMatch, a not-for-profit, free recruitment initiative that is supported by a National Institutes of Health (NIH) Clinical and Translational Science Award Program grant. ResearchMatch identifies participants from a pool of registered study volunteers that fit within specified demographic filters and will email a de-identified group of eligible participants. ResearchMatch volunteers are individuals who have self-registered their interest to be contacted about participating in research studies that may be a good match for them. Recruitment access to ResearchMatch requires evidence of having IRB approval and only lasts as long as the IRB-study approval. The expiration date of recruitment access will mirror the expiration date of the study. After a researcher has been granted recruitment access, they are able to search for appropriate matches amongst the non-identifiable ResearchMatch volunteer pool by entering the study's criteria into the ResearchMatch search builder. Search criteria will be adults living within 20 miles of a TOPS and/or Wegmans. This process will yield a list of potential matches, and these individuals will be contacted with the IRB-approved recruitment content in an initial recruitment message via a secure

ResearchMatch system. These potential matches will then have the option to reply yes, no, or no response.

In addition, we will share study information with individuals from several databases; first, we will access the contact information from a database of potentially interested participants maintained by our department. Our department's centralized database includes hundreds of individuals with prediabetes or type II diabetes who indicated interest but did not participate in prior studies. In addition, there are several similar but smaller databases maintained by individual labs within our department. These labs also conduct studies with type II diabetic and/or prediabetic patients, and maintain a list of individuals who were interested in participating, but did not meet the eligibility criteria for the given study. We plan to collaborate with these labs, sharing information about our study with these potential participants who indicated an interest in hearing about other study opportunities, and also sharing information about these colleagues' studies with individuals who were interested in, but not eligible for, the present study. Two other IRB-approved studies within the Division of Behavioral Medicine, STUDY00002659 and STUDY00003608, are recruiting pre-diabetic and type II diabetic participants. To minimize the likelihood participants screen for multiple projects in the lab, and in order to efficiently direct participants to the study that might suit them, a shared online (Qualtrics) questionnaire will be used that asks participants questions about their height and weight, diabetes/prediabetes status, if they are taking medications for blood glucose management, hypertension, or high cholesterol, if they are interested in weight loss, if they shop at local grocery stores, and if they are on public assistance. No personally-identifiable information will be collected on this survey; it is completely anonymous and it will only be used to direct participants to the IRB-approved online screening questionnaire for the aforementioned studies.

We will also utilize the I2B2 dashboard, a secure, HIPAA compliant database maintained by the Institute for Healthcare Informatics within the University at Buffalo. In addition, we have previously collaborated with Independent Health Foundation on research, and our colleagues there have indicated their willingness to share information about this study in two ways: 1) with contacts from their database, and 2) via the Brook app. With regard to the latter, our colleagues at Independent Health Foundation are collaborating with Brook (*https://www.brook.health/),* encouraging Independent Health members who are diabetic to download the app to help track and manage their diabetes. Study information can be sent to these individuals via the app. Similar to our outreach via the other methods described above, potential participants who receive study information through these avenues will be able to read the recruitment text and decide whether to contact the study team for more information using the information provided and/or whether to access and fill out the study screener,

with screening information collected on a different platform and protected as indicated herein.

Efforts will be made to recruit low-income individuals (e.g., by mailing recruitment postcards to low-income census tracts of Buffalo and/or connecting with clinic locations in these tracts). Even though we are excluding SNAP/WIC recipients as mentioned above, there are low-income individuals who do not meet eligibility criteria for these programs or who do not sign up for these programs despite eligibility. Participants will provide informed consent prior to 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:

We will not contact anyone who has requested to be removed from our Division's database of contact information. We will keep all recruitment and screening information confidential.

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:

For recruitment, materials will include advertisements in print and on social media, mailings, newspapers and periodicals, and flyers in clinics and other community locations. These materials are attached (see recruitment flyer and postcard).

As mentioned, with regards to social media, the study will be advertised on our lab and our Division's Facebook and Twitter pages (UB Child Health and Behavior Lab, UB Division of Behavioral Medicine). The information will also be posted on our lab's website (http://ubhablab.weebly.com/). We will upload/link the attached recruitment postcard as our advertisement on these sites. These public sites are accessed by potential participants via their own free will. No information will be collected from participants by the researchers via these sites. The participants instead will be able to read the recruitment text and decide whether to contact the study team for more information using the contact information provided and/or whether to access and fill out the study screener. Information completed during the screening is on a separate website and is stored securely and not viewable to anyone besides the study staff.

We will collaborate with the UB contracted media-buying agency Fahlgren Mortine (FM) for the purposes of study recruitment. FM services include media planning, placement, management of assets, and creative support specific to study objectives. For the purposes of our study, FM will utilize a digital pharmacy network to display recruitment advertisements on digital screens in three pharmacies in Erie and Niagara counties. These advertisements will be adapted from our standard recruitment materials to better suit the digital display platform. This advertisement will be used for print and digital media platforms where limited text is appropriate (e.g. newspaper advertisements, social media). These advertisements will be shown in public spaces that potential participants can view of their own free will. The potential participants will be able to access the link on the advertisement to decide whether to contact the study team for more information and/or whether to access and fill out the study screener, with screening information collected on a different platform and protected (e.g. Survey Monkey) as indicated herein.

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:

The proposed study will occur during 2019-2020 with data collection occurring for about 17 months. Recruitment and data collection will occur on a rolling basis, with individual participants' involvement being for about 6 weeks. All data will be collected online or via phone.

Following completion of initial screening, participants will complete consent procedures and a HIPAA form for their physician to confirm their diabetes/prediabetes diagnosis, or specific health characteristics that increase their risk of developing type 2 diabetes in accordance with the American Diabetes Association Type 2 Diabetes Risk Test [see Consent and HIPAA form]. Physicians will be contacted using their modality of choice; this may include phone, email, fax via efax.com, or in-person communication). Participants will be mailed their Clincard for participant payment and move on to baseline procedures: a questionnaire [See attachment: Questionnaires], a baseline shopping trip and receipt submission, and a brief phone interview with questions about their shopping trip [See attachment: Phone interview]. Any participant who does not follow guidelines for baseline procedures will not proceed to randomization (but will be compensated for their time, as detailed below).

Participants' baseline shopping trips will be in-person at their usual grocery store. Following their baseline shopping trip, participants will submit a photograph of their household receipts via email and of a receipt information form (attached). Study staff will contact participants to remind them about this if photographs are not received within the time frame discussed during consent procedures. When the photos are received, study staff will mail participants their Clincards to be used for participant payments and will contact participants via phone to ask follow-up questions and share with participants their assigned study group [See attachment: Phone interview].

Participants will be randomized in blocks to the *Online, Defaults*, or *Control* group, stratifying by diabetes status (diabetes vs. increased risk for developing type 2 diabetes). Study staff will consult a pre-populated spreadsheet in order to determine the study group of each participant. Participants in the *Online* and *Defaults* groups will receive instructions on how to access an online grocery shopping account on Instacart (www.instacart.com). Instacart is a platform through which customers can grocery shop online and have their groceries delivered within a designated window. Many leading grocery retailers offer grocery shopping via Instacart, including Tops and Wegmans, both of which are based in Western New York; there are approximately 250 locations of these chains throughout the Northeastern United States, including but not limited to: New York, New Jersey, Pennsylvania, and Massachusetts.

Accounts will be set up for the participants by study staff, with shared access. Participants will enter their credit/debit card information and purchase their own groceries, to enhance ecological validity. Only the last 4 digits of the participant's credit or debit card number will be visible to study staff when accessing the account to download receipt data (*Online* and *Defaults* groups) and populate the default cart (*Defaults* group). During the 3 weeks that follow randomization, *Control* group participants will be asked to shop as they normally would, in-person at Tops or Wegmans. Those in *Online* and *Defaults* groups will be asked to shop as they normally would but using their grocery store's Instacart platform. In addition, the *Defaults* group will be told that their cart will be pre-filled with items that conform to adiet appropriate for diabetes management, prevention, and overall health. The items will correspond to the DASH diet. All participants will receive 3 DASH-diet friendly recipe cards each week, and the items in the *Defaults* group's carts will correspond to the recipes. The default cart will be populated by study staff after study group assignment and will be re-populated to prepare for the next purchase each time the participant completes a shopping trip. During the post-test week, all participants will be asked to shop using the method of their choice (in-person, online); no default carts or recipe cards will be given. At post-test participants will also complete a Food Frequency Questionnaire as well as an Exit Questionnaire (see attachment: Questionnaires).

Based on inclusion criteria, we expect each participant to shop at least once during each of the three intervention weeks; participants can shop more than once per week if this is what they typically do. Either way, they will be instructed to continue to submit their receipts from all household grocery shopping at

Tops/Wegmans via email as done at baseline. Participants will be prompted weekly, reminding them to shop as they normally would and to ask whether the household has completed any shopping trips without submitting receipts. Participants will also be asked about foods purchased from other locales during phone interviews following submission of receipts each week (See attachment: Phone interview). Although receipts are downloadable from Instacart in the intervention groups and weeks, we will collect these receipts from participants as well, for consistency and as an indicator of the extent to which the number of submitted receipts corresponds to the number of actual receipts, to further inform feasibility for subsequent larger-scale work.

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:

Data to be collected include:

*Confirmation of diabetes status or diabetes risk status (see attachments: Consent and HIPAA Form)

*Demographic questions collected at baseline (see attachment: Questionnaires)

*Changes in daily routine, perceived stress and loneliness questions at baseline (see attachment: Questionnaires)

*Calories, carbohydrates, sugar (total sugar and/or added sugar), and food groups each week of the 5-week shopping period, from receipts (see additional details below)

*Information on which purchased items will be consumed by the participant and information about foods acquired from other sources besides the target grocery store that week (administered after each shopping trip, see attachment: Phone interview)

*Dollars spent on groceries at each time point, from receipts (each week)

*Dietary intake from a Food Frequency Questionnaire (see details below and attachment: Questionnaires; collected at post-test)

*Exit questionnaire (completed at the end of the study; see attachment: Questionnaires)

Additional details:

Calories, carbohydrates, sugar (total sugar and/or added sugar), and food groups will be generated from each of the five weeks of receipt data using Nutritionist Pro software. Each item on the receipt, as well as the item quantity and weight, will be entered into the software following procedures from Hollis-Hansen et al. (Hollis-Hansen, Seidman, O'Donnell, & Epstein, 2018). Standard values from the USDA will be entered in the case of any missing information as done previously. Nutritional quality will be examined using the DASH diet scores based on the amount of 8 food types encouraged or discouraged by the DASH diet (e.g., fruits,

vegetables, sweetened beverages). Methods previously used to calculate DASH diet scores from intake data will be adapted for use in this context.

The food frequency questionnaire is used to calculate nutrient intake. It is a structured self-administered questionnaire with pre-specified response options.

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 demographic questionnaire – (see attachment: Questionnaires)
- Food frequency questionnaire (to be completed at post-test) – (see attachment: Questionnaires)
- Food receipt collection instructions (see attachment: Receipt collection)
- Food receipt form (see attachment: Receipt collection)
- Exit survey – (see attachment: Questionnaires)
- Consent and HIPAA form

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

Response:

N/A, no source records will be used to collect data about subjects.

*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:

N/A, no individual subject results will be shared with subjects or others.

*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:

No, study results will not be shared with subjects or others besides publication of study results in scientific journals and accompanying write-ups (e.g., conference presentations, press releases to promote published articles). All such publications will feature data in aggregate and no identifying information.

13.0 Study Timelines*

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

Response:

It is anticipated that recruitment for this study will take approximately 18 months. Recruitment will begin in Summer 2019, pending IRB approval.

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:

An individual subject's participation in the study will take place over about 6 weeks.

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 proposed study will take place over approximately 2 years.

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:

Research will be conducted in the Division of Behavioral Medicine Laboratory located in 151 Farber Hall, or remotely using UB's secure VPN in accordance with laboratory emergency procedures. 151 Farber Hall is secured suite with multiple private rooms. For this study, all participant contact will be remote (online or phone), and study staff will utilize computer/phone stations within 151 Farber Hall for these contacts. The study team may receive some additional office space in Farber Hall over the next 1-2 years. If study staff are seated in these offices, participant contact could take place in these additional offices within Farber Hall. These locations would have the same security features as the 151 Farber Hall location (door able to be closed and locked to ensure security and a private space for speaking with participants, computers password-protected, files saved on secure server, etc.).

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:

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

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

Response:

☒ **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:

All faculty, staff, and students on this protocol have completed CITI training. Additionally, all staff and research assistants working with human subjects in the Child Health and Behavior Lab undergo a Background Check.

Dr. Stephanie Anzman-Frasca (PI) and Drs. Leonard Epstein and Leone (co-Is) have extensive experience in behavioral and/or community research. Student

Research Assistants Kelseanna Hollis-Hansen, Sara Tauriello, and Eunice Mak have prior experience collecting data from children and with community outreach.

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:

It is planned for the PI to devote about 5-15% effort to this study while it is taking place, with more effort anticipated at the beginning and end of the project. It is expected that study staff and students will spend about 5-20 hours per week on this project, depending on their particular role.

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:

We do not anticipate that subjects will need medical or psychological resources as a result of the study.

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 personnel working on the project are required to complete the CITI training as required by the IRB. Additionally, all study staff will be trained on data collection procedures by senior team members (the PI, graduate students working on the project, and/or Eunice Mak, a senior undergraduate student with substantial research experience). The PI will provide initial training and continued oversight when students assume any leadership roles on the study.

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:

☒ **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:

The recruitment procedures described in this protocol make use of posted flyers web postings, and secure databases of interested potential participants – methods approved by previous IRB committees. With regards to public postings, participants may call the laboratory or complete the online screening questionnaire of their own free will, and thus are controlling access to their privacy.

Other participants will be recruited using secure databases of interested participants maintained by the Division of Behavioral Medicine, Independent Health, the Center for Translational Sciences Institute (CTSI) and I2B2.Potential participants have signed up for these databases of their own free will. All recruitment details will be kept confidential and private. During the initial phone or online screening, data will be collected in the secure laboratory environment and will be recorded within password-protected files, to which only select staff have access. All information will be treated in strict confidence to the extent provided by the law.

All study data will be stored on a secure password-protected server, UBBox, and/or external hard drive locked in a cabinet in a secure room (151 Farber). Only the PI and members of the research staff will have access to the data. Personally identifiable information will be stored separately from coded data. A file linking participant identities with participant ID numbers will be stored separately from these data sources and will be password-protected and accessible only by the PI and senior Child Health and Behavior Lab staff. Participants' identities will not be linked with any published results.

Participants will be told they have the right to refuse to answer any question that makes them uncomfortable and to stop participating in the study at any time should they so choose.

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:

Participants will indicate their consent after reviewing consent forms and having the chance to ask the study team any questions. A HIPAA authorization will be completed before the research team can access medical information about participants' diabetes status and/or diabetes risk status (See attachment: Consent and HIPAA form). Then, HIPAA forms will be used to collect information needed to access information about participants' diabetes status and/or diabetes risk status. Physicians will be contacted using their modality of choice; this may include phone, email, fax, or in-person communication.

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:

Linear mixed models will be used to test effects of the interventions on total calories, carbohydrates, sugar (total sugar and/or added sugar), and nutritional quality of grocery purchases, with study group, time, and their interaction as factors. Primary comparisons will be between-groups comparisons of these variables at post-test. We will also examine whether these variables differ overall by study group and whether changes in these variables differ by study group. We will conduct each analysis once for the total cart and then again examining these variables relative to household size and for items that the respondent indicated they would be consuming. We will conduct parallel analyses with total dollars spent each week and with DASH diet scores as outcomes to examine effects on spending and intake. We will also explore whether effects differ for participants with prediabetes vs. diabetes and whether results change when adjusting for food purchases beyond the target stores. Finally, we will test for relationships between purchases (calories, carbohydrates, and sugar (total sugar and/or added sugar)) and intake (DASH diet scores). We will also explore whether results differ when considering shopping trips completed by the participant only (vs. all trips for the household).

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:

To estimate the sample size needed for this study, effect sizes from the most similar existing study were used: a proof-of-principle study examining the effects of defaults, incentives, and education strategies on healthfulness of grocery purchases among undergraduate students (Coffino & Hormes, 2018, Obesity). Based on the observed differences in calories purchased at post-test between defaults and education control groups (Cohen's d=0.96), 15 participants would be needed for the primary comparison in the present study, with alpha=.05 and power=.80. We repeated this analysis using the difference between controls and

the prior study's intermediary group (incentives; Cohen's d=0.44) to conduct a more conservative sample size calculation, given our interest in detecting effects on purchasing between our intermediary group (*Online*) and the other groups. This calculation yielded a sample size of 54. We increased this to account for participants lost during the run-in period (i.e. failure to confirm diabetes diagnosis, failure to complete baseline procedures) as well as participants lost due to attrition, with a plan to enroll up to 100 participants.

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

Response:

Some data will be entered directly by participants (online questionnaires). All other study data will be entered by trained staff: study staff will enter participant responses into online forms while phone screening/phone interviews are completed. Study staff will also enter information from receipts into NutritionistPro (e.g., nutrition information) and Microsoft Excel (e.g., dollars spent) for analysis of study aims. Entered data will be double entered and/or checked for quality control.

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:

All electronic study data will be stored on a secure server (the S drive within the School of Medicine and Biomedical Sciences), UBBox, and/or external hard drive locked in a cabinet in a secure room (151 Farber). Any paper forms will be stored in a locked file cabinet in 151 Farber. Only the PI and members of the research staff will have access to the data. Personally identifiable information (e.g., HIPAA forms/addresses) will be stored separately from coded data. A file linking participant identities with participant ID numbers will be stored separately from these data sources and will be password-protected and accessible only by the PI and senior Child Health and Behavior Lab staff. Participants' identities will not be associated with any published results.

Only study staff associated with the project will have access to the data. Identifiable data and any links to identifiable data will be kept in the aforementioned secure locations for up to ten years after the study, at which point

they will be destroyed. At that point, the coded data will be de-identified, and such data will be kept indefinitely.

No information will be collected from social media sites. Any participants who see recruitment materials on these websites will be directed to connect with the researchers via phone, email, or screener survey, and any information exchanged from there will be protected as described herein. Potential participants will view these advertisements on public pages/sites of their own free will, and should they decide to comment on the post, they will do that of their own free will, with this information not used by the research team in any way.

20.2 A. How long will the data be stored?

Response:

Identifiable data and any links to identifiable data will be stored for up to ten years following study completion, after which the data will be destroyed. Upon destruction of identifiable data, coded data will be de-identified and then retained indefinitely.

20.3 A. Who will have access to the data?

Response:

Only study staff working on the project will have access to the data.

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

Response:

Dr. Anzman-Frasca is responsible.

20.5 A. How will the data be transported?

Response:

Data will not be transported locally; it will remain at the local site.

B. Confidentiality of Study Specimens

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

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

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:

Since the proposed study poses no greater than minimal risk to participants, a DSMB is not necessary. The Principal Investigator, Stephanie Anzman-Frasca, will be responsible for ensuring data integrity and safety monitoring of human subjects who are involved in the research.

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

Response:

Data will be checked to make sure that:
A. All study data are coded with a unique participant ID.
B. All electronic data are stored securely on password-protected server, UBBox, and/or external hard drive locked in a cabinet in a secure room (151 Farber).
C. When the results of the study are presented and/or published, no individual

participant will be identifiable. Demographic data will only be presented in aggregate. Identifiable data will be retained for up to ten years.

21.3 Describe any safety endpoints.

Response:

Since this study involves less than minimal risk, there are no 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:

N/A, this study involves less than minimal risk so safety information will not be collected.

21.5 Describe the frequency of safety data collection.

Response:

N/A, this study involves less than minimal risk so there will be no safety data collection.

21.6 Describe who will review the safety data.

Response:

N/A, this study involves less than minimal risk so no one will review safety data.

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

Response:

N/A, this study involves less than minimal risk so there will be no revision of safety data.

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

Response:

N/A, this study involves less than minimal risk, so there will be no statistical tests for safety data.

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

Response:

N/A, this study involves less than minimal risk so there will be no stopping criteria.

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:

Participants who do not comply with study guidelines at baseline (including guidelines for receipt submission) will not be randomized for further participation and withdrawn from the research. Participants also have the ability to stop participating at any time if they so choose.

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:

Participants will be debriefed about the nature of the study and the reason for their removal.

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:

Participants can withdraw from the research at any time. If participants withdraw, no further data will be collected, but any information that had been provided may be retained and analyzed.

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:

There is no greater than minimal physical, psychological, social, or legal risks associated with participating in the study.

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

Response:

We do not anticipate participants reaching high or prolonged levels of distress as a result of participating in this study.

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

Response:

N/A, there are no currently unforeseeable risks to 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:

Pregnant women are not the focus of this study, but it is possible that one of the participants could be pregnant. The participant's roles in this study are to grocery shop, submit photographs of receipts, and complete questionnaires. Therefore, there are no risks to an embryo or fetus beyond those in everyday life.

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

Response:

There are no risks to others who are not subjects.

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:

Potential benefits include: participants being more likely to choose healthy options later on after exposure to the recipe cards provided to all groups or to our interventions (Defaults and Online groups).

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:

Subjects will pay for their own groceries as they would normally do. Participant payments (detailed further below) account for the additional costs of shopping online during the 3 intervention weeks. Therefore, subjects should not be responsible for any new/added costs as a result of participation in the study.

☐ **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:

All participants will receive up to $75 for their participation in the study, with $20 provided after completing baseline measures ($20), $10 after each intervention measure, and another $25 provided after post-test. Participants will be paid as they complete study tasks using Clincard. Clincards will be provided after all screening procedures are completed, and eligibility (and interest in participating) has been determined. Payments during intervention weeks will also include reimbursements for typical costs of online shopping in Online and Defaults groups, given that these participants typically shop in-person but are being asked to shop online as part of the study. The typical cost of online shopping was estimated by applying Instacart service fees (5% of purchase) and data on average mark-ups on Wegmans items purchased via Instacart (~15% of purchase) to weekly grocery shopping amounts estimated using the USDA's official food plans (moderate-cost plan for a given family size: https://www.cnpp.usda.gov/sites/default/files/CostofFoodMar2019.pdf). We also added the estimated cost of delivery ($5.99) to the estimates. The payment to subsidize costs of online shopping will be calculated in this manner for each participant based on their family size. For example, for a 19-50-year-old single female participant, the USDA's moderate cost plan estimates $59.60 in weekly food expenditures. Calculating the costs of online shopping indicated above (service fees, item mark-ups, and delivery) at this budget, we will provide an additional $53.73 to this participant over the course of the study ($17.91 per intervention week). For a family of two adults, this estimate changes to $103.47 or $34.49 per intervention week. As with other study payments, these payments will be provided to participants via Clincard provided they complete the study activities of the week.

☐ **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 27.0.

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

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

Response:

The study is designed, so that all study contact will be remote (online, phone, or paper mail), allowing participants to complete consent from the private location of their choosing (such as their own home). The initial screening questionnaire can be done via phone or via online survey; in both cases, information will be recorded using online survey software and stored in password-protected files. If a prospective participant consents to the information from the phone screen being stored, there is a button to click that indicates that they have been asked and agreed.

If the prospective participant meets the criteria gathered from the initial screen and is interested, they will move on to the consent process. Study information will be provided electronically, with opportunities for potential participants to ask study staff any questions they may have and then indicate their consent to participate electronically if interested. After consent is obtained, participants will move onto the other steps of the study described herein, with all study data stored securely within the team's research offices in Farber Hall and/or on a secure electronic platform (password-protected server, UBBox).

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:

Participants will be able to take as much time as they need to read and understand the consent documents, and ask any questions.

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:

Subjects will only consent once to participating in the study.

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 26.8)*

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 6.4 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 26.9)

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 26.13)*

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

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 27.0)*

*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:

We are requesting a waiver of consent for the screening survey as described herein. Participants will access the screening survey of their own free will and indicate that they wish to proceed with the questions after hearing the description of the study. Because our screening interactions are all via phone and online, the research could not practicably be carried out without the waiver.

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:

This research does not involve a waiver for planned emergency research.

30.0 Process to Document Consent

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

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:

☒ 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. See "WORKSHEET: Communication and Responsibilities (HRP-830).":*

- *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 (see "WORKSHEET: Communication and Responsibilities (HRP-830)"):

- *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. (See "WORKSHEET: Communication and Responsibilities (HRP-830).")*

- *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 elsewheres 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: