Information Sheet- Client

Official title: Identifying food pantry client and staff preferences for nutritious no prep ready-to-eat meals versus ingredient bundles as an effort to increase food security, improve nutrition, and promote well-being

NCT number: NCT05593510

IRB Approved date: 02-02-23

Information Sheet about participation in a research study titled: Identifying food pantry client and staff preferences for nutritious no prep ready-to-eat meals and ingredient bundles

To be conducted at
Crossroads Community Services
4500 S Cockrell Hill Rd, Dallas, TX 75236

Who is conducting the study? Dr. Kelseanna Hollis-Hansen an Assistant Professor at UT Southwestern Medical Center is conducting this study.

What is the purpose of the research? *To learn how people that use the food pantry feel about no prep ready to eat meals and meal kits.*

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who is asked to participate? 1) Adult 18 years of age or older; 2) able to read, write, and speak English or Spanish fluently; 3) able to give informed consent; 4) a pantry user at Crossroads; 5) no illnesses, dietary restrictions, allergies, or sensitivities that would put the participant at-risk of harm from consuming study foods; and 6) willing to participate.

Do you have to be in this study? You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this study, it will not affect your relationship with UT Southwestern staff or Crossroads Community Services staff. Whether you participate or not will have no effect on your legal rights or the services you receive at Crossroads now or in the future. The study will take place over a period of 14-days, but data will only be collected on two days (at your first appointment and your second appointment). The maximum active time commitment for this study is 2-hours and 30-minutes. 1-hour and 30-minutes at the first appointment and 1-hour at the follow-up (second) appointment.

What are the Research Procedures? If you decide to participate you will first be assigned by chance like flipping a coin, into one of two groups. You have a 50/50 chance of being assigned to either group and you cannot switch groups. One group will select and receive meal kits, which are packages of food with a recipe that explains how to make different meals out of the ingredients. In the other group, participants will receive no prep ready to eat meals. Each group will have the opportunity to select the same number of meals (up to 84 meals), it will just be packaged differently.

After you're assigned to one of the two groups, you will complete a survey about yourself (age, race/ethnicity, etc.), your current use of Crossroads food pantry, your diet, and how you feel about the study meals. When you are done with the survey you will select the meals you would like to receive. Once you have chosen your preferred meals and received the meals, you will be scheduled for a follow-up appointment at Crossroads.

In-between your appointments you and the members of your household that you selected food for will be asked to eat the meals you selected and think about how they taste, if you like or dislike the meals, and if you would choose them if they were offered at Crossroads in the future. You will also receive reminder phone calls, texts, and/or emails to remind you to return for your follow-up appointment. You will choose how we contact you. For example, if you want us to call you, we will call. If you want us to text, we will text.

At your second appointment, you will complete similar surveys as the ones you completed at the first appointment. When you are done with the surveys you will be thanked and paid for participating in the study.

What are the Risks and Benefits? Potential risks are minimal and include potential discomfort with answering personal questions or trying new study foods and loss of confidentiality. You will be assigned a special code instead of using your name to help reduce the confidentiality risk. This study is voluntary, and you do not have

to answer questions that make you feel uncomfortable, you do not have to eat any foods you do not want to eat, and you do not have to participate to continue receiving services at Crossroads. You may not receive any personal benefits from being in this study. We hope the information learned from this study will benefit other people in the future.

Costs and Compensation There are no costs associated with this study. You will receive all study meals at no cost to you. Like all food you receive from Crossroads, the meals are free. When you complete the study, you will receive a $100 ClinCard, which is a prepaid credit card. You will have to provide your social security number for the private ClinCard system to avoid paying taxes on the study payment OR you can choose not to provide your social security number and instead pay a 24% tax on the payment, in which case the total payment will be lowered to $76 – you get to choose your preference. If cards are lost or stolen, no replacement cards will be provided, so be sure to keep track of your ClinCard.

Confidentiality Information we learn about you in this study will be confidential. If we publish the results of the study in a scientific journal or book, we will not identify you. Any data collected as part of this study may be used for future research studies without your consent. Any information that identifies you will be removed before it is used for future research studies.

Certificate of Confidentiality:
To help us further protect your information, the investigators will obtain a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). This Certificate adds special protections for research information that identifies you and will help researchers protect your privacy.

With this Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you in any judicial, administrative, legislative, or other proceeding, whether at the federal, state, or local level. There are situations, however, where we will voluntarily disclose information consistent with state or other laws, such as:

- to DHHS for audit or program evaluation purposes;
- information regarding test results for certain communicable diseases to the Texas Department of State Health Services, including, but not limited to HIV, Hepatitis, Anthrax, and Smallpox;
- if you pose imminent physical harm to yourself or others;
- if you pose immediate mental or emotional injury to yourself;
- if the researchers learn that a child has been, or may be, abused or neglected; or
- if the researchers learn that an elderly or disabled person has been, or is being, abused, neglected or exploited.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research study. In addition, the researchers may not use the Certificate to withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information (including your employer or an insurance company). This means that you or your family must also actively protect your privacy.

A Certificate of Confidentiality does not represent an endorsement of this research project by the Department of Health & Human Services or any other Federal government agency.

Contact Information for questions or comments:
The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments, or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

Before you agree to participate, make sure you have read (or been read) the information provided above; your questions have been answered to your satisfaction; and you have freely decided to participate in this research.

The QR code below links to the study ***eligibility*** screener to determine if you are eligible to participate. The eligibility screener will include personally identifiable information – your name, age, address, and phone number. If you are eligible and decide to participate, your personal information will be linked to a unique study ID, and a study staff member will use that ID to set-up the study surveys, so your name does not have to be linked to the surveys you take during the study appointments.

This form is yours to keep.

Information Sheet- Food Pantry staff

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To be conducted at
Crossroads Community Services
4500 S Cockrell Hill Rd, Dallas, TX 75236

Who is conducting the study? Dr. Kelseanna Hollis-Hansen an Assistant Professor at UT Southwestern Medical Center is conducting this study.

What is the purpose of the research? To learn how Crossroads staff and volunteers feel about no prep ready to eat meals and meal kits and whether they're feasible to regularly distribute from the pantry.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who is asked to participate? 1) Adult 18 years of age or older; 2) able to read, write, and speak English fluently; 3) competent to give informed consent; 4) a current paid or volunteer staff member at Crossroads for at least the past 3-months and familiar with study and pantry operations; and 5) willing to participate.

Do you have to be in this study? You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this study, it will not affect your relationship with UT Southwestern or Crossroads Community Services. Whether you participate or not will have no effect on your legal rights or your job security at Crossroads Community Services. If you choose to participate you will complete a brief survey (<15 minutes) and a one-on-one interview that will last up to 30-minutes.

What are the Research Procedures? You will be asked to answer an online survey on feasibility and satisfaction of no prep ready to eat meals and meal kits, such as the resources needed to carry out either food distribution strategy longer term, any challenges experienced with distributing meal kits or no prep ready to eat meals, or things that worked and didn't work about each strategy. Surveys will be followed by one brief (30-minute) virtual interview conducted with UT Southwestern study staff on Microsoft Teams where you can directly voice any challenges or preferences that come up when implementing either approach.

What are the Risks and Benefits? Risks are minimal and include potential discomfort with answering personal questions and loss of confidentiality. To reduce the risk, you will be assigned a special code instead of using your name. This study is voluntary, and you do not have to answer questions that make you feel uncomfortable, and you do not have to participate to continue working or volunteering at Crossroads. You may not receive any benefits from being in the study. We hope the information learned from this study will benefit other people in the future.

Costs and Compensation There are no costs associated with this study. When you complete the study, you will receive a $75 ClinCard, which is a prepaid credit card. You will have to provide your social security number for the private ClinCard system to avoid paying taxes on the study payment OR you can choose not to provide your social security number and instead pay a 24% tax on the payment, in which case the total payment will be lowered to $57 – you get to choose your preference. If cards are lost or stolen, no replacement cards will be provided, so be sure to keep track of your ClinCard.

Confidentiality Information we learn about you in this study will be confidential. If we publish the results of the study in a scientific journal or book, we will not identify you. Any data collected as part of this study may be used for future research studies without your consent. Any information that identifies you will be removed before it is used for future research studies.

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- to DHHS for audit or program evaluation purposes;
- information regarding test results for certain communicable diseases to the Texas Department of State Health Services, including, but not limited to HIV, Hepatitis, Anthrax, and Smallpox;
- if you pose imminent physical harm to yourself or others;
- if you pose immediate mental or emotional injury to yourself;
- if the researchers learn that a child has been, or may be, abused or neglected; or
- if the researchers learn that an elderly or disabled person has been, or is being, abused, neglected or exploited.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research study. In addition, the researchers may not use the Certificate to withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information (including your employer or an insurance company). This means that you or your family must also actively protect your privacy.

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This form is yours to keep.