Information Sheet about participation in a research study titled: Medically tailored groceries and food resource coaching for patients of a safety-net clinic

To be conducted at
Parkland Health - Parkland C.V. Roman Health Center
3560 W. Camp Wisdom Rd, Suite 100 Dallas, TX 75237

Who is conducting the study? Dr. Kelseanna Hollis-Hansen, PhD, MPH, Dr. Jaclyn Albin, MD, and Dr. Tammy Leonard, PhD researchers at UT Southwestern Medical Center and Parkland Health are conducting the study.

What is the purpose of the research? To determine feasibility and to learn how people that use the Parkland C. V. Roman Health Center feel about receiving services from a free community food market.

Who is participating in the research? 1) Adults 18 years of age or older; 2) Income less than 185% of the federal poverty threshold (self-report); 3) diagnosis of a diet-related chronic disease (i.e., Diabetes, Dyslipidemia, Hypertension) verified by electronic health record; 4) residence in one of the 18 ZIP codes served by Crossroads Community Services that surround the RedBird clinic (75203, 75208, 75211, 75212, 75216, 75217, 75224, 75232, 75233, 75236, 75237, 75241, 75249, 75052, 75104, 75115, 75116, 75137); 5) able to give informed consent; 6) willing to participate; 7) not moving or planning to move from the area within the next 6-months.

Do you have to be in this study? You do not have to participate if you don't want to, and you may stop the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with Parkland, Crossroads, or UT Southwestern. Whether you participate or not will have no effect on your legal rights or the quality of your health care now or in the future.

This study will take place over a period of four and a half months, but data will only be collected on two days (at your first and fifth appointment). The maximum active time commitment is 6 hours. 1-hour and 30-minutes at the baseline appointment, 30-minutes to 1-hour at the second, third, and fourth appointment, and 1-hour and 30-minutes at the fifth appointment.

What are the research procedures? If you're interested, you will complete a screening survey to determine eligibility. If you are eligible and decide to participate, you will be randomly assigned by chance like drawing numbers out of a hat into one of three groups. You have a 33% chance of being assigned to any group and you cannot switch groups.

At the initial appointment, participants will consent, enroll in REDCap, and be randomized. The study team will explain the group you were randomly assigned to and schedule your appointment with Crossroads market for within the next two weeks, depending on your schedule.

Once you're assigned to one of the three groups, you will complete a questionnaire about yourself (age, gender, race/ethnicity, etc.), your diet, and nutrition-related behaviors. Questionnaires will be delivered using REDCap. You will also complete a follow-up questionnaire at the fifth appointment. Questionnaires are estimated to take 20-30 minutes.

Participants in all three groups will then complete 4 monthly in-person visits to Crossroads pop-up market, a free community food market, which is located onsite at RedBird Mall. Participants in one group will complete food resource coaching at the Crossroads market and be advised to select medically tailored groceries from the inventory. Participants in the other group will also be shown the medically tailored groceries but will not receive food resource coaching. Participants in the third group will independently make their food selections from the market with assistance from a volunteer or Crossroads staff member.

After you have completed your appointment and selected your food, you will be scheduled for a follow-up appointment in one month.

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Additionally, 60 participants will be randomly selected to complete one-on-one telephone interviews with a study team member. This will take place after the initial and fifth appointment, after completing the questionnaires. Questions will cover techniques to best screen and link patients to supportive services and community resources. These interviews are estimated to take 30-45 minutes. Additional payments will be provided for these interviews.

What are the risks and benefits? Potential risks are minimal and may include slight discomfort with answering personal questions 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, and you do not have to participate to continue receiving services at Parkland. As a part of this study, you will receive free nutritious food from Crossroads market, which we anticipate will benefit participants. We hope the information learned from this study will also benefit other people in the future.

Costs and Compensation. There are no costs associated with this study. You will receive pantry services and groceries at no cost to you. You will receive a set of cooking utensils after completing the consent process, and you will receive $15 after completing the baseline questionnaire and attending your first appointment at Crossroads RedBird. When you complete the follow-up questionnaire at the fifth appointment, you will receive another $15.

If you complete all study activities, you will be given an additional $15 bonus payment at the end of the study. This includes completing the two questionnaires, plus attending all pantry appointments and coaching appointments (if applicable). This makes the total study payment up to $45.

The 60 randomly selected participants that complete telephone interviews will receive an additional payment of $25 per interview, making their total study payment up to $95.

Confidentiality. Information we learn about you in this study will be handled in a confidential manner. 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.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)? Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include: *diagnosis of diabetes, dyslipidemia, and/or hypertension; height, weight, and body mass index*.

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We will get this information by using EPIC to access your health record.

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The Sponsor, American Heart Association, Inc. funding the study. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the research. The sponsor may look at your health information to assure the quality of the information used in the research.
- The members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center and Parkland Health and Hospital System
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?

In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the University of Texas Southwestern Medical Center or Parkland for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?

You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to:

Dr. Kelseanna Hollis-Hansen
UT Southwestern Medical Center
O'Donnell School of Public Health
5323 Harry Hines Blvd.
Dallas, TX 75390

If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the

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study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?

The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

How long will your PHI be used?

You agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

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.

This form is yours to keep.

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