Study Title: Evaluating the Effectiveness of a Multi-level Health-Related Social Needs Initiative

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VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Lyndsay Nelson, PhD
Study Title: Evaluating the Implementation of a Multi-level Social Drivers of Health Initiative
Institution/Hospital: Vanderbilt University Medical Center
Revision Date: 01/03/25

Name of participant: _____ Age: _____

Greetings, thank you for your interest. This form tells you about our research study. Please read carefully. We are happy to answer any questions. You will be given a copy of this consent form.

Key Information:

We are doing a study to learn more about a new project in the Vanderbilt primary care clinics. This project does two things: 1) it collects information from patients about their social needs, and 2) it offers help and referrals to patients who want support. We want to know about your experience with this project during a recent primary care visit and if it helps with managing diabetes and other chronic conditions.

If you join this study, you will need to complete two surveys: one now and one in six months. You can receive up to $50 for participating: $20 for the first survey and $30 for the second survey. The time it takes to complete the surveys may be inconvenient for you and you may feel nervous about some questions. Your survey responses will be assigned a study number with no personal identifying information and stored securely. Joining this study is your choice, and you can stop at any time.

Detailed Information:

Why are we doing this research and why are you asked to participate?
We are doing this study to learn more about a new project in the Vanderbilt primary care clinics. As part of the project, patients are being asked about their social needs. Social needs are things outside the doctor's office that can affect your health. These are things like difficulty with getting food, housing, or transportation. If patients have any social needs and want support, the clinic team will offer help and referrals to resources.

You are being asked to join this study because you were asked about social needs during a recent primary care visit. We want to learn about your experience with the project and if it helps with managing diabetes and other long-term health problems. Your participation can help us learn more about how social needs affect diabetes management.

Do you have to be in this research and can you stop if you want to?
You do not have to be in this study, and you can stop being in this study at any time. You may choose not to be in this study. This is not a treatment study, so there are no alternative treatments.

What will you do and how long will it take?
This study lasts 6 months. We will ask you to complete 2 surveys. The first survey will be completed now, and we will ask you to complete a second survey six months later. Each survey will take approximately 30 minutes to complete. You can complete these surveys online, over with the phone with someone from our study team, or we can send you a paper survey in the mail to complete and send back to us. The surveys will ask information about you, including your race, education, income, your health history, how you take care of your diabetes, and your perceptions of the project. The information you provide us is only for research purposes. It will not affect the care you receive at your clinic.

Also, some participants will be contacted about 3 months after completing the first survey to complete a 30-45 minute follow-up interview via phone or video chat, such as Zoom. The interview will ask more questions about your experience with the project. The interviews are considered research and are voluntary. They will be audio-recorded. Your interview information will be de-identified and will not be shared outside of our research team.

What good things might come from this study?
By being in this study, you can help us learn about the best ways to ask patients about their social needs and how to provide support. We also want to see if there is any benefit of this project to patients.

Are there any risks or discomforts for this study? Can anything bad happen to you?
The time it takes to complete the surveys may be inconvenient for you. You may feel nervous about answering certain questions. You do not have to answer any questions you do not want to answer.

What compensation will you receive for participating in the study?

If you join this study, you will earn up to $50 for completing the surveys. Specifically, you will get $20 for completing the first survey and $30 for completing the second survey 6 months later. If you complete a follow-up interview, you will receive an additional $50 in compensation.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

What happens if you choose to stop being in the study?
Joining this study is your choice, and you can stop at any time. You do not have to answer any questions you do not want to answer. If you decide to stop being in the study, this will not affect the care you receive at your clinic.

If you join and then change your mind and do not want your responses used, please contact Dr. Nelson in writing and let her know that you withdraw your consent. Her address is: Lyndsay Nelson, Division of General Internal Medicine & Public Health, Vanderbilt University Medical Center, 2525 West End Ave. Suite 450, Nashville, TN 37203.

Clinical Trials Registry:
A description of this clinical trial will be available on clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who can you talk to about this study?
If you have any questions about this research study, please feel free to contact the study team at (615) 601-0869. For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

What will you do with my data?
This research study is part of HEAN which stands for the Health Equity Action Network This research and HEAN are funded by NIMHD which stands for the National Institute on Minority Health and Health Disparities. NIMHD funds health research in people from groups with more illness or less access to care.

The survey data you provide us with for this study will have your personal information removed and then be shared with HEAN's Research Coordinating Center at the University of California San Fransisco (UCSF). Personal information are things like your name and contact information. Data with personal information removed is called de-identified data. Researchers may use de-identified data to learn more about long-term health among people at higher risk for disease. You will not receive any direct benefit from sharing your data, but sharing your

data may help researchers learn how to better help others like you in the future. NIMHD chose UCSF to hold the de-identified data from all HEAN studies in a database. Databases are collections of information stored on computer.

UCSF will keep your data securely. This means with extra protection. The database will only hold de-identified data. This means the database information will not hold data that can easily identify you.

- We will send these data to a secure National Institute of Health (NIH) database to store for future researchers to use. No one can easily identify you from these data.
- Other researchers may use these data for future research.

How will your confidentiality and privacy be maintained?
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. We may share some information about you for others to use for research, but to protect your privacy we will not share information that could identify you, like your name.

Your survey responses will be given a study number with no personal identifying information and stored securely. Only approved research staff can access this information. They will only use your personal information when necessary, like to pay you. Your payment information will not be linked to your other study information and will be stored securely to protect your privacy. All your information will be password protected and kept on a secure server for up to 6 years after the study ends. At that time, all data will be destroyed.

This study has support from the NIH. Therefore, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help. Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Your information may be shared with Vanderbilt or the government, such as the Vanderbilt University Institutional Review Board, the Office for Human Research Protections, and the National Institutes of Health, if you or someone else is in danger or if we are required to do so by law.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and have been given the opportunity to contact the research team. All my questions have been answered, and I freely and voluntarily choose to participate.

_____ _____
Date Signature of patient/volunteer

Do you agree to be contacted for future research studies? (please circle Yes or No)

Yes No