Informed Consent Form

Official Study Title: My Diabetes, My Community

IRB number: 20-0870

NCT Number: NCT04970810

Approval date: 12/16/2022

The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: IRB20-0870 Name of Subject: _____
Medical History Number: _____

STUDY TITLE: My Diabetes, My Community

Doctors Directing Research:

Elbert Huang, MD, MPH Address: University of Chicago, 950 E. 59th St., AMB B214, Chicago, IL 60637 Telephone number: 773-834-3419

Stacy Tessler Lindau, MD, MAPP Address: University of Chicago, 5841 S. Maryland Ave. MC 2050, Chicago, IL 60637 Telephone number: (773) 834-8986

Study Manager:
Jacqueline Kanoon, MBA, MPH Address: University of Chicago, 5841 S. Maryland Ave. MC 2007B, Chicago, IL 60637 Telephone Number: 773-702-9521

KEY INFORMATION

We are asking you to choose whether or not to volunteer for a research study about personalized diabetes care and older adults. This section gives you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, contact anyone on the research team listed above.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to help older adults with diabetes better address their diabetes care goals. We are studying different ways to personalize care for older adults with diabetes. We want to learn if one way is better than the others. You will be randomly assigned to receive 1 of 3 different types of support for diabetes management. You have an equal chance of being assigned to each group, but you will not know which group you are assigned to. By doing this study, we hope to learn about the best ways to personalize care for older adults with diabetes. Your participation in this research will last about one year. All participants will be asked to complete 3 surveys and to allow the study team to collect information from your medical records and health insurance claims.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

While there is no direct benefit for participating in this study, it is possible that you may see an improvement in your health through additional screening for risks associated with chronic diseases, improved communication with your physician, referrals to beneficial resources that you may not be aware of, which could improve your outcomes. There may also be a benefit to society by contributing to research to support personalized healthcare for older adults with diabetes. The majority of patients at the University of Chicago hospitals are African American. This study aims to fill knowledge gaps about

how to personalize diabetes care for older African American adults with diabetes. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
The main reason why you might not choose to volunteer for this study is the risk of loss of confidentiality (privacy). The other reason you might not choose to volunteer for this study is the risk of psychological and/or emotional discomfort associated with the survey questions. You can refuse to answer any questions. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?
Taking part in this study is voluntary. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

You may choose not to participate at any time during the study. You will not lose any services, benefits or rights you would normally have if you choose to leave the study. The University of Chicago/University of Chicago Medical Center will not condition (withhold or refuse) treating you on whether you sign this Authorization or revoke your authorization at a later time. If you do not sign this form, you will not receive the research-related intervention(s).

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The people in charge of the study are Elbert Huang, MD, MPH and Stacy Tessler Lindau, MD, MAPP of the University of Chicago. If you have questions, suggestions, or concerns regarding this study or you want to with withdraw from the study, you can contact Dr. Lindau or Dr. Huang. Dr. Huang's phone number is: (773) 834-9143. Dr. Lindau's phone number is: (773) 834- 8986.

For questions about your rights as a research subject, please contact the University of Chicago Biological Sciences Division Institutional Review Board at 773-702-6505.

OTHER KEY INFORMATION
We also want to tell you that some of the information tools we are using for this study are provided by UniteUs, LLC. Dr. Lindau, who is the principal investigator on this study, founded a company called NowPow which developed some of the information tools being used for this study. This company has now been acquired by a company called UniteUs, and Dr. Lindau owns equity in this company and is a paid advisor to UniteUs. Both Dr. Lindau and the University of Chicago do stand to potentially receive financial benefit from this company if these tools prove to be successful. If you have any questions about this information, you can call Dr. Lindau. Her phone number is (773) 834-8986.

DETAILED CONSENT

WHAT IS INVOLVED IN THE STUDY?
About 612 people will take part in this study at the University of Chicago.

As part of this study, you will receive support for the care of your diabetes, which might include monthly calls with a member of our study team, or personalized referrals for community-based support. Calls could include information on general health topics, a diabetes care needs assessment, and referrals

to community-based support could include where to get medications or assistance with housing or nutrition.

You will be randomly assigned to receive some or all of these diabetes support measures. You have an equal chance of being assigned to each group, but you will not know which group you are assigned to.

You will have the opportunity to receive messages from us and send messages to us throughout the study, either over text and also by phone or e-mail.

After signing this consent form, you will get a text message from us. You will have the opportunity to receive messages from us and send messages to us throughout the study.

You will be asked to complete surveys after signing this consent form and again at 6 and 12 months. These surveys may be given over the phone or online, and will take approximately 25 minutes to complete each survey.

The study team will also look at and collect information from your electronic medical record and your health insurance claims. We will only collect data pertaining to the time you are in the study The only information we would get from your health insurance claims are:
1. The number of times you go to the doctor, have a hospital stay or go to the emergency room;
2. The dates of those visits;
3. Any charges associated with those visits

During this study, Dr. Huang and his research team will also collect information about you for the purposes of this research. This includes your name, phone number, medical record number, insurance information, email address, mailing address, birth date, blood pressure and A1c values, medication, weight, demographic information, and the frequency of referrals to telephonic care management, and the source of those referrals.

In the future, identifiers associated with your data could be removed from the data. The de-identified data could then be used for future research by our research team or other researchers without notifying you or asking your permission for this use.

Dr. Huang or Dr. Lindau may decide to take you off of the study without your consent if:

- You are unable to meet the requirements of the study or your medical condition changes;
- New information becomes available that indicates that participation in this study is not in your best interest; or
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

Psychological and/or emotional discomfort associated with the survey questions is possible, but this is unlikely. You can refuse to answer any question or stop taking the survey(s) at any time.

If during the course of the study we believe you are in immediate health danger, we will call 911. When the paramedics arrive, you can refuse treatment if you do not want to go to the hospital. If you choose to go to the hospital, the researchers are not responsible for any costs that you may have from going to the hospital.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?
Being in this study may help you directly. By tracking your personal diabetes goals in your medical record, you may have improved communication with your physician. If you are linked to additional services, you may have improved management of your diabetes. We hope the information learned from this study will benefit other individuals with diabetes in the future.

WHAT OTHER OPTIONS ARE THERE?
Instead of being in this study, you may choose not to participate. If you do not want to participate but would like some of the information provided in the study, we would be happy to provide you with this information.

WHAT ARE THE COSTS?
There will be no costs to you or your insurance company resulting from your participation in this research study. However, you or your insurance company will be responsible for costs related to your usual medical care.

WILL I BE PAID FOR MY PARTICIPATION?
For participation in this study you will receive a $25 gift card in the mail in compensation for completion of the survey today. You will receive an additional $50 gift card in the mail after completing the 6-month survey, and finally, you will receive a $75 gift card in the mail for completing the final 12-month survey at the end of the study. If you do not complete all of the surveys, you will not receive the $50 and $75 gift cards. You may receive up to $150 for participating in this study.

You will be entered into a raffle to win a $50 gift card if you participate in 4 monthly phone calls (up to 3 times in the study period). Each verification (one at 4-months, one at 8-months, and one at 12-months) counts as one raffle entry. Within 3 months of each verification, you will receive an email notification about whether you are the raffle winner. If you're the winner, you will receive your compensation by mail within 4 weeks of the email notification.

WHAT ABOUT CONFIDENTIALITY?
There is a risk of potential loss of confidentiality. To minimize this risk, study records that identify you will be kept confidential. Data will be stored on a secure password-protected, HIPAA-compliant hospital server, and coded, with access limited only to study staff. This consent form will be your only paper record and it will be stored in a locked cabinet within locked offices only accessible by the study team. All researchers working with this information, including the people collecting and accessing secure information, go through ethics training about conducting research with human subjects.
The results from tests and/or procedures performed as part of this study may become part of your medical record. Any research information in your medical record will be kept indefinitely.

During this study, Dr. Huang and his research team will collect protected health information (PHI) about you for the purposes of this research. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago. Protected Health Information (PHI) consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. Some of this information will come from your medical record. The information to be used on this study includes your phone number, email address, mailing address, birth date, blood pressure and A1c values, medication, weight, demographic information, and the frequency of referrals to telephonic care management, and the source

of those referrals. This information will be used to collect the data needed for this study look at the impact of the study interventions and to mail your gift cards to you.

We will collect your name and telephone number into the study to conduct the follow-up surveys. This information will be sent to a text messaging service called Mosio so we can send you text messages about the study. Your name, address and date of birth may also be sent to an information tool called NowPow. If so, this information will be kept by Mosio and NowPow only for the duration of this study. When the study is over, both Mosio and NowPow will destroy this information. When the study is over, both Mosio and NowPow will destroy this information. Both Mosio and NowPow meet the University of Chicago Medicine's security standards. We will collect your name and address in order to pay you for your participation; this information will be given to our accounting department for reconciliation of your payment.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Office of Human Research Protections (OHRP). Representatives of the University of Chicago, including the Institutional Review Board (a committee that oversees the research) and the Office of Clinical Research may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

Once information is shared outside the University of Chicago, please note that your identifiable health information may be shared with someone else. The same laws that the University of Chicago must obey may not protect your health information.

During your participation in this study, you will have access to your medical record. Dr. Huang is not required to release to you research information that is not part of your medical record.

This consent form will be kept by the research team for at least six years. The study results will be kept in your research record and be used by the research team. The study results will be kept in your research record and be used by the research team until completion of the study.

At the time of study completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from study results.

Data from this study may be used in medical publications or presentations. Your name and any other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time. We may also share de-identified data with collaborators or others for research purposes.

Individual research results from this study will not be shared with you.

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.

To help us protect your privacy, the National Institutes of Health (NIH) has issued a Certificate of

Confidentiality for this research. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. There are specific circumstances when the Certificate of Confidentiality does not prevent researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research. For example: suspected child abuse, elder abuse, or urgent risk of harm to self (suicide) or others (homicide).

WHAT ARE MY RIGHTS AS A PARTICIPANT?
If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Huang in writing at the address on the first page. Dr. Huang or Dr. Lindau may still use your information that was collected prior to your written notice.

You will be given a signed copy of this document. Your authorization to use and disclose your health information does not have an expiration date.

MAY WE CONTACT YOU IN THE FUTURE?

Lastly, we would like to be able to contact you in the future in the event that there are other studies that you may be interested in or eligible for. We will keep your name, telephone number, address and email address in order to re-contact you. This portion is optional; if you do not agree to be re-contacted, it does not affect your ability to be in the current study or any services that you would typically receive as part of your standard of care at the U of C.

__ Yes, I agree to be re-contacted for future research
__ No, I do not agree to be re-contacted for future research

Initials of Subject: ___
Date:_____

CONSENT

SUBJECT
The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject: _____
Date: _____ Time: _____ AM/PM (Circle)

PERSON OBTAINING CONSENT
I have explained to _____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject.

Signature of Person Obtaining Consent: _____
Date: _____ Time: _____ AM/PM (Circle)