Electronic Consent

Title of Research Study: Promoting Preconception Care and Diabetes Self-Management among Reproductive-Aged Women with Diabetes: The PREPARED Trial

IRB Study Number: STU00214604

Investigator: ***Stacy Bailey, PhD MPH***

Supported By: This research is supported by the National Institute of Diabetes and Digestive and Kidney Diseases.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you are a female, age 18-44, with type 2 diabetes. You cannot participate in this study if you are currently pregnant.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
This study is being done to test an educational strategy to help women better manage their diabetes and reproductive health.

How long will the research last and what will I need to do?
We expect that you will be in this research study for 3 months.

You will be asked to complete 3 telephone interviews during this study. You will also be asked to complete a survey over text message. This survey consists of 6 questions and is usually completed in 3 minutes. You will complete this text survey as part of your first interview.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?
There always exists the potential for loss of private information; however, there are procedures in place to minimize this risk. You may also stop participation at any time or skip any question if you feel uncomfortable.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Electronic Consent

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include a better understanding of diabetes self-care activities and better understanding of diabetes and preconception care.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (312) 503-3272.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 840 people will be in this research study.

What happens if I say "Yes, I want to be in this research"?

If you participate in this research study, you will be randomized to be in 1 of 2 groups. The group you are assigned to will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given either treatment. The groups are:

(1) Usual Care Group: Patients in the usual care group will receive the current standard of care.
(2) PREPARED Strategy: Patients assigned to the intervention group may receive tools at their index visit and post-visit, including additional diabetes counseling, diabetes educational materials, and text messages related to diabetes self-care behaviors.

Interviews

All participants, regardless of study arm, will be asked to complete 3 interviews. During your interviews, you will be asked questions about your diabetes, the medications you take, how you understand health information, questions related to reproduction and contraception, and questions about your background. The first interview will take place over the phone and will take less than an hour to complete. After this interview, you will be asked to complete a short survey of 6 questions via text message. The interview at 1 month will take place over the phone and will take about 30-40 minutes to complete. The interview at 3 months will take place over the phone

and will take about 45 minutes to complete. You may also receive SMS text message alerts for scheduling purposes. If you are in the intervention group, we will send you health education text messages. You may opt out of these messages at any time.

Medical Record Review
In addition to the interviews, we will also collect health information from your medical record. We will collect information about your diabetes, clinical values, and medications. We will get this information directly from your clinic, so you won't need to do anything.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to complete 3 interviews.

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time; it will not be held against you. We will keep all data collected until the time you change your mind. Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Detailed Risks: Is there any way being in this study could be bad for me?
This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any costs to you.

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include a better understanding of diabetes self-care activities and better understanding of diabetes and preconception care.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution, and the National Institute of Diabetes and Digestive and Kidney Diseases.

If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings; for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. You should understand that 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, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?

If you agree to take part in this research study, we will pay you $85 total for your time and effort. You will receive $40 after your 1st interview, $20 after your 2nd interview, and $25 after your 3rd interview. You will be compensated within a few weeks of when you complete each phone interview either by Visa gift card or money order.

Please note there are additional instructions should you wish to use the gift card to withdraw cash from an ATM, at a restaurant or a gas station. These instructions will be mailed to you with the gift card. You will incur fees if the card is not used in 12 months or more.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study tools
- Pregnancy status

During this study, you may be coming to a Northwestern Memorial HealthCare/Northwestern Medicine entity for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the

purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- The National Institute of Diabetes and Digestive and Kidney Diseases, who is sponsoring the study, and that company's contractors and partners.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the end of the research study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Electronic Consent

Stacy Bailey, PhD MPH
Northwestern University
Department of General Internal Medicine and Geriatrics
750 N Lake Shore Dr, 10th Floor
Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Center for Applied Health Research on Aging (CAHRA).
_____	_____	The researcher may take a screen shot (photograph) of my pills during a video call to aid with data analysis. The researcher will not share these photographs with anyone outside of the immediate study team.

Consent:

Once completed, you will get an automatic email with the signed version of this consent. If you want a paper copy of this consent for your records, you can print it from the screen.

By clicking 'I agree', I certify that I give my consent freely to participate in this study.

- ☐ I agree
- ☐ I disagree

_____ _____
First Name Last Name

_____ _____
Electronic Signature Date of Birth

_____ _____
Consent Date Study ID (to be added by RC)

_____ _____
First Name of Person Obtaining Consent Last Name of Person Obtaining Consent

_____ _____
Electronic Signature of Person Obtaining Consent Date