San Diego State University
INFORMED CONSENT FORM
Consent form version date: 01 JUN 2024

Study Title: Increasing Access to Continuous Glucose Monitoring for Patients with Type 2 Diabetes (Phase 1 Survey)

IMPORTANT THINGS TO KNOW ABOUT THIS STUDY

This study is funded by the National Institute on Minority Health and Health Disparities. We are asking you to join a research study. The purpose of this study is to evaluate a toolkit training about continuous glucose monitors (CGM) that was developed for healthcare providers and staff who are involved in the provision of care to patients with Type 2 Diabetes at Innercare. We would like to know whether participation in the training is associated with changes in CGM-related attitudes, knowledge, or use. We would also like to know what can be improved about the toolkit training. You are being invited to participate because you are an adult healthcare provider who treats patients with Type 2 diabetes at Innercare.

You do not have to join this study. These are the reasons you might want to join this study: patients with Type 2 Diabetes may experience challenges obtaining prescriptions for CGM devices; your participation can help us understand how to improve access to CGMs. These are the reasons you might not want to join this study: you will be asked to answer questions about your medical practices and knowledge, which may make you feel uncomfortable; the study takes about 20-25 minutes to complete and you may feel you do not have time to participate.

If you choose to participate in this study, you will be asked to complete three brief surveys lasting between 5-10 minutes each. The surveys will assess your knowledge and attitudes towards and use of CGM in your practice; the second and third surveys will also ask for your feedback about the CGM training and toolkit you will have completed. You will be offered a $10 gift card for each of the first two surveys and a $25 gift card for completion of the third survey.

We will give you information about the purposes, procedures, risks and possible benefits related to this study. We will explain other choices you have. We will also give you more information that you need to make an informed decision about joining this study.

The following information is a more detailed description of the study. Please read this description carefully. We want you to ask us any questions that will help you decide whether you want to join this study. If you join the study, we will give you a signed copy of this form to keep to remind you of what being in the study involves.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS?

Clinical Research Coordinator: Caroline Trujillo
Innercare-El Centro 852 E Danenberg Dr, El Centro, CA 92243
Phone: 760-344-9951 extension 10255
Email: ICCRN@innercare.org

Co-Principal Investigator: Emily Schmied
SDSU Department: School of Public Health
Address: 5500 Campanile Dr. San Diego, CA 92182

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Co-Principal Investigator: Shiloh Williams
SDSU Department: School of Nursing
Address: 5500 Campanile Dr. San Diego, CA 92182
Phone: 760-768-5500
Email: Shiloh.williams@sdsu.edu

Human Research Protection Program at San Diego State University
Telephone: 619-594-6622
Email: irb@sdsu.edu

WE ARE INVITING YOU TO JOIN A RESEARCH STUDY.

We are asking you because you are a healthcare provider (e.g., physician, nurse, medical assistant) involved in the provision of care for patients with Type 2 diabetes within primary care settings at Innercare.

Up to 150 participants will be included.

WHY ARE WE DOING THIS STUDY?

The purpose of this study is to evaluate a toolkit training about continuous glucose monitors (CGM) that was developed for healthcare providers and staff who are involved in the provision of care to patients with Type 2 Diabetes at Innercare. We would like to know whether participation in the training is associated with changes in CGM-related attitudes, knowledge, or use. We would also like to know what can be improved about the toolkit training.

WHAT IS THE TIME COMMITMENT IF I JOIN THIS RESEARCH STUDY?

Your participation will last about 20-25 minutes in total and will be completed over a period of approximately 4 months. You will not be asked to travel; either our study team members will meet you at your Innercare clinic location, or you will be invited to participate remotely.

The research scientist could stop your participation in the research study at any time even if you want to still be in the study. This would happen if:

- They think it is in your best interest to stop being in the study.
- You are not willing or able to do all the things needed in the study.
- The whole study stops.

If you stop being in the study, your information collected before you stopped being in the study will be included in the study because we will not be including an identifying information on the surveys and thus we will have no ability to distinguish your survey data from the data collected from other participants.

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WHAT WILL I BE ASKED TO DO IN THIS RESEARCH STUDY?

To determine if you can join the study, we will ask you some questions, including your employment status. If your answers indicate you can participate, we will ask you to participate in the study. If you are not eligible to participate, you will not be invited to participate.

If you are eligible to participate and provide your consent to do so, you will be asked to do the following:

1. *Surveys (5-10 minutes each).* You will be asked to complete three surveys. The first will be completed before your participation in the CGM toolkit training, the second will be completed about 1-2 weeks later, and the third will be completed about 2-3 months later. You will complete the survey either on your own phone or computer, on a tablet provided by the research team, or on paper.

WHAT ARE THE RISKS OR DISCOMFORTS INVOLVED IN THE RESEARCH?

In the interview, we will ask you about your attitudes and practices related to CGM, which you may not want to share. You can refuse to answer any questions that you don't want to answer. You also can decide you want to stop participating at any time.
While we will not ask for any personally identifiable information as part of the survey, we will keep a separate record with the names and contact information for all participants so that we can remember who agreed to participate and where to send gift card incentives. Because of this, there is a possible risk of loss of privacy. We will store all survey data in secure, password-protected, controlled-access drives, where only approved study personnel can access.

ARE THERE ANY BENEFITS TO PARTICIPATION?

You may not benefit from participating in this study. However, by joining this research study, you are helping to provide information which may help science and society.

ARE THERE ANY ALTERNATIVES TO JOINING THIS RESEARCH STUDY?

The alternative is to not participate in the research.

WILL MY INFORMATION BE PRIVATE?

We will keep your information private. Survey data will be stored in a password-protected, secure network managed by the SDSU Information Technology department. We will collect your contact information, such as your email address and phone number, so that we can schedule your surveys and deliver your gift card incentives; however, we will never store your contact information with any study data, and we will permanently delete your contact information as soon as your participation is complete. Instead, you will be prompted to create unique study identification number that will be entered onto all study data records so that your name or contact information will not appear with your study data. Research data will be destroyed 5 years after the end of this study.

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There is a policy at the National Institutes of Health (NIH), which is the organization that funded this study, about the data collected for this study. The ethics board reviewing this study must follow the NIH policy. The data collected for this study will be made available to other scientists as part of a repository. Before submitting our study data to the repository, we will make sure that anything that could identify you will be removed. Sharing your data with other scientists will allow for future health and wellness discoveries. Research results from this study may be used in published articles or for presentations to other scientists, but it will be presented in pooled form without any identifiers so that no one could link your data back to you as an individual. Others will not be able to identify you in those papers, presentations, or records. No identifying information will be maintained in the research records.
Additionally, because this is part of a clinical trial, a description of the study will be available on http://www.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.

DO I HAVE TO JOIN THIS STUDY?

No, you do not have to join this research study. Even if you agree to join, you can decide later that you do not want to be in the research. If you choose not to join or later decide that you do not want to be in the study, there is no penalty or loss of benefits to which you are otherwise entitled

WILL I BE TOLD ABOUT THE RESEARCH RESULTS?

We will not contact you with results of this study after this study is completed; however, you are welcome to reach out to our research team to ask for a copy of study results at any time.

WILL IT COST ME ANYTHING TO BE IN THE RESEARCH?

There are no costs to you.

WILL I BE PAID IF I JOIN THE RESEARCH?

You will be offered a $10 gift card after you complete the first survey, a $10 gift card after you complete the second survey, and a $25 gift card after you complete the third survey.

WHOM DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS?

If you have questions now, please ask. If you have questions later about the research, you may contact Caroline Trujillo (760-344-9951 extension 10255) or Co-Principal Investigator Emily Schmied (425-417-0884; eschmied@sdsu.edu).

If you have any questions about your rights as a research participant, or in the event of a research related injury, you may contact the Human Research Protection Program at San Diego State University:

- Telephone: 619-594-6622
- Email: irb@sdsu.edu

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At any time during the research, you can contact the IRB for questions about research rights, to discuss problems, concerns, give suggestions, or to offer input.

CONSENT TO PARTICIPATE:

Do you have any questions about participation? ☐yes ☐ no
Do you feel comfortable beginning participation? ☐yes ☐ no

The San Diego State University Institutional Review Board has approved this consent form as signified by the Board's stamp.

The choice to sign this consent document is yours. However, you may sign this form. The choice is yours. If you choose to sign, the researchers will keep your participation confidential. If you do sign this form, your signature below indicates that you have read the information in this document and the study team has explained the study to you. You have had a chance to ask any questions that you have about the study. Your signature also indicates that you agree to join the study. The study team has told you that you can change your mind and choose to stop participating in this study at any time.

The investigator or a member of his/her research team has provided you with a copy of this consent form with information about whom to contact in the event you have questions.

I have been told that my signature is not required, but I may choose to sign the consent form anyway.

Signature of the participant_____ Date_____

Signature of the person conducting consent process _____Date_____