INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Diabetes Solutions International / "Establishing a Sustainable Diabetes Care Management Program using CGM and RPM for Underserved Populations in Safety Net Clinics"**
Protocol Number:	**IIS-2024-172**
Principal Investigator: (Study Doctor)	**Sushma Reddy, MD**
Telephone:	**413-325-8500 (24-Hour)**
Address:	**Community Health Center of Franklin County 102 Main Street Greenfield, MA 01301**

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. You may also take this form home to further review at your leisure. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form.

KEY INFORMATION

You are invited to take part in a glucose monitoring research study called the Diabetes Care Management Program (DCMP) study. This research study is investigating whether a Diabetes Care Management Program using a continuous glucose monitor (CGM) and remotely monitoring glucose readings can help

improve glucose levels and quality of life in individuals with uncontrolled type 2 diabetes. This study is being done as an additional supplement to usual diabetes care provided by your regular doctor. This study is sponsored by Diabetes Solutions International.

A continuous glucose monitor (CGM) can tell you how your glucose level responds to food, physical activity, medications and daily life. The CGM, also called a sensor, is worn on the arm or abdomen and measures glucose levels continuously through a slim sensor wire. The study staff will help you insert the sensor using an automatic applicator. You may feel a pinch or pressure while the sensor is being inserted, although many find it to be painless.

You will see your primary care provider (PCP) for usual diabetes management. Your diabetes care team will consist of your PCP, diabetes educator and medical assistant.

You will be asked to fill out a survey about how diabetes affects you and your satisfaction with the Diabetes Care Management Program.

The duration of the study is 24 weeks with an option to continue in the study for an additional 28 weeks. The CGM used in the study is the Dexcom G7 (G7) where you will be able to see your glucose levels. The G7 monitor has been approved by the United States Food and Drug Administration (FDA). The G7 can be worn on the back of your arm or abdomen.

You will be started on the Dexcom G7 at your first visit. The study staff will help you insert the G7 and show you how to use it. If you have a smartphone, you will be able to see your glucose readings on your phone. If you do not have a smartphone, you will be given a receiver and you will be able to see your glucose readings on the receiver. You will be asked to record your food intake, physical activity and medications for the first 10 days.

Your second visit will be 10 -14 days after the first visit. During this visit, the diabetes primary care team will explain your glucose data to you and go over any questions you have on using the G7. Each G7 sensor lasts for 10 days. The study staff will teach you how to insert and take off your G7 sensor. Your PCP will adjust

your medications as needed. You will be asked to continue to wear the G7 for 12 weeks.

The diabetes primary care team will be remotely monitoring your glucose data from the CGM throughout the study. They will reach out to you to make adjustments in your treatment regimen as needed. However, the monitoring is not real-time, 24/7 monitoring. Therefore, if you have concerns about your glucose readings, you should reach out to your medical doctor, the study team, or seek emergency care. If you do not have a smartphone and are using a receiver, you will need to come to the clinic on a weekly basis to upload the glucose data from the receiver.

At the 12 week visit, you and your PCP will decide how often you need to wear the G7 for the subsequent 12 weeks. At the 24 week visit, you can decide whether you would like to continue in the study for an additional 28 weeks.

All personal information is confidential and securely stored. Also, if the information collected is used for publication, no identifying information (names, addresses etc.) will be attached to it.

This DCMP study is the first time remote monitoring of glucose data from a CGM is being used in individuals with type 2 diabetes seen at the study center. We expect to enroll 40 subjects. This study has the potential to improve your glucose levels and quality of life, and help you find out exactly how your glucose responds to food, physical activity, medications and daily life, but this is not guaranteed. In addition, by participating in the DCMP study, you are helping to develop a Diabetes Care Management Program that improves glucose levels and quality of life for individuals with type 2 diabetes seen in Community Health Centers. The results from the DCMP study can help establish similar Diabetes Care Management Programs in Community Health Centers across that country to improve glucose levels and quality of life for underserved populations.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you have uncontrolled type 2 diabetes.

Individuals with uncontrolled diabetes are at risk for complications of diabetes such as blindness, heart attacks, kidney problems and foot ulcers. Getting the glucose levels near normal substantially reduces the risk of complications. Yet, this is difficult to achieve as diabetes is invisible and it is hard to know what to eat or do daily.

CGMs track glucose levels continuously and help individuals to know how their body responds to physical activity and different foods. It makes the invisible visible as you are now able to see your glucose levels. It was found that when individuals used CGM, they were more likely to modify their physical activity and eating habits.

Patients with diabetes typically see their health care team every 3 months and it is hard to know what to do between visits. Remote monitoring of the glucose data allows the diabetes care team to reach out to the patient as needed between visits to help optimize glucose control. In addition, patients can reach out to the diabetes care team whenever they have questions about their diabetes as they are now able to see their glucose levels.

We would like to develop a Diabetes Care Management Program using CGM and remote monitoring of glucose levels that helps individuals with diabetes seen in Community Health Centers improve glucose levels and quality of life.

WHAT WILL HAPPEN DURING THE STUDY?

Your participation in this study will last approximately 24 weeks and will include approximately 4 study visits to the study center. If you do not have a smartphone, you will have approximately 20 additional brief weekly visits to the study center to upload the glucose data from the receiver.

You will have an option to continue in the study for an additional 28 weeks. If you decide to continue in the study, you will have approximately 3 visits to the study center. If you do not have a smartphone, you will have approximately 25 additional brief weekly visits to the study center to upload the glucose data from the receiver.

Screening:

Before any study-related tests and interventions are performed, you will be asked to read and sign this consent document. The following screening test results will be obtained to determine if you qualify to take part in this study:

- A1c test: this is a blood test that measures the average amount of glucose in your body over the last 3 months
- Enrollment form: medical history and personal information. This is done as part of your usual clinic visit

This study will use competitive enrollment. This means that when a target number of subjects begins the study, all further enrollments will be closed. Therefore, it is possible that you could be in the screening phase, ready to begin the study, and be discontinued without your consent if the target number of 40 subjects has already begun the study.

If you qualify to take part in this study and proceed with study enrollment, then the following will happen:

Baseline Assessment:

You will be assigned a study specific number. All information, questionnaires and assessments are de-identified and collected under your study specific number rather than your name.

You will be asked to fill out the following questionnaires:

- Enrollment questionnaire: medical history, medication list, ER visits & hospitalizations. This is done as part of your usual clinic visit
- Problem Areas in Diabetes Questionnaire (PAID): 20 questions that help us understand how diabetes affects your quality of life.

Study Treatment:

You will be started on the Dexcom G7 at your first visit. The G7 is a CGM that tracks your glucose levels continuously. It is a small discreet device that you wear

on your arm or abdomen. It measures glucose levels in the space just under your skin through a slim sensor wire. A patch holds the CGM device in place so it can measure glucose readings throughout the day and night. The study staff will help you insert the G7 using an automatic applicator and show you how to use it. You may feel a pinch or pressure while the sensor is being inserted, although many find it to be painless

If you have a smartphone, you will be able to see your glucose readings on your phone. If you do not have a smartphone, you will be given a receiver and you will be able to see your glucose readings on the receiver. You will be asked to record your food intake, physical activity and medications for the first 10 days. You may remove the sensor at day 11 or return to the clinic to have it removed.

Your second visit will be 10 -14 days after the first visit. During this visit, the diabetes primary care team will explain your glucose data to you and go over any questions you have on using the G7. Each G7 sensor lasts for 10 days. The study staff will teach you how to insert and take off your G7 sensor. Your PCP will adjust your medications as needed. You will be asked to continue to wear the G7 for 12 weeks.

All clinic visits with your PCP and diabetes educator will be as per your usual diabetes care. The A1c blood test is performed as part of your usual diabetes care.

At the 12 week visit, you and your PCP will decide how often you need to wear the G7 for the subsequent 12 weeks. At the 24 week visit, you can decide whether you would like to continue in the study for an additional 28 weeks.

The diabetes primary care team will be remotely monitoring your glucose data from the CGM throughout the study. This is a weekly retrospective review of the glucose data. The study team and/or diabetes primary care team will not have real-time notification of glucose readings. They will reach out to you to make adjustments in your treatment regimen as needed. You can also reach out to the team during normal clinic hours with any questions about your glucose readings. However, this is not an emergency service. You must go to the emergency room or call 911 if you are experiencing any acute problems with low or high glucose. If

you do not have a smartphone and are using a receiver, you will need to come to the clinic on a weekly basis to upload the glucose data from the receiver.

After Study Treatment:

The CGM device and remote monitoring of the glucose levels is part of the research study. Because this is a research study, the CGM device will not be provided after the study is completed.

EXPECTATIONS

If you participate in this study, you will be expected to:

- Wear a CGM
- Attend clinic visits
- Provide results of the A1c blood test at the beginning of the study, at 12 weeks and at the end of the study (24 weeks)
- Fill out questionnaires at the beginning of the study, at 12 and 24 weeks
- Come to the clinic weekly to upload the glucose data from the CGM if you do not have a smartphone
- Optional extension: if you choose to continue in the study for an additional 28 weeks, you will need to provide results of the A1c blood test at 36 and 52 weeks and fill out questionnaires at 52 weeks

ARE THERE RISKS INVOLVED IF I AM IN THIS STUDY?

This study is being performed as an additional supplement to your usual diabetes care. You will be asked to wear a CGM that measures glucose levels continuously in the interstitial fluid. The CGM devices are FDA approved for use in individuals with diabetes. Risks associated with CGM insertion and use are infection, bleeding, and skin irritation at the site of insertion and pain. There is also a possibility of inaccurate sensor readings.

Some people feel uncomfortable when answering questions about the quality of their life. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you feel uncomfortable.

You cannot participate in the study if you are pregnant. If you become pregnant during the study you must tell your study doctor immediately. All pregnancies will be followed to outcome.

WILL BEING IN THIS STUDY HELP ME?

Being in the study may help you learn about how your glucose levels respond to food, physical activity, medication and everyday life. You will have the opportunity to modify your eating habits and physical activity based on your glucose levels. Your PCP will have a complete picture of your glucose levels and be able to make appropriate changes in your treatment regimen.

You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

There will be no additional charge to you for your participation in this study. Your clinic visits and A1c testing are part of your usual diabetes care and will be billed to your insurance company as usual. You will be responsible for all copays and deductibles for your clinic visits and lab work. The study does not pay for a smartphone or any charges such as wi-fi associated with use of the smartphone or receiver.

The CGM and remote monitoring of glucose levels will be provided at no charge to you.

WHO IS PAYING FOR THIS STUDY?

This study is being conducted by Diabetes Solutions International (DSI). DSI has received a grant from Dexcom to help pay for the expenses associated with the study.

WILL I RECEIVE PAYMENT?

You will be paid for the visits you complete according to the following schedule:

- $30 for completing the 2nd study visit at 10 to 14 days
- $30 for completing each study visit and questionnaires at 12 and 24 weeks
- $30 for completing each study visit and questionnaires at 36 and 52 weeks (if you opt to continue in the study)
- $15 for each additional study visit that is needed for follow up or to upload glucose data from the receiver

You will be paid at the completion of each study visit

If you do not complete the study, for any reason, you will be paid for the portion of study visits you complete.

DO I HAVE TO BE IN THIS STUDY?

Your participation in this study is voluntary. You can decide not to be in the study and you can change your mind about being in the study at any time. There will be no penalty to you and you will not lose any benefits. Your ability to obtain medical care at the study center will not be affected whether or not you decide to be in the study. If you want to stop being in the study, tell the study doctor or the study staff. If you leave the study, the study doctor and the study staff will still be able to use your information that they have already collected.

ALTERNATIVES TO PARTICIPATION

You do not have to be in this study to receive treatment for diabetes. Your options may include:

- Continue regular clinic visits
- Obtaining a CGM over the counter or through your regular doctor
- Increasing your physical activity, eating healthy foods and losing weight

Please talk to the study doctor about your options before you decide whether or not you will take part in this study.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Your identity and protected health information will be protected according to HIPPA regulation, as required by law and as per the privacy practices of the study center. Be aware that your CGM data, A1c, medical history, consent form and all questionnaires will be shared as needed with the study staff to analyze data and report outcomes. Information about the data collected in this study may be published in reports or journals or presented at scientific meetings; however, you will not be identified in these reports.

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed.

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.

COMPENSATION FOR INJURY

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating

you that you are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need.

If it is determined you are injured as a result of using the CGM, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. By signing this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By mail:

  Study Subject Adviser

  Advarra IRB

  6100 Merriweather Dr., Suite 600

  Columbia, MD 21044

- or call toll free: 877-992-4724
- or by email: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00084125.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions, and all my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

_____

Subject's Printed Name

_____ _____

Subject's Signature Date

_____

Printed Name of the Person Conducting the

Consent Discussion

_____ _____

Signature of the Person Conducting the Date

Consent Discussion

IMPARTIAL WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ (if applicable)

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of Diabetes Solutions International
- Representatives of Dexcom
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Outside individuals and companies, such as laboratories, statisticians and data storage companies, that work with the researchers and the sponsor and need to access your information to conduct this study.
- A data safety monitoring board which oversees this study

Your health data will be used to conduct and oversee the research, including for instance:

- To see if CGM and remote monitoring improves glucose levels

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ (if applicable)

The study subject has indicated that he/she is unable to read. This Authorization document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date