# PATIENT COPY

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| **Sponsor / Study Title:** | **Savvysherpa, Inc. / "Empowering Medicare Patients to Self-Manage Their Type 2 Diabetes Using Continuous Glucose Monitoring (CGM) – Investigational Device Pilot"** |
| **Protocol Number:** | **CGM_IRB_002** |
| **Principal Investigator:** | **Jared Jones, Ph.D.** |
| **Principal Investigator Telephone Numbers:** | **(763) 549-3540 x 8199**<br>**(702) 266-9129 (24 Hours)** |
| **Clinical Site Address and Phone Number:** | **Machuca Family Medicine**<br>**1501 South Eastern Avenue**<br>**Las Vegas, NV 89104**<br>**(725) 400-2550** |

Please read this form carefully. Take time to ask as many questions about the study as you would like. The study staff can explain words or information that you do not understand. Reading this form and talking to study staff may help you decide whether to take part or not.

## Questions? Call study staff at (702) 266-9129.

If you decide to take part in this study, you must sign your name at the end of this form and date it. You cannot take part in this research study until you sign and date this form.

## Consent to Take Part in a Research Study

**INTRODUCTION TO THE RESEARCH STUDY**

You are being asked to take part in this research study because you have type 2 diabetes and may benefit from a program designed to help you learn how to better manage your type 2 diabetes by using continuous glucose monitoring (CGM). The program study is being offered to eligible people who are patients at Machuca Family Medicine in Las Vegas, NV. The study is designed to evaluate the program to learn how well the program works for you and other participants. The program is sponsored by Savvysherpa, Inc., and its fully-owned subsidiary SavvySugars, LLC.

When you use a CGM system, a thin sensor inserted under your skin will read your glucose levels every 5 minutes. (The glucose in your body is sometimes informally called your "sugar.") You will be able to track your glucose levels on a smartphone you'll be given to carry with you. You will not be able to use the smartphone to make calls during the study.

With the help of a coach, you will learn how diet, physical activity, and medication affect your glucose levels. You will also be able to see what your glucose levels are when you sleep. You will be able to use this information to help you keep your glucose in a safe range.

To help you understand how physical activity affects your glucose, you will also have the option to wear an activity tracker on your wrist. The tracker will tell you how many steps you've taken each day, and may include other features to help you keep track of your activity and health (such as your heart rate).

As part of the program, you will receive your CGM system without needing to get a prescription, and you will get a smartphone with apps that have been set up ahead of time to help you use your CGM system and activity tracker.

Taking part in this study is entirely voluntary. The program is educational only and does not replace the normal care you receive from your doctor. During the study you should continue to follow the care instructions you have received from your doctor.

One hundred people will participate in this study. The study will run through February 28, 2018.

**PURPOSE OF THE RESEARCH STUDY**

The purpose of this study is to evaluate the effectiveness of a program designed to help people with type 2 diabetes use CGM to better manage their diabetes and stay healthier.

**INFORMATION ABOUT THE STUDY**

In this program you will need to use a CGM system for 10 weeks. After using the CGM we would like you to report your fasting blood glucose to us each day through the end of the study.

If you are taking basal insulin we would like you to report your daily insulin dose to us every day throughout the study.

Every week during the study you will talk with a personal coach by phone. You will also be able to use your study phone to text with your coach. The coach will help you learn more about how you can manage your diabetes using your CGM.

You will also have the option to wear an activity tracker. If you complete 10 weeks of CGM use, start wearing your tracker during those 10 weeks, and continue to track and upload your steps through the end of the study period (uploading at least once every three weeks through February 28, 2018), you will get to keep the activity tracker and smartphone (no phone, text, or data plan included). The study staff will explain how to track and upload your steps. While you won't be able to use the smartphone to make

calls during the study, you will be able to make calls and use the phone like any other smartphone after the study has ended.

Before you begin the program, you must first read, sign, and date a copy of the study consent and authorization form. Next, please complete the program survey. Return both the signed and dated study consent and authorization form and the program survey.

You will need to get three A1C tests during the study: the first test when you begin the study, the second test after 90 days, and the third test another 90 days later.

To start using your CGM system, you can choose one of two options:

- Self Setup:
  Set up the CGM system on your own using informational materials, videos, and help by phone if you need it. If you have any trouble, you can call to schedule a group visit at Machuca Family Medicine.

- Group Visit at Machuca Family Medicine:
  You can attend a group visit at Machuca Family Medicine where clinic staff will explain the CGM system and help you learn how to put it on.

Following set-up, you will continue to have access to information and phone support to help you use your CGM system.

Your CGM system has a sensor that lasts ten days. Every ten days you will need to replace the sensor with a new one. To use the CGM system, you will need to calibrate it. To calibrate your sensor you will need to take a fingerstick reading and enter your blood glucose value into your CGM system. During the first 24 hours that you wear the CGM system you will need to do four calibrations (two initially, one after 12 hours, and another 12 hours later). After that you will need to do one calibration every 24 hours. The CGM app on the smartphone will notify you when it's time for you to complete these tasks.

Once you start using the CGM system, a coach will schedule a weekly call with you to help you understand your CGM data. The coach will give you ideas of what to look for when you eat, sleep, take medicine, and exercise. You can also call or text your coach any time if you have questions. Your coach will respond to you within two business days.

After you have worn your CGM system for 10 weeks, you'll receive a report summarizing your CGM data. You will also be asked to complete another survey and to return your unused CGM sensor/applicators. You will also need to return the activity tracker and smartphone unless you are still using them. When the study period ends on February 28, 2018, you will receive a final survey to complete.

Your weekly calls with your coach will continue throughout the study to help you continue to apply what you've learned from using the CGM.

If at any time your system does not function properly, you will need to return the study device(s) to Savvysherpa and they will be replaced if at all possible at no cost to you.

To withdraw early from the study, you should call the program phone number and notify your coach. If you withdraw early, you will need to return the smartphone, transmitter (if unused), unused sensors, and activity tracker at that time.

During the course of the study, your program-related phone calls, texts, and/or participation in educational classes may be recorded. These recordings will be used to improve the program, including the training of coaches. The recordings may be shared with Dexcom, the CGM device manufacturer. Your identity will not be anonymous (coded) in these recordings. However, access to the recordings will be restricted to study staff working on quality improvement.

We will use information from your medical records, claims about your prescription medication use, and costs of your regular medical care outside of the study through February 28, 2028, even if you stop using the study devices before February 28, 2018 (unless you withdraw early from the study and ask us in writing not to collect any further data).

**STUDY DEVICE SET-UP**

To prepare the smartphone you will use for the study, we will load the Dexcom, Glucose Guide coaching tool, and Fitbit apps onto the smartphone. To do this, we will create a special email address and password for you that is controlled by Savvysherpa and set up app accounts on the smartphone. We will also collect from you and enter into the apps personally identifying information (PII) to include first name/last name, address, phone number, date of birth, gender, height, and weight.

In addition, we will connect your CGM transmitter to the smartphone before delivering it to you, and allow Dexcom's CGM to access the smartphone's location. As part of the set-up process, Savvysherpa will provide your name, special email address, and password to Dexcom and Fitbit, and click through the agreements and information for each of these apps. You can read this information now and at any time by visiting the program website at www.FixMyGlucose.com. Safety information for the CGM system is contained in this agreement and also in an instruction booklet you will receive with your CGM system.

Signing this consent form gives Savvysherpa permission to perform the activities described above on your behalf.

**YOUR ROLE IN THE STUDY**

Taking part in a research study can be an inconvenience to your daily life. Please consider the study time commitments and responsibilities as a research subject when you are deciding to take part. Your responsibilities as a study subject include the following:

- Tell the truth about your medical history and current conditions.
- Tell the program staff if you are currently in another research study.
- Make sure you review and understand all safety information that we send you with the program devices.
- Continue to follow your normal medical care instructions from your doctor, including taking any medications as prescribed and relying on self-monitoring blood glucose (SMBG) meter readings for all diabetes-related treatment decisions. You are expected to already own your own blood

glucose meters as part of your normal standard-of-care. If you do not have a glucose meter, notify the program staff and you will be provided with one to use and keep following the study.
- Contact your doctor if you have any medical concerns about participating in this study.
- Tell your coach if you no longer meet the study eligibility criteria.
- Contact Machuca Family Medicine if you have a health problem related to your participation in this study, or any major health event that happens to you while you're in the study (tell them you are in this study and would like to speak to a member of the study staff):
  Machuca Family Medicine: **(725) 400-2550**
- Call Dexcom for help if you experience any problems related to your CGM system:
  Dexcom Patient Care and Technical Support line: **(844) 857-6319**
- Notify your coach if you are having any problems with your study devices:
  Glucose Monitoring Program Coach line: **(702) 266-9129**
- Do not let anyone else use your activity tracker or CGM system (including the program's smartphone).

**RISKS OF THE STUDY**

This is a study of an educational program. Your participation in this program does not replace your normal medical care. During the program you will use a CGM system, communicate with a coach, and have the option to wear an activity tracker. Participating in the program should present minimal risk to you. However, we want you to be aware of these possible risks:

Risk of glucose meter: You will have to do fingerstick blood samples during this study. This may cause some discomfort, pain, bruising, and/or soreness afterwards. Rarely, an infection may occur.

Risks of the Dexcom Investigational Use Only CGM System:

The CGM system used in this study is intended for investigational use only and has not been approved by the FDA. However, significant or serious health risks with CGM are not anticipated.

To keep your CGM system reading accurately, after the first day of calibrations you should calibrate it at least once every 24 hours. You should also store your sensors between 36° F – 86° F (2° C – 30° C) If your readings are not accurate, you may miss seeing when your glucose is too high or too low.

If you experience symptoms of high or low glucose, you should always check your blood glucose with a fingerstick blood glucose meter and follow your normal care, regardless of what is displayed on your CGM system.

The CGM sensor contains a short wire that will read the glucose levels in your tissue. You will use an applicator to insert the sensor's wire just under your skin. Application takes less than one second, with one click of a button. At the sensor site you might experience discomfort, pain, inflammation, redness, swelling, minor bleeding, and/or minor infection. This may be related to the wires or the adhesive pad of the sensor that sticks to your skin. In rare cases, an infection can spread to other parts of the body. Allergic reactions can develop in response to the sensor, adhesive, and other parts of the CGM. If you remove the sensor these symptoms will usually clear up within a week.

It is also possible that your sensor and/or applicator may break during use. If this happens you should contact Dexcom Patient Care and Technical Support at **(844) 857-6319**. On rare occasions, the sensor wire may break or detach from the transmitter holder. If a sensor wire remains in your skin, you should not try to remove it, and contact Machuca Family Medicine clinic at **(725) 400-2550**, even if you do not have redness, swelling, or pain at the sensor insertion site.

If your transmitter is damaged or cracked, you should not use it. This could create an electrical safety hazard or malfunction, which might cause electrical shocks. If your transmitter is damaged or cracked you should contact Dexcom Patient Care and Technical Support at **(844) 857-6319**.

**IMPORTANT:** Before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy (heat) treatment, you must remove the sensor, transmitter, and smartphone. You can replace them after completing your imaging/test/procedure. The CGM device is MR Unsafe. You should not bring any part of your CGM system into the MR environment. The Dexcom IUO CGM system has not been tested during MRI or CT scans or with diathermy (heat) treatment. The magnetic fields and heat could damage it, causing it to stop displaying glucose readings, display inaccurate glucose readings, or prevent alerts.

It is possible that certain metal detectors, x-ray machines, or Advanced Imagining Technology (AIT) body scanners could affect the performance of your CGM system, making measurements unreliable. For this reason, when going through security checks (such as at an airport), these security devices should not be used with any part of your CGM system. Instead, you should request visual inspection of any baggage, and hand-wanding or full-body pat-down with visual inspection when wearing your CGM system.

It is also possible that accessory devices (like a smartwatch) might override the smartphone settings. After connecting any accessories, make sure that the smartphone settings allow you to keep receiving your usual alarms and alerts. Also, be aware that in order for your CGM system to work, the smartphone's Bluetooth® function needs to be turned on.

All precautions are being taken to make sure that the privacy of your personal glucose values is preserved. However, the CGM app you will be using is still being tested to make sure it is reliable. Be aware that your CGM system does not replace normal blood glucose measurements. Also, your blood glucose values may differ from the CGM readings. Any treatment decisions should be made based on your fingerstick blood glucose value on a blood glucose meter.

You can and should view your CGM device safety information in the *Watch Your Glucose on Your Phone* instruction booklet that will be provided to you with your CGM system. You can also call the Dexcom Patient Care and Technical Support line at **(844) 857-6319** now or at any time if you have any questions.

Risks of the Fitbit Activity Tracker Device: You will receive a Fitbit activity tracker. Some people may experience skin irritation or allergies when they wear the tracker for a long time. To prevent this, wear your tracker loosely enough to allow some air circulation, and clean and dry your tracker regularly with a damp cloth. If you have problems with skin irritation, please remove the tracker during sleep and/or wear the tracker on your other wrist.

There is also a slight risk that the privacy of the activity tracker data could be exposed if someone hacks into the tracker's data system. Savvysherpa has taken steps to minimize this risk.

Risks of Working with a Coach: You may experience embarrassment or concern in talking with your coach about your lifestyle (for example, physical activity, dietary intake), sleep, social support, depression, anxiety, and stress. You can choose not to discuss any topics that make you feel uncomfortable.

Risks of Medical Record Review and Data Collection: The study involves recording information from your medical records and the program devices you will use. There is a risk that the information could be accidentally shared to another entity outside of the research team. However, great effort and many security precautions are in place to keep your information secure.

You might have side effects or discomforts that are not listed in this form. Some side effects may not be known yet. New ones could happen to you. Tell the study investigator or study staff right away if you have any problems.

**ALTERNATIVES TO BEING IN THE STUDY**

You do not need to take part in this research study. However, at this time, the program we are evaluating is only available within this research study. Your study investigator can discuss educational alternatives and the risks and benefits of these alternatives with you.

**POTENTIAL BENEFITS OF BEING IN THE STUDY**

You may or may not receive any benefit from being in the study. It is possible that you may get better, stay the same, or get worse.

By participating in this study you may:

- Gain information about your glucose levels and how they change during the day.
- Better understand how medications, exercise, sleep, the foods you eat, and other factors affect your glucose levels.
- Learn how to keep your glucose levels in a safe range.
- Help others with type 2 diabetes use CGM to better manage their diabetes and stay healthier.

When you complete 10 weeks of CGM use, you will receive a report from your coach summarizing your CGM data. You can also request a summary of your CGM data to-date at any time during the study.

**COSTS OF BEING IN THE STUDY**

This program, including all program devices and coaching, is being provided at no cost to you. If you happen to receive a bill from your insurance company related to this study, please contact study staff immediately so they can resolve this issue for you.

If you choose to attend a group visit to learn how to apply your CGM system, you will need to provide your own transportation. You will need to use your own phone to communicate with your program coach; however, all calls will be to numbers in your local area code or toll-free.

**YOUR PAYMENT FOR BEING IN THE STUDY**

You will not be paid for participating in this study.

If you complete 10 weeks of CGM use, start wearing your tracker during those 10 weeks, and continue to track and upload your steps through the end of the study period (uploading at least once every three weeks through February 28, 2018), you will get to keep the activity tracker and smartphone (no phone, text, or data plan included). After the study has ended you will be able to make calls and use the phone like any other smartphone after the study has ended.

You will also continue to have access to your personal online activity-tracking dashboard after the study ends.

If you do not have a glucose meter, you will be provided with one to use and keep following the study.

To help compensate you for your time and travel related to certain data you provide to us, we will pay you as follows:

- You will receive $40 for your first A1C test at the beginning of the study; $20 for your second A1C after 90 days; and $20 for your third A1C another 90 days later.
- If you are taking basal insulin and report your insulin dose each day, you will receive $0.50 for each day you provide this data.
- After you have finished wearing the CGM system for 10 weeks, you will receive $0.50 for each day you report your fasting blood glucose through the end of the study.

**STUDY STAFF PAYMENT**

Savvysherpa is paying the study investigators and study staff for their work in this study.

**COMPENSATION FOR INJURY**

If you become ill or are injured from applying or wearing the CGM system or activity tracker, you should seek care from Machuca Family Medicine clinic. If it is an emergency, call 911. Your insurance may be billed for any injuries or illness resulting from your participation in this study. Any copays or costs related to injuries from the application or wearing of the CGM devices and activity tracker which are not paid for by your insurance will be covered by Savvysherpa, Inc.

To pay these medical expenses, the sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number (if you have a Medicare plan). This is because the sponsor has to confirm that you receive Medicare and if you do, report the payment it makes to Medicare.

In no way does signing this consent form waive your legal rights nor does it relieve the investigators, Sponsor, or involved institutions from their legal and professional responsibilities.

**PROTECTING THE PRIVACY OF YOUR HEALTH DATA**

Certain people and organizations will need to see, copy, and use your health data so that they can do their part in the study. They are called "authorized users." Authorized users will be given access to and may make copies of your health data. This health data may or may not include your name. It may be traced back to you even if it does not include your name.

Your name will not be used whenever possible to ensure that the information collected about you for this study will be kept private. A code will be used instead of your name. All of your study data will be kept in a secure location.

Authorized users may include:

- Representatives of Savvysherpa, Inc.
- Representatives of Chesapeake IRB (a Research Ethics Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US governmental agencies.
- Other authorized users.

Your health data needs to be shared for this research. Therefore, complete privacy of your health data cannot be promised. However, sharing your health data will be guided by professional standards and the law.

Information from this study may be presented at meetings or published in medical journals. The information included at meetings or in journals will not include your name or information that can easily be traced back to you.

**GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY**

You can ask questions about this consent form or the study before you decide to start the study, at any time during the study, or after completion of the study. Questions may include:

- Payment or compensation for being in the study, if any
- Your responsibilities as a study subject
- Eligibility to participate in the research
- The study investigator's or study site's decision to exclude you from participation
- Other questions, concerns, or complaints

***Contact the study investigator or study staff listed on the first page of this form with any questions, concerns, or complaints.***

**GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT**

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  Chesapeake IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@chesapeakeirb.com

Please reference the following number when contacting the Study Subject Adviser: Pro00021722.

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 of the study. You can search this Web site at any time.

**ELIGIBILITY TO PARTICIPATE IN THE STUDY**

In order to participate in this study, you must meet certain criteria.

To be eligible for this study you must:
- Be diagnosed with type 2 diabetes
- Be able to read, speak, and understand English
- Have access to a telephone

You are **not** eligible for this study if you are:
- Pregnant
- Blind
- Deaf
- Receiving chemotherapy or radiation therapy to treat cancer (either now or within the last six months)
- Addicted to any drugs (such as alcohol, pain-killers, hallucinogens, or others)
- Critically ill

You are **not** eligible for the study if you are you diagnosed with or experiencing:
- Kidney disease, stages 4 or 5
- End-stage renal disease
- Severe liver disease
- Dementia
- Schizophrenia
- Bipolar disorder
- Autism

- An intellectual or learning disability
- Arrhythmias other than atrial fibrillation
- Congestive heart failure

You are **not** eligible for the study if you have experienced any of these health events:

- Heart attack (myocardial infarction) within the last 6 months
- Stroke within the last 6 months
- Stroke that resulted in a significant disability (e.g., unable to write clearly or walk)

**BEING A STUDY VOLUNTEER**

Entering a research study is voluntary.

- You may always say no. You do not have to take part in the study.
- If you start this study, you may stop at any time. You do not need to give a reason.
- If you do not want to be in the study or you end your participation in the study at a later time, you will not be penalized or lose any benefits.
- Once you receive your study devices, you will be considered enrolled in the study. If the study is filled before you have enrolled, you may choose to be notified of other upcoming study opportunities for which you may be eligible.
- If you end your participation, you should tell the study staff and follow the instructions they give you.

Your part in the research may stop at any time for any reason, such as:

- The sponsor or the study investigator decides to stop the study.
- The sponsor or the study investigator decides to stop your part in the study for your safety.
- You do not follow the study rules.
- You have a new injury or illness.
- You decide to stop.

You may be asked to stop the study even if you do not want to stop.

**NEW INFORMATION ABOUT THE STUDY**

You will be told about any new information found during the study that may affect whether you want to continue to take part.

**TERMS OF USE, PRIVACY POLICY, and SAFETY INFORMATION**

Both the CGM system and the activity tracker manufacturers have information that the manufacturers want you to review and agree to. You may view all applicable information at the following website:

www.FixMyGlucose.com/terms

Safety information for your CGM system will be provided in the *Watch Your Glucose on Your Phone* instructional booklet that you'll receive when you get your CGM system.

# HIPAA Authorization Agreement

## Permission to Review, Use, and Release Information about You

If you decide to be in this study, the study investigator and research team will use and share health data about you to conduct research. Health data may include your:

- Name
- Address
- Phone number
- Date of birth
- Gender
- Height
- Weight
- Medical history/clinical records
- Claims costs
- Information from your doctor visits, including all test results
- Information collected from your CGM system
- Information collected from your activity tracker

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 research team may share health data about you with authorized users if needed or required. Authorized users may include:

- Representatives of Chesapeake IRB (a Research Ethics Review Board that reviews this study)
- The Food and Drug Administration (FDA) and other US governmental agencies
- Other authorized users

The sponsor and those working for the sponsor may use the health data sent to them:

- To see how well the diabetes educational program works
- To compare the program to other studies
- For other research activities related to the program.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law.

Your permission to use and share health data about you will not end unless required by state law. If state law applies, your permission to use and share health data about you will end on February 28, 2067.

You may take back your permission to use and share health data about you at any time by writing to the study investigator. 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.

**AGREEMENT NOT TO DISCLOSE STUDY DETAILS**

By signing this consent form you agree not to disclose, share or use any information gathered during the course of this study. All information about the study, including the study product and study procedures, is confidential. Any publication about the products or the study by print or electronic format (such as blogging or discussions on online chat forums) is strictly prohibited.

**INFORMED CONSENT AND AUTHORIZATION**

I have read and understood this form, including the risks and safety information for the study devices. I have reviewed the eligibility criteria and confirm that I am eligible to participate in this study. All of my questions were answered to my satisfaction. I agree to be in this research study for the purposes listed above. I voluntarily agree to allow study staff to collect, use, and share my health data as specified in this form. I am keeping 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.

_____ ____/____/____
Signature of Research Subject Date

_____
Printed Name of Research Subject

_____ ____/____/____
Signature of Study Staff Date

_____
Printed Name of Study Staff