

CONSENT TO TAKE PART IN A RESEARCH STUDY

STUDY TITLE: Virtual Diabetes Specialty Clinic: A Study Evaluating Remote Initiation of Continuous Glucose Monitoring (VDiSC)

SUMMARY

This consent form will give you important information about this study. It will help you decide if you would like to take part in the study. You do not have to be in this study. You can stop the study at any time.

- **The study is being done to see if a virtual diabetes clinic model can help adults who live with diabetes improve their diabetes management. You will be taught how to start and use a continuous glucose monitor (CGM) without a visit to the doctor's office. The CGM system includes a sensor which has a thin needle and a small wire that is inserted under the skin. Once inserted, the needle is removed, and the sensor wire stays under the skin. Some CGM systems also have a transmitter that attaches to the sensor. A CGM receiver or reader allows you to see your blood sugar (glucose) levels. Depending on which CGM you use, you may view a blood sugar level every five or 15 minutes. Depending on which CGM you use, you will need to put in a new sensor after 10-14 days.**
- **You will receive instructions and be trained on how to use the CGM. You will upload data from the CGM and other devices you use for your diabetes. You will also complete questionnaires online. You will do a fingerstick at the start of the study and mail the blood samples to a lab that will measure HbA1c. HbA1c tells us your average blood sugar level over a period of time (about 2-3 months). You will also do a fingerstick every three months for up to 12 months to measure HbA1c. If you take insulin by multiple daily injections (MDI), you may be asked to record your insulin dose through an app or use an investigational device that collects data about your insulin doses. Investigational means the device has not been approved by the Federal Drug Administration (FDA) for regular use. This device is like an attachment to your insulin pen and only collects information. It will not change how you take your insulin.**
- **This study is called a minimal risk study. This is because the risk for the study is like the risk you would have if you were not in the study.**
- **The most likely risks to you are slight discomfort while inserting the sensor into your skin, a loss of confidentiality, or the possibility that completion of questionnaires could make you feel uncomfortable.**
- **The possible benefit of participation is that using a CGM and receiving care from the virtual clinic may provide more information about how you can manage your diabetes. This is what we are trying to find out.**

WHAT IS INFORMED CONSENT?

You are being asked to take part in a research study. Taking part is voluntary. You can choose whether or not you want to be part of the study. You can take as much time as you need to think about whether or not you want to be in this study. You can also discuss the study with friends, family, or doctors to help you decide. Please read this document carefully. Do not agree to be in this study unless all of your questions have been answered. If you decide to be in the study, you will need to indicate at the end of this form that you want to be in the study. You will be able to print a copy of this form for your records. If you have any questions before you decide to participate, you can call the VDiSC Study staff at 813-975-8690 or email vdisc@jaeb.org.

WHO IS DOING THE STUDY?

This study is being done by the Jaeb Center for Health Research (JCHR) and a team of researchers throughout the United States. The study is interested in learning how working with a virtual clinic and use of CGM outside of a doctor's office can help people living with diabetes. It is being paid for by the Helmsley Charitable Trust.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to provide access to a virtual clinic that may help people living with diabetes learn to use a CGM and manage their diabetes. About 300 people are expected to be part of the study. Each person will be in the study for up to 12 months. For the first 6 months, you will work with the virtual clinic team. If you decide to continue using the CGM after the first 6 months, then we will ask you to agree to allow us to keep collecting data for the next 6 months.

WHO CAN PARTICIPATE IN THIS STUDY?

In general, to take part in this study, you must:

1. be at least 18 years old.
2. have diabetes and use insulin daily (at least 3 injections of insulin per day or use an insulin pump that can connect to Tidepool software).
 - If you take multiple daily injections of insulin, you must be willing to use a device provided by the study that records the insulin doses every time you inject insulin and/or enter insulin dosing information through an app.
3. see a healthcare provider at least once a year.
4. be living in the United States for the duration of the study.
 - The reason for U.S. residency is because the virtual clinic staff is licensed to provide care only in the U.S. and may not be licensed in every state, and also because some study software and devices are only able to be used in the U.S.
5. use an Android or iOS smartphone that is compatible with the apps that will be used in the study.
6. have access to a compatible computer with internet that you can use to download devices and complete questionnaires.
7. understand written and spoken English.
8. be willing and able to follow the study procedures.

Also, you cannot:

1. have used a real-time CGM, including an Abbott Libre or an integrated pump system (a pump that is connected to your CGM) in the last year.
2. use any glucose-lowering medications that are not approved for your diabetes type during the study.
 - For example, if you have Type 1 diabetes, you cannot use an SGLT2 inhibitor like canagliflozin (Invokana®), dapagliflozin (Farxiga®) or empagliflozin (Jardiance®).
3. be pregnant, plan on becoming pregnant, or be breastfeeding while you are in the study.
4. be on renal dialysis.
5. be undergoing active cancer treatment.
6. have a serious vision or hearing impairment that would interfere with CGM use.
7. have a known adhesive allergy or previous skin reaction that would interfere with CGM use.
8. be participating or planning to participate in another research study in the next 12 months.

WHAT WILL HAPPEN IN THIS STUDY?

If you agree to take part in this study, we will ask you to (1) complete questionnaires, (2) learn to use a CGM and share your CGM and insulin data, (3) allow us to collect data from your insurance company if they are involved in the study, (4) provide blood samples for HbA1c testing, and (5) work with a virtual clinic team to help you with diabetes management.

First, we will ask you to complete an online questionnaire to make sure you qualify to participate. You will also complete online questionnaires that ask about your diabetes management, problems, and stresses; other medical problems you have; medications you take; your education, income, and insurance; and what you know about CGM. You will be asked to provide your diabetes healthcare provider's contact information. By providing this contact information, you are giving us permission to contact your healthcare provider about your study-related activities and information.

You will be able to use a commercially approved CGM, like the Dexcom G6 CGM. We will provide you with information about the CGM system. If more than one CGM system is available for the study, you will be able to decide which system you would like to try. We may ask you to tell us why you selected a CGM system. For about 2 weeks, you will wear a blinded CGM. A blinded CGM will record the blood sugar levels, but you won't be able to see the results. You will return the CGM and we will check the CGM to see if it has been worn enough. If there is not enough data on the CGM, you may be asked to wear the blinded CGM again. The blinded CGM will show us your current blood sugar patterns. After you successfully complete blinded CGM wear, you will receive training on regular CGM use that will let you see the results. If data from the blinded CGM wear time cannot be successfully obtained, you cannot be part of the study.

1. HbA1c Measurement

You will receive kits by mail to collect fingerstick blood samples. After you collect each sample, you will send it to a laboratory in a prepaid shipping package. The laboratory will use the sample to measure your HbA1c. The HbA1c measurement will be done at the start of the study and about every three months until you finish the study. You will be able to view your HbA1c data on the study website.

2. Working with the Virtual Clinic

During the study, you will work with a virtual clinic team for about 6 months. The virtual clinic team includes a Certified Diabetes Care and Education Specialist (CDCES) who will be your primary contact and trainer. A CDCES is a healthcare professional that works with people who have diabetes to help them take care of their diabetes. CDCES are trained to help you learn to use the CGM and learn how to use the CGM data to manage your diabetes. The virtual clinic team will also include endocrinologists and behavioral coaches. If the virtual clinic team thinks that changes in your insulin type or dosing should be considered, they will work with you to make these changes. The virtual clinic team may also ask you questions about your answers to online questionnaires and may connect you with a behavioral coach on the virtual clinic team who can provide support for diabetes management stress. This would be at no cost to you. We will ask you for contact information of the healthcare provider who helps you to manage your diabetes so that the virtual clinic team can notify your healthcare provider of any changes or updates. Contacts with the virtual clinic will be recorded for quality assurance but will not be used for anything else.

3. CGM Use and Instruction

You will receive enough CGM supplies for about 6 months. If you decide you want to continue to use CGM after the first 6 months, you will need to work with your insurance company to get coverage for additional supplies. If you decide to continue using the CGM after the first 6 months, then we will ask you to agree to allow us to keep collecting data including questionnaire data and HbA1c samples.

Your CGM kit will be sent to you with a user's manual. The study website will have information and links to online lessons for setting up and using your CGM. Your CDCES will teach you to set up and start your CGM during a videoconference or phone call. You may ask your CDCES questions during this training.

You will be given instructions on how to share your CGM data with the study team so that the CDCES and study staff can review your data. If you use an insulin pump or smart pen, we may teach you how to link your device to the CGM.

After you have used the CGM for about 1 week, your CDCES will help you learn to use your CGM data so that you can decide if you need to make changes in insulin dosing, especially when you eat or exercise. You will have another scheduled time to talk with your CDCES after using your CGM for about 3 weeks. Your CDCES will check in with you to review your CGM data. You can request additional contact with your CDCES at any time. Live webinars may be available for those who want to learn tips and tricks for using CGM.

If you decide to stop using CGM before you complete the study, we will ask you why. You may be asked to send a fingerstick blood sample to measure your HbA1c and complete some questionnaires if you stop using CGM. Then your study participation will end.

4. Questionnaires

You will be asked to complete questionnaires about every four weeks until you complete the first 6 months of the study. The questions should not take more than 30 minutes to complete. You will

receive a text or email asking you to complete the questionnaires and reminders if the questionnaires are not completed. These questionnaires will ask about how diabetes is affecting your life, stress in your life, and your views on technology. You will also be asked to answer questions about whether you have had severe hypoglycemia, diabetic ketoacidosis, were hospitalized, or if you have had any device issues during the study. When you complete the study or if you decide to stop using the CGM, we may ask you some questions about your experience with the study. You may also be asked if you are willing to allow us to share comments about your experience for research and education purposes. We would not share any information that could identify you. You will not have to answer any questions you do not want to unless the information is needed to make sure that you are eligible for the study or to set up devices needed for the study.

5. Insulin Use

If you use an insulin pump, we will give you instructions to upload the data from your pump to a software system called Tidepool.

If you use an insulin pen to take insulin by multiple daily injections (MDI), we may give you a device to attach to your insulin pen that will keep track of the time and amount of each insulin dose. You may be asked to use a device called Mallya to track insulin dose. Mallya is made by a company called Biocorp. Mallya is an Investigational Device. This means that the Mallya device has not been approved by the Food and Drug Administration (FDA) for regular use. You will load an app on your smartphone that will help to get the data from the device. If you do not use an insulin pen where data can be tracked with a device, we will ask you to record your insulin doses and times through an app.

6. Study Apps

You will load all apps needed for the study onto your personal smartphone. We will set up the accounts for you or we will help you to set up accounts during training.

The Dexcom Clarity App will let you look at your CGM data. You will share your CGM data with the study team. Your CDCES will help you read and use the data from this app to help you take care of your diabetes.

The DreaMed app will let you look at your CGM data and your insulin data. The virtual clinic team will be able to review these data and they may send you recommendations about your insulin dosage through the app. You may need to record your insulin doses and times through the DreaMed Diary during the study.

WHAT ARE THE RISKS OF THIS STUDY?

It is not expected that there would be any significant risks from being in this study. Some possible risks are as follows:

CGM Risks

The CGM sensor may be painful when the CGM sensor is inserted into the skin, like a pump site insertion or insulin injection. Rarely, a skin infection can occur at the insertion site of the sensor. Itchiness, redness, bleeding, and bruising at the insertion site may occur. An allergy to the tape that

holds the sensor to the skin is possible. The risk of skin problems could be greater if you use a sensor for longer than it is supposed to be used. There is a chance that the sensor or needle may break under your skin. This is not expected to occur, but if it does, you should speak with your healthcare provider about what to do.

Risks to Confidentiality

This study will be capturing some information about you that includes identifiable, personal information, like your date of birth and contact information. This information needs to be collected as part of the study so that we can ship study supplies to you and communicate with you. The study has procedures in place to protect that information. There is a chance that a loss of that protection could occur. This would be a loss of confidentiality. Please see the “How will my information be protected and kept confidential” section below for more information.

The study staff may use your contact information to call, text or email you during the study. They may do this to send you things like reminders about visits with the virtual clinic or to complete study questionnaires or enter information in the study apps. They are not allowed to send you identifiable health information by text or email because it is insecure. This means that there is a risk that a message may be seen by someone that is not supposed to see it, like when an email gets hacked. Your email, phone number and name will likely be in the text or email. If you think that the study staff have texted or emailed information that they should not have please contact JCHR at 813-975-8690 and ask to speak to the IRB Administrator. If you text or email the study staff it is insecure and what you put in the text or email is not protected.

If your insurance company is involved in the study, a unique number may be assigned to you so that they can give JCHR information about you. This information is called claims data, and it may help the researchers understand how well patients are managing their diabetes. Claims data that is tagged with a unique number instead of a name can be more securely transmitted between JCHR and the insurance company. This means that your insurance company might know that you are in a study, but other than that, JCHR will not be giving your insurance company any other study information about you. For more information, please see the section below called “HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL.”

Risks Related to Questionnaires

You will be asked questions about your diabetes, areas of stress in your life, and how stress might affect your diabetes management. Though uncommon, it is possible that some people may find these questions to be a little bit upsetting. If any questions make you uncomfortable, you can refuse to answer unless the information is needed to make sure that you are eligible for the study or to set up devices needed for the study. You can decide to take a break or stop taking part in the study at any time.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

It is possible that using a CGM will help your diabetes management. People who take part in this research study will add new knowledge that may help other people with diabetes.

CAN I STOP BEING IN THE STUDY?

You can stop being in the study at any time. The study may stop at any time, or the study team can stop your participation at any time. You do not have to give permission for the study to stop, or for your participation to be stopped by the study team. You will be told if this happens. If you stop being in the study, please be sure to remove the study apps from your phone.

You can decide to stop being in the study or stop getting text messages, emails, or contacts at any time. You will need to tell the study staff if you would like to stop. You cannot still be in the study if you do not want to keep using the CGM or get text messages, emails, or contacts anymore.

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

The cost of your routine care, including insulin, will be covered like it normally would be if you were not in a study. The study will provide you with a CGM device, blinded CGM supplies and unblinded CGM supplies, the HbA1c kits, and access to the virtual clinic for about 6 months at no cost. There is no cost to download the mobile apps that may be used in this study. You will get to keep the CGM supplies provided at the end of the study.

The study will not pay for personal data charges, so participants are strongly encouraged to use Wi-Fi to send data.

IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?

If you take part in the study, you will receive up to \$100 total in electronic gift cards, like an Amazon gift card, for completing all the study requirements. The gift cards will be sent to your email.

If you take part in the study, you will receive a \$50 gift card after you complete both the baseline questionnaires and the blinded CGM data collection and your HbA1c sample is received. You will be eligible for additional gift cards at the completion of 6-months of follow up if you complete the items listed below.

Participant Payment Schedule	
	Maximum Total
Completion of: Enrollment and Screening Questionnaires HbA1c sample Blinded CGM use	\$50
Completion of: 3-month HbA1c sample 3-month Questionnaires including Adverse Event Reporting	\$25
Completion of: 6-month HbA1c sample 6-month Questionnaires including Adverse Event Reporting	\$25
Maximum Total Amount Possible	\$100.00

If you are asked to take part in additional studies in the future, additional compensation may be offered for participation in those studies. For any future surveys or study opportunities, the amount of compensation will be indicated with the information about the survey or study, and you can decide if you want to participate. For example, if you are going to continue using CGM, then we will ask you to enroll in an additional 6-month follow-up and additional compensation will be offered.

WHAT HAPPENS IF I HAVE AN ILLNESS OR INJURY FROM BEING IN THE STUDY?

This is a study with minimal risk. For this reason, it is not expected that there would be any study related illness or injury. If you have an illness or injury that is related to your participation in the study, then you can get care like you normally would. The study does not plan to provide costs for care or other expenses relating to illnesses or injuries.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

If you have any questions, concerns or suggestions about this study, then please contact the study team at vdisc@jaeb.org.

Also, you can contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or irb@jaeb.org if you:

- Have questions about your rights as a research participant
- Wish to talk about your concerns or suggestions about the research
- Want additional information about the research, or
- Want to provide comments about the research.

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

As required by law, study-related records with identifying information will be kept confidential. Safety measures for the access, security, and privacy of your information have been put in place by law. Unless the law requires it, your name, email address, or any other direct identifying information will not be used to identify you.

Purpose of Authorization

We have rules to protect information about you. Federal and state laws also protect your information. By signing this form you are giving your permission, called your “authorization,” for the use and disclosure of information protected by the law.

You must sign this form, including the Protected Health Information Authorization statement in the signature box at the end of this form if you want to be in the study. When you sign the form, you give permission for the use and sharing of your Protected Health Information (PHI) for the study. PHI is health information that identifies you. Your authorization is beneficial and important for the study. Without your authorization, you will not be able to be in this study.

Using and Sharing Your PHI

Information will be collected about you in this study. This information includes your name, email address, telephone number, mailing address and date of birth. These are examples of identifiable information. Additional identifiable information such as prescriptions, doctors' visits, hospitalizations, diabetes diagnosis codes and evidence of insulin use may be collected from your insurance carrier. These types of data are known as **claims data** and can help us understand how CGM use and virtual clinic support can improve your health. If you are insured by certain health plans, your insurance carrier or their designee will provide the claims data to JCHR. We will need to let them know you are in the study to get this claims data about you, but JCHR will not be giving the insurance company any other study data about you.

A copy of the information collected will be kept in a secure database at JCHR. This will allow the new information to be linked to this other information and may include the PHI described. Information may need to be entered into an app that is being used for the study, so the company that makes the app may have access to your information. As an example, when you set up the DreaMed app, DreaMed will have access to your email address and diabetes treatment information, like your CGM data and your insulin use data. DreaMed collects this information so that you and the virtual clinic team can see all of your data in one place so that they can make recommendations about your treatment if needed. Another example is companies that make the CGM may have access to your CGM data, which may include your email and date of birth.

The virtual clinic team can also contact your healthcare provider and discuss you and your data with them. By signing this authorization, you are giving permissions for this to happen.

Study results without the identifiable information may be shared in medical journals and at scientific meetings. Your records will be confidential. No one will share your identity in a medical journal or at a scientific meeting. Results from the study will not be sent to you.

If you are covered under an Aetna Health Plan:

By signing this authorization, you permit JCHR to request your claims data from Healthagen LLC, an affiliate of your Aetna health plan. You also permit Healthagen to share your claims data with JCHR. Healthagen has rules to protect information about you. Federal and state laws also protect your information. Healthagen will not transfer claims data to anyone other than JCHR, unless you authorize Healthagen to do so.

Who Can Receive and Use Your Study Information?

It is possible that people outside the Jaeb Center may need to see or receive your information from this study. Some examples include the study staff and researchers, the laboratory that is measuring HbA1c, companies involved in the study, government agencies (such as the National Institutes of Health), committees that monitor safety, other sites in the study, and companies that sponsor the study. In most cases the information will have a code number with it instead of your name or email address.

There are some situations where the information will not have a code number but may include your name, email address, or phone number. Everyone who needs to see your information will be told it is confidential, but we cannot guarantee full confidentiality.

Can You Cancel Your Authorization?

You may cancel your permission for the use and sharing of your study PHI at any time. You will need to contact the JCHR IRB to cancel this. When you cancel your permission or when you withdraw from the study directly, you are no longer part of the study. No new information about you will be gathered for the study. The Jaeb Center will receive all the information that was collected for the study up to the time that you cancel or withdraw from the study.

When Will the Use and Sharing of Your PHI Stop?

Some of your study PHI does not have a code number with it. Your permission for the use and sharing of your PHI lasts 50 years from the date that you sign this form or until the end of the study, whichever comes first. The rest of your study information does have a code number with it. When it is collected, it becomes part of a research report. Your permission for the use and sharing of this coded information will never end. This coded data does not have your name or email address.

Other Considerations

The information collected in the study may be used in future studies without additional permission from you. This may include research done by other researchers. The information that may be shared will not contain any information that could identify you. There may still be a chance that someone could identify you, but this is not likely. The study results will also be made public. These results will not have any information that could identify you. After the study is completed, the Jaeb Center for Health Research in Tampa, FL may share your information collected as part of the study with the Helmsley Charitable Trust in New York, NY. Your information collected as part of this study may be stored, maintained or used for future research by the Helmsley Charitable Trust.

Contact from the Jaeb Center

The Jaeb Center for Health Research will be provided with your email address to send emails on further opportunities for you to participate. You do not need to participate if you do not want to.

Contact from Study Staff

You will need to provide your name and mailing address so that we can ship the study supplies to you. You will need to provide an email address and a cell phone number to receive communications from the study staff at JCHR or the virtual clinic.

You will have communication with the study and virtual clinic staff by phone, text, or video (like FaceTime, Zoom, or Skype). You may also receive text messages through a third-party texting service. There is a chance that someone could see or hear the conversation like they could if you were speaking or texting with anyone.

If you do not want to provide contact information or receive study communications, you should not agree to take part in the study. If you decide later that you no longer not want to receive study communications, you will not be able to stay in the study.

AUTHORIZATION AND AGREEMENT TO BE PART OF THE STUDY

If you agree to take part in the study, please click the ‘I agree to take part in this study’ button below. Clicking the button below signs this document.

If you only want to be part of this study and you do NOT want to be contacted by email about future studies or other opportunities for which you might be able to participate, check this box
(If you do not check this box now, you will be able to opt out of receiving additional information at any time in the future)

By clicking the box below, you are confirming that you have read this document and want to be part of the study. You also are authorizing the use and disclosure of your protected health information as described. This information is collected as part of participation in this study. You cannot be in this study if you do not provide this permission. Clicking the box below is the same as signing your name.

Email address (this will be used to identify you and your data in the study): [Label]
Enter today’s date _____
Enter your date of birth [Date picker]

I agree to take part in this study

Please print a copy of this consent form for your records by using your browser Print Screen feature.