OREGON HEALTH & SCIENCE UNIVERSITY

**IRB#: 25174**

MED. REC. NO. _____
NAME _____
BIRTHDATE _____

## CLINICAL RESEARCH CONSENT AND AUTHORIZATION
## SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

**TITLE:** A crossover study to assess the effect of an artificial intelligence (AI)-based bedtime *smart snack* intervention in preventing overnight low glucose in people with type 1 diabetes on multiple daily injections.

**PRINCIPAL INVESTIGATOR**: Clara Mosquera Lopez PhD *(503) 346-0100 pager 13209*

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not.

**PURPOSE:**
The purpose of this study is to learn more about a decision support tool that may be helpful in managing your diabetes. The study device, called DailyDose, is a phone application that will track your sensor glucose and make personalized snack recommendations at bedtime to prevent low glucose while you sleep.

**DURATION:**
Your participation in the study will consist of 6 clinic and 6 phone visits over approximately 12 to 14 weeks. Some visits can be virtual.

**PROCEDURES:**
If you decide to take part in this study, you will have a number of tests and procedures.

- There are two 4-week study periods, a control period and intervention period. The order will be randomly assigned.
- The control period will begin with a 30-90 minute training visit on the Dexcom G6 continuous glucose monitoring system. You will use the sensor at home for 4 weeks, managing your glucose as you normally would.
- The intervention period will begin with a 2-3 hour training on using the DailyDose app with the Dexcom G6 system, including how to accept/decline snack recommendations.
- At the end of the each 4-week period, you will meet with staff to complete the visit.
- You will wear an Apple watch during the day and night while on study to collect sleep data and complete a survey about sleep quality each week.

CO1450

- At the end of the study, you will complete a short exit visit.
- You will complete 3 surveys at the beginning and end of the study.

**RISKS:** There are risks involved in participating in the study, some of which may be very serious. These may include, but are not limited to, common risks such as high glucose, low glucose.

**BENEFITS:** You may or may not directly benefit from taking part in this research. This research may benefit in the future people with type 1 diabetes by helping to develop better management tools for diabetes.

**ALTERNATIVES:** You may choose not to participate in this study or participate in another study if one is available.

This is a voluntary research study. You do not have to join the study. Even if you decide to join now, you can change your mind later. Please ask the Investigator if you have any questions about the study or about this consent form.

**END OF CONSENT SUMMARY**

OREGON HEALTH & SCIENCE UNIVERSITY

MED. REC. NO. _____
NAME _____
BIRTHDATE _____

**IRB#: 25174**

## Clinical Research Consent and Authorization Form

**TITLE:** A crossover study to assess the effect of an artificial intelligence (AI)-based bedtime *smart snack* intervention in preventing overnight low glucose in people with T1D on multiple daily injections.

**PRINCIPAL INVESTIGATOR**: Clara Mosquera Lopez PhD *(503) 346-0100 pager 13209*

**WHO IS PAYING FOR THE STUDY?**: National Institutes of Health (NIH)

OHSU is being compensated by the funder to conduct this study. This is to pay for tests performed only for study purposes, and for the time involved on the part of the investigator(s) and study staff. You may freely discuss this with your physician and the investigator if you have concerns. Your study doctor and the research staff have no financial involvement with the funder and are not being paid directly by the funder for conducting this study. However, they may have travel expenses covered by the funder to attend study training meetings.

**WHO IS PROVIDING SUPPORT FOR THE STUDY?:** Dexcom will provide the Dexcom G6 Continuous Glucose Monitors (CGM) that will be used in this study.

**WHY IS THIS STUDY BEING DONE?:**
You have been invited to be in this research study because you have type 1 diabetes. The purpose of this study is to learn more about DailyDose, called the study device, that will track your sensor glucose and make personalized snack recommendations at bedtime to prevent low glucose while you sleep.

The study device, the DailyDose smartphone application, is considered investigational and is not currently available for consumers. It has not been approved for use for treatment of type 1 diabetes by the FDA because we do not know enough about it. You will be using the Dexcom G6 CGM system including a sensor and transmitter. The Dexcom G6 CGM system is an FDA approved device.

CO1450

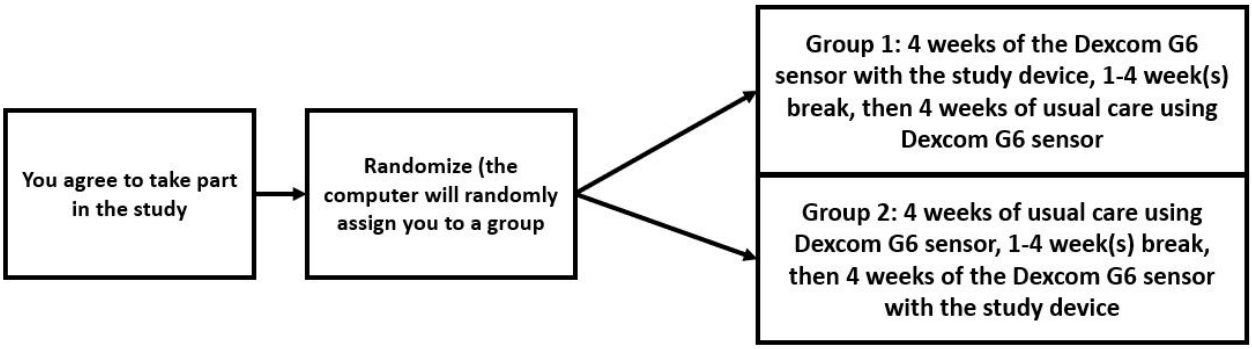
Your participation in the study will consist of 6 clinic and 6 phone visits over approximately 12 to 14 weeks. We expect enroll up to 20 participants at OHSU.

The data we collect during your study will be kept in a data bank, also called a repository. This data will be stored indefinitely and may be used and disclosed in the future for research.

## WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?

See **Figure 1** below for a diagram of the study design.

**Figure 1: Study Flow Design**




**Clinic Visit #1: Screening Visit**:
The screening visit will be completed at the Biomedical Engineering Point of Care (BME POC) Laboratory, the Harold Schnitzer Diabetes Health Center or virtually. After this consent form is signed, you will have blood drawn for tests. The blood test is to monitor diabetes control, liver and kidney function, electrolytes, and blood count. About one tablespoon of blood is needed for these tests. If you have had any of these tests completed in the last 6 months and we can access the results, we will not draw blood for that test. If the blood tests show that you have medical problems such as kidney disease, liver disease or anemia, it will not be possible to include you in the study.

You will also be asked questions about your medical history. Your vitals will be taken (height, weight, pulse, blood pressure) along with a brief physical unless you have an exam with vitals available to review within the last year in your chart. If you are a person who can become pregnant, you will need to take a urine pregnancy test. This test must be negative for you to participate in the study. As part of the screening procedures for this study, the investigator will review your medical records for information related to your eligibility in the study. For example, they may review your recent lab results and visit notes from your endocrinologist. We will download your sensor to determine if you have experienced overnight low glucose in the last 30 days. You will be asked to fill out 3 surveys. This visit will take about 1 ½ hours.

After you qualify, you will be randomly assigned to complete the 4-week control period or 4-week intervention period first. There will be one to four weeks in between the two periods during which you would continue your usual care, which includes your personal CGM and insulin therapy.

You will be given a study Apple iPhone as well as an Apple Watch that will be paired with the study iPhone, and a study scale.

If you are currently using the Dexcom G6 CGM for personal use, you will continue to use your own Dexcom G6 sensor and transmitter supplies for the study, as explained below:

- During the 4 weeks of usual care using the Dexcom G6 sensor, you will continue your normal diabetes care which will include using your sensor and transmitter with the Dexcom G6 app on your personal phone. We will ask you to share your Dexcom Clarity data with the clinic research team. The sharing code you provide will give our team access to your data for 3 months.

- During the 4 weeks of the Dexcom G6 sensor with the study device, you will pair your personal G6 sensor transmitter to the study app on a provided study iPhone. You will not be able to pair your G6 transmitter to both your personal phone and the provided iPhone at the same time.

If you are not already using a Dexcom G6 transmitter for personal use, the study will provide the G6 sensors and transmitter to use during the study. We will provide the snacks to you that will be recommended by the device. These supplies, including a urine pregnancy test if applicable, will be given to you either at the screening visit if we can access your lab results to determine if you are eligible or delivered via courier.

If you qualify for the study and choose to participate, you will complete the following:

- You will be trained how to use the Apple Watch with the study iPhone. You will be asked to wear the watch overnight to measure your sleep quality.
- You will weigh yourself at the beginning of each 4-week period. You will be instructed to report your weight weekly in the morning before eating breakfast. Staff may provide you with a bathroom scale to use during the study.
- Study staff will contact you weekly to collect your weight and response to the sleep survey.
- Study staff may contact you via text message to remind you of study procedures or to give assistance. Regular text messages are not secured by a technical process called encryption so there may be some level of risk the information could be read by someone besides you. If you agree to the text option, you are accepting this risk.
- There is the option for some visits to be completed by video with the study devices being delivered to you by mail. For the screening visit, if you had lab tests in the last 3 months and a physical exam with heart rate and blood pressure in the last year that we can access in your medical records you may qualify for a virtual visit. If applicable, we will mail you a pregnancy test for the virtual visit.
- For virtual visits, you will need to install a software program called WebEx on your personal device for the video visits. WebEx is a secure virtual software platform approved for use with OHSU patients. Study staff are available to assist with the install. Study staff will virtually connect with you for study procedures while you are at home. Study staff may ask for your responses to the surveys.

**Control period start-up visit**

This visit will be completed at the Biomedical Engineering Point of Care (BME POC) Laboratory, the OHSU Harold Schnitzer Diabetes Health Center or virtually. If you are a person who can become pregnant, you will take a urine pregnancy test. If you test positive, you will not be able to continue in the study. If you don't normally use the Dexcom G6, you will be shown how to insert the G6 wire glucose sensor using the Dexcom G6 app on a provided study iPhone and calibrate/replace according to the manufacturer's directions. The CGM alerts will be set at 70 mg/dL and 250 mg/dL. You will be shown how to use the Apple Watch. This visit will take approximately 30-90 minutes, depending on your experience.

**Control period closeout visit**

After 4 weeks, study staff will connect with you virtually or by phone to close out the control period visit. This visit will take about 10-15 minutes. If you used your own Dexcom G6 CGM during the control period, we will ask you to share your Dexcom Clarity data with the study team.

**Intervention period start-up visit**

This visit will be completed at the Biomedical Engineering Point of Care (BME POC) Laboratory, the OHSU Harold Schnitzer Diabetes Health Center or virtually. If you are a person who can become pregnant, you will take a urine pregnancy test. If you test positive, you will not be able to continue in the study.
At this visit, you will learn how to use the study device to assist in managing your glucose at night. You will go through the onboarding process including how to use the app for the following:

- Dexcom G6 glucose sensor
- Setting sensor and bedtime alerts
- Accepting/declining snack recommendations
- Logging exercise

This training visit will take about 2-3 hours, depending on your experience. Several snack options will be provided for bedtime. Study staff will follow-up with you within the first 4 days, after 7-11 days, after 21-25 days on study. Additionally, a study investigator will review your sensor glucose data every week.

**Intervention period closeout visit**
After 4 weeks, study staff will connect with you virtually or by phone to close out the intervention period visit. You will be asked to fill out the same 3 surveys that you completed at the screening visit. This visit will take about 30 minutes.

**Time between study periods**
For the 1-4 week(s) between the study periods, you will continue your usual care, which includes your personal CGM and insulin therapy.

**Potential additional time on study**
If your control or intervention study period is paused due to technical problems, you may be asked to complete additional time on study, up to 4 weeks. Additional compensation will be provided for any extra time as outlined below in the section "What are the costs of taking part in this study?". It will be optional to complete extra study time. Technical reasons to pause your study may include the following:

1. Not having enough study supplies, such as Dexcom supplies or bedtime snacks
2. Issues with the study phone that prevents access to the DailyDose app, such as damage to the phone or problems with the internet connection that prevents data from being uploaded to the remote monitoring system
3. Issues with the CGM system that prevents DailyDose from generating bedtime recommendations
4. Scheduling issues where you are unable to complete the control or intervention period continuously

**Study completion visit**
Study staff will connect with you virtually or by phone to close out the study. This visit may be combined with the control or intervention period closeout visit but no later than 2 weeks after you finish the study. Study staff will share with you the factors that contributed to a higher chance of overnight low glucose during your study. For example, a certain type of exercise may have been the biggest contributor to your overnight low glucose risk. You will complete a survey about the study device. You will be given shipping boxes for sending all devices back at the end of the study. You will be given a checklist of equipment to return. This visit will take about 1 hour.

In the future, your information may be shared with other investigators for future research studies. The information will be labeled as described in the **WHO WILL SEE MY PERSONAL INFORMATION?** section.

If you have any questions regarding this study now or in the future, call (503) 346-0100 and page the Principal Investigator Clara Mosquera Lopez PhD at pager 13209 or call Deborah Branigan at (503)418-9070.

## Clinic Visit Schedule

| | | 1st 4 weeks | | | | | 2nd 4 weeks | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Description of visit procedures** | **Screening** | **DailyDose or Control initiation visit** | **Phone check-in** | **Phone check-in** | **Phone check-in** | **DailyDose or Control (CG)[2]close out visit** | **DailyDose or Control initiation visit** | **Phone check-in** | **Phone check-in** | **Phone check-in** | **DailyDose or Control close out visit** | **Study Completion Visit** |
| **Visit Number** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** |
| **Visit Window** | | **1-84 days** | **7 days** | **7 days** | **7 days** | **7 days** | **7 days** | **7 days** | **7 days** | **7 days** | **7 days** | **14 days** |
| **Visit Activities and Data Collection** | | | | | | | | | | | | |
| Height collection | X | | | | | | | | | | | |
| Weight collection | X | X | X | X | X | X | X | X | X | X | X | |
| Blood pressure and heart rate collection | X | | | | | | | | | | | |
| Physical exam | X | | | | | | | | | | | |
| Medical history collection | X | | | | | | | | | | | |
| Pregnancy test if applicable | X | X | | | | | X | | | | | |
| Blood collection for A1c, Complete blood count, Comprehesive metabolic panel | X | | | | | | | | | | | |
| Medication review | X | X | X | X | X | X | X | X | X | X | X | |
| Download Your glucose sensor | X | | | | | | | | | | | |
| Surveys | X | | X | X | X | X | | X | X | X | X | X |
| Randomization | | X | | | | | | | | | | |
| Collection of any side effects | | X | X | X | X | X | X | X | X | X | X | |
| Training on study procedures | | X | | | | | X | | | | | |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Use apple tracking watch | | X | X | X | X | X | X | X | X | X | X | |
| **Time** | 1 ½ hours | 30-90 min or 2-3 hours | 30 min | 30 min | 30 min | 10-15 min or 30-90 min | 30-90 min or 2-3 hours | 30 min | 30 min | 30 min | 10-15 min or 30-90 min | 1 hour |

## WILL I RECEIVE RESULTS FROM THE TESTING IN THIS STUDY?

Some of the information collected and created in this study may be placed in your OHSU medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your OHSU medical record. If you have questions about what study information you will be able to access, and when, ask the investigator.

We will run routine labs at your screening visit to monitor diabetes control, liver and kidney function, electrolytes, and blood count to determine if you are eligible for the study. We do not plan to share your test results with you or your primary care provider. However, if we discover information that is important for your health care, either in this study or in the future, we will contact you and ask if you want to know the results. If you choose to receive the results, you may need to have the test repeated in a non-research laboratory. You may learn information about your health that is upsetting or that impacts your health. You will be able to ask the investigator about any of the study results.

## WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?:

### Risk of Low and High Glucose

Low glucose could occur. Symptoms of low glucose can include sweating, weakness, shaking and not feeling well. The study device and the Dexcom G6 smart phone app will have high and low glucose alerts that you can adjust. There is a very low glucose alert that cannot be adjusted. When using the study device, you will be able to receive recommendations if your glucose is predicted to go low overnight. High glucose also could occur. Symptoms of high glucose includes increased thirst, tiredness, blurred vision and irritability. It is unlikely that you will experience severe low or high glucose because of the use of the study device and Dexcom G6 app with alarms set.

### Blood Draw Risks

We will draw blood from your arm at the screening visit. You may feel some pain when your blood is drawn. There is a small chance the needle will cause bleeding, a bruise, an infection, or fainting.

### CGM

The CGM sensor may produce pain when it is inserted into the skin, similar to a pump site insertion or insulin injection. Rarely, a skin infection can occur at the site of insertion of the sensor. Itchiness, redness, swelling, bleeding and bruising at the insertion site may occur. An allergy to the tape that holds the sensor onto 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 a study investigator.

### Using the Dexcom G6 for Treatment Decisions

The study device uses the Dexcom G6 values for glucose alerts. The Dexcom G6 Continuous Glucose Monitoring System is FDA approved to use for treatment decisions such as calculating insulin doses for food and corrections. However, there are risks associated with using the G6 as

the values can be inaccurate, can vary with each newly inserted sensor and might work differently in different situations (meals, exercise, first day of use, etc.) You will be trained before using the G6 to always use your own judgment when determining if the G6 is matching what your body is telling you. In the event your symptoms do not match the value on the G6, you will be instructed to perform a fingerstick and use this value to make treatment decisions and, if needed, to calibrate the Dexcom G6 device.

**Pregnancy Risks**

If you are nursing an infant or you are pregnant now, you cannot be in the study. This study may involve risks to an embryo, fetus, or nursing infant that are currently unknown. If you are sexually active and could become pregnant, you and your partner(s) must use birth control that works well or you must not have sex. The investigator will talk to you about the types of birth control that are acceptable. You will have to do this the whole time you are in this study. If you become pregnant during the research study, please tell the investigator and your doctor immediately.

**Other Side Effects**

One risk to taking part in this study is that the study may not be effective in helping to treat your disease. This means you may spend time in the study that may not provide you with any health-related benefits. You may have some side effects we do not expect because we are still learning about this blood glucose control system.

**Risks from Storage of Data in Repository**

There is a slight risk of a breach of confidentiality from keeping your data in a repository. However, the plan listed in the section "WHO WILL SEE MY PERSONAL INFORMATION?" makes it unlikely that a breach would occur.

**Risks from Using Provided Study Phone**

You will be provided with a phone with security controls in place. These controls include password access so only you can access the phone. However, if you lose the phone - or it is stolen - data could be accessed by other individuals not authorized by you to view your information. In using the study phone, you accept the risk, however slight, that your information could be compromised.

**WHAT ARE MY CHOICES IF I DECIDE NOT TO TAKE PART IN THIS STUDY?**

You may choose not to be in this study. If you do not take part in this study, the alternative is to continue your current diabetes treatment and care. You could choose to use the Dexcom G6 CGM system for management of your diabetes without being in the study. We encourage you to discuss your options with your study doctor, your general primary care physician, or another health care professional.

**WHO WILL SEE MY PERSONAL INFORMATION?**

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. To protect your privacy, you will be assigned a 3-digit number to identify your study data. The key associating the 3-digit number and your personal identifying information will be restricted to the study staff. It will also be encrypted and kept secure on a restricted OHSU drive in a limited access folder. The lead coordinator, Deborah Branigan, and research coordinators listed on this IRB protocol will have access to this encrypted key but outside researchers will not. The study phone you will use will be registered to this 3-digit number. All of the data stored on

the study iPhone and pushed to our cloud server will be associated with this ID. The data that will be stored includes:

- sleep data from the Apple watch
- glucose sensor data from the Dexcom G6 CGM
- self-logged snacks and exercise into the study device

We will create and collect health information about you as described in the WHY IS THIS STUDY BEING DONE? and the WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY? sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study and store in a repository.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The funder of this study, the National Institutes of Health and the funder's representatives
- The Food and Drug Administration
- Dexcom Inc.
- The Office for Human Research Protections, a federal agency that oversees research involving humans

Those listed above may also be permitted to review and copy your records, including your medical records.

Your name, date of birth and social security number may be provided to the study funder (or an organization acting on their behalf) so the funder can meet Medicare reporting requirements.

Data from this study may be shared with other investigators for future research studies. All identifying information about you aside from some dates will be removed from the data before it is released to any other investigators.

By participating in this study, you are giving permission for your data to be stored indefinitely in a repository in order to be used in future research studies. Generally, a research repository collects, stores and distributes data for use in future research projects. Storing and gathering lots of data together can help to conduct future research and avoid re-collecting data over and over again. The purpose of this data repository will be to combine all of the study data from the OregonAPC group into one set for future engineering development of diabetes technologies.

The data stored on the phone is uploaded into a secure OHSU approved cloud database repository along with your blood glucose data from the meter and your answers to the surveys. Data access will be reviewed and tracked to ensure that data is only released to authorized individuals. The data will remain in the cloud database until the PI for the repository, Dr. Leah Wilson, decides to discontinue the repository. The termination will include the destruction of the data in a secure way. If you withdraw your consent from this project, your data will be destroyed.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

To help us protect your privacy, we have obtained a Certificate of Confidentiality to protect your privacy even from people who try to get your information using a court order. One exception is if you agree that we can give out research information with your name on it. Another exception is information about child or elder abuse or neglect and harm to yourself or others or communicable disease reporting. Note that this doesn't prevent you from releasing the information yourself.

When we send specimens or information outside of OHSU, they may no longer be protected under federal or Oregon law. In this case, your specimens or information could be used or re-released without your permission.

We may continue to use and disclose your information as described above indefinitely.

Some of the information collected and created in this study may be placed in your OHSU medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your OHSU medical record. If you have questions about what study information you will be able to access, and when, ask the investigator.

***WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT?***

Any data obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your information.

**WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?**

There will be no cost to you or your insurance company to participate in this study. You will receive $400 for completion of all study visits. If you withdraw early from the study, compensation will be given as follows: $40 per week for the control or intervention periods. There is no compensation for the screening visit. If you are asked to repeat any time on study due to technical problems, you will receive an additional $40/week. We will request your social security number in order to process any payments for participation.

You may receive payment via a debit card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and FAQ sheet given to you with the debit card.

Payment received as compensation for participation in research is considered taxable income for a research participant. If payments are more than $600 in any one calendar year, OHSU is required to report this information to the Internal Revenue Service (IRS). Research participant

payments exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the research participant and a copy will be sent to the IRS.

**WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?**:
If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact Clara Mosquera Lopez PhD (503) 346-0100 pager 13209.

If you are injured or harmed by the study device or study procedures, you will be treated. OHSU and the funders do not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

**WHERE CAN I GET MORE INFORMATION?**
If you have any questions, concerns, or complaints regarding this study now or in the future, call (503) 346-0100 and page Clara Mosquera Lopez at pager 13209 or call Deborah Branigan at (503)-418-9070.

This research has been approved and is overseen by an Institutional Review Board ("IRB"), a committee that protects the rights and welfare of research participants. You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

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

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

**WHAT ARE MY RESPONSIBILITIES IN THIS STUDY?**
There are important instructions for you to follow during the study. We will ask you to use the study devices and Dexcom G6 sensor. We will ask you to respond to the glucose sensor alarms and other alerts from the system as directed. We will ask you to complete several surveys during the study.

**DO I HAVE TO TAKE PART IN THIS STUDY?**
Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about

your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

**IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?**

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

***Clara Mosquera Lopez, PhD***
***Oregon Health and Science University***
***Center for Health and Healing***
***3303 SW Bond Ave.***
***MC: CH13B***
***Portland, Oregon 97239***
***mosquera@ohsu.edu***

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

If you choose to withdraw from the study, you will be asked to bring in all of the study devices and have the Dexcom sensor removed.

If in the future you decide you no longer want to participate in this research, we will destroy all your information. However, if your samples are already being used in an ongoing research project and if their withdrawal jeopardizes the success of the entire project, we may ask to continue to use them until the project is completed.

You may be removed from the study if the investigator stops the study, you become pregnant, you develop serious side effects, or you do not follow study instructions.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

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.

Study staff may contact you via text message to remind you of study procedures or to give assistance. There is some level of risk information in an unencrypted text message or email. We recommend that you password protect your mobile phone. Study staff will follow OHSU policy for secure transmission of your protected health information.

_____ I agree to receive email or text messages from study staff.

_____ I do not agree to receive email or text messages from study staff.

**SIGNATURES:**
Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

| Participant Printed Name | Participant Signature | Date |
|---|---|---|

| Person Obtaining Consent Printed Name | Person Obtaining Consent Signature | Date |
|---|---|---|