CONSENT TO TAKE PART IN A RESEARCH STUDY

If the participant cannot read this form (like when they cannot see or read well), then the study doctor must use an IRB approved short form process or a consent form in their language.
This form is not intended to be read to the participant as written.

STUDY TITLE: CGM FOR THE EARLY DETECTION AND MANAGEMENT OF HYPERGLYCEMIA IN PREGNANCY: "IMAGINE"

STUDY DOCTOR'S INFORMATION
Site PI Name:
Site Name:
Mailing Address:
Emergency (24-hour) Number:

SUMMARY
Informed consent is the process that tells you about what is involved in a research study. It tells you about the study, study procedures, and study treatments. It tells you about how study treatments are given and what side effects could happen. This process usually involves reading a form like this one, someone on the study team talking to you about the study, and getting your questions and concerns addressed. The goal is that you have all of the information you need so that you can decide if you want to participate in the study.

You do not have to be in this study. You can stop being in the study at any time. If you decide not to be in this study, you will not have any penalty or loss of any benefits that you normally get. You should read and discuss all of the information in this consent form with the study doctor or study health care provider (which will be referred to as 'doctor'). You can ask for a copy to share with other people to help you decide. Do not agree to be in this study unless all of your questions have been answered. Please take as much time as you need.

- This study will include healthy pregnant individuals who do not have known diabetes but whose sugar levels are sometimes higher than what is considered normal. The purpose of the study is to find out if lowering sugar (glucose) levels early in pregnancy (starting before the end of 16 weeks) will reduce infant and maternal complications. The study will be carried out at about 10-12 sites in the US or England.

- The first step will be for the site staff to determine if you are eligible for the study. Information will be collected about your pregnancy, medical conditions, and laboratory test results. In addition, your sugar levels will be measured by having you wear a small sensor on your skin called a continuous glucose monitor or CGM for up to 10 days. The CGM sensor is inserted under the skin using a small, retractable needle. The sensor will measure glucose levels every 5 minutes. You won't be able to see the glucose measurements. If the sensor comes out or stops working, it might need to be replaced.

- While you are wearing the CGM, we will see how often your glucose levels are higher than normal. Most pregnant individuals have some amount of high glucose values. If you have more high glucose values than expected but not too many, you will be eligible to continue in the main study. We expect that about 1 in 4 individuals who wear the CGM sensor will be eligible for the main study.

- If you don't have very many high glucose values or you have a lot of high glucose values, you will not be able to participate in the main study. Instead you will just follow your usual obstetrical care outside of the study. At the end of your pregnancy, we will be collecting health information about you and your infant from your medical record . This information will help us understand the effects of glucose levels early in pregnancy on the health of the mother and child.

- In the main study, half of the participants will continue routine obstetrical care which will be the same care they would have if not in the study. These participants will wear a CGM sensor about once every four weeks for 10-14 days starting at the 18-22 week routine care clinic visit. The sensors will be placed at your regular obstetrical care visits. If a sensor stops working, it might need to be replaced. The glucose levels won't be visible to you. If you have a lot of high glucose values during the first sensor wear period, we inform your study clinical team who will decide if treatment is needed.

- The other half of the participants will begin treatment to reduce sugar levels. These participants will wear a CGM sensor all the time and be able to see the glucose values. Your glucoses will be reviewed by study clinical team to determine the recommended treatment such as diet and activity and/or medications.

- The most likely risk to you is brief mild discomfort when the CGM sensor is inserted. It is not expected that there will be any risk to your unborn baby. Treatment used to reduce sugar levels could cause a low blood sugar. Symptoms of a low blood sugar include sweating, jitteriness, and difficulty concentrating. In rare cases, a very low sugar could result in loss of consciousness or a seizure. It is possible that very frequent low blood sugars could affect the growth of the fetus. If you are in the Glucose Lowering treatment group, your glucose levels will be monitored to avoid frequent low readings.

- The possible benefit is the possibility that treating high sugars early in pregnancy will reduce infant and maternal complications such as an increased risk of larger baby size, your infant having low blood sugar after birth, or your developing high blood pressure in pregnancy.

- If you do not participate in the study, you will receive your usual pregnancy care.

WHO IS DOING THE STUDY?

This research study is being coordinated by researchers at the Jaeb Center for Health Research. It is being paid for by Leona M. and Harry B. Helmsley Charitable Trust, Dexcom Inc., and Abbott Diabetes Care, Inc. The Jaeb Center for Health Research Foundation, Inc. will use the funding to organize the study. Your study doctor and clinic staff will use the funding to carry out this study. The study doctor's contact information is listed on the first page of this form. If one of the study doctors gets money or benefits from a company that makes the drugs or devices in this study, then they have to tell the Jaeb Center.

WHY IS THIS STUDY BEING DONE?

Gestational diabetes mellitus (GDM) is a condition in which diabetes (high blood sugars) occurs during pregnancy in individuals who don't otherwise have diabetes. Currently, GDM is diagnosed by having an oral glucose tolerance test at 24 to 28 weeks of gestation. We don't know if diagnosing GDM early would be beneficial.

The study is being done in healthy pregnant individuals without known diabetes to find out if starting treatment of high sugar (glucose) levels, identified using a continuous glucose monitor (CGM), before about 16 weeks of gestation would be beneficial for improving the health of the mother and infant.

WHO CAN PARTICIPATE IN THIS STUDY?

Approximately 6,000 women are expected to be screened and 1,500 will participate in the main study at approximately 10-12 sites in the United States or England.

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

- have a single pregnancy verified by ultrasound (ie, not pregnant with twins)
- be at least 18 years old
- be pregnant for less than 14 weeks 6 days when screened and less than 16 weeks 6 days after completing the CGM screening
- speak English or Spanish
- have a HbA1c level <6.5% (48 mmol/mol) (HbA1c is a test for diabetes)
- have no prior history of GDM
- be willing to wear a CGM sensor during your entire pregnancy

To participate in the main part of the study, you must:

- have more than the expected amount of high sugar values when wearing the screening CGM sensor

Also, you cannot take part if you:

- have diabetes or take drugs to treat your blood sugar
- have had prior gastric bypass surgery
- plan to terminate the pregnancy
- are participating in another trial in which you are receiving treatment of any kind

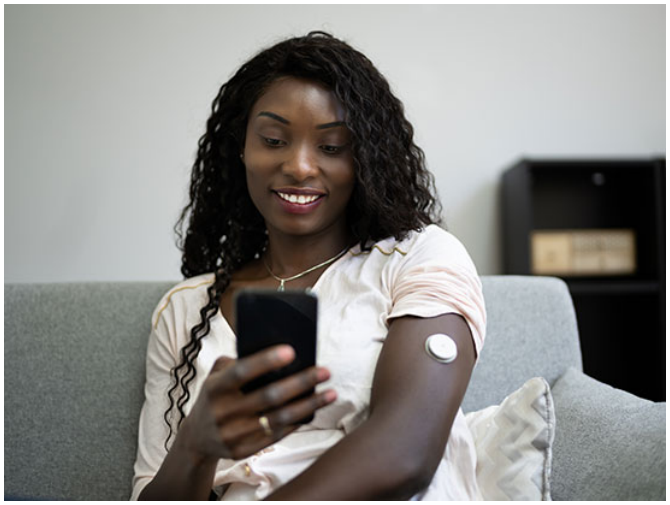
Your study doctor and staff will review more health-related requirements with you.

WHAT WILL HAPPEN IN THIS STUDY?

If you are eligible, the clinic staff will explain what is involved in the study. You will need to read and sign this form to confirm you want to participate.

Screening

We will collect information from your medical record and ask you questions to see if you are eligible for the study.
To see if you qualify for the main study, a CGM sensor will be placed on your skin. You will wear the sensor for up to 10 days to collect glucose data. The CGM system has a small needle and sensor that is inserted under the skin. The sensor probe is about twice the thickness of a human hair and is about a ½ inch long. The needle is slightly thicker. The sensor probe is inside the needle. After the needle is inserted, the needle is pulled out and the sensor probe stays under your skin. It will be inserted on the arm unless you prefer a different allowable location on the skin. The sensor will measure the glucose level every 5 minutes. You will not be able to see the glucose levels.



After about five or ten days, your study team will contact you to inform you if you are eligible for the main study.

- If you are not selected to be part of the main study, there is nothing further for you to do for the study. At the end of your pregnancy, we will collect information from your medical record. This will include medical history, results of an oral glucose tolerance test, any complications you have with the pregnancy, and the outcome of your pregnancy.

Main Study

If you qualify for the main study, you will come in for a study visit. The study procedures will again be explained to you. We want to make sure you understand what will be involved if you take part in the study. After this visit, there are no office visits for the study. All visits during the rest of your pregnancy

will be same as they would be if you are not in the study. At the end of the study, information from these visits and information about the birth of your infant will be collected from your medical record.

In the study, half of the participants will continue routine obstetrical care which will be the same care they would have if not in the study. We will refer to this as the Usual Care group. The other half of the participants will begin treatment to reduce blood sugar levels. We will refer to this as the Glucose Lowering group. A computer program will be used to determine which group you will be in. This process is like flipping a coin to decide. Neither you nor your study doctor can pick which group you will be in.

Glucose Lowering Group

If you are in the Glucose Lowering Group, you will begin treatment to reduce blood sugar levels. You can expect to have obstetrical visits about every 4 weeks just as you would have if your glucose levels were being treated outside of the study. At the end of the study, we will collect information on any pregnancy complications you or your infant experienced.

You will be asked to wear a CGM sensor all the time. You will be able to see the glucose values. We will train you on how to place a new sensor every 10-14 days. We also will give you training on how to interpret the glucose levels to make changes in your diet and exercise. Diet and exercise changes will be the first step to keep glucose levels in the recommended range for pregnancy. We also will give you a blood glucose meter and train you on how and when to use it.

Your study doctor will be reviewing your glucose levels regularly and providing treatment recommendations to you. The specific treatment you receive will be decided by your study doctor. The type of treatment you receive will be similar to what would be prescribed if you were diagnosed to have gestational diabetes based on an oral glucose tolerance test later in pregnancy. In addition to making changes in your diet and exercise, your doctor might try to manage your glucose levels by using a drug called insulin or metformin. Insulin is a drug that helps regulate your glucose levels. The insulin could be the type that you inject under your skin, or it could be the type that is inhaled through your mouth. Metformin is a pill that lowers glucose levels. If your doctor does think using medication might help with managing your glucose levels, the type of insulin that is prescribed or metformin will depend on what your doctor thinks is best for you and what type of insulin you would prefer to use. The study is not providing insulin or metformin. You will be given a prescription to fill at your pharmacy for whatever is prescribed.

Usual Care Group

If you are in the Usual Care group, you will receive the same obstetrical care you would receive if not in the study. Routine obstetrical visits are usually about every four weeks. Starting with the first routine obstetrical visit after 17 weeks, a CGM sensor will be placed for you to wear for 10 to 14 days. It will be the same type of CGM sensor you will have worn for the screening. You will not be able to see the glucose values. Thereafter, a CGM sensor will be placed about every 4 weeks at your routine obstetrical visits.

- If you have a lot of high glucose values during the first sensor wear period, we will inform your study clinical team who will decide if treatment is needed.

There won't be any other procedures done or information collected that are not part of your routine care. As part of your routine care, at about 24 to 28 weeks of your pregnancy, you will have an oral glucose tolerance test done to check for diabetes. If this test shows you have GDM, you will receive treatment by your provider, or they may refer you to receive treatment from a specialist, just as you would if you were not in the study. This treatment may involve using insulin. The insulin could be the type that you inject under your skin, or it could be the type that is inhaled through your mouth. The type of insulin will depend on what your doctor prescribes for you. Your obstetrical provider may prescribe fingerstick glucose monitoring or a CGM to monitor your glucose levels.

If your obstetrical care provider prescribes a CGM for you, you can use one of the study CGMs and you will be able to see the glucose values. If you choose to use an unblinded CGM that the study provides, then you will no longer have to wear the blinded CGM. If you choose to wear a CGM that is not study related, then you must wear the blinded CGM as outlined above.

WHAT ARE THE RISKS OF THIS STUDY?

Glucose Lowering Treatment

If you are in the Glucose Lowering Group, you will be receiving treatment to lower your blood sugar levels. The study doctor will discuss treatment options with you and prescribe whatever treatment they think would be best for you. As noted earlier, this will be the same type of treatment you would receive if you were diagnosed to have GDM on an oral glucose tolerance test at 24 to 28 weeks. It is just that in the study the treatment is starting earlier.

Risks of Insulin

Although it is unknown if your doctor will prescribe insulin to help manage your glucose levels, it is important for you to be aware of the potential risks associated with insulin use and the specific types of insulin that might be prescribed. If you are started on insulin, your blood sugar could drop to a low level. This is called hypoglycemia. Symptoms of hypoglycemia can include sweating, jitteriness, and difficulty concentrating. In rare cases, a very low blood sugar could result in loss of consciousness or a seizure. It is possible that very frequent low blood sugars could affect the growth of the fetus. If you are using insulin, your glucose levels will be monitored to avoid frequent low readings.

Other symptoms from insulin are uncommon. Rarely, you can have an allergic reaction or retain fluid in your arms and legs.

If you are prescribed injections of insulin, you might experience temporary pain or bleeding where you inject. You also could develop irritation at the site of injection on your skin.

If you are prescribed inhaled insulin, there are some specific risks. The more common side effects that might occur include:

- Cough
    - A brief cough can occur when you inhale the insulin. The cough is generally mild and lasts for a few seconds after the inhalation.
- Sore Throat
    - A very brief slight sore throat is possible.

The less common side effects that can occur with inhaled insulin include:

- Bronchitis
  - Irritation of your airways could occur. It will go away over time or if the inhaled insulin is stopped.
- Bronchospasm
  - In other studies, some people with lung problems (such as asthma or COPD) had tightening of the airways (bronchospasm) after using inhaled insulin. When people have bronchospasm, they usually have a cough with wheezing. If you have any current lung problems, your study doctor won't prescribe inhaled insulin.
- Decreased lung function
  - If your study doctor prescribes inhaled insulin, you will need to have a simple test that measures how well you can breathe out after taking a breath. There is a small chance of an effect on your breathing over time. However, this usually goes back to normal after the inhaled insulin is stopped.
- Allergic reaction
  - Rarely, an allergic reaction could occur when you use inhaled insulin for the first time. This could cause difficulty breathing, tingling, a rash, or other symptoms. If an allergic reaction occurs, it usually is mild. It might require treatment. In very rare cases, an allergic reaction could be life-threatening.
- Other risks
  - There has been no evidence that using inhaled insulin for a long time increases the risk of lung cancer.

Risks of Metformin

Although it is unknown if your doctor will prescribe metformin to help manage your glucose levels, it is important for you to be aware of the potential risks associated with metformin. If you are prescribed metformin, most people use it without having bothersome side effects. Serious side effects are not common. If you are started on metformin, you may experience nausea, diarrhea, or stomach pain related to the medication. A low blood sugar is possible although not as common as with insulin. Rarely, some people experience an unpleasant metallic taste when starting metformin, but it only lasts a short time. In very rare cases, metformin can lead to kidney or liver problems or cause what is called lactic acidosis. Lactic acidosis occurs when lactic acid, an acid that naturally forms in the body when glucose is broken down, builds up in your blood. Some signs of lactic acidosis include: feeling weak or tired, unusual muscle pain, trouble breathing, unusual stomach discomfort, feeling cold
dizziness or lightheadedness, a sudden irregular or rapid heartbeat, rapid breathing, or shortness of breath.

CGM and Blood Glucose Meter

The CGM sensor may cause brief pain when it is inserted into the skin, similar to an insulin injection. Rarely, a skin infection can happen at the site of insertion 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 ask your study doctor what to do.

At times, you may need to check your sugar level with a blood glucose meter. This is done by pricking your finger. A fingerstick can cause brief pain. A small bruise could occur. This could be followed by a small scar on your fingertip for several weeks.

Unknown Risks
It is always possible that anyone trying something for the first time may have an allergic reaction. Also, there may be additional risks from the study that are not known.

If we find out that there are any new risks, you will be told about them. You will be able to decide if you want to continue in the study based on the new information.

Risks for Fetus
It is not expected that there will be any risk to your fetus with any treatments that are prescribed.

Gestational diabetes can lead to babies being born larger than normal for their age (LGA). Managing blood sugar levels has helped lower the chances of LGA. In treating gestational diabetes, the risk of having a baby smaller than normal for their age (SGA) may be increased.

If you are prescribed insulin, studies of injectable insulin and inhaled insulin used during pregnancy have not shown an association with birth defects. The insulin in inhaled insulin is a powder form of human insulin that has been in use for many years. The inhaled material also includes a substance that helps the insulin get into the lungs. Studies in animals have not found concerns that this substance could affect the fetus. However, we don't know this for certain. If your study doctor thinks that inhaled insulin might help you, they will explain the possible risks and benefits.

Metformin is thought to be safe to use during pregnancy. However, there have not been good studies to evaluate whether there are any effects on the fetus. Generally, insulin is used instead of metformin but your study doctor may think that metformin will be beneficial for you.

Risks to Confidentiality
This study will be collecting some information about you that includes identifiable, personal information, like your date of birth. The study has plans in place to protect that information. There is a chance that a loss of this confidentiality could occur. Please see the "How will my information be protected and kept confidential" section below for more information.

Data Entry/Uploads
A smart phone app will be used to upload your CGM data. The companies that own these apps have policies in place to protect your information. They use this information to provide the services of the apps and for internal purposes, like training and making the apps work better. For more information on their privacy policies, please visit their websites or ask the study team for copies.

Text or Email Messaging

The study doctor and staff may use your contact information to call, text or email you during the study. They may do this to send you things like appointment reminders. They are not allowed to send you private information by text or regular email because it is unsecure. 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 your name will likely be in the text or email. If you think that the study doctor's office has 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 send a regular email to the study doctor's office, it is unsecure and what you put in the text or email is not protected.

Please discuss the risks with your study doctor or any other health care provider.

CAN I STOP BEING IN THE STUDY?

You can stop being in the study at any time. If you decide to stop being in this study, you will not have any penalty or loss of any benefits that you normally get. You can get regular care like you normally would, but you will not be able to keep using the study CGM.

If you decide you no longer want to be in the main study, please tell your study doctor. If you decide to stop being in the main study, the study team will still collect information from your medical record at the end of your pregnancy. This will include medical history, results of an oral glucose tolerance test, any complications you have with the pregnancy, and the outcome of your pregnancy.

If you stopped taking part in the main study, or if you were not eligible for the main study and are participating in the observational part of the study, and you decide that do not want the study team to collect information at the end of your pregnancy, please notify your study doctor in writing, like with a letter or an email, that you do not want this data collected for the study. You can also use the JCHR IRB Withdraw Letter found on our website at www.jaeb.org/research-participants.

If we find out that there is any important new information, you will be told about it. You will be able to decide if you want to continue in the study based on this new information.

The study may stop or the study doctor may decide to take you out of the study at any time too. You do not have to give permission for the study to stop or for the study doctor to remove you from the study. You will be told if this happens. Some reasons why you may be removed from the study include:

- The doctors feel that it is in your best interest
- You do not follow the study instructions

ARE THERE COSTS RELATED TO THE STUDY?

The study will provide CGM and blood glucose meter supplies needed for the study. The study will not be covering the costs of office visits, procedures or any drugs that your doctor prescribes. These will be your responsibility like they would be normally if you were not in the study.

Please ask to speak to someone at your study doctor's office if you want more information about what you or your insurance will be expected to pay.

IS THERE PAYMENT FROM THE STUDY?

If you take part in the study, you will receive $25 for wearing the blinded CGM sensor for screening. If you take part in the main study, you will receive $50 for the first main study visit where your treatment group will be determined. This payment will include your first sensor as part of the main study. If you are in the Glucose Lowering Group, you may receive up to $275 for wearing a CGM for your entire pregnancy. This is calculated as $1.50 for every day you wore the sensor with glucose values. If you are in the Usual Care Group, you may receive up to $150 for wearing 6 or more sensors. If you withdraw from the study, you will still be paid for the CGM sensors you have worn. You will be paid at about the 28th week of pregnancy and at the end of your study participation.

Because payments made to you for participating in this study may be reportable to the Internal Revenue Service (IRS) as income, you may need to provide a Tax Form W-9 to your study doctor's office. These will not be shared outside of your doctor's office, other than as required by the IRS.

When thinking about being in a study, there are some money-related issues to consider as a part of making your choice. For example:

- If you get certain benefits from the government, like food assistance, then getting paid by the study might affect your ability to keep getting these benefits. You may need to talk to your benefits representative.
- If you are a non-US citizen, but you are participating within the US, then the IRS may require a withholding. You many need to talk to a tax consultant.
- If you have a US Visa, then your status may have earning limits. You may need to speak to an immigration attorney.

Please note that you can choose not to get paid. You will need to tell the study team or study doctor if you do not want to get paid. You do not have to tell them why. No one can make you choose this. It is up to you.

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

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. If you have an emergency, please seek emergency care as soon as possible. Please tell the emergency doctor that you are in a research study. Please also tell your study doctor about the emergency as soon as you can. Care will be billed to you or your insurance like it normally would. The study does not have funds set aside for care or other expenses relating to illnesses or injuries.

Signing this form and agreeing to be in this study does not mean that you lose any of your legal rights or release anyone involved in the research from their responsibilities.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

If you have questions about this study or a research illness or injury, or if you have concerns, suggestions or questions about the study, then contact your study doctor using the contact information on the first page of this form.

If you have questions, comments or suggestions about the research you can contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or irb@jaeb.org . You can also contact the IRB if you want more information about your rights, injury reimbursement, or the future use of your information or samples.

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

This section tells you about the use and disclosure (or "sharing") of your personal Protected Health Information (PHI). This is like the information that is usually found in your medical records that will be collected for the study. Only the health information about you that is needed for this study will be used or disclosed. This information will be kept confidential and private as required by law. The specific types of information that will be released and used for this study are:

- Hospital discharge summaries
- Medical history / treatments
- Laboratory / diagnostic tests
- Operative report (about an operation)
- Biological specimen(s) and/or slide(s)
- Medical records including glucose data from the CGM.

You are being asked to give your permission for your PHI to be shared from your doctors, clinics, and hospitals to the researchers doing this study. This is called giving your Authorization. The PHI is needed to do the study, so you will have to give your Authorization in order to be in the study. If you do not want to give Authorization, then you will not be able to be in the study.

Your Authorization for PHI lasts 50 years from the date that you sign this form or until the end of the study, whichever comes first. You may cancel your Authorization at any time. You will need to contact your study doctor's office in writing, or you may contact the JCHR IRB Office at 813-975-8690 or irb@jaeb.org. When you fully cancel your Authorization, you are no longer part of the study. No new PHI will be collected or shared for the study, except if there is a safety concern. If there is a safety concern, you may be asked for more information, or your entire medical record may need to be reviewed. The researchers will have all the information that was collected for the study up to the time that you canceled your Authorization or are no longer in the study. Any information that has been received will remain in the study database after you withdraw.

The researchers will use a code that may have your initials or date of birth to keep your study information (or "study results") together at the Jaeb Center for Health Research in Tampa, Florida. Your Authorization for the use and sharing of the coded study results will never end. Also, the following people or companies involved in this study may see your study results with things like your date of birth, initials, and date of procedures:

- your treating healthcare providers and their staff

- associated healthcare institutions and hospitals where you receive care
- Jaeb Center for Health Research
- Helmsley Charitable Trust
- Dexcom
- Abbott Diabetes Care
- Precision Digital Health
- Researchers involved in the study

Sometimes people not directly working on the study need to see your PHI. For example, the Food and Drug Administration (FDA), other federal agencies, and committees that monitor safety may look at your information in the study. In most cases, the information will be coded instead of having your PHI, but not always. For example, if you are in this study, then this form could be reviewed and it would have your name on it. Once PHI is shared, it may no longer be covered by the privacy laws. Only the people that need to see your information are allowed to see it.

You have the right to see your records too. During the study, you may not be able to see or get copies of everything. The study doctor will be able to tell you if you will have to wait to get some information. When the study is over, you have the right to see all of your study records.

Clinical Trial Reporting
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. A copy of one of the study consent form templates will also have to be posted on a federal Web site.

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 PHI that could identify you. There may still be a chance that someone could identify you, but this is not likely. A copy of the information collected as part of the study will be made public in a dataset. This will be done after the study ends. This dataset will not contain any PHI. The study results will also be made public. These results will not have any PHI either. Study results without PHI may be shared in medical journals and at scientific meetings.

A limited dataset that contains some PHI may be provided to certain researchers. This PHI will not include things like your name, address, identifying pictures, or medical record numbers. Any researcher would need to sign an agreement to protect your PHI before getting this dataset as required by law.

If you are part of the Usual Care group, you may receive information about your glucose levels and results of the study from the blinded CGM wear, once the study ends. This might be useful should you have a future pregnancy. The results of the study will not be sent to you.

Permission to Notify Primary Provider About Participation

If you are in the Glucose Lowering Group and your obstetrical care is provided by a doctor that is not part of the study team, it is recommended that the study doctor's office lets your regular provider or doctor's office know that you are in this study. This is important to help make sure that the participants in this study are safe. With your permission, we will contact your regular provider or doctor's office if you are in the Glucose Lowering Group and will give them information about the study and your health. **Please sign your initials next to one** of the following choices to confirm whether you give us permission to notify your regular provider.

_____ (sign initials) I ***do*** give my permission for the study team to contact the regular provider or doctor's office to tell them about participation in this study. I understand that I may need to sign a separate release of information form too; or

_____ (sign initials) I ***do not*** give my permission for the study team to contact the regular provider or doctor's office to inform them about participation in this study.

Consent and Authorization

Participant's Full Name (printed)**:**_____

By signing below, I agree to take part in this study. My signature means that:

- the consent form was provided in a language that I understand, and I have read this informed consent form
- I have been given the chance to discuss the study, in a language that I understand, and to ask questions to my satisfaction
- I freely choose to participate and I can withdraw at any time
- I will receive a copy of this consent form
- I authorize the use and disclosure of protected health information. This information is collected as part of participation in this study. I cannot be in this study without this permission.

_____ _____

Participant Signature Date of Signature

Investigator's or Designated Person Obtaining Consent Certification

I certify that to the best of my knowledge:

- **The participant is who they say they are**
- **That the study information and written materials were provided to the participant in a language that they understand, and that they understand the nature, demands, risks, and benefits involved in the participation of this study**

Further, I certify that researchers have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; nor will the researchers have any part in determining the viability of a neonate; nor will there be any inducements (monetary or otherwise) offered to terminate a pregnancy.

I attest that I will ensure that study records will show that the participant provided consent and that I have co-signed *before* any study procedures, including data collection.

_____	_____	_____
Investigator/Designee's Printed Name	**Investigator/Designee's Signature**	**Date**