Official Title: Phentermine/Topiramate in Adolescents with Type 2 Diabetes and Obesity

NCT#: NCT04881799

Date of the Consent: 2025Jan08

Consent Form

Title of Research Study: ***Phentermine/Topiramate in Adolescents with Type 2 Diabetes and Obesity***

Investigator Team Contact Information: ***Megan Bensignor, MD***
For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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If your doctor is also the person responsible for this research study, please note that she is interested in both clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Supported By: This research is supported by the National Institutes of Health.

Key Information About This Research Study
The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?
Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you have type 2 diabetes and have difficulty maintaining a healthy weight.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not to part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- If you decide not to participate or to leave the study, it will not change your relationship with your doctors of the medical care you receive.

- You can ask all the questions you want before you decide.

Why is this research being done?
This study is being done to see if a combination medicine called phentermine/topiramate (or Qsymia) might help kids with type 2 diabetes who are overweight to better control their weight and control their blood sugar levels. Doctors are investigating if adding Qsymia to diabetes medicines might help to control glucose levels so that less diabetes medicines might be needed.

Qsymia is approved for use by the U.S. Food and Drug Administration for weight loss in adults and it was just recently approved for use in children.

How long will the research last?
We expect that you will be in this research study for about one year.

What will I need to do to participate?
You are being asked to have 15 total visits with the study team. Three of the visits will be in person at the Fairview MHealth Clinical Research Unit and the Delaware Clinical Research Unit. Two of the visits will take place only at the Fairview MHealth Clinical Research Unit. There will also be nine telephone visits to review your blood sugar levels and medications. You will need to come into research center monthly to pick up study drug and testing supplies. If you can become pregnant, you will also have to take a urine pregnancy test monthly.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?
The biggest risk to participating in this study is taking the medication Qsymia. One of the medications that is part of that combination pill, phentermine, may cause high blood pressure, fast heart rate, feeling that your heart is pounding, restlessness, dizziness, trouble sleeping, shakiness, headache, dry mouth, diarrhea, and constipation.

The other medication that is part of the combination pill, topiramate, may cause tingling, loss of appetite, weight loss, loss of taste, tiredness or sleepiness, dizziness, nervousness, slowed movements, trouble remembering or concentrating, trouble thinking, confusion, mood changes, fever, infection, kidney stones or flushing. Topiramate can also increase the risk of suicidal thoughts or behaviors

More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)" and in the "What happens to the information collected for the research?" section***

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include weight loss and better blood sugar control of your diabetes which may result in taking less diabetes medications.

What happens if I do not want to be in this research?
You do not have to participate in this research. Instead of being in this research study, your choices may include maintaining your current diabetes regimen or adding lifestyle modification where healthy

eating habits are discussed. You may also be eligible to receive Qsymia via prescription without being in the study.

Detailed Information About This Research Study
The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?
We expect about 30 teenagers or young adults at the University of Minnesota will participate in this research.

What happens if I say "*Yes, I want to be in this research*"?
If you would like to be in the study, this is what will happen at each visit:

Screening visit: You will meet with the study team at the Delaware Clinical Research Unit and the study will be described to you. You will be able to ask any questions that you have, and you will be given answers. You can take your time to decide about whether or not you want to participate. If you want to be in the study, you will sign this consent form. Your medical history and medication history will be reviewed. Your blood pressure and heart rate will be measured. You will have a physical exam and your puberty status may be assessed. You will be asked to complete questionnaires about whether or not you are depressed or have had thoughts of suicide. Your height and weight will be collected. Blood will be drawn for labs to see if you meet criteria to participate in the study. You will then be scheduled for another visit within the next 4 weeks if you meet the criteria to participate.

Baseline visit: You will be asked to fast for at least 10-12 hours before this visit. You will have a physical examination, your height and weight will be measured and your blood pressure and heart rate will be measured. Your total daily insulin dose will be reviewed. You will also receive a Bluetooth scale (called a smart scale) to take home. The smart scale should only be used by you. You will be taught how to use the smart scale. You will also be given a continuous glucose monitor (or CGM). CGMs are placed on the body and register glucose levels every minute. CGMs will stay in place for about 10 - 14 days (depending on brand of CGM) and then a new one will need to be placed. The CGM that will be used for this study will either automatically download data to your cell phone or you will need to have data uploaded by swiping the CGM with a sensor. Every month you will be asked to download the CGM data and share the application where it is collected with the study team. It is possible you may be provided with a CGM where the data is automatically downloaded and you will not need to swipe the CGM. You will be provided with an Information Sheet with important safety information about the operation of the CGM depending on the brand. You will then be asked to go to the Center for Pediatric Obesity Medicine Research Unit. A 2-hour blood glucose measurement (oral glucose tolerance test) will be administered. An oral glucose tolerance test is where you have been fasting for at least 10-12 hours and then has blood drawn to measure blood glucose levels before you drink a sugar drink and at four timepoints after you drink the sugar drink. Approximately two tablespoons of blood will be drawn as part of the glucose tolerance test. You will be asked to complete questionnaires about your eating habits, and feelings about your general health and diabetes, and about whether or not you are depressed or have had thoughts of suicide. You will have an EKG, which is a test that measures the electrical activity of the heart. You will have an iDXA scan which is a test that measures visceral and total body fat. This test is done while you lie on your back for approximately 20 minutes. If you are capable of getting pregnant, you will have a pregnancy test before this scan. The risk of DXA on an unborn child are not known. You will be talked to about contraception. You will undergo counseling on healthy eating and increasing physical activity. You will also be randomized, chosen like the toss of a coin, to receive either Qsymia or

to receive a placebo (a drug that looks like Qsymia but has no medicine in it). No one will know whether you were selected to receive the Qsymia or the placebo, but this information will be available in an emergency. You will be instructed on how to administer Qsymia, which is a pill, and should be taken in the morning. You will take Qsymia every day and will keep track of the doses in a diary. The dose of Qsymia will be increased every fourteen days over two months. We anticipate that this visit will take 4 hours.

Week 4 visit: This visit will be conducted over telephone. Your contraception choices will be reviewed. . You will be asked about you have been feeling. The study team will review your CGM information, and you may be asked to adjust your insulin or metformin dose. We anticipate that this visit will last for 30 minutes. You will also be asked to come to the Delaware Clinical Research Unit to pick up the next month's supply of Qysmia and upload your CGM data if you cannot do so at home. If you are a person of childbearing potential, you will be asked to take a pregnancy test.

Week 8 visit: This visit will be conducted over telephone. Your contraception choices will be reviewed. You will be asked about how you have been feeling. The study team will review your CGM information, and you may be asked to adjust your insulin or metformin dose. We anticipate that this visit will last for 30 minutes. You will also be asked to come to the Delaware Clinical Research Unit to pick up the next month's supply of Qysmia and upload your CGM data if you cannot do so at home. If you are a person of childbearing potential, you will be asked to take a pregnancy test.

Week 12 visit: This visit will take place at the Fairview MHealth Research Unit. You will be asked about how you have been feeling. Your total daily insulin dose will be reviewed. Your contraception choices will be reviewed. You will be asked to complete questionnaires about your eating about depression and suicide. The study team will review your CGM information, and you may be asked to adjust your insulin or metformin dose. Your blood pressure, heart rate, weight and height will be measured. You will have a physical exam and your puberty status may be assessed. A urine pregnancy test will be done if you are someone who can become pregnant. You will upload your CGM data if you cannot do so at home. Additional medication and new study supplies will be dispensed.

Week 16 visit: This visit will be conducted over telephone. Your contraception choices will be reviewed. You will be asked about how you have been feeling. The study team will review your CGM information, and you may be asked to adjust your insulin or metformin dose. We anticipate that this visit will last for 30 minutes. You will also be asked to come to the Delaware Clinical Research Unit to pick up the next month's supply of Qysmia and upload your CGM data if you cannot do so at home. If you are a person of childbearing potential, you will be asked to take a pregnancy test.

Week 20 visit: This visit will be conducted over telephone. Your contraception choices will be reviewed. You will be asked about how you have been feeling. The study team will review your CGM information, and you may be asked to adjust your insulin or metformin dose. We anticipate that this visit will last for 30 minutes. You will also be asked to come to the Delaware Clinical Research Unit to pick up the next month's supply of Qysmia and upload your CGM data if you cannot do so at home. If you are a person of childbearing potential, you will be asked to take a pregnancy test.

Week 24 visit: You will be asked to fast for at least 10-12 hours before this visit. You will meet with the study team in the Fairview MHealth Clinical Research Unit. Your total daily insulin dose will be reviewed. Your CGM data will be reviewed and you may be asked to change your insulin or metformin schedule. You will have a physical exam and your puberty status may be assessed. Your blood pressure

and heart rate will be measured. You will be asked about how you have been feeling and the medicines you have been taking. You will then go to the Delaware Clinical Research Unit. Your height and weight will be measured. You will have blood drawn for a hemoglobin A1c level, cholesterol level, vitamin D and measures of kidney function. Blood will be drawn for a 2-hour blood glucose measurement (oral glucose tolerance test). An oral glucose tolerance test is where you have been fasting for at least 10 hours and then have blood drawn to measure blood glucose levels before you drink a sugar drink and at four timepoints after you drink the sugar drink. Approximately two tablespoons of blood will be drawn as part of the glucose tolerance test. You will be asked to complete questionnaires about your eating habits, general feelings of health, and your diabetes, and about whether or not you are depressed or have had thoughts of suicide. You will have an iDXA scan which is a test that measures visceral and total body fat. This test is done while you lie on your back for approximately 20 minutes. If you are someone who is capable of getting pregnant, you will have a pregnancy test before this scan. The risk of DXA on an unborn child are not known. You will be talked to about contraception. You will also receive counseling about healthy eating and physical activity. At this visit, if you had been taking the placebo, you will start taking Qsymia. You will be asked to increase your dose every 14 days over the next two months. We anticipate that this visit will last for approximately four hours.

Week 28 visit: This visit will be conducted over telephone. Your contraception choices will be reviewed. You will be asked about how you have been feeling. The study team will review your CGM information, and you may be asked to adjust your insulin or metformin dose. We anticipate that this visit will last for 30 minutes. You will also be asked to come to the Delaware Clinical Research Unit to pick up the next month's supply of Qysmia and upload your CGM data if you cannot do so at home. If you are a person of childbearing potential, you will be asked to take a pregnancy test.

Week 32 visit: This visit will be conducted over telephone. Your contraception choices will be reviewed. You will be asked about how you have been feeling. The study team will review your CGM information, and you may be asked to adjust your insulin or metformin dose. We anticipate that this visit will last for 30 minutes. You will also be asked to come to the Delaware Clinical Research Unit to pick up the next month's supply of Qysmia and upload your CGM data if you cannot do so at home. If you are a person of childbearing potential, you will be asked to take a pregnancy test.

Week 36 visit: This visit will take place at the Fairview MHealth Clinical Research Unit. You will be asked about how you have been feeling. Your contraception choices will be reviewed. You will receive counseling on healthy eating and physical activity. You will be asked to complete questionnaires about your eating, depression and suicide. Your total daily insulin dose will be reviewed. The study team will review your CGM information, and you may be asked to adjust your insulin or metformin dose. Your blood pressure, heart rate, weight and height will be measured. You will have a blood draw to measure your hemoglobin A1c level. You will have a physical exam and your puberty status may be assessed. A urine pregnancy test will be done if you are a person of childbearing potential. You will also receive counseling about healthy eating and physical activity. You will upload your CGM data if you cannot do so at home. Additional medication and new study supplies will be dispensed.

Week 40 visit: This visit will be conducted over telephone. Your contraception choices will be reviewed. You will be asked about how you have been feeling. The study team will review your CGM information, and you may be asked to adjust your insulin or metformin dose. We anticipate that this visit will last for 30 minutes. You will also be asked to come to the Delaware Clinical Research Unit to pick up the next month's supply of Qysmia and upload your CGM data if you cannot do so at home. If you are a person of childbearing potential, you will be asked to take a pregnancy test.

Week 44 visit: This visit will be conducted over telephone. Your contraception choices will be reviewed. You will be asked about how you have been feeling. The study team will review your CGM information, and you may be asked to adjust your insulin or metformin dose. We anticipate that this visit will last for 30 minutes. You will also be asked to come to the Delaware Clinical Research Unit to pick up the next month's supply of Qysmia and upload your CGM data if you cannot do so at home. If you are a person of childbearing potential, you will be asked to take a pregnancy test.

Week 48 visit: This visit will be conducted over telephone. Your contraception choices will be reviewed. You will be asked about how you have been feeling. The study team will review your CGM information, and you may be asked to adjust your insulin or metformin dose. We anticipate that this visit will last for 30 minutes. You will also be asked to come to the Delaware Clinical Research Unit to pick up the next month's supply of Qysmia and upload your CGM data if you cannot do so at home. If you are a person of childbearing potential, you will be asked to take a pregnancy test.

Week 52 visit: You will be asked to fast for at least 10-12 hours before this visit. You will meet with the study team in the Fairview MHealth Clinical Research Unit. Your total daily insulin dose will be reviewed. Your CGM data will be reviewed and you may be asked to change your insulin or metformin schedule. You will have a physical exam and your puberty status may be assessed. You will be asked about how the medicines you have been taking and how you have been feeling. Your blood pressure and heart rate will be measured. You will then go to the Delaware Clinical Research Unit. Your height and weight will be measured. You will have blood drawn for a hemoglobin A1c level, cholesterol level, vitamin D and measures of kidney function. Blood will be drawn for a 2-hour blood glucose measurement (oral glucose tolerance test). An oral glucose tolerance test is where you have been fasting for at least 10 hours and then have blood drawn to measure blood glucose levels before you drink a sugar drink and at four timepoints after you drink the sugar drink. Approximately two tablespoons of blood will be drawn as part of the glucose tolerance test. You will be asked to complete questionnaires about your eating habits, general feelings of health, and your diabetes, and about whether or not you are depressed or have had thoughts of suicide. You will receive counseling on healthy eating and physical activity. You will have an iDXA scan which is a test that measures visceral and total body fat. This test is done while you lie on your back for approximately 20 minutes. If you are someone who is capable of getting pregnant, you will have a pregnancy test before this scan. The risk of DXA on an unborn child are not known. You will be talked to about contraception. At this visit, you will be instructed on how to wean off of the study medication. We anticipate that this visit will last for approximately four hours.

The medication that you will receive for the first 24 weeks of this will be chosen by chance, like flipping a coin. Neither you, nor the study doctor will choose what medication you will receive. You have a 50% chance of receiving Qsymia and a 50% chance of receiving a placebo (which looks like Qsymia but contains no medicine).

Starting at the Week 24 visit, you will receive the medication Qsymia. You will be on this medicine until the end of the study.

Schedule of Events

	Screening	Baseline	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52
Demographics	X														
Medical and medication history	X														
Randomization		X													
Urine pregnancy test	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Physical exam and puberty assessment	X				X			X			X				X
Height/weight	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood pressure and heart rate	X	x			X			X			X				X
EKG	X														
Contraceptive counseling	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Review of how you have been feeling			X	X	X	X	X	X	X	X	X	X	X	X	X
Blood draw for lab tests	X	X			X			X			X				X
Oral glucose tolerance test and timed blood collection		X						X							X
iDXA		X						X							X
Questionnaires	X	X			X			X			X				X
Lifestyle and behavior counseling		X			X			X			X				X
Review of your insulin dosing		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Review glucose monitor (CGM) data			X	X	X	X	X	X	X	X	X	X	X	X	X
Insulin adjustment based on CGM			X	X	X	X	X	X	X	X	X	X	X	X	X
Receive new CGM sensor			X	X	X	X	X	X	X	X	X	X	X	X	
Receive new study medication		X	X	X	X	X	X	X	X	X	X	X	X	X	
Review study medication adherence					X			X			X				X
Review current medications	X	X			X			X			X				X

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible for coming to the visits as outlined, recording daily insulin doses, placing/replacing the CGM every 14 days, swiping the CGM twice each day, downloading the CGM data every month, and taking the study medication as outlined. You will be asked to return medications at the visits at Weeks 12, 24, 36 and 52 including any unused medications.

What happens if I say "Yes", but I change my mind later?
If you decide to take part in this research study, but change your mind, you should tell us. Your choice not to participate in this study will not negatively affect your right to any present or future medical care.

If you decide to leave the research study, tell the study doctor or staff about your decision. You will be asked to slowly stop taking the medication over the course of 7 days. This is typically done by having you stop taking the medication every other day over the course of a week, but the study team will develop a plan specifically for you. This is because abruptly stopping the medication may lead to seizures.

If you stop being in the research, information about you that has already been collected will not be removed from the study database, but you will not be asked for any additional information.

What are the risks of being in this study? Is there any way being in this study could be bad for my me? (Detailed Risks)
There are risks associated with being in this study. The most common risks of Qsymia have been noted above. Here are some additional risks:
Risks of Qsymia: The most common side effects of Qsymia (seen in more than 10% of people) are paresthesia (tingling, burning, numbness of the skin), dry mouth, constipation, upper respiratory infection, and headache. Less common effects (seen in 5-10% of people) are dizziness, dysgeusia (abnormal taste sensations), insomnia, nausea, diarrhea, fatigue, blurred vision, nasophyngitis (common cold symptoms), sinusitis (swelling of the tissue lining the sinuses), bronchitis, urinary tract infection and back pain. On rare occasions, people can develop kidney stones. It is recommended that you increase your fluid intake in order to help prevent kidney stones.

Risks of Blood Draws: You may experience some mild discomfort at the site where the needle enters the skin. You may bleed for a bit or have some bruising. You might feel lightheaded or faint from having blood drawn. On rare occasions, an infection can develop at the site where the needle enters the skin.

Risks of EKGs (electrocardiograms): EKGs measure the electrical activity of the heart. The test takes just a few minutes and does not hurt. Sticky pads that have wires attached to them will be placed on different places on your chest. You may feel a pulling sensation when the sticky pads are removed, like the sensation when you remove a Band-Aid.

Risks of Questionnaires: You may feel uncomfortable discussing your eating choices or experience distress thinking about your depression or suicidal symptoms. If your depression or suicidal symptoms are significant, you may be referred to a mental health professional.

Risks of the Oral Glucose Tolerance Test: You will be asked to come to the research clinic after having fasted for at least 10 hours before this test, which may make you irritable. You will be asked to drink a sugary drink and have blood draws (one before drinking the sugary drink and three at specific times

after drinking the drink). You may feel temporarily hyperglycemic during the testing.

Risks of iDXA Scans: The iDXA scan involves exposure to a low dose of ionizing radiation to generate their picture. As part of this study, you will undergo three iDXA scans. The average amount of radiation that the average person would receive from these procedures is approximately 1% of that received from natural sources of radiation by a Minnesota resident in one year (3 mSv). This exposure involves minimal risk and is necessary to obtain the research information desired. If you have participated in a research study in the past 12 months that used ionizing radiation, you should tell the study doctor, as the amount of radiation that you have been exposed to will need to be reviewed.

Risks of Continuous Glucose Monitor: As part of this study, you will be asked to wear a glucose monitor which will measure your glucose levels every minute. You will remove the sensor and replace it with a new one every 10 or 14 days. The CGM may either automatically upload your glucose levels or you may need to swipe the CGM at least twice daily depending on the brand of CGM used. You will be asked to upload your glucose levels to the study team once per month so that they can be reviewed. The study team will review your glucose levels and may ask you to change your insulin or metformin doses as a result of this information.

Risks of Suicidal Behavior and Thoughts: Antiepileptic drugs, like topiramate (one of the study drugs), increase the risk of suicidal thoughts or behaviors. You will be monitored for new or worsening depression, suicidal thoughts or behavior, or any mood changes throughout the study. If you are found to have moderately severe or severe depression or suicidal thoughts or behaviors you will not be able to participate in the study or may be taken off the study medication.

You may experience unforeseen risks that are not anticipated by the study team.

What do I need to know about reproductive health and/or sexual activity if I am in this study?
The medications provided in this study are known to cause harm to an unborn baby. People who are pregnant or breastfeeding may not participate in this study. If you are capable of becoming pregnant, you will have a pregnancy test at each study visit to ensure that you are not pregnant and, therefore, not exposing your unborn child to medicines which may be harmful or to radiation which can also be harmful. You will also be provided with urine pregnancy tests monthly.

If you are sexually active, you should use at least two effective means of birth control while participating in this research study. According to the World Health Organization and the United States Center for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable, but least effective, methods of birth control include male condoms (with or without spermicide) and female condoms.

Will it cost me anything to participate in this research study?

The costs of the routine care items associated with this study (reviewing your blood glucose levels, insulin dosing, hemoglobin A1c tests at Week 12 and 36, and vital signs) will be charged in the usual manner, to you or your insurance company. The research study will pay for the costs of the height and weight measurements, pregnancy tests, the EKG, iDXA scans, lifestyle and behavior counseling, the oral glucose tolerance tests , the hemoglobin A1c tests at screening. Week 24, and 52 and the other laboratory tests.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance (such as the Quality Assurance Program of the Human Research Protection Program (HRPP), and the Food and Drug Administration (FDA).

Certificate of Confidentiality
To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the certificate to resist any demands for information that would identify you, except as explained below.

The certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You should also understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the certificate to withhold that information.

Additional sharing of your information for mandatory reporting
If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

A description of this clinical trial will be available at 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.

Will I receive research test results?
Most tests done on samples in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results. Labs results associated with your diabetes management as part of typical clinical care will be shared directly to you by Dr. Bensignor.

What will be done with my data when this study is over?
We will use and may share data for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will be able to identify you. Therefore, you will not receive any results or financial benefit from future research done on your data.

Will anyone besides the study team be at my consent meeting?
You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g., name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?
This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach 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 information or provide input about this research.

Will I have a chance to provide feedback after the study is over?
The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Can I be removed from the research?
The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include not attending the visits, not taking the study medication, or not utilizing the CGM consistently.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What happens if I am injured while participating in this research?
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

Will I be compensated for participation?
If you agree to take part in this research study, we will pay you up to $2265 for your time and effort. The amount to be paid will depend on the visits and activities that you complete. Attached is a schedule of what will be compensated:

- Screening: $75
- Baseline: $100
- Week 4: $20 for review of CGM data
- Week 8: $20 for review of CGM data
- Week 12: $115 ($95 for the visit and blood draw, $20 for review of CGM data)
- Week 16: $20 for review of CGM data
- Week 20: $20 for review of CGM data
- Week 24: $120 ($100 for the visit and $20 for review of CGM data)
- Week 28: $20 for review of CGM data
- Week 32: $20 for review of CGM data
- Week 36: $115 ($95 for the visit and blood draw, $20 for review of CGM data)
- Week 40: $20 for review of CGM data
- Week 44: $20 for review of CGM data
- Week 48: $20 for review of CGM data
- Week 52: $120 ($100 for the visit and $20 for review of the CGM data)

If you are provided with a continuous glucose monitor that needs to be swiped, you will be paid for swiping your glucose monitor. You will get $2/swipe. You are asked to swipe the monitor twice per day, so the maximum that you will get is $4/day or a maximum of $120/month). If your CGM does not require swiping, you will be paid $4/day or a maximum of $120/month for wearing the CGM. Payment will be added to the gift card after the Zoom visits where your CGM data is reviewed. The maximum that you will receive for swiping or wearing the CGM for the study is $1440.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard, or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name and social security number. They will use this information only as part of the payment process. Greenphire will only need your social security number if the payment exceeds $599. Greenphire will not receive any information about your health status or the study in which you are participating.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Use of Identifiable Health Information
We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

How will my information be used in publications and presentations?
We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify your (such as his/her name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

Optional Elements:
The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may contact me in the future to see whether I am interested in participating in other research studies by Megan Bensignor, MD and the Center for Pediatric Obesity Medicine.

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant. Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent