Consent Form

Title of Research Study: Role of Pharmacotherapy in Counteracting Weight Regain in Adolescents with Severe Obesity

Investigator Team Contact Information

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Aaron Kelly, PhD Investigator Departmental Affiliation: Pediatrics Phone Number: (612) 626-3492 Email Address: kelly105@umn.edu	Study Staff: Patti Laqua Phone Number: (612)624-2151 Email Address: laqua001@umn.edu

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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. This study is being done to help determine if taking a medication can help people lose weight and keep the weight off over the course of a year and to measure your health over the course of the year.

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.

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 had trouble maintaining a healthy weight.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
This research is being done to help study why it is difficult to maintain weight loss over time and to study the impact of weight loss and weight gain on the body. It is hoped that the information learned from this study will help to identify ways in which maintaining weight loss over time might be more successful. This study will use a medication called Qsymia, which is a combination of two drugs called Phentermine and Topiramate. The medication was approved by the U.S. Food and Drug Administration (FDA) for weight loss in adolescents aged 12+ years old on 6/27/2022. However, children who were enrolled in this study before 6/27/2022 were taking a medication that was investigational, meaning it was not approved by the FDA for children aged 12-17 at that time.

How long will the research last?
We expect that you will be in this research study for up to 58 weeks.

What will I need to do to participate?

There will be two phases to this study: 1) a weight loss phase and 2) study medication/placebo phase.

Phase 1 (6 weeks long): During the first 6 weeks you will be asked to lose weight by strictly following a prescribed daily meal plan that consists of:

- 2 nutritional shakes
- 2 pre-packaged frozen meals
- 2 servings of fruit
- 3 servings of vegetables

The study will provide the shakes and frozen meals. You will be asked to buy the fruits and vegetables. The shakes and frozen meals will be delivered by a delivery service at a pre-arranged time that is convenient for you. A weight loss goal will be calculated for you that is 5% of your BMI (typically between 10-20 pounds, depending on your starting weight). You must reach the goal weight at the end of 6 weeks in order to move on to Phase 2. If you do not reach the weight loss goal in six weeks, your participation in the study will be complete. You will not move on to Phase 2.

Phase 2 (52 weeks long): For the second phase of the study, you will be randomly assigned (like the flipping of a coin) to take either Qsymia, the study medication, or a placebo (a pill with no medicine in it). Qsymia is called a combination pill, which means that it has two medicines in it. Neither you nor the study team will know if you are taking the medication or the placebo.

Is there any way that being in this study could be bad for me?
Lifestyle therapy may make you feel frustrated if you find it difficult to follow the dietary and lifestyle plans.

One of the medications that is part of the combination pill, phentermine, may cause high blood pressure, fast heartrate, 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 or flushing. On rare occasions (less than 2% of the time), topiramate may cause a severe rash (with blisters and peeling skin, especially around the mouth, nose, eyes and genitals). You should contact the study team right away if you develop a rash so that can be evaluated.

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)"***

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 improvement to your health, such as lower blood pressure and improved blood sugar tests.

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, you may continue to receive standard treatment such as lifestyle therapy, or treatment with medications approved for the management of obesity, including the medication being used in this study, or bariatric surgery. The study doctor and your primary care physician can tell you more about these standard treatments if you have questions.

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 approximately 100 teens will be in this research study at the University of Minnesota.

What happens if I say "*Yes, I want to be in this research*"?
Part 1
Screening Visit:

- You will be asked about your medical history and your medication history.
- You will be asked questions about your demographics and environment.
- You will have a physical examination and a doctor will do a puberty assessment by looking at your body.
- You will have blood drawn (about one teaspoon) for safety tests and to check your hemoglobin A1c level. If you are a person who is capable of getting pregnant, a urine

pregnancy test will be conducted.
- Your height, weight and blood pressure and heart rate will be measured and your hips and waist will be measured.
- You will be asked to fill out questionnaires about your environment and about how you are feeling.
- You will have an electrocardiogram (also called an ECG) to help determine the health of your heart.
- You will be asked to complete questionnaires about depression and suicide.

Baseline visit:
- You will be asked to come to this visit after not having had anything to eat or drink for 12 hours, including any medications. You can bring your morning medications to the visit and you may take them after some of the testing has been performed. If you have concerns about delaying your morning medications, let the study team know.
- You may have blood drawn (about one tablespoon) for fasting labs and biomarker tests. You may have an additional teaspoon of blood drawn for safety labs if this visit does not occur within 30 days of the screening visit. This will not be drawn if this visit occurs within 30 days of the Screening visit. If you are a person who is capable of getting pregnant, a urine pregnancy test will be conducted.
- You will be asked questions about how you have been feeling and your medications and their doses will be reviewed.
- Your height, weight, heart rate and blood pressure will be measured and your hips and waist will be measured.
- You will have a DXA scan to measure your body fat and bone density. This test involves exposure to a small amount of radiation; risks of radiation are described below.
- You will have an x-ray of your left hand and wrist to measure your bone age.
- You will have a test to measure your resting metabolic rate. You must have been fasting for 12 hours prior to this visit. You will sit inside a ventilated hood while a machine measures your exhalations.
- You will be asked to walk for 400-meters wearing comfortable shoes, such as tennis shoes. This test will measure how much oxygen is consumed by your body each minute during the exercise and also tests physical fitness.
- You will be asked to complete some memory tests and questionnaires about your physical activity and eating behaviors.
- You will be asked to complete questionnaires about depression and suicide.
- Some participants (about 60) will have their total energy expenditure measured. This will be done by drinking water with added isotopes (these are tracers which are not harmful) and will provide information about how oxygen is eliminated from the body. You may be asked to drink this water and provide urine samples at specified times over the course of one week.
- You will have lifestyle counseling.

Phone Call:
During the 2-week and 4-week visits in Phase 1, you will complete a phone call to reorder the nutrition shakes and meals.

Randomization Visit:

- You will be asked to come to this visit after not having had anything to eat or drink for 12 hours, including any medications. You can bring your morning medications to the visit and you may take them after some of the testing has been performed. If you have concerns about delaying your morning medications, let the study team know.
- You will have blood drawn (about four teaspoons) of blood drawn for fasting labs, biomarker and safety tests. If you are a person who is capable of getting pregnant, a urine pregnancy test will be performed.
- You will be asked questions about how you have been feeling and whether or not you have been hospitalized since the last visit.
- Your height, weight, heart rate and blood pressure will be measured and your hips and waist will be measured.
- You will have a DXA scan to measure your body fat and bone density. This test involves exposure to a small amount of radiation; risks of radiation are described below.
- You will have a test to measure your resting metabolic rate. You must have been fasting for 12 hours prior to this visit. You will sit inside a ventilated hood while a machine measures your exhalations.
- You will be asked to walk for 400-meters wearing comfortable shoes, such as tennis shoes. This test will measure how much oxygen is consumed by your body each minute during the exercise and also tests physical fitness.
- You will be asked to complete some memory tests and questionnaires about your physical activity and eating behaviors.
- You will be asked to complete questionnaires about depression and suicide
- Some participants (about 60) will have their total energy expenditure measured. This will be done by drinking water with added isotopes (these are tracers which are not harmful) and will provide information about how oxygen is eliminated from the body. You may be asked to drink this water and provide urine samples at specified times over the course of one week.
- You will have lifestyle counseling.
- At this visit, the weight loss goal assessment will be done. If you have met your weight loss goal, you will be randomized to receive either Qsymia or the placebo and you will be instructed on how to take it. Neither you nor the study staff will know which medicine you are receiving. If your weight is above the weight loss goal, this will be your final visit.

Phase 2: You will attend 6 in-person visits at the research clinic.
Week 4:

- You will have blood drawn (about one teaspoon) for safety labs. If you are a person who is capable of getting pregnant, a urine pregnancy test will be done.

- You will be asked questions about how you have been feeling and whether or not you have been hospitalized since the last visit.
- Your medications and medication doses will be reviewed.
- Your height, weight, heart rate and blood pressure will be measured and your hips and waist will be measured.
- You will be asked to complete questionnaires about depression and suicide.
- You will have lifestyle counseling.
- You will be asked to return any unused study medication and will be provided with more of the study medication. Your dose of study drug will be increased at this visit.

Week 8:

- You will be asked questions about how you have been feeling and whether or not you have been hospitalized since the last visit.
- Your medications and medication doses will be reviewed.
- Your height, weight, heart rate and blood pressure will be measured and your hips and waist will be measured.
- You will be asked to complete questionnaires about depression and suicide.
- You will have lifestyle counseling.
- If you are capable of getting pregnant, you will be asked about the results of the pregnancy tests you have taken at home.
- You will be asked about the medication that you have taken and whether or not you have missed doses.
- You will be asked to return any unused study medication and will be provided with more of the study medication. Your study drug will be increased at this visit.

Week 12:

- You will have blood drawn (about one teaspoon) for safety labs. If you are a person who is able to become pregnant, a urine pregnancy test will be performed.
- You will be asked questions about how you have been feeling and whether or not you have been hospitalized since the last visit.
- Your height, weight, heart rate and blood pressure will be measured and your hips and waist will be measured.
- Your medications and medication doses will be reviewed.
- You will be asked to complete questionnaires about depression and suicide.
- You will have lifestyle counseling.
- You will be asked to return any unused study medication and will be provided with more of the study medication

Week 26:

- You will be asked to come to this visit after not having had anything to eat or drink for 12 hours, including any medications. You can bring your morning medications to the visit and you may take them after some of the testing has been performed. If you have

concerns about delaying your morning medications, let the study team know.

- You will have blood drawn (about four teaspoons) for fasting labs, biomarker tests and safety tests. If you are a person who is able to get pregnant, a urine pregnancy test will be conducted.
- You will be asked questions about how you have been feeling and whether or not you have been hospitalized since the last visit.
- Your medications and medication doses will be reviewed.
- Your height, weight, heart rate and blood pressure will be measured and your hips and waist will be measured.
- You will have a DXA scan to measure your body fat and bone density. This test involves exposure to a small amount of radiation; risks of radiation are described below.
- You will have a test to measure your resting metabolic rate. You must have been fasting for 12 hours prior to this visit. You will sit inside a ventilated hood while a machine measures your exhalations.
- You will be asked to walk for 400-meters wearing comfortable shoes, such as tennis shoes. This test will measure how much oxygen is consumed by your body each minute during the exercise and also tests physical fitness.
- You will be asked to complete some memory tests and questionnaires about your physical activity and eating behaviors.
- You will be asked to complete questionnaires about depression and suicide.
- Some participants (about 60) will have their total energy expenditure measured. This will be done by drinking water with added isotopes (these are tracers which are not harmful) and will provide information about how oxygen is eliminated from the body. You may be asked to drink this water and provide urine samples at specified times over the course of one week.
- You will have lifestyle counseling.
- You will be asked to return any unused study medication and will be provided with more of the study medication

<u>Week 39:</u>

- You will have blood drawn (about one teaspoon) for safety tests. If you are a person who is capable of getting pregnant, a urine pregnancy test will be performed.
- You will be asked questions about how you have been feeling and whether or not you have been hospitalized since the last visit.
- Your medications and medication doses will be reviewed.
- Your height, weight, heart rate and blood pressure will be measured and your hips and waist will be measured.
- You will be asked to complete questionnaires about depression and suicide.
- You will have lifestyle counseling.
- You will be asked to return any unused study medication and will be provided with more of the study medication

Week 52:

- You will be asked to come to this visit after not having had anything to eat or drink for 12 hours.
- You will have blood drawn (about four teaspoons) for fasting labs, biomarker tests and for safety tests. If you are a person who is capable of getting pregnant, a urine pregnancy test will be performed.
- You will be asked questions about how you have been feeling and whether or not you have been hospitalized since the last visit.
- Your medications and medication doses will be reviewed.
- You will have a physical examination and a puberty assessment by looking at your body
- Your height, weight, heart rate and blood pressure will be measured and your hips and waist will be measured.
- You will have a DXA scan to measure your body fat and bone density. This test involves exposure to a small amount of radiation; risks of radiation are described below.
- You will have an x-ray of your left hand and wrist to measure your bone age.
- You will have a test to measure your resting metabolic rate. You must have been fasting for 12 hours prior to this visit. You will sit inside a ventilated hood while a machine measures exhalations.
- You will be asked to walk for 400-meters wearing comfortable shoes, such as tennis shoes. This test will measure how much oxygen is consumed by your body each minute during the exercise and also tests physical fitness.
- You will be asked to complete some memory tests and questionnaires about your physical activity and eating behaviors.
- You will be asked to complete questionnaires about depression and suicide
- Some participants (about 60) will have their total energy expenditure measured. This will be done by drinking water with added isotopes (these are tracers which are not harmful) and will provide information about how oxygen is eliminated from the body. You may be asked to drink this water and provide urine samples at specified times over the course of one week.
- You will have lifestyle counseling.
- You will be asked to return any unused study medication, provided new medication and be given instructions on how to wean off of the study medication.

Telephone visits at Week 16, Week 20, Week 30, Week 34, Week 43, and Week 47:

- You will be asked questions about how you have been feeling and whether or not you have been hospitalized since the last visit.
- Your medications and medication doses will be reviewed.
- You will have lifestyle counseling.
- If you are capable of getting pregnant, you will be asked about the results of the pregnancy tests you have taken at home.
- You will be asked about the medication that you have taken and whether or not you have missed doses.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for attending the study visits as directed, following the instructions of your health coach and study team, taking study medication if instructed by the study team, and telling the study team about any side effects that you experience.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision.

If you decide to leave the research study, tell the study doctor or staff about your decision. When you stop taking the study medication, the study doctor will determine how it is best for you to do so. Most times, people are asked to do this slowly over the course of 7 days because abruptly stopping the medication can lead to seizures, but in rare circumstances people are asked to stop the study medication immediately.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to present or future medical care, your academic standing as a student, or your present or future employment.

If you stop being in the research, information about you that has already been collected may not be removed from the study database.

If you want to stop taking the study medicine, you can stay in the study but be slowly taken off of the medicine but still attend the study visits. Please let the study staff know if you would like to remain in the study but come off of the study medication.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

Lifestyle Therapy: You may feel sad or frustrated if it is difficult to follow the dietary and activity guidance. You may experience injury related to increasing your physical activity.

Risks of Qsymia: The most common side effects occurring at least or greater than 5% (5 times out of 100 events) and at a rate at least 1.5 times more frequently than those that received placebo in previous clinical studies:

- Numbness or tingling in the hands, arms, feet or face (paresthesia)
- Dizziness
- Change in the way foods taste or loss of taste (dysgeusia)
- Trouble sleeping (insomnia)
- Constipation
- Dry mouth

Other possible side effects may include:

- Changes in mood
- Depression
- Trouble with concentrating or paying attention
- Difficulty speaking
- Trouble with memory
- Confusion
- Increased acid in your bloodstream which if left untreated can lead to brittle or soft bones, or kidney stones. If this occurs you may:
    - Feel tired
    - Not feel hungry (appetite loss)
    - Feel changes in your heartbeat
    - Have trouble thinking clearly
- Low blood sugar (hypoglycemia) in people with type 2 diabetes
- Seizures may occur if you stop taking Qsymia too fast
- Kidney stones
- Decreased sweating
- Increased body temperature
- Palpitations
- Increased heart rate
- Rash (with blisters and peeling skin, especially around the mouth, nose, eyes and genitals)

The study doctor might order additional blood tests if they are concerned about side effects that you might be experiencing or if lab values from scheduled tests show potential side effects.

The post-marketing side-effects reported are not different than what is already known about the study drug with the exception of:

- Sudden decrease in vision
- Increased eye pressure, and
- Suicidal ideation and suicidal behavior

These side-effects have occurred more than what was seen in clinical trials. If you experience these events, you should contact the study team immediately.

You should exercise special caution when driving, biking, or using machinery since the study drug may cause dizziness. Additionally, you should not drink alcohol while taking Qsymia. Alcohol and Qsymia can affect each other causing side effects such as sleepiness and dizziness.

Phentermine, a component of Qsymia, is a controlled substance. This means that it could show up in a urine or blood drug screen (drug testing). If you require drug screening, you may need to show this informed consent to prove that you are participating in a research drug study. Also, the study doctor or study staff may be able to verify your participation.

When abruptly stopped, topiramate (a component of Qsymia) has been associated with seizures in individuals without a history of seizures or epilepsy. Stopping the study drug without medical supervision could possibly result in a sudden seizure, even if you have not had seizures in the past. When you need to stop study drug, the study doctor will advise you to take the study drug every other day for a week prior to stopping completely.

If you take birth control pills or use the birth control patch, Qysmia can reduce the amount of estrogen you are exposed to and may result in breakthrough bleeding. While taking birth control pills, it is important to use an extra method. The study doctor will talk to you about the options.

In addition to these risks, this research may hurt you in ways that are unknown. These risks might be minor or be severe as to cause death. We will tell you about any new information that may affect your health, welfare, or choice to stay in this study. The University of Minnesota Institutional Review Board (IRB), that oversees human research may also ask us to provide information to you if they feel that it would meaningfully add to the protection of the rights of welfare participants.

Blood draws: You may have pain at the needle site, with some bruising. Some people feel light headed or faint. There is a small risk of infection.

Fasting: You may feel hungry or have symptoms of drop in blood sugar (shakiness, dizziness, irritability, anxiety, headache). If you need to carefully control your blood sugar, you may need to monitor this more closely while you fast.

DXA Scan and X-ray**:** As part of this study you will undergo two wrist x-rays and four DXA scans. These procedures involve exposure to ionizing radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. The average amount of radiation that the average person would receive from these procedures is less than 2% 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 need to tell the study doctor, as the amount of radiation that you have been exposed to will need to be reviewed.

Questionnaires: You may feel distress as you think about your anxiety or depression symptoms. You may tire of answering questions. If the results of the depression and suicide assessments reveal suicidal behavior or thoughts of suicidal ideation, you will be referred to a mental health professional (MHP), or to see your primary care provider. You will be provided with contact information for the nationwide Suicide and Crisis Lifeline (telephone 988 or 988lifeline.org) and the study team will meet to determine whether or not you may remain in the study. You will be asked if you feel safe enough to leave the research clinic and with the established plan. If you are endorsing current (in that moment), active suicidal ideation with plan and intent, you

will be referred to the emergency department, and one of the study clinicians will be consulted before your referral. If self-harm tendencies are identified, your confidentiality will need to be breached for safety reasons.

Resting metabolic rate: You may feel claustrophobic as you sit inside the hood.

Total Daily Expenditure: If you are chosen to have this measurement, you will drink water that has an additional isotope added, which can help us show how the body eliminates oxygen. You will be asked to provide urine samples at specific times during this two week test. There is no known risk to drinking the water in this type of test.

400-Meter Walk Testing: You will be asked to wear a device that will measure your heart rate. You will be asked to walk about a quarter mile at a pace that is typical for you. You will be asked about your breathing and how your muscles feel during the test. You can slow down, rest or stop the test if you feel unwell at any time. Your heart rate will be measured two minutes after the test is completed.

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. A person who is pregnant or breastfeeding may not participate in this study. If you are a person who is 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 to take at home monthly when there is no in-person visit and you will be asked the results of these at home tests.

If you are a female who is sexually active with males, you should use two forms of birth control while participating in this research study and you will be reminded of this at every visit. Effective contraception for this study is defined as double barrier methods, stable hormonal contraception plus a single barrier method, tubal ligation, or abstinence. We will instruct all females who miss a menstrual period or when pregnancy is otherwise suspected to perform a pregnancy test.

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

There will be no cost to you for any of the study activities or procedures. You will have to pay for basic expenses like food.

If you need treatment for side effects while you are on the study, you or your insurance will need to pay for this treatment.

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)), the National Institutes of Health (NIH) and the Department of Health and Human Services (DHHS).

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.

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 also should 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.

The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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 and will not be disclosed to you. The results of the blood tests analyzed by the Fairview laboratory will be posted to your medical record and will be available to you via MyChart.

What will be done with my data when this study is over?

We will use and may share data and/or specimens for future research. Data collected in this study may be made available for others to use, including for future research studies on similar or different topics, teaching or other purposes. This could include for profit companies. Our goal is to make more research possible. We will not ask you for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or 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 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 or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- Pregnancy
- If you do not follow the instructions of the study team
- If you have any side effects, abnormal lab results, or other medical conditions so that the study doctors feel that it is no longer in your best interest
- If you are unable to take the study medication for 7 days

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 my participation?

If you agree to take part in this research study, we will pay you up to $960 for your time and effort. Payments will be broken down by visits as follows. You will receive payment for visits at the end of each completed visit:

- Screening visit: $100
- Baseline visit: $100
- Randomization visit: $100
- Week 4 visit: $100
- Week 8 visit: $100
- Week 12 visit: $100
- Week 26 visit: $100
- Week 39 visit: $100
- Week 52 visit: $100

- Phone visits: $10 for the completion of each phone visit. You may earn up to $60 for completing the phone visits

You will also receive an incentive payment for the number of lifestyle visits (conducted by telephone) that you complete. This payment will be made after the Week 52 visit or after your last visit if you leave the study early. This brings the total you can earn to $1060.

- 3 or more therapy visits: $25
- 6 or more therapy visits plus the Week 52 visit: $75

If you are selected to complete the energy expenditure testing and collect your urine, you are eligible to receive additional compensation of up to $80 (bringing the maximum you can earn up to $1140). Specimens will need to be dropped off 7 days after the visit.

- Baseline + 7 days: $20
- Randomization + 7 days: $20
- Week 26 + 7 days: $20
- Week 52 + 7 days: $20

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, address, date of birth, 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 your 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 you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an 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.

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