Consent Form

Title of Research Study: ***Lifestyle Counseling and Medication for Adolescent Weight Management***

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

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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.

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 are you being asked to take part in this research study?
We are asking you to take part in this research study because you have difficulty in maintaining a healthy weight.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you participate in the study 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 study is being done to find out more about treatments that might be helpful for teens who struggle to keep a healthy weight. Some treatment options include learning how to change eating and exercise habits to help with weight loss. Other treatment options include medicines that might help someone lose weight. This study will compare a therapy that focuses on learning to change eating and activity habits against a medication called semaglutide.

Semaglutide is a medication that was recently approved for use by the U.S. Food and Drug Administration for the treatment of obesity in children aged 12-17. It is approved for the treatment of obesity in adults.

How long will the research last?
We expect that you will be in this research study for 56 weeks.

What will I need to do to participate?
You will be asked to do the following things:

- Come to the research unit 9 times for clinic visits where your height, weight , blood pressure and heart rate will be recorded. Your hip and waist measurements will also be taken.
- Have a physical exam and a healthcare professional will look at your body to help determine what stage of puberty you are in (called a Tanner stage) at 2 of the clinic visits.
- Have blood drawn for safety labs (approximately 1.5 teaspoons) at 4 visits and for specialized biomarker tests (approximately 5 teaspoons) at 3 of these visits.
- Complete questionnaires about depression and thoughts of self-harm at 3 visits.
- Complete questionnaires about eating habits and quality of life at 3 visits
- Answer questions about how you have been feeling at all clinic visits, including questions about changes in your mood and thoughts of self-harm as well as gastrointestinal symptoms.
- Have a test to look at your body fat and composition, called an iDXA, at 3 visits. If you are a female who is capable of getting pregnant, a urine pregnancy test will be performed before this test.
- Be randomly assigned (like flipping a coin) to one of two groups. Both groups will:
    - Track eating and activity habits in a notebook.
    - Work on changing eating and activity habits so you can lose weight and be healthier.
    - Attend in-person classes and virtual, self-paced sessions followed by a phone call with a dietitian or a specially-trained coordinator.

  The differences between the groups are:
    - Group #1: Behavioral Weight Loss
        - 52 weekly sessions: 26 in-person and 26 virtual + phone call
    - Group #2: Medication + Behavioral Weight Loss
        - Take a weekly medication called semaglutide

- 12 monthly sessions: 6 in-person and 6 virtual + phone call

You will not have any control over which group you are placed into.

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?
Since all medications have side effects, one potential risk of participating in this study is taking semaglutide. If you are randomized to take semaglutide, you will be taught how it should be taken. You will start taking a small dose at first and then increase the amount every four weeks over the first sixteen weeks of the study. Semaglutide is an injectable medication, which means that you must give yourself a shot. A micro-needle is used to give semaglutide injections, the needle is short and very thin, it may not be as painful as getting a regular injection. You will take semaglutide every week and be asked to keep the empty injector pens and bring them along with any unused pens to the next clinic visit.

The most common side effects (those seen more than 5% of the time) of semaglutide include:

- nausea
- diarrhea
- vomiting
- constipation
- abdominal pain and upper abdominal pain
- headache
- feeling tired
- upset stomach
- feeling dizzy
- feeling bloated
- burping
- decrease in blood sugar
- flatulence
- gastritis (a short-term illness from infection or inflammation of the digestive system)
- hair loss

Rare but serious side effects that have been seen with the use of semaglutide include:

- Medullary thyroid carcinoma (or MTC). For these reasons, individuals who have a history of medullary thyroid carcinoma or a family history of medullary thyroid carcinoma will not be allowed to participate in the study.
- Pancreatitis, or an inflammation of the pancreas. This is seen in less than 1% of people who take semaglutide. The study team will be asking you about abdominal pain at every visit.
- Acute gallbladder disease.
- Acute kidney injury.

- Hypersensitivity including severe anaphylactic reactions and swelling
- Increases in heart rate.
- Suicidal behavior and ideation

Taking the study medication may involve risks that are unforeseen.

The study team will ask you at all the clinic visits about whether you have experienced any of these things and the dose of semaglutide may be adjusted.

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 from taking part in this research. However, possible benefits may include weight loss and improvement to your health, such as lower blood pressure or improved blood glucose tests, and better quality of life.

What happens if I do not 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 standard treatment such as behavioral therapy to learn how to make healthier eating choices, other medications approved to help with weight loss, including semaglutide or orlistat, or bariatric surgery. The study doctor and your primary care physician can tell you more about these standard treatments if you have questions. If you do not want to participate in the study, your refusal will involve no penalty or loss of benefits to which you are otherwise entitled.

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 120 adolescents at the University of Minnesota will be in this research study.

What happens if I say "*Yes, I to be in this research*"?

If you agree to participate in the research study, here is a detailed chart that lists what will happen at each visit:

Study Activity	Screening	Randomization	Year 1						
			Week 4	Week 8	Week 12	Week 16	Week 26	Week 39	Week 56
Allowable window		± 30d	± 3d	± 3d	± 3d	± 3d	± 3d	± 3d	± 15d
Informed consent, assent	X								
Review of eligibility	X								
Physical exam and puberty assessment	X								X
Baseline demographics	X								
Blood draw for fasting labs: lipids, glucose, insulin, and hemoglobin A1c, and storage of blood for batched biomarker assessment^		X					X		X
Blood draw for safety labs: comprehensive metabolic panel, complete blood count and hemoglobin A1c (hemoglobin A1c only at screening) ~	X			X		X			X
Urine pregnancy test	X	X					X		X
Height. Weight, hip and waist circumference, blood pressure and heart rate measurement, calculation of body mass index (BMI)	X	X	X	X	X	X	X	X	X
Dual energy x-ray absorptiometry (iDXA) (total/regional body fat, body mass composition)		X					X		X
Suicidality assessment • Peds Health Questionnaire-9 (PHQ-9) • Columbia-Suicide Severity Rating Scale (C-SSSRS)	X	X					X		X
Assessment of mood changes and thoughts of self-harm; gastrointestinal (GI) symptom assessment		X	X	X	X	X	X	X	X
Neurobehavioral assessments		X			X		X	X	X
Eating behavior, mood and quality of life questionnaires		X			X		X	X	X
Acceptability questionnaire							X		X
Study drug titration and dispensing#		X	X	X	X	X	X	X	X
Adverse event (AE) assessment		X	X	X	X	X	X	X	X
Behavioral Program (Intense Arm)		← 52 weekly sessions: 50% in person and 50% virtual →							
Behavioral Program (Medication Arm)		← 12 monthly sessions: 50% in-person and 50% virtual →							
Length of Visit (in hours)	2	3.5	1	1	2.5	1	3	2.5	3.5

If you are randomized to receive semaglutide, you will be taught about how semaglutide is to be administered and you will take this every week for the next year. You will take a small dose of semaglutide in the beginning, and this will be increased each week for the next sixteen weeks.

The following table provides an example of your schedule for the behavioral weight loss program depending on which group you are randomized to. (These are in addition to the clinic visits). Specific dates will be given at the randomization visit.

YEAR 1*	WEEK	BEHAVIOR GROUP	MEDS + BEHAVIOR GROUP	PARENT
Kickstarter: Build Your Knowledge	1-wk	In-person Individual	In-person Individual	In-person Individual
	2-wk	Virtual Session + Call		
	3-wk	In-person Individual		
	4-wk	Virtual Session + Call		
Rethink Your Drink	5-wk	In-person Group	Virtual Session + Call	Virtual Session
	6-wk	Virtual Session + Call		
	7-wk	In-person Group		
	8-wk	Virtual Session + Call		
Let's Be Active	9-wk	In-person Group	In-person Group	Virtual Session
	10-wk	Virtual Session + Call		
	11-wk	In-person Group		
	12-wk	Virtual Session + Call		
It's All in the Planning	13-wk	In-person Group	Virtual Session + Call	Virtual Session
	14-wk	Virtual Session + Call		
	15-wk	In-person Group		
	16-wk	Virtual Session + Call		
High Quality vs Low Quality Foods	17-wk	In-person Group	In-person Group	Virtual Session
	18-wk	Virtual Session + Call		
	19-wk	In-person Group		
	20-wk	Virtual Session + Call		
Mindfulness	21-wk	In-person Group	Virtual Session + Call	Virtual Session
	22-wk	Virtual Session + Call		
	23-wk	In-person Group		
	24-wk	Virtual Session + Call		
Let's be Balanced	25-wk	In-person Group	In-person Group	Virtual Session
	26-wk	Virtual Session + Call		
	27-wk	In-person Group		
	28-wk	Virtual Session + Call		
Outside Influences	29-wk	In-person Group	Virtual Session + Call	Virtual Session
	30-wk	Virtual Session + Call		
	31-wk	In-person Group		
	32-wk	Virtual Session + Call		
Eating Away from Home	33-wk	In-person Group	In-person Group	Virtual Session
	34-wk	Virtual Session + Call		
	35-wk	In-person Group		
	36-wk	Virtual Session + Call		
Boost Your Activity	37-wk	In-person Group	Virtual Session + Call	Virtual Session
	38-wk	Virtual Session + Call		
	39-wk	In-person Group		
	40-wk	Virtual Session + Call		
Thoughts and Feelings	41-wk	In-person Group	In-person Group	Virtual Session
	42-wk	Virtual Session + Call		
	43-wk	In-person Group		
	44-wk	Virtual Session + Call		
Self Care	45-wk	In-person Group	Virtual Session + Call	Virtual Session
	46-wk	Virtual Session + Call		
	47-wk	In-person Group		
	48-wk	Virtual Session + Call		
Staying the Course	49-wk	In-person Group	In-person Group	Virtual Session
	50-wk	Virtual Session + Call		
	51-wk	In In-person Group		
	52-wk	Virtual Session + Call		

*Items to foster change will be distributed during class to intensive lifestyle arm – water bottle, overnight oats kit, crystal light packets, portion-control zip-lock bags.

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

If you participate in this research, you will be responsible for coming to the visits and

participating in the behavioral program as scheduled. If you are chosen to take semaglutide, you will be responsible for taking the study medication weekly.

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 to not participate in this study will not negatively affect your right to any present or future medical care. If you are not able to tolerate the study medication due to side effects, there may be other options (such as lowering the dose or stopping the study medication) and staff can talk to you about these options.

We will make sure that you stop the study safely. We will also ask you to attend one final visit to return the study medication.

If you stop being in the research, information about you that has already been collected will not be removed from the study database, but no new information will be collected.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)
A lot of the things that happen in this study are similar to what would happen at a routine doctor visit such as the physical exam and review of your body, having height, weight, blood pressure and heart rate measured, or having urine collected. Here is a review of what you can expect from some of the other study activities:

Blood Draws: You might experience some discomfort at the site where the needle enters the skin, develop a bruise or bleed for a little bit. Some people feel light-headed or faint when blood is drawn. On rare occasions, an infection at the site where the needle entered the skin can develop.

Questionnaires and Neurobehavioral Assessments: You may feel emotional distress related to thinking about sensitive topics and possible "test fatigue." You always have the option not to respond to 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). You will be asked if you feel safe enough to leave the research clinic with the established plan. If you endorse current (in that moment), active suicidal ideation with plan and intent, you will be referred to the emergency department.

iDXA scan: For this test, you will be asked to lie on your back and be still for about 20 minutes while the machine looks at your body composition. If you are a female who is capable of getting pregnant, you will need to have a negative pregnancy test before this test is done. This is because the iDXA scan uses radiation to generate its picture. 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 approximately 1% of

that received from natural sources of radiation by a Minnesota resident in one year (3mSv). 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.

Behavioral Program: You may or may not lose weight during the study. You may feel sad or frustrated if it is difficult to follow the dietary and activity guidance from the coach. You may experience injury related to increasing your physical activity.

Semaglutide: If you are randomized to take semaglutide, you will be taught how it should be taken. You will start taking a small dose at first and the amount that you take will increase over the first sixteen weeks of the study. Semaglutide is an injectable medication, which means that you will have to give yourself a shot. The semaglutide is given with what is called a micro-needle, which means that the needle is short (about 4 mm long) and very thin, so using it may not be as painful as getting a regular injection. You will take semaglutide every week and will be asked to keep your empty injector pens and bring them along with any unused pens to the visits. The side effects of semaglutide include nausea, diarrhea, vomiting, constipation, abdominal pain, headache, feeling tired, upset stomach, feeling dizzy, feeling bloated, burping, decrease in blood sugar (in people with type 2 diabetes), flatulence, gastritis, and hair loss. The study team will ask you about whether or not you have experienced any of these things and your dose of semaglutide might be adjusted.

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

What do I need to know about reproductive health and/or sexual activity if I am in this study?
The effects of semaglutide on an unborn child are not known. So, if you are a female capable of getting pregnant, you will need to have a negative pregnancy test before starting the medication.

You should not be or become pregnant while on this research study. If you are sexually active, both men and women 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. Any two of the methods listed above is acceptable.

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any costs to you.

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 U.S. Food and Drug Administration, and the National Institutes of Health.

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.

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. It is unclear if the Certificate will work in foreign countries.

The Certificate does not prevent a researcher from reporting information learned in research when required by the state or federal laws, such as mandatory 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 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.

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 blood tests analyzed by the hospital lab at the screening, randomization, week 8, week 16, week 26 and week 56 visits will be posted in your medical record and are available to you through My Chart. The remainder of the tests will not be shared.

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

We will use and may share data and/or specimens 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 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 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 (called the Principal Investigator) can remove you from the research study without your approval. Possible reasons for removal include not attending the study visits, not participating in the behavioral therapy sessions, not taking the study medicine, or if there is an increase in concern for your mental health.

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 his/her participation?
If you agree to take part in this research study, we will provide you with gift cards for the visits that you complete. If you complete all visits for the study, you will receive $800 in gift cards. Here is what you will receive for each visit:

- Screening visit: $50
- Randomization visit: $150
- Week 12 visit: $50
- Week 26 visit: $250
- Week 39 visit: $50
- Week 56 visit: $250

You will also receive a completion bonus of $100 for the week 56 visit, which means that you could earn a total of $900.

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 3 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 system. Your information will not be used for any other purposes and will not be given or sold to any other company. 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 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.

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 Aaron Kelly or the Center for Pediatric Obesity Medicine.
_____	_____	I would like to receive reminders using Greenphire.

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