Title: Adjunctive Anti-Obesity Pharmacotherapy in Adolescents and Young Adults after Bariatric Surgery: A Randomized Controlled Pilot Study

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Consent Form For:
1) The parent/guardian of all 12-24 year olds because they independently participate in the study
2) Participants 13-24 years old with decisional capacity
3) The legally authorized representative or proxy of a participant who is 18-24 who *does not have* decisional capacity

Study Title: Adjunctive Anti-Obesity Pharmacotherapy in Adolescents and Young Adults after Bariatric Surgery: A Randomized Controlled Pilot Study

Key Information

Please read all the information below and ask questions about anything you don't understand before deciding if you want to take part. If you are the parent or legal guardian of participant in this study, throughout this document "you" = "your child".

You are being asked to be in a research study. Participation in Research is voluntary.

Purpose of the Study: The purpose of this study is to learn more about whether investigational weight loss medications (phentermine and topiramate) can help people 12 to 24 years old who, between 6 and 12 months after bariatric surgery, have either not lost as much weight as expected and/or who still have a diagnosis of severe obesity.

Procedures: If you agree to participate, the following will happen:
- You will have one screening visit to make sure you are eligible to join this study.
- If you are found to be eligible, you will be assigned to one of two study groups. You cannot choose which group you will be in, and you will not know which group you are in after you've been assigned. One group will receive two active drugs and the other will receive placebos, which are pills that looks like medicine but is not real and will have no medical effect on you.
- You will be asked to make 4 in-person study visits over the next 3 months.
- If you agree to participate, you may be asked to participate in an optional banking procedure.

Risks: Participation in research involves risks, including the following:

If you are assigned to the group that receives active medication, there are possible associated risks such as anxiety, dizziness, insomnia, increased heart rate and/or blood pressure, trouble breathing, low blood sugar, mood problems, psychosis, kidney stones, nausea/vomiting, and negative interactions with alcohol. Withdrawal symptoms can occur if study drugs are stopped suddenly.

Benefits: There is no guarantee that your health will improve if you join this study. This study may lead to information that could help patients and health care providers in the future.

Alternatives: You may be able to receive any of the treatments in this study without participating in this study. Please discuss standard treatment and care options with your doctor.

Detailed Consent

You are being asked to be in a research study. If you are the parent or legal guardian of participant in this study, throughout this document "you" = "your child". This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about whether weight loss medications can help people 12 to 24 years old who had bariatric surgery between 6 and 12 months ago and have either not lost as much weight as expected and/or who still have a diagnosis of severe obesity.

There is currently very little information about what treatment may be best for this group of adolescents and young adults to decrease their ongoing health risks related to weight. Weight loss medications have been used successfully in this age group, but have not yet been well studied. More information can help patients, families, doctors, and weight management programs understand whether weight loss medications are acceptable to adolescents/young adults and their families. This includes learning whether adolescents/young adults can consistently take the medication and whether the possible side effects and monitoring for these medications are acceptable. It will also allow us to learn about how weight, blood pressure, cholesterol, liver health, glucose control, dietary intake, resting metabolism, body composition, bone density, quality of life, and eating behaviors change for each individual participant.

You are being asked to be in this research study because you or your adolescent/young adult is 12-24 years of age, had bariatric surgery between 6 and 12 months ago and has either a) not lost the average expected amount of weight compared to other adolescents/young adults at the same time point after bariatric surgery and/or b) has significant extra weight on the body consistent with a diagnosis of severe obesity.

Other people in this study

Up to *60* people (patients and their parents) in the Children's Colorado Bariatric Surgery Center will be asked to participate in this study.

What happens if I join this study?

This study compares active drugs (phentermine and topiramate) to placebo pills. A placebo is an inactive substance made to look/taste like an active medicine, but it has no real medicine in it. If you join the study, you (the adolescent/young adult) will either take the active study drugs (phentermine + topiramate pills) or placebo pills for 14 weeks. This will be determined at random and neither you nor the study team will know what you receive. Researchers use a placebo to see if the study drug works better or is safer than not taking anything.

Phentermine and topiramate act on the brain to decrease hunger and increase fullness. In large studies of adults who took this combination of medications at a similar dose (but *not* after bariatric surgery), the average weight loss was 20 pounds at 1 year.

In this study, the active medications/placebos will be gradually increased to goal doses over the first 4 weeks of the study (from 4mg to 16mg for phentermine and from 25mg to 100mg for topiramate), and will be maintained at the goal doses from week 4 through week 12. Phentermine/placebo will be stopped after week 12 and topiramate/placebo will be gradually stopped over weeks 13 and 14. If you cannot tolerate the maximum goal dose of either medication because of side effects, a lower dose will be tried to see if that reduces side effects to an acceptable level.

There is a Screening/Enrollment visit followed by 4 in-person study visits:

- Study Visit 1: 6-12 months + ~1 week after surgery
- Study Visit 2: ~1 month after Visit 1
- Study Visit 3: ~2 months after Visit 1
- Study Visit 4: ~3 months after Visit 1

Study consent will either occur in person or electronically through secure video or phone call. If your surgery was 6 or 9 months ago, study visits 1, 2 and 3 are outside of the usual times you would come to bariatric surgery clinic. Study visit 4 will be coordinated with your usual 9 month (for 6 month postop start) or 12 month (for 9 month postop start) clinic visit. If your surgery was 12 months ago, all 4 study visits are outside of the usual times you would come to bariatric surgery clinic. The average estimated time required for each study visit is: 2 hours for visits 1 and 4 and 1 hour for visits 2 and 3.

Your weight, height, temperature, heart rate, and blood pressure will be measured at each study visit.

You (adolescent/young adult) will be asked to have bloodwork related to this study on the day you enroll and at Visits 2 and 4. You may have been asked to fast before today's visit and will be asked to fast for 8-12 hours prior to the blood draw for Visit 4. Most people are already scheduled to have blood drawn for routine clinical care the same day you enroll and for Visit 4. But, Visit 2 will be a separate blood draw, and Visit 4 will be a separate blood draw if your surgery was 12 months ago. This study includes 2 additional procedures at Visits 1 and 4: a test to measure how many calories you burn at rest and one to measure your body composition and bone strength.

If you have the potential to become pregnant, you will be asked to provide a urine sample for a pregnancy test on the day of enrollment and at every study visit because it is not safe to take phentermine or topiramate during pregnancy. If you are female and do not have an intrauterine device (IUD) or subdermal implant (e.g. Nexplanon) for contraception, you will be asked to use 2 forms of birth control.

You and/or your parent/guardian/legally authorized representative will also be asked to complete questionnaires at each study visit. Questionnaires will ask about how often you have taken your study pills, barriers to taking them, how you think the medication or placebo is affecting you (including effects and side effects), your dietary intake for 3 days (for Visits 1 & 4), quality of life, eating behaviors, and your satisfaction with the study. Because of COVID-19 precautions, certain questionnaires may be completed with the study staff remotely by secure video call or by phone call with the questionnaires emailed to you, to reduce your time on campus.

There will also be eight standard study phone calls, which will take no more than 10 minutes each. The purpose of these calls is to provide reminders about medication dosing, see how you think the study pills are affecting you, and to remind you of anything you need to bring with you to the next study visit. If study medication doses need to be changed after the first four weeks, there will be additional weekly phone calls (10 minutes each) until stable doses are achieved.

Information about the study measures:

Medication adherence/tolerability: At each study visit, the adolescent/young adult will be asked about how often the study pills were taken/missed and any barriers to taking the medication. They will also be asked to complete a checklist about effects and side effects. The study team will also do a quick head to toe review to determine if any other adverse events were experienced since the previous study visit or phone call. *Estimated time to complete: 10 minutes*

Non-Study Medications: At each study visit, you will be asked to report any changes that have been made to your existing non-study medications and any new medications that you have started. *Estimated time to complete: 1 minute*

Weight, Height, Heart Rate, Blood Pressure, and Physical Exam: A research study member will measure your weight, height, heart rate, and blood pressure three times at the beginning of each study visit and take the average of each. Your temperature will be taken once at each study visit. The study physician will perform a physical exam at every study visit. *Estimated time to complete: 10 minutes*.

Cholesterol panel, Alanine aminotransferase, Hemoglobin A1c, Basic Metabolic Panel: This bloodwork will be taken from a vein with a needle puncture at Enrollment, Visit 2, and Visit 4. The basic metabolic panel includes kidney function and acid/base status (bicarbonate) to ensure it is safe to start and continue study medications.

Urine pregnancy test: Any females for whom it is possible to become pregnant will be asked to have a urine pregnancy test at all study visits because it is not safe to take either of the active study medications while pregnant. Additionally, all females who can become pregnant and do not have an IUD or contraceptive implant will be asked to commit to using two forms of birth control throughout the study.

Urine amphetamine screen: All participants will be asked to have a urine amphetamine screen done at study visits 1-4. This will help the study team understand how consistently participants are taking the phentermine medicine. This urine test *only* looks for the presence of amphetamine medications, no other substances.

Resting Metabolic Rate: At Visits 1 and 4, participants will have their resting metabolism (caloric needs) measured using a “hood” system. *Estimated time to complete: 30 minutes*

DEXA-scan: At Visits 1 and 4, participants will have a low-dose x-ray performed to determine muscle and fat mass and bone strength. *Estimated time to complete: 20 minutes*

3-day diet record: The adolescent/young adult will be asked to complete a “food journal” for 3 full days before Visits 1 and 4. You will carry this journal with you throughout the day and record detailed descriptions of all food and beverages you eat or drink using an example provided to you. *Estimated time to complete: 15-20 minutes per day*

Previous Day Physical Activity Recall (PDPAR): The adolescent/young adult will be asked to complete a questionnaire about physical activity (type and intensity) at Visits 1 and 4. *Estimated time to complete: 5 minutes*.

Eating Behavior Questionnaires: The adolescent/young adult *and* his/her parent/guardian/legally authorized representative will complete questionnaires before or during every visit, which ask about hunger and fullness. *Estimated time to complete: 15 minutes*

Impact of Weight on Quality of Life-Kid (IWQOL-Kids) & PedsQL: The adolescent/young adult *and* his/her parent/guardian/legally authorized representative will complete questionnaires about health-related quality of life and the impact of weight on quality of life at Visits 1 and 4. *Estimated time to complete: 10 minutes*

Center for Epidemiologic Studies Depression Scale: The adolescent/young adult will complete this 20-item questionnaire at every study visit, which asks about symptoms of depression over the past week. This is the same questionnaire about mood that you complete at every clinical follow-up visit in the bariatric surgery center. *Estimated time to complete: 3 minutes*

Columbia Suicide Severity Rating Scale: This is a standard screen required by the Food and Drug Administration for many research studies that use weight loss medications. The study staff will administer this at enrollment and every study visit. *Estimated time to complete: 2 minutes*

Satisfaction Survey: At study visit 4 *only*, the adolescent/young adult and his/her parent/guardian/legally authorized representative will be asked questions about the experience participating in this study. *Estimated time to complete: 5 minutes*

You and your adolescent/young adult may be asked to complete additional questionnaires and will be asked to answer additional questions by the bariatric surgery clinic team as part of usual medical care. However, only the items listed above are specific to this study.

Summary of what happens at each study visit:

R= will be done remotely by secure video call or phone call/email	Screening/ Enrollment 6-12 months after surgery	VISIT 1 ~1 week after study Enrollment	VISIT 2 ~1 month after study Visit 1	VISIT 3 ~1 month after study Visit 2	VISIT 4 ~1 month after study Visit 3
Estimated time the study visit will take	60 minutes	4 hours	1 hour	1 hour	4 hours
What happens with study meds at this visit:		Active meds/placebo are started the morning after this visit	Continue active meds/placebo	Continue active meds/placebo	Phentermine/placebo is stopped; topiramate/placebo is decreased slowly
Review study criteria/Consent	X				
Study medication adherence/tolerability			X	X	X
Pill counts of study meds by study staff			X^R	X^R	X^R
Review of non-study meds	X	X^R	X^R	X^R	X^R
Weight, height, temperature, heart rate, blood pressure, head to toe questions, physical		X	X	X	X
Blood Draw (Visits 1,4 to measure cholesterol, liver test, blood sugar test and at Visits 1,2, 4 to monitor the study medicines)	X		X		X
Urine pregnancy test (females)	X	X	X	X	X
Urine screen for amphetamine		X	X	X	X
Resting Metabolic Rate		X			X
Low-dose x-ray scan (DEXA) to measure muscle/fat mass, and bone strength		X			X
3-day diet record is reviewed/brought to this visit		X^R			X^R
Eating behavior questionnaires		X^R	X^R	X^R	X^R
Quality of life questionnaires		X^R			X^R
Mental health questionnaires	X	X	X	X	X
Patient/family satisfaction survey					X^R

What are the possible discomforts or risks?

Active medications (phentermine and topiramate): If you are assigned to the group that receives active medication, there are possible risks associated with these medications, which are listed for each medication below. There is no data to suggest that there are unique or increased risks associated with the combination of these two medications, compared to the individual risks of each medication alone. The "monitoring plan" noted in the table below applies to all study participants and includes reviews of medication effects, side effects, other adverse events, physical exams, and blood and urine tests through in-person study visits and study phone calls.

Phentermine	**Study Plan to reduce risk**	**What you can do to reduce the risk**	**When to notify your Study team & Bariatric Clinic team**
Common side effects (symptoms you feel or signs seen on exam or labs)- some may be serious			
Restlessness Irritability Anxiety (This can feel like not being able to calm down, short-temper, or feeling very worried)	-Monitoring plan -Mood assessments at every visit -Prompt mental health evaluation by the bariatric clinic psychologist available as needed	Take study medications as instructed	When you feel restlessness, short-temper, or anxiety that disrupt your normal thinking or activities
Dizziness	-Monitoring plan	1) Take study medications as instructed 2) Meet your usual hydration goals	Dizziness disrupts your normal activities or concerns you
Insomnia (difficulty falling asleep or staying asleep)	-Phentermine should be taken in the morning to prevent sleep disruption	Take study medications as instructed in the morning	Difficulty falling asleep or staying asleep that is concerning to you
Dry mouth, change in taste, diarrhea, constipation	-Monitoring plan	Meet your hydration and nutrition goals set by the bariatric team	Diarrhea or constipation that persist for at least 3 days that concerns you
Increased heart rate and/or blood pressure ***Symptoms*** *can*	-Phentermine is started at the lowest possible dose and gradually increased -Monitoring plan (blood	1) Take the study medications as instructed 2) Meet your hydration and	Any rapid heart rate, chest pain, shortness of breath, or new headaches

include: rapid heart rate you feel, chest pain, shortness of breath, or headaches	pressure, heart rate, checklist of symptoms, and physical exam at every visit) -For individuals who qualify for the study and either have well-controlled high blood pressure or severe sleep apnea with frequent missed nights of using their sleep apnea mask (≥30% nights with ≤4h/night), a cardiac echocardiogram will be obtained and cleared by a heart doctor prior to starting phentermine as part of standard of care.	nutrition goals set by the bariatric team 3) Take all of your non-study medications as prescribed	
Tolerance (your body can get used to phentermine over time)	-The relatively short exposure to the medication (12 weeks) in this study may reduce the possibility of your body getting used to it.	Take the study medications as instructed	You can call the study staff if you notice this and it is concerning to you. Study staff will ask you about this at every visit.
Rare side effects- serious			
Primary pulmonary hypertension (elevation in pressure of the blood vessels in the lungs), Regurgitant cardiac valvular disease (leaky heart valves) ***Symptoms*** *can include*: chest pain, shortness of breath, not being able to do as much exercise as before without feeling tired, or swelling in your feet, hands, or face	-Monitoring plan (blood pressure, heart rate, checklist of symptoms, and physical exam at every visit) -For individuals who qualify for the study and either have well-controlled high blood pressure or severe sleep apnea with frequent missed nights of using their sleep apnea mask (≥30% nights with ≤4h/night), a cardiac echocardiogram will be obtained and cleared by a heart doctor prior to starting phentermine as part of standard of care.	1) Take the study medications as instructed 2) Take all of your non-study medications as prescribed	**Call right away if you experience <u>any</u>: chest pain, shortness of breath, not being able to exercise as much, or swelling**

Serotonin Syndrome (potentially life-threatening reaction when multiple drugs that act on the chemical serotonin are in the body at the same time) ***Symptoms*** *can include*: fever, high heart rate, agitation/confusion, sweating, tremor (shaking), vomiting	-Drug interaction check by study staff -Monitoring plan	1) Take the study medications as instructed 2) Report all other medications/over the counter products you are taking to the study staff	**Call right away if you experience: fever, significant sweating, agitation, or confusion**
Low blood sugar (if also taking medications that lower blood sugar) ***Symptoms*** *can include* feeling anxious, shaking, sweating, or confusion ***Sign****:* low blood sugar if measured	-Patients with diabetes are not participating -Drug interaction check by study staff -Monitoring plan -Availability of pediatric endocrinologist to adjust medications as needed to keep glucose in the normal range	1) Take the study medications as instructed 2) Meet your hydration and nutrition goals set by the bariatric team 3) Take all of your non-study medications as prescribed 4) Report all other medications/over the counter products you are taking to the study staff	**Follow your medical plan for low blood sugars, then call**
Psychosis (serious disruption in normal thoughts and perceptions)	-Monitoring plan -Mood assessment at every visit -Prompt mental health evaluation/management available on site	1) Take the study medications as instructed 2) Avoid using illicit substances (e.g. alcohol, marijuana)	Call if there is any severe change in mood
Can be harmful to a fetus during pregnancy	-Requirement for females to either have an IUD or a subdermal implant (e.g. Nexplanon) or commitment to use 2 forms of birth control	Females must be on an acceptable form of birth control throughout the study	If there is an unexpected change in birth control (e.g. IUD spontaneously comes out), refrain from sex, and call for guidance

	while on active drug/placebo -Pregnancy tests for females at every visit		
Topiramate	**Study Plan to Reduce Risk**	**What <u>you</u> can do to reduce the risk**	**When to notify your Study team & Bariatric Clinic team**
Common side effects- some may be serious			
Paresthesia (tingling or numbness of the fingers, toes, or other body parts)	-Monitoring plan	Take the study medications as instructed	If numbness or tingling is severe or concerning to you
Decreased appetite, Weight Loss	-What we want to happen to help you lose weight	-	-
Change in taste	-Monitoring plan	Take the study medications as instructed	If this change is concerning to you
Fatigue (feeling tired)	-Taken with phentermine/placebo	Take the study medications as instructed	If the tiredness is interfering with your activities
Dizziness	-Monitoring plan	1) Take study medications as instructed 2) Meet your hydration goals set by the bariatric team	Dizziness disrupts your normal activities or concerns you
Difficulty with memory, concentration, or attention; Confusion	-Gradual increase from 25mg to the goal 100mg dose	Take study medications as instructed	Any changes in memory, concentration, or thinking that affect what you need to do during the day
Mood problems ***Symptoms*** *may include*: feelings of depression, sadness, or hopelessness	-Monitoring plan -Mood assessment at every study visit -Prompt mental health evaluation by the bariatric clinic psychologist available as needed	1) Take the study medications as instructed 2) Take all of your non-study medications as prescribed	Any change in mood that concerns you or your parent/guardian
Fever, Infection	-Monitoring plan	-	Call with any fever or infection
Flushing (facial redness/warmth)	-Monitoring plan	Take study medications as instructed	Call if this is severe or concerns you

Rare side effects- serious			
Topiramate-Alcohol interaction (dangerous combination that can increase impairment)	**-Avoid drinking any type of alcohol while participating in this study**. -Also remember that it is recommended that alcohol not be consumed for at least 1 year after bariatric surgery and until you are at least 21 years old.	Do NOT drink alcohol during this study	If you plan to drink alcohol, notify study staff
Kidney stones	-Baseline acid-base level (bicarbonate) -Drug interaction check performed by study staff -Hydration goals set by dietitian as part of standard of care -Monitoring plan	1) Take study medications as instructed 2) Meet your **hydration goals** set by the bariatric team (typically a minimum of 64oz of clear fluids/day)	Call right away if you develop severe back, abdominal, or groin pain, or blood in your urine
Acute myopia (***Symptom:*** suddenly not being able to see far away) **Secondary angle closure glaucoma** (***Symptoms:*** eye pain, seeing halos around lights)	-Monitoring plan	Take study medications as instructed	Call right away if you develop any sudden changes in vision
Increased body temperature, decreased ability to sweat, flushing, fever (especially when in hot temperatures)	-Monitoring plan (including temperature at in-person study visits)	1) Take study medications as instructed 2) Meet your **hydration goals** set by the bariatric team (typically a minimum of 64oz of clear fluids/day and **more on hot days**)	Call with any fever, inability to cool down, overheating, or new decrease in sweating
Metabolic acidosis (increased acid in your blood)	-Measured acid-base levels in the blood at baseline and after goal doses of study meds	Take study medications as instructed	Call with significantly reduced energy or new nausea/vomiting

Symptoms *can include:* low energy, nausea/vomiting, fast breathing	are reached		
Thoughts or actions of hurting or killing yourself	-Monitoring plan	Take study medications as instructed	**Establish safety first, then call if you <u>ever</u> develop these feelings**
Toxic to a fetus if pregnant	-Requirement for females to either have an IUD or a subdermal implant (e.g. Nexplanon) or commitment to use 2 forms of birth control while on active drug/placebo -Pregnancy tests for females at every study visit	Females must be on an acceptable form of birth control throughout the study	If there is an unexpected change in birth control (e.g. IUD spontaneously comes out), refrain from sex, and call for guidance
Withdrawal symptoms if stopped suddenly ***Symptoms***: there is a theoretical risk of seizure if topiramate is stopped abruptly	-Topiramate is gradually stopped at the end of the study	Discontinue medications as instructed	Call study staff if study medications are stopped for any unplanned reason
High ammonium levels ***Symptom***: confusion, disorientation	-Drug interaction check by study staff -Monitoring plan	Take study medications as instructed	Call if you/your child experiences any new confusion

<u>Blood draw from a vein</u>: Taking blood may cause some pain, bleeding, or bruising at the spot where the needle enters your body. Rarely, taking blood may cause fainting or infection.

<u>Weight, Height, Temperature, Heart Rate, and Blood Pressure measurements</u>: There are no physical risks, but you may experience momentary embarrassment or discomfort. If you don't want to look at your measurements, you don't have to.

<u>Questionnaires and Surveys</u>: There are no physical risks, but you may experience momentary embarrassment or discomfort. You do not have to answer any questions that make you too uncomfortable. There also may be minor inconvenience because of the time required to complete the questionnaires and surveys. Whenever possible during study visits 1 and 4, the study team will try to give the questionnaires during times when you are waiting to see other providers on the team (down time).

DEXA Scan: DEXA is a type of x-ray used to measure bone strength and body composition. The cumulative radiation exposure from this test (performed twice during the study) is considered small and is not likely to adversely affect you. However, the effects of radiation add up over a lifetime. It is possible that having many of these tests may add to your risk of injury or disease. When deciding to enter this study, you may want to think about your past and future contact with radiation.

Based on the design of this study, there is a risk that you will get the placebo and not the active phentermine and topiramate drugs. Therefore, it is possible that your weight may not be as effectively treated compared to if you are assigned to the active drug group, or if you were to start the weight loss medications outside of the study. If you are assigned the placebo, you will still receive more clinical contacts with the study team compared to someone not in the study, which may help you lose weight and you will continue to receive all standard of care treatments offered by the multidisciplinary team in the Children's Colorado Bariatric Surgery Center.

During the study, there may be unexpected findings (for example abnormal kidney function from the bloodwork drawn). If unexpected findings are identified, you will be referred to the Bariatric Surgery clinical team to manage these.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it can not be guaranteed.

Other possible risks include unforeseen risks associated with study participation that are not known at this time.

Optional Consent for Data and Specimen Banking for Future Research

Dr. Moore would like to keep some of the data, blood, and urine that is taken during the study but is not used for other tests. If you agree, the data and samples will be kept and may be used in future research to learn more about weight loss and how different people respond to the study medications. The research that is done with your data and samples is not designed to specifically help you. It might help people who have difficulty losing weight and other diseases in the future.

Reports about research done with your data and samples will not be given to you or your doctor. These reports will not be put in your health records. The research using your data and samples will not affect your care.

The choice to let Dr. Moore keep the data and samples for future research is up to you. No matter what you decide to do, it will not affect the care that you will receive as part of the study. If you decide now that your data and samples can be kept for research, you can change your mind at any time and contact your study doctor to let him or her know that you do not want Dr. Moore to use your data and samples any longer, and they will no longer be used for research. Otherwise, they may be kept until they are used up, or until Dr. Moore decides to destroy them.

If your data and samples are given to other researchers in the future, Dr. Moore will not give them your name, address, phone number or any other information that will let the researchers know who you are.

Sometimes data and samples are used for genetic research (about diseases that are passed on in families). Even if your data and samples are used for this kind of research, the results will not be told to you and will not be put in your health records. Your data and samples will only be used for research and will not be sold. The research done with your data and samples may help to develop new products in the future, but there is no plan for you to be paid.

We may share data from our research with other researchers or data banks. One such data bank is called dbGAP, which collects genetic and other data and is sponsored by the National Institutes of Health. By broadly sharing data in data banks like this, we can make our discoveries more accessible to other researchers. Information which directly identifies you will not be sent to these data banks.

Because your genetic information is unique to you, there is a small risk that someone could connect the information back to you. Also, genetic research and broadly sharing data may involve risks to you or people like yourself that are unknown at this time.

The possible benefits of research from your data and samples include learning more about weight management and other diseases, and how to treat weight after bariatric surgery. The greatest risk to you is the release of your private information. Dr. Moore will protect your records so that your name, address and phone number will be kept private. The chance that this information will be given to someone else is very small. There will be no cost to you for any data or sample collection and storage by Dr. Moore.

Please read each sentence below and think about your choice. After reading each sentence, circle “yes” or “no.” If you have questions, please talk to your doctor. Remember, no matter what you decide to do about the storage and future use of your data and samples, you may still take part in the study.

I give my permission for my data, blood and tissue samples to be kept by Dr. Moore for use in future research to learn more about how to prevent, detect, or treat extra weight on the body.

Yes No _____Initials

I give my permission for my data, blood and tissue samples to be used for research about other health problems (for example: causes of heart disease, osteoporosis, diabetes).

Yes No _____Initials

I give my permission for my study doctor (or someone he or she chooses) to contact me in the future to ask me to take part in more research.

Yes No _____Initials

What are the possible benefits of the study?

This study is designed to learn more about weight loss medications for adolescents and young adults who continue to struggle with their weight *after* bariatric surgery.

If you are assigned to the active medication group (phentermine + topiramate), possible individual benefits to participating in this study include receiving weight loss medications at no cost. These medications typically cost between $25-40 per month. Another possible benefit is feeling less hungry and feeling full faster, which can lead to losing more weight and improving your blood pressure, cholesterol, liver and/or prediabetes/diabetes tests more than you may achieve from standard of care treatment alone. You will also provide important information that can help other adolescents and young adults who continue to struggle with their weight and health problems related to their weight *after* bariatric surgery.

If you are assigned to the placebo group, you may not benefit directly from participation in the study, but you will provide important information that can help other adolescents and young adults who continue to struggle with their weight and health problems related to their weight *after* bariatric surgery. Some individuals may experience a "placebo effect" of being on medications, which may lead to more weight loss.

Are there alternative treatments?

If you choose not to participate in this study, your medical provider in the Children's Colorado Bariatric Surgery Clinic may still recommend starting weight loss medications. Anyone who begins weight loss medications is still required to come to clinic monthly for three months for monitoring, regardless of study participation.

Other ways of managing your weight may include more frequent visits with a dietitian, exercise specialist, medical provider, and/or clinical psychologist/social worker on the Bariatric Surgery Clinic team. In some cases, your bariatric surgeon may recommend additional imaging to make sure your sleeve/pouch looks ok. You could also choose to get no treatment at all.

You should talk to you doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

This research is being paid for by the Nutrition Obesity Research Center at University of Colorado, Colorado Clinical and Translational Sciences Institute at and the University of Colorado Anschutz Medical Campus, and the Children's Hospital Colorado Research Institute.

Will I be paid for being in the study?

<u>Compensation</u>

- You will be paid $100 for each study visit, with a possible additional $50 earned if you meet goals for taking the study medications.
- This will add up to a maximum of $450 if you complete all study visits and meet the goals for taking the study medications.
- If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.
- It is important to know that payments for participation in a study is taxable income.

Reimbursement

- If you are traveling specifically for participation in this research study (i.e. not already traveling for a clinical reason) and If you live >100 miles away from the Anschutz Medical Campus, you will be reimbursed up to $300 for lodging, flight, and/or gas mileage expenses per study visit.

Will I have to pay for anything?

It will not cost you any money to be in this study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled. If you choose not to take part in this study, it will not affect the rest of your care through the Bariatric Surgery Center. If you decide to leave the study, data collected up to that time will remain in the trial database and be included in the data analysis.

If you leave this study, the adolescent/young adult will still receive standard medical care. The only care that you might lose is weight loss medications at no cost and more detailed information collected about your experience in this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?

The study doctor may decide to stop one or both study medications without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. However, with your permission, you will continue to be followed through the end of the study.

Reasons that phentermine/placebo will be stopped: If the adolescent/young adult develops: a severe allergic reaction, primary pulmonary hypertension (a type of high blood pressure in the lung blood vessels), new heart valve problems, uncontrolled high blood pressure, a new unhealthy heart rhythm, severe anxiety that does not improve with dose decrease, psychosis, suicidal thoughts/actions, serotonin syndrome, or pregnancy, phentermine/placebo will be stopped.

Reasons that topiramate/placebo will be stopped: If the adolescent/young adult develops: a

severe allergic reaction, kidney stones, an inability to cool the body down, new serious vision problems called acute myopia or secondary angle closure glaucoma, severe and persistent changes in thinking/concentration/memory that affect work or school performance, severe depression, suicidal thoughts/actions, confusion, severe increased acid levels in the blood, or pregnancy, topiramate/placebo will be stopped.

What happens if I am injured or hurt during the study?
If you have an injury while you are in this study, you should call Dr. Jaime Moore immediately. Her phone number is 303-724-8419.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care. The investigator will determine if your injury or illness is research-related. The term "research-related injury" means physical injury caused by drugs or procedures required by the study which are different from the medical treatment you would have received if you had not participated in the trial.

Who do I call if I have questions?

The research physician carrying out this study is Dr. Jaime Moore. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Jaime Moore at 303-724-8419. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Jaime Moore with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who will see my research information?

The University of Colorado Denver (UCD) | Anschutz Medical Campus (the University) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include

- Children's Hospital Colorado (CHCO)

CHCO shares a medical record system with the Barbara Davis Center and PedsConnect; therefore, it is also possible that your information could be viewed by healthcare professionals at these organizations.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Jaime Moore, MD
12631 E 17th Ave, Mail Stop F561
Academic Office Building, Room 2600
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make *all or some* of the following health information about you collected in this study available to:

Some of the optional research procedures involve genetic testing or the use of your genetic information. Your genetic information will not be released to others.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records

- Psychological and mental health tests
- Alcoholism, Alcohol or Drug abuse
- Billing or financial information

What happens to Data, Blood and Specimens that are collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data, tissue, blood, or other specimens given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data, blood, or other specimens collected from you.
- If data, blood, or other specimens are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

HIPAA Authorization for Optional Additional Study Procedures

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

Some of these optional procedures may involve genetic testing or the use of your genetic information. Your genetic information will not be released to others.
If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

Both the records that identify you and the consent form signed by you may be looked at by others.

These include:

- Federal agencies that monitor human subject research
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The group doing the study
- The group paying for the study

- Regulatory officials from the institution where the research is being conducted who want to make sure the research is safe

The results from the research may be shared at a meeting. The results from the research may be in published articles. Your name will be kept private when information is presented.

Some things we cannot keep private:

- If you give us any information about adolescent/young adult abuse or neglect we have to report that to Colorado Social Services.
- If you tell us you or your adolescent/young adult is going to physically hurt yourself or someone else, we have to report that to the study clinical psychologist and possibly to law enforcement.
- Also, if we get a court order to turn over your study records, we will have to do that.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name:_____

Signature:_____ Date:_____
(Select one: □*Legally Authorized Representative* **OR** □*Proxy Decision Maker*)

Print Name:_____

Signature: _____ Date:_____
(Child Subject 13-17 years old; ***In addition*** to Parent Signature)

Print Name:_____

A signature of a witness is required for consent of non-reading subjects and consent using a short form.

Witness Signature: _____ Date:_____

Consent Form

Print Name:_____

Witness of Signature ☐
Witness of consent process ☐