Study Title: SMART Use of Medication for the Treatment of Adolescent Severe Obesity

NCT04007393

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Title of Research Study: ***Smart Use of Medication for the Treatment of Adolescent Severe Obesity***

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

Supported By: This research is supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study: The investigator has no relevant disclosures.

Key Information About This Research Study

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

What is research?

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

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

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

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you were between the ages of 12-17 when you first enrolled into the study, had visited an M Health Fairview clinic within the past 2 years and may be able to be part of a research study looking at new ways to achieve a healthy weight and lifestyle.

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?

The purpose of this study is to determine the best time to start weight loss medication when lifestyle therapy (healthy eating and activity advice) is not enough for losing weight, how to change medications if a patient does not lose weight, and what types of patients might lose more weight with lifestyle therapy or different medications. We will be examining 2 different medications that are both used for weight loss, phentermine and topiramate, to see if they are safe and effective in children and young adults. Both drugs are considered to be experimental when used to treat children for "weight loss".

How long will the research last?

We expect that you will be in this research study for about 72 weeks (a year and a half). This includes 15 in-person visits to the study center, and 7 phone visits. Most visits will take approximately one hour. The visit at Baseline will take 4-5 hours. The screening, Week 12, Week 24, Week 36 and Week 48 visits will take 2 hours.

What will I need to do to participate?

You will be asked to follow all instructions given to you by the study team, which may include participating in lifestyle therapy with a health coach and taking study medication to treat your obesity. You will also have blood draws (including fasting blood draws), a DXA scan, and you will complete some questionnaires.

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?

Lifestyle therapy may make you feel frustrated, if it is difficult to follow the dietary and lifestyle plans.

One drug in this study, 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.

Another drug in this study, 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.

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, treatment with weight loss medications that have recently been approved by the FDA, 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 about 150 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"*?

If you decide you want to be in this study, you will have a screening visit and then a baseline visit. Starting at the baseline visit you will meet every 4 weeks for 48 weeks with a health coach for advice about healthy eating and activity. You will be asked to track your food and activity.

Also at the baseline visit you will be randomized to one of two groups but neither you nor the health coach will know which group you are in. (Randomized means being assigned to a group by chance, like flipping a coin.) One group will have their weight loss progress assessed earlier in the study and one group will have their weight loss progress assessed later in the study.

At the weight loss progress assessment:

- if you **do** lose enough weight, you will stay on lifestyle therapy until the end of 48 weeks
- if you do **not** lose enough weight, you will be started on a medication called phentermine in addition to lifestyle therapy

For those people who are started on phentermine in addition to lifestyle therapy, your weight loss progress will be checked again after 3 months of treatment:

- if you **do** lose enough weight with phentermine and lifestyle therapy, you will stay on this treatment plan until the end of 48 weeks
- if you do **not** lose enough weight with phentermine and lifestyle therapy, you will be randomized again to 1 of 2 groups. Again, neither you nor the health coach will know which group you are in. One group will get topiramate plus phentermine and lifestyle therapy until the end of 48 weeks and the other group will get topiramate plus placebo pill (fake pill) and lifestyle therapy until the end of 48 weeks.

At the end of 48 weeks, the lifestyle therapy and medications will be stopped and you will return 6 months later for the very last visit.

All study visits will be the same, no matter which weight loss progress assessment group you are in, or what treatment you are receiving. You can expect the following at your study visits:

Screening Visit (about 2 hours):

- Participants younger than 18 will sign an assent form, and a parent or guardian will sign a consent form
- You will be asked questions about your medical history
- You will be asked questions about your demographics and environment
- You will be asked to fill out questionnaires about your health and your emotions
- You will have a physical exam (including height, weight, blood pressure, and heart rate)
- You will have a puberty assessment
- You will have a blood draw. This is a fasting blood draw, so you must not have eaten within the last 12 hours before your visit. If you have eaten, tell your study doctor. You may need to return for the blood draw later on after you have fasted. Approximately one teaspoon of blood (5 mL) will be taken
- If you are a girl who can have children, you will have a urine pregnancy test
- You will have an ECG to measure the electrical current in your heart

Baseline Visit (Week 0, about 4-5 hours):

- Your height, weight, blood pressure, and heart rate will be measured
- You will be asked to fill out questionnaires about your health and your emotions
- If you are a girl who can have children, you will have a urine pregnancy test
- 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 exposure are described below.
- You will have an x-ray or your left hand and wrist to measure your bone age.
- You will take some tests to assess depression, anxiety, brain function (memory and thinking speed), eating behaviors, and physical activity
- You will have five minutes to drink a meal replacement drink. You will have blood draws before and after this test, and you will be asked questions about your appetite, how full you feel, if you want to eat, and if you feel nauseous. Approximately one teaspoon of blood (5 mL) will be taken

for these tests).
- You will have an in-person lifestyle therapy visit with your health coach

Phone Therapy Visits (Weeks 2, 6, 10, 14, 18, 22, and 26):
- You will have a phone call with your health coach
- You will be asked about your eating and exercise habits

In-Person Therapy Visits (Weeks 4, 8, 16, 20, 28, 32, 40, and 44, about one hour):
- Your height, weight, blood pressure, and heart rate will be measured
- If you are a girl who can have children, you will have a urine pregnancy test
- You will be asked about any side effects you may be feeling, and how well you have been following your therapy instructions and (if applicable) if you have been taking your medication every day
- You will have an in-person lifestyle therapy visit with your health coach
- You will fill out questionnaires about your health and your emotions
- You will be asked to bring your medication with you and your medication will be reviewed to see if you have been taking it regularly

In-Person Therapy+ Visits (Weeks 12, 24, and 36, about 2 hours):
- Your height, weight, blood pressure, and heart rate will be measured
- You will have a blood draw. This is a fasting blood draw, so you must not have eaten within the last 12 hours before your visit Approximately 1 teaspoon of blood (5 mL) will be collected.
- If you are a girl who can have children, you will have a urine pregnancy test
- You will fill out questionnaires about your health and your emotions
- You will have a DXA scan to measure your body fat and bone density.
- You will take some tests to assess depression, anxiety, brain function (memory and thinking speed), eating behaviors, and physical activity
- If you are in a group assigned to receive medication, you will be given medication to take home with you
- You will be asked about any side effects you may be feeling, and how well you have been following your therapy instructions and (if applicable) if you have been taking your medication every day
- You will have an in-person lifestyle therapy visit with your health coach
- You will be asked to bring your medication with you and your medication will be reviewed to see if you have been taking it regularly
- At week 12 or 24, depending on when you started on medication, you will be asked questions about your satisfaction with the study and about your weight loss.

Week 48 Visit (about 2 hours):
- You will have a puberty assessment
- Your height, weight, blood pressure, and heart rate will be measured
- You will have a blood draw. This is a fasting blood draw, so you must not have eaten within the last 12 hours before your visit. Approximately one teaspoon of blood (5 mL) will be drawn.
- If you are a girl who can have children, you will have a urine pregnancy test
- You will be asked to fill out questionnaires about your emotions

- You will have an ECG to measure the electrical current in your heart
- You will have a DXA scan to measure your body fat and bone density.
- You will have an x-ray or your left hand and wrist to measure your bone age.
- You will take some tests to assess depression, anxiety, brain function, eating behaviors, and physical activity
- If you are in a group assigned to receive medication, you will be asked to turn in any study medication in at this visit.
- If you are in a group assigned to receive medication, you will be given medication to take home with you. This will only apply to the people who are taking topiramate: you will be given 7 days of a smaller dose of topiramate (to wean off the medication.).
- You will be asked about any side effects you may be feeling, and how well you have been following your therapy instructions and (if applicable) if you have been taking your medication every day

Week 55 Visit (by Phone)
You will answer questions about your health and how you have been feeling, and whether or not you have been hospitalized since your last visit

Final Visit (Week 72, about one hour):

- Your height, weight, blood pressure, and heart rate will be measured
- You will do the brain function test (memory and thinking speed)
- You will be asked about how you have been feeling and about the medications you have been taking

A study visit table is shown on the next page to summarize these procedures.

Study Visit Table

	Screening	Baseline	2-wks	4-wks	6-wks	8-wks	10-wks	12-wks	14-wks	16-wks	18-wks	20-wks	22-wks	24-wks	26-wks	28-wks	32-wks	36-wks	40-wks	44-wks	48-wks	55-wks	72-wks
Review of medical history	X																						
Questions about demographics and environment	X																						
Physical exam	X																				X		
Ht, Wt, BP, HR	X	X		X		X		X		X		X		X		X	X	X	X	X	X		X
Questionnaires	X	X		X		X		X		X		X		X		X	X	X	X	X	X		
12-Hour Fasting Blood Draw	X							X						X				X			X		
Urine pregnancy test	X	X		X		X		X		X		X		X		X	X	X	X	X	X		
ECG	X																				X		
iDXA		X						X						X				X			X		
Bone Age X-ray		X																			X		
NIH Toolbox		X						X						X				X			X		X
Meal test		X																					
Drug Dispensing (Drug Groups Only)								X						X				X			X		
Side Effects Check		X		X		X		X		X		X		X		X	X	X	X	X	X	X	X
Therapy in person		X		X		X		X		X		X		X		X	X	X	X	X	X		
Therapy by phone			X		X		X		X		X		X		X								

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

If you take part in this research, you will be responsible for attending all study visits as directed, following the instructions of your health coach and the study team, taking study medication if instructed by the study team, and telling the study team about any side effects 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. Depending on the medication you are taking, you may be asked to slowly wean off the medication over the course of 7 days.

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 any 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. You will be asked whether the investigator can collect information from your routine medical care, such as your medical records. If you agree, this information will be handled the same as the information obtained for the research study.

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 from your health coach. You may experience injury related to increasing your physical activity.

Phentermine: In addition to the most common side effects mentioned earlier in this form, possible risks of phentermine use include:

- Pulmonary hypertension (high blood pressure that affects your lungs and heart), leaking heart valves, or a restriction in blood supply to your tissues
- Overstimulation, a feeling of excitement, a feeling of unease, or psychosis
- Dry mouth, unpleasant taste in mouth
- Hives
- Impotence or changes in libido
- Risk of drug abuse or dependence

Topiramate: In addition to the most common side effects mentioned earlier in this form, possible risks of topiramate use include:

- Nearsightedness or glaucoma
- Lack of sweating, overheating
- Metabolic acidosis (when too much acid accumulates in the body)
- Suicidal behavior or thoughts
- Toxicity to fetus
- Kidney stones
- Seizures, if patient withdraws from drug suddenly
- Low body temperature

To minimize the risks related to topiramate and phentermine, ensure that you stay well hydrated, especially in hot weather, avoid drinking alcohol, and exercise caution when biking, driving or operating machinery. Tell your research coordinator if you start any new medications.

Notify the research coordinator or your health care provider immediately if you develop a sudden change in vision, eye pain, high fever that does not go away, thoughts of suicide or dying, or worsening mood or behavior. If you have thoughts of suicide, a member of the study team will contact a psychologist to meet with you or you will be referred to an emergency room for evaluation.

It is possible that you will not lose any weight by being in this study and this could be sad or frustrating for you.

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

Fasting: You may feel hungry or have symptoms of a 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: These scans involve exposure to a very low dose of ionizing radiation. The amount of radiation that you will receive from the DXA scan is less than 1% of that received from natural sources of radiation by a Minnesota resident in one year.

Questionnaires: You may feel distress as you think about your anxiety or depression symptoms. You may tire of answering questions.

Meal Test: You may feel pain or have bruising with the blood draws.

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 fetal toxicity. Women who are pregnant or breastfeeding may not participate in this study.

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

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

- 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 medical service providers (for clinical trials), Food and Drug Administration (FDA), Health and Human Services, when the research is conducted or funded by the DHHS, the sponsor, contract research organization, sponsor's agent and other collaborating institutions.

If you tell us about child abuse or neglect, we may be required or permitted by law or policy to report to authorities.

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 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.

Data or Specimens Collected

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies. Future tests done on these samples may include DNA or genetic analysis. You will have the option to consent to this optional storage at the end of this consent form. You can still participate in the study, even if you do not want your samples stored for future research.

During the study, you may change your mind and choose not to have your samples stored for future research. However, once the study is completed, your samples cannot be removed.

Genetic Information

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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. The investigator(s) will not contact you or share your individual test results. The information collected during this study is not intended to be used for personal healthcare reasons such as medical diagnosis or treatment.

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 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 is no longer in your best interest
- If you are unable to take study medication for 7 days

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

What happens if I am injured while participating in this research?

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

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you up to $1,150 for your time and effort. Payments will be broken down by visits as follows. You will receive payment for in-person visits at the end of each completed visit:

- Screening visit: $25
- 5 long assessment visits (Baseline, Weeks 12, 24, 36, 48): $100 each
- 19 lifestyle therapy visits: $10 each
- Week 72: $50

You will also receive incentives for completing increasing amounts of your therapy visits. You will receive your total bonus amount at the end of Week 72. If you leave the study sooner, your bonus will be mailed to your house.

- ≥10 therapy visits: $50 bonus
- ≥ 15 therapy visits: $100 bonus
- ≥ 18 therapy visits: $200 bonus
- ≥19 therapy visits + Week 48 visit: $385 bonus

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 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.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

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 store my de-identified biological samples for use in future research studies. This means that any biological samples (such as blood, urine or stool) will not have your name or information on the tube. The doctor can use your samples for future tests, including gathering information about your genes (or DNA). You will not get information back about the tests that are done on these samples.

Consent Form

Signature Block for Adult Participant:

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

WITNESS STATEMENT:

The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is unable to read the information

Statement from a Non-Interpreter:
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____

Printed Name of Witness

_____ _____

Signature of Witness Date