Title of Research Study: Efficacy and safety of GLP-1 agonist therapy in overweight and obese subjects with cystic fibrosis-related diabetes: a pilot study

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

Investigator Name: Amir Moheet, MD Investigator Departmental Affiliation: Medicine, Division of Diabetes, Endocrinology and Metabolism Phone Number: 612-624-3209 Email Address: mohee002@umn.edu	Study Staff (if applicable): Cathy Larson, Primary Research Coordinator Phone Number: 612-625-2153 Email Address: cftrials@umn.edu 24-Hour Emergency Number: 612-273-3000 (Ask for the CF doctor on call)

If your doctor is also the person responsible for this research study, please note that he 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 Cystic Fibrosis Foundation.

Key Information About This Research Study

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

What is research?

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

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

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

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

We are asking you to take part in this research study because you have been diagnosed with CFRD (Cystic Fibrosis Related Diabetes) and are overweight.

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?

Cystic Fibrosis (CF) has traditionally been associated with malnutrition and being underweight. Because of this, the dietary recommendations for people with CF have been to consume a high calorie diet. Due to the advancements in care for people with CF, it is becoming common for people living with CF to develop obesity along with Cystic Fibrosis Related Diabetes (CFRD).

This study is looking at a drug called Semaglutide (brand name: Ozempic). We would like to learn how safe and how well tolerated this medication is for people with CFRD. This medication has been proven safe and effective in people without CF and has been approved by the Food and Drug Administration (FDA) to treat type 2 diabetes.

If you choose to participate in this study, we will ask you to add Semaglutide to your current medications. We want to see if your glucose is better controlled.

How long will the research last?

We expect that you will be in this research study for 15 weeks.

What will I need to do to participate?

For your participation in this study we ask that you do not start any new diabetes medications. If you are currently on insulin therapy, we ask that you do not change the way that you are currently administering your insulin.

This study will involve you to attending 5 in-person visits and complete 4 telephone visits. Visit

1 will take place at M Health Fairview Clinic and Surgery Center (CSC) or M Health Clinical Research Unit (CRU). Visits 2-5 will take place at the CRU.

At visits 2 and 5, you will be asked to complete an OGTT (oral glucose tolerance test). This test will take about 2 hours. During the test you will be asked to drink a sweet liquid that contains glucose (sugar). Then blood samples will be drawn using a small plastic tube (IV), which will be placed using a needle, in a vein in your arm. You will also have 2 finger stick tests done to monitor your blood glucose during this time.

Also at visit 2 you will learn to inject the study medication. You will continue this weekly injection at home while you are enrolled in this study.

For up to 20 days (two sets of up to 10 consecutive days), you will be asked to monitor your glucose at home using a CGM (Continuous Glucose Monitor). You may already be using a monitor to manage your diabetes, but if you do not have a CGM, one will be provided to you. If you use a CGM provided to you by the study team, we will ask you to mail it back to us or return it at a study visit when no longer needed for the study. If you choose to mail it back, we will provide a pre-paid mailer.

If you are on insulin therapy, to reduce the risk of hypoglycemia, your doses of bolus and basal insulin will be reduced by 20% at the time of initiation of semaglutide treatment. Your blood sugar readings will be monitored during the study and insulin doses will be adjusted as needed.

If you are a person who can become pregnant, we will ask that you take a serum pregnancy test at visit 1 and agree to take precautions that are effective in preventing pregnancy.

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?

Side effects from the use of the study medication Semaglutide. Most common are: nausea, vomiting, diarrhea, abdominal pain, and constipation.

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

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, one possible benefit could include better blood glucose control of your diabetes.

What happens if I do not want to be in this research?
There are no known alternatives, other than deciding not to participate in this research study. You do not have to participate in this research. Instead of being in this research study, your choices may include maintaining your current regimen and following up with your current doctor. You may be eligible to receive this medication without being in this study.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?
We expect about 15 adults at the University of Minnesota will participate in this research study.

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

Visit 1: Review and sign consent form, complete questionnaires, start CGM (Continuous Glucose Monitoring) this will be done for up to 10 days. If you are currently using a CGM you may continue with that one. If you are not currently using a CGM the study will provide one for you to use during your time in the study. This visit will last 60-90 minutes and take place at the CSC or CRU. If you are a person who is capable of becoming pregnant you will be asked to complete a serum pregnancy test.

Visit 2 & 5: At these two visits you will have an Oral Glucose Tolerance Test (OGTT). For this test, you will be asked to arrive fasting (having nothing to eat or drink except water for at least 8 hours) - if you are not fasting the visit will need to be rescheduled.

When you arrive, you will meet with a member of the study team to review your medications and have your vital signs and weight checked.

During the OGTT test, you will be asked to have your blood drawn 6 times. To make it easier for you, we will place an IV in a vein in your arm. The IV will be used to draw blood from your arm throughout the study visit. Your first blood draw will take place immediately after your IV is placed. After this first blood draw, you will be asked to drink a sweet drink (Glucola). Your next blood draw will take place 10 minutes after you finish your Glucola, and again about every 30 minutes for two hours. We will also take blood samples from your IV to check your lipase, electrolytes, HbA1c, liver and kidney function. Each time they draw blood they will take about 20-40 ml (about 4-8 teaspoons) from your arm.

Blood samples maybe taken from your IV or a separate blood draw depending on the study

visit.

In addition to the blood draws from your IV, you will also have a finger stick blood glucose test (only a few drops of blood) completed at 90 and 120 minutes.

You will be monitored for safety while having the OGTT and a study doctor will be updated about how you are doing.

These visits will last 4 -5 hours and take place at the CRU.

At visit 2 (only), the study staff will review with you how to self-administer the first dose of the study medication (semaglutide) and answer any questions you may have. If you are a person who is capable of becoming pregnant you will be asked to complete a urine pregnancy test.

At visit 5 (only), we will ask you to bring any remaining study drug to your appointment.

Visit 3 and 4: You will meet with a study team member to review your medications, and have your vital signs and weight checked. Discuss how your feeling, review your blood glucose readings and, if applicable, how much insulin you are using. We will also ask you bring the study medication with you to this visit. You will also have one blood draw to check HbA1c, liver and kidney function. During this blood draw, we will take about 10-20 mls (2-4 teaspoons) from your arm. If you are a person who is capable of becoming pregnant you will be asked to complete a urine pregnancy test. These visits will take place at the CRU and will take about 60 minutes.

At visit 4, start CGM this will be done for up to 10 days. If you are currently using a CGM you may continue with that one. If you are not currently using a CGM the study will provide one for you.

Telephone visits: For the telephone visits, a researcher will call you to ask how you are feeling; review your home blood glucose readings and, if applicable, find out how much insulin you are using. We will work with you to schedule the telephone visits ahead of time so you know when a researcher will be calling.

Schedule of Events

	Screening/Visit 1	Visit 2	Telephone contact	Visit 3	Telephone contact	Visit 4	Telephone contact	Visit 5 End of study	Final Telephone contact
Time (weeks)	-2 ± 1	0	2 ± 1	4 ± 1	6 ± 1	8 ± 1	10 ± 1	12 ± 1	13 ± 1
Estimated time for study visit	60-90 min	4-5 hours	30 min	60 min	30 min	60 min	30 min	4-5 hours	30 min
Review current Medications	X	X		X		X		X	
Consent	X								
Review any symptoms			X	X	X	X	X	X	X
Blood draw		X		X		X		X	
Review Blood glucose results and insulin usage.			X	X	X	X	X	X	X
Questionnaires	X			X		X		X	
Vital signs, weight		X		X		X		X	
Oral glucose tolerance test (OGTT)		X						X	
Continuous Glucose Monitoring (CGM)	X					X			
Serum Pregnancy test – if needed	X								
Urine Pregnancy test – if needed		X		X		X			
Adjust Insulin dose if needed	X	X	X	X	X	X	X	X	X
Review study medication usage				X		X		X	
Adjust study medication – if needed				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 study visits, being available for telephone visits, following instructions that were given to you by the researcher, and returning your glucose monitor (if it was given to you at the start of the study).

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

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care.

We will make sure that you stop the study safely. We will also talk to you about follow-up care,

if needed.

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

Can I be removed from the research?

It is possible that we will have to ask you to discontinue your treatment and leave the study before you finish it. If this happens, we will tell you why. The Investigator may discontinue your treatment or study participation if they decide it is not in your best interest or if it is discovered that you no longer meet study participation criteria. We will also help arrange other care for you, if needed.

We will notify you if there are significant new findings discovered during the course of this research that may affect your willingness to continue your participation in this 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)

Risks associated with the use of the study medication Semaglutide (Ozempic): In addition to the ones noted in "Is there any way that being in this study could be bad for me?"

Most common (>10%)

- Nausea
- Hypoglycemia (Low blood glucose) with concomitant use of insulin or other diabetes medications
- Weight loss
- Increase in amylase and lipase (pancreatic enzymes) levels

Common (5-10 %)

- Vomiting
- Diarrhea
- Abdominal pain
- Constipation

Less Common (<5 %)

- Gastroesophageal reflux disease (acid reflux, heartburn)
- Flatulence
- Cholelithiasis (acute gallbladder disease)
- Increased heart rate

- Fatigue
- Dizziness
- Altered sense of taste
- Diabetic Retinopathy related complication s(damage to the blood vessels in the eyes)

Rare (<1 %)

- Injection site reaction (discomfort, redness at injection site)
- Pancreatitis (Inflammation of the pancreases)
- Acute kidney injury
- Allergic reaction to the medication
- Suicidal behavior and ideation (thinking or planning suicide)

Other concerns

- Risk of Thyroid tumors (this was noted in mice and rats). There is insufficient information to establish or exclude that Ozempic causes thyroid cancers in humans.

Risks of the OGTT (oral glucose tolerance test): you may have low blood glucose readings and have an upset stomach after drinking the sugary drink.

Risk of getting an IV: There may be pain involved with the IV placement. There is a small risk of bleeding under the skin that will produce a bruise. There is a small risk of light-headedness and/or fainting when placing an IV. An infection is extremely rare with the placement of the IV for frequent sampling.

Risk of fasting (Not eating for a period of time): You may experience hunger, irritability, and fidgetiness. You may also have a harder time cooperating or paying attention. You may also experience mild headaches, shakiness and/or dizziness. Fasting may also increase risk of low glucose (hypoglycemia) in people on insulin. If applicable, we will review and adjust your insulin as needed during the study visit.

CGM (Continuous Glucose Monitoring) Skin Reactions: The CGM sensor may produce pain when it is inserted into the skin. There is a low risk for developing a local skin infection at the site of the sensor needle placement. Itchiness, redness, bleeding and bruising at the insertion site may occur as well as local tape allergies.

Questionnaires: The questionnaires will be asking about your symptoms as well as how you are feeling and thinking. Some questions have a slight risk of making you feel uncomfortable. Please skip any questions that make you uncomfortable.

Risk of loss of confidentiality: There is always the risk of a loss of confidentiality in any study.

Participant identifiable information will be stored securely to minimize this risk.

There may be direct access to your original medical records for trial-related monitoring, audit, IRB review, and regulatory inspection.

What do I need to know about reproductive health and/or sexual activity if I am in this study?

You should not be or become pregnant while in this research study.

There is not enough information on Semaglutide and its use in people who are pregnant to inform you of any adverse developmental outcomes.

If you agree to take part in this study than you agree to take precautions that are effective in preventing pregnancy throughout this study, which could include complete abstinence from sexual intercourse; oral, injectable, or implanted hormonal contraceptives; intrauterine device; or tubal ligation.

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.

If you or your partner are considered to be postmenopausal, you are not required to use contraception while participating in this research study. Postmenopausal women rarely become pregnant. If you become pregnant while participating in this research, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other clinical care options will be discussed with you at that time if necessary.

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.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily

covered because these services are performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Parking for your in-person study visits will be paid by the study.

Will being in this study help me in any way? (Detailed Benefits)

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include treatment with Semaglutide may result in improved blood glucose levels and weight loss; however, these benefits cannot be guaranteed.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☒ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits,

and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☐ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)

☐ My HIV/AIDS testing records _____ (initial)

☒ My genetic testing records _____ (initial)

☐ My mental health diagnosis/treatment records ____ (initial)

☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;

- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);

- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;
  The Cystic Fibrosis Foundation

- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S.

government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and

- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

- Greenphire

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.

How will my information be used in publications and presentations?

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

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

We will use and may share data for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

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 your name or any other direct identifiers such as your contact information. The Web site may include a summary of the results of this research. 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. If the research with your identifiable information or samples gives results that do have meaning for your health, the investigators will contact you to let you know what they have found.

If requested we will share the results of your hemoglobin A1c and the OGTT with you in-person, via letter or by email. If requested we will also fax a letter with these same results to your CF pulmonary provider.

Will anyone besides the study team be at my consent meeting?

The study team may ask you 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.

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 compensate you up to $600 for your time and effort. You will also be reimbursed for travel expenses including mileage, as per standard federal rates for reimbursement.

You will receive your compensation at the completion of visits 2,3,4,5 at the following rates:

- Visit 2: $100

- Visit 3: $100
- Visit 4: $100
- Visit 5: $100
- Study Completion: $200

Payment will be made using a pre-paid debit card called Greenphire ClinCard or by a check issued by the University of Minnesota to your home address. Greenphire CliniCard 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 a cardholder agreement. Be sure to read all of this information for details about fees.

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

Additionally, you will have the option to receive updates related to payment reminders and updates via text message and email message (Standard text messaging rates will apply). You will have the opportunity to opt-in to receive these messages, you are not required to provide your cell phone or email address to be enrolled in the study or use a ClinCard. If you choose to receive messages and decide at a later date that you want to stop these messages, you will have the ability to opt-out. If you choose to receive any communications via texts or emails, you will be asked to sign a separate form.

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.

Because CF is a rare disease, please note that if you are currently receiving SSI, Medicaid or Medicare low-income subsidies, you are now able to receive up to $2000 in a calendar year as

payment for study participation without it affecting your continued eligibility for these benefits. Please ask your study coordinator for details.

Optional Element:
The following research activity is optional, meaning that you do not have to agree to it in order to participate in the research study. Please indicate your willingness to participate in this optional activity by placing your initials next to it.

Yes, I agree (Initial)	**No, I disagree (Initial)**	
_____	_____	The investigator may contact me in the future to see whether I am interested in participating in other research studies by Dr. Amir Moheet.

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