National Institutes of Health (NIH)
Gastroparesis Clinical Research Consortium (GpCRC)

ADULT INFORMED CONSENT/HIPAA AUTHORIZATION

Study Title: Buspirone for Early Satiety and Symptoms of Gastroparesis: A Multicenter, Randomized, Placebo-Controlled, Double-masked Trial (BESST).

NCT Number: NCT03587142

Principal Investigator:

PI Version Date: 15 September 2021

IRB No.: Pro000054803

What is the purpose of this consent form?

This form is called a consent form. The purpose of this form is to let you know about a research study being done here at *insert institution name*. It tells you about the purpose, risks and benefits, and describes what is involved in the study. It also tells you what other choices you have.

What you should know about this study

- This study is funded by a grant from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).
- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You may choose not to take part in the study at all, and if you join, you may quit at any time. There will be no penalty if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.

Purpose of research project

This study is to find out if the study medication, buspirone, improves the symptoms of gastroparesis (or slow emptying of the stomach). The purpose of the BESST Trial is to find out whether taking the drug buspirone improves symptoms of gastroparesis (such as fullness and inability to finish a meal) compared to taking a placebo (an inactive study drug like a sugar pill). The placebo capsule looks just like the buspirone capsule, but has no active ingredients. Half the participants in this trial will receive the placebo, and the other half will receive buspirone. The United States Food and Drug Administration (FDA) has approved buspirone to treat anxiety. It is not FDA-approved for symptoms related to gastroparesis; however, some doctors use it to reduce the feeling of early fullness when eating. This is a nationwide study funded by the National Institutes of Health (NIH) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Your participation could last up to 14 weeks.

We intend to learn more about how buspirone affects other gastroparesis symptoms like nausea, hunger, bloating, abdominal pain, how rapidly the stomach empties the food, and if there are any significant side effects. There will be an NIH database to store medical information collected during this study, and blood will be collected for serum and plasma analysis and storage (banking) in a NIH-

sponsored biorepository.

Why we are asking you to participate

We are asking you to take part in this research study because you have a condition suggesting gastroparesis (delayed stomach emptying) that causes long-term (chronic) symptoms including feeling full early when you eat, fullness after eating, nausea, and abdominal discomfort. People with diabetes, prior stomach surgery, or those who have had certain viral infections seem to be at greater risk of developing this condition. If you are eligible for this study and you agree to join the study, then you will be one of about 108 adults nationwide enrolled in this study.

Procedures

Adults that will be participating in this study will be randomly put into one of two groups by using a chance mechanism, similar to flipping a coin: (1) those taking buspirone or (2) those taking placebo only. Neither you nor the study staff will know which drug you are taking. This "masking" of study drug is done so that the study gives fair and unbiased results. The type of study drug you are taking will be unmasked if needed in an emergency.

If you agree to participate in this study, the following will happen:

Visit #1 - Screening for Eligibility ~ 2.0 hours

The first visit will focus on seeing if you are eligible for this study. In addition to the information collected at this visit, there will be two additional screening visits: one to have a Gastric Emptying Scintigraphy Test (GES) and the other to have an Electrogastrogram (EGG) with a water load test.

You will be asked to sign this consent and HIPAA authorization form allowing us to look at your medical records and begin screening tests. We cannot begin qualifying you to participate in the BESST study until this form is signed.

The study doctor will conduct a detailed physical exam and review your medical history. The study doctor will listen to your heart and lungs, record your blood pressure, check your eyes, limbs and abdomen, chest and nervous system. You will also have an Electrocardiogram (ECG) to measure the electrical activity of your heart to show whether it is working normally. You will also be interviewed about any medications that you are taking now or in the past. The doctor will also review your medical history to see if you have had an upper endoscopy (EGD) or an upper GI radiographic series in the past two years, and if not, one will be scheduled for you as part of your gastroparesis diagnosis. You will be given several questionnaires to complete about your gastroparesis symptoms, quality of life, and mood.

You may not enroll in this study if you are pregnant or breastfeeding an infant, because it is not known whether buspirone will harm the baby. If you become pregnant during the study, your study doctor will have you immediately stop the study drug, and just return to the clinic for follow-up. If you are able to become pregnant, we will perform a urine pregnancy test at every visit to ensure your and the baby's safety. If you are able to become pregnant and are sexually active, you must use two effective forms of birth control during the study. Examples of birth control are: no sexual intercourse, hormonal contraceptives (oral, implant, transdermal patch, or injection) at a stable dose for at least 1 month prior to screening, an IUD (intrauterine device), and barrier (condom with spermicide, diaphragm with spermicide).

We will give you symptom diaries for you to fill out each night (daily diaries). You will record how severe your symptoms were during the day. We will schedule your next visit when you will have a gastric emptying scintigraphy test.

Visit #2 – Screening Test 1 ~ 4.5 hours
You will come to this visit in a fasting state, which is nothing by mouth after midnight the night before the visit. You should not use any narcotics for 3-days before the GES test. You can take your normal morning medications at home with sips of water. However, if you have diabetes and normally take insulin, you will be asked to take one-half the dose of your normal long-acting insulin and to bring in your regular short acting insulin if you take this with meals. Your fasting blood glucose level will be checked prior to the gastric emptying test to ensure it is above 60 and less than 270 mg/dL. If your blood glucose is not in control, then the GES will be rescheduled.

If you are a female and able to become pregnant, you will have a urine pregnancy test prior to the test. If you are pregnant, the GES test will not be done. You will not be able to enroll in this study.

You will complete a symptom questionnaire immediately before the gastric emptying test and also during the test.

To confirm a diagnosis of gastroparesis, you will have a 4-hour gastric emptying test with solids using a standardized low fat egg meal with toast and strawberry jam.

Visit #3 – Screening **Test 2 ~ 1.5 hours**
You will come to this visit in a fasting state, which is nothing by mouth after midnight the night before the visit except sips of water, and wear clothes that permit access to your chest and abdomen. You will bring your normal morning medications with you and once you have had your blood drawn, you can take them with a few sips of water. If you have diabetes and normally take insulin, you will be asked to take one-half the dose of your normal long-acting insulin and to bring in your regular short acting insulin if you take this with meals. Your fasting blood glucose level will be checked prior to the electrogastrogram test to ensure it is above 60 and less than 270 mg/dL. If your blood glucose is not in control, then the EGG will be rescheduled. You are asked to bring the symptom daily diaries that you were given after the first screening visit with you and give them to the clinical center staff.

If you are a female and able to become pregnant, you will have a urine pregnancy test prior to the EGG. If you are pregnant, the test will not be done. You will not be able to enroll in this study.

You will have about 3 teaspoons (14 mL) blood drawn for laboratory tests and 4 teaspoons (20 mL) for banking (storage for future studies).

You will undergo a study test called an electrogastrogram (or EGG) with a water load satiety test. For this test, electrodes will be placed on the skin of your stomach to record the movements of your stomach. The electrodes are like those used when you have a heart tracing ECG. First, you will mark your nausea and other symptoms on a paper scale. Next, your stomach movements are recorded for 15 minutes. Then you will drink water for up to 5 minutes or until you feel completely full. Your stomach is recorded for 30 minutes after drinking the water. You will mark your nausea and other symptoms on a paper scale at 10, 20, and 30 minutes after you finish drinking the water and then the test is finished.

Visit #4 - Randomization (Treatment Assignment) ~ 30 minutes

The randomization visit occurs after the screening evaluations are complete. We will review that eligibility criteria continue to be met, by conducting a brief physical exam and asking about any changes in medication use and any symptoms. If you are a female and able to become pregnant, you will have a urine pregnancy test to confirm you are not pregnant. You will also affirm that you still consent to participate in the study.

If you are still eligible for the study, we will use a computer to choose the study drug you will be given for the study. This is done randomly, like a flip of a coin. Neither you nor the study team will know whether you are receiving buspirone or placebo. Once we have your drug assignment, the study staff will provide the assigned study drug (in person) and give you verbal instructions for taking the drug, along with written instructions. You will take one capsule three times a day, about 30 minutes before each meal. You will also be given an Information for Patients document with your study medication. Important directions are that you cannot take a monoamine oxidase inhibitor (MAOI) and should avoid drinking alcohol and eating grapefruit or drinking grapefruit juice while you are taking the study drug.

The Study Coordinator will provide educational material regarding diet and healthy lifestyle for adults with gastroparesis. Before you leave the clinic, you will be given more symptom daily dairies that you will complete each night before bed. These will be returned in around two-weeks at your first follow-up visit.

***Four Follow-up visits*:** You will need to return to the clinic every 2 weeks to see how the study medication is working and if it is causing any side effects. You will return for follow-up visits at 2, 4, and 6 weeks after enrollment. The specific procedures to be completed at each of the follow-up visits are detailed below.

Visit #5 - Week 2 Follow-Up Visit ~ 1 hour

Bring your study medication bottle and your daily diaries to the clinic and give to the Study Coordinator. You will come to the clinic in a fasting state, which is nothing by mouth after midnight the night before. If you are a female able to become pregnant, you will have a urine pregnancy test.

The study doctor will ask about your health, conduct a brief physical exam and check for any side effects. You will be interviewed about any new medications, medical issues or illnesses since the randomization visit or any adverse effects you have experienced. You will be given several questionnaires to complete about your gastroparesis symptoms and mood. We will also collect your daily diaries.

You will be given more daily diaries to fill out each night about the severity of your symptoms during the day to bring completed to your next visit in 2-weeks. You will continue to take your study medication three times a day, 30 minutes before meals.

Visit #6 - Week 4 Follow-Up Visit 1 ~ 4.5 hours

You should bring your completed daily diaries, your study medication bottle, and your regular medications with you to this visit. You will come to the clinic in a fasting state, which is nothing by mouth after midnight the night before. You should not use any narcotics during the 3-days prior to the GES test. You will have 1.5 teaspoons (7 mL) of blood drawn for laboratory tests and 4 teaspoons (20

mL) for banking (storage for future studies). Once you have had your fasting blood drawn, you can take your regular medications, except for your study drug. If you have diabetes and normally take insulin, you will be asked to take one-half dose of your normal long-acting insulin and bring in your regular short acting insulin if you take this with meals. You can take your normal morning medications at home with sips of water, but do not take your study drug. If you are a female and can become pregnant, you will have a urine pregnancy test. If you are pregnant, you will not have the gastric emptying test nor will you take your study medication for the rest of the follow-up visits. Otherwise, you will wait and take your study drug about 30 minutes before the gastric emptying test. If you are diabetic, your fasting blood glucose level will be checked prior to the gastric emptying test to ensure it is above 60 and less than 270 mg/dL to continue with the testing done at this visit. If the blood glucose is not in control, then the test must be rescheduled. Otherwise, you will have a 4-hour gastric emptying scintigraphy test (GES) using the Egg Beaters® with toast and jam, which will be started 30 minutes after taking your study medication.

The study doctor will ask about your health, any adverse effects you have experienced, and check for side effects. The study doctor will ask you whether you have taken any new medications or have had any illnesses or medical conditions diagnosed since the last visit. The study doctor will conduct a detailed physical exam similar to the screening visit and you will have another Electrocardiogram (ECG) to measure the electrical activity of your heart. You will be given several questionnaires to complete about your gastroparesis symptoms, quality of life, and mood.

If you **do not agree** to complete the Week 4 follow-up Visit 2 to complete the EGG and water load satiety test in the next 7 days, you will turn in your daily diaries and study drug bottle to the study staff. You will be given another set of daily diaries to complete until the next study visit. You will no longer be taking your study medications.

If you agree to complete the optional week 4 EGG and water load satiety test like you did at screening, you will return within 1-7 days to undergo the EGG and water load test. You will continue to take your study drug and complete your daily diaries and bring them to the next visit.

Visit #7 - Week 4 Follow-Up Visit 2 ~ 1.5 hours- OPTIONAL

You should bring your completed daily diaries, your study medication bottle, and your regular medications with you to the clinic. You should come to the clinic in a fasting state, which is nothing by mouth after midnight the night before, except for small sips of water, and wear comfortable clothes providing easy access to your chest and stomach. If you are a female able to become pregnant, you will have a urine pregnancy test. If you are pregnant, you will not take your morning study drug.

If you have diabetes and normally take insulin, you will be asked to take one-half dose of your normal long-acting insulin and bring in your regular short acting insulin if you take this with meals.

If you are diabetic, your fasting blood glucose level will be checked to ensure it is above 60 and less than 270 mg/dL to continue with the testing done at this visit. You will undergo a repeat EGG with a water load satiety test. You will take your study drug 15 minutes prior to the start of the EGG. Electrodes will be placed on the skin of your stomach to record the movements of your stomach. First, you will mark your nausea and other symptoms on a paper scale. Next, your stomach movements are recorded for 15 minutes. Then you will drink water for up to 5 minutes or until you feel completely full. Your stomach

will be recorded for 30 minutes after drinking the water. You will mark your nausea and other symptoms on a paper scale at 10, 20, and 30 minutes after you finish drinking and then the test is finished.

After the test, you will return your daily diaries and study drug bottle to the study staff if you have not already done so. You will be given another set of daily diaries to complete until the next study visit. You will no longer be taking your study medications.

Visit #8 - Week 6 Follow-Up Visit ~ 1.5 hours
(Completion of the study)
You will come to the clinic in a fasting state. You should bring back your study medication bottle if you did not bring it to the last visit and your completed daily diaries. You will have 1.5 teaspoons (7 mL) of blood drawn for laboratory tests and 4 teaspoons (20 mL) of blood will be drawn for banking (storage for future studies). The study doctor will ask about your health and any adverse effects and check for side effects. You will be asked about any new medications or illnesses since your last visit. You will have a detailed physical exam similar and complete several questionnaires about your symptoms, quality of life and mood. At this time, you will have completed the study and will receive further care as needed.

Risks/discomforts
Buspirone:
Buspirone is an approved drug used to treat certain anxiety disorders or to relieve the symptoms of anxiety. It is not known exactly how buspirone works to relieve the symptoms of anxiety. Buspirone is thought to work by decreasing the amount and actions of a chemical known as serotonin in certain parts of the brain.

Risk of buspirone: The most common buspirone side effects may include: headache; dizziness, tiredness, drowsiness; sleep problems (insomnia); nausea, upset stomach, blurred vision; nervousness or excitement, and rarely, tardive dyskinesia (a disorder that results in involuntary, repetitive body movements). Common drug interactions of buspirone include monoamine oxidase (MAO) inhibitors since the taking both drugs may increase your blood pressure. It is important to tell both the study physician and your primary care doctor that you will be taking buspirone before beginning any new medications, to ensure there are no drug interactions. Thus far, there is no direct evidence that buspirone causes physical dependence or drug-seeking behavior.

Interference with Cognitive and Motor Performance:
Studies indicate that buspirone may make you tired. Because you will not know if you are taking buspirone or a placebo, you should be careful operating an automobile or using complex machinery until you are reasonably certain that the study medication treatment does not make you feel tired or less alert.

You should avoid use of alcohol while taking the study medication.

Contact the study doctor if you have any of the following symptoms:
- Dizziness or lightheadedness especially when getting up from a sitting or lying position suddenly
- Drowsiness (severe)
- Loss of consciousness
- Nausea or vomiting

- Stomach upset
- Very small pupils of the eyes
- Any allergic reaction, including swelling, rash, difficulty breathing
- Any illness that you feel is caused by the study drug

Blood drawing: Blood drawing may cause mild discomfort and bruising. Very rarely, fainting, blood clots or an infection at the site can occur. You will have approximately 2 tablespoons (38 mL) of blood drawn during screening. During the entire study period, you will have approximately 6 tablespoons (88 mL) of blood drawn from you.

Are there risks if I get pregnant? There may be unknown risks to an unborn baby if you become pregnant during the BESST Trial. We do not know how buspirone, the study medication being tested, will affect an unborn baby. The use of buspirone in pregnancy has not been studied in humans. If you decide to take part in this study, and have periods, you must be as sure as possible that you are not pregnant. It is important that you contact the study doctor right away, if you think you may be pregnant, if you missed a period or it is late, or if you have had a change such as heavier bleeding than usual or bleeding between periods. If you become pregnant during the study, you will stop taking the study medication immediately and you will not have the follow-up gastric emptying scintigraphy. You will still continue to be followed during the study.

Questionnaires: The questionnaires ask about your symptoms, quality of life, levels of stress and anxieties. You are also asked about your medical history and medications you take. They will take about 1 hour to fill out. If you have certain scores on the psychological questionnaires such as severe depression, you may be referred to see a clinical psychologist or psychiatrist. The questionnaires can be long, and at times, seem repetitive, which can be tedious.

Electrogastrography (EGG) with water load satiety test: There is a small risk of an allergic reaction to the adhesive used to attach the electrodes to your skin. If you have a reaction, the electrodes will be removed and the test will be stopped. In addition, fasting or adjusting your insulin in preparation of the EGG could drastically reduce your blood glucose. During the water load satiety tests, you will drink water until you feel completely full. If you have diabetes, you will have your glucose checked at the beginning and the end of the tests, with appropriate measures being taken if low blood sugar (hypoglycemia) or high blood sugar (hyperglycemia) is detected.

Radiation risk -Gastric emptying scintigraphy tests: If you take part in this research, you will undergo two gastric emptying scintigraphy tests (GES). The GES is a type of medical imaging study that exposes you to radiation. In this study, you will be exposed to radiation called "ionizing radiation," which is like x-rays. A millirem (mrem) is how we measure radiation doses. The effective dose to a patient per test from the 0.5 -1 microcurie (mCi) Tc-99m egg meal that is used for this test is estimated to be 37-53 millirem (adult male and adult female, respectively), assuming normal transit times. The total radiation dose for the 0.5 – 1 mCi administration of 99m-Tc sulfur mixture in the meal for two gastric emptying studies included in this trial would be an Effective Dose Equivalent of 74-106 millirem. This is below the total average annual dose a person in the United States receives from natural background radiation that we are exposed to all the time – like from the sun. This exposure averages 300 millirem (3 millisievert (mSv)). Although no immediate harmful effects are expected, there is a very small, theoretical (that means not proven) long-term health risk from this small amount of radiation exposure. The amount of radiation to which participants may be exposed could be higher or lower than this value depending on their body

weight or size. Neither chest x-rays nor background radiation have been found to harm most healthy adults. The radiation dose we have discussed is what you will receive from this study only and does not include any exposure you may have received or will receive from other tests or treatments.

In addition, fasting or adjusting your insulin in preparation for the scintigraphy test, could lower your blood glucose. If you have diabetes, you will have your glucose checked at the beginning and the end of the test, with appropriate measures being taken if low or high blood sugar is detected.

General risks: Your condition may not get better or may become worse while you are in the study. During the study, you will still be getting clinical care by your physician and will be able to remain on your regular medications if you have been on a stable dose for at least 3-months prior to study enrollment.

Benefits

You may or may not receive a direct personal benefit from being in the study. The study drug may help your gastric symptoms and it may not. We will not know until we complete this study. You may help future patients by providing important information about whether the study drug helps your symptoms of gastroparesis. If you ask us, we will provide the results of any procedures done to screen you for this study to other doctors involved in your care.

Payment

<<insert your clinic policy guided by your institution's policies, if different >>

You will be given a $50 reimbursement for time and travel for each of the study visits completed. This stipend can be up to $150 for the screening study visits and $50 for each of the four follow-up visits. You will receive up to $350 if you complete all aspects of the study.

Protecting data confidentiality

Every effort will be made to maintain your privacy. Your health and medical information will be labeled with only an identifying number and a random three-letter code that cannot be linked to your name or other personal identifiers, except at the clinical center where you complete your visits. All study material will be kept in strict confidence in locked cabinets and on computers that have password-protection and use security measures such as encryption. Only study-certified, trained and certified study personnel are able to access the clinic computers or your information. Your health and medical information will be sent over a password-protected, encrypted transmission to the Scientific Data Research Center currently located at The Johns Hopkins Bloomberg School of Public Health in Baltimore, Maryland. At the end of the study, a dataset is sent to the NIDDK Central Repository; however, it does not include any personal identifiers, your date of birth, and a random patient identifier. Therefore, the Repository will not be able to give out your name or other information that identifies you to any researchers approved to use your study data. A Data and Safety Monitoring Board will have access to research records including your health information, but not your personal identifiers.

All research projects carry some risk that information about a participant may become known to people outside of a study, if a person with the right skills would determine how to get access to your research record, and then work hard to connect the report with other information about you. If that happened, you could experience stress, anxiety, or embarrassment. Your participation in this study will be kept confidential and will not be made known to anyone other than the study staff at your clinic. When

results from this study are published in the medical literature, you will not be identified by name or any personal identifiers.

Your study information is protected by an NIH Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to you or others.

Disclosures that you consent to in this document are not protected under HIPAA. This includes putting research data in the medical record or sharing research data for this study for future research. Disclosures that you make yourself are also not protected.

Protecting subject privacy during data collection
Researchers have an obligation to respect and protect your right to privacy. Any discussions with you and a study staff member concerning private health information or sensitive subjects are done in a private setting and are kept confidential. Your information will not be shared with anyone outside the certified study personnel at your clinic, including your family members, unless you give permission, or there is a strong, compelling medical reason for the need to share information.

Alternatives to procedures or treatments
You may choose not to participate in this study without any penalty by the study physician. There are no proven drug treatments for gastroparesis. You can continue to see a gastroenterologist and discuss other alternatives with your doctors.

Biological specimens
The blood and data collected from you during the study are important to science. The blood is separated into two parts: plasma and sera. You will not own the plasma, sera, or data after you give it to the study. You will not receive any financial benefit from any product or idea created by the investigators using the data or materials collected from you. Neither the NIDDK, the sponsor of this study, nor the NIDDK Central Repository will benefit financially from such ventures. Your biospecimens are identified only with an identifying number that can be linked to the 4-digit identifier used with your other data. Therefore, your name and personal identifiers are not linked to your specimen.

The sera and plasma samples collected as part of this study will be sent to the NIDDK Biosample Repository as they are collected during the study. At the end of the study, the data collected on you will be sent to the NIDDK Data Repository. The NIDDK Central Repository is a research resource supported by the NIH. The Repositories store and distribute samples and study data from people with many kinds of disorders, from unaffected family members, and from other healthy people. The purpose is to make samples and data available for use in health research. Your samples and data will be used by the researchers carrying out the BESST Trial, but they also may be used by other researchers and/or commercial companies after the study ends. Your samples and data may be stored indefinitely.

We will remove direct identifiers (such as your name, date of birth) and instead code your information before sending your samples and data to the NIDDK Central Repository. NIH will never get the identifiers we have removed. The repository is a controlled-access repository. Controlled-access data are only available to researchers and companies who apply to the NIH. The NIH will review data requests for scientific merit and for methods to protect data and methods to ensure data will be used for the

approved purpose. We will not know what types of health-related research will be done with the data and samples that are sent to the repository.

How will your data and/or biospecimens be shared now and in the future?
Sharing data and/or biospecimens is part of research and may increase what we can learn from this study.

Often, data/biospecimen sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

Your data and/or biospecimens may be shared:

- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners, including commercial companies
- through government or other databases/repositories

Data/biospecimen sharing could change over time, and may continue after the study ends.

We will do our best to protect and maintain your data/biospecimens in a safe way. Generally, if we share your data/biospecimens without identifiers (such as your name, address, date of birth) further review and approval by an IRB is not needed. However, when we share data/biospecimens, we limit the uses of the information and whether these data/biospecimens can be shared with another research team. If data/biospecimens are shared with identifiers, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

If you do not agree to have your samples and data sent to the NIDDK Central Repository, you may not participate in the BESST trial. If you agree to have your samples and data sent to the NIDDK Central Repository, you can change your mind up until the end of the BESST trial. When study researchers receive written instructions from you, they will destroy your unused samples and all information that identifies them. No additional samples will be sent to the NIDDK Central Repository and no further data will be collected on you, but samples and data already collected and used will continue to be used. After the BESST study ends, you will not be able to withdraw your samples or data because the Repository will not know which are yours. The samples will stay in the NIDDK Central Repository indefinitely.

Because researchers will not have access to your identity, you will not get the results of any studies that might be performed on your samples. Sometimes research leads to findings or inventions that have value if they are made or sold. These findings or inventions may be patented or licensed, which could give a company the sole right to make and sell products or offer testing based on the discovery. Some of the profits may be paid back to the researchers and the organizations doing this study, but you will not receive any financial benefits.

Cost of participation in the study
There are no costs to you regarding this study.

What happens if you leave the study early?
Participation in this study is entirely voluntary. You may refuse to participate or decide to stop participating at any time without jeopardy to the medical care you receive.

If you are found to be ineligible to continue with the study, or had to stop taking the study medication, we ask that you still come to all study visits. We will keep your data in the database.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. Your decision will not result in any penalty or loss of benefits to which you are entitled. If you have questions about your rights, or to report research related problems, please contact: << insert contact info>>

Payment of treatment costs for injury or illness from study participation

<< Insert local institutional language here if required or use language below >>

If you are injured as a direct result of participation in this research, the <<insert your Institution>> will provide any medical care needed to treat those injuries. The <<insert your Institution>>> will not provide any other form of compensation to you if you are injured. You may call the <<insert your Institution>> Human Research Protections Program office to inquire about your rights as a research subject or to report research-related problems at (xxx) xxx-xxxx.

Clinical Trial Registration

A description of this trial will be available on 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.

Authorization for Disclosure of Protected Health Information for Research

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (<<insert your institutions>>,) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at <<*your institution*>>, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others inside of <<*your institution*>>. Also, some other people may see your private health information (but nothing that can identify you) outside of the research team or <<*your institution*>>. They may include the sponsor of the study, study safety monitors, government regulators, legal compliance staff, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, and if possible, that it is de-identified, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

All these people must also keep your information confidential.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study. It is your choice.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

Ending Consent
You may end your consent at any time. Information obtained and used before you end your permission will continue to be used for research. If you wish to end your permission to participate, let us know, preferably in writing.

Who do I call if I have questions or problems?

- Call the principal investigator [use the name of the local PI], <<insert name>>, at <<telephone number>> if you have questions, complaints, or get sick or injured as a result of being in this study.

- Call or contact the [insert local IRB Office] if you have questions about your rights as a study participant. Contact the IRB if you feel you have not been treated fairly or if you have other concerns. The IRB contact information is:
    - By mail:
      Study Subject Adviser
      Advarra IRB
      6940 Columbia Gateway Drive, Suite 110
      Columbia, MD 21046
    - or call toll free: 877-992-4724
    - or by email: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00054803

Keep the questions below on the same page as the signature lines.
What does your signature (or thumbprint/mark) on this consent form mean?
Your signature on this form means:

- You have read the above information about the study and have been informed about this study's purpose, procedures, possible benefits and risks.
- You have been told that you can change your mind about participating later if you want.
- You have been given the chance to ask questions to help you understand what you will do in the study and any risks.
- You have voluntarily agreed to participate in this study.

You will be given a copy of this consent form to keep.

Print name of Adult Participant	Signature of Adult Participant	Date

Print name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

Print name of Witness	Signature of Witness	Date

Give one copy to the participant and keep one copy in your study records