INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**National Institute on Alcohol Abuse and Alcoholism (NIAAA)/ "Randomized, Double-Blind, Placebo-Controlled Trial of the Efficacy and Safety of Intranasal Oxytocin for the Treatment of Alcohol Use Disorder"**
Protocol Number:	**NCIG-007R**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

KEY INFORMATION

You are invited to take part in a research study. This research study is studying oxytocin nasal spray as a possible treatment for alcohol use disorder. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) is sponsoring this research study.

- Your participation in this study is completely voluntary.
- Your participation will last about 17 weeks and will include about 9 visits to the study center. You will be paid for your participation. You will have to take the study drug home with you and bring it back to the clinic for each visit.
- You will have your blood drawn about 5 times (25 mL; about 5 teaspoons), an electrocardiogram (ECG), physical exam (including the nose), review any medications you are taking, have a urine drug screen, take a smell test, you will be asked not to get pregnant/not to get your partner pregnant.
- You will be asked about your drinking for the past 28 days and throughout the study.
- You will be asked many questions about your mental health, drinking, drug use, and wellbeing.
- You will be asked to think about how much you are drinking.
- You will need to provide a contact person in case you are not able to be reached.
- You will be asked about your occupation and income.
- Participating in this study will not affect your ability to seek treatment for your alcohol use.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

BACKGROUND AND PURPOSE

You are being considered for participation in this study because of the amount of alcohol you consume, and you have indicated the desire to stop or reduce your alcohol drinking. Oxytocin, the medication we are testing, is a human hormone that acts on the brain. It is approved by the United States Food and Drug Administration (US FDA) as an injectable to create contractions in pregnant women and control bleeding after childbirth, but it also is thought to affect social connections. Oxytocin is not approved by the FDA for the treatment of alcohol use disorder but is being studied because when someone stops drinking alcohol, their anxiety and craving for alcohol increases, and oxytocin is thought to help control this anxiety and craving. This may aid someone trying to reduce their alcohol drinking.

The purpose of this research study is to:

- Test the safety and effectiveness of the study drug, oxytocin nasal spray
- See how your drinking changes during the study

This is a research study to test a new investigational drug with a placebo. An investigational drug is one that is not approved by the US FDA. The concentration of oxytocin being used in this study is 70 IU/mL in the nasal spray preparation, which is higher than the concentration in US FDA-approved products containing oxytocin.

About 100 participants will participate in this study at 4 separate locations. Each location is expected to enroll about 25 participants.

WHAT WILL HAPPEN DURING THE STUDY?

Screening:

Before any study-related tests and procedures are performed, you will be asked to read, sign, and date this consent document. There will be 2 screening visits. At the beginning of Screening Visit #1, your blood alcohol level will be measured using a breathalyzer and if it is greater than 0.000% of alcohol, you will not be able to complete your visit as scheduled. Note: a breathalyzer test of 0.08% or greater blood alcohol is considered legally intoxicated.

The following screening tests and procedures will then be performed to determine if you qualify to take part in this study:

- Provide your age
- Urine Drug Screen - provide a urine sample to test for drug use
- Medical and Surgical History – provide study staff with any past/current medical issues and your past or upcoming surgeries
- Physical Exam - undergo a Physical exam (including the nose) to assess your general health including your weight, vital signs, and an electrocardiogram (ECG)
- Liver and Kidney Function tests - provide a blood sample to see how your liver and kidneys are working

- Urine Pregnancy test - provide a urine sample to test for pregnancy for females of childbearing potential
- Birth Control - If you are female, you will be asked about your method of birth control
- We will ask about your drinking habits and alcohol use for the previous 28 days
- Past and Current Medications - provide the names of any prescription and "over the counter" medications you are currently taking or have taken in the past 2 months
- Answer questions about your mental health, and withdrawal symptoms from alcohol
- Goals you have with drinking
- Smell test – a scratch and sniff test of different odors

You will be asked to provide background information such as your gender and your race/ethnicity.

You will be asked to provide addresses and telephone numbers for yourself and other people, such as family members or friends who will know how to contact you if you fail to show up for clinic visits, or if study personnel have problems getting in touch with you. In doing so, you give study personnel permission to contact these people to find out how to contact you. Please be aware that telling others you are in this study could jeopardize your privacy.

At the beginning of Screening Visit #2, your blood alcohol level will be measured using a breathalyzer and if it is greater than 0.02% blood alcohol level, you will not be able to complete your visit as scheduled. Note: a breathalyzer of 0.08% or greater blood alcohol is considered legally intoxicated. At the Screening Visit #2 the following screening tests and procedures will be performed to determine if you qualify to take part in this study:

- Review of your medical and surgical history
- Review any changes to your general physical health (including the nose) since the last visit and taking your vital signs
- Current Medications - review any prescriptions or "over the counter" medications you are taking
- Urine Drug Screen - provide urine samples for a urine drug screen
- Urine Pregnancy Test - If you are female of childbearing potential provide a urine sample for a pregnancy test
- Birth Control - if you are female, you will be asked about your method of birth control
- Ask about your alcohol use since your last visit
- Smell Test -a scratch and sniff test of different odors
- You will be asked questions about your mental health and drinking
- Answer questions about thoughts you may have about harming yourself
- Answer questions about any visits with health professionals for assistance in reducing or stopping drinking

This study will use *competitive enrollment*. This means that when the target number of 100 participants begin the study, all further enrollment will be closed. Therefore, it is possible that you could be in the screening phase, ready to begin the study, and be discontinued without your consent if the target number of participants has already begun the study.

If you qualify to take part in this study and go on to receive the study treatment, then the following will happen:

Study Treatment:

You will be randomly assigned by chance (like the flip of a coin) to receive either oxytocin nasal spray (active substance) or placebo nasal spray (the same spray without oxytocin). You will have a 50% (1 in 2) chance of receiving oxytocin nasal spray and a 50% (1 in 2) chance of receiving placebo. This is a double-blind study, which means neither you nor the study doctor will know to which of these study drug groups you are assigned. In case of an emergency, however, the study doctor can get this information.

You will receive your first bottle of study drug (either oxytocin nasal spray or placebo nasal spray) to take in the clinic and at home. You will be shown how to use the nasal spray the first time you receive study treatment. You will self-administer the spray 5 times switching between nostrils with each spray. You will need to wait for 30 seconds in between sprays. For the first two weeks, you will do this once per day in the morning. For the next two weeks, you will do this twice per day, in the morning and evening (10 sprays total per day). Please bring this bottle (and any empty bottles) along with your diary card to each clinic visit.

During Study Weeks 1 through 12 of the treatment phase of the study, you will be seen in person at the clinical site 7 times and assessed by telephone 5 times. There is a final clinic visit at Week 13 at the end of the 12-week study treatment period. The following assessments and procedures will be performed at each clinic visit unless otherwise noted:

- Alcohol breathalyzer
- Urine Drug Screen - provide a urine sample for drug testing
- Review how you have been feeling
- Current Medications - Ask you about any medications you have taken
- Have an exam of your nasal cavity
- Smell Test - a scratch and sniff test of different odors that measures your ability to smell (Weeks 1, 3, 6, 8, 10, and 13)
- Vital Signs and weight - vital signs will be taken (weight will be recorded at Week 6, 8, 10, and 13)
- ECG (Week 13 only)
- Side Effects – answer questions if experiencing side effects
- Review any alcohol withdrawal symptoms you may be experiencing.
- Answer questions about thoughts you may have about harming yourself

- Fill out questionnaires or answer questions about your anxiety, impulsiveness, and drinking patterns at Week 1 only.
- Fill out questionnaires or answer questions about your mood, sleep habits, pain, aggressive feelings, appetite, drinking urges, and smoking cigarettes (Weeks 1, 6, 8, and 10).
- Answer questions about negative emotions at Weeks 1 and 13.
- Fill out questionnaire or answer questions about alcohol craving and consequences of alcohol use (Weeks 1, 3, 6, 8, 10, and 13).
- Answer questions about your attendance at group meetings and visits with health professionals for assistance in reducing or stopping drinking (Week 13 only).
- Provide your daily alcohol use since your last visit.
- Liver and Kidney Function tests - provide a blood sample for clinical laboratory tests to monitor your health (Weeks 6, 8, and 10).
- Review the study diary card with clinic staff.
- Watch a video that provides educational information about alcohol and importance of taking your study medication.
- Urine Pregnancy Test – provide a urine sample to check for pregnancy if you are female (Weeks 1, 6, 8, 10, and 13)
- Answer questions about your birth control methods if you are female.

All participants will participate in the online "Take Control" program which consists of a series of 7 computerized modules. The intervention is derived from a self-help approach developed by NIAAA and provides evidence-based information for individuals with alcohol problems, and suggestions for making changes in their drinking.

During the telephone visits you will be asked how you have been feeling, about any new medications you are taking, reminded about how to use the study drug, the dose you should be taking, and reminded of any upcoming visits to the study clinic.

<u>After Study Treatment</u>:
Because this is a research study, the study drug will be given to you only during this study and not after the study is over.

One to two weeks after the study is over a study staff member will contact you by phone to ask you questions about your alcohol use and any side effects that you have noticed since you stopped taking the study drug. If study staff has problems getting in touch with you, they may contact friends or family members you provided at screening to get your new contact information. Please be aware that telling others such as family and friends that you are in this study could risk your privacy. To maintain your confidentiality when attempting to contact you or a contact person by telephone, the research staff will not say that you are a participant in this research study. Once we have contacted you and/or the contacts you gave us, your participation in the study will end.

EXPECTATIONS

If you participate in this study, you will be expected to:

- Bring your used and unused study drug bottles, and diary card, with you every time you attend a clinic visit.
- Provide truthful and honest information when answering any of the study related questions.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

Risks from Taking Oxytocin Nasal Spray:

Some people may experience some side effects from the study drug while others may not experience any side effects. Side effects of oxytocin nasal spray are rare. Decreased sodium (salt) levels in the blood, mild dizziness, dry mouth, headache, and heart rate changes (increases and decreases) nausea, nasal irritation, increased thirst, increased urination, increased appetite, weight gain, and drowsiness have been reported. There is a risk of losing your sense of smell which may not be reversible.

Warnings and Precautions when Taking Oxytocin Nasal Spray:

Oxytocin can cause changes in blood pressure if taken with anesthesia. If you are planning elective surgery or are having emergency surgery let your doctor know of your possible use of oxytocin.

Risks from Alcohol Withdrawal:

Some people may experience symptoms of alcohol withdrawal if they stop drinking suddenly. At your screening visit, you will be given information to help you recognize the symptoms of withdrawal. You will be monitored carefully throughout the study in case you begin to have symptoms of alcohol withdrawal. If you experience any of these symptoms, you will be instructed to call the clinical site using the 24-hour phone number provided to you. When you contact the clinical site, a study staff member will ask you questions to determine if you are having serious withdrawal symptoms and will arrange for medical supervision to help you during withdrawal, if needed. During your in-person clinic visits and telephone interviews throughout the study, you will be assessed for withdrawal symptoms you might be experiencing. You will be asked about changes in your health and drinking status. If you experience significant withdrawal symptoms, you will be asked to come to the clinical site or report to your local emergency room for further evaluation.

RISKS OF STUDY PROCEDURES

- Blood samples: Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.
- ECG: Skin irritation is rare but could occur during an ECG from the electrodes or gel that is used. Hair on your chest may need to be removed to obtain the best electrical contact between the adhesive electrodes and your skin.

- Some of the questions about your personal habits, lifestyle, emotional state and drug and alcohol use may embarrass you. If any question makes you feel uncomfortable you may discuss its importance and the need to answer it with the specially trained interviewer. You may refuse to answer a question if it is upsetting to you.
- If you are having suicidal thoughts call the study doctor at the telephone number listed on the first page of this form. If you feel in crisis, you can call 911 and/or a Nationwide Suicide Hotline that is answered 24 hours a day with a skilled, trained counselor. One example is the National Suicide Prevention Lifeline at 1-800-273-TALK (8255).
- You may become bored with answering questionnaires.

If you receive placebo (the inactive substance) as part of this study, your desire to reduce your drinking, may not improve or may get worse.

UNFORESEEN RISKS
Since the use of the study drug is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you or your female partner become pregnant.

EMERGENCY CARE
If you experience any medical problems or psychological symptoms at any time during your participation, please contact the study doctor at the number listed on page 1 of this form.

You will be given and encouraged to carry a wallet card that identifies the research study by number, states that you are taking either oxytocin or placebo, and indicates that you are participating in a double-blind clinical trial; however, this card does not identify you as a participant in alcohol research. This card provides the name and phone number of the main study doctor who can provide information to other doctors in the event of an emergency. The card also instructs the emergency room, or other doctor treating you to provide information to the study doctor about your care.

BIRTH CONTROL RESTRICTIONS
Taking the study drug may involve risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. Therefore, if you are pregnant, planning to become pregnant, planning to father a child, or are breastfeeding a child, you cannot participate in this study.

<u>Females</u>:
To reduce the risk of pregnancy, you must use an effective method of birth control while you are participating in this study. Acceptable methods of birth control for use in this study are:

- Oral contraceptives
- Contraceptive sponge
- Patch
- Double barrier (diaphragm/spermicidal or condom/spermicidal)
- Intrauterine contraceptive system
- Etonogestrel implant

- Medroxyprogesterone acetate contraceptive injection
- Complete abstinence from sexual intercourse
- Hormonal vaginal contraceptive ring

The study doctor or study staff will discuss this with you.

If you become pregnant while you are participating in this study after you have stopped taking the study drug, tell your study doctor or study staff immediately. You may be asked to allow the study staff to collect information about the pregnancy, its outcome, and the health of the child after birth.

ALTERNATIVES TO PARTICIPATION
You do not have to be in this study to receive treatment for your alcohol use**.** There are several alternative treatments that may be effective for treating alcohol problems, including FDA approved medications such as Naltrexone, Acamprosate or Antabuse, counseling, and AA. These other treatments are not offered to you as part of this research study, but if you decide not to participate, or are not eligible, study personnel will give you contact information for existing treatment programs in your area.

NEW FINDINGS
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

BENEFITS
You may benefit because of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

COMPENSATION FOR PARTICIPATION
«Compensation»
You will be paid either in cash or vouchers up to a total of $XXX if you complete this study. You will be paid for the visits you complete according to the following schedule: (site to define their specific payment schedule)

- XXXXXX

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid after each visit. If you have any questions regarding your compensation for participation, please contact the study staff.

CONFIDENTIALITY

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the US FDA and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

A description of this clinical 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.

To make sure that the health information collected in this study is accurate, it will need to be checked from time to time against your medical records. Some persons may need to see these records to monitor the research and verify the accuracy of the study data, including:

- A limited number of representatives from the study sponsoring drug company (namely its monitors and auditors),
- The research ethics review board – *Advarra* IRB (an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants),
- Government regulatory authorities including the US FDA and other foreign regulatory agencies.

Your study records including confidential information about you collected during the study will be kept at a secure location.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

By signing and dating this information and consent form, you consent to the collection, access, use and disclosure of your information as described above.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any legal action unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal FDA. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The CoC does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

COMPENSATION FOR INJURY

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need.

No medical care, evaluations or financial compensation for research-related injuries or illness will be provided. The costs of such additional treatment will be paid by you or by your health insurance carrier. You also have the right to pursue legal remedy if you believe that your injuries justify such action. Compensation for injury/illness may be payable under the Federal Tort Claims Act. The availability of this compensation may vary depending upon the circumstances involved and there are certain limitations.

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information

By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

COSTS

There will be no charge to you for your participation in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company.

FUTURE RESEARCH STUDIES

Identifiers will be removed from your identifiable private information and so that your study data could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

If you agree, NIAAA may share your data without direct identifiers as part of the combined study database through controlled access without additional informed consent. This means the data are made available for other research only after the researcher has obtained approval from NIAAA to use the requested data for a particular project. The data will not include direct identifiers like your name, medical record number or date of birth. To use your data, researchers must promise not to try to re-identify you. You can tell us at the end of this form whether you will allow us to share your data in this way.

RESEARCH RESULTS

Researchers are required to publish the results of this study. These results will be based on outcomes for the entire group of participants and will not identify you as a participant. No individual information about you or your participation in this research will be made public without your express written permission. You will not be told the results of this research, however, after the end of the study, you may request and be provided with the name of the study drug that you received, oxytocin nasal spray or placebo nasal spray.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00061563.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate, or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

You should not stop taking the study drug without consulting the study doctor. If you decide to stop taking the study drug, you are encouraged to participate in the other study procedures. If you leave the study, you may also be eligible to receive other services at the clinic or referrals to other clinics, if appropriate.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If the study is canceled;
- For administrative reasons; or
- The Sponsor stops the study for any reason.

If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests for your safety.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Participant's Printed Name

_____ _____

Participant's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date

Attachment #1

CONSENT FORM QUESTIONS
Oxytocin Nasal Spray for Alcohol Use Disorder

Check the appropriate response:	**TRUE**	**FALSE**
1) If a study participant becomes pregnant while participating in this study, she will be taken off the study drug.		
2) Oxytocin nasal spray has already been approved by the Food and Drug Administration (FDA) as a treatment for alcohol use disorder.		
3) You are expected to give truthful answers about your alcohol use.		
4) You will be told whether you are receiving oxytocin nasal spray or placebo.		
5) You will have to give blood and urine samples during the study.		
6) The study staff may end your participation in this study if they feel that it is in your best interest.		
7) You will be compensated for your time and travel.		
8) You must bring your spray bottle to every visit.		
9) You will never be contacted by telephone during the study.		
10) You must inform the study staff of starting any new medications that you take during the study.		
11) The research data I provide in this study may be made available to the general research community but will be de-identified so that any personally identifiable data will be removed.		

The correct answers to the questions above have been discussed with me.

_____
Participant Signature

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Valid form of ID.
- Information from brief psychiatric examination.
- Emergency contact information
- Initial telephone screening information
- Allergies.
- Information from Physical Exam
- ECG results
- Blood Alcohol Results
- Urine Drug Screen Results
- Pregnancy Test results if you are female
- Clinical Laboratory test results
- Healthcare, drinking, mood, sleep, and questionnaires/forms
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of NIAAA.
- Representatives of Fast-Track Drugs and Biologics, LLC.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.

- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study.
- A data safety monitoring board which oversees this study.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you has no time limit.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date