Study Title: **Optimizing Ultrasound-induced Anti-inflammation in Human Subjects**

NCT number: **NCT05685108**

Version Date: **18Feb2025**

Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a copy of this form.

Who is funding this study?

This study is being funded by the National Institutes of Health (NIH) and the University of Virginia.

Key Information About This Research Study

Principal Investigator:	Mark D. Okusa, MD, FASN Division of Nephrology Center for Immunity, Inflammation & Regenerative Medicine University of Virginia 1300 Jefferson Park Avenue Charlottesville VA 22908 Telephone: 434 924 2187

You are being asked to take part in a research study. You do not have to take part in this study. You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers or others before you make a decision.

What is the purpose of this study?

Inflammation is part of the body's defense mechanisms against infection and injury and plays an important role in the healing process. However, excessive inflammation can lead to organ damage and additional health problems, which is why we normally use medicines to reduce it. A common example of excessive inflammation is sepsis, which is the body's overwhelming and life-threatening response to an infection that results in organ damage and dysfunction. Another example of excessive inflammation is rheumatoid arthritis, which is a chronic condition where the immune system attacks healthy parts of the body by mistake, causing additional inflammation and damage in the joints. This research is being done to investigate the usefulness of ultrasound technology as a way to control inflammation in humans.

Traditional anti-inflammatory drugs, such as steroids, ibuprofen, and naproxen, work by blocking the actions of immune cells and the molecules they produce. Although effective, the long-term use of anti-inflammatory drugs may carry harmful risks or inconvenient side effects. For instance, anti-inflammatory drugs can interact

with other medicines and cause unwanted effects. They can also suppress the immune system and lead to decreased resistance to infections. Ultrasound has been widely used for many years in clinics across the world and has shown essentially no negative effects. This work is designed to explore different intensities of ultrasound treatment to determine whether it is an effective tool for regulating the immune system with minimal inconvenience to the recipient.

In recent years, medical advances have shown that the nervous system can regulate inflammation via chemical messengers and potentially other mechanisms. The vagus nerve is the main nerve of the nervous system and is involved in the regulation of various body functions, including the immune system. Currently, clinical studies have focused on whether electrical stimulation of the vagus nerve can trigger the body's own biological responses to allow treatment of inflammatory conditions. However, this type of treatment normally requires the surgical placement of an electrical device under the skin, which limits its widespread use. Ultrasound is the most commonly used non-invasive imaging method for assessing the health of organs and tissue. Based on previous research, ultrasound may also be an effective technology for directly regulating inflammation by pulsing mechanical energy to the spleen (a major organ of the immune system) or the vagus nerve. The mechanical force delivered to the tissue by ultrasound from outside the body may be a less invasive strategy with less side effects for stimulating the nervous system than current strategies that use electrical energy to stimulate the vagus nerve.

The purpose of this study is to determine the effectiveness of different intensities of ultrasound treatment for reducing the inflammatory response of cells from the blood. We will also be gathering feedback from participants as they go through the study to verify that the ultrasound treatments do not cause discomfort. In addition, we would like to assess kidney biomarkers in urine to confirm the safety of the ultrasound treatment. If effective, pulsed ultrasound therapy may eventually become an alternative to traditional anti-inflammatory drugs and invasive surgical placement of electrical devices. Pulsed ultrasound generates short pulses of ultrasound and, therefore, it does not produce images as compared to the continuously emitting ultrasound used for imaging.

You are being asked to take part in this study as a healthy volunteer. Up to 55 people will be in this study at UVA.

Background Information on the ultrasound scanner:

During study treatments, a trained study team member with long-term experience in ultrasound imaging will perform ultrasound stimulation of the spleen and / or the neck using the Siemens Sequoia clinical ultrasound scanner.

The ultrasound scanner that will be used in this research is an older model of scanners currently in use in hospitals. These devices use a transducer probe to convert electrical energy into sound energy, similar to the way rubbing a finger around the rim of wine glass produces sound. The sound waves produced by the probes are beyond the range of human hearing and this is why it is referred to as ultrasound technology. The probes can focus and deliver this sound energy to a focal region which generates physical waves, also called mechanical waves, in the target area as the ultrasound waves interact with solid tissue and material surrounding it. Based on current knowledge, we believe it is this non-invasive delivery of mechanical pressure that allows stimulation of the nervous system and immune-regulatory effects. The major differences between

current models and the machine that will be used in this study is image resolution and quality. Safety and the effective delivery of ultrasound energy are equal between this model and currently used devices, since both were designed to limit the energy output to stay within US Food and Drug Administration (FDA) approved levels. The machine will be operated by a trained professional to safely deliver the proper ultrasound treatment. The probe that is in contact with you is also clinically approved. The ultrasound energy delivered throughout this study is consistent with and will not exceed levels permitted by the FDA.

Why would you want to take part in this study?
You will not be helped by being in this study, but the information gained by doing this study may help others in the future.

Why would you NOT want to take part in this study?
You might not want to take part in this study because you will have to come to UVA for 4-5 extra times in the next month and have blood drawn and ultrasound treatment.

What will I have to do if I take part in this study?
Full details of all the procedures are found later in this form. If you agree to take part in this study, you will:

- have to come to your UVA for 4-5 visits, each visit will take approximately 30 to 90 minutes and contain a blood draw;
- be treated with ultrasound or have one sham treatment and one ultrasound treatment at 2 of the visits;
- have two abdominal ultrasound imaging exams
- answer questions about how you are doing.
- be asked to provide optional urine sample at each visit.

What is the difference between being in this study and getting usual care?
All activities in the study will be done with research purpose and are not related to your usual health care.

How long will this study take?

Your participation in this study will require 4-5 study visits over two months. Each visit will last about 30 to 60 minutes.

What will happen if you are in the study?

SCREENING

(will last about 30 minutes)

If you agree to participate, you will sign this consent form before any study related procedures take place. Before you can start in the study, there will be a screening period. You will have tests during this time to make sure you are eligible, and it is safe for you to participate. These include the following:

- Review of your medical history from information provided by you and available medical records;
- Physical exam and vital signs (blood pressure, heart rate, etc.);

- Standard blood tests (1 tablespoon of blood) to check your blood counts, liver and kidney function, and glucose (blood sugar) level. The blood sugar levels will be tested in fasting state. Fasting means after not having anything to eat or drink (except water) for at least 8 hours before the test. This test is usually done first thing in the morning, before breakfast;
- If you are a female able to get pregnant, you will have a urine pregnancy test that must be negative in order to participate. If you are pregnant, breastfeeding, or plan to become pregnant during the study period, you cannot participate in this study.

If these tests show you are eligible, in good health with no underlying or chronic medical conditions and do not take any medications that could invalidate the results of the study, you will be contacted within three business days via phone to schedule an appointment to begin study treatment.

Furthermore, we will ask you:
•to abstain from alcohol for 24 hours before the start of each visit;
•to abstain from nicotine-containing products (including nicotine patches) during the entire study period;
•to abstain from strenuous exercise for 24 hours before each blood collection;
•to abstain from non-steroidal anti-inflammatory drugs (such as ibuprofen, naproxen, diclofenac), if any taken, before the start of each visit up to each blood collection. If you take any non-steroidal anti-inflammatory drugs, please inform the study team who will then guide you regarding the appropriate timing of discontinuation of these drugs.

You will be assigned to one of the two groups. 20 of the first 30 participants will be assigned to Group 1 and have two ultrasound treatments of the spleen. 10 of the first 30 participants will also be assigned to Group 1, but will receive one sham treatment and one ultrasound treatment of the spleen. Sham treatment mimics an actual treatment but lacks its active component, ultrasound – it is analogous to placebo treatment. The last 10 participants will be assigned to Group 2 and have one treatment of the spleen and the other of the neck. You will be assigned to a subgroup within each Group using a method called randomization. Randomization means that the subgroup you are in is assigned by chance, like a flip of a coin. The subgroups within Group 1 differ in the parameters of ultrasound treatments and the subgroups within Group 2 differ in the order of treatments (spleen first, then neck or neck first, then spleen).

GROUP 1: Two ultrasound stimulations of the spleen **OR** one sham treatment of the spleen and one ultrasound stimulation of the spleen.

GROUP 2: One ultrasound stimulation of the spleen and one ultrasound stimulation of the neck/vagus nerve area

STUDY TREATMENT

(2 treatment visits, each will last about 1 hour, and 2 post-treatment visits, each will last about 30 minutes).

Visit 1

The first treatment visit will consist of a blood draw (one teaspoon) followed by the first ultrasound treatment depending on your group assignment as mentioned above. The study team will perform a physical examination and record your vital signs before and after each ultrasound stimulation, including oral or ear

temperature, pulse, respiratory rate, systolic and diastolic blood pressure. Also, the study team will review your medications at each visit. As an optional choice, you will be asked to provide spot urine samples before and after ultrasound treatment for measurement of kidney biomarkers.

Ultrasound requires the use of a water-based gel. The gel that we use is the same as any other ultrasound gel used in the hospital. The gel may feel slightly cold upon first contact. A study team member trained in ultrasound will deposit ultrasound gel on your skin over either your left flank near the rib cage or left neck and then position an ultrasound probe in the same area. The ultrasound operator may press the transducer against your skin or ribs. If this causes any pain at all, you should let the ultrasound operator know at once. You may be asked to undo or unzip portions of clothing to provide access to the left flank and / or the left neck. It will not be necessary to undo any clothing to the extent that it creates a privacy problem. You may ask the ultrasound operator the extent to which any clothing may need to be loosened in advance to verify that you are satisfied with what is required. We recommend planning your outfit for days you will be receiving ultrasound in order to ensure easy access to your left rib cage and neck and minimize the need for clothing removal.

The ultrasound probe will pass across your skin while the study team member locates the stimulation target. Once the study team member locates the ideal position, he/she will measure the spleen size and then modify the settings of the ultrasound machine to switch from an imaging set-up to a stimulation set-up. The ultrasound stimulation will be approximately 12 minutes long. If you are assigned to Group 1 in the sham treatment subgroup, the first treatment will be done similarly to an actual treatment but without pulsed ultrasound. During this stimulation period, you will have to remain mostly still to ensure that the ultrasound is properly delivered to the target area. Overall, the experience should feel very similar to what would occur during any ultrasound imaging procedure. While we have no reason to expect there will be any harm caused by this treatment, if you experience any significant discomfort or other sensations you are concerned about, please vocalize them to the study team member so they can be considered, addressed, and recorded. At the end of the exam, the ultrasound operator will wipe away gel to the extent that is possible. You can have additional tissues to further wipe your skin. If the gel dries on your skin, it leaves a harmless white “chalky” appearance that washes off easily (from clothes and skin) with soap and water. After the stimulation, you will be given a brief survey to record your experience of the sensations caused by the ultrasound, if any.

Visit 2

The first post-treatment visit should occur 24-48 hours after the stimulation and will consist of another brief experience survey and blood draw (one teaspoon). The survey is for you to let us know if you have noticed any changes since the stimulation that may have been delayed in onset. The blood draw will be for determining the abundance of immune cell populations and testing their responsiveness to inflammatory triggers. In addition, the study team member will repeat the diagnostic ultrasound to measure the spleen size; however, at this visit no ultrasound treatment will be performed. As an optional choice, you will be asked to provide a spot urine sample for measurement of kidney biomarkers.

Visit 3

You will then be scheduled for your second treatment visit which should be 14 days or more after the first treatment visit. The process will then be repeated with a blood draw, assessment of vital signs and medication review, measurement of the spleen size, and delivery of the second ultrasound treatment to high left flank

area or left side of the neck depending on your group assignment and experience survey. As an optional choice, you will be asked to provide spot urine samples before and after ultrasound treatment for measurement of kidney biomarkers.

Visit 4

The second post-treatment visit should occur 24-48 hours after Visit 3 and include blood draw (one teaspoon) and experience survey. In addition, the study team member will repeat the diagnostic ultrasound to measure the spleen size; however, at this point no ultrasound treatment will be performed. As an optional choice, you will be asked to provide a spot urine sample for measurement of kidney biomarkers.

FOLLOW UP:

Approximately 30 days after the last ultrasound stimulation, you will be recontacted via phone and/or e-mail to report any new experiences that may have developed within the last month and you believe may be due to the ultrasound treatment. You may also contact us at any time with observations, concerns, or questions. We do not anticipate the treatment to have any noticeable impacts on overall health, comfort, or daily life, but part of this study is to determine if this is true.

Study Schedule

Procedures	Screening/Baseline Day -2 to -1	Study Visit 1, Day 1	Study Visit 2 Day 2 (+1) day	Study Visit 3 Day 14	Study Visit 4 Day 15 (+1) day	Final Study Visit 5 (via phone) Day 30 +/-2 days
Informed consent	X					
Demographics	X					
Medical history	X					
Group assignment	X					
Receive pulsed ultrasound or sham treatment		X				
Receive pulsed ultrasound treatment				X		
Diagnostic ultrasound (without pulsed ultrasound treatment)		X	X	X	X	
Medication review	X	X----------X				
Physical exam	X			X		
Vital signs	X	X		X		
Height	X					
Weight	X	X	X	X	X	
Experience survey		X	X	X	X	X
Blood test	X	X	X	X	X	
Spot urine test (optional)		X	X	X	X	
Pregnancy test (for women of childbearing potential)	X					

Procedures	Screening/Baseline Day -2 to -1	Study Visit 1, Day 1	Study Visit 2 Day 2 (+1) day	Study Visit 3 Day 14	Study Visit 4 Day 15 (+1) day	Final Study Visit 5 (via phone) Day 30 +/-2 days
Adverse event review and evaluation		X----------X				X

What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- You must come to each study visit.
- You must be completely truthful about your health history.
- Follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- Answer all of the study-related questions completely.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over-the-counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.

Blood Testing

We will take up to 2 tablespoons of blood per week for a month when you are participating in the study. The total amount of blood we will take will be 4 tablespoons.
The blood we take will be tested to measure your blood counts, liver and kidney function, glucose level and to run study-specific tests to characterize immune response.

When these tests are done any left-over blood sample will be thrown away or they will be de-identified. This means there is no information that could be used by anyone to determine who the sample came from.

Urine Testing (Optional)

If you agree, we will collect your spot urine samples before ultrasound stimulation, and 30 minutes and 24-48 after ultrasound stimulation. The urine samples will be tested for biomarkers to confirm that ultrasound stimulation does not cause kidney stress.

When these tests are done any left-over urine sample will be thrown away or they will be de-identified. This means there is no information that could be used by anyone to determine who the sample came from.

<u>Collection of urine samples before and after ultrasound treatment:</u>

Please indicate your choice by placing your initials below:

___ YES **I agree to provide my urine samples before and after**

ultrasound treatments.

___ NO **I do not agree to provide my urine samples before and after ultrasound treatments.**

___ Not Applicable

If you want to know about the results before the study is done:

During the study you are having an investigational test done. The purpose of the test is NOT to diagnose any disease or abnormality you may have. Because the test is investigational there is no way for the study leader to understand if the results are "normal" or "abnormal". However, if any test results are concerning, your study leader will let you know.

In addition, as the research moves forward, your study leader will keep you informed of any new findings about the research itself that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you may ask for more information about the study results.

What are the risks of being in this study?

Risk of pulsed ultrasound

While ultrasound carries risks related to thermal (tissue heating) and mechanical (movement) effects, these are dependent on the amount of energy deposited to the tissue site over time. Tissue heating can cause damage to cells, including nerve cells. Mechanical forces can lead to shear stresses within tissue and formation of gas bubbles due to rapid changes in pressure generated by ultrasound pulses. Both of these can damage cells or tissue structures if not managed properly. These elements have led to the FDA establishing an upper limit for ultrasound intensity that is delivered to humans. All ultrasound treatments in this study are below that limit and we have no reason to believe there is a risk of harm or even discomfort. Further, the ultrasound scanner we are using has safeguards in place that do not allow the user to exceed those levels. By limiting the exposure to and power of our ultrasound treatment and remaining within the FDA prescribed values, we do not view this study as carrying any more risk than a standard ultrasound imaging procedure.

Risks of having your blood drawn:

Having blood drawn may cause:

- ✓ pain (common),
- ✓ a bruise (sometimes),
- ✓ fainting or passing out (not very often), and
- ✓ infection (rare).

If the people doing the study are exposed to your blood or body fluids in a way that could give them a disease, your blood may be tested. The tests might check for:

- ✓ hepatitis,
- ✓ HIV (Human Immunodeficiency Virus), or
- ✓ other infections.

You and the person exposed would be told the test results. However, your name would be kept private. If your test is positive for hepatitis or HIV or any other infection that may affect your clinical care, we will tell you the results and help you understand what the results mean for you.

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You will not benefit from being in this study. However, the information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

The only choice is not to be in this study.
If you are a patient at UVA, your usual care will not be affected if you decide not to participate in this study.
If you are an employee of UVA, your job will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will be paid $400 for finishing this study by check. You should get your payment about one month after finishing the study. The income may be reported to the IRS as income.
If you do not finish the study, you will be paid $200 for completing each of the two ultrasound treatments, each including a treatment visit and a post-treatment visit.

By agreeing to be in this study, you are donating your blood for research, and giving up any property rights you may have in them. The results of this research using your donated materials may have commercial value. However, you will not receive any payments.

Will being in this study cost you any money?

All study procedures and tests will be provided at no cost to you or your health insurance. You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

How will your personal information be shared?

The UVA researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all the following information about you:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results

- People or groups that oversee the study to make sure it is done correctly
- Tax reporting offices (if you are paid for being in the study)
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

Information and samples obtained from you during this study will not be used in future research.

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.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the Principal Investigator listed BELOW to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Mark D. Okusa, MD, FASN
Division of Nephrology
Center for Immunity, Inflammation & Regenerative Medicine
University of Virginia
1300 Jefferson Park Avenue
Charlottesville VA 22908 Telephone: (434)924-2187

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22903 Telephone: 434-924-2620

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the UVA Study Tracking Number (at the bottom of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

You may also report a concern anonymously by calling the UVA Compliance Hotline phone number at 1-800-235-8700.

Would you like the study team to communicate with you by email or text message?
If you choose to communicate with the study team by unsecure email (email that is not encrypted) or text message to your personal phone, there is some risk that your health information could be read or accessed by someone else while the information is sent or saved by your email or phone provider.

Your personal email or phone provider may also share or release your information because they do not have to follow the privacy laws that UVA follows. Sometimes email and phone providers release information to marketing companies for use in direct advertising. If you choose to communicate by email or text messaging, UVA cannot control this potential loss of privacy, but we want to tell you about this possible risk.

You do not have to agree to communicate with the study team by email or text message to be in this study. If you agree to texting or emailing, the study team will collect your phone and /or email address from you that you would like them to use to contact you. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

Signatures

What does your signature mean?
Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form, it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent
By signing below, you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT(PRINT)	DATE

Signature of Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

Please indicate with check box the identified individual(s):

☐ Subject

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Notification of My Health Care Provider

Please indicate below whether you want us to notify your health care provider that you have agreed to take part in this study.

_____ Yes, I want the study doctor to notify my health care provider that I have agreed to take part in this study.

Health Care Provider Name:
Health Care Provider Address:
Study team will send a copy of the consent form to the health care provider.

_____ No, I do not want the study doctor to notify my health care provider that I have agreed to take part in this study or I do not have a health care provider.

Leaving the Study Early

Signatures should be obtained in this section if the subject decides to leave the study early.

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

Check one option below:

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.

The follow up information will be collected by:

- Obtaining information from my medical records
- One phone call within 2 weeks after I withdraw my consent from the intervention or treatment part.

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow up information from my medical records.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below, you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT(PRINT)	DATE