# Medical University of South Carolina
# CONSENT TO BE A RESEARCH SUBJECT

**TITLE OF RESEARCH:**
***Neurobehavioral and Immune Effects of Citicoline in Youth Alcohol Use Disorder***
***NCT05870111***

*If participants include those under 18 years of age: 1) The subject's parent(s) or legal guardian(s) will be present when the informed consent form is provided. 2) The subject will be able to participate only if the parent or legal guardian provides permission and the adolescent provides their assent. 3) In statements below, the word "you" refers to your child or adolescent who is being asked to participate in the study.*

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part.

We are evaluating how citicoline, an over-the-counter supplement, versus a placebo pill (i.e., an inactive pill) affects the immune system, brain, and cognition ("thinking") in youth who may use alcohol. Given the brain is still developing until age 25, we consider all participants in this study (ages 16-22) youth. Citicoline has been examined in children and adults for improving cognitive abilities, but little is known about its effect on inflammation, brain function, and thoughts in youth who may use alcohol. All participants will receive two sessions of brief counseling from a trained clinician and will undergo a brain scan (Magnetic Resonance Imaging or MRI) and cognitive testing at the beginning and end of the treatment (4 weeks). Half of the participants will be randomly assigned to receive citicoline (2000mg per day) and the other half of participants will receive placebo for four weeks. We will also collect blood, breath, saliva, and urine samples; and several questionnaires at each visit. Daily text questionnaires and medication reminders will be sent over the course of the study. The full study will last approximately one month.

Given the investigational nature of this study, benefit cannot be guaranteed or promised. There are minimal risks related to citicoline, which include stomach pain and headache. There is a risk of loss of confidentiality, but the researchers will code the samples and research information to protect privacy. All participants will receive individualized brief counseling as part of this study. We hope the information will help us develop treatments for youth who use alcohol. You may choose not to participate in this study. Participants who wish to receive information on mental health and/or substance use treatments will be referred clinically.

If you are interested in learning more about this study, please continue to read below.

## A. PURPOSE OF THE RESEARCH

The purpose of the study includes evaluation of both the safety and the effectiveness of the study medication, which is called citicoline, for youth who use alcohol. Its use for this purpose is investigational. Citicoline has not been approved for any use by the Food and Drug Administration

(FDA). You are being asked to participate in this study because you are between 16-22 years old and have used alcohol. A grant from the National Institutes of Health (NIH) sponsors this study. Portions of Dr. Squeglia and her research team's salaries will be paid by this grant. This study is being conducted at one site, the Medical University of South Carolina, and will involve approximately 60 volunteers.

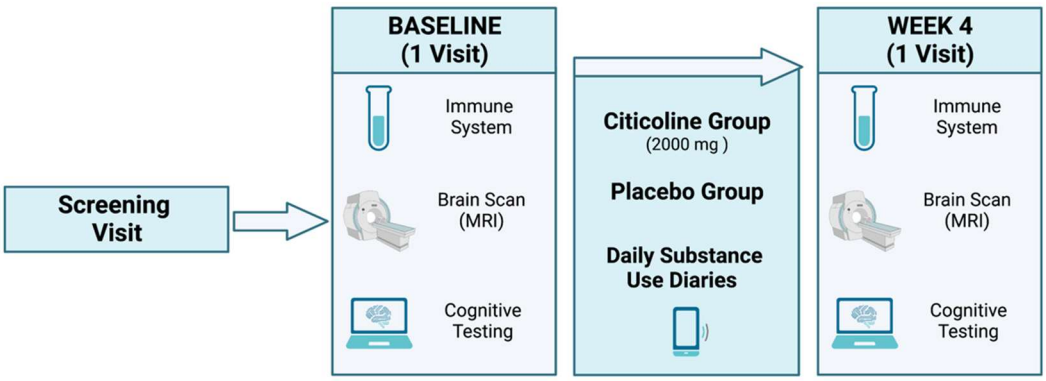
## B. PROCEDURES

*Overview:* You will be randomly assigned to one of two groups to receive either citicoline (2000mg per day) or placebo (an inactive substance given in the same form as the active drug) for four weeks. You will receive two sessions of brief alcohol counseling with a trained clinician, and you will complete two magnetic resonance imaging (MRI) scans over the course of one month (one scan before you start your medication and one scan after you complete your four weeks of medication). Blood (via a needle stick), breath, saliva, and urine samples will be collected, and you will fill out several questionnaires at each visit. You will be sent a daily text questionnaire and reminders to upload video of yourself taking the study pills twice a day for approximately a month of the study. If you are unable to attend or complete a visit due to unexpected conflict (e.g., transportation issues, travel, University closings), arrangements may be made to remotely complete as much of the visit procedures as possible.

Parents or legal guardians will **not** be informed about their child's substance use.Youth self-report and lab data are confidential except for any acute safety issues (e.g., suicidality, abuse).

The research team will use several methods of contact to keep in touch with you. We will ask you to provide us with phone numbers, e-mail addresses, current addresses, and contact information of family and friends who may know how best to reach you.

Here is a visual overview of the study:




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

***Screening (30 minutes)**:* Data collected during the Entryway Intake will be carried over and included to avoid repeating any data collection. Examples of such data include answers to completed surveys and questionnaires about your substance use and urine & breath results.

Additional screening for this study will include a brief medical history, questions on mood, reactions to drinking, and a review of medications by a trained clinician. If on a different day than the Entryway Intake, a urine sample will be collected for a urine drug test and pregnancy test (only for those assigned female at birth). The pregnancy test will be completed prior to the drug testing. Participants testing positive on the pregnancy test or those who plan to become pregnant during the study period cannot participate in the study and no further study procedures will be completed. Participants will need to take steps to avoid becoming pregnant (e.g., oral contraceptives, contraceptive patch, barrier, intrauterine contraceptive system, abstinence) during the study. We will also check your pulse, blood pressure, height, and weight (vitals). You will be asked questions about your general substance use, mood, and alcohol use and craving, treatments received, and sleep quality.

***Visit 1 (2.5 hours):*** When you come in for your visit, you will receive your first brief counseling session with a trained clinician, who will again ask questions about your mood and reactions to drinking. You will also answer surveys about daily substance use, thoughts on drinking, treatments received, and sleep quality, and take learning tests.

You will provide urine, breath, saliva (to measure the microorganisms in your body, such as fungi, bacteria, and viruses), and approximately one tablespoon of blood (collected through a needle stick) to measure how your immune system is working and to measure substance use and test for pregnancy (only participants assigned female at birth). You will then have a 1-hour MRI scan.

MRI scans use a magnet and radio waves to make diagnostic medical images of the body. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will hear a loud machine-like noise. There is no radiation with MRIs.

During the MRI scan the following will happen:

1. If you would like, you may first be introduced to the mock (fake) MRI scanner. This is a model of a scanner that is not magnetically active. It is used to introduce people (that may or may not have ever been in an MRI scanner) to the size, shape, and sounds associated with the scanning procedure. During the introduction to the mock scanner, you will be asked to lay down on the scanner bed. This bed will then be slowly pushed back into the tube of the scanner and we make sure you are comfortable enough to participate in the actual scan.
2. Before you go in the scan room, we will make sure you have no metal on your clothes or body. You may be asked to change into university approved clothing, like scrubs or a hospital gown. You will then lay down on the MRI scanner bed and your head and shoulders will be inside the MRI tube during the scan. You will be given earplugs and headphones to wear while you are in the scanner. You will be able to speak to and hear the research staff during the scan. While you are in the MRI scanner, we will take pictures of your brain during several scanning sessions. You will be asked to lay still in the MRI scanner during this time. In between each scanning session we will talk to you through the speakers in the MRI scanner to see how you are feeling. You will be given a pressure-sensitive ball which you can squeeze at any time to end the MRI scan if you feel uncomfortable.
3. Several tasks will be completed during the 1-hour MRI scan. These tasks involve looking at different images on a screen.

At the end of the visit, you will be given citicoline or the inactive substance, which you will take for four weeks. You will have a 50:50 chance (like the flip of a coin) of receiving either citicoline or the inactive pill for the four-week period. Neither you nor your study team will know the substance you are receiving; however, the researchers can find out what you are taking if there is a need to do so. You will be shown how the text messages will arrive and how to make a video of taking medication.

***Visit 2 (2.5 hours):*** Approximately four weeks after your **Visit 1**, you will go through the same procedures as the first visit with the exception of providing a saliva sample.

*Daily Texts:* Beginning the day after Visit 1, you will be sent a daily text questionnaires. These will take less than 3 minutes per day to complete and will continue throughout the course of the study. You will also be sent at least twice daily text reminders to take the study pills and to upload a video of you taking them.

You will receive two brief alcohol counseling sessions with a trained clinician at Visits 1 and 2; however, at any point in the study, you will have the opportunity to meet with a clinician if you choose.

You may be withdrawn from this study without your consent if the researchers believe it is in your best interest or if you fail to follow study procedures.

You may withdraw from the study at any time. If you decide to stop participating in the study, you are encouraged to talk to study staff first so that stopping can be done safely. Another reason to tell study staff that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful to you.

## C. COLLECTION OF SPECIMENS

As part of this study, we would like to store blood and saliva specimens collected from you for future research on youth substance use. This future research may be conducted by Dr. Lindsay Squeglia or by other researchers who obtain Institutional Review Board (IRB) approval for their research. This research may involve genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) studies. There are several things you should know before allowing your blood and saliva to be studied or to be stored.

1. The specimens will be labeled with a code that only study personnel can link back to you. Researchers outside of this study will not be given a link between the code number and your name or any other identifying information. While we hope this will prevent any potential loss of privacy or confidentiality, we cannot make any guarantees.
2. In addition to your name, other information about you might be connected to your sample. For instance, information about race, ethnicity, sex, your medical history, and so forth might be available to investigators studying your specimen. Such information might be important for research or public health. It is possible that this information (including genetic information) might come to be associated with your racial or ethnic group.

3. The specimens obtained from you in this research may help in the development of a future commercial product. There are no plans to provide financial compensation to you should this occur. Research results from any additional research will not be placed in your medical record.
4. Loss of privacy or confidentially is a risk of collection of specimens; however, we have procedures in place to minimize this risk (see C.1 above, Section E.5 below). There are no direct benefits to you for the collection, storage, and subsequent research use of specimens.

In this study, investigators will not tell you what they find out about you, nor will they contact you for additional consent or if a test becomes available to diagnose a condition you might have or later develop.

You may request at any time that your research samples be removed from storage and not be used for future research. If you decide you want your samples removed, you may contact Dr. Lindsay Squeglia at the following email address: squegli@musc.edu. Once the request is received, and if your samples have not already been used for other research, they will be destroyed. If you do not make such a request, your specimens will be stored indefinitely or until completely used.

## D. DURATION

Participation in the study will include a brief screening visit (less than one hour), 2 MRI visits (~2.5 hours each), and daily text questionnaires (less than 3 minutes per survey) and twice daily upload of medication taking videos over a period of approximately one month. No more than 35 total daily text questionnaires will be sent if there are scheduling delays.

## E. RISKS AND DISCOMFORTS

There are minimal risks involved with participating in this study, including risks associated with citicoline, the MRI scan, study procedures, emotional distress from answering personal questions, and loss of confidentiality.

In this study, you will have a 50% chance of being randomized to take citicoline. All medications may cause side effects, and there are risks and discomforts associated with citicoline. You will be monitored closely by the medical clinician associated with the study. If the medical clinician or you decide to stop your participation in the study due to unwanted experiences or side effects, you will receive appropriate follow-up care as determined by the medical clinician.

1) Adverse Effects of citicoline
   Citicoline is often well-tolerated, is non-intoxicating, and demonstrates no signal of abuse liability. While unlikely, it could cause side effects, such as stomach pain and headache. These side effects are usually mild and go away even with continued use of citicoline. Current medications will be reviewed by the clinician to assess for any potential interactions with citicoline.

There are no known interactions between citicoline and other medications. However, it will still be important for you to report to the research staff any medications you may be taking before, during, or after the study. Medications include prescription medications from a doctor, over-the-counter medications that you may buy in a drug store, herbal medications that you may buy in a health food store, or any other drugs you are using.

If you are an individual able to have children, you should not become pregnant or nurse a baby while in this research study. If you become pregnant during the study, you must notify the research staff immediately. In addition, if you are an individual able to have children, you must agree to use at least one of the following methods of birth control:

- oral contraceptives (birth control)
- contraceptive patch
- barrier (diaphragm or condom)
- intrauterine contraceptive system
- levonorgestrel implant
- medroxyprogesterone acetate contraceptive injection
- hormonal vaginal contraceptive ring
- complete abstinence from sexual intercourse

2) Risks associated with MRI

We are performing imaging solely for the research purposes described above. It is not a clinical scan intended for diagnosing or treating illness. If you want your scan to be reviewed by a physician so that the physician can look for medical issues, you can request a copy of your scan. We will provide an electronic copy at no charge.

The risks associated with MRI are minimal for individuals who do not have metal and are not claustrophobic (fear of small spaces). Some discomfort may result from lying in the scanner for up to 60 minutes.

There have been no ill effects reported from exposure to the magnetism or radio waves used in this test. A known risk is that the magnet could attract certain kinds of metal. Therefore, we will carefully ask you about metal within your body (this includes certain dyes found in tattoos). If there is any question about potentially hazardous metal within your body, you will be excluded from participation in this research study. We will also keep the examining room locked so that no one carrying metal objects can enter while you are in the scanner. Please inform the study staff if you have a history of claustrophobia (extreme anxiety in close spaces). This may also be a contraindication to participation in the study.

You are welcome to take short breaks between the various tasks if needed. During the MRI scan, there are potential risks that are detailed below.

Potential Risks of MRI:

- Although the risks from magnetic resonance imaging (MRI) are low, it is critical that

participants do not have metal in the skull, metal implants, a cardiac or brain pacemaker, or old metal fragments in the eye or retina. If participants have a question about metal their body, they should inform the researchers and they will determine whether it is safe in an MRI scan.

- Some discomfort may occur from having to remain still while in the MRI scanner. During the scanning, an emergency ball will be given to squeeze if there are any feelings of discomfort or desire to be pulled out of the scanner.
- Although the MRI scanner is open on both ends, some people become anxious or claustrophobic when entering the MRI scanner due to the feeling of being enclosed. If participants have a history of experiencing this, they should inform the study personnel.
- There is a chance that the technologist doing the scan could see something that does not look normal, in which case they would ask a radiologist to review the scan. If the radiologist recommends further action, we will contact you regarding their suggestion. This may cause you anxiety while you wait for further information or follow-up.

3) Interviews/Rating Scales (Questionnaires)
The questions that will be asked may be sensitive in nature and make you feel uncomfortable. You may be asked personal questions that you may find distressing. You may refuse to answer any question(s) that you do not wish to answer.

4) Blood Draw
Risks associated with drawing blood (via a needle stick) from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting is possible, although unlikely.

5) Risk of Loss of Confidentiality
All study records will be placed in a locked, secure, limited access location or a password-protected electronic database. Your participation in the study and the information you provide will be treated as confidential. The information we collect will contain a code and not your name to protect your confidentiality. Codes linking numbers and names will be kept in a password-protected secure database and will not be accessible to anyone outside the research team.

The information you share with us is confidential. That means we do not share information you tell us with anyone outside our research team. This helps us maintain privacy so we are able to get honest answers. However, you should also know that if you threaten to harm yourself or others or give information about child or elder abuse or neglect, this information will be reported to appropriate clinical staff and other persons outside the research program as necessary to protect yourself and others as mandated by law.

6) Unknown Risks
The experimental procedures may have unknown side effects. The researchers will let you know if they learn anything during the study that might make you change your mind about participating in the study.

## F. BENEFITS

As part of the study, you will complete two sessions of brief counseling from a trained clinician, which you may find to be beneficial. Citicoline may improve your cognitive functioning and/or reduce your alcohol use. However, given the investigational nature of this study, a benefit cannot be guaranteed or promised. Information gained from this study may help other investigators have a better understand how citicoline affects immune functioning and the brain.

## G. COSTS

You will be receiving daily texts with a link to an online survey and medication reminder texts asking for video upload. Your normal cell usage and data rates will apply. We can also send the link via email if preferred. Otherwise, there will be no cost to you because of participation in this study.

## H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will receive $495 for completing the two MRI visits ($210 Visit 1 and $285 Visit 2) and $25 for the screening ($520 total). Also, you can earn a bonus of up to $3 per day for completing the remote text questionnaires and videos (up to a maximum of $105). We will offer a $10 bonus to your compensation when you show up for your first scheduled Visit 1 without rescheduling. Mileage reimbursement is available for participants who live more than 25 miles away and will be reimbursed based on the state's most updated reimbursement mileage rate.

You will be paid in through a pre-paid debit card, called ClinCard. ClinCard works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. You may also be paid in cash if necessary.

You are also invited to participate in the recruitment of other participants. If you choose to participate, we can provide you with materials to share with people in your social network (friends, peers, family) who you think would be interested in participating in one of our research opportunities. You cannot provide names/contacts for the study team to contact; these individuals must contact the study office themselves. If any contact identifies you as their source of learning about our research group and successfully enrolls into one of the other current specific substance use studies, you may be elligble for a $30 bonus provided by Entryway. Please note that many substance-related studies are available at MUSC, but only participating studies within our group are eligible. Participation in this process is completely voluntary, and if you elect not to participate your participation in this study will not be affected in any way.

*Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you*

*receive from MUSC reaches or exceeds $2,000.00 in a calendar year, you will be issued a Form 1099.*

## I. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.
Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to

review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.
If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

## J. ALTERNATIVES

The study involves investigational medication. You have the option of not participating in this study. Alternative treatments for alcohol use disorder are available. There are forms of talk therapy and behavior therapy that may be helpful, or medications for those over age 18.

## K. DISCLOSURE OF RESULTS

The procedures in the study are being done solely for the purposes of research. If any finding has the potential of clinical significance, you will be notified to follow up with your doctor.

## L. CERTIFICATE OF CONFIDENTIALITY

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed to meet the requirements of the study sponsor and related agents participating in the study.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

## M. NIAAA DATA ARCHIVE ($NIAAA_{DA}$)

Data from this study will be submitted to the National Institute on Alcohol Abuse and Alcoholism Database (NIAAA$_{DA}$) at the National Institutes of Health (NIH). NIAAA$_{DA}$ is a large database where deidentified study data from many NIAAA studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate, and phone number) is removed and replaced with a code number. The date of your visits though, will be linked with your code number to support appropriate secondary use of the data. Sharing your deidentified study data helps researchers learn new and important things about alcohol problems more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NIAAA$_{DA}$. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NIAAA$_{DA}$. The study data provided to NIAAA$_{DA}$ may help researchers around the world learn more about alcohol problems and how to help others who have problems with alcohol. NIAAA will also report to Congress and on its website about the different studies using NIAAA$_{DA}$ data. You will not be contacted directly about the study data you contributed to NIAAA$_{DA}$.

You may decide now or later that you do not want your study data to be added to the NIAAA$_{DA}$. You can still participate in this research study even if you decide that you do not want your data to be added to the NIAAA$_{DA}$. If you know now that you do not want your data in the NIAAA$_{DA}$, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to the NIAAA$_{DA}$, call or email the study staff who conducted this study, and they will tell NIAAA$_{DA}$ to stop sharing your study data. Once your data is part of the NIAAA$_{DA}$, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NIAAA$_{DA}$, this is available on-line at https://nda.nih.gov/niaaa.

## N. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the study, you will be notified.

## O. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

## P. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

## Q. CLINICAL TRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

## R. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below or if consenting electronically, scroll down to the bottom of the screen and select your choice:

_____Yes, I agree to be contacted

_____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. The researchers can use this Certificate of Confidentiality to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

**Volunteer's Statement**
I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Lindsay M. Squeglia at (843) 792-5451. I may also contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input about my rights as a research subject in this study, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792- 4148.

I agree to participate in this study. I have been given a copy of this form for my own records.

| | |
|---|---|
| Signature of Person Obtaining Consent | Date |

*If you wish to participate, you should sign below for paper consents, or scroll down to the bottom of the screen and sign electronically:*

| | |
|---|---|
| Signature of Adult Participant (18 years or older) | Date |

**If minors (ages 16-17) are research participants, a parent or guardian must sign this consent form, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal custody of a child.**

| | |
|---|---|
| Name of Authorized Representative | Relationship to minor participant:<br>☐ Parent ☐ Legal Guardian |
| Signature of Authorized Representative | Date |

**For Minors 16-17 years of age**: "My participation has been explained to me, and all my questions have been answered. I am willing to participate."

Signature