Participant's Name: _____

Participant's Medical Record Number: _____

Augusta University

Biomedical Research informed Consent Document

Thoracic Neuromodulation for Diabetic Gastroparesis

Principal Investigator: Amol Sharma, MD, MS	**Principal Investigator telephone number (available 24/7 and for emergencies):** 706-721-0211
Sponsor: National Institute of Health (NIH)	**Faculty Advisor:**
	Other Study Contact Numbers: 706-721-9875

Key Information Section

You may be eligible to take part in this research study. Taking part in this study is completely voluntary.

This form contains information that will help you decide whether to take part. All of this information is important, but here are some key important points to keep in mind:

- It is completely up to you whether you take part in this study.
  - Even if you decide to join the study, you are free to leave at any time if you change your mind.
- This is research; medical scientists do research to learn about diseases or conditions and how to treat them.
  - Research is different from regular medical care, which has already been tested in research.
- Gastroparesis is a disorder that slows or stops the movement of food from your stomach to your small bowel. When this happens because of diabetes, we call it diabetic gastroparesis. There is currently no effective treatment for this condition. One reason for this has been the lack of knowledge as to why this happens.
- Purpose of this study is to see if stimulating upper back nerves using magnetic energy can reduce symptoms of delayed stomach emptying and determine if low or high frequency energy use makes a difference in treatment response.
- Your participation in the study could last up to 4 weeks. We plan to finish the study in 3 years.
- Possible risks may include upper back discomfort, pain, tingling, headache, nausea, and light headedness.
- Benefits may include decreased symptoms of delayed stomach emptying. This may help you to eat more by mouth without feeling sick. If your symptoms improve you could be able to eat and better control your diabetes.

You are being asked to take part in this research study about Thoracic Spinal Magnetic Neuromodulation Therapy (ThorS-MagNT) because you have had diabetic gastroparesis (DGp) for the past six months or longer.

The purpose of this document is to:

- Explain your rights and responsibilities
- Explain the purpose of the study
- Describe what will happen if you decide to take part in this study
- Explain the potential risks and benefits of taking part in the study

Participation in research studies is voluntary. Please read this consent form carefully and take your time making your decision. As the study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand. You are encouraged to talk with your family and friends before you decide to take part in this study.

Please tell the study staff if you are taking part in another study.

Why is this study being done?

This is a study to understand the usefulness of a new treatment. The purpose of this study is to see if stimulating upper back nerves using magnetic energy can reduce symptoms of delayed stomach emptying due to diabetes. Also, we want to understand how this may change the disease process. We invite you to take part in this study because you are not responding to the current treatment. We have developed a way to stimulate nerves outside the brain and spinal cord using magnetic energy. We have tested this treatment in a small number of patients with diabetic gastroparesis. This treatment improved nerve function and reduced nausea vomiting in these patients. Here we want to see if this treatment can reduce the symptoms of delayed stomach emptying compared to placebo.

There will be up to 42 participants enrolled at Augusta University over a 3-year period.

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.

How long will I be in this study?

Your active participation in this study is expected to take up to 4 weeks. You can choose not to be in the study or stop participating at any time without penalty or loss of any rights or benefits you are entitled to. Please talk to the study staff first before you stop participating in the study.

What will happen to me in the study?

If you are eligible, the study team will talk to you about taking part in this study. During this talk, the study team will tell you the details of this study and will explain the risks / benefits. We will give you time to read the consent form and ask any questions you may have about the study. If you are happy to do this study, we will ask you to sign this IRB approved informed consent document. We will give you a copy of the signed consent form. During the study period you are expected to come for 9 study visits.

The study consists of a one week "screening period", where you will be asked to maintain a daily symptom diary every day for at least seven days. If you meet symptom severity and are eligible, you will be enrolled, and we ask you to keep a daily diary record during the entire study period. We will also ask you to fill out other study-related questionnaires.

Upper endoscopy (standard of care): This is done as a part of your clinical care. This procedure will be done in the Digestive Health Center Endoscopy clinic at Augusta University. During this procedure we will take out some of juice from your small bowel and small tissue samples from stomach and small bowel. Removing a sample of your tissue may cause minor local bleeding and pain, and there is a small risk of infection at the site where the sample is removed. Your study doctor will discuss these risks in detail before you undergo the procedure and will also provide instructions on the care of any wounds or infections that you may have after having this procedure. The juice taken from your small bowel and the tissue samples taken from stomach and small bowel will be sent to a microbiology lab and a pathology lab for analysis. Data from these tests will be used for research purposes.

Resting state functional MRI Brain : We will get a resting state functional MRI scan of your brain. An MRI scan does not involve radiation like X rays but, instead, generates images using a magnetic field and radio signals. Because an MRI scanner uses strong magnets, you cannot have any metal implants in your body to have an MRI. (Example: people with an artificial heart valve, pacemaker, insulin pump, metal plate, pin, or other metallic objects in their body, including gun shot or shrapnel). Study personnel will ask you questions to make sure you can safely have an MRI. Imaging will be performed at the Augusta University site in Augusta, GA with Siemens 3 Tesla MRI scanner equipped to obtain a resting-state functional MRI. Prior to the scan, MRI technologist will review a standard screening checklist for MRI safety. This checklist will ask the subjects whether they have any metals or any other materials that might be harmful when they are in the MRI scanner. Subjects will be examined in the supine position. Subjects will be given instructions to try and relax with their eyes open and minimize movement during scanning. They will be told the MRI technologist will be in contact through the voice intercom for any questions or concerns throughout the scanning process. If at any time they wish to stop, they can communicate to the technologist via the intercom. Resting-state functional MRI of brain will be collected twice, once before treatments during Visit 1, 2 or just prior to Treatment 1. The remaining fMRI will be collected any time after the 3rd day of treatment until and including the final visit of the study. Resting-state fMRI scans will undergo image processing and BOLD signals will be obtained.

There may be some anxiety and claustrophobia associated with the scanner. Staff at the imaging center use techniques to help reduce these feelings in patients. Your doctor may also prescribe mild sedatives or anti-anxiety drugs to help manage your symptoms.

The Gastric Emptying Breath Test (GEBT): This breath test uses a safe, natural form of carbon to measure how fast your stomach empties. The test is done over a 4-hour period. You will prepare for this test by fasting for 8 hours (usually overnight fast). On the day of the test, we will collect a breath sample before you eat the test meal. The test meal contains scrambled eggs (about two eggs) and spirulina. Spirulina is a type of blue-green algae that is safe, easy to digest and full of nutrients. It is eaten as a health food in the United States and is approved by the FDA. We will collect breath samples at 15, 30, 45, 60, 90, 120, 150, 180, 210 and 240 minutes from the time you finish eating the test meal. Breath samples are sent to a central laboratory for analysis.

Neuroinflammatory Markers: Blood samples will be collected in clot activator tubes, allowed to clot at room temperature for 30 min prior to centrifugation at 3,000× g. Separated serum will then aliquoted into cryovials by aliquoting 1–2 mL of serum per vial. All samples will be stored at −80°C until use. We selected to measure proteins: Lipopolysaccharide-binding protein (LBP), neurofilament light-chain (NfL), Serotonin, BDNF, CRP, SAA, SPG, ILs and TNFs in our study subjects. Further selections may be done based on published literature and following IRB approval on role of such proteins in inflammation and diabetes and will be analyzed using accepted methods. Blood samples will be collected before treatment and after completing all treatment sessions.

ThorS-MagNT Procedure: First we must find the locations we need to stimulate. This is normally in halfway between the lower angles of your shoulder blades. We will do a mapping procedure to find these locations. The mapping is done only before the first treatment. We will not repeat it during any other treatment sessions. To map, we will place 4 surface electrodes on your belly. Then you will sit with your head and shoulders bent slightly forward. We will expose your upper back and mark the stimulation sites using a marker pen. Then we will place a magnetic coil on your upper back. Using magnetic energy, we will stimulate at marked sites. We may stimulate each site up to 10 times. During this stimulation we will find the lowest amount of magnetic energy needed to see a movement in your belly muscle. When Motor Evoked Potentials (MEP) are unable to be obtained due to patient's body habitus (excess tissue overlying recording sites on the abdominal wall), a graded approach to stimulation intensity will be followed (55% intensity for BMI <30, 65% intensity BMI 30-39.9, 75% intensity BMI >40). If you cannot tolerate the energy level, we will use a lower energy level. Treatment will happen with you lying flat with the chest down and the back up with the head slightly bent down. Treatment will be given using a 70-mm self-cooling coil placed over the locations marked earlier. You will receive a total dose of 1200 stimulations in one treatment session. We will continuously monitor you throughout the treatment sessions by recording your blood pressure, pulse, respiratory rate, and/or oxygen saturation (Sp02) and closely watch for any adverse events during your participation in this study. Each treatment session will last up to 30 mins. After 5 days of treatment, you will finish the treatment sessions of this study. Then we will draw another blood sample to measure the current level of protein we measured before treatment.

Dipolar Source Localization : This test will help us understand how your gut talks with your brain. You will be asked not to eat anything for 10 hours before the test. We will give you a cap to wear. This cap has 256 surface electrodes. These electrodes will pick up your brain activity. Study staff help you adjust the cap. The electrodes will not give you any sensations. When you have the cap in place, we will ask you to lie on your left side and put on headphones to reduce any outside noise. A pencil-thick, flexible probe will be placed inside your rectum and securely taped in place. This probe has separate electrodes for stimulating your rectum and your anus. Next, in small increasing amounts, electrical current will be delivered through the probe to the rectum site or the anus site. The amount of current used is very small. Electrical current will be delivered about

50 times (on average) to the rectum or to the anus. During electrical stimulation, you may not notice any difference in the feelings between your rectum and your anus. Electrical stimulation in the anal and rectal area may be perceived as a twitch, and/or burning sensation of mild intensity. After 50 stimulations, there will be a 5-minute rest period, followed by three more cycles of 50 stimulations each with a rest period in between. When this procedure is completed, we will remove the surface electrodes from your scalp. This procedure will take approximately 1-1.5 hours. This test will be repeated after completion of treatments.

Quantitative Sensory Testing (QST) : This test allows us to measure changes in sensitivity to different types of sensations that can include temperature, touch, or pressure. Before the test starts, we will make sure you are seated comfortably in a chair. We will then explain the tests to you and show you equipment. First, we will put a temperature sensor that produces temperature changes on the skin, usually on your hand or foot. We will ask you to push a button when you start to feel changes in temperature such as cool, cold, warm, or hot. We may also move small warm and cool rollers over your skin to see if there are any areas that feel more or less sensitive. We will also touch different nylon hairs, brushes or blunt probes on the skin and ask how they feel. All the tests start with very weak tests that change gradually until you feel a difference or press the button. You should feel little or no discomfort during the test. If you are not happy, you can stop the testing at any point either by pressing your control button or asking us to stop. As an extra safety measure, a computer controls the temperature and pressure tests and stops it before it becomes too strong, even if you do not press the control button. This procedure will take approximately 40 minutes. We will repeat this test after completion of treatments.

Satiety test (Nutrient Drink test) : You will be asked to refrain from eating food for 10 hours before the satiety test visit. You will be given a high caloric nutrient drink (Ensure™) and asked to drink it slowly. After that, every 5 mins you will be asked to rate the fullness on a scale. You will be asked to stop drinking at the moment you reach complete fullness. In addition to fullness, you will rate the severity of other symptoms including nausea, bloating, heartburn, and stomach pain on a scale at before drinking and 5-, 10-, 15- and 20, 25, 30-min while drinking. Final symptom assessment will be conducted at 60 minutes, or 30 minutes after drinking is completed. The total amount of drink consumed by you will be recorded. This procedure is not associated with major discomfort. This procedure will take approximately 60 minutes. We will repeat this test after completion of treatments.

Autonomic Function Testing (AFT) : These tests measure how your heart rate and blood pressure respond during exercises such as deep breathing and forcefully exhaling (Valsalva maneuver). You will receive a list of medications that may affect the results of the test. You will be asked to discuss your medications with your physician. Eight hours before the test we ask you to stop nicotine (cigarettes), caffeine (coffee, cola, energy drinks, tea, etc.), alcohol and medical or recreational marijuana for at least three days prior to the test. You can eat and drink normally for 24 hours prior to testing and make sure you are hydrated before your test. For deep breathing and forcefully exhaling tests, we will place electrodes on your chest and a small blood pressure cuff on your arm. For the deep breathing test, you will take slow, deep breaths for one minute. For the Valsalva maneuver, you will breathe out forcefully through a mouthpiece while your nose is pinched shut. After a rest period we will ask you to stand up fast and then stand still for 5 minutes. The electrodes and cuff will record your heart rate and blood pressure. Next, we will place electrodes on your foot, arm, and leg. These electrodes will contain a substance that stimulates sweating. A mild electrical current will be sent through the electrodes. You might feel a warm, tingling sensation as this is done. A computer will analyze how your nerves and sweat glands react to the electrical current. The test takes about 45 minutes to an hour to complete. This procedure is not associated with major discomfort. We will repeat this test after completion of treatments.

Four weeks after your final treatment you will come back to the Digestive Health Center research area for the final study visit. During this visit you will complete the Satiety test (Nutrient drink test) and submit your completed diaries.

The table below summarizes what happens at each study visit.

Study Visit	**Procedures**
Visit 1: Screening Baseline Testing and Baseline Questionnaires can be completed in any order prior to first Treatment Visit	• Review and sign Informed Consent Document • Document eligibility checklist and medications ANMS-GCSI-DD given to subject to assess severity of symptoms • Pregnancy testing if subject is female of reproductive age group, and no history of tubal ligation or hysterectomy
Visit 2: Baseline Testing Table: Summary of Visits and Procedures	• Autonomic Function Testing (AFT) • Quantitative Sensory Testing (QST) • Satiety (Nutrient Drinking) Test • Dipole Source Localization- Pre- treatment • ClinCard given to subject and ClinCard receipt and Form W-9 completed • •

Visit 3: Pretreatment assessment/ Baseline Testing	Resting-state fMRI Brain (Pre-treatment) • Gastric Emptying Breath Test • Validated Questionnaires (Sociodemographic form, PaGI-QoL, VSI, MAIA, and HADS) • Blood sample
Visit 4: 1st and 2nd Therapy Sessions	• Randomization (1 Hz, 10 Hz or Sham) • ThorS-MagNT (1 Hz, 10 Hz or Sham) • Pregnancy testing if subject is female of reproductive age group
Visit 5: 3rd and 4th Therapy Sessions	• ThorS-MagNT (1Hz, 10Hz or Sham)
Visit 6: 5th and 6th Therapy Sessions	• ThorS-MagNT (1Hz, 10Hz or Sham)
Visit 7: 7th and 8th Therapy Sessions	• ThorS-MagNT (1Hz, 10Hz or Sham) • Autonomic Function Testing • Quantitative Sensory Testing Satiety/ Nutrient DrinkingTest Dipole Source Localization- Post-treatment
Visit 8: 9th and 10th Therapy Sessions and Post treatment assessment	• ThorS-MagNT (1Hz, 10Hz or Sham) • Resting-state fMRI Brain (Post-treatment) • Gastric Emptying Breath Testing • Validated Questionnaires (PaGI-QoL, VSI, MAIA, and HADS) • Blood Sample
Visit 9: Treatment follow up/Final Visit (approximately 4 weeks after final treatment session)	• Collect and review ANMS-GCSI- Daily Diaries • Complete any procedures/testing/questionnaires not obtained during the prior study visits •

What tests and/or extra tests will I have if I take part in this study?
You will have no additional tests other than the tests described above if you decide to take part in the study.

What are the risks of being in this study?
You may experience the following side effects and / or discomforts from the treatment and tests in this study. We have done upper back nerve stimulation with magnetic energy in a small number of people. Therefore, we do not know the full risks of this treatment. From our experience with nerve stimulation with magnetic energy in 7 patients with diabetic gastroparesis and about 90 patients with bowel leakage, we predict some of the risks given below.

More likely

- Treatment may cause some upper back discomfort, skin irritation and soreness. You may feel twitching, tingling or numbness in your upper back and / or chest during the treatment. This may resolve after the treatment is completed.
- You may feel a sense of warmth or flushing after being given the contrast dye.

Less Likely

- Stimulating your nerves could make you feel dizzy, break out in a sweat, and cause your heart rate or blood pressure to drop. This could happen because of the way your body react to the stimulation. We will stop the treatment immediately if you develop any of these symptoms.

- Some patients have reported feeling sick or stomach discomfort or dizzy (signs of high or low blood glucose) after eating, the breath test, and/or satiety test meal. These symptoms are similar to what you feel after eating when you have slow stomach movements.
- Electrical stimulation of anorectum and skin may cause muscle twitching, burning, or discomfort, to the lining of the anus or rectum and skin. The risk of muscle twitching, burning, discomfort, or any injury to the lining of the anus or rectum, or bleeding is very rare because we use very small amounts of electrical current that you may barely feel.
- As with any research study, there is a potential for the confidentiality to be breeched. We estimate the risk of breech of your private information to be minimal.
- Discomfort from noise coming from the MRI coil. Earplugs will help reduce this.
- Contrast dye may cause temporary nausea, headaches, rash, or a drop in blood pressure.
- Removing a sample of your tissue may cause minor local bleeding and pain, and a small risk of infection.
- Taking a blood sample may cause momentary discomfort and/or bruising.

Rare, but serious

- You may accidentally breathe in stomach content due to sudden stomach movements caused by the treatment. We will work with your doctors to reduce what is in your stomach before the treatment. Also, we will keep you in a slightly bent position to reduce this risk.
- You may experience fast heart rate or changes in heart rhythm and/or slow or fast breathing during the treatment. We will monitor you during treatment for these symptoms using a monitoring device. We will stop the treatment if we see any signs of these symptoms.
- There have been rare reports of a severe and potentially fatal condition known as nephrogenic systemic fibrosis (NSF), which has occurred in some patients who received gadolinium-based dyes.

You cannot take part in this study if any of the following conditions apply to you, and it is VERY IMPORTANT that you tell the research team if you have or are:

- Metal implants (within 30 cm of the stimulation area)
- Presence of increased intracranial pressure
- Cardiac pacemaker
- Implanted medication pump
- Presence of an intracardiac line
- Any history of stroke, epilepsy, or other brain lesions
- A nursing mother

Reproductive Risk

Being a part of this study while pregnant may expose the unborn child to significant risks, some of which may be currently unforeseeable. Therefore, pregnant women will be excluded from the study. If you are a woman of childbearing potential, a urine pregnancy test will be done at each study visit and it must be negative before you can continue in this study.

If sexually active, you must agree to use appropriate contraceptive measures for the duration of the study. Medically acceptable contraceptives include:

- Surgical sterilization (such as a tubal ligation or hysterectomy),
- Approved hormonal contraceptives (i.e., birth control pills, patches, implants, or injections),
- Barrier methods (such as a condom or diaphragm) used with a spermicide, or
- An intrauterine device (IUD).

If you do become pregnant during this study, please inform the study staff immediately.

Other Risks

- There may be more risks that are not known or not expected.
- The study staff will tell you about new information that may affect your health, welfare, or willingness to stay in this study.
- The questionnaires you will be asked to complete are not expected to create any harm or come with a risk.

You should discuss these with the study doctor and your regular health care provider if you choose to do so Results of the research that may be relevant to your clinical care will be shared with you under the following conditions:

- If your symptoms do not improve
- If you develop an adverse event.

There may be more risks that are not known or not expected. The study staff will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Will I benefit from this study?
The possible benefits of this study are improvements in symptoms associated with your gastroparesis.

What are my other choices if I do not take part in this study?
You are not required to take place in this study. Some other options for you are:

- Medicines that promote bowel movements and stop you feeling nausea.
- Gastric electrical stimulation (GES)
- A tube placed directly into the small bowel for long-term feeding.
- A drainage tube put into your stomach to drain stomach juices and fluids
- Other research studies

The study staff will discuss these other options with you if you are interested.

Who will see my study information?
Study team members, the sponsor of the study, and their representatives will be able to see your study information. Your records may also be reviewed in order to meet federal or state regulations. Reviewers may include the Augusta University Institutional Review Board (the committee who oversees safety of volunteers in research studies), institutional officials, and outside agencies, such as the Food and Drug Administration (FDA).

How will you keep my study information confidential?
Study records that identify you will be kept confidential except as required by law. You will not be identified in study records or publications disclosed outside Augusta University.

What will happen to my identifiable private information/biospecimens once collected?
Identifiers will be removed from your identifiable private information or identifiable biospecimens collected as a part of this research. After such removal, the information or biospecimens could be used for future research studies or be distributed to another investigator for future research studies without getting additional informed consent from you or your legally authorized representative.

What are my costs (what will it cost me) for taking part in the study?
If you agree to participate in this study, you and/or your insurance will not be billed for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. You will be responsible for all co-pays, deductibles and denied claims.

You have the right to ask what it will cost you to take part in this study. You have the right to contact your insurance company to discuss the costs of your routine care and whether these will be covered if you participate in this study. You may choose not to be in this study if your insurance does not pay for your routine care. In that case, your doctor will discuss other treatment plans with you.

Will I be paid for participation in this study?

You will receive $25.00 for each completed treatment session, to compensate you for your time and effort. You will receive $250.00 for completing all the 10 treatment sessions. In addition, you will receive $150.00 for participating in the informed consent and initial enrollment and $100.00 for the final research visit 4 weeks after treatment sessions are completed . In total you will receive $500.00 for completing all the study related activities. Augusta University is required by law to report any payments we make to the Internal Revenue Service (IRS)

You will be compensated with the Greenphire ClinCard. It works like a bank debit card. We will give you a Greenphire ClinCard and each time you receive a payment for completing a study visit, the money will be added to the card.

You may use this card at any store that accepts debit cards, or you can use a bank machine to remove cash. However, you may get fees for cash withdrawals, or for not using the card. You will receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for information about fees.

The debit card system is managed by an outside company, Greenphire. When you are given the debit card the following information will be entered into the Greenphire computer system:

- Your Name
- Your Date of Birth
- Your Address
- Your social security number
- The name of the study you are in

This information will be used for tax reporting. This is also the information needed to identify you if you call Greenphire with questions or service requests (for example, replacing a lost or stolen card). Greenphire will only use this information for setting up your account, keeping your account active, and paying you. Your information will not be used for any other reasons and will not be given or sold to any other company.

Please be aware that receiving payment for being in a research study may be considered taxable income. Augusta University requires that we track these payments so if you receive $600 or more in a calendar year, the university can be compliant with tax requirements. The information that Augusta University collects may include:

- Your name
- Your address, and
- Your social security number

If you are an Augusta University employee, payment will be included in your payroll check. This payment will be subject to Federal and Georgia state withholding taxes as well as FICA tax and will reflect on the W-2 form at calendar year end.

What happens if I am injured or hurt because I took part in this study?

If you think that you have suffered a research related injury, seek medical care right away and contact the study team as soon as possible at **706-721-9875**. In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company.

No reimbursement, compensation, or free medical care is offered by Augusta University (AU), AU Medical Center, AU Medical Associates, AU Dental Associates, AU Nursing Associates, Inc., AU Health Professions Associates, Inc. collectively designated AU Affiliates. You do not give up your legal rights by participating in this study.

Who can answer my questions about this study?

You can ask questions about this study at any time. Please contact the study staff listed on page 1 of this document if you have questions about:

- Study procedures or treatments
- Reporting an illness, injury, or other problem

  Leaving the study before it is finished
- Expressing a concern about the study
- Any other questions you may have about the study

Who can I contact to discuss my rights, problems, concerns, questions, or complaints I have as a study participant?

Contact the Augusta University Institutional Review Board at (706) 721-1483.

Could there be any harm to me if I decide to stop participating in the study before it's finished?

If you decide to stop taking part in the study, the study staff will discuss ways to safely remove you from the study. You should follow the instructions the study staff gives you.

Can I be removed from the study?

Yes, you may be removed from the study if:
Some examples are:

- The sponsor or study doctor decides to stop the study.
- The study doctor stops your taking part in the study for your safety.
- You are not eligible to take part in the study.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow the instructions from the study staff.

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to Augusta University and AU Affiliates to use or disclose your health information that identifies you for the study described earlier in this document.

The health information Augusta University and AU Affiliates may use or disclose for this study includes information in your medical or dental record, results of physical exams, medical or dental history, lab tests or certain health information indicating or relating to your condition.

The health information listed above may be used by and/or disclosed to the following, as applicable:

- Researchers and their staff;
- The sponsor of the study including its agents such as data storage banks 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;
- Health insurers or payers in order to secure payment for covered treatment;

  Parents/Guardians of children younger than 18 years
- Vendors to facilitate payment or reimbursement for your participation in this study;
- Federal/state agencies and Augusta University and AU Affiliates committees having authority over the study. These may include, but are not limited to:

    - The Institutional Review Board (IRB) overseeing this study;
    - Committees with quality improvement responsibilities;
    - Office of Human Research Protections;
    - Privacy and Security staff for oversight and investigations;
    - Food and Drug Administration;
    - National Institutes of Health;
    - Other governmental offices as required by law.

Augusta University and AU Affiliates are required by law to protect your health information. By signing this document, you authorize Augusta University and AU Affiliates to use and/or disclose your health information for this research.

Once your information has been disclosed outside Augusta University and AU Affiliates, it may no longer be protected by federal laws and regulations and might be further disclosed by the persons or institutions receiving the information.

Please note that:

You cannot receive research-related treatment if you do not sign this Authorization.

Augusta University and AU Affiliates may not withhold treatment whether or not you sign this Authorization.

You may change your mind and take back (revoke) this Authorization at any time. If you revoke this Authorization, Augusta University and AU Affiliates may still use or release health information and any data and/or specimens already obtained about you as necessary for this study. If you revoke this Authorization, you cannot continue to participate in this study. To revoke this Authorization, you must write to the Principal Investigator listed at the top of this document.

You may not be allowed to see or copy the study information described on this Authorization as long as the study is in progress. When the study is complete, you have a right to request a copy of your personal health information collected for the study.

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 study will reveal your identity without another signed authorization from you.

You will be given a copy of this Authorization. This Authorization does not have an expiration date. If you have questions or concerns about this Authorization or your privacy rights, please contact the Augusta University and AU Affiliates Enterprise Privacy Officer at 706-721-0900 or the toll-free compliance and ethics hotline at 1-800-576-6623.

Regulations require that you be given a copy of the Augusta University and AU Affiliates Notice of Privacy Practices describing the practices of Augusta University and AU Affiliates regarding your health information.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except

- if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below),
- if you have consented to the disclosure, including for your medical treatment; or,
- if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Sharing of information must be done for audit or program review if needed by the group that is paying for this study or for information that is needed by the Food and Drug Administration (FDA), or for other auditing groups.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also protect your own privacy.

The investigator can still do what is needed, including reporting to local legal groups (police, etc.), to prevent serious harm to yourself or others.

STATEMENT OF CONSENT

I have read this form and the information in it was explained to me. My taking part in the study is voluntary. All of my questions were answered. I will receive a copy of this form for my records. I agree to take part in this study. **I am not giving up my legal rights by signing this form.**

_____

Participant's Name (print)

_____ _____

Participant's Signature Date /Time (00:00)

INVESTIGATOR STATEMENT

I acknowledge that I have discussed the above study with this participant and answered all of his/her questions. They have voluntarily agreed to participate. I have documented this action in the participant's medical record source documents or research chart source documents, as applicable. A copy of this signed document will be placed in the participant's medical record or research chart, as applicable. A copy of this document will be given to the participant or the participant's legally authorized representative.

_____

Printed name of Investigator obtaining consent

_____ _____

Signature of Investigator obtaining consent Date /Time (00:00)