Official Title: A Pilot Study of Spinal Cord Stimulation for the Symptomatic Treatment of Rigidity and Painful Spasm in Stiff Person Syndrome

NCT06242678

IRB Approval Date: 01/08/2026

A Pilot Study Evaluating Spinal Cord Stimulation for Stiff Person Syndrome

Informed Consent Form to Participate in Research
Janus Patel, M.D., Principal Investigator

SUMMARY

You are invited to participate in a research study. You are being asked to participate in this pilot study because you have been diagnosed with a condition called Stiff Person Syndrome (SPS). The investigators leading this pilot study believe the use of spinal cord stimulation (SCS) may be effective in alleviating the symptoms of SPS. Your participation in this research will involve 3 in person study-related visits and 4 virtual visits. Total study participation will last for up to 2 months total.

Participation in this study will include a screening visit, SCS trial lead placement that will last for up to 10 days prior to removal, and lastly a 2 week and 4 week follow up visit (virtual or in person) after trial leads are removed. Included in these visits are physical exams, questionnaires evaluating pain and disease symptoms with their manifestations in your daily life, the SCS trial lead procedural visit, and follow up. A detailed list of the questionnaires and study visits to be completed are listed later in this informed consent form.

All research studies involve some risks. A risk to this study that you should be aware of is discomfort from the placement of the SCS trial leads, risk of infection, and unintentional movement of the spinal cord stimulator trial leads. There are additional risks related to the procedures done that will be discussed in further detail later in this form. There is also the risk that you may not benefit from your participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There will not be alternative treatment modalities offered for SPS, and would recommend discussing any further treatment options with your provider currently treating your SPS. You will not lose any services, benefits, or rights you would normally have if you choose not to participate. The alternative is to continue receiving the medical care you have already been receiving for your diagnosis of SPS.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Janus Patel, M.D. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is:

Janus Patel, M.D.
[redacted]

[redacted]

If you want to obtain additional information, you should contact the Wake Forest University Health Sciences Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have been diagnosed with Stiff Person Syndrome (SPS). Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

You are being asked to participate in this pilot study because you have been diagnosed with a condition called Stiff Person Syndrome (SPS). The investigators leading this pilot study believe the use of spinal cord stimulation may be effective in alleviating the symptoms of SPS. Your participation in this research will involve 3 in person as well as 4 virtual study-related visits and last for up to 2 months from start to finish.

Spinal cord stimulator implants are currently cleared by the FDA to treat patients who experience chronic back pain, diabetic neuropathy, and other painful neuropathic conditions. Using spinal cord stimulation for patients with stiff person syndrome is experimental. Prior to having this device implanted all patients must undergo spinal cord stimulator trial lead placement to demonstrate effectiveness of the device in treating pain. It was during one of these trial lead placements that it was discovered it could potentially prove beneficial in the treatment of the symptoms related to SPS. The SCS trial lead placement involves the placement of 2 electrical leads into the epidural space under x-ray guidance called fluoroscopy. The epidural space is the space just outside of the sac that holds your spinal fluid, nerves. The leads are made up of insulated wires with conductive tips near the end of the lead. These conductive tips go into the epidural space. During the SCS trial lead procedure, the leads themselves connect to a special battery which is secured outside the body near the insertion site. This pulse generator battery sends an electrical current that will stimulate the spinal cord. This generator can be programmed by the manufacturer's field engineer to maximize the relief for the subject receiving this device.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We plan to enroll up to 10 subjects who have received a diagnosis of Stiff Person Syndrome over a 12 month period of time.

WHAT IS INVOLVED IN THE STUDY?

You will have the following study visits. A description of each visit is noted after each header. The study visits will be conducted in the Atrium Health-High Point Premier Pain Medicine Clinic.

For each study participant, we anticipate the total duration of your participation to be approximately 2 months. You may choose to exit the study at any time.

If you take part in this study, you will have the following visits:

Screening Visit:
An initial screening call will be conducted with a member of the research team. The study will be discussed and, if interested, this informed consent form will be emailed to you for your review. If after your review of the consent form you are interested in participating in this study, you will be asked to sign this form via DocuSign. At that time, you will be asked to provide your medical history, current medication use, and any treatments you have had in regard to your current diagnosis. This virtual visit will take approximately 2 hours. You will be receiving a copy of this completed form and a copy will also be placed in your permanent medical record.

If you continue to meet eligibility after your screening visit, a visit will be scheduled with the investigator on the day prior to your scheduled procedure. Prior to this visit you will be asked to complete a Subject Daily Diary Questionnaire for the 7 days prior to this scheduled appointment. This questionnaire will be used throughout your study participation and includes pain, muscle spasm, and fatigue assessments. At this visit a physical exam will be performed by the medical provider (investigator), and movement tests and your lung capacity tested by taking deep breaths, measured using an incentive spirometer. A member of the study team will confirm your demographic information, medical history, and review previous radiological tests that you have had in the course of your diagnosis of your SPS. The following questionnaires will be completed at this time as well:

- Visual Analog Scale (VAS) pain assessment
- Penn Spasm Frequency and Severity Scale (PSFS)
- Michigan Body Map
- Pain Disability Index (PDI)
- Pittsburg Sleep Quality Index (PSQI)
- Fatigue Severity Scale (FSS)
- Depression Assessment (PHQ-8)
- Anxiety GAD-7 questionnaire
- EuroQol (EQ-5D-5L)
- Columbia Suicide Severity Scale

You will also be reminded that the Subject Daily Diary Questionnaire (SDQ) that will need to be completed throughout the study period: every day during the trial period, and for 7 days following the end of trial visit. The SDQ will continue to include the following questionnaires:

- Visual Analog Scale (VAS) pain assessment
- Penn Spasm Frequency and Severity Scale (PSFS)
- Fatigue Severity Scale (FSS)

- Medication usage

Lab work will include a complete blood count, if needed, to look at your platelet level and, if appropriate, a urine pregnancy test.

A psychiatric evaluation by a licensed mental health provider will also be done for clearance of the study procedure. The appointment for this evaluation will be made between you and the mental health provider at your convenience.

Procedure visit:
After all of the above results are received and you meet the eligibility criteria, you will then be scheduled for a procedure visit. This visit will take approximately 2 hours and include the placement of the spinal cord stimulator trial leads in the AH-WFB: High Point Premier Pain Clinic procedural area. Prior to the lead placement you will have the following reviewed:

- Review concomitant medications and treatments
- Review your entries into your SDQ daily for the 7 days prior to the SCS Trial Procedure visit
- Document any adverse events (AEs)

You will have an IV placed and receive a dose of IV antibiotics. You will then have the spinal cord stimulator trial leads placed with the study investigator. This is done with local anesthetic only. It is performed using two needles and x-ray guidance. When the wires are in the correct area, we will turn on the device to see where you feel the tingly sensation. The wires will be adjusted so the tingly sensation you feel is along the areas of your stiffness and spasms. Then the needles are removed, leaving only the wires exiting your skin. The wires are sutured to your skin and bandaged. You must minimize bending forward, twisting, and getting the wires wet for the duration of the trial period. Therefore, you cannot shower or bathe or go underwater for the duration of the trial.

After discharge and you are home, the following will be evaluated at 2, 4, 6, and 8 hours after the procedure:

- Michigan body map
- VAS pain assessment
- PSFS
- FSS

You will also be asked to complete the SDQ daily at bedtime for the trial period until the trial leads are removed.

You will be contacted by the trial lead manufacturer every 2-4 days in order for the SCS to be wirelessly programmed to reach maximum effectiveness. This would be done if you were having a SCS placed under “normal” circumstances.

End of Trial Visit:
Within 7-10 days you will return to the Atrium Health-Wake Forest Baptist High Point Premier pain clinic to have your SCS trial leads removed. At this visit the following will occur:

- Review concomitant medications and treatments
- Review SDQ
- Document any AEs
- Physical exam (including neurological exam, musculoskeletal exam, and inspection of the surgical site)
- Complete the following questionnaires:
    - Visual Analog Scale (VAS) pain assessment
    - Penn Spasm Frequency and Severity Scale (PSFS)
    - Michigan Body Map
    - Pain Disability Index (PDI)
    - Pittsburg Sleep Quality Index (PSQI)
    - Fatigue Severity Scale (FSS)
    - Depression Assessment (PHQ-8)
    - Anxiety GAD-7 questionnaire
    - EuroQol (EQ-5D-5L)
    - Patient Global Impression of Change (PGIC)
- Complete the following assessments:
    - Timed Up and Go (TUG)
    - Trunk Impairment Scale (TIS)
    - Lung Capacity (Incentive Spirometry)
- Removal of SCS trial leads. Removal of the wires is quick and painless, and involves snipping the sutures, and gently removing the wires. No anesthesia is involved.

You will also be asked to complete the SDQ daily at bedtime for the next 7 days as follow-up.

One week after the trial leads have been removed you will be contacted by phone to review any medications you are using for pain, your SDQ, and to make sure you have not had any issues since the trial leads were removed.

Two Week and Four Week Follow-Up Visit
This visit will occur virtually or in-person. The following questionnaires will be completed at this time:

- Visual Analog Scale (VAS) pain assessment
- Penn Spasm Frequency and Severity Scale (PSFS)
- Michigan Body Map
- Pain Disability Index (PDI)
- Pittsburg Sleep Quality Index (PSQI)

- Fatigue Severity Scale (FSS)
- Depression Assessment (PHQ-8)
- Anxiety GAD-7 questionnaire
- EuroQol (EQ-5D-5L)
- PGIC-Patient Global Impression of Change

After this visit, your study participation is completed.

How Long Will I Be in the Study?

You will be in the study for a total of 6 weeks after the SCS trial leads are placed.
You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first.

The entire study or trial could be stopped early if:

- Lack of efficacy is observed from SCS
- Overwhelming Positive efficacy is observed from SCS
- Unforeseen increase in symptom severity due to/during SCS therapy administration
- enrollment issues
- loss of funding
- regulatory decisions

This would affect your participation in the study by:

- If you are in the middle of your SCS trial period, you may complete the trial period and the entirety of the study, or you may end your trial period early and have the leads removed
- If you have enrolled but not yet had your trial procedure, you may choose to withdraw or complete the study in its entirety.
- You may withdraw at any time

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to this study include:

-Bleeding, infection, nerve damage, unintended movement or removal of the wires, post-procedure pain, epidural hematoma, failure of therapy to have an effect, chest wall/abdominal pain, leakage of spinal fluid, allergic reaction to stimulator wires, MRI incompatibility, death.

How Are These Risks Are Minimized?

- Allergy to SCS trial leads is reduced based on allergic severity and reaction. If unable to treat with medication, the final treatment is removal of temporary SCS leads

- Infection – Risk is reduced with sterile procedure conditions, antibiotics for SCS trial period, no bathing or showering during trial period, and final treatment is removal of temporary SCS trial leads. The presence of infection will continue to be evaluated at the 2 and 4 week visits after lead removal.
- Risk of Spinal fluid leakage is reduced by performance of procedure using x-ray. If leakage happens, you may develop a headache, conservative treatment with adequate fluid intake and caffeine is first line treatment. This condition usually self resolves over 2 weeks.
- Epidural hematoma, bleeding – This risk is mitigated by pausing blood thinner medications prior to and during the trial procedure and trial period. You prescriber of the blood thinner will have to approve pausing your blood thinner for an appropriate amount of time. An epidural hematoma is a serious risk from the procedure and may warrant emergent spine surgery. The risk of epidural hematoma is highest during lead placement and removal and apparent at the time of the in-person visits for SCS lead placement and removal.
- There is no risk from anesthesia as the procedure is performed using local anesthetic only.
- SCS trial leads are MRI Unsafe/incompatible. If you require an emergent MRI for any purpose, SCS trial leads will simply require removal. You will be supplied with a contact sheet in which other caregivers or medical personnel can contact the study investigator for further information, as well as information regarding the MRI Incompatibility of the SCS trial leads.
- Malfunction of the SCS trial system –If there is a device malfunction, the SCS representative during your trial and the lead investigator can easily analyze and correct the issue.
- Stimulation may cause untoward gastrointestinal or bladder symptoms which may cause nausea, diarrhea, urinary leakage or increased urge to urinate. Should this occur, the stimulation may be adjusted via programming such that the symptoms are eliminated. The stimulation may also be turned off if necessary. The final solution would be removal of the trial leads ahead of schedule if necessary.
- If you are receiving regularly scheduled intravenous immunoglobulin (IVIG) infusions, you will not be allowed to undergo trial lead placement if you have had an IVIG infusion 10-14 days prior to the SCS trial procedure. You cannot have an IVIG infusion while the SCS trial leads are in place (7-10 days), and up to 48 hours after the removal of the SCS leads. You may resume IVIG infusion 48 hours after removal of the SCS leads, if needed.
    - IVIG infusions and SCS trial lead placement procedures both have their own risks. If an adverse event were to occur, the investigators would want to determine the cause. The IVIG infusion must be sufficiently spaced apart from the SCS trial in order to better determine if any adverse event was caused by the IVIG infusion or the SCS trial.
- If you have a baclofen pump, there are additional risks to consider:
    - Baclofen pump catheter fracture or displacement: The thin tube (catheter) that delivers medication from your pump to your spinal fluid may be damaged or

moved during the SCS trial. This could lead to loss of medication delivery, withdrawal symptoms, or the need for surgical repair.

- Baclofen pump malfunction: The pump may stop working, deliver too much or too little medication, or develop other problems. Malfunction can cause overdose (drowsiness, trouble breathing) or withdrawal (increased muscle stiffness, fever, confusion).
- The additional risks due to the baclofen pump will be reduced by:
  - Before the procedure, we will use imaging (such as X-rays or fluoroscopy) to map the location of your baclofen pump and catheter before placing the SCS leads.
  - Monitor your pump function before, during, and after the SCS trial procedure, including device interrogation and clinical assessment for signs of overdose or withdrawalProvide close monitoring for infection, device malfunction, and neurological changes during the SCS trial period and after lead removal.
  - Educate you and your caregivers about warning signs of device problems and the importance of reporting symptoms promptly
  - Ensuring the external SCS trial device is kept away from your pump location to avoid any electromagnetic interference

Needle Insertion
You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy, lightheaded or feel faint. Infection may occur on rare occasions.

Spinal Cord Stimulator Trial Lead Placement
The SCS trial leads are placed in the procedure area of the pain clinic. You are asked to lie face down on the table. The procedure is done under sterile conditions to reduce the risk of infection. The placement is done while being viewed under x-ray to allow the leads to go into the correct position to obtain the best pain relief. Once the leads are placed, the needles are removed and the leads remain exiting the skin. The leads are sutured to your skin to help prevent movement, and insertion sites bandaged. In addition to the risk of infection, some additional risks of this placement include the following: discomfort, bruising, and/or bleeding where the needle is inserted for the placement, dural puncture, leads moving out of position, leads breaking or not working appropriately, nerve damage/paralysis.

Questionnaires
The questionnaires that are being asked of you to complete may ask sensitive questions that make you uncomfortable. Please discuss with the study team if you have any concerns about responding to these questions.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks to your health.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study to identify possible safety issues to participants and to provide advice and recommendations on possible changes to the research study for the protection of participants.

Reproductive Risks and other Issues to Participating in Research

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, OrthoEvra patch, NuvaRing, intrauterine devices (IUD), Nexplanon implant, DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a diaphragm with spermicide with Plan B used for any noticed condom or diaphragm failures. We encourage you to discuss this issue further with your physicians if you have any questions.

Pregnant women are excluded from participation in this study. Because NO method of birth control is 100% reliable, a pregnancy test is required from all subjects considered of childbearing potential at the time of study enrollment.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

This is a pilot study to determine if this procedure will assist with the pain you are experiencing as a result of your medical diagnosis. We do not know if you will receive pain relief or not, so therefore, we cannot guarantee that you will receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

The purpose of the study is to evaluate a potential treatment for those suffering from stiff person syndrome. Your participation is voluntary and optional. Alternatives to participating include

continuing your current medication prescribed by your personal physician, as well as treatments including nonsteroidal anti-inflammatory drugs, topical patches/creams/gels/ointments, physical therapy, acupuncture, bracing, assistive devices, and lifestyle modifications.

What Are the Costs?

All study costs, including any study products or procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

Will Your Research Records be Confidential?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required or permitted by law, or necessary to protect the safety of yourself or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

_____ *Please initial if you agree to the following statement for **text** messaging contact*

TEXT MESSAGE COMMUNICATION. I give permission to Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to contact me by text message at the number I provided to send information, reminders, and to communicate with me about the research study. I understand that I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication and I accept the risk that individuals not involved in the research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

_____ *Please initial if you agree to the following statement for **email** contact*

EMAIL COMMUNICATION. By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to \send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid a total of $1300 if you complete all the scheduled study visits and procedures. If you withdraw for any reason from the study before completion you will be paid according to the description below.

Screening/baseline visit: $200.00
Procedural SCS trial placement visit: $450.00
End of Trial Study Visit: $450
2 week Follow-Up Visit: $200

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study, but you will not be paid.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Neuroscience Clinical Trial and Innovations Center (NCTIC). This grant is providing money or other support to the researchers to help conduct this study. The researchers do not, however, hold a direct financial interest in the conduct of this study.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. To the extent research insurance coverage is available under this policy, the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related

illness, adverse event, or injury you should call Janus Patel, MD at [redacted] or, after hours, you should call the study coordinator at [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** medical history and medication history.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and Atrium Health Facilities; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS), the National Institutes of Health (NIH) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs, videotapes, audiotapes or other recorded media which are identify you unless we you're your written authorization.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire.

You can tell Dr. Patel that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Janus Patel, M.D.
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

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 Web site at any time.

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A medical record will be created for all study participants seen on-site and if a medical record doesn't already exist. Information about your participation in the study will be placed in the medical record, along with any routine medical test results that were obtained as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Patel at [redacted] or after hours, you should call the study coordinator by calling [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____

Date: _____ Time: _____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent: _____

Date: _____ Time: _____ am pm