Randomized Injection Technique for Chronic Plantar Fasciitis

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Wake Forest University
School of Medicine

Department of Orthopaedic Surgery

Infracalcaneal Peppering Injection Technique for Chronic Plantar Fasciitis: Protocol for a Parallel Randomized Clinical Trial

Randomized Injection Technique for Chronic Plantar Fasciitis

Informed Consent Form to Participate in Research

Michael A. Jones, D.P.M., Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to evaluate the safety, efficacy, and clinical outcomes related to a treatment for chronic plantar fasciitis using an injection technique called needle peppering. This technique involves repeatedly injecting small quantities into several spots in your symptomatic heel. You are invited to be in this study because you have chronic plantar fasciitis, a painful heel condition. Your participation in this research study will involve five visits. The first visit where you will receive the injection will last approximately 60 to 90 minutes. The four follow-up visits will last 30 to 60 minutes. The length of participation in the study will be twelve (12) weeks in total.

Participation in this study will involve receiving one of two injections, either a local corticosteroid (anti-inflammatory medicine) or saline, both with the addition of a local anesthetic (numbing medicine). This will be injected in a peppering fashion as described above on the affected heel. In this study, the local corticosteroid injection will be compared to a placebo, which in this study will be the saline injection. A placebo is a substance, like a sugar pill, that is not thought to have any effect on your disease or condition. Placebos are used in research studies to see if the drug being studied really does have an effect. You will be randomly assigned to receive the local corticosteroid or the placebo. You nor the physician administering the injection will be told which of the two injections you received until the conclusion of the twelve-week study period.

All research studies involve some risks. A few risks to this study that you should be aware of is the potential for pain, bleeding, decreased sensation, and or infection at injection sites. Additionally, swelling in the treated area, weakness of the injected foot, and allergic reaction (ranging from minor to severe life-threatening anaphylaxis) to the corticosteroid or placebo is possible. Receiving the corticosteroid carries the risk of gradual heel fat loss, rupture of the connective tissue on the bottom of your foot, and break down of fibroblasts (cells that are responsible for connective tissue formation). You may or may not benefit from participation in this study, meaning that your heel pain might not get better while you are in this research study and could potentially become worse.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include continuation of conservative treatment such as shoe inserts/orthoses and stretching exercises. Additionally, you may discuss with your health care provider alternative treatments such as physical therapy, surgery, extracorporeal shock wave therapy, and steroid injections. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

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. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator, Dr. Michael A. Jones, at [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, please contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies help scientists learn new information that may help other people in the future. You are being asked to be in this study because you have chronic plantar fasciitis, a painful heel condition. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. 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?

The purpose of this research study is to assess the safety, efficacy, and clinical outcomes associated with an injection technique called infracalcaneal needle peppering. This technique involves the physician inserting the needle into the tender spot of your heel and injecting a substance while withdrawing the needle at the same time. Before actually allowing the needle to completely exit the skin, the physician instead will redirect and reinsert the needle to again inject some more of the substance into this new area, repeating this process 20-25 times. Needle peppering allows for the creation of various fenestrations (small holes), allowing for extra blood flow to your heel and your body to respond to the disrupted tissue. Peppering is thought to encourage your body's natural reparative response, leading to recovery, hence potentially decreasing the heel pain that you are experiencing. The principal investigator believes that it is the injection technique that creates the benefit, regardless of what substance is being injected. In this study, we will be comparing how patients' symptomatic heel feels after infracalcaneal needle peppering as their therapeutic treatment for their chronic plantar fasciitis. Participants of this study will be randomized to receive either a local corticosteroid (anti-inflammatory medicine) with a local anesthetic (numbing medicine) or a placebo, saline, with a local anesthetic. The local

anesthetic that will be used in this study is lidocaine. If you are randomized to receive the local corticosteroid, the corticosteroid that will be injected is dexamethasone.

Specific Goals

Phase 1	Assess the feasibility of injecting a local corticosteroid using the infracalcaneal needle peppering technique versus the placebo (a saline injection) and see what effects (good and bad) it has on you and your condition. This includes how well you tolerate the injection, how long it takes to administer, and other factors.
Phase 2	Assess how effective (good and bad) the intervention is on you and your condition.

In this study, the local corticosteroid will be compared to a placebo. A placebo is a substance that is not thought to have any effect on your disease or condition. In this study you will either receive the local corticosteroid injection or placebo which is not active. Placebos are used in research studies to see if the drug being studied really does have an effect. The placebo in this study is saline.

Local corticosteroids have been approved by the US Food and Drug Administration (FDA) for treatment of plantar fasciitis. In this study, our investigators are proposing that it may be the peppering technique, as opposed to the substance, that is therapeutic.

How Many People Will Take Part in the Study?

Approximately 50 people will take part in this study. This is a single institution study that will be conducted at Atrium Health Wake Forest Baptist Department of Orthopaedic Surgery – Podiatry Services located in High Point, North Carolina.

What Is Involved in the Study?

At your first visit, you will be randomized into one of the study groups. You will either be randomly assigned to receive the local corticosteroid with a local anesthetic (numbing medicine) or the placebo with a local anesthetic. Randomization means that you are put into a group by chance. It is like flipping a coin.

Neither you nor the investigator will know which study injection you are receiving. This is done so that a fair evaluation of results can be made. This information is available to the researchers if needed in an emergency.

You will be asked to complete self-assessments of your foot function, general heel pain, and also first step pain (pain you feel in your heel when you get out of bed in the morning or after prolonged sitting). The physician will perform a physical exam including measuring your foot posture, assessing your heel tenderness score, and performing a baseline heel pain pressure threshold reading using a dolorimeter (device used to help quantify pain). An x-ray of your symptomatic foot/heel will be taken if not previously performed. This is considered standard of care, meaning that regardless of your decision to participate in this study, this could be

diagnostic imaging that a provider may order to better understand your heel pain. Additionally, an ultrasound will be obtained of your symptomatic foot/heel. The ultrasound is only for investigational research purposes, and is not considered standard of care for diagnosis and treatment of plantar fasciitis.

Once you and the physician are ready, your heel will be sterilely prepped with alcohol. A topical anesthetic "cold spray" (i.e. ethyl chloride) will be sprayed onto your skin. The unlabeled syringe wrapped in non-see-through material will be given to the physician, who will then inject the contents of the concealed syringe using the needle peppering technique described above. You will be given care instructions and an appointment to return for your first follow-up visit in 2 weeks. Additionally, you will be taught 3 exercises and encouraged to do these exercises at home to help your heel. An exercise diary will be given to you, and you will be asked to track when you complete the recommended exercises over the next 2 weeks. You will be instructed to bring the diary with you to your next visit. You will receive 1 phone call from a study team member to remind and encourage you to complete your exercise diary.

At the first follow-up visit (2 weeks after the initial injection), you will once again be asked to complete self-assessments of your foot function, general heel pain, and first step pain. Additionally, you and the physician will review the 3 exercises and your completed exercise diary. You will discuss with the physician how you are feeling and any changes and or progress that you have noticed since your last visit. A physical exam will be performed, in addition to getting another heel pain threshold reading using a dolorimeter and heel tenderness score. Any questions you have will be answered. A new exercise diary will be given to you, and you will be asked to track anytime you complete 1 of the 3 exercises over the next 2 weeks. A study team member will call you 1 time before the next visit to remind and encourage you to complete your exercise diary.

You will be asked to return for a second follow-up visit in 2 weeks (4 weeks after the initial injection). At this visit, you will once again be asked to complete self-assessments of your foot function, general heel pain, and first step pain. Like the first follow-up visit, you and the physician will review the 3 exercises and your exercise diary again. You will receive a new exercise diary and be asked to track your exercise over the 4 weeks between your next visit. A physical exam including a heel tenderness score evaluation and heel pain threshold reading using a dolorimeter will be performed. You will receive 1 phone call from a study team member to remind and encourage you to complete your exercise diary.

Two more follow-up visits will be scheduled (one 8 weeks after the initial injection, and the last follow-up visit being 12 weeks after the initial injection). At these two visits, you will be asked to complete self-assessments of your foot function, general heel pain, and first step pain. Your exercise diary will be reviewed and the 3 exercises will be instructed again. You will receive one last reminder phone call. The final exercise diary will be given at the 8-week follow-up visit with the final review happening at the 12-week follow-up visit. You will have the opportunity to discuss any improvements or concerns with the physician at both visits. Any questions you have will be answered. A physical exam will be performed, in addition to getting another heel pain

threshold reading using a dolorimeter and heel tenderness score. At your last visit (12 weeks after the initial injection), you will have one final ultrasound of your affected foot/heel. An exit survey will be given to you to be completed at the end of the visit.

All 5 study visits will happen in an outpatient setting, specifically Atrium Health Wake Forest Baptist Department of Orthopaedic Surgery – Podiatry Services located in High Point, North Carolina.

A summary of what will happen at each visit can be found in the table below, with characters designating whether the task is standard of care for plantar fasciitis or for investigational research purposes.

Visit #1 – initial study/injection visit	• The physician will perform a physical exam. (*) • The physician will measure your foot posture, assess your heel tenderness score, and perform a baseline heel pain pressure threshold reading using a dolorimeter. (*) • An x-ray of your symptomatic foot/heel will be taken if not already taken. (*) • An ultrasound of your symptomatic foot/heel will be taken if not already taken. (#) • You will complete self-assessments regarding foot function, general heel pain, and first step pain. (#) • You will be randomly assigned to receive the local corticosteroid or the placebo, saline. (#) • You will receive either the local corticosteroid or placebo injections with a local anesthetic. The physician will use the needle peppering technique when administering the injection. (#) • You will receive instruction on how to properly complete 3 exercises to help your heel. An exercise diary will be given to you to record when you complete the exercises over the period of time between visits. (#)
Visit #2 – first follow-up (2 weeks after Visit #1)	• You will complete self-assessments regarding your foot function, general heel pain, and first step pain. (#)

	• You will review your completed exercise diary with the physician. Afterwards, you will receive instruction on how to properly complete the 3 exercises again. A new exercise diary will be given to you to record when you complete the exercises over the period of time between visits. (#) • The physician will perform a physical exam. (*) • The physician will assess your heel tenderness score and perform a baseline heel pain pressure threshold reading using a dolorimeter. (#) • You and the physician will discuss progress and any concerns. All questions will be answered. (*)
Visit #3 – second follow-up (4 weeks after Visit #1)	• You will complete self-assessments regarding foot function, general heel pain, and first step pain. (#) • You will review your completed exercise diary with the physician. Afterwards, you will receive instruction on how to properly complete the 3 exercises again. A new exercise diary will be given to you to record when you complete the exercises over the period of time between visits. (#) • The physician will perform a physical exam. (*) • The physician will assess your heel tenderness score and perform a baseline heel pain pressure threshold reading using a dolorimeter. (#) • You and the physician will discuss progress and any concerns. All questions will be answered. (*)
Visit #4 – third follow-up (8 weeks after Visit #1)	• You will complete self-assessments regarding foot function, general heel pain, and first step pain. (#) • You will review your completed exercise diary with the physician. Afterwards, you will receive instruction on how to properly complete the 3 exercises again. A new exercise diary will be given to you to

	record when you complete the exercises over the period of time between visits. (#) • The physician will perform a physical exam. (*) • The physician will assess your heel tenderness score and perform a baseline heel pain pressure threshold reading using a dolorimeter. (#) • You and the physician will discuss progress and any concerns. All questions will be answered. (*)
Visit #5 – fourth follow-up (12 weeks after Visit #1)	• An ultrasound of your affected foot/heel will be taken. (#) • You will complete self-assessments regarding your foot function, general heel pain, and first step pain. (#) • You will review your completed exercise diary with the physician. (#) • The physician will perform a physical exam. (*) • The physician will assess your heel tenderness score and perform a baseline heel pain pressure threshold reading using a dolorimeter. (#) • You and the physician will discuss progress and any concerns. All questions will be answered. (*) • You will complete an exit survey. (#)

* = standard of care, meaning that this would take place regardless of your participation in the research study
# = for investigational purposes
Not noted in chart above: Between visits, you will receive 1 phone call to remind you to complete the exercise diary. This is not considered standard of care and is for investigational purposes only.

You may opt out of receiving reminder phone calls by checking this box. ☐

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study. Things such as x-rays and diagnostic ultrasounds can be shared with your personal physician.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

How Long Will I Be in the Study?

You will be in the study for about 12 weeks.

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.

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 the injection we are studying include:

- Pain at the injection sites
- Decreased sensation at the injection sites
- Bleeding of the injection sites
- Infection of the injection sites
- Weakness of the injected foot/leg
- Swelling in the treated area
- Tissue death (at the site of injection or throughout the body)
- Allergic reaction to the local corticosteroid or placebo (ranging from minor to severe life threatening **anaphylaxis**)
    - **Anaphylaxis** is a severe, potentially fatal, systemic allergic reaction that may cause airway constriction, skin and intestinal irritation, and altered heart rate, resulting in complete airway obstruction, shock, and death.

Your heel pain might not get better or may even get worse while you are in this research study.

Local corticosteroids, when given as directed, are expected to act at the site of application. Potential side effects of receiving a local corticosteroid (anti-inflammatory medicine) are:

- Fibroblast degradation (reduction in cells in the body that contribute to connective tissue formation and the structural framework of the human body)
- Fat pad atrophy (gradual loss of fat from the heel of your foot)
- Skin depigmentation (loss of skin color and or lightening of skin at affected sites)
- Plantar fascia rupture (tear of the connective tissue on the bottom of the foot)

There may be risks associated with the use of local corticosteroids that are not yet known. Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the research study, whether or not you think they are related to the study drug.

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.

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.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. Your heel pain might get better, stay the same, or may even get worse while you are in this research study. Payments offered to potential subjects should not be considered a benefit to be gained from this research. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study. You should talk to the researchers about all the choices you have. Instead of being in this study, you have these options:

Stretching/Strengthening Exercises

- Benefits – non-invasive
- Risks – optimal frequency and duration of stretching or strengthening exercises has not been established

Shoes Inserts / Orthoses

- Benefits – non-invasive, may provide pain relief
- Risks – controversial evidence supporting their efficacy

Steroid Injections

- Benefits – may provide short term pain relief
- Risks – tendon rupture / weakness
- * Note: A corticosteroid is a type of steroid. You could be treated with the study treatment even if you do not take part in the study.

Extracorporeal Shock Wave Therapy

- Benefits – non-invasive
- Risks – skin bruising, reddening, and swelling around the treated area

Surgery

- Benefits – *may* achieve permanent pain relief
- Risks – invasive, bleeding, infection, recurrence, fallen arch, pain worse than before surgery

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.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a research study. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

Will You Be Paid for Participating?

You will be paid a total of $100.00 if you complete all the scheduled study visits. Payments will be given by the following timeline:

Study Visit #1 – Enrollment/Injection Day	$20.00
Study Visit #2 – 2 weeks post-treatment intervention	No payment. Next payment at 4 week follow-up study visit (visit #3).
Study Visit #3 – 4 weeks post-treatment intervention	$40.00
Study Visit #4 – 8 weeks post-treatment intervention	No payment. Next payment at 12 week follow-up study visit (visit #5).
Study Visit #5 – 12 weeks post-treatment intervention	$40.00

If you withdraw for any reason from the study before completion, you will be paid only for the corresponding visits you have completed. For example, if you decide to withdraw from the study during Visit #2, you will be paid a total of $20.00.

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 Clinical and Translational Science Institute (CTSI). The sponsor 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 sponsor or the product being studied.

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 Michael A. Jones, D.P.M., at [redacted] during normal business hours or after hours and on weekends and holidays, call the after hours' pager. If calling the after hour's pager, dial [redacted] and then enter the [redacted]. You will then enter your telephone number starting with the area code where you wish to be called back at and press # again.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** demographic information (such as gender, age, race, and ethnicity), clinical office notes, and diagnostic imaging, and laboratory results.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information, collected from you during this study, will be placed in your medical record, and will 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) 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..

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 at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.

You can tell Michael A. Jones, D.P.M. 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:

Michael A. Jones, D.P.M.
[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.

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 your best medical interest, your condition worsened, 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, Michael A. Jones, D.P.M.,[redacted] during normal business hours or after hours and on weekends and holidays, call the after hours' pager. If calling the after hour's pager, dial [redacted]. You will then enter your telephone number starting with the area code where you wish to be called back at and press # again.

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