**Subject Consent for Research Study of :**

**TITLE:** A Prospective Study of Recurrence Risk in Diabetic Foot Ulceration after Nerve Decompression

**PROTOCOL NO.:** None
WIRB® Protocol #20122035

**SPONSOR:** Stephen Barrett, DPM

**INVESTIGATOR:**
Stephen L Barrett, DPM
2520 Windy Hill Rd SE Suite 205
Marietta, GA 30067
(470) 382-0886
United States

**SITE(S):**
Maria M. Buitrago, D.P.M., M.S
810 Waugh Dr. Suite 200
Houston, TX 77019
United States

Damien Dauphinee, DPM
Complete Foot and Ankle Care of North Texas, PA
Suite 111
3319 Unicorn Lake Blvd
Denton, Texas 76210
United States

Indiana Foot & Ankle
645 W5th Street
Jasper, Indiana 47546
United States

Stephen L Barrett. DPM
2520 Windy Hill Rd SE Suite 205
Marietta, GA 30067
United States

John Powers, DPM
NW Allied Physicians
6130 N La Cholla Blvd #135A
Tucson, AZ 85741
United States



Subject Initials _____

Douglas P. Murdoch DPM
Director - Podiatric Medicine and Surgery Residency Program
Baylor Scott & White Health
Department of Surgery – Division of PODIATRY
Temple Podiatry – South Loop Clinic
2601 Thorton Lane, Suite 200
Temple, Texas 76502

NW WY Wound Care Center
1401 W 5th Street
Sheridan, Wyoming 82801
United States

**STUDY-RELATED PHONE NUMBER(S):**

Stephen L Barrett, D.P.M.
(832) 524-7254
(470) 382-0886)

D. Scott Nickerson, M.D.
307-674-9875
307-752-9875

You have been informed of the research study "A Prospective Study of Recurrence Risk in Diabetic Foot Ulceration after Nerve Decompression" which is testing whether this surgery can provide improved protection against getting another foot ulcer. You have been informed that you are qualified to participate in this study and are willing to have the nerve decompression surgery.

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

**SUMMARY**

- You are being asked to be in a research study.
- Your decision to be in this study is voluntary.
- If you decide to be in this study and then change your mind, you can leave the study at any time.
- You are a desirable study participant because you have diabetes, nerve damage (neuropathy), adequate circulation and have healed a previous foot ulcer.

- The study will compare your risk of having a foot ulcer recur using either the best current treatments and foot care, or best treatments plus an outpatient operation for release of foot and leg nerves.
- The care (treatment) you receive in this study is standard medical care and will not change or replace your usual medical care from your doctor.
- The surgical procedure in this study is not experimental. The known risks of the surgery include delayed healing of the operation wound (5%). Any surgical wound can become infected (2% or less). Also, a nerve could be accidentally damaged during the course of the procedure.
- You will be in this study for about *2 years* and have about *8* study visits.
- If you agree to be in this research study, your medical records will become part of this research. They may be looked at or copied by the sponsor of this study or government agencies or other groups associated with the study.
- If you are injured in this study, your medical insurance may be billed for any treatment you need, or for standard medical care that you receive as a part of this study. Your insurer would then have access to the research records and would know that you were in this study. Your insurance company may not pay for treatment associated with a research study, and your participation could affect your insurance coverage.

More detailed information about this study is in this consent form. Please read it carefully.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time using ClinicalTrials.gov identifier #NCT01762085.

**PURPOSE OF THE STUDY**

The purpose of this research study is to test an experimental use of a common surgery called nerve release, nerve decompression or neurolysis. Such surgeries are used for relief of pain and numbness in conditions where nerves are pinched, such as carpal tunnel syndrome. The surgery may protect against or prevent re-occurrence of your diabetic foot ulcer, and the foot infections or amputation complications which can follow.

You are being asked to be in this study because you have diabetes, nerve damage (neuropathy), adequate circulation and have recently healed a previous foot ulcer. Foot ulcers can lead to serious complications, sometimes even as serious as amputation of a toe, the foot or leg, or even death. You currently have a risk of developing another foot ulcer of 25% per year.

Small studies of nerve release have shown that previous diabetic foot ulcer patients who have had this nerve release surgery have recurrence rates of under 5% per year. This use of nerve release specifically for prevention of another diabetic foot ulcer is investigational.

In this study, all subjects will receive the usual care for healed foot ulcers. Two thirds of the people in the study will be randomly selected to also have the outpatient surgery called nerve decompression. The additional effects of nerve surgery on *reducing risk of another foot ulcer, and how well people tolerate it* will be measured. It will be compared to the results for subjects receiving only the usual care for healed foot ulcers. The usual care will be called placebo treatment. The surgical intervention procedure will be called nerve release, nerve decompression or neurolysis.

You cannot choose if you will be receiving usual care or nerve release. This is decided by chance. You will not know in advance which treatment will be assigned to you.

You will be in this study about *24* months or longer. Approximately *120* subjects will participate in this study at several sites around the country, each treated by their usual foot care specialists. If you are assigned to the surgery group, both legs will need to be treated with nerve decompression, otherwise surgery would only protect one of your two legs. Three weeks or more will separate the two surgeries.

**PROCEDURES**

You will be asked to sign the consent document before any study-specific assessments or procedures are performed.

A screening examination (medical history, physical and neurological examination including vital signs, height and weight) will be performed. You will be asked to complete a questionnaire during your screening visit to evaluate the severity of your neuropathic symptoms and pain.

You will be randomly assigned (by chance) to one of the following groups:

*Usual Care*- Foot care instructions, professional foot examinations every 3 to 6 month, callus trimming as needed, recommendations about footwear and insoles

*Usual Care plus Nerve Decompression Surgery*- Outpatient surgery under anaesthesia for nerve decompressions, through 4 small incisions at four locations: leg, ankle and foot.

If you are assigned to the decompression surgery you will need protected walking with walker or crutches and full weight bearing for 2-3 weeks after surgery until stitches are removed.

You cannot choose which group of treatment you will be in.

You have a 1 in 3 chance to either be in the group that will receive Usual Care 2 in 3 chance of being in the group that will receive the Usual Care plus Nerve Decompression

Surgery.

**RISKS AND DISCOMFORTS**

Any surgery around nerves has a risk of an injury to the nerve, even with very experienced surgeons. The injury might recover fully, or result in permanent numbness or pain. The risk is under 1%.

Anaesthesia risk is small with current techniques and monitoring, also under 1%. These risks vary with the anesthesia technique used. You will need to discuss the risks of your anesthesia with the study doctor.

Mild incisional soreness may last for a few days. Pain pills can be used if needed although many patients do not find this necessary.

Surgical wound infections are risks present with this surgery, and you are at higher risk because you have diabetic neuropathy. Other research has found infections in 10% or more of foot and ankle operations on diabetic patients. The infection risk has been much lower in studies of this nerve surgery, perhaps because the neuropathy has been improved.

Occasionally minor skin loss or delayed wound healing, requiring only wound dressings, has occurred at the ankle incision of this surgery. This risk may be around 5%.

There may be side effects which are unknown at this time.

Your diabetes and its control should not be affected by nerve surgery. Your medications for diabetes treatment will most likely be unchanged.

**NEW FINDINGS**

You will be told about any new information that might change your decision to be in this study. 2017 data suggests that the nerve decompression surgery is effective and long-lasting for painful diabetes neuropathy.

**BENEFITS**

Your pain and numbness in the feet may improve as a result of your participation in this study. However, there is no guarantee of this.

The information from this research study may lead to a better treatment in the future for people with diabetic nerve damage (neuropathy), pain and numbness. There may be a reduced risk of another foot ulcer wound.

## COSTS

There are no additional charges for the study visits. Your insurance may be billed for the costs of your surgical care. If you have Medicare Advantage (Medicare managed care plan), you should contact someone at your plan before you start a clinical trial. They can provide more information about additional costs you could incur from participating in clinical trials. You will not be responsible for charges above the insurance payments. If you do not have insurance, talk to the study doctor about whether you will receive a discount on the surgery.

## PAYMENT FOR PARTICIPATION

You will not be paid for participating in this study.

## ALTERNATIVE TREATMENT

If you decide not to enter this study, there are other choices available. The usual foot care by your treating doctor will continue to be available. Ask the study doctor to discuss these alternatives with you. You do not need to be in this study to receive treatment for your condition. Your alternative is to choose not participate in this study.

## AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

**What information may be used and given to others?**
If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about:
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires

If you receive hospital services as part of this trial, this consent form will be placed in and made part of your permanent medical record at the hospital.

**Who may use and give out information about you?**
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

**Who might get this information?**
Your information may be given to the sponsor of this research, "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor.

For this study, "sponsor" is the Association of Extremity Nerve Surgeons (AENS) Extremity Nerve Research Foundation (ENRF).

Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Western Institutional Review Board

**Why will this information be used and/or given to others?**
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The information may be reviewed by Western Institutional Review Board, WIRB®. WIRB is a group of people who perform independent review of research as required by regulations.

**What if I decide not to give permission to use and give out my health information?**
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

**May I review or copy the information obtained from me or created about me?**
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information *until after the research is completed*.

**May I withdraw or revoke (cancel) my permission?**
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission. This permission will be good until the end of the research study.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

**Is my health information protected after it has been given to others?**
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

## COMPENSATION FOR INJURY

If you are injured or become ill as a result of participation in this study, contact the study doctor immediately. Emergency medical treatment will be provided by the study doctor. Your insurance will be billed for such treatment. The sponsor will not pay any charges that your insurance does not cover. No other compensation is routinely available from the study doctor or sponsor.

By signing this consent form, you will not give up any legal rights.

## VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- if it is in your best interest;
- or for any other reason.

Please contact the study doctor at 602-938-6960 if you decide to withdraw from the study. If you leave the study before the final regularly-scheduled visit, you may be asked by the study doctor to make a final visit for some of the end of study procedures.

**SOURCE OF FUNDING FOR THE STUDY**

The study doctor is not being paid by the AENS ENRF to conduct this research. The ideas being studied in this research are an effort by your study doctor and others in the AENS to investigate their suspicions that nerve decompression is unrecognized as a treatment for protection of the feet of patients with diabetes from high risk of recurrence of ulcer and more serious associated complications like wound infection and amputation. Private donations may be covering some of the research expenses of this study.

**QUESTIONS**

Contact your surgeon at their office number for any of the following reasons:

- if you have any questions concerning your participation in this study,
- if at any time you feel you have experienced a research-related injury or a reaction to the study drug, or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research participant or concerns, input or complaints about the research you may contact WIRB at:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

**CONSENT**

I have read the information in this consent form (or it has been read to me). All my questions about the study and my participation in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____
Subject Name

**CONSENT SIGNATURE:**

_____ _____
Signature of Subject Date

_____
Printed Name of Person Conducting Informed Consent Discussion

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

**---------- Use this witness section only if applicable ----------**

*If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:*

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

_____
Signature of Impartial Witness Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.