

Research Subject Screening Document

Project: Nerve Decompression for Ulcer Recurrence Avoidance (DURA)

We are responding to your expression of interest in a research study we will be doing. The purpose of the study is to evaluate the effectiveness and safety of a simple nerve surgery procedure for protecting you against recurrence of your recent diabetic foot ulcer.

Participation in this study would last about 2 years, would require up to 9 visits to our office. About half of study participants will have an outpatient surgery to relieve compression of trapped nerve in your leg and ankle. The comparison control group will continue with usual “best” care.

To see if you might qualify for this study, I need to ask you some questions about your health history and present condition. Some of these questions may be sensitive, such as questions about your alcohol use or diabetes control. You do not have to answer any questions you do not want to answer. You may stop this interview at any time. If you do not qualify for this study, the information you give me will be destroyed immediately or handed over to you. Do I have your permission to proceed?

Thank You.

To be eligible to participate in this study you must have previously healed a diabetic foot ulcer and have good circulation in your feet. Is this true in your case? You must be willing to allow researchers to review the details of your past medical history, laboratory tests and treatments and provide a complete list of prescriptions and over the counter medicines and any herbal remedies you use.

You must be willing to answer questionnaires about nerve problems and pain, and to allow painless testing of your sensation of vibration and touch. You must commit to participation in follow-up exams and questionnaires every three months for two years.

Most importantly, you may be selected to have nerve surgery to free up four nerves in both of your legs and feet. Some subjects in this study will receive the usual care which your doctors provide after an ulcer has healed. The other group will have the nerve releases to test whether they have fewer repeat ulcers. If you are not willing to have the nerve surgery you cannot be a part of the study.

Are you willing to have the nerve decompression surgery?

Are you willing to be assigned by chance to the group not having surgery?

If you want to have the nerve surgery, and are unwilling to risk assignment to the group receiving only usual care, you can enter another arm of the study, which is not randomized by chance to either of the treatment groups. This study arm will be called

the Prospective study group and will be different only in the statistical methods used to analyze the results.

Have you had any of the following situations, which will disqualify you from the study:

- trouble with anaesthesia
- surgical wound infection or wound healing troubles **aside from your foot ulcer**
- poor leg circulation or blood vessel surgery
- absent foot pulses or predictable muscle cramps and pain with walking
- past leg nerve problems including nerve surgery or pinched nerve in the back
- thyroid disorders, vitamin B12 or Folate deficiency, liver disease, kidney disease, nerve toxin exposure including alcohol abuse(more than 2 drinks most days) or chemotherapeutic agents
- nerve or muscle diseases in your family.
- Severe ankle swelling
- **Hemoglobin A1c value higher than 8.0 will delay your participation until sugar levels are improved.**

Introductory Statement Continued:

Body of Screening Form

- The Board expects to see the actual questions that will be asked, not just a general statement such as “inclusion/exclusion criteria addressed.”

Closing Statement

- The script must include a closing statement informing the subject of whether or not they have met the preliminary screening requirements.
- The script must address in a closing statement whether the information received from the subject will be destroyed immediately, or whether it will be stored, and if so for how long and where.
- If the site would like to keep information for future contact for new studies, this must be described to the subject as well, and the subject must have an opportunity to decline.

Additional Issues

- The screening script must be in language understandable by lay people. If complicated medical terms must be included in the screening script, please provide WIRB with an explanation of how they will be explained to the subjects.
- WIRB realizes that the script may not be followed verbatim, as subjects may ask additional questions or stray from the topic. This is acceptable, but WIRB expects that the interviewer will keep as closely as possible to the spirit and letter of the script.
- It is useful to WIRB if the investigator informs WIRB of the use of the recruitment screen; e.g., if it is going to be used with subjects calling in from advertisements, for calling patients listed in a database, or for conducting cold calls.

