Diabetic Neuropathy Clinical Trials: Determining Patterns About Medical Trial Experiences of Diabetic Neuropathy Patients

Informed Consent Form For Diabetic Neuropathy Clinical Trial Patients Enrolled in Power Clinical Trial's Observational Study

Date: July 13, 2022

Initial Note

This Informed Consent Form is divided into two sections:

- Information Sheet (This is where we share information about the clinical trial with you)
- Declaration of Consent (This is where you put your signature if ever you agree to participate)

A copy of this document will be provided to you upon accomplishment.

Part I: Information Sheet

Introduction

This informed consent form is an invitation to join an observational medical study that aims to understand the different factors that affect your clinical trial experience - why you join, continue to join, or withdraw from a clinical trial.

Please do not rush your decision to participate in this research. You can consult with someone you trust to discuss this.

This consent form may have some terms that are not familiar to you. Please note that you can request the personnel conducting the informed consent discussion to halt and explain any words or terms you do not understand.

This proposal has been reviewed and has received approval from our Institutional Review Board (IRB). Our Ethics Review Committee also carefully reviewed the proposal to protect participating diabetic neuropathy patients from harm. This research is certified and compliant with prevailing ethical principles and federal human subject regulations.

Purpose of This Diabetic Neuropathy Clinical Trial

Historically, participation in clinical studies is highly skewed towards some groups. However, the studies pinpointing the negative and positive factors that impact participation are limited.

We believe that as a diabetic neuropathy clinical trial patient, you can help us find these factors by sharing your experiences during the course of the interventional medical study you are currently enrolled in.

This study will invite several participants to gather a wide range of information on clinical trial experiences. We hope to find factors that limit the ability of a person to join in a diabetic neuropathy clinical trial and the reasons why they finish or withdraw.

The analyzed data will then be used to help future diabetic neuropathy patients recruited to participate in a medical study.

Type of Research

This is an observational clinical trial. If you decide to participate, you will not be required to take on a new treatment program. Your current care process shall remain unchanged. You will only undergo a series of interviews so that we can gather data. The researcher involved in this observational study cannot diagnose or advise any treatment.

Observational Clinical Trial Participant Selection

As a participant, it is a requirement that you are already enrolled in a separate interventional diabetic neuropathy clinical trial. We wish to understand what made you decide to join your current trial and know the reason why you would choose to continue or stop your treatment process.

Voluntary Participation in the Diabetic Neuropathy Clinical Trial

Your participation in this research is purely voluntary. It is your decision to join this or not. Your participation in the trial will not affect your current treatment process under a separate interventional clinical study. You can even choose to participate and then stop any time if you do not feel comfortable with the process. Whatever your choice, it will have no bearing on your work or job evaluations, and you are not waving any right.

Observational Diabetic Neuropathy Clinical Trial vs. Other Trials

Other clinical studies available for diabetic neuropathy patients are interventional, which require that you enroll in a definite course of treatment. Since our trial is observational, we will not offer you a treatment or care program of any sort.

Our staff cannot memorize all studies regarding diabetic neuropathy trials. However, if you feel you want to know more, kindly read diabetic neuropathy trials on clinicaltrials.gov or find other diabetic neuropathy clinical trials on Power's reference site.

Procedures and Duration

If you accept participation in this research, you will be asked to answer bi-weekly surveys. These surveys usually take 30 minutes to complete. We will also conduct quarterly check-in calls throughout the duration of the separate interventional clinical trial you are involved in.

Please note that even if your enrollment in a separate interventional clinical study is required before you can participate, that trial, from the diagnosis to treatment, and care process, is completely unrelated to our observational clinical trial. If you have questions regarding your other trial, please direct them to your personal care team.

You will not be required to share personal opinions, experiences, or learnings, especially if you are not comfortable sharing them.

You can accomplish the survey yourself, or personnel can read it to you, and you can state your answer out loud. If you do not want to discuss any of the queries in the survey, you may skip them and then proceed to the next one.

The data that will be collected is confidential, and your name will not be reflected on the survey forms.

Risks

There is a risk that you might divulge confidential data by chance or that you may be uncomfortable discussing some questions or topics. We want to avoid this. You do not have to discuss information or answer a question if you think that the topic is too personal or if it makes you uncomfortable in any way.

Benefits

As a diabetic neuropathy patient, there will be no direct benefit to you, but your decision to participate will help us find out the positive and negative factors influencing clinical trial experiences of diabetic neuropathy patients. This will greatly benefit individuals who will enroll in future trials for this condition.

Confidentiality

Please be assured that we will maintain complete data confidentiality with respect to the information you share, including any personal data. We will not share this data with anyone outside the research team. All call logs, digital copies of the consent forms, and data obtained will be handled privately and protected by encryptions and passwords. Any information about you will be labeled through numbers instead of your name to uphold the anonymity of the diabetic neuropathy patients.

Right to Refuse or Withdraw

This is a reconfirmation that your participation in this clinical trial is voluntary. You do not have to join this clinical trial if you do not wish to. Choosing to participate also includes your right to refuse participation at any time, should the process be against your beliefs or if it is too uncomfortable for you.

Learning More About Representation in Clinical Studies

There are some studies that have researched clinical trial participation rates. You can read a few of them below:

Woods-Burnham, Leanne, Jabril R. Johnson, Stanley E. Hooker Jr, Fornati W. Bedell, Tanya B. Dorff, and Rick A. Kittles. "The role of diverse populations in US clinical trials." *Med* 2, no. 1 (2021): 21-24.

Sekijima, Yoshiki. "Clinical diversity, diagnosis and treatment of hereditary amyloid neuropathy." *Rinsho Shinkeigaku= Clinical Neurology* 54, no. 12 (2014): 953-956.

Part II: Certificate of Consent

Participant's Declaration

I have been invited to participate in this observational diabetic neuropathy clinical trial. I am currently enrolled in a separate interventional clinical trial as a diabetic neuropathy patient.

I have read the foregoing consent form, or it has been discussed with me. I was allowed to ask questions about topics I did not understand. My questions have been answered satisfactorily. I voluntarily consent to join this observational study.

A copy of this consent form has been furnished to me.

Print Name of Participant: _____

Signature of Participant: _____

Date: _____
Day/Month/Year

If Illiterate

I have witnessed the permission form correctly read to the prospective participant, and the subject has had the opportunity to ask questions. I certify that the individual willingly provided consent.

Print Name of Witness:_____ Thumb Print of Participant

Signature of Witness: _____

Date: _____
Day/Month/Year

Declaration by the researcher/person taking consent

I read the consent form to the prospective participant properly and, to the best of my abilities, ensured that the person understood the procedure.

I affirm that the participant was given a chance to ask questions concerning the study and that all questions were answered appropriately and to the best of my abilities. I affirm that the subject was not pressured into consenting and that the consent was given freely and voluntarily.

The participant has been given a copy of this ICF.

Print Name of Person Taking the Consent: _____

Signature of Person Taking the Consent:_____

Date: _____
Day/Month/Year