Multiple Sclerosis Clinical Trials: Finding Patterns In Clinical Study Experiences of Multiple Sclerosis Patients

An Informed Consent Form For Multiple Sclerosis Clinical Trial Patients Joining Power Clinical Trial's Observational Study

Date: August 10, 2022

Initial Notes

If you are joining this observational clinical trial, please note that this informed consent form has two parts:

- Information Sheet
- Consent Declaration

The information section is where we share the things you need to know regarding the clinical trial, and the consent declaration section is where you must sign after making the decision to enroll.

Additionally, we will give a document copy of this ICF after signing.

Section One: Information Sheet

Introduction

Thank you for your interest to join in this observational clinical trial. This document for consent declaration will serve as an invitation for you to join this study with the purpose

of understanding the many factors affecting your overall clinical study experience. We aim to study why you decide to enroll, stay, or quit a clinical study.

It is important that you think about your decision carefully. You are allowed to talk to other people, especially your care providers or family, to help you decide.

If you encounter any unfamiliar terms while going over this consent form, please raise your hand and ask personnel to explain what you don't understand.

Why is This Multiple Sclerosis Clinical Trial Being Done?

Usually, medical study participation favors some specific demographic. The problem is that the number of research revealing the positive and negative factors that affect clinical trial participation is scarce.

As a multiple sclerosis patient, you can allow us to find these patterns by disclosing what you feel or know while you are undergoing a clinical trial.

This research involves a lot of participants with the aim of gathering data on their experiences. By analyzing the data, the research team can learn about the reasons why an individual decides to join, stay, or withdraw from a multiple sclerosis trial.

The assessed data will be utilized to improve the future medical trial experiences of multiple sclerosis patients.

About the Research

The clinical trial that you are about to enroll in is observational. If you join, we will not impose a new care program or treatment for you. Your current clinical trial will not be altered in any way. You will take surveys and interviews for the benefit of data collection. The personnel or researcher that will help you in this observational trial will not give any diagnosis or suggest treatments.

Choosing of Participants

You must be a participant in another independent medical trial for multiple sclerosis to take part in this research. We are interested to know why you made the decision to enroll in this study and other factors that influence you to continue receiving treatment or not to continue it.

Participation in the Multiple Sclerosis Clinical Trial

Your contribution to this research is on a voluntary basis. This will not impact your independent treatment course under another interventional clinical trial. Even if you make the decision to join, you are welcome to stop participating if you don't feel safe with the process and procedure. You are not renouncing any legal rights.

Comparing With Other Trials

Multiple sclerosis patients can enroll in interventional medical studies. With this type of trial, you would need to adopt a particular treatment plan. Unlike interventional studies, we will not recommend or give a new therapy routine because our research study is observational.

Our staff cannot recall every piece of research or literature on multiple sclerosis. Please read about multiple sclerosis trials on clinicaltrials.gov or look for multiple sclerosis clinical trials on Power's website if you want some more trusted resources.

Duration and Procedures

As a participant, you must respond to questionnaires biweekly. It normally takes half an hour to complete one of these survey forms. Throughout the trial, you must attend check-in calls conducted every three months.

Kindly note that, even if you must take part in an independent interventional study as a requirement, everything about that other trial—from the initial diagnosis to the care and treatment process—is fully independent of our observational medical experiment. Kindly have a discussion with your own care team once you have something to inquire about your other medical trial.

If you find yourself feeling uncomfortable discussing your beliefs, lessons learned, or experiences, you will not be forced to share anything.

You can write on the questionnaires and surveys yourself or have staff read them to you while you give your answers aloud. Kindly skip any survey questions and jump to the next portion if you are not comfortable talking about them.

Be assured that your name is not reflected on the documents, and the details we will gather are anonymous.

Risk and Benefits

Please know that we will keep confidential any informational material you share, including any personal data. The data in this study is limited to the research team. The information gleaned, including phone logs and digital consent forms, will be kept and secured by encryption and passwords. We aim to protect the identities of patients who have multiple sclerosis, so you will be identified by numbers rather than your name.

A breach of confidentiality may happen if you reveal personal or private information unknowingly. We aim to prevent this. If you believe that the subject is a tad too personal or if you feel awkward answering the staff, you are not forced to divulge details or respond to a question.

This study affords no direct advantage or benefit to patients with multiple sclerosis, but your participation will shed light on the factors that influence clinical research experiences for patients with multiple sclerosis. This will be very helpful for anyone who will enroll for future tests for this condition.

Declining or Ending the Trial

Your voluntary participation in this study is important. You can participate or withdraw, depending on whether the process does not align with your personal values or makes you feel uncomfortable. If you choose not to participate in this clinical study, we will not coerce you to do so.

Useful Links On Representation in Clinical Research

If you want to read about other studies on clinical study participation, here are some links you might find useful:

Knepper, Todd C., and Howard L. McLeod. "When will clinical trials finally reflect diversity?." (2018): 157-159.

Kailas, Ajay, Morgan Dawkins, and Susan C. Taylor. "Suggestions for increasing diversity in clinical trials." *JAMA dermatology* 153, no. 7 (2017): 727-727.

Section 2: Consent Declaration

Participant's Declaration

I have read this informed consent form and have had it thoroughly explained and discussed. I was allowed to ask questions about the portions of this informed consent form that I did not fully comprehend. All my queries have been answered to my satisfaction.

Thus, I am voluntarily joining this observational clinical trial and declare my intention to do so by signing below. A copy of this document for consent has been given to me after signing.

Printed Name of Participant: _____

Signature of Participant: _____

Date: _____
Day/Month/Year

If Illiterate

I hereby certify that the prospective participant has willingly consented to join this clinical trial. I personally attest that this informed consent form was correctly discussed and read to the patient. The participant was given the time to ask questions to avoid misunderstanding.

Print Name of Witness:_____ Thumb Print of Participant

Signature of Witness: _____

Date: _____
Day/Month/Year

Declaration by the researcher/person taking consent

I read this informed consent form and made sure the individual understood all portions of the document. The individual had the opportunity to ask questions and clarify things. I affirm that the questions were answered correctly. The prospective participant was not coerced to give consent. The participant signed this form voluntarily.

After signing, the participant was handed a copy of this document.

Printed Name of Person Taking the Consent: _____

Signature of Person Taking the Consent:_____

Date: _____
Day/Month/Year