Parkinson's Clinical Trials: Assessment of Clinical Trial Experiences of Patients with Parkinson’s Disease

An informed consent form for participants in Power Clinical Trial’s observational medical study.

Date: January 5, 2023

Overview of This Consent Form

You are invited to participate in an observational clinical study on Parkinson’s. This consent form provides information about the purpose and details of the study, including what will happen during the course of the study, the potential benefits and risks, and how to ask questions or seek further advice.

Please read this form carefully and consider discussing your participation with your primary care physician, friends, or loved ones. If you decide to participate, you will be asked to sign this form and will receive a copy for your records.

Parkinson's Clinical Trials Overview

Parkinson's disease is a progressive neurological disorder that affects movement and can cause tremors, stiffness, and difficulty with balance and coordination. There is no cure for Parkinson's disease, but medications and therapies can help manage the symptoms and improve quality of life.

The purpose of this study is to examine and understand the various factors that may impact your ability to enroll and complete a clinical trial for Parkinson’s. The findings of this study will be analyzed for trends in the experiences of Parkinson’s patients that may

contribute to low enrollment or completion rates, but will not include any personally identifying information.

Please note that this study is observational and will not affect your treatment in any way. This document serves as a record of the information shared with you by our site staff or recruitment coordinators, and can also be used as a reference as a participant in this clinical study.

Parkinson's Clinical Trials - Why Are They Done?

Clinical trials often attract participation from specific demographic groups, but there is limited research on which trial attributes influence participation. This study aims to collect a diverse range of data on the clinical trial experiences of Parkinson’s patients to identify factors that may hinder a patient's ability to enroll or complete a trial. The study will also examine the data from different demographic perspectives to identify any recurring trends that may be useful for future Parkinson’s patients.

What Are the Benefits?

By participating in this observational clinical trial, you will contribute to our understanding of how to improve the experiences of future Parkinson’s patients. The findings of this study may increase enrollment and expand the diversity of future studies. Your participation will be valuable in advancing our knowledge in this area.

What Are the Risks?

Participating in clinical trials can sometimes involve changes to your treatment plan, which can carry certain risks. However, since this is an observational clinical study, there will be no changes to your treatment and therefore no risk associated with treatment changes.

The trial will involve online reporting and video calls with participating Parkinson’s patients, and there is a risk of a data breach in this process. At Power's clinical trials, we take measures to minimize this risk by ensuring that data from these calls are secured and encrypted, and call logs and electronic copies of consent forms are stored anonymously in a highly-secure environment.

What Sets This Study Apart From Other Trials For Parkinson's?

Many other studies for Parkinson's are interventional clinical trials, in which patients are required to follow a specific treatment plan that may differ from their current treatment. In contrast, this study is an observational clinical trial and will not involve any treatment recommendations or changes.

If you are interested in exploring other studies, you can search for Parkinson's trials on clinicaltrials.gov or look for other active Parkinson's clinical trials on Power's online page.

Can I Read More Related Studies on Clinical Trial Participation?

To learn more about clinical trials related to participation rates, you may find the following resources helpful:

Gray, Darrell M., Timiya S. Nolan, John Gregory, and Joshua J. Joseph. "Diversity in clinical trials: an opportunity and imperative for community engagement." *The Lancet Gastroenterology & Hepatology* 6, no. 8 (2021): 605-607.

Woodcock, Janet, Richardae Araojo, Twyla Thompson, and Gary A. Puckrein. "Integrating research into community practice—toward increased diversity in clinical trials." *New England Journal of Medicine* 385, no. 15 (2021): 1351-1353.

What Do You Have To Do in This Parkinson's Clinical Trial?

As a participant in this study, you will be required to complete bi-weekly surveys lasting approximately 30 minutes and participate in quarterly check-in calls throughout the duration of the trial.

To be eligible to participate, you must currently be enrolled in an interventional clinical trial. Your existing treatment plan as prescribed by your primary care physician will not be affected by your participation in this observational study. If you have any questions or concerns at any point during the trial, please do not hesitate to contact our staff. To enroll in this clinical study, you must also consult with your care team.

Participant Statement

I confirm that I have read the information provided above and that it has been verbally explained to me. All of my questions have been answered to my satisfaction.

I understand that participating in this observational study is voluntary and that I may withdraw at any time. Signing this form does not waive any of my legal rights. I will be provided with a copy of this consent form. By signing below, I am indicating my willingness to participate in this clinical study.

_____
Printed Name of Participant

_____
Participant Signature

_____
Date

Statement of Person Conducting Informed Consent Discussion

I have thoroughly reviewed the information in this form with the participant and can confirm that they understand the benefits, risks, and procedures associated with this Parkinson's clinical trial.

_____
Printed name of Person Conducting Informed Consent Discussion

_____
Person Conducting Informed Consent Discussion Signature

_____
Date