Clinical Trial - Analyzing Participation Experiences Of Amyotrophic Lateral Sclerosis Patients

An informed consent form for participants in Power Clinical Trial's observational clinical trial.

Date: June 14, 2022

Amyotrophic Lateral Sclerosis (ALS) Observational Study Overview

This document formally invites you to engage in an observational clinical study to learn how a range of factors during your clinical trial enrollment process affects your capacity or interest in participating in and then completing your clinical trial.

The findings of this observational research will be anonymized and examined in order to uncover trends in the patient experience that regularly contribute to lower completion or enrolment rates.

This clinical trial is an observational research, which means that if you choose to join, your treatment regimen will not be adjusted or determined. Being a participant in an observational study is not the same as being a patient.

This form is a written account of the in-person chat you had with our recruitment coordinators and site personnel. It is also meant to be a handy reference for you as a participant through the clinical trial procedure.

Important things you need to know about this clinical trial

1. Participation is entirely optional, and you may withdraw at any time.
2. Because this is an observational study, your participation has no bearing on your care. It is crucial to note that the study's staff will not be able to diagnose illnesses, provide medications, or oversee your treatment.
3. If you do not understand what our team is saying during this process, please raise your hand and let us know.

This medical research has been authorized by our Institutional Review Board (IRB). These committees, known as ethics committees in other countries, formally review research proposals to guarantee the safety and well-being of participants in line with federal human subject regulations and ethical standards.

Why is this ALS research being done?

Clinical trial participation has always been substantially skewed toward certain demographic groups.

However, there has been little study on whether trial qualities impact participation in either a positive or negative way.

The goal of this research is to identify the characteristics that consistently restrict patients' ability to participate in or complete a trial in which they were initially interested.

This data will be analyzed via a number of demographic lenses in order to find trends that could benefit future ALS sufferers.

How does this trial compare to others for ALS?

Many additional clinical trials for patients with ALS are interventional clinical studies, which require patients to follow a specific course of therapy. As this is an observational clinical trial, no therapy will be enforced or provided.

Our personnel are not well-versed in every one of the available ALS clinical trials. If you want to learn more, search clinicaltrials.gov for ALS studies or Power's participant reference site for further ALS clinical trials.

What hazards should I be aware of before participating in this medical trial?

There will be frequent online reporting and video conference meetings with participants during the project.

Changing medication regimens is always risky; therefore, enrolling in clinical research in the first place should be carefully considered.

This observational research, on the other hand, will have NO IMPACT on your treatment plan.

A violation of confidentiality is one specific danger associated with a trial.

A breach of confidentiality might result in the disclosure that individuals contacted staff to be screened and completed informed consent forms.

The likelihood of this occurring is low, and the threat of identity theft is restricted by how this data is managed. In a safe and closed office, the call log, electronic copies of informed consent forms, and de-identified information are saved and processed using rigorous encryption and password security.

This inquiry cannot be carried out without the usage of data.

What benefits should I consider before participating in this medical trial?

The outcomes of this medical study may improve participation rates and patient variety in future clinical trials targeted at recruiting ALS patients.

What should I expect as an ALS patient?

This study will include bi-weekly questionnaires that will take around 30 minutes to complete. For the duration of any clinical trial(s) you are participating in outside of this observational research, quarterly check-in calls will be organized.

While participation in a separate interventional clinical trial is necessary, the exact logistics of that trial, including therapy and method, are fully independent of this inquiry and will not be altered in any way.

Please contact your care team if you have any questions about the interventional clinical research in which you are enrolled.

Can I read more about representation in clinical studies?

Yes. You can check out the following studies on clinical trial participation rates:

Chiò, Adriano, A. Canosa, S. Gallo, Stefania Cammarosano, Cristina Moglia, G. Fuda, Andrea Calvo, and M. Gabriele. "ALS clinical trials: do enrolled patients accurately represent the ALS population?." *Neurology* 77, no. 15 (2011): 1432-1437.

Su, Xiaowei W., James R. Broach, James R. Connor, Glenn S. Gerhard, and Zachary Simmons. "Genetic heterogeneity of amyotrophic lateral sclerosis: implications for clinical practice and research." *Muscle & nerve* 49, no. 6 (2014): 786-803.

Powell, James H., and Yoland Fleming. "Making medicines for America: the case for clinical trial diversity." *Journal of the National Medical Association* 92, no. 11 (2000): 507.

Participant Statement

I have read and been orally provided with the aforementioned material, and all of my queries have been adequately answered.

I understand that my participation in the study is totally optional and that I can opt out at any time.

By signing this form, I am not waiving any of my legal rights. I understand that a copy of this consent will be provided to me.

I hereby agree to participate in this research study by signing below.

_____

Printed name of Participant

_____

Participant Signature

_____

Date

Statement of Person Conducting Informed Consent Discussion

I went through the information in this document with the participant and feel he or she understands the risks, benefits, alternatives, and procedures connected with this research endeavor.

_____

Printed name of Person Conducting Informed Consent Discussion

_____

Person Conducting Informed Consent Discussion Signature

_____

Date