A Comprehensive View of Patient Experiences of Individuals Participating in Pulmonary Fibrosis Clinical Trials

This is an informed consent form for pulmonary fibrosis patients joining Power Clinical Trial's observational medical trial.

Date: June 2, 2023

Introducing the Clinical Trial for Pulmonary Fibrosis

Pulmonary fibrosis is a complex and progressive lung disorder characterized by the scarring and thickening of lung tissue. This condition results in the impairment of lung function and restricts the ability to breathe effectively. Pulmonary fibrosis can be caused by various factors, including exposure to environmental toxins, certain medications, autoimmune diseases, and genetic predisposition.

Amidst the challenges posed by pulmonary fibrosis, a new chapter of potential breakthroughs emerges in the form of clinical trials. Clinical trials aim to revolutionize the understanding and treatment of this respiratory disorder, as researchers delve into unexplored avenues, assess promising interventions, and gather vital data to shape the future landscape of pulmonary fibrosis care. Through this clinical trial, new horizons of hope and progress are illuminated for patients and healthcare providers alike.

For this study, we are going to conduct an observational clinical trial which will not involve any new treatment or changes to your care regimen.

Our goal is to make sure you understand the study well and feel comfortable throughout the research experience. If you have any doubts or need more information, we strongly urge you to ask for clarification without any hesitation. Our study team is always available to answer any questions or concerns you may have about instructions, explanations, or any part of the study. We greatly appreciate and respect your understanding and comfort in this process.

The Purpose of This Pulmonary Fibrosis Clinical Trial

This research study aims to uncover the challenges faced by specific demographic groups of pulmonary fibrosis patients when participating in clinical trials, which have traditionally lacked diverse representation. We need to gather in-depth information from participants and identify common factors that hinder their enrollment or completion of these trials.

Through careful examination of data from various demographic perspectives, the study seeks to identify patterns that influence the experiences of future pulmonary fibrosis patients. Your active involvement in this significant research is highly valuable as it can provide unique insights to enhance the participation and completion rates of pulmonary fibrosis patients in clinical trials.

What You Need to Know and Agree to

It is entirely up to you whether or not to take part in this study, and you are free to stop at any time. It is crucial to stress that your choice to participate or not will have no bearing on how you will be treated.

In medical research investigations, ensuring voluntary involvement is a normal procedure. Furthermore, it is critical to stress that this research is purely observational, meaning that if you are already receiving therapy, your diagnosis, meds, and care will continue as usual. It is expressly forbidden for the study team to interfere with your medical care or keep track of how you are being treated.

Interventional vs. Observational Studies for Informed Participation

Enrollment in an interventional clinical trial is necessary for your participation in this research study. It is important to note that if you are already involved in a separate clinical trial for pulmonary fibrosis, joining this observational clinical study will not disrupt your current treatment plan.

If you have any concerns or questions about your participation in the interventional clinical trial, it is highly advised to consult your healthcare team for more information and clarification. Having a thorough understanding of the differences between interventional

and observational studies is crucial to ensure informed participation in this research endeavor.

Active Engagement and Follow-up Calls

You will be required to complete biweekly surveys, which should take no more than 30 minutes to complete, in order to fully participate in this observational clinical study. Additionally, particular quarterly follow-up conversations are planned for your participation in the interventional clinical trial. In order to actively participate in both components of the research, it is imperative to follow the study's guidelines by quickly scheduling and attending these calls.

Assessing Risks and Precautions in the Research Study

Within the purview of this observational clinical trial, it is crucial to underscore the risks that will be involved. As the study exclusively adopts an observational methodology, there will be no alterations to the established care regimens, thereby unequivocally obviating any potential for adverse effects upon participating individuals. Furthermore, to ensure the utmost confidentiality, we have diligently instituted robust encryption mechanisms and stringent password protection measures to fortify the impregnability of all electronic data. These rigorous safeguards efficiently mitigate the risk of unauthorized access or breaches during customary video conferences and online reporting, thereby fortifying the comprehensive framework for data protection.

Possible Benefits

This study entails significant potential benefits that merit diligent evaluation. The results from this trial will generate invaluable insights into the determinants that affect the enrollment and retention rates of a heterogeneous group of patients with pulmonary fibrosis in clinical studies. This knowledge will constitute a vital basis for improving subsequent clinical trials that seek to incorporate individuals with pulmonary fibrosis. By actively partaking in this study, you have the chance to render a considerable and meaningful contribution to the progress of our comprehension of the factors that may influence the engagement of diverse patient populations in these trials.

Highlighting the Distinctions of This Study from Other Pulmonary Fibrosis Clinical Trials

This study differs from other pulmonary fibrosis investigations in that it only uses an observational methodology, which means that participants are not required to follow a specific treatment plan.

It is important to recognize that, despite the study team's possible lack of considerable experience in prior pulmonary fibrosis research, there are resources available to offer help and direction. People might look into further study choices by looking through the extensive collection of pulmonary fibrosis studies provided by ClinicalTrials.gov. Power's reference page offers interested people additional chances for future involvement by listing a current list of pulmonary fibrosis clinical trials that are actively seeking participants.

Examining Diversity in Clinical Trials: Recommended Resources

There is not much research on the presence of diverse populations in clinical trials, but there are some studies that deliver valuable insights. We have gathered a list of recommended readings that you may find appealing and informative:

Fatumo, Segun, Tinashe Chikowore, Ananyo Choudhury, Muhammad Ayub, Alicia R. Martin, and Karoline Kuchenbaecker. "A roadmap to increase diversity in genomic studies." *Nature medicine* 28, no. 2 (2022): 243-250.

Casals-Pascual, Climent, Antonio González, Yoshiki Vázquez-Baeza, Se Jin Song, Lingjing Jiang, and Rob Knight. "Microbial diversity in clinical microbiome studies: sample size and statistical power considerations." *Gastroenterology* 158, no. 6 (2020): 1524-1528.

These suggested readings present valuable insights into the involvement of diverse populations in clinical trials, granting a wider understanding of the relevance of inclusivity in research.

Ensuring Privacy

The confidentiality of your personal information privacy and confidentiality is a primary concern in this clinical study. To certify the highest level of safety, we have implemented stringent measures.

Your records will be assigned a specific code or number to sustain absolute anonymity throughout the study. All identifying materials will be securely stored in a locked file cabinet under close monitoring of the researcher. We regard your privacy highly and are resolved to not disclose any personal information without your explicit consent, except in cases where the law compels disclosure, such as situations involving abuse or suicide risk.

Granting of Consent

By placing my signature below, I declare that I have received complete information about the nature and purpose of this study. I realize that my participation is fully voluntary, and I have the option to withdraw from the study at any time without experiencing any negative consequences. I greatly esteem the confirmation that my decision to withdraw will not affect my current or future medical care. I respectfully request a copy of this consent form for my personal records.

_____

Printed Name of Participant

_____

Signature

_____

Date

Confirmation of Participant's Extensive Understanding

As the clinical trial personnel responsible for expounding the consent form to the participant, I am glad to confirm that the participant has shown a comprehensive understanding of the risks, benefits, and procedures associated with this clinical research. Through frank and informative discussions, all questions and concerns have

been adequately addressed, ensuring that the participant has a coherent understanding of the implications and protocols of the study.

_____

Printed Name of Person Getting Consent

_____

Signature of Person Getting Consent

_____

Date