Assessing Patient Engagement and Understanding in Chronic Fatigue Syndrome Clinical Trials

This is an informed consent form for chronic fatigue syndrome patients joining Power Clinical Trial's observational clinical study.

Date: July 21, 2023

Starting Your Clinical Trial Journey With Us

As a chronic fatigue syndrome patient, you are invited to join us as a valued participant in our research study. To ensure absolute clarity on the study's purpose and the requirements for participation, we have thoughtfully written this consent form. In case you encounter any unfamiliar terms or concepts while reviewing the document, our dedicated research staff stands ready to provide comprehensive explanations.

We encourage you to take all the time you need to carefully consider your decision to participate, and we are here to address any questions or concerns that may arise. Should you find it beneficial, we also recommend discussing the study with your family or trusted healthcare professionals. It is vital to emphasize that participating in this study is entirely voluntary, and you are under no obligation whatsoever to partake.

Your involvement as a participant will play a significant role in advancing knowledge and contributing to meaningful medical research.

Introduction to the Study

Chronic Fatigue Syndrome (CFS), also known as Myalgic Encephalomyelitis (ME), is a complex and debilitating medical condition characterized by persistent and profound fatigue. This fatigue is not alleviated by rest and tends to worsen with physical or mental

activity. Individuals with CFS often experience a significant reduction in their ability to carry out daily activities, and their quality of life is severely impacted.

The purpose of this study is to meticulously examine and comprehend the various factors influencing your ability to participate in and successfully complete the chronic fatigue syndrome clinical trial enrollment process.

The data collected throughout this study will be anonymized, allowing us to analyze trends related to the experiences of chronic fatigue syndrome patients. These insights are vital as they shed light on the factors contributing to suboptimal enrollment rates and incomplete trials.

It is important to emphasize that this study is purely observational. Therefore, there will be no changes to your ongoing treatment regimen if you decide to participate.

Furthermore, this document stands as written confirmation of all the discussions you've had with our site staff or recruiting coordinators. As a participant in this clinical investigation, you can also refer to this document as a point of reference throughout your involvement in the study.

Understanding Chronic Fatigue Syndrome Clinical Trial Participation

Clinical trials have historically shown biases towards specific demographic groups, leading to a limited understanding of the factors influencing trial participation. To bridge this knowledge gap, our study endeavors to gather extensive data on the experiences of chronic fatigue syndrome patients participating in clinical trials. The primary objective is to uncover the predominant factors that impede a patient's ability to enroll or successfully complete a trial.

Additionally, our research team will conduct a meticulous analysis of the collected data from various demographic perspectives. This analytical approach aims to uncover recurring trends that hold the potential to provide invaluable insights for the future benefit of chronic fatigue syndrome patients. Armed with this knowledge, we can take proactive steps to enhance the design and execution of clinical trials, promoting broader and more inclusive participation for improved research outcomes.

Empowering Progress: The Significance of Engaging in an Observational Clinical Trial

When you choose to be part of this observational clinical trial, you become a driving force behind advancing our knowledge of chronic fatigue syndrome and how we can better support upcoming patients. Your involvement serves as a crucial contribution, unearthing invaluable insights that can pave the way for improved participation rates and greater inclusivity in future studies.

Through the meticulous collection and thorough analysis of data sourced from your participation, our mission is to pinpoint key factors that can revolutionize the overall experience for chronic fatigue syndrome patients. The findings derived from this study have the potential to revolutionize research and clinical practices, ultimately benefiting individuals impacted by this complex condition. Your active participation brings us closer to fostering a brighter future for those facing chronic fatigue syndrome.

Navigating Risks: Understanding the Safety Measures in this Observational Clinical Study

When considering participation in clinical trials, addressing potential risks is of utmost importance. However, it is essential to emphasize that this observational clinical study will not necessitate any changes to your current treatment plan, mitigating any associated risks related to treatment modifications.

Throughout the study, interactive online reporting and video calls serve as the primary means of engaging with chronic fatigue syndrome patients. It is essential to acknowledge the potential risk of data breaches during these interactions. At Power's clinical trials, we prioritize the security and privacy of your sensitive information. Robust protocols, including secure and encrypted communication channels, are meticulously implemented to safeguard the data exchanged during these calls. Furthermore, all call logs and electronic consent forms are stored anonymously within a highly-secure environment, guaranteeing the confidentiality of your data throughout the study.

More Chronic Fatigue Syndrome Clinical Trials to Consider

What sets this study apart from other clinical trials for chronic fatigue syndrome is its distinct observational approach. Diverging from the conventional interventional clinical

trials, this study is centered around careful observation and comprehensive data collection, rather than implementing specific treatment interventions.

As an observational clinical trial participant, you can rest assured that there will be no treatment recommendations or changes to your existing treatment regimen. The primary aim is to gather an extensive array of data and insights concerning chronic fatigue syndrome, its progression, and its profound impact on patients' lives. By participating in this study, you have the remarkable opportunity to contribute significantly to the growing body of knowledge and potentially influence future advancements in chronic fatigue syndrome.

For those intrigued to explore other research avenues, clinicaltrials.gov serves as an excellent resource to discover additional chronic fatigue syndrome studies. Moreover, Power's online page offers a dedicated section that delves into chronic fatigue syndrome clinical trials, providing a valuable platform for further investigation and informed decision-making.

Exploring Resources on Participation in Clinical Studies

For those seeking to further their understanding of participation rates in clinical trials, we highly recommend delving into the following valuable sources. These references offer an abundance of information and studies solely dedicated to examining and comprehending the factors that influence individuals' decisions to participate in clinical research.

By immersing yourself in this literature, you stand to gain invaluable insights into the intricate dynamics that impact participation rates. Armed with this knowledge, you contribute to the broader comprehension of clinical trial recruitment, potentially paving the way for the development of strategies that foster increased engagement and inclusivity in future research endeavors.

Resources to consider:

Jagsi, Reshma, Amy R. Motomura, Sudha Amarnath, Aleksandra Jankovic, Nathan Sheets, and Peter A. Ubel. "Under-representation of women in high-impact published clinical cancer research." *Cancer: Interdisciplinary International Journal of the American Cancer Society* 115, no. 14 (2009): 3293-3301.

Patry, Christian, Simon Kranig, Neysan Rafat, Thomas Schaible, Burkhard Toenshoff, Georg F. Hoffmann, and Markus Ries. "Cross-sectional analysis on publication status and age representation of clinical studies addressing mechanical ventilation and ventilator-induced lung injury in infants and children." *BMJ open* 8, no. 11 (2018): e023524.

Participation Guidelines for Chronic Fatigue Syndrome Patients in the Study

Embarking on this study requires active engagement in bi-weekly surveys, with each session lasting approximately 30 minutes. Additionally, throughout the duration of the clinical trial process, quarterly check-in calls will be scheduled to gather invaluable data and insights pertaining to your unique experiences as a chronic fatigue syndrome patient.

Importantly, this observational study exclusively caters to individuals presently enrolled in an interventional clinical trial. Rest assured, your primary care doctor's prescribed treatment and methodology will remain entirely unaffected by your participation in this observational study. The overarching aim is to acquire a comprehensive understanding of your journey without exerting any influence on your ongoing treatment plan.

Should any concerns or questions arise during the trial, our dedicated staff stands ready to offer unwavering clarification and support. We actively encourage you to reach out to our compassionate team at any juncture, as we are committed to providing personalized assistance and guidance throughout your participation.

Enrollment in this clinical study mandates consulting and seeking permission from your existing care team. Their invaluable guidance will serve as a guiding compass, helping to determine if this study aligns harmoniously with your individual circumstances and well-being.

Affirmation of Informed Consent

With utmost assurance, I confirm that I have devoted ample time to thoroughly read and comprehend the entire contents of the informed consent form, either independently or with the invaluable support of a trusted individual who diligently read it to me. Each of

my queries and uncertainties has been thoughtfully addressed to my absolute satisfaction.

I am unequivocally cognizant that my engagement in this study is entirely voluntary, granting me the liberty to withdraw my consent at any juncture, devoid of any obligation to furnish a rationale or encounter any financial encumbrance. Equally significant, I have been duly apprised that a copy of this informed consent form will be furnished for my personal record-keeping.

Following meticulous contemplation and contemplative introspection on all the disseminated information, I wholeheartedly bestow my consent to participate in this study, driven purely by my own volition.

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Printed Name of Participant

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Participant Signature

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Date

Confirmation of Informed Consent Discussion: Statement by the Facilitator

I hereby validate that I have engaged in a meticulous and comprehensive discussion with the participant, ensuring a thorough understanding of the contents outlined in this form.

I affirm that the participant has not only comprehended the implications but has also embraced a clear understanding of the potential benefits, risks, and procedures involved in their active participation in this chronic fatigue syndrome clinical trial. Every essential detail regarding the study has been diligently explained, and any queries or uncertainties voiced by the participant have been met with utmost attentiveness and resolution.

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Printed Name of Person Taking Consent

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Signature of Person Taking Consent

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Date