Examination of Participation Trends and Engagement Patterns of Participants in Post Traumatic Stress Disorder Clinical Trials: An Observational Study

This is an Informed Consent Form For Post Traumatic Stress Disorder Patients in Power Clinical Trial's Observational Study

Date: November 17, 2023

Introduction to the Informed Consent Form

Your completion of this form signifies potential eligibility to take part in a distinctive observational clinical investigation targeting individuals grappling with treatment-resistant depression. This detailed guide outlines the principal objectives of the study, the applied research methodology, and the potential ramifications, encompassing both positive and potentially adverse effects. Prior to making a decision, it's imperative to fully comprehend the possible consequences of engagement, and seeking guidance from your healthcare provider can offer crucial perspectives. For any uncertainties or if any part of this document seems unclear, please don't hesitate to contact the researcher or the designated personnel.

Unveiling the Importance of Clinical Trials in the Context of Post Traumatic Stress Disorder

Clinical trials dedicated to post traumatic stress disorder hold significant importance in evaluating the safety and efficacy of novel treatments designed for this condition. They serve as critical evaluative tools to discern whether new therapeutic approaches surpass traditional methods, providing substantial evidence for their broader adoption.

What distinguishes this study is its central emphasis on understanding the personal journeys of individuals contending with post traumatic stress disorder, actively involved in a clinical trial integrating medical interventions. The primary objective centers on a meticulous examination of trial completion rates and voluntary withdrawals within this distinct patient population.

How Important Are Observational Clinical Trials?

Engaging in this medical trial entails participation in an observational study, an integral facet of clinical research structured to gather insights through non-invasive monitoring of patients as they adhere to their treatment plans.

Researchers will solely observe your journey, meticulously evaluating the outcomes of your condition while maintaining the continuity of your treatment. This trial framework plays a vital role in enhancing our understanding of the natural course of a specific medical condition and its impact on individuals affected by it. Your voluntary participation in this observational study serves as a crucial contribution to advancing medical knowledge and refining the care provided to individuals facing similar health challenges.

Differentiating This Trial from Other Post Traumatic Stress Disorder Clinical Trials

It is critical to recognize the uniqueness of this study endeavor. It operates solely on an observational basis, implying that your participation will not entail any specific therapies or interventions. To make an educated choice regarding future clinical trial participation, it is critical to understand the breadth of post traumatic stress disorder clinical research, including interventional trials in which patients receive a variety of treatment regimens.

Crafting an informed decision about your prospective participation in a clinical trial necessitates an active approach involving thorough research and comparative analysis among trials. Resources such as ClinicalTrials.gov offer extensive information about post traumatic stress disorder studies. Moreover, Power's specialized online platform offers a comprehensive repository of ongoing post traumatic stress disorder clinical trials actively seeking volunteers. With thorough exploration and a comprehensive

understanding of different clinical trial types, you can confidently decide your potential involvement.

Ensuring Your Anonymity Throughout the Study

Maintaining the utmost confidentiality of your information is paramount throughout this research. To safeguard your anonymity, please refrain from including any personal or identifiable specifics in your responses to the questionnaires. The dedicated research team is steadfast in their commitment to bolstering the protection of your privacy and confidentiality. However, it's essential to recognize that specific legal situations might necessitate the disclosure of personal data.

Your Participation in the Clinical Trial

We invite you to actively contribute to this observational clinical study by sharing your perspectives and experiences. Your participation involves completing surveys every two weeks, requiring about 20-30 minutes of your time. Additionally, our team remains available for quarterly check-in calls to maintain continuous support and your ongoing involvement in the trial.

It's imperative to highlight that your participation in the survey phase of this trial is entirely voluntary. You have the choice to respond to specific questions or complete the entire questionnaire based on your preferences. Furthermore, you maintain the freedom to withdraw from the trial at any juncture. Understanding the personal significance of joining a clinical trial, our commitment is to provide essential support, uphold your privacy, and assist in your decision-making process throughout the trial.

Potential Benefits

While immediate advantages might not be readily apparent for participants in this observational clinical research, their engagement holds the promise of substantial long-term effects. The information collected from participants will be invaluable in shaping future strategies for engaging individuals facing post traumatic stress disorder, potentially expanding the scope of medical research. Participants in this clinical trial have the potential to catalyze meaningful advancements in the field of medical

research, potentially reshaping the landscape for future post traumatic stress disorder patients.

Possible Risks

Although clinical trials have led to significant progress, comprehending potential health implications for participants, particularly in drug evaluation studies, remains crucial.

Nevertheless, in observational clinical research, we adopt a unique approach to mitigate these impacts by refraining from administering experimental drugs to participants. Our central emphasis lies in careful monitoring and evaluation of outcomes, ensuring the prevention of any avoidable health risks.

Exploring Diversity in Clinical Trials

For those seeking to explore the intricate facets of diversity within clinical trials, there exists a wealth of online resources to aid in your exploration.

Whether your objective is to comprehend the complexities of diversity-related challenges and opportunities in clinical trials or broaden your own perspectives, the following resources could offer invaluable insights:

De Lacharrière, Olivier, Claire Deloche, Cosimo Misciali, Bianca Maria Piraccini, Colombina Vincenzi, Philippe Bastien, Isabelle Tardy, Bruno A. Bernard, and Antonella Tosti. "Hair diameter diversity: a clinical sign reflecting the follicle miniaturization." *Archives of dermatology* 137, no. 5 (2001): 641-646.

Editors. "Striving for diversity in research studies." *New England Journal of Medicine* 385, no. 15 (2021): 1429-1430.

Confirmation of Participant

I confirm that I've thoroughly understood and absorbed the information presented in the informed consent form. This understanding was achieved through independent review or with the guidance of professionals who explained its contents to me. I'm pleased to say that all my queries have been sufficiently answered.

_____

Participant Name

_____

Participant Signature

_____

Date

Confirmation of Facilitator

As a facilitator, I affirm that I conducted an extensive discussion with the participant, elucidating the complexities outlined in this written document. My primary aim was to guarantee the participant's comprehensive comprehension of the primary research goals, the methodology employed, the potential risks and benefits, and other integral aspects of the post traumatic stress disorder clinical trial.

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Printed Name of Assisting Researcher

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Signature of Assisting Researcher

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Date