Exploring the Clinical Trial Journey of Patients in Substance Abuse Disorder Clinical Trials

This is an informed consent form for substance abuse disorder patients joining Power Clinical Trial's observational medical study.

Date: May 19, 2023

Substance Abuse Disorder Clinical Trial Overview

Substance abuse disorder, also known as substance use disorder, refers to a condition characterized by a pattern of harmful or problematic use of substances such as drugs or alcohol. It is a complex and chronic condition that affects a person's brain and behavior, leading to difficulties in controlling substance use and experiencing negative consequences as a result.

Patients living with substance abuse disorder can actively contribute to the development of new treatments and support programs by participating in clinical trials. This trial offers them a valuable platform to share their unique experiences and perspectives. By doing so, we can deepen our understanding of substance abuse disorder and work towards improving outcomes for patients.

In order to better comprehend the reasons behind lower participation or completion rates among substance abuse disorder clinical trials patients, we are conducting an observational study. Our objective is to identify any consistent patterns in the patient experience that might contribute to these rates. We kindly invite you to participate in this trial, assuring you that all information you provide will remain anonymous and will be thoroughly analyzed.

Please be aware that this trial is purely observational and will not result in any alterations to your treatment plan. Your involvement in this trial does not entail receiving any form of treatment. This document provides detailed information about the recruitment process and the trial staff, which you can refer to whenever necessary during the trial's progression.

Informed Consent and Study Details

Your participation in this study is entirely voluntary, and you have the freedom to withdraw at any point if you choose to do so. This is a common practice in medical research studies. It's crucial to understand that your treatment plan will not be affected by your decision to participate. As an observational study, your diagnosis, medications, and care will remain unchanged if you are currently receiving treatment. The study team is strictly prohibited from interfering with your treatment or monitoring your care status.

Seeking Clarification and Support

Throughout the study, it's important to feel comfortable and fully comprehend the details. If you have any uncertainties or require further explanations, please don't hesitate to ask for clarification. The study team is readily available to address any questions or concerns you may have regarding instructions, explanations, or any aspect of the study. Your understanding and peace of mind are of utmost importance to us.

Why Conduct This Substance Abuse Disorder Observational Study?

Historically, clinical trials have predominantly focused on specific demographic groups, leaving a dearth of research on the factors that impede substance abuse disorder patients' participation in these trials.

The purpose of this research study is to gather comprehensive and in-depth information from participants to identify consistent factors that hinder individuals from enrolling or completing clinical trials. The collected data will be meticulously analyzed from diverse demographic perspectives, allowing for the identification of patterns that may influence the experiences of future substance abuse disorder patients. By actively participating in this study, you can contribute invaluable insights that have the potential to enhance the participation and completion rates of substance abuse disorder patients in clinical trials.

Navigating Interventional and Observational Studies

To participate in this study, enrollment in an interventional clinical trial is required. It is important to understand that your involvement in this observational clinical study will not have any impact on your existing substance abuse disorder care regimen if you are currently enrolled in a different clinical trial. If you have any concerns or questions regarding your interventional clinical trial, we strongly encourage you to reach out to your care team for additional information and clarification.

Study Requirements and Check-up Calls

As a participant in this observational clinical study, you will be requested to complete bi-weekly surveys, which typically take around 30 minutes to complete. In addition, there will be quarterly check-up calls scheduled specifically for your interventional clinical trial, which are separate from this observational research. It is crucial to ensure that you schedule these calls as required to maintain active participation in both aspects of the study.

Understanding Potential Risks

Participating in a medical study inherently carries potential risks. However, in this particular observational clinical trial, there are minimal risks involved. The risk of changing care regimens, which could lead to negative consequences, is not a concern as this study is purely observational. Your treatment plan will remain unaffected throughout the trial. Another potential risk is the breach of confidentiality due to regular communication through video conferences and online reporting. To mitigate this risk, we employ encryption and password protection to ensure the security of all electronic data.

Exploring Potential Benefits

Participating in this study also presents potential benefits. The findings from this trial will provide invaluable insights into the factors that may influence the participation and completion rates of diverse substance abuse disorder patients in clinical studies. This knowledge will be instrumental in improving future substance abuse disorder clinical trials. By actively participating in this study, you have the opportunity to contribute to a better understanding of the factors that can impact the involvement of diverse patient populations in these trials.

This Observational Study vs Other Substance Abuse Disorder Clinical Trials

This research, in contrast to many others for substance abuse disorder patients, is entirely observational. This implies that there is no set course of therapy that participants must follow. It is significant to highlight that the study's staff might not have in-depth knowledge of all substance abuse disorder research. However, there are tools at your disposal to help you. Visit ClinicalTrials.gov for a complete list of studies on substance abuse disorders. Additionally, you may consult Power's reference page if you're looking for a list of substance abuse disorder clinical trials that are currently looking for volunteers.

Recommended Readings: Exploring Diversity in Clinical Trials

While there is a scarcity of research on the representation of diverse populations in clinical trials, there are several studies that provide valuable insights. We recommend the following readings that you may find interesting:

1. Nicum, Shibani, and Sarah P. Blagden. "PARPs: All for One and One for All? Enhancing Diversity in Clinical Trials." *Clinical Cancer Research* 28, no. 11 (2022): 2201-2203.

2. Joseph, Galen, and Daniel Dohan. "Diversity of participants in clinical trials in an academic medical center: the role of the 'Good Study Patient?'." *Cancer* 115, no. 3 (2009): 608-615.

Ensuring Confidentiality Measures

Maintaining the privacy and confidentiality of your personal information is of utmost importance in this clinical study. To uphold this commitment, we have implemented stringent measures. Your records will be assigned a unique code or number, ensuring that your identity remains anonymous. All identifying materials will be securely stored in a locked file cabinet, supervised by the researcher. We prioritize the protection of your privacy and will not disclose any personal information without your explicit consent, unless mandated by law, such as in cases involving abuse or suicide risk.

Participant Consent and Understanding

By signing this form, I acknowledge that I have received comprehensive information regarding the nature and purpose of this study. I fully understand that my participation in this research is entirely voluntary, and I retain the right to withdraw from the study at any time without facing any negative consequences. It is reassuring to know that my decision to withdraw will not impact my current or future medical care. I appreciate the opportunity to receive a copy of this consent form for my reference.

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Printed Name of Participant

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Signature

_____

Date

Confirmation of Participant Understanding

As the clinical trial personnel responsible for discussing the consent form with the participant, I can confidently confirm that the participant has demonstrated a clear understanding of the risks, benefits, and procedures associated with this clinical research. We have engaged in thorough discussions, addressing any questions or concerns raised, to ensure the participant's comprehension of the study's implications and requirements.

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Printed Name of Person Getting Consent

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Signature of Person Getting Consent

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Date