Analyzing Enrolment and Engagement Trends in Individuals Confronting TBI: Insights from TBI Clinical Trials

The following is the Informed Consent Form tailored for individuals experiencing TBI participating in Power Clinical Trial's Observational Study

Date: February 23, 2024

Participant Consent Form for an Exploratory Observational Study

Your invitation to complete this form implies potential eligibility for participation in a groundbreaking observational clinical study focused on individuals dealing with traumatic brain injury disorder. This comprehensive guide outlines the study's primary objectives, research approaches, and potential consequences, encompassing both positive and potentially adverse effects. Before making a decision, it is imperative to thoroughly grasp the potential implications of your involvement, and seeking guidance from your healthcare professional can provide valuable insights. If any aspect of this material raises queries or confusion, please don't hesitate to contact the researcher or the designated point of contact.

Recognizing the Importance of Clinical Trials in Addressing TBI

TBI stands for Traumatic Brain Injury. It refers to damage to the brain caused by an external force, often resulting from a sudden blow or jolt to the head or a penetrating head injury. TBIs can range from mild, with temporary symptoms, to severe, leading to long-term cognitive, physical, or emotional impairment. Common causes of TBI include falls, vehicle accidents, sports injuries, and assaults. Symptoms may include headaches, confusion, memory loss, altered consciousness, and sensory or motor

function issues. Treatment and recovery depend on the severity of the injury and may involve medical intervention, rehabilitation, and ongoing support.

Clinical trials targeting TBI play a crucial role in evaluating the safety and effectiveness of novel treatments tailored for this condition. They act as essential tools in determining whether new therapeutic approaches outperform existing methods, offering substantial evidence for their broader implementation.

This research uniquely focuses on comprehending the individual experiences of those grappling with TBI, actively participating in a clinical trial incorporating medical interventions. The primary goal revolves around a thorough examination of trial completion rates and voluntary withdrawals within this specific patient cohort.

Actively Engaging in Surveys for Clinical Trial Participation

Your active involvement plays a pivotal role in this observational clinical study, and we encourage you to share your thoughts and experiences. This entails completing questionnaires every two weeks, requiring approximately 20-30 minutes of your time. Additionally, our team has scheduled quarterly check-in calls to ensure continuous support and your ongoing commitment to the trial.

It is essential to underscore that your participation in the survey segment of this experiment is entirely optional. You have the flexibility to choose which questions to respond to or complete the entire questionnaire based on your preferences. Furthermore, you have the autonomy to exit the trial at any juncture. Acknowledging the personal value of engaging in a clinical study, we are dedicated to offering assistance while upholding your privacy.

Investigating the Significance of Observational Clinical Trials

Engaging in this medical trial involves immersion in an observational study, an integral aspect of clinical research carefully crafted to gather insights through non-intrusive monitoring of patients following their treatment protocols.

Researchers will strictly observe your experience, thoroughly evaluating the outcomes of your condition without modifying your treatment plan. This trial framework is essential for enhancing our comprehension of the natural progression of a specific medical condition and its effects on individuals facing it. Your voluntary participation in this

observational study significantly contributes to advancing medical knowledge and refining care for individuals sharing the same medical condition.

Distinguishing This Study from Other TBI Clinical Trials

Recognizing the unique characteristics of this research study is crucial. It exclusively operates on an observational basis, signifying that your involvement will not include specific therapies or interventions. In order to make an informed decision about potential participation in a clinical trial, it is essential to comprehend the breadth of TBI clinical research, which includes interventional studies incorporating diverse treatment regimens.

Making a well-informed decision about your potential involvement in a clinical trial requires an active approach, involving thorough research and comparison among trials. Resources such as ClinicalTrials.gov offer comprehensive information about TBI studies. Additionally, Power's specialized online platform presents a detailed catalog of ongoing TBI clinical trials actively seeking volunteers. Through meticulous exploration and a comprehensive understanding of various clinical trial categories, you can confidently determine whether or not to participate.

Ensuring Your Anonymity in the Study

Maintaining the absolute confidentiality of your data is a fundamental principle of this study. To safeguard your anonymity, please avoid including any personal or identifiable information in your responses to the questionnaire. The committed research team is actively working to strengthen privacy and security protocols. Nevertheless, it's important to be aware that certain legal situations may require the disclosure of personal data.

Anticipated Health Impacts and Risks

Understanding the potential health effects on participants, particularly in studies assessing new drugs, is paramount despite the strides made through clinical trials.

Nevertheless, in observational clinical research, we adopt a unique strategy to mitigate these effects by abstaining from administering experimental medications to participants.

Our primary focus remains on meticulous monitoring and assessing outcomes, ensuring the avoidance of any preventable health risks.

Anticipated Benefits

Although participants in this observational clinical research may not witness immediate advantages, their participation could lead to significant long-term impact. The information collected from participants will contribute to the formulation of future strategies for engaging individuals affected by TBI, potentially expanding the realm of medical research. Those participating in this clinical trial have the potential to catalyze substantial advancements in the field of medical research, potentially transforming the landscape for future TBI patients.

Exploring Diversity in the Context of Clinical Trials

For those intrigued by the nuanced aspects of diversity in clinical trials, a plethora of online materials is ready for exploration.

Whether your aim is to comprehend the intricacies of challenges and opportunities associated with diversity in clinical trials or broaden your perspectives, the following resources can be instrumental in this pursuit:

Walker, Daniel M., Christine M. Swoboda, Karen Shiu-Yee, Willi L. Tarver, Timiya S. Nolan, and Joshua J. Joseph. "Diversity of Participation in Clinical Trials and Influencing Factors: Findings from the Health Information National Trends Survey 2020." *Journal of General Internal Medicine* 38, no. 4 (2023): 961-969.

Simari, Robert D. "When Will Clinical Trials Finally Reflect Diversity?." *Circulation* 140, no. 13 (2019): 1048-1049.

Participant Acknowledgment

I verify that I have taken the essential time to grasp and absorb the contents of the informed consent form, either through independent review or with the guidance of professionals who clarified its details. I am content to state that all my questions have been addressed to my satisfaction.

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Participant Name

_____

Participant Signature

_____

Date

Confirmation by Facilitator

I confirm that I conducted a detailed discussion with the participant, providing a thorough explanation of the complexities outlined in this written document. My primary goal was to ensure the participant's comprehensive understanding of the primary research objectives, the methodology utilized, potential risks and benefits, and other essential aspects of the TBI clinical trial.

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Printed Name of Assisting Researcher

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Signature of Assisting Researcher

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Date