Study on Glioma Patients: Understanding Their Glioma Clinical Trial Experiences

This is an informed consent form for Glioma Patients joining Power Clinical Trial's observational clinical study.

Date: July 14, 2023

General Overview of the Informed Consent Form

You are cordially invited to be a part of our research study. This document serves as a consent form, providing you with information about the study and outlining the implications of your participation. If there are any terms or phrases that are unclear to you, please do not hesitate to seek clarification from our research team.

We strongly encourage you to take your time in making a decision about your participation and feel free to ask any questions that may arise. Should you find it helpful, we recommend discussing the study with your loved ones, personal physician, trusted health professionals, or members of your community. We want to emphasize that participation in this study is entirely voluntary, and you are not obliged to take part.

Observational Study Overview

Glioma refers to a broad category of tumors that originate in the glial cells of the brain or spinal cord. Glial cells are non-neuronal cells that provide support, protection, and nourishment to the nerve cells (neurons) in the central nervous system.

The primary aim of this study is to observe and comprehend the various factors involved in the enrollment process of glioma clinical trials. We seek to understand how these factors might impact your ability to participate in the trial and successfully complete it.

The data collected will be de-identified to ensure confidentiality and will be analyzed to identify patterns and trends related to the experiences of glioma patients. These experiences often contribute to lower enrollment rates and incomplete trials. It is important to note that this study is purely observational, and your treatment will remain unchanged once you decide to participate.

This document serves as written documentation of the discussions you have had with our site staff or recruitment coordinators. Furthermore, you can utilize it as a point of reference throughout your participation in this clinical study.

Glioma Clinical Trial Purpose

Clinical trials often exhibit disparities in participation, favoring specific demographic groups. However, there is a scarcity of research that comprehensively explores the trial attributes that affect participation. This study aims to bridge this gap in knowledge by gathering extensive data on the clinical trial experiences of glioma patients.

The primary objective is to identify the key factors that hinder a patient's ability to enroll or successfully complete a clinical trial. By analyzing the collected data, we seek to shed light on these influential factors and their prevalence in limiting patient participation. Additionally, the study aims to examine the data from diverse demographic perspectives to identify recurring trends.

The insights gained from this study will contribute to the understanding of barriers to participation in glioma clinical trials. It may also offer valuable guidance for future trials, enabling the development of more inclusive and patient-centered approaches that cater to the needs of a broader range of individuals affected by glioma.

Benefits

Enrolling in this observational clinical trial presents a unique opportunity for you to actively contribute towards enhancing the support and care provided to glioma patients in the future. By sharing your experiences and insights, you can significantly influence the outcomes of this study, ultimately leading to improvements in participation rates and the diversity of future research endeavors.

Through rigorous data collection and analysis, we aim to uncover valuable information that can address the existing gaps in glioma research. Your involvement in this study

will help identify factors that can shape future studies and interventions, leading to more personalized and effective approaches to care. Together, we can make a meaningful difference in the lives of individuals affected by glioma.

Risks

When considering participation in clinical trials, it is important to acknowledge the potential risks that can arise from changes in treatment regimens. However, in the case of this observational clinical study, there will be no alterations to your current treatment regimen, mitigating any associated risks related to treatment changes.

The study utilizes online reporting and video calls with participating glioma patients throughout its duration. One potential risk involved in this process is the possibility of a data breach. At Power's clinical trials, we prioritize data security to minimize this risk. Stringent measures, including secured and encrypted communication channels, are implemented to safeguard the data exchanged during these calls. Call logs and electronic copies of consent forms are stored in a highly-secure environment, ensuring anonymity and confidentiality.

Difference of This Study From Other Glioma Clinical Trials

Unlike many other trials focused on glioma, this study stands out due to its observational nature. Most trials in this field are interventional clinical trials, where patients are required to undergo a specific course of treatment that may differ from their current regimen.

However, in this observational clinical trial, there will be no treatment recommendations or modifications. The primary objective is to gather comprehensive data and insights without interfering with your current treatment plan. By participating in this study, you can contribute valuable information to enhance our understanding of glioma, its impact, and potential avenues for improvement.

If you are interested in exploring other studies, you can visit clinicaltrials.gov and search for glioma clinical research. Additionally, Power's online page provides information on glioma clinical trials for further exploration.

More Studies on Diversity in Clinical Trials

If you wish to expand your knowledge of clinical trials and their associated participation rates, we invite you to explore the following resources. These sources provide valuable insights and information, shedding light on the factors that influence the engagement of individuals in clinical research studies.

By browsing through these materials, you can gain a deeper understanding of the challenges, barriers, and facilitators that impact participation rates. This knowledge can help shape future strategies to enhance recruitment, increase diversity, and foster greater engagement in clinical trials across various fields of research.

More studies:

Bird, Chloe E. "Women's representation as subjects in clinical studies: a pilot study of research published in JAMA in 1990 and 1992." *Women and health research: Ethical and legal issues of including women in clinical studies* 2 (1994): 151-173.

Motazedian, Pouya, Thais Coutinho, and F. Daniel Ramirez. "Female representation in clinical studies informing atrial fibrillation guidelines: have we built a house of cards?." *Canadian Journal of Cardiology* 38, no. 6 (2022): 709-711.

Requirements for Participation For Glioma Patients

As a participant in this study, your involvement entails attending bi-weekly surveys with an estimated duration of 30 minutes each. Additionally, there will be quarterly check-in calls throughout the clinical trial process. These surveys and calls are crucial for collecting essential data and insights pertaining to your experiences as a glioma patient.

It is important to clarify that this observational study is specifically designed for individuals who are currently enrolled in an interventional clinical trial. Your primary care doctor's prescribed treatment and methodology will remain unchanged throughout your participation in this observational study. The objective is to gain a comprehensive understanding and knowledge about your unique journey without altering your ongoing treatment plan.

In case you have any concerns or questions at any point during the trial, our team of experienced staff members is readily available to provide clarification and support. We

strongly encourage you to reach out to our team whenever you require assistance or guidance.

Please ensure that you consult and seek permission from your care team before enrolling in this clinical study. They will be able to provide further information, assess your eligibility, and guide you through the enrollment process.

Participant Statement: Understanding and Consent for Clinical Study

Having thoroughly read the information provided above and received comprehensive verbal explanations, I affirm that I have a clear understanding of the study's details. All of my queries have been addressed satisfactorily.

I acknowledge that my participation in this observational study is entirely voluntary, and I retain the right to withdraw from the study at any time, without any negative consequences. It is important to note that signing this form does not waive or diminish my legal rights.

I am aware that I will be provided with a personal copy of this consent form for my records.

By affixing my signature below, I confirm my voluntary participation in this clinical study, expressing my consent and dedication to contribute to the research objectives.

_____

Printed Name of Participant

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Participant Signature

_____

Date

Confirmation of Informed Consent Discussion: Statement by the Facilitator

I affirm that I have conducted a comprehensive discussion with the participant, thoroughly covering the information provided in this form.

I can confidently state that the participant has demonstrated a clear understanding of the potential benefits, risks, and procedures associated with their involvement in this clinical trial for glioma. All relevant aspects of the study have been explained, and any questions or concerns raised by the participant have been addressed to their satisfaction.

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Printed Name of Person Conducting Informed Consent Discussion

_____

Person Conducting Informed Consent Discussion Signature

_____

Date