Glioblastoma Multiforme Patients in Clinical Trials: An Examination of Their Clinical Trial Experiences

This is an informed consent form for glioblastoma multiforme patients joining Power Clinical Trial's observational clinical study.

Date: July 14, 2023

Understanding the Informed Consent Form

We extend an invitation to you to become a valuable participant in our research study. To ensure your full understanding of the study and what it entails to participate, we have prepared this consent form. If there are any unfamiliar terms or concepts within this document, please do not hesitate to approach our research staff for further explanation.

We encourage you to take your time in contemplating your decision to participate, and we are here to address any queries you may have. If you find it beneficial, we encourage you to discuss the study with your family, friends, personal physician, other trusted healthcare professionals, or members of your community. It is crucial to remember that participation in this study is entirely voluntary, and you are under no obligation to take part.

Introduction to This Glioblastoma Multiforme Study

Glioblastoma, also known as glioblastoma multiforme (GBM), is a type of malignant brain tumor that arises from the glial cells in the brain. Glial cells provide support and protection to the nerve cells in the brain. Glioblastoma is the most common and aggressive form of primary brain cancer, meaning it originates in the brain rather than spreading from other parts of the body.

This study attempts to monitor and comprehend the many elements that influence your capacity to engage in and finish your glioblastoma multiforme clinical trial enrollment procedure.

The data will be non-personally identifiable and will be examined for trends in glioblastoma multiforme patient experience, which frequently leads to poor enrolment rates or completion.

Because this is an observational research, nothing will change about your treatment if you choose to join.

This form serves as written confirmation of everything you discussed with our site employees or recruiting coordinators. As a participant in this clinical investigation, you may also use this as a reference.

Clinical Trial Purpose

Clinical trials often exhibit a bias towards specific demographic groups, yet there is a lack of comprehensive research investigating the factors that impact trial participation. This study aims to address this knowledge gap by collecting a wide range of data on the experiences of glioblastoma multiforme patients in clinical trials. The objective is to identify the prevailing factors that hinder a patient's ability to enroll or successfully complete a trial.

Moreover, the study will conduct an analysis of the collected data from different demographic perspectives. This analysis aims to identify recurring trends that may offer valuable insights for the benefit of future glioblastoma multiforme patients. By understanding these factors and trends, we can strive to enhance the design and implementation of clinical trials, ensuring broader and more inclusive participation for improved outcomes.

Benefits

By joining this observational clinical trial, you play a pivotal role in advancing our understanding of glioblastoma multiforme and how we can better support future patients. Your participation will contribute to uncovering valuable insights that can lead to improvements in participation rates and the broader inclusivity of future studies.

Through the collection and analysis of data from your participation, we aim to identify key factors that can enhance the overall experience for glioblastoma multiforme patients. The results derived from this study have the potential to shape future research and clinical practices, ultimately benefiting individuals affected by the condition.

Risks

Addressing concerns related to potential risks is crucial when considering participation in clinical trials. While certain trials may necessitate changes in treatment regimens, it is essential to note that this observational clinical study will not alter your current treatment plan. Consequently, there are no associated risks stemming from treatment modifications.

During the study, online reporting and video calls are utilized to engage with participating glioblastoma multiforme patients. It is important to acknowledge that one potential risk in this process is the potential for data breaches. At Power's clinical trials, we prioritize the security and privacy of your information. Robust protocols, including secure and encrypted communication channels, are in place to safeguard the data transmitted during these calls. Moreover, call logs and electronic copies of consent forms are stored anonymously within a highly-secure environment, ensuring the confidentiality of your data.

Difference of This Study From Other Glioblastoma Multiforme Clinical Trials

What sets this study apart from other trials for glioblastoma multiforme is its observational approach. Unlike many studies that fall under the category of interventional clinical trials, this study focuses on observing and collecting data rather than implementing specific treatment interventions.

As an observational clinical trial participant, there will be no treatment recommendations or changes to your current treatment regimen. The main objective is to gather comprehensive data and insights about glioblastoma multiforme, its progression, and its impact on patients' lives. By joining this study, you have the opportunity to contribute to the existing body of knowledge and potentially influence future advancements in glioblastoma multiforme care.

To explore other studies, you can refer to clinicaltrials.gov and search for glioblastoma multiforme studies. Additionally, Power's online page provides a dedicated section on

glioblastoma multiforme clinical trials, offering a resourceful platform to further investigate available options.

Other Resources on Representation in Clinical Studies

Benefits to further explore the topic of participation rates in clinical trials, we recommend delving into the following sources. These references offer a wealth of information and studies dedicated to examining and understanding the factors that influence individuals' decisions to participate in clinical research.

By immersing yourself in this literature, you can gain valuable insights into the dynamics that impact participation rates. This knowledge contributes to the broader understanding of clinical trial recruitment and can potentially lead to the development of strategies that promote increased engagement and inclusivity in future research endeavors.

Resources you can check:

Ramos, Edward, Katie Baca-Motes, Jay A. Pandit, and Toluwalase A. Ajayi. "Improving participant representation in the era of digital clinical studies." *Trends in Molecular Medicine* (2022).

Hurwitz, Brian. "Form and representation in clinical case reports." *Literature and Medicine* 25, no. 2 (2006): 216-240.

Study Participation Guidelines for Glioblastoma Multiforme Patients

To take part in this study, it is necessary to engage in bi-weekly surveys, each lasting approximately 30 minutes. Additionally, there will be quarterly check-in calls throughout the duration of the clinical trial process. These interactions are designed to gather valuable data and insights related to your experiences as a glioblastoma multiforme patient.

It is important to note that this observational study is specifically tailored for individuals currently enrolled in an interventional clinical trial. Rest assured, your primary care doctor's prescribed treatment and methodology will remain unaffected by your participation in this observational study. The objective is to comprehensively understand the nuances of your journey without influencing your ongoing treatment plan.

Throughout the trial, if any concerns or questions arise, our dedicated staff is readily available for clarification and support. We encourage you to reach out to our team at any point for assistance and guidance.

To enroll in this clinical study, it is imperative to consult and seek permission from your existing care team. They will provide further guidance and determine if this study aligns with your individual circumstances.

Acknowledging Informed Consent

I hereby confirm that I have taken sufficient time to thoroughly read and comprehend the contents of the informed consent form, either independently or with the assistance of a trusted individual who has read it to me. All of my questions and concerns have been adequately addressed to my complete satisfaction.

I am fully aware that my participation in this study is entirely voluntary, and I have the right to withdraw my consent at any time, without the need to provide a reason or face any financial obligations. I have been informed that I will receive a copy of this informed consent form for my personal records.

After careful consideration and thoughtful reflection on all the provided information, I willingly give my consent to participate in this study of my own free will.

_____

Printed Name of Participant

_____

Participant Signature

_____

Date

Validation of Informed Consent Discussion: Statement by the Facilitator

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

I attest that the participant has grasped the implications, including the potential benefits, risks, and procedures involved in their participation in this glioblastoma multiforme clinical trial. All necessary details pertaining to the study have been explained, and any inquiries or uncertainties expressed by the participant have been adequately addressed and resolved.

_____

Printed Name of Person Taking Consent

_____

Signature of Person Taking Consent

_____

Date