Glioblastoma Clinical Trials: Pinpointing the Factors Affecting Clinical Trial Experiences of Glioblastoma Patients

Informed Consent Form For Glioblastoma Clinical Trial Patients Enrolled in Power Clinical Trial's observational research.

Date: February 3, 2023

ICF Overview

This Informed Consent Form comprises two distinct parts: the Information Sheet and the Declaration of Consent.

The Information Sheet serves as an informational tool, providing you with details regarding the clinical trial. Here, we will share important information with you to help you make an informed decision about your participation.

The Declaration of Consent, on the other hand, is where you will be asked to put your signature if you agree to participate in the trial. This section serves as a formal declaration of your willingness to take part in the study.

Upon completion, a copy of this Informed Consent Form will be given to you for your records.

Section I: Information Sheet

Glioblastoma Clinical Trial Overview

This Informed Consent Form is an invitation for you to join a medical observation study, aimed at gaining a deeper understanding of the various factors that influence your experience during a glioblastoma clinical trial. The goal of this research is to explore why some patients choose to participate, continue participating, or withdraw from clinical trials.

It is important that you take your time when considering whether to participate in this study. We encourage you to discuss your decision with someone you trust. If you have any questions or concerns, we are here to help.

The informed consent form may contain some technical terms or language that you are not familiar with. If this is the case, please do not hesitate to ask the personnel conducting the informed consent discussion to pause and explain any terms or words that you are unsure about.

Your understanding and comfort with the information presented are of the utmost importance to us. We take the protection of participating patients very seriously and are committed to conducting our research in a safe and ethical manner.

Type of Research

This is an observational clinical trial. If you decide to participate, you will not be required to take on a new treatment program. Your current care process shall remain unchanged. You will only undergo a series of interviews so that we can gather the necessary data. The researcher involved in this observational study cannot diagnose or advise any treatment.

Purpose of The Glioblastoma Clinical Trial

Historically, clinical study participation has been biased toward certain demographics. However, there is a shortage of studies that delve into the underlying factors that influence patient participation, both positively and negatively.

As a patient enrolled in a glioblastoma clinical trial, you have the opportunity to play a crucial role in helping us understand these factors by sharing your experiences throughout the course of the study.

This research aims to gather a diverse range of information on clinical trial experiences by inviting a number of participants to participate. Our goal is to identify any limitations that prevent individuals from participating in glioblastoma clinical trials, as well as the reasons for completing or withdrawing from the study.

The data collected from this study will be analyzed and used to improve the experiences of future glioblastoma patients who are recruited for medical trials. By participating, you will be contributing to the advancement of knowledge in the field and helping to improve the lives of other patients.

Voluntary Participation

This is an observational clinical trial, meaning that if you choose to participate, you will not be required to make any changes to your current treatment plan. Your ongoing care and treatment regimen will remain unchanged. The only addition to your routine will be a series of interviews, during which we will collect important information and data.

It is important to note that the researchers involved in this observational study are not authorized to diagnose any medical conditions or provide treatment advice. The purpose of the study is to gather information and observe the experiences of participants, and the researchers will not interfere with or alter any existing care plans.

By participating in this study, you will be contributing to the advancement of medical knowledge in the field and helping to improve the experiences of future patients. However, it is entirely up to you to decide whether or not you wish to participate, and you should always prioritize your own health and well-being when making any decisions related to your medical care.

Participant Selection For the Observational Clinical Trial

As a participant in this study, it is a prerequisite that you are already enrolled in an independent interventional glioblastoma clinical trial. Our aim is to gain insights into the decision-making process behind your enrollment in the current trial and understand the factors that influence your choices to continue or discontinue your treatment.

By participating in this observational study, you will have the opportunity to share your experiences and provide valuable insights that can help improve the experiences of future patients. This information will contribute to the advancement of medical knowledge and help researchers to better understand the factors that influence patient participation in clinical trials.

It is important to note that your participation in this study will not impact your current treatment plan or interfere with your ongoing care. The study will involve a series of interviews, during which you will be asked to share your thoughts and experiences related to your participation in the clinical trial. Your participation will be valuable in helping researchers to gain a deeper understanding of the challenges and opportunities that patients face when enrolling in and participating in clinical trials.

Glioblastoma Clinical Trial vs. Other Trials

While there are other clinical trials available for glioblastoma patients that are interventional in nature and require participants to enroll in a specific treatment program, this trial is observational in nature and does not involve the provision of any treatment or care plan.

It is important to note that the research staff involved in this trial may not be able to recall all the details of other glioblastoma trials. However, if you are interested in learning more about other glioblastoma studies, you can find additional information on clinicaltrials.gov or through other reference sites such as Power, which provides a list of glioblastoma clinical trials you can enroll in.

Participating in an observational study such as this one allows you to contribute to the advancement of medical knowledge without the obligation of enrolling in a treatment program. Your participation will help researchers to better understand the experiences of glioblastoma patients and identify factors that impact participation in clinical trials.

Procedures and Duration

As a participant in this observational clinical trial, you will be asked to complete bi-weekly surveys, which typically take about 30 minutes to complete. Additionally, there will be quarterly check-in calls conducted throughout the duration of the separate interventional clinical trial that you are enrolled in.

It is important to note that the interventional clinical trial that you are already enrolled in is not connected to this observational clinical trial in any way, and any questions or concerns regarding your other trial should be directed to your personal care team.

While participating in this research, you are not required to share any personal opinions, experiences, or insights if you do not feel comfortable doing so. The surveys can be completed by you or a staff member can read the questions to you and you can respond verbally. If there are any questions that you do not wish to answer, you may simply skip them and move on to the next.

The data collected through these surveys will be kept confidential and your name will not appear on the survey forms. Your privacy and confidentiality will be respected throughout the duration of the study.

Confidentiality

If you decide to participate in this research, you can be confident that the information you share with us will be kept confidential and secure. Our research team is committed to protecting your privacy, and we will not disclose your personal data to any outside parties. All records related to the study, including call logs, digital copies of consent forms, and data collected, will be kept private and secured through encryption and password protection. Additionally, to maintain anonymity for all glioblastoma patients participating in the study, any information about you will be assigned a unique identifier instead of using your name.

Risks and Benefits

Participating in this research comes with a potential risk of accidentally disclosing sensitive information, or feeling uncomfortable discussing certain topics. Our primary concern is to ensure your comfort and avoid any adverse experiences. If at any point during the research, you feel that a question or topic is too personal or makes you uncomfortable, you are not obligated to answer or discuss it.

Your participation in this observational medical study as a glioblastoma patient will not result in direct benefits for you, but it will greatly contribute to our understanding of the various factors that influence the clinical trial experiences of individuals suffering from glioblastoma. The information gathered from this research will be invaluable in

improving the experiences of future glioblastoma patients who may choose to participate in clinical trials for their condition.

Learn More About Clinical Trial Diversity

You can read more studies on clinical trial diversity by checking the following links:

Charrow, Alexandra, Fan Di Xia, Cara Joyce, and Arash Mostaghimi. "Diversity in dermatology clinical trials: a systematic review." *JAMA dermatology* 153, no. 2 (2017): 193-198.

Charrow, Alexandra, Fan Di Xia, Cara Joyce, and Arash Mostaghimi. "Diversity in dermatology clinical trials: a systematic review." *JAMA dermatology* 153, no. 2 (2017): 193-198.

Section II: Certificate of Consent

Participant's Declaration

As a glioblastoma patient, I have been extended an invitation to participate in this observational clinical trial.

I am already undergoing a separate interventional clinical trial for the same condition. I have been provided with the necessary information and consent form, either through personal reading or through an explanation given to me. I was given ample time and opportunity to ask questions regarding any confusion or uncertainty I had, and I am satisfied with the answers I received.

I have voluntarily decided to participate in this observational study and have been given a copy of the consent form for my own records.

Print Name of Participant: _____

Signature of Participant: _____

Date: _____
Day/Month/Year

Researcher/Staff Declaration

I affirm that I have thoroughly read through the consent form and have made sure to effectively convey all the important information to the prospective participant. I have taken the time to answer any questions the participant may have had regarding the study and have made sure that all information was thoroughly understood.

The participant's consent was given freely and voluntarily, without any form of coercion or pressure. I am confident that the participant was able to make an informed decision about their participation in this study.

The participant has been given a copy of this ICF.

Print Name of Person Taking the Consent: _____

Signature of Person Taking the Consent:_____

Date: _____
Day/Month/Year