Brain Injury Clinical Trials: Examining the Experiences of Brain Injury Patients in Medical Trials

An Informed Consent Form for brain injury clinical trials patients enrolled in Power Clinical Trial's observational study.

Date: January 10, 2023

About This Informed Consent Form (ICF)

This Informed Consent Form (ICF) is divided into two parts. First is the Information Sheet, where we provide information about the clinical trial. The other one is the Declaration of Consent, which you sign if you agree to participate in the trial.

You will receive a copy of this document once it has been completed.

Part I: Information Sheet

Introduction

This informed consent form invites you to participate in an observational medical study that aims to understand the various factors that influence your experience in clinical trials, such as why you choose to participate, continue to participate, or withdraw.

Please take your time in considering whether you want to participate in this research. You are welcome to discuss this opportunity with someone you trust.

If there are terms in this consent form that you are not familiar with, please feel free to ask the person conducting the informed consent discussion to stop and explain them to you.

Purpose of Brain Injury Clinical Trials

Brain injury, also known as traumatic brain injury (TBI), is an injury to the brain that is caused by external physical force, such as a blow to the head or a penetrating injury.

Clinical trials for a brain injury can help to determine the safety and effectiveness of a new treatment, as well as identify any potential side effects. They also provide an opportunity for people with brain injury to access new treatments that are not yet widely available. Joining clinical trials allows individuals to contribute to the advancement of medical knowledge and potentially benefit from new treatments that are being tested.

Historically, participation in clinical trials has been skewed towards certain groups. However, research on the factors that influence participation, both positive and negative, is limited.

We believe that as a brain injury clinical trial patient, you can help us identify these factors by sharing your experiences during the course of the interventional medical study you are currently enrolled in.

This study will include a diverse group of participants to gather a wide range of information on clinical trial experiences. We aim to discover factors that may prevent individuals from participating in brain injury clinical trials and the reasons for completing or withdrawing from the trial.

The collected data will then be used to benefit future brain injury patients who are considering participating in a medical study.

Type of Research

This is an observational clinical trial.

An observational clinical trial is a type of research study in which participants are observed and their outcomes are measured, but they are not assigned to a specific treatment or intervention. In other words, participants in an observational clinical trial receive the treatments that they would normally receive as part of their routine care, and the researchers simply observe and record the outcomes.

Observational clinical trials are typically used to study the natural course of a disease or condition or to compare the outcomes of different treatments or interventions. They can also be used to identify risk factors for a particular condition or to evaluate the effectiveness of a treatment in a real-world setting.

Unlike interventional clinical trials, which assign participants to different treatment groups, observational clinical trials do not involve any interventions or manipulations by the researchers. Participants in observational clinical trials are simply observed and their outcomes are recorded.

Eligibility For the Brain Injury Clinical Trial

To be eligible to participate in this study, you must be already enrolled in a separate interventional brain injury clinical trial. We are interested in understanding why you decided to join your current trial and the factors that influence your decision to continue or stop treatment.

As a participant in this study, you will be asked to share your experiences during the course of the interventional trial you are enrolled in. Your participation will involve a series of interviews to gather data for the study.

Voluntary Participation in the Brain Injury Clinical Trial

Your participation in this research is completely voluntary. It is up to you to decide whether or not you want to participate. Joining this will not affect your current treatment plan in a separate interventional clinical study. You are also not giving up any rights if you do so. If at any time you feel uncomfortable with the process, you are free to stop participating.

Observational Brain Injury Clinical Trial vs. Other Studies

Other clinical studies for brain injury patients may be interventional, which means that you are required to follow a specific treatment plan. In contrast, our trial is observational, which means that we will not offer you a treatment or care program.

Our staff may not be aware of all brain injury clinical trials. You can visit clinicaltrials.gov if you would like to learn more about other brain injury trials, or consult Power's reference site for information on additional brain injury clinical trials.

Clinical Trial Process

If you agree to participate in this research, you will be asked to complete bi-weekly surveys. These surveys typically take 30 minutes to finish. In addition, we will conduct quarterly check-in calls during the separate interventional clinical trial you are enrolled in.

You can complete the survey yourself or you can have a staff member read it to you and you can respond out loud. If you do not wish to answer any of the questions on the survey, you may skip them and move on to the next ones.

The data that is collected will be kept confidential and your name will not be included on the survey forms.

Risks and Benefits

There is a risk that you may accidentally disclose confidential information or that you may feel uncomfortable discussing certain questions or topics. We want to avoid this and want you to feel comfortable. You do not have to share information or answer a question if you feel that it is too personal or makes you feel uncomfortable in any way.

As a brain injury patient, there will be no direct benefit to you from participating in this study. However, your participation will help us understand the factors that influence the clinical trial experiences of brain injury patients, which will ultimately benefit individuals who enroll in future trials for this condition."

Confidentiality

Please be assured that we will maintain complete confidentiality concerning the information you share, including any personal data. We will not share this information with anyone outside of the research team. All call logs, digital copies of the consent forms, and data collected will be handled securely and protected by encryption and passwords. To maintain anonymity, any information about you will be identified by numbers rather than your name.

We are committed to protecting the privacy of all brain injury patients involved in this study.

Learning More About Clinical Trial Diversity

The following studies have investigated clinical trial participation rates:

Michos, Erin D., and Harriette GC Van Spall. "Increasing representation and diversity in cardiovascular clinical trial populations." *Nature Reviews Cardiology* 18, no. 8 (2021): 537-538.

Blumenthal, David, and Cara V. James. "A Data Infrastructure for Clinical Trial Diversity." *New England Journal of Medicine* (2022).

Part II: Declaration of Consent

Participant's Declaration

I have been invited to participate in this observational brain injury clinical trial as a brain injury patient currently enrolled in a separate interventional clinical trial.

I have read or had the consent form explained to me and have had the opportunity to ask any questions I had about topics I did not understand. My questions have been satisfactorily answered. I choose to voluntarily participate in this observational study.

I have been given a copy of this consent form.

Print Name of Participant: _____

Signature of Participant: _____

Date: _____
Day/month/year

If illiterate

I have witnessed the permission form correctly read to the prospective participant, and the subject has had the opportunity to ask questions. I certify that the individual willingly provided consent.

If illiterate:

I vouch that the consent form was read to the participant and that the participant had the opportunity to ask questions. I stand witness that the participant has given consent to participate in this study.

Print name of witness:_____ Thumb print of participant

Signature of witness: _____

Date: _____
Day/month/year

Declaration by the researcher/person taking consent

I properly read the consent form to the prospective participant and did my best to ensure that they understood the procedure.

I confirm that the participant had the opportunity to ask questions about the study and that all questions were answered to the best of my ability. I confirm that the participant was not pressured into giving their consent and that they provided consent freely and willingly.

The participant has been given a copy of this Informed Consent Form (ICF).

Print Name of Person Taking the Consent: _____

Signature of Person Taking the Consent:_____

Date: _____
Day/month/year