Neuroblastoma Clinical Trials: Looking at Patterns About How Patients Feel About Participating in Clinical Trials

Informed Consent Form (ICF) For Power Clinical Trial's Neuroblastoma and Pulmonary Hypertension Medical Trial

Date: June 15, 2023

About This ICF

This document comprises two sections that aim to furnish you with crucial information concerning the clinical study and your participation as a subject. The Patient Information Sheet's first segment includes essential details concerning the study's characteristics, objectives, and obligations. This segment intends to facilitate comprehension of the research and enable an informed determination regarding your involvement. The second segment is the Consent Section, where you affix your signature.

Part I: Patient Information About This Trial

Overview

We invite you to partake in a medical research study that seeks to comprehend the diverse factors that influence your encounter in a clinical trial. Understanding the rationale behind your enrollment, persistence, or discontinuation from the clinical trial is something that you have to do. It is essential to allocate sufficient time to contemplate whether or not to partake in this study. It is advisable to consult with your healthcare team or loved ones regarding this opportunity.

Acknowledging that the consent form may include medical jargon that may not be within your scope of knowledge is essential. If you have any inquiries or apprehensions concerning any medical terminology in this document, you retain the prerogative to request that the research personnel explicate them. The research has undergone ethical review and has been deemed compliant with federal regulations that safeguard the rights of human participants.

Understanding the Objective of this Clinical Research on Neuroblastoma

We invite you to share your invaluable experiences as active participants in Power's interventional medical trial. By doing this, you will play a pivotal role in advancing our knowledge of patient characteristics within the Neuroblastoma

This research undertaking aims to ensure inclusivity by involving diverse individuals. Our objective is to gather comprehensive data about clinical trial experiences. Through this, we aspire to uncover the barriers and hurdles that impede participation in clinical trials and the underlying reasons for withdrawal or discontinuation.

The profound insights from this study will ultimately pave the way for improved opportunities and outcomes for individuals facing neuroblastoma. Your contribution will impact the future of medical research, benefiting those who may be invited to participate in clinical trials in the years ahead.

Exploring Patient Experiences: An Observational Study

As part of our investigation into patient experiences, this observational study does not propose any new treatment plans. Participating in this research means you can maintain your current treatment regimen. Your routine will remain unchanged, with the only modification being the inclusion of interviews conducted by our researchers to gather valuable information. Our researchers cannot diagnose your condition or provide treatment recommendations. The sole objective of this study is to accumulate data to enhance our understanding.

Eligibility Criteria For Participation In The Study.

The inclusion criteria for this research necessitate concurrent enrollment in an ongoing clinical trial for neuroblastoma. This study aims to obtain a deeper understanding of the

underlying motivations that led to your participation in this research, as well as the various determinants that impact your decision to either persist with or terminate treatment.

Our research aims to understand the variables that have contributed to your decision to participate in the study and the factors that impact your choice to continue or discontinue your involvement in the trial. The objective of our research is to determine the primary determinants that influence patient decision-making in the setting of clinical trials for neuroblastoma.

Voluntary and optional participation is a fundamental aspect of this study. Your enrollment in this study will not affect the current therapeutic regimen for participating in the other clinical trial. Participants can withdraw from the study at any time if they experience discomfort. Please be advised that your decision will not lead to any forfeiture of legal entitlements.

This Neuroblastoma Clinical Trials vs Other Trials

Interventional clinical trials are a viable option for individuals diagnosed with neuroblastoma involving specific treatment plans. However, the clinical trial we invite you to is solely observational, meaning it does not require enrollment in a particular treatment plan.

Since providing an exhaustive list of all neuroblastoma studies in this document is not feasible we recommend visiting other websites like clinicaltrials.gov, which provide an exhaustive repository of neuroblastoma studies. We also suggest accessing Power's website for more comprehensive information on available studies to assist you in exploring other neuroblastoma clinical trials that you may consider applying to.

Additional Information Regarding Representation in Clinical Studies

To find out more about representation in clinical trials, consult the following published studies:

Melloni, Chiara, Jeffrey S. Berger, Tracy Y. Wang, Funda Gunes, Amanda Stebbins, Karen S. Pieper, Rowena J. Dolor, Pamela S. Douglas, Daniel B. Mark, and L. Kristin Newby. "Representation of women in randomized clinical trials of cardiovascular

disease prevention." *Circulation: Cardiovascular Quality and Outcomes* 3, no. 2 (2010): 135-142.

Denby, Kara J., Natalie Szpakowski, Julie Silver, Mary Norine Walsh, Steve Nissen, and Leslie Cho. "Representation of women in cardiovascular clinical trial leadership." *JAMA Internal Medicine* 180, no. 10 (2020): 1382-1383.

Patient Responsibility

You must complete a questionnaire every two weeks. Typically, it takes approximately 30 minutes to finish one of these questionnaires. We will also schedule check-in calls with you every three months.

We emphasize that although you might need to enroll in another interventional clinical trial to participate in our study, our research is purely for observational purposes. It will not impact your diagnosis or treatment plan related to that trial. Feel free to contact your healthcare team with any inquiries about the other problem.

Rest assured that you are not obligated to provide any information that makes you uncomfortable. You can complete the survey by yourself or have someone read it aloud to you while you respond. Furthermore, you can skip any questions you prefer not to answer.

Your name will not be included on the survey forms to ensure your privacy. Moreover, all the information we gather will remain anonymous. We take the confidentiality of your data very seriously. It will only be accessible to the research team and protected using encryption, passwords, and anonymity. For instance, we will utilize numerical identifiers instead of names to safeguard the identity of patients. Additionally, we will handle phone logs and digital permission forms securely.

Part II: Consent Certificate

Patient's Confirmation of Participation

The undersigned individual hereby consents to participate in a clinical study focused on patients diagnosed with pulmonary hypertension. As a participant diagnosed with a particular type of cancer, the individual has been chosen to participate in an innovative clinical trial actively.

After scrutiny of the consent document, extensive discussions, and the opportunity to seek clarification or address any concerns I may have had, I am entirely satisfied with the responses. Therefore, I voluntarily consent to my involvement in this study.

I received a personal copy of this consent form for record-keeping purposes. I understand that my participation in this study is entirely voluntary, and I reserve the right to withdraw my involvement at any time without experiencing any negative repercussions. Additionally, I acknowledge that the research team will ensure the confidentiality of my personal information and safeguard the security of all data collected during the study.

Participant's Printed Name: _____

Participants Signature: _____

If Illiterate

The consent document was comprehensively discussed and explained to the potential participant who cannot read or write. They were given ample time to ask questions and received satisfactory answers. The participant clearly understands the study's objectives, the intended outcomes, and the potential risks involved.

Name of Witness: _____ **Participant's Thumbprint**

Witness Signature: _____

Date: _____
Day/Month/Year

Consent Statement of the Participant's Representative

Considerable efforts were made to ensure the potential participant fully understood the study's process and possible consequences. I meticulously explained the contents of the consent form, providing ample opportunities for them to ask questions. All queries were answered honestly and to the best of my ability. Notably, the participant's decision to participate in the study was entirely voluntary, free from coercion or undue influence.

The participant has been provided with a copy of this form for their records.

Name of the Researcher: _____

Signature of the Researcher: _____

Date: _____
Day/Month/Year