Retinitis Pigmentosa Clinical Trials: Examining the Clinical Trial Journey of Retinitis Pigmentosa Patients

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

Date: April 28, 2023

Introduction

You are invited to take part in a non-interventional research study, and your participation is voluntary. If you decide to participate, you have the right to withdraw your consent at any time during the study.

The reason you are being invited to participate in this research study is that you have retinitis pigmentosa, and we aim to examine and comprehend various factors that could affect your capability to participate and complete your clinical trial during the retinitis pigmentosa interventional study enrollment process.

Should you choose to participate in this study, you will be required to sign this consent form, acknowledging that you have been informed of the study, and all your questions have been answered. Participation in this study will not alter your regular medical care provided by your physician.

Purpose of the Study

You are being invited to participate in a research study, and before you make a decision, it is crucial that you understand the purpose of this research and what it entails. Kindly read the information below carefully, and do not hesitate to seek clarifications from the researcher if needed.

The primary objective of this research is to gather a broad range of data on the clinical trial experience of retinitis pigmentosa patients. The aim is to identify the factors that limit patients' ability to participate or complete a trial successfully. Typically, clinical trial participation favors a specific demographic group, and little research exists on how trial attributes affect participation. As such, this study seeks to analyze data from different demographic groups and check for recurring trends that could provide valuable insights for future retinitis pigmentosa patients.

Study Activities

As a participant in this study, you will be required to complete bi-weekly questionnaires, which will last approximately 30 minutes each. Additionally, there will be quarterly check-in calls during the clinical trial procedure.

To take part in this study, you must currently be a participant in an interventional clinical study. Please note that your primary care doctor's recommended treatment and methods will not be altered if you decide to participate in this observational research. If you have any questions or concerns at any stage during this trial, please contact our team for clarification.

This Trial Versus Other Retinitis Pigmentosa Clinical Trials

Most retinitis pigmentosa studies are interventional clinical trials where patients undergo a specific treatment regimen that may differ from their current treatment. In contrast, this study is an observational clinical trial that does not involve any changes to your current treatment plan.

If you want to learn more about other retinitis pigmentosa studies, you can search for ongoing trials on websites like clinicaltrials.gov or Power's online page which lists the top retinitis pigmentosa clinical trials accepting participants.

You can also explore more research on participation rates in clinical trials to gain further insight. Here are some of them that you might be interested in reading:

Unger, Joseph M., Julie R. Gralow, Kathy S. Albain, Scott D. Ramsey, and Dawn L. Hershman. "Patient income level and cancer clinical trial participation: a prospective survey study." *JAMA oncology* 2, no. 1 (2016): 137-139.

Nipp, Ryan D., Hang Lee, Elizabeth Powell, Nicole E. Birrer, Emily Poles, Daniel Finkelstein, Karen Winkfield, Sanja Percac-Lima, Bruce Chabner, and Beverly Moy. "Financial burden of cancer clinical trial participation and the impact of a cancer care equity program." *The Oncologist* 21, no. 4 (2016): 467-474.

Potential Benefits and Risks

While there are no direct benefits to your participation in this study, we hope that the information gathered will aid in the future treatment of individuals with retinitis pigmentosa.

This study is purely observational, and therefore, there will be no changes made to your treatment regimen, resulting in no associated risk due to treatment change. Throughout the duration of the trial, you will be reporting online and participating in video calls, along with other retinitis pigmentosa patients.

Please be advised that there is a risk of someone accessing your protected health information and identifying you. However, we will use a code of letters and numbers to safeguard your identity and the associated data and samples collected. The coded data may be retained for a lengthy period, and you may inquire about the duration of your coded samples with the study doctor or study staff.

Confidentiality

We value your privacy, and all information you provide in the survey will be kept anonymous. To maintain your confidentiality, the researcher will assign code names or numbers for participants to all research notes and documents.

Additionally, any identifying information about the participants, including notes, interview transcriptions, and other materials, will be stored securely in a locked file cabinet under the control of the researcher.

However, if the researcher is legally obligated to report any specific incidents such as abuse or suicide risk, participant data may be shared.

Voluntary Participation

Participation in this study is entirely voluntary, and you have the right to decide whether or not to take part. You will be required to sign a consent form if you choose to participate, but you may withdraw from the study at any time, without any explanation. Your relationship with the researcher will not be affected by your decision to withdraw, and any data collected before your withdrawal will be returned to you or destroyed.

Consent

By signing this consent form, I acknowledge that I have carefully read and understood the information provided and that I have been given the opportunity to ask any questions. I understand that my participation in this study is entirely voluntary and that I am free to withdraw at any time without any consequences. I understand that I will receive a copy of this consent form and that my agreement to participate is entirely voluntary.

_____
Printed Name of Participant

_____
Signature

_____
Date

Declaration

I have extensively conversed with the participant about the details outlined in this form. I confirm that the participant has a clear understanding of the potential benefits, risks, and procedures associated with their participation in this retinitis pigmentosa clinical trial.

_____

Printed Name of Person Getting Consent

_____

Signature of Person Getting Consent

_____

Date