Clinical Study - Analyzing Clinical Trial Experiences of Prostate Cancer Patients

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

Date: June 5, 2022

General Overview About This Consent Form

This is an opportunity to take part in an observational clinical study.

This consent form reveals important information about the overview of the Prostate Cancer observational clinical trial and why it is done.

It also includes what happens during the course of the study, benefits, and possible risks.

Please be sure to read the form carefully.

After reading it, ask the researcher some questions. You may also want to consult with your primary care doctor, friends, or loved ones regarding your interest in joining this clinical trial.

If you want to take part in this clinical trial, you will be required to sign this form. A copy will be given to you for your reference.

Prostate Cancer Observational Study Overview

This study aims to observe and understand the different factors during your Prostate Cancer clinical study enrollment process and how they will affect your capability to participate and complete your clinical trial.

The results will be non-personally identifiable and will be checked to see trends in relation to prostate cancer patient experience that often leads to unsatisfactory enrolment rates or low completion.

Since this clinical study is observational, nothing will change when it comes to your treatment once you decide to participate.

This document is written proof of whatever you discussed with our site staff or recruitment coordinators. You can also use this as a reference as a participant in this clinical study.

Why is this Prostate Cancer research being done?

Participation in clinical trials usually favors a particular demographic group. But there is limited research available to explain what trial attributes affect the participation or completion of these specific demographic groups.

This study will admit a wide range of data on the clinical trial experience of Prostate Cancer patients to determine which factors prevail in limiting a patient's ability to join or finish a trial.

It will also try to analyze data from the perspective of different demographic groups to check for recurring trends which might shed insights for the sake of future Prostate Cancer patients.

Do I get benefits if I join this clinical study?

If you participate in this observational clinical trial, you will be instrumental in finding out how we can help future Prostate Cancer patients. The results may help improve participation rates and diversify the reach of future studies.

Are there risks involved in this observational clinical study?

Joining clinical trials sometimes require changes in your treatment regimens and doing this always poses certain risks.

However, since this is an observational clinical study, there will be no changes to your treatment regimen, so there is no associated risk due to treatment change.

The trial uses online reporting and video calls with participating Prostate Cancer patients throughout its duration. One risk involved in this process is the possibility of a data breach.

With Power's clinical trials, this risk is minimized. We make sure that the data during these calls are secured and encrypted. Call logs and electronic copies of these consent forms are stored anonymously in a highly-secure environment.

What makes this study different from other trials for Prostate Cancer?

Most of the other studies are interventional clinical trials.

In interventional clinical trials, Prostate Cancer patients are required to undergo a course of treatment that might be different from what they are currently receiving.

Since this is an observational clinical trial, there will be no treatment recommendations or changes.

If you are interested in seeing what other studies say, you can check Prostate Clinical Trials on clinicaltrials.gov or prostate cancer clinical trials on Power's website.

You can also learn more about clinical trials examining participation rates by browsing the following:

PMID: 32503813 - Diversity of Enrollment in Prostate Cancer Clinical Trials: Current Status and Future Directions

PMID: 33835826 - Tackling Diversity in Prostate Cancer Clinical Trials: A Report From the Diversity Working Group of the IRONMAN Registry

What does a Prostate Cancer patient have to do in this study?

In this study, you are required to attend bi-weekly surveys lasting around 30 minutes. There are also quarterly check-in calls throughout the clinical trial process.

To participate, you have to be currently enrolled in an interventional clinical trial. Your treatment and methodology as prescribed by your primary care doctor will not be affected if you join this observational study.

At any point in this trial, if you have concerns or questions, you have to reach out to our staff for clarification.

You are required to ask your care team if you wish to enroll in this clinical study.

Participant Statement

I have read the above information and everything was verbally explained to me. All my questions were answered to my satisfaction.

I understand that joining this observational study is voluntary and that I can stop at any time. Signing this form does not extinguish my legal rights.

I understand that a copy of this consent form will be given to me.

By signing below, I am expressing my intent to participate in the clinical study.

_____
Printed Name of Participant

_____
Participant Signature

_____
Date

Statement of Person Conducting Informed Consent Discussion

I have thoroughly discussed the information contained in this form with the participant.

I vouch that the participant understands the benefits, risks, and procedures involved with this Prostate Cancer clinical trial.

_____
Printed name of Person Conducting Informed Consent Discussion

_____
Person Conducting Informed Consent Discussion Signature

_____
Date