Orthopedic Clinical Trials: Analyzing Patient Experience Patterns in Medical Trials

Power Clinical Trial's Orthopedic Medical Trial Observational Study Participant's Informed Consent Form

Date: July 27, 2022

First Remarks

There are two sections in this document:

The first part is the **Information Sheet,** where we give you data about the clinical study with you as a patient.

The second part is the **Statement of Consent,** where you affix your signature once you decide to join.

Upon completion, you will receive a duplicate of this form.

Part I: Information Sheet

Foreword

This document is an offer to participate in an observational medical trial that seeks to identify the various elements that influence your clinical trial experience, including the reasons you enroll in, stay enrolled in, or leave a clinical trial.

Kindly take your time deciding whether to take part in this study. You can talk about this with your family or care team.

There may be certain terminology on this permission form that you are unfamiliar with. Please be aware that you have the right to ask the staff member leading the informed consent conversation to stop and clarify any terminology or phrases you are confused about.

Our Institutional Review Board has looked over this idea and approved it (IRB). In order to safeguard orthopedic participants from injury, the plan was thoroughly examined by our ethics review group as well. This study has been approved as ethically sound and in accordance with federal laws protecting the rights of human subjects.

The Goal of This Clinical Trial For Orthopedic Patients

Clinical study enrollment has historically been heavily biased toward specific demographics. There aren't many studies, though, that identify the elements, both good and bad, that affect involvement.

We feel that by sharing your experiences while participating in Power's interventional medical trial you are now engaged in, you may assist us in identifying these characteristics as a patient in an orthopedic clinical trial.

Several people will be invited to participate in this study so that it may collect a variety of data about clinical trial experiences. We want to identify barriers to participation in orthopedic clinical trials well as the causes of participants' failure or withdrawal.

In the future, people with orthopedic disorders who are invited to take part in medical research will benefit from the analysis of the data.

Research Method

This clinical experiment is an observational one. You won't have to start a new treatment regimen if you choose to enroll. The way you are now being treated won't change. Only a series of interviews will be conducted with you to collect data. This observational study's researcher is unable to make a diagnosis or recommend a course of action.

Selection of Participants in Observational Clinical Trials

You must be engaged in a different interventional clinical study for orthopedic disorders in order to participate. We want to know why you chose to enroll in this research and why you would decide to either continue receiving therapy or discontinue it.

Voluntary Participation in the Orthopedic Clinical Trial

The involvement in this study is entirely optional and voluntary. Your choice to participate in this is your own. Your existing course of therapy under a different interventional clinical investigation will not be impacted by your participation in the trial. Even if you decide to take part, you are free to stop at any point if you become uncomfortable with the procedure. Whatever decision you choose will not affect how your job or work evaluations are handled, and you will not be waiving any legal rights.

Orthopedic Clinical Trial Comparison

Interventional clinical trials are another option for orthopedic sufferers, but they need you to sign up for a specific treatment plan. We won't provide you with any form of therapy or care regimen because our experiment is purely observational.

Our team is unable to recall every study on orthopedic trials. Please read about orthopedic studies on clinicaltrials.gov or locate additional orthopedic clinical trials on Power's reference website, though, if you feel the need for more information.

Procedures and Time Frame

You will be required to respond to questionnaires every two weeks if you agree to take part in this study. It normally takes 30 mins to finish one of these questionnaires. Throughout the course of the additional orthopedic interventional clinical study you are also a part of, we will also hold quarterly check-in calls.

Please be aware that, even if it is necessary for you to enroll in a different interventional clinical research before you may take part, everything about that trial—from providing a diagnosis to recommending treatments and care processes—is fully unrelated to our observational clinical experiment. Please contact your personal care team if you have any queries about your other trial.

If you are not comfortable discussing your own beliefs, experiences, or lessons learned, you are not obligated to do so.

You have the option of completing the survey on your own or having staff read it to you while you respond aloud. You can skip any of the survey questions and go on to the next if you don't want to talk about them.

Your name won't appear on the survey forms, and the data that will be gathered is anonymous.

Benefits

Although there will be no direct benefit to you as a patient with an orthopedic illness, your choice to participate will enable us to learn more about the factors that influence clinical trial experiences for orthopedic patients. This will be very helpful for anyone who signs up for future trials for this ailment.

Risk

There is a danger that you could accidentally reveal private information or that you might feel awkward talking about certain issues. This must be prevented. If you feel that the subject is too intimate or if it causes you any kind of discomfort, you are not required to divulge information or respond to a question.

Confidentiality

Please rest assured that we will keep any information you give, including any personal data, completely secret. We won't divulge this information to anyone except the study team. The data acquired, including phone logs and digital copies of permission forms, will be managed secretly and secured by encryption and passwords. In order to protect the patients' identity who suffer from orthopedic illness, any information about you will be identified by numbers rather than your name.

Right to Decline or Quit

Your voluntary enrollment in this research investigation is once again confirmed. If you choose not to participate in this clinical study, you are not required to. You have the option to participate or not at any moment, depending on whether the process conflicts with your values or makes you feel uncomfortable.

Studying Representation in Clinical Studies in More Detail

Several studies have examined the participation rates in clinical trials. Here is a handful of them for you to read:

Mason, Su, Mahvash Hussain-Gambles, Brenda Leese, Karl Atkin, and Julia Brown. "Representation of South Asian people in randomised clinical trials: analysis of trials' data." *Bmj* 326, no. 7401 (2003): 1244-1245.

Yates, Isabelle, Jennifer Byrne, S. Donahue, Linda McCarty, and Allison Mathews. "Representation in clinical trials: A review on reaching underrepresented populations in research." *Clinical Researcher* 34, no. 7 (2020).

Part II: Certificate of Consent

Participant's Statement

This is to declare that I was invited to take part in this medical study for orthopedic patients. As a patient with an orthopedic disorder, I am now involved in a different interventional clinical trial.

I have read the aforementioned consent document or have had a discussion about it. I was free to inquire about subjects that confused me. My inquiries have received satisfactory responses. I willingly agree to participate in this study.

I have been given a copy of this permission form.

Participant's Printed Name: _____

Participants Signature: _____

Date: _____
Day/Month/Year

If Illiterate

I heard the consent document properly read to the potential volunteer, who also got the chance to ask any questions. I attest that the subject voluntarily gave consent.

Witness Printed Name:_____ Participant Thumb Print

Witness Signature: _____

Date: _____
Day/Month/Year

Statement of Person Taking Participant Consent

I did my utmost to ensure that the potential participant understood the process by carefully reading the permission form to them.

I certify that the participant had the opportunity to ask questions about the study and that I answered any queries truthfully and to the best of my ability. I declare that the subject's permission was freely and voluntarily provided without being coerced.

A copy of this form has been furnished to the participant.

Printed Name of Individual Taking the Consent: _____

Signature of Individual Taking the Consent:_____

Date: _____
Day/Month/Year