Leiomyosarcoma Clinical Trials - Exploring Clinical Trial Experiences of People with Leiomyosarcoma

An informed consent form for Power Clinical Trial's observational clinical study participants

Date: September 16, 2022

About This Informed Consent Form

This informed consent form may have terms you do not understand. Please raise your questions to the study doctor or research staff so that they can explain the information that you do not understand.

In this consent form, the term "you" always refers to the subject, meaning the individual with leiomyosarcoma. As the research proponent, we are interested in your clinical welfare and the conduct of this clinical trial. Before joining, you may want to consult your care team or a doctor who is not an investigator in this trial. You can also discuss this with your friends or family. This is to make sure that you are making an informed decision before you enroll in this clinical trial.

The Purpose of This Leiomyosarcoma Clinical Trial

Leiomyosarcoma, also known as LMS, is a rare cancer that develops within smooth muscles. It mostly occurs among adults than in children. It is also considered a form of soft tissue sarcoma. Around 7 to 11 % of soft tissue sarcoma cases involve leiomyosarcoma.

The purpose of this clinical trial is to check for patterns when it comes to the factors affecting the enrolment, withdrawal, or completion rates of leiomyosarcoma patients while they are undergoing treatment under a separate clinical trial.

You are being asked to become a subject of this study because you have been diagnosed with leiomyosarcoma and may meet the study entry requirements.

Procedures

This leiomyosarcoma medical trial is observational. In an observational study, we will not recommend any intervention or care system. You will only be observed, and outcomes will be measured. While you are enrolled in a separate clinical trial that involves undergoing treatment, you can still join this study without impacting any changes to your current care regimen.

For this study, you must answer surveys conducted twice a week. These questionnaires would usually take 30 minutes to finish. Take your time when answering the questions in the survey. And if you have parts you do not understand, do not hesitate to ask the researcher in charge. You can skip some or all of the questions if you feel that you are not comfortable answering them. We will also make quarterly check-in calls while you are enrolled in the clinical trial.

As for your involvement in the study, your consent should be given voluntarily. If ever you decide to join this leiomyosarcoma clinical study, you will be given a copy of this form as proof that you have understood and have given consent of your own free will. As a voluntary participant, you can terminate your participation at any time, even without stating a valid reason for doing so.

Other Trials For Leiomyosarcoma

Most clinical trials available online are interventional and will require that you undergo a novel treatment or take a new medicine. As such, before engaging in any clinical trial, whether observational or interventional, it is best that you are well informed and familiar with existing studies regarding your condition.

To read about leiomyosarcoma studies, you can head to clinicaltrials.gov. You can also check Power's reference site to find different leiomyosarcoma clinical trials that you can browse.

Confidentiality

Your responses will be anonymous to protect your identity. Do not put your name or any identifying data in the survey forms. The information used in this study will be limited to

the research team members. However, the results of this study may be presented in meetings or published in publications. During these instances, your identity will not be exposed.

Risks

When joining clinical trials, there may be health risks whenever you try new treatments. But since this study is an observational clinical trial, the risk is reduced dramatically.

With clinical trials, there is a possibility of a breach of confidentiality. But the possibility is reduced when conducting this study because the information we collect is anonymous. All online transaction forms, call logs, surveys, and forms are securely stored and guarded by passwords and encryption.

Benefits

Since this is only an observational clinical trial, there will be no direct benefit to the leiomyosarcoma patient. However, the results of this clinical trial can be beneficial in discovering the different factors impacting withdrawal and enrolment rates among patients with leiomyosarcoma.

Additional Research on Representation in Clinical Trials

If you are interested in reading more resources about representation in clinical trials, check out the following research:

Carcel, Cheryl, Katie Harris, Sanne AE Peters, Else Charlotte Sandset, Grace Balicki, Cheryl D. Bushnell, Virginia J. Howard et al. "Representation of women in stroke clinical trials: a review of 281 trials involving more than 500,000 participants." Neurology 97, no. 18 (2021): e1768-e1774.

Ding, Jeffrey, Youwen Zhou, Muhammad Shahzeb Khan, Rebecca N. Sy, and Faisal Khosa. "Representation of sex, race, and ethnicity in pivotal clinical trials for dermatological drugs." International journal of women's dermatology 7, no. 4 (2021): 428-434.

Rehman, H. U. "Under-representation of the elderly in clinical trials." European journal of internal medicine 16, no. 6 (2005): 385-386.

Consent of the Participant

I have carefully read this form or had it read to me from beginning to end. I have had the chance to ask questions, and I comprehend the information that has been offered. I am aware that my participation is entirely optional and that I can stop at any moment, for any reason, and without incurring any fees. I am aware that a copy of this permission form will be provided to me. I freely consent to participate in this study.

_____

Name of Participant

_____

Signature of Participant

_____

Date

Statement of Person Taking Participant Consent

I have read this informational material to the participant and made sure he/she comprehends the trial's goals, procedures, risks, advantages, and other important details. The patient had the chance to explain terms and ideas, and I did my best to respond to any questions he or she had. The participant freely provided consent. A copy of this document was handed to the signer after the signature.

_____

Printed Name of Person Taking Consent

_____

Signature of Person Taking Consent

_____

Date