Exploring the Real-life Stories of Individuals Enrolled in Lymphedema Clinical Trials

Informed Consent Form (ICF) For Power Clinical Trial's Lymphedema Observational Study

Date: July 7, 2023

Understanding the Informed Consent Document

Since you have been invited to consider participation in an observational clinical trial targeting individuals grappling with lymphedema, you are given this informed consent form. It aims to provide a comprehensive account of the study's intricacies. This includes its overarching goals, the process, as well as a balanced portrayal of the potential advantages and disadvantages involved. Before making your decision, it is of utmost importance to thoughtfully deliberate your choices and seek guidance from a trusted confidant or your care team. In case any queries arise regarding the information presented, do not hesitate to approach the researcher for further clarification.

The Purpose Behind This Clinical Trial

Lymphedema is a medical condition characterized by swelling, usually in the arms or legs, caused by a buildup of lymphatic fluid. The lymphatic system is responsible for draining excess fluid from the body's tissues and maintaining the body's immune system. When there is a disruption or blockage in the lymphatic system, such as after surgery, radiation therapy, or an infection, the flow of lymphatic fluid can be impaired, leading to the development of lymphedema.

Common symptoms of lymphedema include persistent swelling, a feeling of heaviness or tightness in the affected limb, restricted range of motion, discomfort or pain, and

recurrent infections in the affected area. Lymphedema can have a significant impact on a person's quality of life, causing physical discomfort and functional limitations.

The primary goal of conducting clinical trials for lymphedema is to evaluate the safety and efficacy of new therapies. Researchers want to acquire convincing data to promote their broad usage by conducting these studies to see whether novel therapies are more successful than existing ones.

This study intends to investigate the personal experiences of lymphedema patients who take part in a separate clinical trial including a specific medication intervention. The major focus will be on closely following these individuals' rates of trial completion and withdrawal.

Exploring the Significance of Observational Clinical Trials

Enrolling in this medical trial involves participating in an observational study, a distinct clinical trial approach that aims to gather crucial information by closely observing individuals while maintaining their existing care plans unchanged.

Throughout the trial, researchers will closely monitor your journey and diligently assess the outcomes of your condition without implementing any interventions. Such trials serve as invaluable tools for developing a deep understanding of the inherent progression of a specific condition and its impact on individuals who have received a diagnosis. Your active engagement in this observational study will make a meaningful contribution to the advancement of medical knowledge, ultimately leading to enhancements in the care provided to individuals who share the same condition.

Exploring Choices: Comparing Clinical Trials for Lymphedema

While the current clinical trial adopts an observational approach without administering specific treatments or interventions, it is essential to recognize the existence of other lymphedema clinical trials that follow an interventional path, requiring participants to undergo targeted treatment regimens.

To make a well-informed decision about potential participation in a clinical trial, it is crucial to engage in comprehensive research and conduct comparative analysis of different studies. Valuable information regarding lymphedema studies can be obtained from clinicaltrials.gov or by visiting Power's website, which offers insights into ongoing

lymphedema clinical trials open for recruitment. By investing time and effort into understanding the various types of clinical trials available, you can confidently explore your options and make a discerning choice regarding your suitability for trial participation.

Survey Participation: Important Insights in an Observational Clinical Trial

As a volunteer in this observational clinical research, your feedback is much appreciated as we work to get vital insights into your experiences. This will be performed by completing surveys every two weeks, which will take around 20-30 minutes of your time. Additionally, quarterly check-in calls will be performed during your participation in the study.

It is critical to emphasize that your participation in the survey portion of this study is entirely optional. You have the flexibility to pick which questions to answer, and you have the option to withdraw at any time. We appreciate that participating in clinical research is a personal decision, and we are committed to offering assistance throughout the process. Your privacy and comfort are our top considerations, and we will completely respect your decision while ensuring a courteous trial experience.

Preserving Confidentiality: Ensuring Anonymity in Survey Responses

During this clinical trial, we place the utmost importance on maintaining the confidentiality of your information. To guarantee complete anonymity, we kindly request that you refrain from providing any personal or identifying details in your questionnaire responses. Rest assured that the research team will implement all necessary measures to protect your privacy. However, it is essential to be aware that specific legal requirements may dictate the disclosure of your data under certain circumstances.

Driving Change through Participation: Empowering Future Lymphedema Patients

Although participants in this observational clinical trial may not experience immediate benefits, their involvement can have a profound impact on the lives of others. The data collected from participants will be instrumental in enhancing the enrollment process for future individuals with lymphedema, streamlining their access to valuable medical

research opportunities. By choosing to join this clinical trial, individuals have a unique chance to contribute to the betterment of future lymphedema patients' lives and actively shape the landscape of medical research.

Safety and Risk Mitigation in Observational Trials

Clinical trials are important for improving medical knowledge, but they also pose health hazards, especially when new therapies are being investigated. It is crucial to note, however, that our observational clinical study removes such risks because participants are not subjected to any additional therapies. Instead, individuals are continuously monitored and outcomes are recorded to assure their safety throughout the research.

The anonymity of participants is critical in clinical studies, and our medical study takes stringent safeguards to secure participant information. All participant data is anonymised, and access to this information is tightly restricted to the study team.

Furthermore, extensive security mechanisms are in place to protect all records, including phone logs, online transactions, forms, and surveys. These records are securely maintained utilizing encryption and password protection, ensuring participant confidentiality and protection. This strict method guarantees that participant data stays safe and protected from unwanted access, putting the privacy and confidence of all trial participants first.

Clinical Trial Participation Investigation

We invite you to participate voluntarily in an observational research study designed to explore the factors that drive patients' decisions to take part in clinical trials for lymphedema. It is important to note that this study does not involve proposing new treatment protocols or making any alterations to your current treatment plan.

Throughout this study, the researcher will conduct interviews to gather valuable information about your experiences. However, apart from the interviews, all aspects of your treatment and care will remain unchanged. The researcher will not provide a diagnosis or recommend any specific course of treatment. The primary objective of this study is to collect data for research purposes.

To be eligible for participation, it is necessary for you to be currently enrolled in another clinical trial for lymphedema. By delving into the motivations behind your decision to

participate and the factors influencing your determination to continue or discontinue treatment in that trial, we aim to gain deeper insights into patients' perspectives and experiences within clinical trials for lymphedema.

Please remember that your participation in this study is entirely voluntary, and you have the freedom to withdraw at any time if you feel uncomfortable. Your decision to withdraw will not impact any of your legal rights, and your ongoing treatment plan in the other clinical trial will remain unaffected.

Diversity in Clinical Trials: Informative Resources for Engagement

For those seeking a more comprehensive understanding of representation in clinical trials, a wealth of online resources is available to explore this important topic. These resources offer valuable insights into the challenges and opportunities surrounding diversity in clinical research, providing a multifaceted perspective:

Varma, Tanvee, Michelle Mello, Joseph S. Ross, Cary Gross, and Jennifer Miller. "Metrics, baseline scores, and a tool to improve sponsor performance on clinical trial diversity: retrospective cross sectional study." *BMJ medicine* 2, no. 1 (2023).

Versavel, Stacey, Alicia Subasinghe, Kenasha Johnson, Nicole Golonski, Janna Muhlhausen, Pamela Perry, and Raymond Sanchez. "Diversity, equity, and inclusion in clinical trials: A practical guide from the perspective of a trial sponsor." *Contemporary Clinical Trials* 126 (2023): 107092.

By engaging with these resources, individuals can acquire valuable knowledge to inform their own participation in clinical trials and actively contribute to advancing diversity and inclusion in the field of medical research.

Affirmation of Informed Consent

I affirm that I have dedicated sufficient time to thoroughly read and understand the content of the informed consent form, either independently or with the assistance of a trusted individual who has read it aloud to me. All of my inquiries and concerns have been adequately addressed to my complete satisfaction.

I am fully aware that my involvement in this study is entirely voluntary, and I retain the right to withdraw my consent at any time, without the need to provide a rationale or face

any financial obligations. I have been informed that I will receive a copy of this informed consent form for my personal records.

After careful contemplation and thoughtful consideration of all the information provided, I willingly provide my consent to participate in this study of my own accord.

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Printed Name of Participant

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Participant Signature

_____

Date

Confirming Informed Consent: Provider's Verification

I hereby confirm that I have thoroughly reviewed the contents of this document with the participant, ensuring their comprehensive understanding of the purpose, methodologies, potential risks and benefits, and other vital aspects related to the lymphedema clinical trial.

During our discussion, I created a supportive environment that encouraged the participant to ask questions and seek clarifications, effectively addressing any concerns or misconceptions they may have had. It is important to emphasize that the participant's participation in this trial is completely voluntary, granting them the autonomy to withdraw their consent at any point without incurring any financial implications.

Following their expression of consent, a copy of this document was provided to the participant for their personal reference.

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Printed Name of Person Taking Consent

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Signature of Person Taking Consent

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Date