Gaining Insights Into Patient Involvement Patterns and Trends in Participation in Lymphoma Clinical Trials

This is an Informed Consent Form For Lymphoma Patients in Power Clinical Trial's Observational Study

Date: September 30, 2023

Understanding the Significance of This Informed Consent Document

If you are currently engaged in the completion of this paper, it signifies that you may be eligible to participate in a unique observational clinical study designed exclusively for individuals with lymphoma. This comprehensive guide elucidates the study's primary objectives, detailed implementation strategy, and various consequences, both positive and potentially negative. Before arriving at a decision, it is vital to thoroughly explore the specifics of your potential participation, and seeking guidance from a reliable source can provide valuable insights. If any part of this document seems perplexing or if you have any inquiries, rest assured that the researcher is prepared to provide answers.

Unveiling the Significance of Lymphoma Clinical Trials

Lymphoma is a type of cancer that originates in the lymphatic system, which is a key component of the body's immune system. The lymphatic system includes lymph nodes, lymph vessels, and various organs, such as the spleen and the thymus. Lymphoma primarily affects lymphocytes, which are a type of white blood cell involved in the body's defense against infections.

Clinical studies, with a distinct focus on lymphoma, play a pivotal role in assessing the safety and effectiveness of novel treatments for this disease. These trials serve as

crucial instruments in determining whether new medications outperform conventional therapies, providing substantial evidence for their widespread adoption.

What distinguishes this study is its central emphasis on the firsthand experiences of individuals contending with lymphoma, actively participating in a clinical trial incorporating medicinal interventions. The primary aim is to meticulously scrutinize trial completion rates and voluntary withdrawals within this specific patient group.

Revealing the Heart of Observational Research

Engaging in this medical trial entails immersing oneself in an observational study, a unique dimension of clinical research meticulously constructed to unearth insights through unobtrusive observation of patients while preserving their treatment regimens.

Researchers will solely observe your journey, methodically assessing the outcomes of your condition without any interference. This specific trial design carries immense significance in deepening our understanding of the natural progression of a particular medical ailment and its implications for individuals affected by it. By actively participating in this observational study, you take on a crucial role in expanding the boundaries of medical knowledge and advancing improvements in the care provided to those enduring the same condition.

Setting This Trial Apart in Lymphoma Clinical Research

Recognizing the distinctive characteristics of this research study is of utmost importance. It operates solely on an observational basis, indicating that your participation will not entail any specific treatments or interventions. To arrive at an informed decision regarding potential involvement in a clinical trial, it is essential to understand the spectrum of lymphoma clinical investigations, including interventional studies where participants undergo diverse treatment regimens.

Formulating an educated choice concerning your potential participation in a clinical trial necessitates an active approach that includes research and a comparison of various trials. Resources such as Clinicaltrials.gov and similar platforms offer a wealth of information on research pertaining to lymphoma. Moreover, Power's specialized web platform provides a comprehensive list of ongoing lymphoma clinical trials actively recruiting volunteers. Equipping yourself with diligent research and a comprehensive

understanding of different clinical trial categories empowers you to decisively shape your participation decision.

Active Participation in Clinical Trial Surveys: Your Contribution Matters

We warmly invite you to actively contribute your experiences as part of this observational clinical investigation. This endeavor entails completing questionnaires every two weeks, requiring approximately 20-30 minutes of your valuable time. Furthermore, we are fully prepared to conduct check-in calls at quarterly intervals, a practice that will continue throughout your participation in the trial.

It is essential to emphasize that your engagement in the survey phase of the trial is entirely at your discretion. You have the autonomy to decide whether to respond to specific questions or complete the entire questionnaire. Additionally, you maintain the freedom to withdraw from the trial at any time, should you choose to do so.

Understanding that the decision to participate in a clinical study is deeply personal, we are dedicated to providing the necessary support. Your privacy and comfort are of the utmost importance to us, and we are committed to respecting and assisting your decision-making process throughout the trial.

Protecting the Privacy of Your Responses

Protecting the absolute confidentiality of your information is a cornerstone of this research study. To maintain your anonymity, we respectfully urge you not to include any personal or identifiable details in your questionnaire responses. The committed research team is unwavering in their commitment to enhancing the security of your privacy. However, it's important to recognize that specific legal situations may emerge, requiring the disclosure of personal data.

Acknowledging Potential Health Challenges

Despite the remarkable progress achieved through clinical trials, it is crucial to acknowledge the potential health challenges that participants may encounter, especially in studies evaluating new medications.

Nevertheless, our approach in observational clinical research takes a unique path, intentionally mitigating these challenges by refraining from the application of experimental therapies to participants. Our primary emphasis is on thorough monitoring and outcome evaluation, assuring the avoidance of any undue health risks.

Anticipated Gains

Though immediate advantages may not be readily apparent to participants in this observational clinical research, their involvement harbors the potential to leave a significant impact on others. The information amassed from participants will serve as a catalyst for advancing future approaches to recruiting individuals with lymphoma, potentially broadening the scope of medical investigation. Those who undertake this therapeutic odyssey have the capability to initiate substantial changes in the landscape of medical research, potentially guiding the course for future lymphoma patients.

Nurturing Diversity in Clinical Studies

An abundance of online resources enthusiastically welcomes your active participation if you are fueled by an insatiable curiosity to delve into the intricate subject of diversity within clinical trials.

Whether your aim is to understand the intricacies of the challenges and opportunities linked to clinical trial diversity or to broaden your own horizons, the following resources can be an invaluable asset:

Mendis, Shehara, Seerat Anand, Joanna M. Karasinska, Arvind Dasari, Joseph M. Unger, Anirudh Gothwal, Lee M. Ellis et al. "Sex representation in clinical trials associated with FDA cancer drug approvals differs between solid and hematologic malignancies." *The Oncologist* 26, no. 2 (2021): 107-114.

Debevec, Hana, Douglas R. Pedersen, Aleš Iglic, and Matej Daniel. "One-legged stance as a representative static body position for calculation of hip contact stress distribution in clinical studies." *Journal of applied biomechanics* 26, no. 4 (2010): 522-525.

Acknowledgment of Informed Agreement

I acknowledge that I have dedicated sufficient time to grasp and internalize the information presented in the informed consent form. This understanding has been achieved through either independent review or with the assistance of a trusted individual who has elucidated its contents to me. All of my inquiries and concerns have been addressed thoroughly to my complete satisfaction.

I am fully aware that my participation in this study is a result of my own choice, and I possess the sole authority to withdraw my consent without any obligation to provide explanations or assume financial responsibilities. It has been made clear to me that a copy of this informed consent form will be provided for my personal records.

After careful deliberation and a comprehensive review of all the materials presented to me, I hereby grant my consent to participate in this study, signifying my informed and autonomous decision.

_____

Participant Name

_____

Participant Signature

_____

Date

Validation by Informed Consent Facilitator

I hereby validate that I have engaged in a thorough discussion with the participant, meticulously elucidating the intricacies contained within this written document. My objective was to ensure that the participant possessed a comprehensive understanding of the primary research goals, the methodology employed, potential risks and benefits, and other essential components inherent to the lymphoma clinical trial.

The participant was given ample opportunity to pose questions and express concerns or seek clarifications. It is imperative to underscore that the participant's involvement in this

study is entirely voluntary, and they retain the unencumbered right to withdraw at any time, for any reason, without incurring any financial obligations.

Following the participant's granting of consent, a diligently maintained duplicate of this written document was provided to them, serving as a repository for their specific information.

_____

Printed Name of Assisting Researcher

_____

Signature of Assisting Researcher

_____

Date