Delving Into the Patterns of Patient Engagement and Trends in Participation Within Recurrent Ovarian Cancer Clinical Trials

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

Date: September 30, 2023

Appreciating the Importance of This Informed Consent Form

If you are currently in the process of completing this document, it signifies that you may meet the criteria to participate in a distinctive observational clinical study designed for individuals with recurrent ovarian cancer. This comprehensive guide outlines the study's primary objectives, intricate implementation plan, and various implications, both positive and potentially adverse. Before reaching a decision, it is crucial to delve into the specifics of your potential participation and seeking guidance from a trusted source can provide valuable insights. If any part of this document appears unclear or if you have questions, the researcher is readily available to provide clarification.

Understanding the Importance of Clinical Trials for Recurrent Ovarian Cancer

Recurrent ovarian cancer, also known as recurrent ovarian carcinoma, refers to the return or reappearance of ovarian cancer after a period of initial treatment and remission. When ovarian cancer is initially diagnosed, treatment typically involves surgery to remove as much of the cancerous tissue as possible, followed by chemotherapy and/or radiation therapy to kill any remaining cancer cells. In many cases, this initial treatment is successful, and the cancer goes into remission.

Clinical trials, with a particular focus on recurrent ovarian cancer, play a crucial role in assessing the safety and efficacy of novel treatments for this condition. These trials serve as essential tools to determine whether new medications outperform traditional therapies, providing substantial evidence to support their widespread adoption.

What sets this study apart is its emphasis on the firsthand experiences of individuals grappling with recurrent ovarian cancer, actively participating in a clinical trial incorporating medicinal interventions. The primary objective is to meticulously examine trial completion rates and voluntary withdrawals within this specific patient group.

Revealing the Essence of Observational Trials

Embracing this medical trial entails immersing oneself in an observational study, a distinctive facet of clinical research carefully designed to uncover insights through unobtrusive observation of patients while maintaining their treatment protocols. Researchers will purely observe your journey, methodically assessing the outcomes of your condition without any alterations. This specific trial design carries immense significance in enhancing our understanding of the natural progression of a particular medical ailment and its implications for individuals grappling with it. By actively participating in this observational study, you assume a pivotal role in expanding the boundaries of medical knowledge and advancing the quality of care provided to those enduring the same condition.

Actively Participating in Clinical Trial Surveys

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

It is crucial to emphasize that your engagement in the survey phase of the trial is entirely voluntary. You have the autonomy to choose whether to respond to specific questions or complete the entire questionnaire. Furthermore, you retain the freedom to discontinue your participation in the trial at any time, should you choose to do so. Recognizing that the decision to enroll in a clinical study is highly personal, we are committed to providing the necessary support. Your privacy and comfort are of utmost

importance to us, and we are dedicated to respecting and assisting your decision-making process throughout the trial.

Distinguishing This Trial from Other Recurrent Ovarian Cancer Clinical Investigations

Recognizing the unique characteristics of this research study is of paramount importance. It operates exclusively on an observational basis, signifying that your participation will not entail any specific treatments or interventions. To make an informed decision regarding potential involvement in a clinical trial, it is crucial to grasp the spectrum of recurrent ovarian cancer clinical investigations, encompassing interventional studies where participants undergo diverse treatment regimens.

Formulating an educated choice regarding 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 related to recurrent ovarian cancer. Furthermore, Power's specialized web platform provides a comprehensive list of ongoing recurrent ovarian cancer clinical trials actively seeking volunteers. Equipping yourself with diligent research and a comprehensive understanding of different clinical trial categories empowers you to decisively shape your participation decision.

Recognizing Potential Health Concerns

While clinical trials have contributed significantly to medical progress, it is essential to recognize the potential health concerns that trial participants may face, particularly in studies evaluating novel medications.

Nevertheless, our observational clinical research takes a unique stance, purposefully minimizing these concerns by refraining from the administration of experimental therapies to participants. Instead, our primary focus lies in meticulous monitoring and outcome assessment, assuring the avoidance of any unwarranted health risks.

Anticipating Potential Benefits

While immediate benefits may not be immediately apparent to participants in this observational clinical research, their involvement carries the potential to exert a significant influence on others. The data gathered from participants will be instrumental in advancing future recruitment strategies for individuals with recurrent ovarian cancer, potentially expanding the horizons of medical investigation. Those who embark on this therapeutic journey have the capacity to catalyze profound changes in the field of medical research, potentially shaping the trajectory for future recurrent ovarian cancer patients.

Safeguarding the Privacy of Your Responses

Ensuring the absolute confidentiality of your data remains a top priority throughout this research endeavor. To protect your anonymity, we kindly urge you to refrain from including any personal or identifiable information in your questionnaire answers. The committed research team is resolute in their commitment to bolstering the security of your privacy. Nevertheless, it's important to acknowledge that certain legal circumstances may emerge, requiring the disclosure of personal data.

Promoting Diversity in Clinical Trials

An array of online resources enthusiastically welcomes your active engagement if you are fueled by an insatiable curiosity to explore the complex landscape of diversity in clinical trials.

Whether your aim is to comprehend the nuances of the obstacles and possibilities associated with clinical trial diversity or to broaden your own horizons, the following resources can be an invaluable asset:

Sanjiv, Nayan, Pawarissara Osathanugrah, Michael Harrell, Nicole H. Siegel, Steven Ness, Xuejing Chen, Howard Cabral, and Manju L. Subramanian. "Race and ethnic representation among clinical trials for diabetic retinopathy and diabetic macular edema within the United States: A review." *Journal of the National Medical Association* 114, no. 2 (2022): 123-140.

National Academies of Sciences, Engineering, and Medicine. "Improving representation in clinical trials and research." (2022).

Affirmation of Informed Consent

I affirm that I have devoted ample time to comprehend and internalize the information contained in the informed consent form. This understanding has been acquired through either independent examination or with the guidance of a trusted individual who has elucidated its contents to me. All of my queries and concerns have been comprehensively addressed to my complete satisfaction.

I am fully aware that my participation in this study arises from my own choice, and I possess the exclusive right to withdraw my consent without any obligation to provide justifications 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 consideration and a thorough review of all the materials presented to me, I hereby extend my approval to participate in this study, representing 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 objectives, the methodology employed, potential risks and

benefits, and other essential components inherent to the recurrent ovarian cancer clinical trial.

The participant was given ample opportunity to pose questions and express concerns or seek clarifications. It is crucial to emphasize 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