A Journey Endometrial Cancer Clinical Trials - Revealing Engagement Patterns Among Individuals Affected by Endometrial Cancer

Understanding the Informed Consent Protocol within Power Clinical Trial's Observational Study: An Informative Guide for Participants Diagnosed with Endometrial Cancer

Date: August 11, 2023

About This Informed Consent Form

If you're tasked with completing this form, it indicates that you are under consideration for participation in an observational clinical trial with a specific focus on individuals grappling with endometrial cancer. This form serves as a comprehensive guide, unveiling the study's overarching objectives, detailed execution plan, and multifaceted implications, both positive and potentially otherwise. Engaging in thoughtful contemplation of your potential involvement before arriving at a decision is of utmost importance, and seeking guidance from a trusted confidant can provide valuable insights. Should any intricacies of the information contained within this document remain unclear or if questions arise, rest assured that the researcher is ready and willing to provide clarifications.

Study Purpose

Endometrial cancer is among the most prevalent forms of gynecologic cancer in women. Its symptoms may encompass irregular vaginal bleeding, pelvic discomfort, pain during sexual intercourse, and alterations in urinary or bowel habits. While the exact cause of endometrial cancer may not always be definitively established, certain risk factors such as hormonal imbalances, obesity, and a history of specific medical conditions may elevate the likelihood of its development.

Clinical trials targeting endometrial cancer are pivotal endeavors that assess the safety and effectiveness of novel treatments for this condition. These trials are instrumental in determining whether these emerging treatments surpass current options and offer substantial evidence to support their wider adoption.

This specific study places meticulous focus on exploring the experiences of individuals diagnosed with endometrial cancer as they actively engage in a unique clinical trial involving medical interventions. The primary emphasis lies in closely examining trial completion rates and instances of voluntary withdrawal among these participants.

Introduction to Observational Studies

Your involvement in this medical trial places you within an observational study, a distinct type of clinical trial designed to gather information by observing individuals without introducing any changes to their care plans.

Researchers will merely observe your progress and assess the outcomes of your condition without intervening in any way. This kind of trial plays a crucial role in deepening our comprehension of the natural progression of a specific condition and its effects on individuals diagnosed with it. By participating in this observational study, you actively contribute to the advancement of medical knowledge and the enhancement of care for individuals sharing the same condition.

Insights into Upcoming Clinical Trials for Endometrial Cancer

It is important to acknowledge that this clinical trial adopts an observational approach, indicating that your participation will not involve the application of specific treatments or interventions as part of the study. Nonetheless, the spectrum of endometrial cancer clinical trials encompasses variations, including interventional trials that necessitate participants to undergo particular treatment protocols.

Making a well-informed decision about your potential engagement in a clinical trial requires an active approach to researching and comparing diverse studies. A wealth of information regarding endometrial cancer-related studies can be accessed through platforms like clinicaltrials.gov. Additionally, Power's dedicated website provides a comprehensive list of ongoing endometrial cancer clinical trials actively seeking participants. Through dedicated research and a comprehensive understanding of

various clinical trial formats, you can confidently arrive at a decision about your participation.

Voluntary Involvement in Clinical Trial Surveys

As a participant in this observational clinical trial, we extend an invitation to share your experiences with us. This will involve your completion of questionnaires every two weeks, a task that is expected to require approximately 20-30 minutes of your time. Moreover, on a quarterly basis, we will arrange check-in calls for as long as you choose to remain engaged in the trial.

It's crucial to underscore that your participation in the survey phase of the trial is entirely at your discretion. You hold the autonomy to decide whether to answer specific questions or all questions, and you retain the right to cease your involvement in the trial whenever you wish. We understand that the decision to participate in a clinical trial is a personal one, and we are fully committed to providing the support you need. Your privacy and comfort are paramount to us, and we will consistently respect your decision-making process throughout the trial.

Protecting the Confidentiality of Your Answers

Ensuring the absolute confidentiality of your information remains a top priority throughout the duration of this clinical trial. To uphold your anonymity, we respectfully request that you refrain from including any personal or identifiable specifics in your responses to the questionnaires. The committed research team is steadfast in their commitment to enhancing the shield of your confidentiality. Nonetheless, it's essential to acknowledge that specific legal circumstances may emerge, demanding the revelation of your data.

Potential Benefits

Although immediate advantages may not be immediately discernible for individuals participating in this observational clinical trial, their engagement holds the potential to leave a significant impact on the lives of others. The reservoir of data gathered from participants will drive the enhancement of future procedures for enrolling endometrial cancer patients, ultimately leading to increased access to medical research avenues. By

embarking on this clinical journey, individuals have the opportunity to act as agents of transformative change within the realm of medical research, significantly altering the trajectory of future endometrial cancer patients.

Possible Risks

The realm of clinical trials has undoubtedly propelled medical advancement, yet it is equally vital to acknowledge the potential specter of health risks that can hang over participants, particularly in trials involving novel treatments.

However, our observational clinical trial stands as an exception, effectively mitigating this risk by refraining from imposing novel interventions on participants. Instead, the primary focus revolves around observation and outcome measurement, without introducing any unnecessary health hazards.

Embarking on a Deeper Journey into Clinical Trial Inclusiveness

For those who hold a curiosity to explore the intricate realm of representation in clinical trials, a trove of online resources eagerly awaits your active engagement.

Whether your goal is to untangle the complexities interwoven with challenges and opportunities, or you simply aspire to enrich your personal odyssey through the realm of clinical trials, these sources of knowledge stand as guiding lights:

Adkins-Jackson, Paris B., Nancy J. Burke, Patricia Rodriguez Espinosa, Juliana M. Ison, Susan D. Goold, Lisa G. Rosas, Chyke A. Doubeni, Arleen F. Brown, and STOP COVID-19 California Alliance Trial Participation and Vaccine Hesitancy Working Groups. "Inclusionary trials: A review of lessons not learned." *Epidemiologic Reviews* 44, no. 1 (2022): 78-86.

Calvert, Melanie J., Samantha Cruz Rivera, Ameeta Retzer, Sarah E. Hughes, Lisa Campbell, Barbara Molony-Oates, Olalekan Lee Aiyegbusi et al. "Patient reported outcome assessment must be inclusive and equitable." *Nature medicine* 28, no. 6 (2022): 1120-1124.

Confirmation of Informed Choice

I hereby confirm that I have invested significant time in thoroughly comprehending and absorbing the contents encapsulated within the informed consent form, either independently or with the guidance of a trusted individual who has conveyed its essence to me. All queries and concerns that occupied my thoughts have been diligently addressed to my complete satisfaction.

I am acutely aware that my engagement in this study is a result of my voluntary decision, and the right to retract my consent rests solely with me, without any obligation to provide justification or encounter financial commitments. I have been explicitly informed that a duplicate of this informed consent form will be provided for my record-keeping.

After careful consideration and evaluation of the entirety of the information presented to me, I hereby provide my agreement to participate in this study, an embodiment of my autonomous choice.

_____

Printed Name of Participant

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Participant Signature

_____

Date

Confirmation by Informed Consent Facilitator

I assertively affirm that I have engaged in an extensive dialogue with the participant, systematically unraveling the intricacies encapsulated within this textual document. My aim was to ensure the participant's thorough comprehension of the trial's overarching

objectives, methodologies employed, potential risks and benefits, as well as other vital aspects inherent to the endometrial cancer clinical trial.

An adequate opportunity was afforded to the participant, encouraging the emergence of inquiries and facilitating the clarification of uncertainties or misconceptions. It is imperative to emphasize that the participant's participation in this trial is an outcome of their voluntary decision, and they retain the unrestricted prerogative to cease their involvement at any point, driven by any rationale, without bearing any financial burden.

Subsequent to the participant's provision of consent, a meticulously preserved duplicate of this textual document was furnished to them, serving as a repository for their individual records.

_____

Printed Name of Person Taking Consent

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Signature of Person Taking Consent

_____

Date