Analyzing Factors of Patient Involvement in Ovarian Cancer Clinical Trials: A Study of Medical Research Trends

A Consent Form For Participants of Power Clinical Trial's Observational Clinical Study

Date: March 24, 2023

Introduction and Important Information

We want to ensure that you have all the necessary information before deciding to participate in our research project. Your consent is required for your participation, but you are not obligated to do so and may withdraw at any time. This brief summary provides an overview of the study, but please review the more detailed information in the consent form.

The primary procedures of this observational clinical study involve completing questionnaires and follow-up calls to understand why patients choose to enroll, remain, or withdraw from clinical trials. These procedures have been designed to minimize any risks to participants, and as an observational study, there may not be any direct medical benefits. However, the data collected can be used to identify ways to improve clinical trial participation rates and ultimately benefit patients with ovarian cancer.

The findings of this study will provide valuable insights into the factors affecting clinical trial participation rates. This information can be used to improve recruitment strategies and patient engagement in clinical trials, ultimately benefiting ovarian cancer patients. However, it is important to emphasize that participation is voluntary and declining to participate will not affect your rights or privileges.

We want to ensure that you are fully informed before making a decision about participation. We encourage you to review the consent form carefully and ask any questions you may have. It is recommended that you discuss the study with your family,

friends, trusted advisors, and healthcare professionals to make an informed decision. Remember that your participation is entirely voluntary, and you have the right to withdraw at any time without consequences.

The Objective of the Clinical Trial

Clinical studies are crucial in developing new treatments for ovarian cancer. However, the participation rates in these studies may not always represent the larger population accurately. This clinical trial aims to examine the variables that influence a patient's decision to enroll, discontinue, or resume participation in an ovarian cancer clinical trial.

By understanding the factors that affect clinical trial participation rates, we can ultimately improve the effectiveness and relevance of future studies.

To ensure the study's results are statistically significant, we are seeking to recruit individuals from diverse demographic groups. This will help us understand how various factors, such as age, race, income, and education level affect a patient's decision to participate in a clinical trial. By gathering this information, we hope to develop better strategies to increase participation rates among underrepresented groups in future clinical trials.

It is important to note that participation in this clinical trial is voluntary, and individuals have the right to withdraw at any time without consequence. The study's primary procedures involve answering questionnaires and making follow-up calls, with minimal risk to the participants. Nonetheless, we strongly encourage potential participants to carefully review the consent form and ask any questions they may have before deciding to participate.

The Methodology of the Clinical Study

As an ovarian cancer patient currently undergoing treatment in an interventional trial, you have been invited to participate in our observational clinical research study. Our research team aims to understand the factors that influence patient enrollment, withdrawal, and completion of clinical trials for ovarian cancer.

To recruit participants who have previously taken part in, withdrawn from, or completed a clinical trial, we will utilize electronic medical record systems. If you decide to

participate, our staff will provide you with a consent form to sign, and they will explain the study's objectives and your rights as a participant.

Participants will receive a questionnaire every two weeks, asking about their demographics, medical history, and reasons for enrolling, withdrawing, or completing the clinical trial. The research team will also conduct phone or video interviews with participants every three months to gather more information about their experiences.

The study team will use statistical analysis to examine the data collected and identify the variables that influence patient participation in clinical trials. The results of the study will be disseminated at conferences and published in scholarly journals, with the aim of improving patient recruitment and retention in future clinical studies for ovarian cancer.

Are There Any Risks?

Participating in an observational clinical research study for ovarian cancer may involve certain risks, even without experimental interventions such as medication treatments or medical procedures. These risks may include privacy violations, emotional distress related to the study's topic, and potential negative outcomes from any procedures conducted during the trial.

It is crucial for potential participants to thoroughly review the informed consent form and discuss any concerns or questions with the research team before deciding to participate. The research team will explain the study's risks and benefits and provide detailed information on how they plan to protect participants' privacy and well-being.

Are There Any Advantages?

Patients with ovarian cancer have the opportunity to contribute to medical research and potentially improve future treatment options by participating in observational clinical trials. Additionally, patients may receive expert care and attention throughout the study, although there may not be direct medical benefits from the trial since experimental therapies are not involved.

Individuals should carefully consider the potential benefits and drawbacks of participating in a clinical trial based on their unique circumstances and goals. Patients are encouraged to discuss their options with their doctor and the study team before making a decision.

Possible Reasons for Stopping Your Participation

It's worth noting that the researcher or sponsor may discontinue your involvement in the study for a variety of reasons, even if you do not consent to it. These reasons may include the suspension or termination of the investigation, the withdrawal, suspension, or removal of funding for the study, or if it is considered to be in your best interests.

Additionally, if your health deteriorates, if you become pregnant, if you choose not to proceed with the research after being informed of any changes that may affect you, or if you fail to comply with the study's protocols, your participation may also be stopped.

Understanding the Differences between Ovarian Cancer Clinical Trials and Others

Participation in this clinical research study is completely voluntary, and you have the freedom to withdraw at any point without facing any negative consequences.

For a comprehensive list of ovarian cancer studies worldwide, visit clinicaltrials.gov, a website managed by the National Institutes of Health (NIH). The website allows you to narrow down your search for trials based on various criteria, including location and medical condition.

Additionally, Power's reference page provides a list of active ovarian cancer clinical trials that are currently accepting participants.

Exploring Clinical Trial Diversity Online

If you are interested in delving into the topic of clinical trial diversity, there are several online resources available. Here are a couple of articles that may be of interest to you:

Kusumoto, Fred M., Hugh Calkins, John Boehmer, Alfred E. Buxton, Mina K. Chung, Michael R. Gold, Stefan H. Hohnloser et al. "HRS/ACC/AHA expert consensus statement on the use of implantable cardioverter-defibrillator therapy in patients who are not included or not well represented in clinical trials." *Circulation* 130, no. 1 (2014): 94-125.

Yates, Isabelle, Jennifer Byrne, S. Donahue, Linda McCarty, and Allison Mathews. "Representation in clinical trials: A review on reaching underrepresented populations in research." *Clinical Researcher* 34, no. 7 (2020).

By visiting these websites, you can gain valuable insights into the challenges with clinical trial diversity and the proposed solutions.

Ensuring Privacy in Research

We are committed to protecting the privacy of the personal information collected for this project. However, we cannot guarantee that your personal information will remain confidential at all times, as there may be instances where it is legally required to be disclosed. Rest assured that any publications or presentations of the research findings will not include your name or any other personally identifiable information.

Your medical information may be accessed by various organizations for research, quality assurance, and data analysis purposes, including accrediting bodies, government, and regulatory authorities (such as the FDA and OHRP), safety monitors, study sponsors, and authorized sponsor representatives.

In rare cases, we may ask you to complete an "Authorization Form" to specify how and with whom we can use your information for the study.

Before sharing any information or research samples you provided for this study with other Power researchers, researchers from other university institutions, or researchers from outside commercial firms for future research, we will first obtain your further informed consent. Your private data will be safeguarded and kept confidential.

Agreement to Participate

By signing this consent agreement, you acknowledge and agree to the following:

- You have read and fully understood this informed consent form. Prior to making a decision, you are encouraged to discuss this information with others and seek alternative perspectives.

- You have received satisfactory answers to all of your questions about the research project and its methods, as well as all the information you need to participate in the study.
- You have considered the benefits, risks, and other options for participating in the research.
- Your voluntary participation in the research study will not affect your ability to exercise your legal rights.
- Any significant updates to the research study that may affect your decision to continue participating will be communicated to you.
- This consent form has been provided to you and you have had the opportunity to ask any questions you may have.

Participant's Signature

_____	_____	_____
Name of Participant	Signature of Participant	Date

Investigator's Signature

I provided the patient with a detailed description of the study and addressed any questions they had. Furthermore, I have verified that their participation is entirely voluntary and based on informed consent.

Signature of Investigator Who Obtained the Consent

_____	_____	_____
Name of Investigator	Signature of Investigator	Date