Patient Perspectives in Squamous Cell Carcinoma Clinical Trials: Unveiling the Realities of Clinical Research in Squamous Cell Carcinoma

Informed Consent Form (ICF) For Power Clinical Trial's Squamous Cell Carcinoma Medical Trial

Date: June 23, 2023

Introduction

As a valuable participant, we invite you to partake in a significant medical research study aimed at gaining comprehensive insights into your clinical trial journey. We are keen to understand the reasons behind your decision to join, continue, or discontinue participation in clinical research.

Before making your choice, we encourage you to carefully consider the benefits associated with this study. It may also be helpful to seek perspectives from trusted friends or medical professionals.

We understand that the consent documents might contain unfamiliar medical terminology, which can be daunting. Please rest assured that the research team is readily available to clarify any uncertainties or confusion you may have regarding medical terms used in the paperwork.

It is important to note that our research has undergone rigorous ethical review and adheres to federal standards that prioritize the protection of human participants. Your active involvement in this research endeavor has the potential to significantly advance medical knowledge.

Squamous Cell Carcinoma Trial Purpose

It is crucial that you have a clear understanding of the purpose and nature of this study before making an informed decision. We encourage you to carefully review the following information and do not hesitate to seek clarification or request additional details from the researcher.

The primary objective of this study is to identify the barriers and challenges that impede participation in clinical trials and to gain insights into the factors that contribute to withdrawal or discontinuation. By delving into these aspects, we strive to shed light on the underlying reasons and facilitate a deeper understanding of the experiences encountered by individuals diagnosed with squamous cell carcinoma.

The valuable knowledge gleaned from this study will ultimately enhance future medical research and potentially improve the journey for those who may be invited to participate in similar trials.

Eligibility of Participants

We invite you to participate in an observational research study aimed at gaining insights into the motivations and considerations that drive patients' decisions to participate in clinical trials for squamous cell carcinoma. It is important to note that this study does not involve suggesting new treatment protocols or altering your current treatment plan.

As part of this study, the researcher will conduct interviews to collect valuable information. However, apart from the interviews, everything else regarding your treatment and care will remain unchanged. The researcher will not provide a diagnosis or recommend any specific course of treatment. The sole objective of this study is to gather data for research purposes.

To be eligible for participation, it is required that you are currently enrolled in another clinical trial for squamous cell carcinoma. By understanding the factors influencing your decision to participate and continue or discontinue treatment in that trial, we aim to gain a deeper understanding of patients' perspectives and experiences in clinical trials for squamous cell carcinoma.

Please remember that participation in this study is completely voluntary and optional. If you choose to participate, your ongoing treatment plan in the other clinical trial will not

be affected. You have the right to withdraw from the study at any time if you feel uncomfortable, and your decision to withdraw will not impact any of your legal rights.

Procedures of the Clinical Trial

As a valued participant in our research, you will be invited to complete a questionnaire every two weeks, with each session typically taking approximately 30 minutes to complete. Additionally, we will schedule quarterly check-in conversations to maintain ongoing contact and ensure your involvement in the study.

It is important to note that our research solely focuses on observation, even if you are required to enroll in an interventional clinical trial. Rest assured that our study will not impact your diagnosis or treatment plan for the clinical trial. If you have any concerns or questions regarding the other trial, we strongly encourage you to reach out to your healthcare team promptly for clarification.

We want to emphasize that you have full control over the information you choose to share. You are under no obligation to answer any questions that make you uncomfortable. Additionally, you have the option to complete the questionnaire independently or seek assistance by having someone read the questions aloud. You may skip any questions you do not wish to respond to.

To protect your privacy, your identity will not be linked to the survey forms. We assure you that all data collected will remain anonymous. Any information you provide, including personal details, will be treated with the utmost confidentiality. We will only share it with the research team and implement stringent security measures, including encryption, passwords, and anonymity protocols. As an additional safety measure, we will replace names with numeric identifiers to further protect patient identities. Furthermore, digital permission forms and phone records will be handled securely to ensure the utmost privacy and data protection.

Comparing Related Squamous Cell Carcinoma Clinical Trials

Our observational clinical trial focuses on gaining valuable insights into squamous cell carcinoma. Unlike interventional clinical trials that involve specific treatment plans, our study is designed solely for observational purposes.

We acknowledge that attempting to list all the available studies related to squamous cell carcinoma in this document would be impractical. To explore additional opportunities for participation in clinical trials specifically related to squamous cell carcinoma, we highly recommend visiting clinicaltrials.gov. This reliable repository provides comprehensive information about various ongoing squamous cell carcinoma studies. Additionally, you may also find detailed information about other squamous cell carcinoma clinical trials on Power's website, which can serve as a valuable resource for considering further applications.

Understanding Potential Risks

As a researcher committed to patient safety and transparency, we want to ensure you are fully aware of the potential risks associated with participating in this trial.

Firstly, please note that this trial will require frequent online check-ins and meetings with the study team throughout the project. We understand that this level of engagement may have an impact on your time and schedule, and we encourage you to consider this before making a decision to join the research.

Additionally, it is crucial to recognize that any changes to your treatment plan can carry inherent risks. Therefore, it is essential to carefully weigh the benefits and potential risks before deciding to participate in any clinical research.

However, it is important to highlight that, unlike interventional trials, this particular study is purely observational. This means that it will not influence or alter your current treatment plan in any way.

Another aspect to consider is the possibility of a confidentiality breach, where information about your participation in the study could be unintentionally shared with unauthorized individuals.

To mitigate this risk, we assure you that all data collected will be handled and stored securely. We will implement robust security measures, including encryption and password protection, to safeguard your personal information. We want to emphasize that the likelihood of a confidentiality breach is minimal, and stringent safety protocols are in place to protect your privacy.

It is crucial to note that for the purpose of this study, we will need to collect and utilize data related to your participation. Rest assured that your privacy and confidentiality remain of utmost importance to us throughout the research process.

Exploring Advantages

As researchers committed to advancing knowledge in squamous cell carcinoma, our study aims to uncover key factors that influence patient participation and completion in clinical trials. By participating in this research, you have the opportunity to contribute to a deeper understanding of these factors, which can ultimately lead to improvements in the design and recruitment strategies for future studies.

We believe that your valuable insights and experiences can play a crucial role in shaping the future of clinical trials for squamous cell carcinoma. Through this study, we aspire to enhance the overall patient experience, increase participation rates, and foster a more diverse and representative patient population.

Your participation in this research can have a lasting impact, potentially improving the quality and effectiveness of future clinical trials. Together, we can work towards advancing medical knowledge and providing better care for individuals affected by squamous cell carcinoma.

Enhancing Inclusivity in Clinical Studies: Exploring Representation and Diversity

For patients interested in gaining a deeper understanding of diversity and inclusion in clinical trials, we recommend exploring the following research articles:

Swift, Hannah J., and Ben Steeden. "Exploring representations of old age and ageing." (2020).

Bass, Sarah Bauerle, Paul D'Avanzo, Mohammed Alhajji, Nicole Ventriglia, Aurora Trainor, Laurie Maurer, Rebecca Eisenberg, and Omar Martinez. "Exploring the engagement of racial and ethnic minorities in HIV treatment and vaccine clinical trials: a scoping review of literature and implications for future research." *AIDS Patient Care and STDs* 34, no. 9 (2020): 399-416.

Voluntary Consent to Participate

I, as an individual diagnosed with squamous cell carcinoma, hereby provide my confirmation of willingness to participate in a medical research study focused on patients with this condition. I have been selected to take part in this active clinical trial, which aims to advance our understanding and treatment options for squamous cell carcinoma.

Prior to making this decision, I have carefully reviewed the consent document provided to me. I have engaged in thorough discussions with the research team, seeking clarifications and raising any concerns I had. I am pleased to acknowledge that all my queries have been adequately addressed, and I am fully informed about the purpose, procedures, and potential risks and benefits associated with this study.

I have received a personal copy of the consent form, which I will retain for future reference. I am aware that my participation in this research is entirely voluntary, and I maintain the right to withdraw from the study at any point without facing any negative consequences. I understand that my decision to withdraw will not affect the quality of care I receive or compromise any legal rights I possess.

Furthermore, I have been assured by the research team that the confidentiality of my personal information will be strictly upheld. All data collected during the study will be treated with utmost care and stored securely to ensure its protection. I trust that the research team will take appropriate measures to maintain the privacy and security of my information, using encryption, passwords, and other anonymity measures.

By confirming my participation in this study, I hope to contribute to the advancement of knowledge and potential improvements in the management and treatment of squamous cell carcinoma. I am committed to actively engaging in this research and sharing my experiences to benefit both current and future patients affected by this condition.

Participant's Printed Name: _____

Participants Signature: _____

Date: _____
Day/Month/Year

Confirmation of Informed Consent: Facilitating Participant Understanding

As the researcher responsible for obtaining consent from participants, I want to emphasize the importance of ensuring a comprehensive understanding of the study's details and implications. I dedicated significant time and effort to clarifying the consent form, providing clear explanations and ample opportunity for participants to ask questions. All inquiries were addressed transparently and to the best of my ability, allowing participants to make an informed decision to join the study voluntarily and autonomously, without any form of coercion or undue influence.

During our discussions, I strived to create an environment where participants felt comfortable expressing any concerns or seeking further clarification. It was my utmost priority to facilitate their understanding of the study's purpose, procedures, potential risks, benefits, and their rights as participants. By engaging in open and transparent communication, I aimed to empower participants to make an informed choice regarding their participation.

I ensured that each participant received a personal copy of the consent form, serving as a tangible reminder of the information shared and their decision to participate. This copy allows them to review the details at their own pace, discuss it with their support network, and keep it for future reference.

I am grateful for the trust placed in me by the participants, and I remain committed to upholding the principles of informed consent throughout the study. Should any further questions or concerns arise during their participation, I am readily available to provide the necessary support and clarification.

Name of Facilitator: _____

Facilitator’s Signature::_____

Date: _____
Day/Month/Year