Studying Patterns in Patient Engagement and Participation in Diabetic Kidney Disease Clinical Trials

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

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Understanding the Importance of This Informed Consent Form

If you are currently in the process of completing this form, it suggests that you may be eligible for participation in a distinctive observational clinical study dedicated to individuals diagnosed with diabetic kidney disease. This comprehensive guide delineates the primary objectives of the study, the detailed implementation plan, and the various implications, covering both positive and potentially unfavorable consequences. Before making any decisions, thoroughly grasping the specifics of your potential participation is crucial, and seeking guidance from a reliable source can provide invaluable perspectives. If any aspect of this document seems perplexing or if you have any inquiries, be assured that the researcher is accessible to provide explanations.

Importance of Trials for Diabetic Kidney Disease

Clinical trials specifically dedicated to diabetic kidney disease are instrumental in evaluating the safety and effectiveness of new therapies for this condition. These trials serve as fundamental instruments in determining whether novel medications surpass traditional treatments, providing compelling evidence to support their wider usage.

What makes this study unique is its central focus on the direct experiences of individuals coping with diabetic kidney disease, actively engaging in a clinical trial incorporating medicinal interventions. The primary aim is to thoroughly analyze trial completion rates and voluntary withdrawals among this specific cohort of patients.

Understanding the Core of Observational Clinical Trials

Diabetic kidney disease, also known as diabetic nephropathy, is a condition characterized by kidney damage as a result of diabetes. It is a leading cause of end-stage renal disease (ESRD) and requires careful management to prevent complications. The condition primarily affects individuals with diabetes, especially those who have had the disease for many years and have difficulty controlling their blood sugar levels.

Engaging in this medical trial involves immersing yourself in an observational study, a distinctive aspect of clinical research meticulously structured to gather insights through unobtrusive observation of patients while preserving their treatment plans.

Researchers will solely monitor your progress, meticulously assessing the outcomes of your condition without implementing any changes. This trial design is essential in enhancing our understanding of the inherent progression of a specific medical condition and its implications for those grappling with it. Your active participation in this observational study plays a pivotal role in expanding the horizons of medical knowledge and driving advancements in the care provided to individuals with the same condition.

This Study Compared to Other Diabetic Kidney Disease Clinical Trials

Appreciating the distinctive nature of this research investigation is essential. It operates purely on an observational basis, indicating that your participation will not entail any specific therapies or interventions. To make an informed choice about potential involvement in a clinical trial, it is crucial to grasp the spectrum of diabetic kidney disease clinical research, which includes interventional studies where participants undergo different treatment regimens.

Creating an informed decision about your potential participation in a clinical trial requires an active approach that involves research and comparison of trials. Platforms such as Clinicaltrials.gov and similar resources offer a wealth of information on <u>diabetic kidney</u> <u>disease research</u>. Additionally, Power's dedicated online platform provides a

comprehensive compilation of ongoing <u>diabetic kidney disease clinical trials</u> actively seeking volunteers. Armed with comprehensive research and a thorough understanding of various clinical trial categories, you can decisively shape your participation decision.

Active Involvement in Clinical Trial Surveys

We warmly welcome your active participation in this observational clinical study, encouraging you to share your experiences. Your valuable insights will be gathered through the completion of surveys every two weeks, taking approximately 20-30 minutes of your time. Moreover, our team is committed to conducting check-in calls on a quarterly basis and maintaining open lines of communication during your involvement in the trial.

It is crucial to underscore that your participation in the survey phase of the trial is entirely voluntary. You have the flexibility to choose which questions to answer or whether to complete the entire questionnaire. Additionally, you retain the right to withdraw from the trial whenever you deem fit. Understanding the personal nature of enrolling in a clinical trial, we are dedicated to providing the necessary support, respecting your privacy, and facilitating your decision-making process throughout the trial.

Ensuring Confidentiality in Your Survey Responses

In the context of this research undertaking, preserving the complete confidentiality of your data remains of utmost importance. To protect your anonymity, we kindly urge you not to disclose any personal or identifiable information in your survey responses. The dedicated research team is unwavering in their dedication to enhancing the protection of your privacy. However, it is important to note that certain legal circumstances may arise, requiring the disclosure of personal data.

Prospective Rewards in Sight

Although participants in this observational clinical research may not witness immediate advantages, their contribution has the potential to generate significant ripples. The insights garnered from participants will be instrumental in refining future methodologies for engaging individuals with diabetic kidney disease, potentially expanding the frontiers

of medical research. Those who embark on this treatment trajectory have the capacity to ignite transformative changes in the field of medical research, potentially influencing the experiences of future diabetic kidney disease patients.

Recognizing Possible Health Complications

Despite the notable progress achieved through clinical trials, it is essential to acknowledge the potential health complications that participants might encounter, particularly in studies assessing new medications.

However, our approach in observational clinical research takes a distinct path, reducing these complications by refraining from the administration of experimental drugs to participants. Instead, our key focus lies in comprehensive surveillance and evaluation of outcomes, ensuring the avoidance of any unwarranted health hazards.

Fostering Diversity in Clinical Research

A plethora of online channels eagerly await your active participation if you possess an unrelenting desire to delve into the multifaceted aspect of diversity in clinical trials.

Whether your objective is to comprehend the intricacies of the challenges and opportunities associated with clinical trial diversity or to expand your own perspectives, the following resources could prove immensely beneficial:

Kelsey, Michelle D., Bray Patrick-Lake, Raolat Abdulai, Uli C. Broedl, Adam Brown, Elizabeth Cohn, Lesley H. Curtis et al. "Inclusion and diversity in clinical trials: actionable steps to drive lasting change." *Contemporary Clinical Trials* 116 (2022): 106740.

Kahn, Justine M., Darrell M. Gray, Jill M. Oliveri, Chasity M. Washington, Cecilia R. DeGraffinreid, and Electra D. Paskett. "Strategies to improve diversity, equity, and inclusion in clinical trials." *Cancer* 128, no. 2 (2022): 216-221.

Affirmation of Informed Consent Understanding

I affirm that I have dedicated sufficient time to comprehend the contents of the informed consent form. This was achieved through either independent review or with the guidance of a trusted individual who has clarified its details to me. All of my concerns and queries have been thoroughly addressed to my complete satisfaction.

I am fully aware that my participation in this study is entirely voluntary, and I retain the exclusive right to withdraw my consent without being required to offer justifications or incur any financial responsibilities. I have been assured that a copy of this informed consent form will be provided to me for my personal records.

After deliberate consideration and comprehensive review of all the materials provided to me, I hereby provide my consent to participate in this study, representing my informed and autonomous decision.

Confirmation from Informed Consent Facilitator

I confirm that I engaged in a thorough discussion with the participant, carefully explaining the important aspects in this written document. My aim was to ensure that the participant fully comprehended the main study objectives, employed methodologies, potential risks and benefits, and other crucial elements of the diabetic kidney disease clinical trial.

The participant was given ample opportunity to ask questions, express concerns, and seek clarification. It is vital to highlight that the participant's participation in this study is

reason, without incurring any financial obligations.	
After the participant's consent, a meticulously preserved duplicate of this written document was provided, serving as a repository for their specific information.	
Printed Name of Assisting Researcher	
Signature of Assisting Researcher	

Date

entirely voluntary, and they retain the absolute right to withdraw at any time, for any