Evaluating the Clinical Trial Experiences of Eczema Patients: An Observational Study

Comprehensive Informed Consent Form for Participants in Power Clinical Trial's Observational Research

Date: February 17, 2023

Eczema Observational Study Overview

The purpose of this document is to provide you with information about the observational clinical trial being conducted by Power Clinical Trials and to obtain your informed consent for participation in the study. The study involves observing patients with eczema over a period of time, without intervening in their treatment. By participating in this study, you will provide valuable data that can inform future research on this medical condition.

Please carefully review the following information before consenting to participate.

Purpose of the Study

The purpose of this study is to observe patients with eczema who are enrolled in an interventional clinical trial. This will help us gather important data on any associated factors that may affect the participation rate of patients as well as the reasons why they stay or withdraw from clinical trials.

Study Procedures

As a participant in this study, you will not receive any specific treatment or intervention beyond what is currently prescribed by your healthcare provider. Your medical information and health outcomes will be observed and recorded by study personnel over a period of time.

This observational study is designed to complement any interventional clinical trials you may be participating in, by collecting additional data through bi-weekly surveys and quarterly check-in calls. The surveys will take approximately 30 minutes to complete, and the check-in calls will be scheduled for the length of your engagement in any clinical trial(s) outside of this study.

It is important to note that the logistics of the interventional clinical trial, including therapy and technique, are entirely separate from this observational study and will not be altered in any way. Therefore, your participation in this observational study will not interfere with or impact your treatment as part of the interventional clinical trial.

If you have any questions or concerns about the interventional clinical trial in which you are enrolled, please contact your care team.

Risks and Benefits

There are no known risks associated with participating in this observational study. The benefit of participating is that your information may contribute to the advancement of medical knowledge and the development of better treatments for the medical condition.

Confidentiality

All of your personal information and medical data will be kept confidential and only accessible to study personnel. Your name and other identifying information will be kept confidential and not disclosed in any reports or publications.

Voluntary Participation

Participation in this study is entirely voluntary. You may withdraw from the study at any time without any negative consequences. Your healthcare will not be affected in any way by your decision to participate or not participate.

By signing this consent form, you acknowledge that you have read and understood the information presented above and freely consent to participate in this observational clinical trial.

Eczema Observational Study in Comparison to Other Trials

There are different types of clinical trials available for patients with various medical conditions. Interventional clinical trials require patients to engage in a specified course of therapy, whereas observational clinical trials do not impose any therapy.

This is an observational clinical study, which means that no therapy will be imposed or offered to participants.

We understand that this may not be the type of clinical trial you were hoping to participate in. If you are interested in finding more eczema studies, you can go to clinicaltrials.gov. You can also find lists of active eczema clinical trials on Power's participant reference website.

More Research On Clinical Trial Diversity

Are you interested to read more on clinical trial diversity? Here are a few studies you can check:

Hwang, Thomas J., and Otis W. Brawley. "New federal incentives for diversity in clinical trials." *New England Journal of Medicine* 387, no. 15 (2022): 1347-1349.

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.

Participant Statement

After thoroughly reviewing the information provided to me both in writing and verbally, and having all of my questions satisfactorily answered, I acknowledge that my participation in this study is voluntary. I understand that I have the right to withdraw from the study at any time without any consequence to my legal rights.

I acknowledge that by signing this consent form, I am not waiving any of my legal rights. Furthermore, I understand that a copy of this consent form will be provided to me for my records.

With this knowledge, I agree to participate in this research study and sign my name below as evidence of my consent. I am aware that my participation is vital for the advancement of medical knowledge and the development of better treatments for my medical condition.

_____

Printed Name of Participant

_____

Participant Signature

_____

Date

Statement of Person Conducting Informed Consent Discussion

After thoroughly reviewing the material in this paper with the participant, I am confident that the individual has a clear understanding of the risks, benefits, alternatives, and procedures associated with this research project.

The participant has been provided with all relevant information and has had the opportunity to ask questions and seek clarification where necessary. Based on our discussions, the participant is equipped with the knowledge required to make an informed decision regarding their participation in the research study.

I am committed to ensuring that the participant's well-being and safety are prioritized throughout the duration of the study. I will continue to monitor the participant's progress closely and provide support and guidance as needed.

In summary, based on my interactions with the participant and my assessment of their understanding of the research project, I endorse the individual's decision to participate in the study.

_____

Printed Name of Person Conducting Informed Consent Discussion

_____

Person Conducting Informed Consent Discussion Signature

_____

Date