Hairy Cell Leukemia Clinical Trials: Navigating the Clinical Trial Process for Hairy Cell Leukemia Patients

This is an informed consent form for hairy cell leukemia patients joining Power Clinical Trial's observational clinical study.

Date: May 5, 2023

Introduction

The non-interventional research study is completely optional and your participation is appreciated. You have the freedom to withdraw your consent at any point during the study if you choose to do so. Our goal is to examine and enhance our understanding of the challenges that you may face in enrolling and completing a clinical trial as a result of your hairy cell leukemia diagnosis.

Upon agreeing to participate, you will be required to sign a permission form confirming that you have been informed about the study and that all of your concerns have been addressed. Your routine medical treatment provided by your physician will remain unchanged throughout the study.

Purpose of the Study

Hairy cell leukemia is a rare type of cancer that affects the blood and bone marrow. It is a type of chronic lymphocytic leukemia, which means it develops slowly over time. Hairy cell leukemia gets its name from the hair-like projections that grow on the surface of the leukemia cells when viewed under a microscope. These projections can make the cells look "hairy" or "frayed."

Clinical studies that are observational are crucial for studying hairy cell leukemia and enhancing patient outcomes. They can also provide the groundwork for future studies in

the area and aid in the identification of potential novel therapeutic alternatives. These studies involve gathering information from patients with hairy cell leukemia in a real-world context without the use of interventions or medications.

In order to make an informed decision about your participation in the research study you have been invited to, it is vital that you understand its objectives and procedures. Please read the following information carefully, and if you have any questions, do not hesitate to seek clarification from the researcher.

The primary aim of this study is to collect a variety of information regarding the clinical trial experiences of individuals with hairy cell leukemia. The study's objective is to identify the factors that hinder patients' ability to participate in or successfully complete a trial.

Clinical trial participation tends to favor specific demographic groups, and little research has been conducted on how trial characteristics affect participation. Thus, this study examines data from various demographic groups to identify recurring patterns and gain a better understanding of hairy cell leukemia patients in the future.

Procedure

This observational research requires you to be actively involved in an interventional clinical trial. You will be required to complete biweekly surveys that will take roughly 30 minutes each, and quarterly check-in calls will be conducted throughout the clinical trial process.

Your participation in this study will not affect your primary care doctor's recommended course of action or treatment. Our staff is available at any time to assist you with any questions or concerns that you may have during the trial. Please do not hesitate to contact us if you require assistance.

This Trial Versus Other Hairy Cell Leukemia Clinical Trials

This research is an observational clinical trial, meaning that there will be no alterations to your current treatment regimen, unlike most hairy cell leukemia studies that are interventional clinical trials. In these trials, patients receive a specific treatment protocol that may differ from their standard of care. To find out more about other hairy cell leukemia research, you can visit clinicaltrials.gov or Power's online page, which features

the most promising hairy cell leukemia clinical trials that are currently accepting volunteers.

If you wish to find other studies on diversity in clinical trials, you can also check the following links for further reading:

Royce, Trevor J., Yihua Zhao, and Cleo A. Ryals. "Improving Diversity in Clinical Trials by Using Real-world Data to Define Eligibility Criteria." *JAMA oncology* (2023).

Rosen, Clifford J., Nakela L. Cook, and Consuelo H. Wilkins. "Diversity in Clinical Trials—Next Steps." *New England Journal of Medicine* 387, no. 15 (2022): e34.

Possible Risks and Benefits For Participants

Your participation in this study won't directly benefit you, but we do hope the data we collect can help with hairy cell leukemia patients' treatment in the future.

Because your treatment plan won't change as a result of this study's strict observational design, there won't be any associated risk. You will be reporting online and taking part in video chats with other hairy cell leukemia patients during the length of the experiment.

You should be aware that there is a chance that someone may obtain your protected health information and figure out who you are. However, in order to protect your identity as well as the associated data and samples gathered, we will use a code of letters and numbers. You can ask the research doctor or study staff for more information about how long the coded data will be kept on file for your coded samples.

Protection of Information

To ensure the confidentiality of your information, we will use a code or number to identify you in the study's records and notes. Additionally, any identifying materials, such as interview transcripts, will be securely stored in a locked file cabinet under the researcher's supervision. Your privacy is of utmost importance to us, and we will not share any of your confidential information without your explicit consent, except as required by law in cases such as abuse or suicide risk.

Voluntary Participation

You are not obligated to participate in this study, and participation is voluntary. If you do choose to participate, you will need to sign a consent form, but you may withdraw from the study at any time without giving a reason. Your decision to withdraw will not affect your relationship with the researcher, and any data collected prior to your withdrawal will be returned or destroyed.

Consent

By signing this form, I confirm that I have read and understood the information provided, and that I have had the opportunity to ask any questions. I understand that my participation in this study is voluntary and that I may withdraw at any time without penalty. I acknowledge that I will receive a copy of this consent form, and my participation is entirely optional.

_____
Printed Name of Participant

_____
Signature

_____
Date

Declaration

I verify that I have thoroughly discussed the information provided in this form with the participant. I certify that the participant comprehends the potential benefits, hazards, and protocols associated with taking part in this clinical research for hairy cell leukemia.

_____

Printed Name of Person Getting Consent

_____

Signature of Person Getting Consent

_____

Date