Hepatocellular Carcinoma Clinical Trials: An In-Depth Analysis of Patient Experiences

This is an informed consent form for hepatocellular carcinoma patients joining Power Clinical Trial's observational clinical study.

Date: May 5, 2023

Preliminary Information

Participation in the non-interventional research study is not mandatory, but highly encouraged. As a person diagnosed with hepatocellular carcinoma, your involvement would assist us in examining and gaining a better understanding of the various factors that may hinder your ability to complete a clinical trial.

Should you choose to take part, you will be required to sign a consent form acknowledging that you have been fully informed about the study and that all your queries have been addressed. Your regular medical care given by your physician will not be impacted by your participation in this study. Remember, you have the right to withdraw your consent at any time throughout the study.

Purpose of the Study

Hepatocellular carcinoma is a type of liver cancer that begins in the cells of the liver called hepatocytes. It is the most common type of liver cancer in adults, and it typically occurs in individuals with chronic liver disease, such as hepatitis B or C or cirrhosis.

Observational clinical trials for hepatocellular carcinoma are crucial because they provide information on the progression and natural history of the disease or in this case, the experiences of patients. These investigations entail interviewing hepatocellular carcinoma patients in a natural setting without the use of interventions or treatments.

You are being invited to participate in a research study, and before you make a decision, it is crucial that you understand the purpose of this research and what it entails. Kindly read the information below carefully, and do not hesitate to seek clarifications from the researcher if needed.

The primary objective of this research is to gather a broad range of data on the clinical trial experience of hepatocellular carcinoma patients. The aim is to identify the factors that limit patients' ability to participate or complete a trial successfully.

Typically, clinical trial participation favors a specific demographic group, and little research exists on how trial attributes affect participation. As such, this study seeks to analyze data from different demographic groups and check for recurring trends that could provide valuable insights for future hepatocellular carcinoma patients.

Study Activities

To participate in this observational research, you must currently be enrolled in an interventional clinical trial. As part of the study, you will be required to complete biweekly surveys that will take approximately 30 minutes each. In addition, quarterly check-in calls will be conducted during the clinical trial.

It is important to note that your primary care doctor's recommended course of action and treatment will not be altered if you choose to participate in this study. If you have any questions or concerns at any point during the trial, please do not hesitate to contact our staff for assistance.

This Trial Versus Other Hepatocellular Carcinoma Clinical Trials

In contrast to interventional clinical trials, this research is an observational clinical trial, which means that there will be no changes to your current treatment regimen. Most studies on hepatocellular carcinoma are interventional clinical trials, where patients receive a specific treatment protocol that may differ from their standard of care.

If you are interested in learning more about other hepatocellular carcinoma research, you can search for ongoing trials on websites such as clinicaltrials.gov or Power's online page, which highlights the most promising hepatocellular carcinoma clinical trials that are accepting volunteers.

You can also find more studies about diversity in clinical trials by clicking the following links:

Stronks, Karien, Nicolien F. Wieringa, and Anita Hardon. "Confronting diversity in the production of clinical evidence goes beyond merely including under-represented groups in clinical trials." *Trials* 14, no. 1 (2013): 1-6.

Garrick, Owen, Ruben Mesa, Andrea Ferris, Edward S. Kim, Edith Mitchell, Otis W. Brawley, John Carpten et al. "Advancing inclusive research: establishing collaborative strategies to improve diversity in clinical trials." *Ethnicity & Disease* 32, no. 1 (2022): 61.

Risks and Benefits

While this study will not directly benefit you, the data collected will be used to help improve the treatment of hepatocellular carcinoma patients in the future. As this is an observational study, your treatment plan will not be altered and there is no associated risk. Your protected health information will be safeguarded by a code of letters and numbers to protect your identity and the associated data and samples. You can inquire with the research doctor or study staff to learn more about how long the coded data will be kept on file for your coded samples.

Patient Privacy

To ensure your privacy is protected, the information you provide in the survey will be kept anonymous. The study notes and records will use code names or numbers to identify participants, and any materials with identifying information will be stored in a secure, locked file cabinet under the researcher's supervision. Rest assured that your confidential information will not be shared with anyone without your explicit consent, except in cases where legal disclosure is required, such as in cases of abuse or risk of suicide.

Voluntary Participation

Participating in this study is entirely voluntary, and you have the freedom to choose whether or not to participate. If you decide to participate, you will be required to sign a consent form, but you may withdraw from the study at any point without providing a

reason. Your decision to withdraw will not impact your relationship with the researcher, and any information collected prior to your withdrawal will be returned to you or destroyed.

Consent

I acknowledge that I have carefully read and comprehended the presented information, and that I have had the opportunity to raise any inquiries. I understand that my participation in this study is entirely voluntary and that I may discontinue my participation at any time without fear of retaliation. I understand that I will receive a copy of this consent form and that participation in the study is optional.

_____

Printed Name of Participant

_____

Signature

_____

Date

Declaration

I confirm that I have had an extensive discussion with the participant about the details presented in this form. I attest that the participant has a complete understanding of the potential benefits, risks, and procedures involved in participating in this clinical trial for hepatocellular carcinoma.

_____

Printed Name of Person Getting Consent

_____

Signature of Person Getting Consent

_____

Date