Bile Duct Cancer Clinical Trials: Looking At Patient Experience Patterns in Medical Trials

Informed Consent Form (ICF) For Power Clinical Trial's Bile Duct Cancer Medical Trial

Date: January 20, 2023

About This ICF

This document is divided into two distinct parts. The initial segment is the Patient Information Sheet, which provides relevant information about the clinical study and your role as a participant. The second section is the Certificate of Consent, where you will be required to sign indicating your agreement to participate in the study. Once completed, you will be given a copy of this document for your records.

Part I: Information Sheet

We are inviting you to participate in a medical research study that aims to understand the various factors that shape your experience in a clinical trial. This includes understanding the reasons for your enrollment, continuation, or withdrawal from the trial. It is important to take the time to carefully consider whether or not to participate in this study. You may want to discuss this opportunity with your loved ones or healthcare team.

You have to note that the consent form may contain technical terms that you may not be familiar with. If you have any questions or concerns regarding any of the terms used on this form, you have the right to ask the research staff to clarify them for you. The study has been reviewed and deemed ethically sound and is in compliance with federal regulations that protect the rights of human subjects.

The Purpose of This Clinical Study For Bile Duct Cancer

Clinical trials can sometimes favor certain demographic groups. Additionally, there is limited research that delves into the factors that influence participation in clinical trials, both positive and negative.

We are inviting you to share your experiences while participating in Power's interventional medical trial to help us better understand the characteristics of patients in bile duct cancer trials.

As part of this study, a diverse group of individuals will be invited to participate to gather a wide range of data on clinical trial experiences. The goal is to identify the obstacles and challenges that prevent participation in bile duct cancer clinical trials, as well as the reasons for withdrawal or discontinuation.

The insights gained from this study will ultimately benefit those with bile duct cancer who may be invited to participate in medical research in the years to come.

The Research Process

As an observational research, this trial will not recommend a new care regimen. If you decide to join this study, you would not have to change your current treatment plan. Everything will stay the same, the only difference will be that the researcher will conduct some interviews with you to gather information. The researcher will not be able to diagnose you or tell you what kind of treatment you should have. The goal is just to collect data.

Eligibility to Participate

To take part in this study, you need to be currently enrolled in another clinical trial for bile duct cancer. We want to understand your reasons for participating in this research, and also what factors influence your decision to continue or stop treatment.

We want to know what made you decide to join the study, and what causes you to decide to stay in or leave the study. The goal is to find out what factors influence patients' decisions in bile duct cancer clinical trials.

Taking part in this study is completely optional and voluntary. If you decide to join, it won't change the treatment plan you are currently on for another clinical trial. You can stop participating at any time if you feel uncomfortable. Your decision will not let you lose any legal rights.

Comparison to Other Bile Duct Cancer Clinical Trials

Bile Duct Cancer patients can participate in interventional clinical trials, but it requires signing up for a specific treatment plan. The clinical trial that we are inviting you to will not do this though, since it is only for observation purposes.

We cannot list every study on bile duct cancer here, so if you want more information on bile duct cancer studies, you can look at clinicaltrials.gov or visit Power's website to check other bile duct cancer clinical trials that you can apply to.

What You Can Expect From The Clinical Trial

If you decide to participate in this study, you will need to fill out a questionnaire every two weeks. It usually takes about 30 minutes to complete one of these questionnaires. We will have check-in calls with you every three months.

Please keep in mind that, even though you may need to be enrolled in another interventional clinical trial to participate in this study, our study is only for observation purposes and will not affect your diagnosis or treatment plan for that trial. If you have any questions about the other trial, please contact your healthcare team.

You don't have to share any information that makes you uncomfortable. You can also choose to complete the survey on your own or have someone read it to you and you can answer out loud. You can also skip any questions you don't want to answer.

Your name will not be on the survey forms, and the information we collect will be anonymous.

Please be assured that any information provided, including personal data, will be kept strictly confidential. It will only be shared with the research team and protected by means of encryption, passwords, and anonymity measures, such as using numerical

identifiers rather than names, to safeguard the identity of bile duct cancer patients. Phone logs and digital permission forms will also be handled securely.

More Details on Representation in Clinical Studies

You can check the following published studies to read more about representation in clinical trials:

Taran, F. Andrei, Haywood L. Brown, and Elizabeth A. Stewart. "Racial diversity in uterine leiomyoma clinical studies." *Fertility and sterility* 94, no. 4 (2010): 1500-1503.

Oh, Sam S., Joshua Galanter, Neeta Thakur, Maria Pino-Yanes, Nicolas E. Barcelo, Marquitta J. White, Danielle M. de Bruin et al. "Diversity in clinical and biomedical research: a promise yet to be fulfilled." *PLoS medicine* 12, no. 12 (2015): e1001918.

Part II: Certificate of Consent

Participant's Statement

I am signing to confirm my participation in the medical study for bile duct cancer patients. As a patient with bile duct cancer, I have been selected to take part in this interventional clinical trial.

I have carefully reviewed the consent document, had a discussion about it, and have had the opportunity to ask any questions or address any concerns I may have had. My questions have been answered to my satisfaction and I voluntarily agree to participate in this study.

I have been provided with a copy of this consent form for my records and understand that my participation in the study is completely voluntary and that I can withdraw my participation at any time without any negative consequences. Additionally, I understand that the study team will ensure the confidentiality of my personal information, as well as the security of any data collected during the study.

Participant's Printed Name: _____

Participants Signature: _____

Date: _____
Day/Month/Year

If Illiterate

I can confirm that the consent document was thoroughly explained to the potential participant, who was given the opportunity to ask any questions and have them answered to their satisfaction. The participant fully understood the nature and purpose of the study, as well as the potential risks

Witness Printed Name:_____ **Participant Thumb Print**

Witness Signature: _____

Date: _____
Day/Month/Year

Statement of Person Taking Participant Consent

To ensure that the potential participant fully understood the process and implications of participating in the study, I took great care in thoroughly explaining the contents of the permission form. This included providing them with ample opportunity to ask any questions they may have had and answering them honestly and to the best of my ability. Additionally, I can confirm that the participant's decision to participate in the study was made freely and voluntarily, without any form of coercion or undue influence.

A copy of this form has been furnished to the participant.

Printed Name of Individual Taking the Consent: _____

Signature of Individual Taking the Consent:_____

Date: _____
Day/Month/Year