Gastric Cancer Clinical Trials - Investigating the Experiences of Individuals With Gastric Cancer Participating in Clinical Trials

An informed consent form (ICF) for Power Clinical Trial's observational medical study participants

Date: January 15, 2023

The Purpose of This Informed Consent Form

This form you are reading is asking for your permission to participate in a study. It might have some words or phrases that you do not understand. If that is the case, it is important to ask the doctor or research staff involved in the study to explain them to you.

It is also important to know that if you choose to participate, you are the one being studied, and the study is focused on gastric cancer. The people running the study want to make sure that you are safe and comfortable, and that the study is done properly.

It is a good idea to talk to your regular doctor, your family or friends, or anyone else you trust before you decide to participate in the study. This way, you can make sure you understand what you are getting into and that you're comfortable with it.

The Purpose of This Gastric Cancer Clinical Trial

Gastric cancer, also known as stomach cancer, is a type of cancer that begins in the lining of the stomach. Stomach cancer is the 18th most common cancer in the United States and the 6th most common cancer worldwide, based on data from the National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) Program.

We are conducting this clinical trial to investigate how certain factors may impact the enrollment, withdrawal, or completion of treatment for individuals with gastric cancer in another clinical trial. You have been selected as a potential participant in this study because you have been diagnosed with gastric cancer and meet the necessary criteria.

Procedures

This gastric cancer medical trial is observational in nature. This means that we will not be providing any interventions or care systems. Instead, we will simply be observing and collecting data on outcomes. You are still able to participate in this study while enrolled in a separate clinical trial that includes treatment, without any changes to your current care regimen.

As a participant in this study, you will be required to complete surveys twice a week. These questionnaires typically take around 30 minutes to finish. We ask that you take your time when answering the questions in the survey, and if there are any parts that you do not understand, do not hesitate to ask the researcher in charge for clarification. If you are not comfortable answering certain questions, you may skip them. Additionally, we will conduct quarterly check-in calls during the duration of the study.

It is important to note that your participation in this study is voluntary. If you choose to participate, you will be provided with a copy of this form as proof of your understanding and voluntary consent. As a voluntary participant, you have the right to terminate your participation at any time, without the need to provide a reason.

Other Trials For Gastric Cancer

Before deciding to participate in any clinical trial, it's important to understand the type of study and what it entails. Many clinical trials that are available online involve testing new treatments, such as drugs or interventions. However, there are also observational studies, where you will not be receiving any new treatments, but rather simply being observed and having outcomes measured.

To learn more about gastric cancer studies, you can visit various resources such as clinicaltrials.gov or other reference sites, like Power, that can provide information about different gastric cancer clinical trials that are available. By researching and familiarizing yourself with existing studies, you can make a more informed decision about whether or not to participate in a clinical trial.

Benefits

This study is observational, meaning that it does not include any interventions or new treatments. As a result, there may not be an immediate benefit for the patient with gastric cancer. However, the data collected from this trial can contribute to a better understanding of the factors that affect withdrawal and enrolment rates in gastric cancer clinical trials, and may ultimately lead to improved patient outcomes in the future.

Risks

Participating in clinical trials can come with certain health risks, especially when new treatments are being tested. However, in this case, as the study is observational, the potential health risks are greatly reduced.

Privacy and confidentiality are also important concerns when participating in clinical trials. However, this study is designed to minimize such risks by keeping the information collected anonymous, and all data such as online forms, call logs, surveys, and forms are securely stored with password protection and encryption to safeguard your privacy.

Confidentiality

Your answers in the survey will not include any identifying information, and will be kept confidential to protect your privacy. Please refrain from writing your name or any other personal information on the survey forms. Only members of the research team will have access to the data collected in this study. However, it is possible that the findings of this study may be shared in professional meetings or publications, but your personal identity will not be revealed in these instances.

Additional Research on Representation in Clinical Trials

If you are looking for further information on representation in clinical trials, there are a variety of resources available for you to explore. Some notable studies that may be of interest include:

Bird, Chloe E. "Women's representation as subjects in clinical studies: a pilot study of research published in JAMA in 1990 and 1992." *Women and health research: Ethical and legal issues of including women in clinical studies* 2 (1994): 151-173.

Motazedian, Pouya, Thais Coutinho, and F. Daniel Ramirez. "Female representation in clinical studies informing atrial fibrillation guidelines: have we built a house of cards?." *Canadian Journal of Cardiology* 38, no. 6 (2022): 709-711.

Participant's Consent

I have fully read and understood this form, or had it read and explained to me. I have had the opportunity to ask any questions and comprehend the information provided. I understand that my participation in this study is completely voluntary, and that I can withdraw at any time, without any penalty or cost. I will be given a copy of this consent form as proof of my understanding and agreement to participate. I willingly give my consent to take part in this study.

_____

Name of Participant

_____

Signature of Participant

_____

Date

Declaration of Researcher Taking Consent

I have thoroughly explained the details of this clinical trial, including its objectives, procedures, potential risks, benefits, and any other important information, to the participant. I have made sure to clarify any terms or concepts that the participant had questions about. The participant has voluntarily provided their consent to participate in this study, and a copy of this document was given to them after it was signed.

_____

Printed Name of Person Taking Consent

_____

Signature of Person Taking Consent

_____

Date