Colon Cancer Clinical Trials: What Are The Clinical Trial Experiences of Colon Cancer Patients?

An informed consent form for colon cancer patients in Power Clinical Trial's observational study.

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Colon Cancer Observational Study Overview

This document is inviting you to take part in a medical research study, also known as a clinical trial, that aims to understand how different factors encountered during the clinical trial enrollment process may impact your willingness and ability to participate and complete the trial. The observations made during this study will be collected and analyzed anonymously to identify patterns in patient experiences that often lead to lower completion or enrollment rates.

It's important to note that this study is an observational study, which means that your current treatment plan will not be changed if you decide to participate. Being a participant in a research study is different from being a patient. This document serves as a written summary of the conversation you had with our recruitment coordinators and site staff, as well as a reference for you as you go through the clinical trial process.

Important Notes to Consider About This Study

1. **It is optional to participate and you have the freedom to withdraw at any time.** This is not unusual. It is important that participation in clinical trials is voluntary to ensure that individuals are not coerced or forced into participating against their will.

   Allowing individuals to make an informed decision about whether or not to participate in a trial respects their autonomy and rights as human beings.

Additionally, voluntary participation helps to ensure that the results of the trial are not biased, as individuals who are not fully committed to the trial may not comply with the protocol, which could skew the results.

2. **As this is an observational study, your involvement will not impact the care you receive.** During an observational clinical trial, individuals are typically not receiving any interventions or treatments as the purpose of the study is to observe and gather data on the natural course of a disease or condition.

   The study's personnel can only gather data on the participant's disease or condition without any interference. This is to ensure that the results of the study are not biased and that the data collected accurately reflects the natural course of the disease or condition being studied.

   Additionally, in an observational study, there is no control group, so any treatment provided to the participant would interfere with the study's ability to gather accurate data about the natural course of the disease or condition being studied.

3. **If you do not comprehend what our team is saying at any time during this process, please inform the person taking consent immediately.** It is important to clarify aspects of an observational clinical trial in the informed consent form before deciding to participate for several reasons:
   - To ensure that individuals fully understand the nature of the study and their role in it, including what will be expected of them and what data will be collected from them.
   - To make sure that individuals are aware of any potential risks or discomforts associated with participation, such as the fact that the study's personnel will not be able to diagnose diseases, administer drugs, or supervise their treatment.
   - To ensure that individuals understand their rights as participants, including the right to withdraw from the study at any time without penalty.
   - To ensure that individuals understand how their personal information will be handled and protected, including how it will be used and who will have access to it.
   - To ensure that individuals understand how the study results will be used and how they will benefit from the study.
   - By ensuring that all of these aspects are clearly outlined in the informed consent form, individuals can make an informed decision about whether or

not to participate in the trial, and can trust that their rights and interests will be protected throughout the study.

Why is This Colon Cancer Research Being Launched?

Historically, there is underrepresentation of certain groups of people in clinical trials for colon cancer, including minorities such as African Americans and Hispanic populations, as well as elderly individuals and people with lower socioeconomic status. This underrepresentation can lead to a lack of data on how certain treatments may affect these populations and can also mean that the results of the trials may not be generalizable to these groups.

It is important to have diversity in colon cancer trials for several reasons:

- To ensure that the results of the trials are representative of the population, and that treatments can be tailored to the specific needs of those populations.
- To understand how the disease affects different groups of people, such as how it may present differently in certain populations or how certain populations may have different risk factors and comorbidities.
- To increase the generalizability of the trial results and to ensure that the findings are applicable to diverse patient populations.
- To increase the likelihood that the treatments will be safe and effective for all populations.

Efforts should be made to increase the representation of underrepresented populations in colon cancer clinical trials, including outreach and education to these populations and to their healthcare providers. It is also important that these trials are designed in a way that is inclusive and culturally sensitive to these populations.

What Risks Should I Consider?

During the study, regular online reporting and video conference sessions with participants will be conducted. Keep in mind that changing treatment regimens always carries risks, so it is important to carefully consider enrolling in a clinical study. However, please note that this observational research will have NO IMPACT on your treatment plan.

A potential risk with this study is the possibility of a breach of confidentiality, which could include revealing that an individual has contacted staff for screening and completed informed consent forms. However, the risk of this happening is low and the risk of identity theft is limited by the way the data will be handled. The call log, electronic copies of informed consent forms, and de-identified information will be stored and analyzed with strict encryption and password protection in a secured and locked office. Additionally, this investigation cannot be conducted without the use of the data.

What Advantages Should I Consider?

There are several advantages to consider before enrolling in an observational medical trial:

- **Advancements in medical knowledge:** Participation in a trial can help to advance medical knowledge and contribute to the development of new treatments for others in the future.
- **Close monitoring:** Participants in a trial are usually closely monitored by a healthcare professional, which can provide a higher level of care than is typically available outside of a trial.
- **Help others:** By participating in a trial, individuals may be helping others by contributing to the development of new treatments and advancing medical knowledge.
- **Opportunity to be part of something meaningful:** Participating in a trial can give the individual a sense of purpose and that they are part of something meaningful.

Where Can I Find More Clinical Studies On Colon Cancer?

As our team is not familiar with all the clinical trials on colon cancer, there are several places you can look to find more studies. Some resources include ClinicalTrials.gov, a database of federally and privately funded clinical studies conducted around the world, including colon cancer trials, and Power's referral site where you can check colon cancer clinical trials which are actively looking for participants.

Research Process For Colon Cancer Patients

Participants in this trial will be required to complete bi-weekly surveys that typically take about 30 minutes. Additionally, to ensure the progress of the trial, participants will have scheduled quarterly check-in calls throughout the duration of any other clinical trials they may be enrolled in.

It's important to note that enrollment in a separate interventional clinical trial is a requirement for participating in this study. However, the logistics of that trial, such as therapy or technique, will not be altered in any way by this observational study. If you have any questions or concerns about the interventional clinical trial you are enrolled in, please reach out to your care team for assistance.

More about Clinical Trial Representation

If you are looking for more studies on clinical trial diversity, you can check the following:

Shavers-Hornaday, Vickie L., Charles F. Lynch, Leon F. Burmeister, and James C. Torner. "Why are African Americans under-represented in medical research studies? Impediments to participation." Ethnicity & health 2, no. 1-2 (1997): 31-45.

Rodrıguez, José E., Kendall M. Campbell, and Roxann W. Mouratidis. "Where are the rest of us? Improving representation of minority faculty in academic medicine." Southern medical journal 107, no. 12 (2014): 739-44.

Statement of Participant

By signing below, I agree to participate in this research study.

I have been provided with the above information both in written form and verbally, and any questions I had were adequately answered. I understand that my participation in this study is completely voluntary and that I am free to withdraw at any time. My legal rights are not affected by my signature on this form. I acknowledge that I will be provided with a copy of this consent form.

_____

Printed Name of Participant

_____

Participant Signature

_____

Date

Statement of Person Taking Consent

I have discussed the contents of this paper with the participants and ensured that they have a clear understanding of the potential risks, benefits, alternatives, and procedures involved in this research project.

Additionally, I have made sure that they understand the voluntary nature of their participation and that they are free to withdraw at any time without any negative consequences. Furthermore, I have provided them with all the necessary information to make an informed decision about participating in the research project, and they have agreed to participate.

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Printed Name of Person Conducting Informed Consent Discussion

_____

Person Conducting Informed Consent Discussion Signature

_____

Date