Medical Study: Determining Medical Study Experiences of Immunotherapy Patients

An informed consent form for participants in Power Clinical Trial's observational medical study.

Date: June 22, 2022

Immunotherapy observational study overview

Through this consent form, you are being invited to join a medical study (clinical trial) to understand how the different factors during the clinical trial enrolment process affect your capacity and interest in joining and then finishing your medical study.

The medical study outcomes will be collected anonymously and investigated to determine the patterns in a patient experience leading to a drop in completion or enrolment rates.

This is an observational medical study, and your treatment regime will not be modified or decided during this trial if you agree to join. Joining a medical study is separate from being a patient.

This consent form summarizes your discussion with our recruitment coordinators and site personnel. This document is also your reference as you proceed with the medical study process.

Essential things to understand about clinical trials

1. Joining a medical study is voluntary, and you can stop anytime.
2. This medical study is only observational, so joining it will not impact your care. Please note that the personnel affiliated with this clinical trial cannot diagnose conditions, give medical prescriptions, or keep an eye on your treatment care for you.
3. If you think that you are having difficulty understanding what our personnel or our team is communicating, it is vital that you let us know.

This clinical trial is approved by our Institutional Review Board. Our ethics committees in other countries thoroughly go over these research proposals to ensure that the well-being of the participants is protected according to the federal human subject regulations and ethical standards.

Why is this immunotherapy research being done?

It has been observed before that participation in medical trials has been in favor of specific demographic groups. But research pointing out which trial attributes impact participation positively or negatively is sparse.

This study invites various participants to collect more data on their clinical experiences. The goal is to know which factors always limit how patients participate or complete the medical study they are first interested in.

The data obtained in the trial will be assessed through a variety of demographic lenses to discover patterns that might improve the experience of immunotherapy patients in the future.

Are there any risks when deciding to join this medical study?

Throughout the trial process, you will be involved in scheduled online reporting and video conference calls.

Clinical trial patients are considered carefully before they are accepted since altering treatment regimens poses risks. The good thing is that the trial you are joining is only an observational study, so your treatment will NOT be modified.

This study can only be conducted using data. Since considerable amounts of data are handled, one other risk in clinical trials is a breach of confidentiality. But in this observational study, the risk of divulging confidential information is minimal.

Identity theft is also limited because the collected data is encrypted and password protected. The call logs, electronic copies of this consent form, and de-identified data will be stored and analyzed in a secured environment.

Are there benefits when I decide to participate in this medical study?

The outcomes of this general study will greatly help future immunotherapy patients and the results may help improve participation rates and diversity in enrolled patients.

How does this trial compare to other trials for immunotherapy?

Other trials for immunotherapy patients are interventional clinical trials. Since it is interventional in nature, the patient is required to follow a treatment process. This medical study is different

since it is purely observational. It will not prescribe you any new treatment or alter your current one.

Our staff is not knowledgeable of every single available immunotherapy clinical trial throughout the United States. However, if you wish to read more about studies on this condition, please feel free to check immunotherapy trials on clinicaltrials.gov or browse immunotherapy clinical trials on Power's website.

Do I need to do anything as an immunotherapy patient?

When you participate in this medical study, you will be required to do bi-weekly surveys, which last around 30 minutes.

Quarterly check-in calls will also be made throughout the duration of the clinical trial process you are involved in outside this observational study.

It is required that you are enrolled in an interventional clinical trial before you can join this observational medical study. Please note that the logistics of the interventional trial you are involved in - including the methodology and prescribed treatment - are separate from this medical study.

If you have any questions about your current interventional clinical trial, they should be directed to your care team to discuss any details.

Where can I find additional information about demographic representation in clinical trials?

There are a few studies on participation rates that you can browse. Below are some of those available:

Loree, Jonathan M., Seerat Anand, Arvind Dasari, Joseph M. Unger, Anirudh Gothwal, Lee M. Ellis, Gauri Varadhachary, Scott Kopetz, Michael J. Overman, and Kanwal Raghav. "Disparity of race reporting and representation in clinical trials leading to cancer drug approvals from 2008 to 2018." *JAMA oncology* 5, no. 10 (2019): e191870-e191870.

Hussain-Gambles, Mahvash. "Ethnic minority under-representation in clinical trials: Whose responsibility is it anyway?." *Journal of health organization and management* (2003).

Ma, Manuel A., Dora E. Gutiérrez, Joanna M. Frausto, and Wael K. Al-Delaimy. "Minority Representation in clinical trials in the United States: trends over the past 25 years." In *Mayo Clinic Proceedings*, vol. 96, no. 1, pp. 264-266. Elsevier, 2021.

Participant Statement

The above information has been verbally explained to me, and I have read the entirety of this document. I have had all my questions answered satisfactorily.

I understand that joining this observational clinical trial is voluntary and that I can end my participation at any time.

Signing this form does not entail any waiver of legal rights. I understand that I will be given a copy of this consent form.

By signing below, I agree to join this medical study.

_____
Printed Name of Participant

_____
Participant Signature

_____
Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information in this consent form with the participant. It is my opinion that he/she understands the benefits, risks, other options, and procedures involved in this observational study.

_____
Printed name of Person Conducting Informed Consent Discussion

_____
Person Conducting Informed Consent Discussion Signature

_____
Date