Informed Consent Form for Observational Metastatic Breast Cancer Clinical Trials

Study Title: Power Clinical Trial's Observational Medical Trial Discovering Patterns in Experiences of Participants of Metastatic Breast Cancer Clinical Trials

Date: February 25, 2023

Introduction:

You are being invited to participate in a research study to investigate experience patterns of metastatic breast cancer clinical trial patients. Before you decide to participate, it is important for you to understand why the study is being done and what it will involve. Please take the time to read this form carefully and ask any questions you may have. You are free to decide whether or not to participate and you may withdraw from the study at any time without penalty.

Purpose of the Study:

The purpose of this study is to determine patterns in the clinical trial experiences of metastatic breast cancer patients.

This clinical trial intends to acquire an understanding of the many elements that influence a patient's capacity and interest in enrolling in and completing medical research during the clinical trial enrollment process. The trial's objective is to identify trends in patient experiences that contribute to a decline in enrollment or completion rates by gathering anonymized medical research results.

As this is an observational medical study, if you opt to enroll, your treatment plan won't be changed or determined throughout the trial. Being a patient is distinct from participating in medical research. The main goal of this study is to collect data and analyze it to learn more about the elements that affect a patient's capacity to participate in and finish medical studies.

Procedures:

If you decide to participate, you will be asked to answer surveys twice a week. Each survey can take up to thirty minutes to accomplish. We will also call you every three months as you continue your participation in a separate metastatic breast cancer clinical trial. The study does not involve any interventions or treatments. Any question about your current treatment must be forwarded to your care team or physician.

Risks and Discomforts:

There are no known physical risks associated with participating in this study. But since the only way to carry out this investigation is with data, one potential danger in clinical trials is confidentiality breach. We process huge volumes of data; nevertheless, there is little chance of revealing sensitive information in this observational study.

Benefits:

There are no direct benefits to you for participating in this study. However, your participation may help to advance scientific knowledge in this area.

Confidentiality:

Your participation in this study will be kept confidential to the extent allowed by law. Your name will not be used in any publication or presentation of the research data.

Voluntary Participation:

Your participation in this study is voluntary. You may refuse to participate or withdraw from the study at any time without penalty.

Other Information About Metastatic Breast Cancer Studies

Clinical trials involving interventions are another type of trial for metastatic breast cancer patients. The patient must comply with a treatment plan because it is interventional in nature. The fact that this medical study is solely observational makes it unique. It won't recommend a new course of therapy for you or change your present one.

All of the clinical studies for metastatic breast cancer are not known to our personnel. But feel free to look up metastatic breast cancer trials on clinicaltrials.gov or browse metastatic clinical trials on Power's website if you want to learn more about research on this condition.

Other Research on Clinical Trial Participation

If you are looking for a few papers on participation rates, these are some of those that are offered online:

Unger, Joseph M., Riha Vaidya, Dawn L. Hershman, Lori M. Minasian, and Mark E. Fleury. "Systematic review and meta-analysis of the magnitude of structural, clinical, and physician and patient barriers to cancer clinical trial participation." *JNCI: Journal of the National Cancer Institute* 111, no. 3 (2019): 245-255.

Roberson, Noma L. "Clinical trial participation: viewpoints from racial/ethnic groups." *Cancer* 74, no. S9 (1994): 2687-2691.

Consent:

I certify that I have read and comprehend this form and have had the chance to ask questions by signing below. I voluntarily and voluntarily consent to take part in this study.

Participant Name: _____

Participant Signature: _____

Date: _____

Person Taking Consent:

I have spoken with the participant about the information on this permission form. I believe that he or she is aware of the advantages, dangers, alternatives, and steps involved in this observational study.

Name: _____

Signature: _____

Date: _____