Investigation of Patterns in Clinical Trial Experiences by Patients Participating in Triple Negative Breast Cancer Clinical Trials

Consent Form For Power Clinical Trial's Observational Research

Date: March 2, 2023

Key Information About The Triple Negative Breast Cancer Clinical Trial

We need your consent to participate in our research study. Your participation is entirely voluntary, and you are free to withdraw from the study at any time. We have provided a brief summary of the study below, and more detailed information can be found in the consent form.

- The purpose of our study is to determine if there are patterns in the experiences of triple negative breast cancer patients joining interventional clinical trials.
- The primary procedures of the study involve conducting surveys and check-up calls to determine the reasons why a patient enrolls, stays, or withdraws in a clinical trial.
- Since we are conducting an observational clinical study, there is minimal risk involved for participants. There may not be a direct medical benefit if you decide to join.
- The findings of this study will help patients with triple negative breast cancer by contributing to a better understanding of the factors influencing participation rates in clinical studies.
- You will not forfeit any of your normal services, benefits, or rights if you choose not to participate in this trial.

We encourage you to take the time to read through the entire consent form and ask any questions you may have before making a decision. It is also recommended that you discuss your decision with family members, close friends, trusted advisors, and/or healthcare providers.

What is the purpose of this clinical trial?

For some time, participation rates in clinical studies are not inclusive of a particular demographic group. We are doing this study to investigate the reasons why patients are enrolling, quitting, or staying in a clinical trial for triple negative breast cancer. Also, we are trying to include participants in different demographic groups to see if there are any significant findings.

What will happen during the clinical trial?

You have been asked to join this study because you are a triple negative breast cancer patient currently enrolled in an interventional study and availing of a particular treatment. This section will give you an overview of what will happen when you enroll in this study.

This is an observational clinical trial. That means we will not be providing you with any treatment, and we will also not administer any medicine for testing. Here is an outline of our process if you choose to participate in this study:

1. **Recruitment of Participants:** Patients diagnosed with triple negative breast cancer who have enrolled, withdrawn, or completed a clinical trial will be identified through the electronic medical records system of the participating clinical trial centers.

2. **Informed Consent:** Potential participants will be contacted by the research team to explain the purpose of the study, and provide them with an informed consent form to sign if they agree to participate. The study will ensure the participants understand the nature of the research and their rights in the process.

3. **Data Collection:** Every two weeks, participants will be asked to fill out a questionnaire designed to collect demographic data, medical history, and their reasons for enrolling, withdrawing, or completing the clinical trial. The research team will also conduct telephone interviews or online video calls with participants

every quarter to obtain detailed information about their experiences during the clinical trial.

4. **Data Analysis:** The research team will analyze the collected data to determine the factors that influence patient enrollment, withdrawal, and completion of clinical trials. Statistical analysis will be used to determine the relationships between the variables.

5. **Dissemination of Results:** The research team will disseminate the results of the study to stakeholders in the clinical trial community through scientific publications and conference presentations. The results will be used to inform future clinical trials and improve patient recruitment and retention in triple negative breast cancer clinical trials.

What are the possible risks?

There may be risks associated with joining an observational clinical trial for triple negative breast cancer.

Although observational trials do not involve experimental interventions like drug treatments or procedures, there are still risks to consider. These risks may include the potential for breaches of confidentiality, psychological or emotional distress related to the study's subject matter, and the possibility of adverse events related to any tests or procedures conducted as part of the trial.

It is important to carefully review the informed consent form for any clinical trial and discuss any questions or concerns with the study team before deciding whether to participate.

Are there benefits to taking part in the study?

Enrolling in an observational clinical trial for triple negative breast cancer patients may provide benefits, such as contributing to the advancement of medical knowledge and potentially improving future treatments for the disease.

Patients may also have access to specialized care and monitoring during the trial. However, it's important to note that observational trials do not involve experimental

interventions like drug treatments or procedures, so there may not be a direct medical benefit to the individual patient.

Ultimately, the decision to participate in a clinical trial should be based on an individual's own personal circumstances and goals and should be made after careful consideration of the potential risks and benefits. It's recommended that patients discuss their options with their healthcare provider and the study team before making a decision.

Why would my participation be stopped?

The researcher or sponsor may halt your participation in this study at any time without your consent for several reasons, including:

- If the study is suspended or terminated;
- If funding for the study is decreased, stopped, or withdrawn;
- If it is deemed to be in your best interest;
- If your condition deteriorates;
- If you become pregnant;
- If you do not agree to continue in the study after being informed of changes that may impact you; or,
- If you fail to comply with the study procedures.

Are there other clinical trials for triple negative breast cancer clinical trials?

Your involvement in this research study is optional, which means that you have the freedom to choose whether or not to participate or withdraw at any time without facing any negative consequences of forfeiting any benefits you would otherwise receive outside the study.

If you are looking for other clinical trials that are actively recruiting for triple negative breast cancer patients, you can go to clinicaltrials.gov, a website maintained by the National Institutes of Health (NIH) and contains a comprehensive database of clinical trials from around the world. You can search for trials by disease, location, and other criteria. Alternatively, you can also check Power's reference site for a list of triple negative breast cancer clinical trials which are currently recruiting patients.

Is there other related literature I can read on clinical trial diversity?

There are a few studies published online regarding clinical trial diversity that you can check. Here are some examples:

Hussain-Gambles, Mahvash. "Ethnic minority under-representation in clinical trials: Whose responsibility is it anyway?." *Journal of health organization and management* 17, no. 2 (2003): 138-143.

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.

Will my information be kept private?

We will take every possible step to ensure the confidentiality of the personal information collected during this study.

However, it cannot be guaranteed that your personal information will remain completely confidential as it may be required to be disclosed by law. Any publications or presentations of the research results will not use your name or any other identifiable personal information. Organizations that may have access to your medical records for research, quality assurance, and data analysis include accrediting agencies, government, and regulatory bodies (such as the FDA and OHRP), safety monitors, study sponsors, and authorized sponsor representatives.

In certain cases, you may be asked to sign a separate "Authorization Form" which outlines how and with whom your information may be shared for research purposes. Your information and/or research samples collected in this study may be shared with other researchers at Power, other academic institutions, or third-party commercial entities for future research without your additional informed consent. Information that identifies you will be removed and kept confidential.

Consent Provisions

By signing below, you acknowledge that:

1. You have read and fully comprehended the information presented in this informed consent form. You are encouraged to discuss this information with others and seek additional opinions before making a decision.
2. The study and its procedures have been thoroughly explained to you, and any questions you had have been answered to your satisfaction.
3. You have received all the information you require concerning your participation in the research study.
4. You have considered the potential risks, benefits, and alternatives associated with your participation in the study.
5. You are voluntarily choosing to participate in the research study.
6. You understand that your legal rights will not be affected by your decision to participate in the research.
7. You will be informed of any significant new findings related to the research study that may affect your willingness to continue participating.
8. You have received a copy of this consent form and have had the opportunity to ask any questions you may have.

Signature by the Participant

_____	_____	_____
Name of Participant	Signature of Participant	Date

Signature by the Investigator

I have personally explained the research to the participant in non-technical terms, answered all questions, and attest that he/she freely consents to participate.

Signature of the Investigator Who Obtained Consent Date of Signature

_____	_____	_____
Name of Investigator	Signature of Investigator	Date