Congestive Heart Failure Clinical Trials - Evaluating Clinical Trial Experiences of Individuals with Congestive Heart Failure

An informed consent form for participants in Power Clinical Trial's observational clinical trial.

Date: August 18, 2022

General Information About The Informed Consent Form

This form will give you important information about the purpose of this study, how it will be conducted, and the benefits and possible risks. Please read the document carefully. After going over the form, talk with the researcher and ask questions. You can also talk to family members, friends, and your health care provider about your interest in participating in this study. Once you decide to join, you will be required to sign this, and we will furnish you with a copy of the signed form.

Congestive Heart Failure Clinical Trial Overview

Congestive heart failure is a serious medical condition that happens when the heart muscles are unable to contract properly or have a mechanical problem that affects how the blood is pumped out. Around 6 million Americans are diagnosed with this condition.

This observational clinical trial invites individuals with congestive heart failure to determine the patterns in completion, enrolment, or withdrawal rates while enrolled in a separate interventional trial.

Since this clinical research is observational, we do not test potential treatments. We only observe participants in their current treatment regimen and track health outcomes. That means there will be no changes to your treatment plan.

Your participation in an independent clinical trial is necessary before you can enroll in this medical study. However, the details pertaining to your other clinical trial are separate from ours,

and we will not suggest any modifications to your care regimen. So, if you have questions about your treatments, you must contact your care team directly.

Why This Congestive Heart Failure Research Is Conducted

For a long time, participation in clinical trials has been known to be skewed toward some demographic groups. Only a few studies explain this.

This clinical trial hopes to reveal why this is happening and study the positive or negative factors affecting the participation of congestive heart failure patients in an interventional clinical trial. It also aims to determine what specific elements are consistently involved in an individual's decision-making process when it comes to participating, completing, or quitting a clinical trial.

Comparing This Trial to Other Trials For Congestive Heart Failure

There are a number of active clinical trials for congestive heart failure. These trials usually prescribe treatment courses. However, our clinical trial is merely observational, so we will not provide any diagnosis or treatment regimen.

Before enrolling in any medical study, reading related literature about congestive heart failure is recommended so you can make an informed decision about your enrollment. For further reference, you can visit trusted clinicaltrials.gov, which has a repository of publications on congestive heart failure studies. You can also read more about congestive heart failure clinical trials on Power's website.

Knowing the Risks and Benefits

Whenever you are enrolling in a new medical trial, changing your current treatment course may pose a risk to your health. This risk is eliminated in our observational clinical trial. Since we are only conducting an observational study, your participation will not have any impact on your treatment plan.

There is also a possibility of a breach of confidentiality in handling sensitive information during clinical trials. However, in our study, the likelihood of a data breach is minimal since we ensure that all the online transactions, documents, call logs, and copies of forms are secured with encryption and passwords. Your data will be shared only with the members of the research team. All information is also anonymized to maintain the confidentiality of the patient's identity.

This study will not benefit the participant directly, but the data obtained will be assessed carefully to find patterns that future congestive heart failure patients can take advantage of. The results may also serve as a beneficial reference for future researchers in improving participation rates in clinical trials for individuals with the condition.

Study Procedures

For this study, we will have you fill out questionnaires every two weeks. You can finish these surveys in 20 to 30 minutes. We will also conduct check-in calls once every three months while you are still enrolled in the clinical trial.

Voluntary Participation

As a patient who is voluntarily participating in this clinical trial, you can make the decision to take part in this study or to decline participation. If you join this study, you are required to sign this informed consent form. After signing, you are still free to withdraw without giving any reason or at any time.

More trusted sources on representation in clinical studies

If you are looking for credible sources of research on representation in clinical studies that have been published online, you can visit the following websites:

Hoffman, Paul J. "The paramorphic representation of clinical judgment." *Psychological bulletin* 57, no. 2 (1960): 116.

Hurwitz, Brian. "Form and representation in clinical case reports." *Literature and Medicine* 25, no. 2 (2006): 216-240.

Participant Statement

By signing this form, I declare that I have read and understood the information mentioned earlier. The person leading the informed consent discussion explained everything to me. I was allowed to ask questions, and all of them were properly and satisfactorily answered. I understand that I am not waiving my rights.

I was given my own copy of this form after signing.

_____

Printed Name of Participant

_____

Participant Signature

_____

Date

Researcher Statement

I have read out the informed consent form to the prospective participant and made sure that the participant understands what the clinical trial is about, the process, risks, benefits, and other important information in this form.

The participant was given the time to clarify and ask questions about the clinical trial, and I answered them to the best of my ability. The consent was freely and voluntarily given by the participant.

After signing, the participant will be given a copy of this form.

_____

Printed name of Person Conducting Informed Consent Discussion

_____

Person Conducting Informed Consent Discussion Signature

_____

Date