Gastric Bypass Clinical Trials: Examining Patterns in the Involvement of Gastric Bypass Patients in Clinical Studies

An informed consent form for participants in Power Clinical Trial's gastric bypass clinical study.

Date: January 26, 2023

Gastric Bypass Observational Study Overview

This document serves as an invitation for you to participate in a medical research study, specifically a clinical trial. The goal of this clinical trial is to answer the following questions:

- What factors encountered during the clinical trial enrollment process can impact a patient's willingness and ability to participate and complete the trial?
- Why do gastric bypass patients withdraw in clinical trials?
- What makes gastric bypass patients stay or finish the trial?
- What compels them to enroll in the first place?

The study will be observational, meaning that it will not alter or determine your treatment regimen. The findings of this study will be collected anonymously and then analyzed to understand trends in patient experiences that may lead to lower completion or enrollment rates.

It's important to note that being a participant in a research study is different from being a patient, and the results of this study may not have a direct benefit for you. However, the information collected from this study can be used to improve patient experience and outcomes for future patients.

Additionally, this study serves as an opportunity to contribute to the advancement of medical knowledge and treatments for gastric bypass.

This ICF also serves as a written summary of the conversation you had with our recruitment coordinators and site staff and it serves as a reference for you as you go through the clinical trial process. If you cannot understand any part of this form, please do not think twice about raising your hand and asking the person taking consent.

Why is this gastric bypass research being conducted?

There is a known problem of underrepresentation of certain groups of people in clinical trials, including gastric bypass patients. This 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.

For example, studies have shown that African American and Hispanic populations are underrepresented in clinical trials for gastric bypass. This lack of representation can lead to a lack of understanding about how the disease affects these populations and how best to treat it. Additionally, these populations may have different risk factors and comorbidities that could affect the course of the disease, making it even more important that they are represented in clinical trials.

This is a widely recognized problem and it is important that efforts are made to increase the representation of underrepresented populations in clinical trials, so that the results of the trials are representative of the population and treatments can be tailored to the specific needs of those populations.

What are the risks?

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

- **Privacy concerns**

  There is a risk of a breach of confidentiality, which could include revealing that an individual has contacted staff for screening and completed informed consent forms. Additionally, personal information and medical data will be collected and handled, so it's important to understand how it will be protected and who will have access to it.

- **No treatment**

  Observational trials do not involve interventions, so the participant's treatment course will not be changed, that means that there will be no direct benefit for the participant.

- **Risk of no study results**

  The study may be closed before any results are obtained, or the results may not be published.

It's important to carefully weigh the potential risks and benefits before deciding to enroll in an observational trial and to fully understand the nature of the study, what will be expected of the participant, and how the data will be used and protected. It's also important to discuss the trial with your healthcare provider and to have all your doubts cleared.

What are the benefits?

The results of this medical study could potentially increase the number of participants and diversity among patients in clinical trials for gastric bypass in the future.

Are there other trials for gastric bypass?

This observational clinical trial does not involve any therapy or treatments being imposed or offered to the patients. Unlike many other clinical trials for patients with conditions, this is not an interventional study.

It's important to note that our team may not be familiar with all the available clinical trials for gastric bypass. However, if you're interested in learning more, you can search for gastric bypass trials on websites such as clinicaltrials.gov or other patient-centered trial databases. These resources can provide more detailed information on the trial's location, duration, and specific inclusion criteria. Furthermore, consulting Power's reference site for gastric bypass clinical trials can also be beneficial in finding the right one that best suits your needs and condition.

What should the gastric bypass patient do in this clinical study?

This trial will consist of bi-weekly surveys that will take around 30 minutes to complete. Quarterly check-in calls will be scheduled for the length of any clinical trial(s) you are engaged in outside of this observational study.

While enrollment in a distinct interventional clinical trial is required for participation, the precise logistics of that trial — including therapy and technique — are completely independent of this investigation and will not be changed in any way. If you have any queries concerning the interventional clinical studies in which you are enrolled, please contact your care team.

Where can I find out more about clinical trial representation?

Here are some published studies on representation in clinical trials:

Saha, Somnath. "Taking diversity seriously: the merits of increasing minority representation in medicine." *JAMA internal medicine* 174, no. 2 (2014): 291-292.

Bird, Chloe E. "Women's representation as subjects in clinical studies: a pilot study of research published in JAMA in 1990 and 1992." *Women and health research: Ethical and legal issues of including women in clinical studies* 2 (1994): 151-173.

Participant's Statement of Consent

I freely consent to take part in the observational clinical study. My questions have all been well addressed, and I now fully understand the study's nature, goal, potential dangers, and advantages. I am aware that my participation in this study is entirely voluntary and that I can stop at any moment without suffering any repercussions. I am also aware that by signing this permission form, I am not waiving any of my legal rights. I understand that a copy of this permission form will be given to me. I give my permission to take part in this research project by signing below.

_____

Printed Name of Participant

_____

Participant Signature

_____

Date

Assisting Person’s Statement

As the person taking consent for the observational clinical trial, I certify that I have thoroughly reviewed the study's nature, purpose, potential risks, benefits, and alternatives with the participant. I have ensured that all of the participant's questions have been answered to their satisfaction and that they have a clear understanding of the voluntary nature of their participation. I have also confirmed that the participant has been provided with a copy of the consent form and that they have given their informed consent to participate in the study. Furthermore, I attest that the participant's rights, safety and well-being are protected throughout the study.

_____

Printed Name of Person Conducting Informed Consent Discussion

_____

Person Conducting Informed Consent Discussion Signature

_____

Date