# Osteosarcoma Clinical Trials - Assessing Clinical Trial Experiences of Patients with Osteosarcoma

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

Date: September 6, 2022

General Information: Informed Consent Form

If you are reading this form, it means you are considered a potential participant in an observational clinical trial involving patients with osteosarcoma. This document will disclose information regarding the study, its purpose, and how it will be conducted, along with the benefits and possible risks.

Before you make a decision to join, you may talk to anyone you feel comfortable talking with about the research. Take time to reflect on whether you want to participate or not. If there are any words or concepts in this document that you do not understand, inform the researcher assisting you so everything can be clarified.

The Purpose of the Osteosarcoma Clinical Trial

Osteosarcoma is a type of cancer that affects the bones. Cancer.org reveals that around 1,000 new cases of osteosarcoma are diagnosed every year.

This clinical study involves patients diagnosed with osteosarcoma. It aims to check for patterns in the completion or withdrawal rates of these individuals while they are enrolled in another independent clinical trial that requires medical intervention.

#### Type of Research

This medical trial is observational. An observational clinical trial is a type of clinical trial wherein researchers do not recommend any particular treatment or intervention. In this type of trial, the individuals are only observed, and outcomes are measured. If you decide to participate, there will be no changes to your current care plan.

### Other Trials For Osteosarcoma

As mentioned, this clinical trial is observational. There are numerous types of clinical research on osteosarcoma published online, and most of them are interventional in nature. This means you will have to undergo a specific treatment if you join those studies. To help you make your decision, you can read about different studies from trusted resources publishing medical journals or clinical research.

You can visit clinicaltrials.gov to find <u>osteosarcoma studies</u>. You can also check different <u>osteosarcoma clinical trials</u> on Power's website.

#### Procedures of the Osteosarcoma Clinical Trial

You will be required to share information regarding your clinical trial experiences. In order to get this information, we will let you answer questionnaires once every two weeks. These survey forms are usually not complicated to answer and can be done in around 20 to 30 minutes. In addition, we will conduct check-in calls quarterly as long as you are still on the clinical trial.

You may decline to answer any or all questions, and you may terminate your involvement at any time if you choose.

#### Confidentiality

Your responses to our questionnaires will be anonymous. Avoid writing any identifying information in your document. The researcher will make every effort to preserve your confidentiality. Your data will be kept confidential except in instances wherein the researcher is legally required to divulge the information.

#### Risks

In clinical trials, there are health risks involved when you undergo novel treatments. Since our clinical trial is observational, this risk is minimized, if not eliminated.

Clinical trial procedures may also pose a breach of confidentiality. In our medical study, this risk is minimized since we ensure that all the data we process are anonymous. We limit the information to the research team only. Additionally, all call logs, online transactions, forms, and surveys are stored securely and protected with encryption and passwords.

#### **Benefits**

There will be no direct benefit to individuals joining this study, but the data you will share will help future osteosarcoma patients' enrolment in clinical trials. The results of this clinical study will be a useful reference for researchers in improving enrolment rates for osteosarcoma medical research.

## Voluntary Participation in the Osteosarcoma Clinical Trial

Your participation in the osteosarcoma clinical trial is voluntary. It is entirely up to you to decide whether or not you will join this study. If you join, you will need to sign this informed consent form. After you sign this document, you are still free to stop your participation at any time and even without giving any reason.

## Additional Research on Representation in Clinical Trials

There are a lot of available online resources where you can read up on representation in clinical trials. Here are some of them that you may be interested in reading further:

Ramos, Edward, Katie Baca-Motes, Jay A. Pandit, and Toluwalase A. Ajayi. "Improving participant representation in the era of digital clinical studies." Trends in Molecular Medicine (2022).

Motazedian, Pouya, Thais Coutinho, and F. Daniel Ramirez. "Female representation in clinical studies informing atrial fibrillation guidelines: have we built a house of cards?." Canadian Journal of Cardiology 38, no. 6 (2022): 709-711.

Consent

I have thoroughly read this form or had the document read to me in its entirety. I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Printed Name of Participant

Participant Signature

Date

Declaration of Person Taking Consent

I have read out this document and have assisted the participant in ensuring that he/she understands the purpose, process, risks, benefits, and other pertinent information about this osteosarcoma clinical trial. The patient had the opportunity to clarify words and concepts, and I answered his/her questions to the best that I could. The participant's consent was given voluntarily. After signing, a copy of this document was given to him/her.

Printed Name of Person Taking Consent

Signature of Person Taking Consent

Date