# Mesothelioma Clinical Trials Review: Evaluating the Clinical Trial Experiences of Patients with Mesothelioma

## Informed Consent Form (ICF) For Power Clinical Trial's Mesothelioma Clinical Trial

Date: April 6, 2023

### A Guide to the Informed Consent Form

This document, referred to as the "ICF" or "informed consent form", serves as a crucial component of the clinical trial process. It is divided into two distinct parts, with the first section being the Patient Information Sheet. This section aims to provide you with relevant information about the clinical study, including its purpose, procedures, potential risks and benefits, and your role as a participant. It is important that you read and understand this section thoroughly, as it will help you make an informed decision about whether to participate in the study or not.

The second section of the ICF is the Certificate of Consent, which serves as proof of your agreement to participate in the study. This section will require your signature, indicating that you have read and understood the Patient Information Sheet, and that you voluntarily agree to participate in the study. It is important to note that signing the Certificate of Consent does not mean that you are waiving your legal rights or that you are obliged to continue participating in the study. You are free to withdraw from the study at any time, without any negative consequences.

Once you have completed the ICF and signed the Certificate of Consent, you will be given a copy of the document for your records. This will allow you to refer back to the information provided and remind you of your decision to participate in the study.

## Overview of the Mesothelioma Clinical Trial

Mesothelioma is a rare form of cancer that affects the lining of the lungs, heart, or abdomen. It is a challenging disease to treat, with limited treatment options available. However, clinical trials offer hope for developing new and improved treatments that can improve patients' outcomes and quality of life.

The importance of mesothelioma clinical trials cannot be overstated. These trials provide researchers with critical insights into the disease's underlying mechanisms and enable them to test new treatments and therapies that may not be available through standard treatment options. Clinical trials also offer patients an opportunity to access cutting-edge treatments and receive expert care from leading healthcare professionals.

However, it is essential to ensure that clinical trial participation rates accurately represent the larger population of mesothelioma patients. Unfortunately, underrepresented groups may have lower participation rates due to various factors, such as a lack of access to information, mistrust of the healthcare system, or language barriers. This clinical trial aims to understand these factors and identify strategies to increase participation rates in future trials.

Our objective is to increase clinical trial participation rates by identifying and understanding the reasons for underrepresented groups' low participation rates. We believe that by identifying these factors, we can develop better strategies to increase participation rates in future clinical trials.

It is important to note that participating in this clinical trial is entirely voluntary, and participants have the right to withdraw at any time without any consequences.

The study's primary procedures involve answering questionnaires and making follow-up calls, with minimal risk to the participants. We encourage potential participants to review the consent form carefully and discuss it with their families, friends, trusted advisors, and healthcare professionals before making a decision.

By participating in this study, individuals can contribute to advancing mesothelioma research and improving patient outcomes.

## The Research Process

This clinical trial is observational and does not involve recommending any new treatment plan. If you choose to participate, your current care regimen will not be altered. The only difference will be that the researcher will conduct interviews to gather data. The researcher cannot provide any diagnosis or treatment recommendations. The study's sole objective is to collect data.

## Eligibility to Join

In order to participate in this study, you must currently be enrolled in another clinical trial for mesothelioma. Our aim is to gain insight into why patients choose to participate in this type of research and what factors affect their decision to continue or discontinue treatment.

We are interested in understanding the reasons behind your decision to join the study, as well as what influences your choice to stay or withdraw. Through this clinical trial, we hope to identify the factors that impact patients' decision-making in mesothelioma clinical trials.

It is important to note that participating in this study is completely voluntary and optional. Joining the study will not affect the treatment plan you are currently receiving in another clinical trial. You are free to withdraw from the study at any time if you are uncomfortable, and doing so will not affect your legal rights.

## Comparison to Other Mesothelioma Clinical Trials

While there are various clinical trials that involve specific treatment plans for mesothelioma patients, the trial we are inviting you to is different. Our trial is solely observational and won't require you to follow a specific treatment regimen.

Please note that there are many other clinical trials available for this condition, and while we cannot provide an exhaustive list, you can find additional information by checking clinicaltrials.gov for a comprehensive list of mesothelioma studies or visiting Power's website for information about mesothelioma clinical trials actively recruiting for participants.

## What to Expect When You Are Joining

If you choose to participate in this clinical trial, you will be required to complete a survey every two weeks. Each survey usually takes about 30 minutes to complete. We will also have check-in calls with you every three months.

It's important to understand that while you may need to be enrolled in another interventional clinical trial, our study is solely for observation purposes and will not impact your diagnosis or treatment plan for that trial. If you have any questions about the other trial, please contact your personal healthcare team.

Your comfort and privacy are important to us. You are not obligated to answer any questions that make you uncomfortable, and you may choose to complete the survey independently or have someone read the questions aloud to you. Additionally, you may choose to skip any questions that you do not wish to answer.

Your privacy is a top priority. We will ensure that any information you provide is kept confidential and anonymous. Your name will not be included on the survey forms, and all data we collect will be kept anonymous.

You can rest assured that we will handle any personal data you provide with the utmost care and confidentiality. To ensure the anonymity of orthopedic patients, we will use encryption, passwords, and anonymity measures, such as numerical identifiers instead of names. Phone logs and digital permission forms will also be treated securely.

## Additional Resources on Inclusivity in Clinical Studies

For those interested in exploring the topic of inclusivity and representation in clinical trials further, we suggest consulting the following published studies. These resources provide a wealth of information and data on the benefits of diverse participation, as well as practical recommendations for enhancing inclusivity in future studies:

Kelsey, Michelle D., Bray Patrick-Lake, Raolat Abdulai, Uli C. Broedl, Adam Brown, Elizabeth Cohn, Lesley H. Curtis et al. "Inclusion and diversity in clinical trials: Actionable steps to drive lasting change." *Contemporary Clinical Trials* (2022): 106740.

Chaudhry, Mohammed Suhail, Jessica Spahn, Shilpen Patel, Charles S. Fuchs, Jennifer Lauchle, Nikheel Kolatkar, Nicole Richie, Quita Highsmith, Meghan McKenzie, and Ruma Bhagat. "Myths about diversity in clinical trials reduce return on investment for industry." *Nature Medicine* 28, no. 8 (2022): 1520-1522.

## Participant’s Statement

I am providing my signature to confirm my participation in a medical study aimed at patients with mesothelioma. As a patient with this condition, I have been chosen to take part in an interventional clinical trial. I have thoroughly reviewed the consent form and had a discussion with the research team to clarify any questions or concerns I had. I have received a copy of the consent form for my records, and I acknowledge that my involvement in the study is entirely voluntary and that I have the right to withdraw at any time without consequence. I am also aware that my personal information and the data collected during the study will be kept confidential and secure.

## Participant’s Signature

| _____ | _____ | _____ |
|---|---|---|
| Name of Participant | Signature of Participant | Date |

## Statement of Person Obtaining Consent

As the person responsible for obtaining the participant's consent, I took the necessary steps to ensure that the participant fully comprehended the process and consequences of taking part in the study. This involved explaining the contents of the consent form in detail and giving them sufficient time to ask any questions they may have had. Furthermore, I can attest that the participant's decision to participate in the study was made without any coercion or pressure from me or anyone else. The participant has also been provided with a copy of the consent form for their records.

## Signature of Person Obtaining Consent

| _____ | _____ | _____ |
|---|---|---|
| Name of Researcher | Signature of Researcher | Date |