# Multiple Myeloma Clinical Trials: An Examination of Trends in Medical Trial Patient Experiences

## Consent Form For Power Clinical Trial's Observational Research

Date: April 21, 2023

### Introduction

We welcome interested volunteers to provide their permission for our study as part of our clinical trial initiative.

Anytime may be used for participant withdrawal from the research. Our study's major goal is to find trends in the behaviors of multiple myeloma patients who opt to participate in interventional clinical trials. To learn why patients participate in, continue in, or leave clinical trials, the study mostly entails filling out questionnaires and making follow-up calls. As an observational research, participation has minimal risk and offers no obvious medical benefits. The study's findings, however, will provide light on the variables affecting patients with multiple myeloma.

Before making a choice, we advise participants to thoroughly read the permission form, ask about any concerns they may have, and seek guidance from their family, friends, trusted advisers, or medical professionals. The decision to participate is entirely up to you, and you will not lose out on any advantages, privileges, or rights if you decide not to.

### About the Observational Study on Multiple Myeloma Patients

A kind of cancer known as multiple myeloma affects the bone marrow's plasma cells, which are in charge of creating antibodies that aid in the defense against infections. A number of symptoms, including bone pain, weariness, anemia, and a compromised immune system, can be brought on by multiple myeloma, which is characterized by abnormal plasma cells accumulating in the bone marrow and forming tumors.

Multiple myeloma observational clinical trials are crucial because they can offer critical insights into the course of the illness and how it affects people over time. This kind of research focuses on gathering information from patients via surveys, medical records, and physical examinations rather than any kind of intervention or therapy. Researchers can learn more about the disease's progression, the variables influencing its course, and the efficacy of the available therapies by analyzing the data.

Studies of uncommon illnesses like multiple myeloma benefit greatly from observational clinical trials since they may yield a wealth of information from a very small number of patients. This might lead to better results for individuals with multiple myeloma by assisting researchers in finding possible new medicines or methods to enhance existing ones. All things considered, observational clinical studies are a vital tool for furthering our knowledge of multiple myeloma and enhancing the lives of individuals afflicted by this difficult illness.

## How the Clinical Trial is Conducted

Our observational clinical research study is seeking multiple myeloma patients who are currently receiving therapy or treatment through an interventional trial to participate in the study.

The purpose of the study is to collect data from participants who have previously taken part in, withdrawn from, or completed a clinical study, to determine what factors influence patient enrollment, withdrawal, and completion.

Recruitment will be done through electronic medical record systems, and participants will be given a consent form to sign after our staff have gone over the study's objectives and their rights as a participant. Data will be collected through questionnaires every two weeks and phone or video chats every three months.

The study team will analyze the data using statistical analysis and present the results at conferences and publish them in scholarly journals to enhance patient recruitment and retention in clinical studies for multiple myeloma.

## Examining Patient Decision-Making in Clinical Trials for Multiple Myeloma

Our research project is dedicated to gaining insight into the decision-making process of patients who are considering participating in clinical trials for multiple myeloma. We are keen to understand why patients choose to enroll in a clinical trial and what factors influence their decision to continue or withdraw.

Your involvement in this study is entirely voluntary, and it will not affect your current treatment plan. Our team will conduct interviews to gather data that will assist us in identifying the obstacles and incentives that impact patient participation in clinical trials.

By joining this study, you will be assisting us in developing more effective methods for enhancing patient recruitment and retention in clinical trials for multiple myeloma. If you opt to participate, you may withdraw from the study at any point without negative consequences. Your contribution will be highly appreciated and respected.

## Risks and Benefits of Participating

There may be dangers associated with taking part in an observational clinical research study for multiple myeloma. It is important to understand that even in studies that do not include experimental interventions, such as medication therapies or medical procedures, hazards may still be present.

The danger of a privacy violation, the potential for psychological or emotional suffering because of the study's topic, and the probability of unfavorable results from any operations carried out during the trial are some possible concerns.

It is advised that persons carefully read the informed consent form and raise any issues or queries with the research team before deciding whether to participate in the study.

## Multiple Myeloma Clinical Trials vs Other Trials

To find medical trials for multiple myeloma, you can visit clinicaltrials.gov, a website backed by the National Institutes of Health (NIH) which provides an extensive list of multiple myeloma studies from all over the globe. You can use filters to sort the trials by criteria such as location and condition. Another option is to check Power's reference page for a list of multiple myeloma clinical trials that are currently accepting new participants.

## Personal Data Safety

Your personal information collected for this research will be kept confidential and protected to the best of our abilities. However, we cannot guarantee complete privacy since it may be required to be disclosed by law. Your personal information will not be disclosed in any research publications or presentations in a way that could identify you personally. Various entities such as accrediting bodies, government and regulatory authorities, safety monitors, study sponsors, and authorized sponsor representatives may access your medical information for research, quality control, and data analysis purposes.

In some cases, you may be required to complete an additional "Authorization Form" that details how and with whom your information may be used for research purposes. Any data and/or study samples you submitted for this project may be shared with other Power researchers, researchers from other academic institutions, or researchers from outside commercial firms for future research without further informing you. Rest assured that your confidential information will be removed and kept confidential.

## Resources to Learn More about Clinical Trial Diversity

We advise anybody interested in learning more about the significance of diversity and inclusion in clinical trials to go through published papers for more information and reading materials:

Walsh, Mary Norine. "Gender diversity in cardiovascular clinical trial research begins at the top." *Journal of the American College of Cardiology* 79, no. 9 (2022): 929-932.

Lund, Mary Jo, Mark T. Eliason, Ann E. Haight, Kevin C. Ward, John L. Young, and Rebecca D. Pentz. "Racial/ethnic diversity in children's oncology clinical trials: ten years later." *Cancer: Interdisciplinary International Journal of the American Cancer Society* 115, no. 16 (2009): 3808-3816.

## Providing Consent

You have read and understand this informed consent form in its entirety. Before making a choice, it is advised that you discuss this information with others and get additional perspectives. By signing, you also agree that:

- You have received complete responses to all of your questions and a detailed explanation of the study's methods.
- You have all the knowledge you need to participate in the research study.
- You have thought about the advantages, drawbacks, and other study participation possibilities.

- You are fully free to take part in the research project.
- You are aware that your decision to participate in the research won't have any legal ramifications.
- You will be informed of any material updates to the study project that could affect your decision to continue participating.
- You were provided with this permission form, and you have the opportunity to ask any questions you may have.

## Signature by the Participant

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

## Statement of Person Getting Permission

I made sure that the participant was fully informed about every element of the study as the designated person in charge of getting their consent to participate in the research study. This includes giving a thorough explanation of the permission form and responding to any queries. I can attest that the participant gave their permission willingly and free from coercion or any undue pressure. Finally, I gave a copy of the consent form to the participant for their own records.

## Signature of Person Getting Permission

| _____ | _____ | _____ |
|---|---|---|
| Name of Investigator | Signature of Investigator | Date |