# A Close Examination of Patient Experiences in Bipolar Disorder Clinical Trials

## This is an informed consent form for bipolar disorder patients joining Power Clinical Trial's observational clinical trial.

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### Introduction to the Bipolar Disorder Clinical Trial

Bipolar disorder, also known as manic-depressive illness, is a mental health condition characterized by extreme mood swings that fluctuate between manic episodes and depressive episodes. It affects a person's mood, energy levels, and ability to function in their daily life.

Individuals living with bipolar disorder can actively contribute their own experiences and unique insights by actively engaging in this observational clinical investigation. These priceless insights have the potential to have a big impact on the development of new therapies and supportive services. The evidence obtained from this experiment will eventually expand our understanding of bipolar disorder and lead to better results for patients.

The major goal of our research is to get a thorough knowledge of the factors that may lead to poorer participation or completion rates in clinical trials among people with bipolar disorder. We cordially invite you to participate in this observational clinical investigation, in which we hope to find recurring trends in the patient experience that may influence these rates. We want to highlight that any information you offer during the trial will be treated with absolute confidentiality and properly reviewed.

It is critical to understand that this experiment is strictly observational and will not entail any changes to your current treatment strategy. Your participation in this research does not imply that you will get any therapy. Throughout the trial, please refer to this page for detailed information regarding the recruiting process and the specialized trial team.

## Voluntary Participation and Study Details

Your involvement in this research study is entirely optional, allowing you the freedom to withdraw at any time you wish. This is a common practice in medical research studies. It is important to emphasize that your treatment plan will remain unaffected if you decide to participate. This study is purely observational, meaning that your diagnosis, medications, and care will continue unchanged if you are currently undergoing treatment. It is strictly forbidden for the study team to interfere with your treatment or monitor your care status.

## Clarity and Support Channels for Study Participants

Ensuring that you have a clear understanding of the study's particulars and feel confident throughout the research process is of utmost importance. If you encounter any uncertainties or require further explanations, we encourage you to seek clarification without hesitation. The study team is readily available to address any questions or concerns you may have regarding instructions, explanations, or any aspect of the study. We highly value and prioritize your comprehension and peace of mind.

## Enhancing Patient Participation in Bipolar Disorder Clinical Trials: Identifying Barriers

Examining historical clinical trials, it is evident that certain demographic groups of bipolar disorder patients have been underrepresented, leading to a limited understanding of their participation challenges. The objective of this research study is to gather comprehensive information from participants, aiming to identify consistent factors that hinder individuals from enrolling or completing clinical trials. By meticulously analyzing the collected data from diverse demographic perspectives, patterns that influence the experiences of future bipolar disorder patients can be uncovered. Your active involvement in this study holds immense value, as it has the potential to provide invaluable insights to enhance the participation and completion rates of bipolar disorder patients in clinical trials.

## Differentiating Interventional and Observational Studies: Insights for Participation

To be a part of this study, enrollment in an interventional clinical trial is required. It is important to understand that your participation in this observational clinical study will not affect your current bipolar disorder care regimen if you are already engaged in a separate clinical trial. If you have any concerns or queries regarding your interventional clinical trial, we encourage you to contact your care team for additional information and clarification. Your understanding of the distinction between these study types is crucial for your informed participation.

## Study Engagement and Follow-up Calls: Fulfilling Requirements

As a participant in this observational clinical study, your involvement will entail completing bi-weekly surveys that are estimated to take approximately 30 minutes. In addition, there will be quarterly check-up calls specifically scheduled for your interventional clinical trial, which are separate from this observational research. It is crucial to ensure that you schedule and attend these calls as required to actively participate in both components of the study.

## Evaluating Potential Risks and Safeguards: Your Safety Matters

When considering participation in a medical study, it is important to assess potential risks. However, in this observational clinical trial, the risks are minimal. There is no possibility of altering care regimens, which eliminates the potential for adverse effects on participants as this study is solely observational. Furthermore, to address concerns about confidentiality, we implement encryption and password protection to secure all electronic data, minimizing the risk of a breach during regular video conferences and online reporting.

## Identifying Potential Benefits: Contributing to Improved Clinical Trials

Participating in this study offers potential benefits as well. The findings from this trial will yield valuable insights into the factors that can impact the participation and completion rates of a diverse range of bipolar disorder patients in clinical studies. This knowledge will be instrumental in enhancing future clinical trials that aim to include individuals with

bipolar disorder. By actively participating in this study, you can make a meaningful contribution towards a deeper understanding of the factors that may influence the participation of diverse patient populations in these trials.

## Contrasting the Nature of This Study with Other Bipolar Disorder Clinical Trials

Unlike much other research, this study is purely observational, meaning that there is no predetermined course of therapy that participants must follow. It is important to note that while the study team may not possess extensive expertise in previous bipolar disorder research, there are resources available to support you. You can find a comprehensive list of bipolar disorder studies on ClinicalTrials.gov, and Power's reference page provides an up-to-date list of actively seeking bipolar disorder clinical trials for potential volunteers.

## Exploring Diversity in Clinical Trials: Recommended Resources

Despite limited research on the representation of diverse populations in clinical trials, several studies offer valuable insights. We have curated a list of recommended readings that you may find engaging and informative:

Patel, Vimla L., José F. Arocha, Melissa Diermeier, Jacques How, and Christel Mottur-Pilson. "Cognitive psychological studies of representation and use of clinical practice guidelines." *International Journal of Medical Informatics* 63, no. 3 (2001): 147-167.

Varma, Tanvee, Joshua D. Wallach, Jennifer E. Miller, Dominic Schnabel, Joshua J. Skydel, Audrey D. Zhang, Michaela A. Dinan, Joseph S. Ross, and Cary P. Gross. "Reporting of study participant demographic characteristics and demographic representation in Premarketing and postmarketing studies of novel cancer therapeutics." *JAMA Network Open* 4, no. 4 (2021): e217063-e217063.

These recommended readings provide valuable insights into the representation of diverse populations in clinical trials, offering a broader understanding of the importance of inclusivity in research.

## Prioritizing Privacy: Robust Confidentiality Measures

Protecting the privacy and confidentiality of your personal information is of utmost importance in this clinical study. To ensure the highest level of protection, we have implemented stringent measures. Your records will be assigned a unique code or number to maintain anonymity throughout the study. All identifying materials will be securely stored in a locked file cabinet under the close supervision of the researcher. We highly value your privacy and are committed to not disclosing any personal information without your explicit consent, unless required by law in situations involving abuse or suicide risk.

## Acknowledgement of Voluntary Participation and Consent

By providing my signature below, I acknowledge that I have received complete information about the nature and purpose of this study. I understand that my participation is entirely voluntary, and I have the freedom to withdraw from the study at any time without facing any negative consequences. I greatly appreciate the reassurance that my decision to withdraw will not affect my current or future medical care. I kindly request a copy of this consent form for my personal records.

_____
Printed Name of Participant

_____
Signature

_____
Date

## Confirmation of Participant Understanding

As the clinical trial personnel responsible for discussing the consent form with the participant, I am pleased to confirm that the participant has demonstrated a comprehensive understanding of the risks, benefits, and procedures involved in this

clinical research. Through open and informative discussions, all inquiries and uncertainties have been addressed, ensuring that the participant has a clear grasp of the implications and protocols of the study.

_____

Printed Name of Person Getting Consent

_____

Signature of Person Getting Consent

_____

Date