# Studying Patient Experiences in Small Cell Lung Cancer Clinical Trials to Identify Influencing Factors

## A Consent Form For Power Clinical Trial's Observational Clinical Study

Date: March 2, 2023

### Introduction and Important Notes

To take part in our research project, you must provide your permission. You are free to leave the research at any moment - participation in it is completely optional. A brief synopsis of the study is provided below, and this permission form contains further information.

- Identifying trends in the experiences of small cell lung cancer patients enrolling in interventional clinical trials is the aim of our investigation.
- The study's main methods include completing questionnaires and follow-up calls to determine why a patient enrolls, continues, or leaves a clinical trial.
- The participants are at very little risk because this is an observational clinical trial. If you opt to participate, there might not be a direct medical benefit.
- The results of this study will advance knowledge of the variables affecting clinical study participation rates, which will benefit patients with small cell lung cancer.
- If you decide not to take part in this trial, you won't lose any of your typical services, advantages, or rights.

Before making a choice, we urge you to thoroughly read the consent form and ask any questions you may have. It is also advised that you consult your loved ones, close friends, trusted advisers, and/or healthcare professionals before making your choice.

## Clinical Trial Purpose

Clinical study participation percentages haven't always been fully representative of a given demographic. We are doing this study to look at the factors that influence a patient's decision to join, leave, or continue participating in a small cell lung cancer clinical trial. Also, we are attempting to enroll people from a variety of demographic categories to determine if any results are statistically significant.

## Clinical Trial Procedures

Since you are a small cell lung cancer patient who is presently enrolled in an interventional trial and receiving a specific therapy, you have been requested to participate in this study.

This clinical study is an observational one. Hence, we would not treat you in any way and would not give you any medication to test for anything. If you decide to take part in our study, the following is a summary of our procedure:

1. **Recruitment of Participants:** The electronic medical records systems of the participating clinical trial sites will be used to identify patients with small cell lung cancer who have participated in, withdrew from, or completed a clinical study.

2. **Data Collection:** Every two weeks, participants will be required to complete a questionnaire that will gather information on their demographics, medical histories, and the factors that led them to join in, leave the clinical trial early, or complete it. Every three months, the research team will also speak with participants via phone or video chat to get more information about their experiences during the clinical experiment.

3. **Data Analysis:** To identify the variables that affect patient enrollment, withdrawal, and clinical trial completion, the research team will examine the data that have been gathered. In order to ascertain the correlations between the variables, statistical analysis will be utilized.

4. **Dissemination of Results:** The study's findings will be presented at conferences and published in scholarly journals for the benefit of clinical trial stakeholders.

The findings will be applied to improve patient recruitment and retention in small cell lung cancer clinical trials as well as future clinical studies.

## Possible Risks

Participating in an observational clinical trial for small cell lung cancer may come with hazards.

There are dangers to take into account even when observational studies do not include experimental interventions like medication treatments or medical procedures. These dangers may include the likelihood of privacy violations, psychological or emotional suffering associated with the study's topic, and the potential for unfavorable outcomes associated with any tests or procedures carried out as part of the trial.

When selecting whether to join a clinical trial, it is crucial to thoroughly read the informed consent form and talk to the research staff about any queries or concerns.

## Possible Benefits

Patients with small cell lung cancer may benefit from participating in an observational clinical trial by advancing medical knowledge and maybe enhancing treatment options in the future.

Throughout the experiment, patients could also have access to specialist treatment and monitoring. It's crucial to remember that observational studies do not contain experimental interventions like pharmacological treatments or surgical procedures, thus the specific patient may not have a direct medical benefit.

In the end, a person's decision to take part in a clinical trial should be based on their unique circumstances and aspirations, and it should be made only after carefully weighing the advantages and disadvantages. Before selecting a choice, patients are advised to explore their options with their doctor and the study staff.

## Termination of Clinical Trial

Without your permission, the researcher or sponsor may end your participation in the study at any moment for a number of reasons, including:

- If the research is stopped or put on hold;
- If the study's financing is cut, halted, or withdrawn;
- If it is determined to be best for you;
- If your condition worsens
- If you conceive a child;
- If, after being notified of changes that might affect you, you decide not to continue with the research; or,
- If you don't follow the study's instructions.

## Other Clinical Trials For Small Cell Lung Cancer

You are free to decide whether or not to engage in this research study at any moment without incurring any penalties because your participation is voluntary.

You can visit clinicaltrials.gov, a website run by the National Institutes of Health (NIH) that has a comprehensive database of clinical trials from all around the world if you're seeking more small cell lung cancer studies. You can filter trials using several search parameters, including location and condition. As an alternative, you may look for a list of small cell lung cancer clinical trials that are presently enrolling patients on Power's reference website.

## Online Research on Clinical Trial Diversity

You may look at a few research about clinical trial diversity that has been published online. These are a few reads you can check:

Jagsi, Reshma, Amy R. Motomura, Sudha Amarnath, Aleksandra Jankovic, Nathan Sheets, and Peter A. Ubel. "Under-representation of women in high-impact published clinical cancer research." *Cancer: Interdisciplinary International Journal of the American Cancer Society* 115, no. 14 (2009): 3293-3301.

Sanjiv, Nayan, Pawarissara Osathanugrah, Michael Harrell, Nicole H. Siegel, Steven Ness, Xuejing Chen, Howard Cabral, and Manju L. Subramanian. "Race and ethnic representation among clinical trials for diabetic retinopathy and diabetic macular edema within the United States: A review." *Journal of the National Medical Association* (2022).

## Confidentiality

We will do all to protect the privacy of the personal data gathered for this project.

Your personal information may need to be revealed by law, thus it cannot be guaranteed that it will stay entirely private. Your name or any other personally identifying information will not be used in any publications or presentations of the research findings. A number of organizations, including accrediting organizations, government and regulatory authorities (such as the FDA and OHRP), safety monitors, study sponsors, and approved sponsor representatives, may have access to your medical information for research, quality assurance, and data analysis.

A supplementary "Authorization Form" that specifies how and with whom your information may be shared for research purposes may occasionally be requested of you. Without your further informed agreement, the information and/or research samples you provided for this project may be distributed to other Power researchers, researchers from other academic institutions, or researchers from third-party commercial organizations for future research. Your personal information will be deleted and kept private.

## Consent Provisions

By checking the box below, you agree that:

1. The information contained in this informed consent form has been read and completely understood by you. Before making a choice, you are urged to share this material with others and get different perspectives.
2. All of your queries have been satisfactorily addressed, and you have received a complete explanation of the study and its methods.
3. All of the information you need to participate in the research study has been sent to you.
4. You have thought through the advantages, drawbacks, and alternatives of taking part in the study.
5. Your decision to take part in the research study is voluntary.
6. You are aware that your decision to take part in the research will not have any impact on your legal rights.
7. Any substantial new information about the research project that could influence your decision to continue participating will be communicated to you.
8. This permission form was given to you, and you have the chance to ask any questions you might have.

## Signature by the Participant

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

## Signature by the Investigator

I personally gave the patient a non-technical explanation of the study, responded to any inquiries, and attested to the fact that the individual voluntarily agreed to participate.

## Signature of the Investigator Who Obtained Consent Date of Signature

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