



Consent and Authorization to Participate in a Research Study KEY INFORMATION FOR COMPARATIVE EFFECTIVENESS STUDY OF DRUG A AND DRUG B IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE PATIENTS

This research study will compare two medicines commonly used to treat Chronic Obstructive Lung Disease (COPD). COPD makes it hard to breathe due to damage to the lungs. We are inviting you to take part in the study because your lung doctor diagnosed you with COPD. This page is to give you key information to help you decide whether to participate. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

We do not know if Drug A or Drug B is better at improving health related quality of life (HRQoL) in COPD patients. By doing this study, we hope to learn which medicine is best at improving breathing and HRQoL.

If you agree to participate:

- The study doctor will **not** pick which drug you will take. We will use a computer to place you in one of the two study groups. The group the computer picks is by chance, like a flip of a coin. You will have an equal chance of being in either group. If you want more information about randomization, we will show you a [brief video](#).
- You will receive either drug A or drug B. We will not tell you which of the two medicines you get. You will take the beginning dose of the study medicine as directed for one year. The dose of the study drug will not change while you are on the study.
- You will have four (4) research clinic visits during the study. The study doctor will perform a brief exam and ask five (5) questions about your quality of life.
- After the study, we will tell you which of the two medicines you took. You and your lung doctor can decide if you should continue taking the drug once the study is complete.

WHAT ARE REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

There is no guarantee that you will benefit personally. The study computer picks which medicine and dose you receive instead of a doctor choosing. Both medicines look the same. You will not be able to tell, by looking, which medicine the study computer picks for you. The Detailed Consent (page X) provides a list of possible risks for each study medicine.

You do not have to participate in the study to receive medication for your COPD. Other treatments, including drug A and B, are available for your lung doctor to prescribe outside of the study. If you decide not to be in the study, your lung doctor will choose a treatment he/she thinks is best for you. For a list of common COPD treatments, see Appendix A.

WHAT ARE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Both medicines used in this study are FDA Approved to treat COPD. The study provides the medicine and research visits to you at no cost. The research team will give you guidance on how to manage your COPD.

The study doctor will know which medicine you are taking. The research team will monitor your COPD closely. If your COPD gets worse or you do not tolerate the medicine, we can remove you from the study. Your lung doctor can then prescribe another medicine based on his/her medical opinion.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. If you decide not to take part, you will not lose any services, benefits, or rights you would normally have. You can choose to withdraw at any time during the study.

WHAT IF YOU HAVE QUESTIONS, PROBLEMS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is ___ - ___, MD, of the University of Kentucky, Department _____. If you have questions, problems, or concerns regarding this study or you want to withdraw from the study; his/her contact information is: [@uky.edu](#); phone: 859-. If you have any questions, suggestions, or concerns about your rights as a research volunteer; contact staff in the University of Kentucky (UK) Office of research Integrity (ORI), Monday – Friday, 8am and 5pm EST, at 859-257-9428 or toll free at 1-866-400-9428.

Continue on to detailed consent