

# **KEY INFORMATION FOR A COMPARATIVE STUDY OF TWO DRUGS**

We want to compare two medicines used to treat Chronic Obstructive Lung Disease (COPD). COPD makes it hard to breath because of lung damage. We are inviting you to take part in a research study because your lung doctor diagnosed you with COPD.

### 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. We hope to learn which medicine will help you breathe better.

If you agree to participate:



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

You may not benefit personally. You will not be able to choose what group you will be in. You may experience side effects from the drug you are given.

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

The Food and Drug Administration (FDA) approved both medicines used in this study to treat COPD. The study provides the medicine and research visits to you at no cost.

#### DO YOU HAVE TO TAKE PART IN THE STUDY?

You do not have to be in the study to receive medicine for your COPD. Drug A and Drug B are available outside of the study. You can withdraw from the study at any time.

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

If you have questions about this study, you can contact: (email and phone number).

If you have any questions 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