### The UNIVERSITY OF CHICAGO

### The Division of the Biological Sciences • The University of Chicago Medical Center

**CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH PROTOCOL**

***(****remove “Authorization” if the form is not a HIPAA authorization)*

Protocol Number: *[insert #]* Name of Subject: Medical History Number:

## STUDY TITLE: *(insert study title)*

Doctors Directing Research: *[include PI & at least 1 other investigator]*

Address: *(insert complete mailing address, including mail code if applicable)*

Telephone Number: *(insert complete telephone number)*

**KEY INFORMATION**

This section 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 above.

**WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?**

This research study will compare two medicines commonly used to treat *[insert condition under study]*. *[Describe condition in lay language. For example:* COPD makes it hard to breathe due to damage to the lungs.*]* We are inviting you to take part in the study because your doctor diagnosed you with *[insert condition under study]*.

We do not know if *[Drug A Name]* or *[Drug B Name]* is better at improving *[insert aim, e.g. symptoms, health related quality of life*, *survival, etc.]* in *[insert condition under study* patients. By doing this study, we hope to learn which medicine is best at *[improving quality of life, decreasing side effects, improving survival, etc]*.

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.

 You will receive either *[Drug A Name]* or *[Drug B Name]*. 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 *[insert #]* of clinic visits during the study. The study doctor will perform a brief exam and ask questions about your quality of life at each visit.

 After the study, we will tell you which of the two medicines you took. You and your 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/or dose *(revise as needed)* 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 that follows this section provides a list of possible risks for each study medicine.

You do not have to participate in the study to receive medication for your *[insert condition under study]*. Other treatments, including *[Drug A Name]* and *[Drug B Name]* are available for your lung doctor to prescribe outside of the study. If you decide not to be in the study, your doctor will choose a treatment he/she thinks is best for you. Other treatments for your *[insert condition under study]* include *[insert alternative treatments here]*.

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

Both medicines used in this study are FDA Approved to treat *[condition under study]*. 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 *[condition under study]*.

The study doctor will or will not know which medicine you are taking. The research team will monitor your *[condition under study]* closely. If your *[condition under study]* gets worse or you do not tolerate the medicine, we can remove you from the study. Your 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 the study is *[Principal Investigator, PI]* of the University of Chicago. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: *[PI contact information].*

*[If the study does not involve ANY physical intervention, this paragraph may be removed.]*

If you have a research related injury, you should immediately contact*(insert name and phone # –the number listed in this section should provide access to someone 24 hours a day, 7 days a week).*

For questions about your rights as a research subject, please contact the University of Chicago BSD Institutional Review Board (IRB) at 773-702-6505.