### 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?**

We are asking you to choose whether to take part in a clinical research study that will test the benefits and safety of Insert study drug name in patients with Insert condition under study here. The purpose of this study is to compare the effects, good and/or bad, of Insert study drug name with a placebo (an inactive pill). The Food and Drug Administration (FDA) has approved insert study drug name here to treat some conditions. FDA has not approved insert study drug name here to treat insert condition under study.

If you are eligible for the study, we will use a computer program to place you in one of the two groups. The group the computer picks is by chance, like a flip of a coin. You will have an equal chance of getting in either group. The test group will take study drug name. The placebo group will take an inactive pill. Neither you nor the study staff will know which pill you get. They both look the same. Participants in both groups will have insert frequency of study visits and duration of the study.

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

***Revise as applicable -***Some doctors have noticed an improvement in insert condition under study on patients taking study drug. While on the study we will monitor your insert condition under study. If your condition under study worsens, the study doctor may take you off the study so that your personal doctor may treat you.

The study will provide the study drug or placebo pill, research tests and research care at no cost to you. The detailed consent has a complete description of possible study benefits.

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

You may decide that you do not want to participate in this study because there is a 50/50 chance of being in the placebo group. If you are in the placebo group, you will take a pill daily for one year that will not help your condition under study. If the study computer places you in the test group, there is no guarantee that study drug will help your insert condition under study. Research has not been done to confirm whether it will improve insert condition under study.

You may have side effects while on the study. The most serious side effect(s) that has happened in insert percentage percent of people who have taken insert drug under study is describe notable significant adverse events. The researchers do not know all of the side effects that could happen. The detailed consent lists the type and rate of known side effects from taking insert study drug.

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

If you decide to take part, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can withdraw at any time during the study. The following graph may help you consider your options.

Choose to Participate

Choose not to Participate

Ask personal doctor about trying other options (if applicable add:) including *name of agent under study*

Half of participants get EXPERIMENTAL DRUG

Stay on current treatments

Half of participants put in Placebo Group

**WHAT IF YOU HAVE QUESTIONS, 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.