Combined Consent and Authorization to Participate in a Research Study

KEY INFORMATION FOR: Randomized, Placebo-Controlled Trial to assess the safety and effectiveness of Investigational Product X in the treatment of Condition Y

We are inviting you to take part in a clinical research study to test the benefits and safety of Investigational Product X in patients with Y Condition.

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

The purpose of this study is to compare the effects, good and/or bad, of product X with a placebo (an inactive pill). The Food and Drug Administration (FDA) has approved X to treat some conditions but it is not approved to treat Y. Patients who are eligible and decide to participate will be randomly assigned (by chance) to receive X pill (test group) or a placebo pill (placebo group). A computer program will pick the groups. You will have an equal chance of getting in either group. The detailed consent gives instructions for taking the pill. The participants in both groups will have monthly research study visits for one (1) year. The study visit schedule is available in Appendix A.

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

There is some evidence that X may improve Y. However, there is no proof of this yet. While on the study, we will monitor your condition. The Detailed Consent includes criteria the study doctor will use to decide if your condition has worsened. If your condition worsens, the study doctor may take you off the study so that your personal doctor may treat you.

In addition, everyone in the study will be taught how to make lifestyle changes that may help Y. Education will be provided at every study visit.

The study product, tests, and care provided as part of the study will be done at no cost to you. For a complete description of possible benefits, refer to the Detailed Consent that follows.

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 you will not choose and will not be told your group assignment. If you are in the placebo group, you will take a pill daily for one year that will not help your condition. If you are placed in the test group, there is no guarantee that X will help your condition.

You may have side effects while on the study. The most serious effect that has happened in one percent of people who have taken X is shortness of breath. The researchers do not know all of the side effects that could happen. Appendix B lists the type and rate of side effects from taking X that researchers know about.

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. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer. You can choose to withdraw at any time during the study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is __________, MD, of the University of Kentucky, Department of ___________. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: researcher@uky or xxx-xxx-xxxx.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

Continue to the Detailed Consent