



## Consent and Authorization to Participate in a Research Study

### **KEY INFORMATION FOR:** Randomized, Placebo-Controlled Trial to assess the safety and effectiveness of Investigational E-FLEX in the treatment of Arthritis

We are asking you to choose whether to take part in a clinical research study that will test the benefits and safety of E-FLEX stiff in patients with Arthritis. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. 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?**

The purpose of this study is to compare the effects, good and/or bad, of E-FLEX with a placebo (an inactive pill). The Food and Drug Administration (FDA) has approved E-FLEX to treat some conditions. FDA has not approved E-FLEX to treat arthritis.

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 E-FLEX. The placebo group will take an inactive pill. Neither you nor the study staff will know to which pill you get. They both look the same. Participants in both groups will have monthly research study visits for one (1) year. See Appendix A for the study visit schedule.

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

Some doctors have noticed an improvement in arthritis on patients taking E-FLEX. While on the study, we will monitor your arthritis. If your arthritis worsens, the study doctor may take you off the study so that your personal doctor may treat you.

The study will provide the E-FLEX or placebo pill, research tests and care at no cost to you. The detailed consent has a complete description of possible study benefits. In addition, we will teach all study participants skills and lifestyle changes that help manage arthritis.

#### **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 chance the study computer will place you 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 arthritis. If the study computer places you in the test group, there is no guarantee that E-FLEX will help your arthritis. Research has not been done to confirm whether it will improve arthritis.

You may have side effects while on the study. The most serious effect that has happened in one percent of people who have taken E-FLEX 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 known side effects from taking E-FLEX.

#### **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.

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

The person in charge of this study is Arthur Young, MD. If you have questions or concerns regarding this study or you want to withdraw from the study his 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.

