UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**Study Title:** Engagement to Inform Adaptive Trial: How do People With Chronic Low Back Pain Weigh Risks and Benefits—Discrete Choice Experiments Measure Patient’s Outcome

Leslie Wilson, Ph.D.

Professor of Health Policy and Economics. University of California San Francisco Departments of Medicine and Pharmacy 3333 California St, Suite 420, Box 0613 San Francisco, CA 94118.

Phone: 415-990.1012; e-mail: [Leslie](mailto:Leslie.Wilson@ucsf.edu)[.Wilson@ucsf.edu](mailto:.Wilson@ucsf.edu)

Research Project Director:

Study Coordinator:

This is a research study to learn patient’s preferences for the risks and benefits of functional and behavioral outcomes of chronic low back pain treatment. The study researcher Leslie Wilson, Ph.D. from the UCSF Departments of Medicine and Pharmacy will explain this study to you.

Leslie Wilson, Ph.D.

University of California San Francisco Department of Pharmacy

3333 California St

San Francisco, CA 94118

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you currently have chronic low back pain.

Why is this study being done?

The purpose of this study is to learn more about how chronic low back pain patients choose between different treatment options.

This study is supported with funding from the National Institutes of Health (NIH).

How many people will take part in this study?

Approximately 300 patients will be taking part in this study.

What will happen if I take part in this research study?

* You will take the survey online or in person.
* The survey will consist of four parts, the first section will ask you basic information regarding you and your medical history. This section will take you about 5 minutes to complete.
* The second section will consist of questions asking you about your experience with chronic low back pain. This section will take you about 5 minutes to complete.
* The third section will ask you to imagine yourself choosing a new therapy for your chronic low back pain. A handout with descriptions of different factors to consider will be given to you. You will then be presented with two different options and will be asked to choose which one you like best 16 to 20 times with the factors differing each time. This section will take you about 15 minutes to complete.
* The fourth section will consist of a series of questions regarding your current level of activity, quality of life, any chronic low back pain-related symptoms you might have experienced in the past four weeks and how you feel about chronic low back pain. This section will take you about 5 minutes to complete.
* The fifth section will ask you to imagine yourself choosing a new therapy for your chronic low back pain. A handout with descriptions of different factors to consider will be given to you. You will then be presented with two different options and will be asked to choose which one you like best 16 to 20 times with the factors differing each time. This section will take you about 10 minutes to complete.
* After completion of all four sections you will be asked a few follow-up questions about taking the survey.
* Leslie Wilson may contact you by phone, email, or mail at a later point in time if she has any further questions about your answers or participation.
* **Study location:** All these procedures will be done at a UCSF-affiliated campus or online on the internet.

How long will I be in the study?

Participation in the study will take a total of about 40 minutes.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study or just stop taking the survey. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

* We do not expect any risks or side effects in this study, but you might be tired from taking the 40- minute survey
* For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, the information

that you provide may help health professionals better understand/learn more about what chronic low back pain patients care about most in their treatment options.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done, we may share your information with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. We will use a unique identifier to allow you to log-in when you take the survey. The identifier will be connected to your name however your personal information will be secured in a database separately from the survey. Only the researchers will be able to access your survey responses as well as your personal information. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

* Representatives of the National Institutes of Health (NIH)
* Representatives of the University of California

Are there any costs to me for taking part in this study?

No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

Will I be paid for taking part in this study?

In return for your time you will be compensated ($20) for completion of the survey in its entirety.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact the researcher Leslie Wilson, Ph.D. at [Leslie.Wilson@ucsf.edu](mailto:Leslie.Wilson@ucsf.edu) (415) 990- 1012. If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date Participant's Signature for Consent

Date Person Obtaining Consent

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Please PRINT participant’s name

Date Participant's Signature for Consent

Date Person Obtaining Consent

Please provide participant’s ADDRESS to receive $20 compensation for completing our survey.

Address:

Please include any additional CONTACT information if you are willing to be contacted again. Email:

Phone:

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