

Terms and Phrases: Meaning Elicitation Survey

Interview Consent Form: Consumers

Introduction and Purpose

You have been invited to take part in a research study. The purpose of the study is to understand how consumers understand terms and phrases that are commonly used in prescription drug advertising materials. RTI International, a non-profit research organization in North Carolina, is conducting this study sponsored by the US Food and Drug Administration (FDA).

Procedures

You are one of 30 people being asked to participate in this phase of the study based on your answers to our screening questions. If you agree to participate, you will take part in a telephone interview. The interview will last up to **60 minutes**. We will audio-record and transcribe your answers to the questions so that we can refer to them later when we write our report. All identifying information will be removed from the transcripts. Other members of the project team, including FDA staff, may be listening to the interviews as they are taking place. All aspects of the study may not be revealed until the end.

Benefits

There is no direct benefit to you for participating. Your responses are very important because they will help researchers understand how people understand information included in prescription drug advertising materials.

Risks

There are no known risks to participating in this study. While the interview questions we ask are not meant to be sensitive, there is always a chance that you may feel uncomfortable with some of the questions. You do not have to answer any question that you don't want to answer. While we have taken steps to ensure your confidentiality, there is still a small risk that your privacy could be broken.

Confidentiality

The privacy and confidentiality of your information is of the highest importance, and we are committed to maintaining a secure environment in which you can participate. All information you share in this study will be kept confidential to the extent provided by law. The study team will not disclose your name or any of your responses, and your personal information (name, address, phone number) will not be linked to any of your responses. The information you share with us will be combined into a summary report so that details of individual interviews cannot be linked to a specific participant. The audio recordings and transcripts from the interviews will be destroyed at the end of the project. You will not be re-contacted about this research study in the future.

Reimbursement

After the interview has been completed, you will receive a check by mail for \$75 within 4-6 weeks in appreciation for your time.

Right to Refuse or Withdraw

Your participation in this study is completely voluntary, and you can withdraw from the study for any reason at any time without penalty.

Persons to Contact

If you have questions about the study, you can call the project director, Dr. Bridget Kelly, at 1-800-334-8571, ext. 22098. She can be reached between 9:00 AM and 5:00 PM Eastern Time Monday to Friday. If you have questions about your rights as a participant, you can call RTI's Office of Research Protection toll-free at 1-866-214-2043.

[CONSENT1.] If you have read the previous screens and agree to participate, please click the Yes button. If not, click the No button.

1. Yes, I agree to participate. [Continue to interview appointment schedule]
2. No, I do not agree to participate. [Go on to next question]

[IF CONSENT1=NO OR SKIP]

[CONSENT2.] Are you sure you don't want to participate? Your opinions are important to us. Please select the Yes button if you'd like to schedule an interview. Select the No button to exit.

1. Yes, I agree to participate. [Continue to interview appointment schedule]
2. No, I do not agree to participate. [Exit]