

FDA Ad Exposure

Consent Form – Cognitive Interviews

Introduction and Purpose:

Thank you for agreeing to participate in this research study. The purpose of the study is to test survey questions to make sure that they are easy to understand. You will see a [TV show and some ads/an advertisement] before looking at the survey questions.

RTI International, a non-profit research organization in North Carolina, is conducting the study. We will be conducting interviews in Raleigh, NC, and Baltimore-Washington, DC. You are one of approximately 18 people being asked to participate in this phase of the study.

You are eligible to participate in this study because you have been diagnosed with seasonal allergies.

Procedures:

If you agree to participate, you will watch a [TV show/advertisement] and then the interviewer will ask you a series of questions about your reactions to, preferences for, and understanding of the TV show/ad. Finally, we will ask you to answer some survey questions. The viewing and interview will last **2 hours**.

Benefits:

There is no direct benefit to you for participating. However, you may find the discussion informative and may learn how other people discuss health issues.

Risks:

There are no known risks to participating in this study. While the 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.

Confidentiality:

We will try to keep the information you share in this interview confidential. The study team will not disclose your name or any of your comments, and your personal information (name, address, phone number) will not be linked to any of your responses.

With your permission, we will audio-tape the discussion to supplement our notes. Recordings will not include full names and will be stored on password protected computers that only project staff can access. At the end of the project, we will destroy the recordings. All hardcopy forms will be kept in a locked file cabinet that only project staff can access.

Observation:

Some project staff may observe the discussion behind a one way mirror. They will not record your name and will keep all of your comments confidential.

Reimbursement:

In appreciation for your time and travel, we will reimburse you **\$125** at the end of the interview.

Right to Refuse or Withdraw:

Your participation in this study is voluntary. You can choose not to talk about any topic, and you can withdraw from the interview 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.

Your Consent:

I have read this consent form. I had a chance to ask questions, and my questions were answered. I was given a copy of this consent form. I agree to participate in the study.

Signature of Participant

Date

Signature of Person Obtaining Consent

Date