

Appendix D: Informed Consent

Consent Form Email

Any text in angle brackets "< >" indicates part of the script that will change based on the participant, or situation. The intended content (or content options) are indicated in the brackets.

Dear **<NAME>**

Thank you for agreeing to participate in our research study assessing healthcare providers' understanding and use of prescription drug labeling. Please review the consent form below.

Introduction and Purpose

You have been invited to take part in a research study. The purpose of the study is to assess how healthcare providers understand and use prescription drug labeling. RTI International, a non-profit research organization in North Carolina, is conducting this study on behalf of the US Food and Drug Administration (FDA) who is sponsoring this research.

Procedures

You are one of 70 healthcare providers 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 an online video interview. The interview will last up to **60 minutes**. We will audio-record your answers to the questions so that we can refer to them later when we write our report. We will not video-record the interview but we will use video to livestream the interview. Members of the project team, including FDA staff, may be listening and observing the interview via livestream as they are taking place. The audio files will be stored on password-protected computers at RTI and will be transcribed. During the interview, please do not tell us anything about yourself that could be used to identify you like your last name (it is okay to tell us your first name) or birthday. If you do tell us information that can identify you by mistake, that part of the audio recording will not be transcribed.

Benefits

There is no direct benefit to you for participating. Your responses are very important because they will help FDA understand how healthcare providers understand and use information included in prescription drug labels.

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. 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 **<\$200 for PCPs; \$300 for specialists>** 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.

Circumstances Under Which Your Participation May Be Terminated:

Your participation will be terminated if you decide you do not want your interview to be audio recorded or livestreamed. If your participation is terminated for these reasons, you will not receive the **<\$200/\$300>**. This condition of participation was explained to you during screening at which time you agreed for the interview be livestreamed and audio recorded.

Persons to Contact

If you have questions about the study, you can call the project director, Dr. Mihaela Johnson, at 1-800-334-8571, ext. 28365. 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.

If you have read the information above and agree to participate, please check the Yes button. If not, check the No button.

Yes, I agree to participate.

No, I do not agree to participate.

Please let me know if you have any questions about this process.

Sincerely,

<RECRUITER'S NAME>

<Signature line with phone number and email>