

## Informed Consent

### [CONSENT]

[CONSENT SCREEN 1]

#### Key Information

- Your participation is voluntary.
- You are being asked to take a survey about prescription drug names and about your reactions to and understanding of the drug names.
- The survey will take about 20 minutes.
- To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life.

#### **What is the purpose of this study?**

- The purpose of the study is to review some product names and answer some questions about the names.
- You are one of approximately 960 people being asked to participate in this phase of the study.

[CONSENT SCREEN 2]

#### **Who is leading the study?**

This survey is being conducted by RTI International (RTI), an independent nonprofit research organization. RTI is working with Lightspeed Health to conduct this survey but is not affiliated with Lightspeed Health in any way. If you have questions about this survey, please contact Lightspeed Health at <http://www.lightspeed-health.com/contact-us/>, and someone will direct your questions to the appropriate researchers at RTI.

#### **Do I have to take part in this study?**

- It is your choice to participate in this survey. No one will be upset if you choose not to participate.
- Even if you decide to be part of the study, you can stop participating at any time. You also do not have to answer any questions that you do not want to.

#### **What will I be asked to do?**

- We are asking you to take a survey about prescription drug names and about your reactions to and understanding of the drug names.
- The survey will last about **20 minutes**.

**What are the possible risks?**

- We do not expect that any of the survey questions will make you uncomfortable or upset you; however, if they do, you can skip any questions you do not wish to answer and continue with the survey.
- RTI will take several steps to keep your participation secure to the extent provided by law. Even with these steps, there is still a small risk that your privacy could be breached.
  - RTI and FDA will not receive any record of your full name or contact information. This means that your personal information (name, address, phone number) will not be linked to any of your responses.
  - All data collected during the survey will be kept confidential to the extent provided by law. The study team will not disclose your name or any of your responses.

**Will I benefit from taking part in this study?**

- There are no direct benefits to you for participating in this study. However, we will use the experiences and thoughts you share to inform FDA on prescription drug names.

**Will I receive any payment for taking part in this study?**

In appreciation for your time, you will receive < **IF GENERAL POPULATION:** \$"1.50 in online points", **IF HEALTH CARE PROVIDER:** "an honorarium of \$50"> for completing the survey.

**Who will see the information I give?**

- Many precautions have been taken to protect your information. All information collected in this survey will be kept confidential to the extent provided by law. You will never be identified by name.
- The information obtained from all of the surveys will be combined into a summary report so that details of individual questionnaires cannot be linked to a specific participant.

**Can my data be kept and used for other research studies?**

- Your data will not be used for any future research after this study is complete.
- You will not be contacted in the future about this research after your participation in the survey ends.

**What if I have questions?**

- If you have questions about the study, you can contact the investigator, 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. Alternatively, you may contact Lightspeed Health at <http://www.lightspeed-health.com/contact-us/> and indicate that you would like to contact the RTI Office of Research Protection, and someone will provide you with the appropriate contact information.
- The (FDA) Institutional Review Board (IRB) is a group of people who are responsible for ensuring that the rights of participants in research are protected. The FDA IRB is not involved in this study but may review the records of your participation in this research to ensure that proper procedures were followed. If you have questions about your rights as a study participant or concerns about how you are treated in the study, you may contact FDA IRB at 1-301-796-9605.

[RADIO]  
[PROMPT IF SKIP]

[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 with next section]
2. No, I do not agree to participate. [Go on to next question]

[RADIO]  
[PROMPT IF SKIP]  
[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 to continue this survey. Select the No button to exit.

1. Yes, I agree to participate. [Continue with next section]
2. No, I do not agree to participate. [End survey]