

## **Consent Form for Primary Care Providers:**

[Programmer: [Link 'click here'](#) to the email address [pi@forsmarshgroup.com](mailto:pi@forsmarshgroup.com)]

[Programmer: [Link 'print a copy now'](#) to the browser's printer options]

Thank you for completing the screening questionnaire. Your opinions are very important to us. Please read this information carefully. If there is anything you do not understand, please [click here](#) to email us. The research team will be happy to answer your questions.

### **INFORMED CONSENT FORM**

**TITLE OF INFORMATION COLLECTION: Prescription Drug Information**

**Sponsor: The Food and Drug Administration (FDA)**

**Principal Investigator: Caitlin Moynihan**

**Telephone: 571-858-3757 (24 Hours)**

**Address: Fors Marsh Group, LLC (FWA00011194)  
1010 N. Glebe Road  
Suite 510  
Arlington, VA 22201**

You are being asked to take part in this study, because you are a healthcare professional who writes prescriptions. After reading this form, which explains the research, you may decide if you would like to participate in the study or not. Your participation is completely voluntary. If you decide to start the study and then change your mind, you can withdraw at any time.

You may ask the research team questions about the study at any time. They will explain anything you do not understand.

**You must complete and submit this form before you can take part in the study. If you would like a copy for your records, you can [print a copy now](#), or you may request a copy from the research team, and they will provide you with a copy.**

**About this study**

Fors Marsh Group is a research company partnering with the U.S. Food and Drug Administration (FDA) to investigate healthcare professionals' reactions to and understanding of information in prescription drug labeling. We plan to conduct remote in-depth interviews with healthcare professionals across the country.

After signing this form, you will be directed to provide your contact information. Recruiters from Lightspeed will contact you over the phone to schedule the telephone interview. During the telephone interview, which will last about 60 minutes, you will be asked to share your thoughts with the moderator about prescription drug information. You will need access to your computer during the interview, and you will be provided an Internet link to access and view materials in real time. You will not need a webcam and there will be no video recording of your image. Your computer screen will be video-captured as you proceed through the materials. There are no costs associated with your participation in this study. You may skip any questions you do not want to answer.

Members of the research team (which may include 1 to 3 FDA research staff) will be observing the session via livestreaming; however, you only will be interacting with the moderator.

**Study Benefits:**

There is no direct benefit to you. Your feedback will help us to decide how professional prescription drug labeling can be improved.

**Incentive:**

You will receive an incentive of \$150 as a token of appreciation for your participation. Lightspeed Health will issue payment to you in the form of your choice (for example, PayPal, gift card, or donation) upon completion of the interview. You will receive the incentive for your time even if you choose not to answer some questions during the discussion.

**Anticipated Risks:**

The identity and information of participants will remain private to the extent permitted by law. In the case of a breach of information and/or identity, appropriate steps will be taken to notify participants. **Remember that you can stop participating in this study at any time.**

**Privacy:**

Everything you say during the interview can be heard by the research team.

The interview will be audio recorded and transcribed for note-taking purposes. It also will be livestreamed so that other researchers can observe. Your computer screen will also be video-captured as you look through the materials, but there will be no video recording of your face. By signing this form, you consent to being recorded and livestreamed during the interview.

Your identity will not be linked to your responses. This means that no one outside of the research team will be able to link what you said back to you. Everything you share will be kept private to the extent allowed by law. Therefore, we will not share anything you provide with anyone outside the study unless it is required to protect you or if required by law. However, if you show a direct threat of harm to yourself or others, we have the right to take action out of concern for you and concern for others.

All information we collect, including anything you say in the interview, information collected during screening, audio files, and transcripts will be stored on a password-protected computer and/or in locked cabinets that only the research team can access. We will collect some personal information from you, such as your age, gender, and race, but it will only be used for eligibility and scheduling purposes. After three (3) years, all collected data will be destroyed by securely shredding documents or permanently deleting electronic information.

Results from this study may appear in professional journals or at scientific conferences. No individual participants will be identified or linked to the results. We will not disclose your identity in any report or presentation. Results also may be used in future research or shared with other researchers. Other researchers will not have your name or any identifying information.

**Participation and Withdrawal:**

Participation in this study is completely voluntary. You may withdraw at any time. You do not have to answer any questions that you do not want to. You will receive the incentive for your time in the interview even if you choose not to answer some questions.

**If you have questions about this interview:**

If you have questions or concerns about the interview, you can contact Caitlin Moynihan at Fors Marsh Group by email at [pi@forsmarshgroup.com](mailto:pi@forsmarshgroup.com) or by phone at 571-858-3757.

The Research Involving Human Subjects Committee (RIHSC) at the Food and Drug Administration has reviewed this research. RIHSC is an institutional review board (IRB), a group of people who are responsible for ensuring that the rights of participants in research are protected. If you have questions about your rights as a study participant or concerns about how you are treated in the study, you may contact RIHSC at 301-796-9605 or [RIHSC@fda.hhs.gov](mailto:RIHSC@fda.hhs.gov).

We advise you to keep a copy of this consent form for future reference. If you would like to do so, [print a copy now](#).

Please read the statement below. Then, using the mouse, please click on the statement that describes whether you want to participate in this study. After checking the box that best represents your willingness to participate, please click "Submit." You will then be asked to share your contact information for scheduling purposes.

By checking "yes" below, you are consenting to participate. If you check "no" below, you are not consenting to participate, and will exit out of this study.

**Consent.** I have read and understand the information provided above, and the study's purpose and procedures are clear to me.

[SINGLE PUNCH]

Yes, I agree to participate in this study. 01

No, I do not wish to participate in this study. 02

[SUBMIT BUTTON]

[IF **Consent**=01 ("Yes, I agree to participate in this study."), CONTINUE TO LIGHTSPEED HEALTH'S SCHEDULING PAGE.]