

INFORMED CONSENT

This research is being conducted by Fors Marsh Group (FMG) on behalf of the U.S. Food and Drug Administration (FDA). You have been asked to participate in a focus group to talk about your thoughts and experiences with prescription drugs. This information sheet describes the purpose, procedures, benefits, risks, and precautions of the study. It also describes your right to withdraw from the study at any time. A member of the FMG team is available to read this information sheet with you and discuss all the information, if you wish.

Why is this study being conducted?

The purpose of this group is to get your thoughts about how you make prescription drug treatment choices at the doctor's office. Your feedback is important to us and will be used to provide guidance to drug manufacturers about the kind of information they should provide to people like you. Your thoughts and experiences will help us make prescription drug information more useful and easier to understand.

What do I need to know about this study?

We are conducting focus groups in several cities. Focus groups will take place on [dates TBD pending RIHSC and OMB approval], 2017. Each focus group will last about an hour, and you will take part in the group with about eight other participants. The discussion will be about your experiences with and thoughts about prescription drugs.

The focus group sessions will be audio recorded and transcribed, but your name will not appear in the transcription and will not be used in any description of findings. Only research staff that are directly associated with this study will have access to the recordings. We are livestreaming this interview so that other members of the research team can observe our interview in a separate room.

What are the potential risks of participating in this study?

The risks associated with participating in this focus group are the same as those you would experience talking in a group of people that you do not know. We do not expect that any of the topics discussed during the focus group will make you uncomfortable or upset you; however, if they do, you do not have to participate in every discussion.

Does participating in this study provide any benefit?

There is no direct benefit to you for participating in this study. However, we will use the experiences and thoughts you share to improve the usefulness of prescription drug information for people just like you.

Will I be compensated?

You will be compensated \$75 for your participation in the study.

Do I have to participate in this interview?

Participation in this study is voluntary. You can stop at any time. You also do not have to answer any questions that you do not want to. You will receive compensation for your time when you complete the study even if you choose not to answer some questions.

Who will have access to the recordings and my contact information?

Other research team members will have access to livestreaming of the interview. Only the staff working on this project will have access to your audio recordings. Your contact information was only collected by the recruiters to schedule you. Your identity will not be linked to your responses. Your personal information will be kept private to the extent allowed by law.

Whom do I contact if I have questions about this study?

If you have questions or concerns about the study, you can contact Dr. Brian Griepentrog at Fors Marsh Group by email at bg@forsmarshgroup.com or by phone at 571-858-3798.

The Research Involving Human Subjects Committee (RIHSC) at the FDA 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.



Your signature below indicates that you understand the conditions stated above and agree to participate in this interview. You may request a copy of this consent form to keep for your records.

Signature: _____ Date: _____