

OMB Control NO. 0910-0497  
Expiration Date: 10/31/2020

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## **CONSENT FORM**

### **ASSURANCE OF CONFIDENTIALITY FOR VOLUNTEER FOCUS GROUP RESPONDENTS - Obstetricians/Gynecologists**

Westat is conducting focus group testing in a study entitled, "End-Under Testing Associated with the "Pregnancy and Lactation Labeling Rule" to Improve Health Communications and Prescribing Decisions in Pregnant Women"" (PLLR Focus Group Study) for the Food and Drug Administration (FDA) to obtain feedback on changes to prescription product labeling. The research will consist of participating in a 75-minute focus group discussion with up to 6 other individuals. Your input is very important, as it will assist FDA with creating useful and informative prescription product labeling.

Your participation in this research is completely voluntary. You can refuse to answer a question or withdraw from the focus group at any time. There are no known risks or benefits from taking part in this focus group.

Everything you say in the focus group will be kept secure to the extent permitted by law. The report summarizing the findings will not contain any names or identifying information, though we may include quotes that you provide in our written reports. Everything shared during the focus group sessions should remain in the session and not shared with anyone outside the group. The focus group will be audio- and videotaped; only staff directly working on the research will have access to the recordings. The audio and video files will be stored securely and only our research team will have access to them. The audio and video files will be destroyed at the end of the study.

You will receive a \$300 token of appreciation if you take part in this 75-minute focus group. You will receive this token of appreciation by mail after the end of the focus group session.

If you have any questions about this study please contact Karen Stein, the Project Coordinator, at 301-610-8869. If you have questions about your role as a research participant, please contact the Westat Human Subjects Protections Office at 1-888-920-7631. Please leave a message with your full name, the name of the study that you are calling about (PLLR focus group study), and a phone number beginning with the area code.

***Research Participant Statement and Signature***

I understand what the study involves, and my questions so far have been answered. I understand that my participation in this research study is voluntary. I agree to take part in this focus group study.

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Participant's signature

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Date

## **CONSENT FORM**

### **ASSURANCE OF CONFIDENTIALITY FOR VOLUNTEER FOCUS GROUP RESPONDENTS - Family Medicine**

Westat is conducting focus group testing in a study entitled, "End-Under Testing Associated with the "Pregnancy and Lactation Labeling Rule" to Improve Health Communications and Prescribing Decisions in Pregnant Women"" (PLLR Focus Group Study) for the Food and Drug Administration (FDA) to obtain feedback on changes to prescription product labeling. The research will consist of participating in a 75-minute focus group discussion with up to 6 other individuals. Your input is very important, as it will assist FDA with creating useful and informative prescription product labeling.

Your participation in this research is completely voluntary. You can refuse to answer a question or withdraw from the focus group at any time. There are no known risks or benefits from taking part in this focus group.

Everything you say in the focus group will be kept secure to the extent permitted by law. The report summarizing the findings will not contain any names or identifying information, though we may include quotes that you provide in our written reports. Everything shared during the focus group sessions should remain in the session and not shared with anyone outside the group. The focus group will be audio- and videotaped; only staff directly working on the research will have access to the recordings. The audio and video files will be stored securely and only our research team will have access to them. The audio and video files will be destroyed at the end of the study.

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#### ***Research Participant Statement and Signature***

I understand what the study involves, and my questions so far have been answered. I understand that my participation in this research study is voluntary. I agree to take part in this focus group study.

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Participant's signature

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Date

## **CONSENT FORM**

### **ASSURANCE OF CONFIDENTIALITY FOR VOLUNTEER FOCUS GROUP RESPONDENTS – Specialty Physicians**

Westat is conducting focus group testing in a study entitled, “End-Under Testing Associated with the “Pregnancy and Lactation Labeling Rule” to Improve Health Communications and Prescribing Decisions in Pregnant Women” (PLLR Focus Group Study) for the Food and Drug Administration (FDA) to obtain feedback on changes to prescription product labeling. The research will consist of participating in a 75-minute focus group discussion with up to 6 other individuals. Your input is very important, as it will assist FDA with creating useful and informative prescription product labeling.

Your participation in this research is completely voluntary. You can refuse to answer a question or withdraw from the focus group at any time. There are no known risks or benefits from taking part in this focus group.

Everything you say in the focus group will be kept secure to the extent permitted by law. The report summarizing the findings will not contain any names or identifying information, though we may include quotes that you provide in our written reports. Everything shared during the focus group sessions should remain in the session and not shared with anyone outside the group. The focus group will be audio- and videotaped; only staff directly working on the research will have access to the recordings. The audio and video files will be stored securely and only our research team will have access to them. The audio and video files will be destroyed at the end of the study.

You will receive a \$300 token of appreciation if you take part in this 75-minute focus group. You will receive this token of appreciation by mail after the end of the focus group session.

If you have any questions about this study please contact Karen Stein, the Project Coordinator, at 301-610-8869. If you have questions about your role as a research participant, please contact the Westat Human Subjects Protections Office at 1-888-920-7631. Please leave a message with your full name, the name of the study that you are calling about (PLLR focus group study), and a phone number beginning with the area code.

#### ***Research Participant Statement and Signature***

I understand what the study involves, and my questions so far have been answered. I understand that my participation in this research study is voluntary. I agree to take part in this focus group study.

\_\_\_\_\_  
\_\_\_\_\_  
signature

Participant's

Date