

Perceptions of Prescription Drug Products with Medication Tracking Capabilities

Appendix C

Informed Consent Form

INFORMED CONSENT

[Consent Screen 1]

OMB Control No. 0910-xxxx

Expiration date: xx/xx/xxxx

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-xxx and the expiration date is xx/xx/xxxx. The time required to complete this information collection is estimated to average 1 minute per response, including the time for reviewing instructions and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRASStaff@fda.hhs.gov.

The Food and Drug Administration (FDA) is conducting this survey to better understand [providers'/consumers'] opinions and preferences about the type of information that is provided about prescription drugs. Your answers will provide FDA with valuable insights. This survey will take 15-20 minutes to complete and your responses will be kept confidential.

[Consent Screen 2]

This survey is being conducted by Westat, an independent social science research firm, on behalf of the FDA. Westat is working with Kantar to conduct the survey but is not affiliated with Kantar.

PRIVACY AND CONFIDENTIALITY

This survey will not collect any personal information, such as your name. Your identity will not be linked to your responses and will be kept private to the extent allowed by law.

RIGHTS AS A PARTICIPANT

This study is voluntary. You do not have to answer any questions that you do not want to and can withdraw from the study at any time. The Institutional Review Board (IRB) at Westat has reviewed this research study.

POSSIBLE RISKS OR DISCOMFORTS

While we will be very careful to let only members of the research team see your information, there is a small risk that others might find out what you say. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants.

BENEFITS

Your responses are very important because they will help researchers understand how people make decisions about medications. There is no direct benefit to you for your participation.

INCENTIVE

In appreciation for your time, you will receive \$[20/13] for completing this survey.

QUESTIONS?

If you have questions about the study, please contact the project director, Dr. Simani Price, at 301-610-5536. If you have any questions about your rights as a participant or concerns about how you are treated in the study, contact Westat Human Subjects Protections office at 1-888-920-7631.

[Consent Screen 3]

If you have read the previous screens and agree to participate, please click the [Yes](#) button.

If not, click the [No](#) button.

Yes, I agree to participate. [\[CONTINUE TO SURVEY INTRODUCTION\]](#)

No, I do not agree to participate. [\[THANK AND TERMINATE \]](#)