

Appendix D
Informed Consent Document

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Purpose of the Study

You are being asked to take part in a research study that entails web-based interviews with physicians. You will be asked to review different prescription drug informational materials online and share your opinions about these items. The interview will take approximately 60 minutes. If you take part in the study, you will be one of about 70 healthcare providers to do so.

Westat, an independent social science research firm, is conducting the study on behalf of the U.S. Food and Drug Administration (FDA). If you have questions about the study, please contact the project director, Dr. Simani Price, by phone (301-610-5536) or email (simaniprice@westat.com).

Privacy and Confidentiality

Although we may include quotes from study participants in our report, we will not link names or any personally identifying information to the quote. All information collected in this study will be seen by study researchers only. Your information will be kept secure to the extent provided by law. Study information will be kept in password protected files on secure servers at Westat and FDA locations. No information that can identify you will be given to FDA. The data collected in this study will be destroyed no later than three years after the project is completed.

We will record the interviews and create anonymous transcripts for the purpose of analysis and reporting. Interviews will be live-streamed to allow FDA and Westat study researchers to listen to the interviews. For this reason, we ask you use only your first name during the interview. If you do not want to be recorded, or you do not consent to having the interview be live-streamed, you will not be able to participate in the study.

Possible Risks or Discomforts

We do not expect any of the interview questions will make you uncomfortable or upset; however, if they do, you can refuse to answer any question or withdraw from the study. There is a slight risk that your personally identifiable information might be shared, but this is unlikely because we only know your first name.

Benefits

There is no direct benefit to you for your participation. However, your responses are very important because they will help provide a better understanding of physician decision making and inform FDA in developing guidance about prescription drug informational materials for healthcare professionals.

Incentive

You will receive an honorarium of [\$200/\$275] for completing the interview as a token of appreciation.

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 approved this research study. 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 and to ensure your rights as a participant 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 the FDA IRB at 1-301-796-9605 or RIHSC@fda.hhs.gov or the Westat Human Subjects Protections office at 1-888-920-7631.

If you have reviewed this informed consent form and agree to participate in this study, please state this when asked by the interviewer.