Study 1 – Print Advertisement

Informed Consent Form

Purpose: We are inviting you to participate in a research study. The study involves helping us test materials and questions, which will be included in a communication and health survey about prescription drug advertising and how it might affect the attitudes and behaviors of adults. The results from the study will help us to develop recommendations for modifying the questionnaire.

Sponsorship: Westat is conducting this project on behalf of the U.S. Food and Drug Administration (FDA).

What is involved: You will view some study materials, complete a paper questionnaire, and then be asked some questions about the materials you viewed and items you answered. Your participation in this research project is voluntary, and you have the right to stop at any time or to refuse to answer any question. The interview will take approximately 60 minutes to complete.

Confidentiality: We would like to audio-record the session. Sometimes it is helpful to review a portion of a recording as we make recommendations for improving the materials and/or questionnaire. If the audio recording is reviewed later, it will only be by project staff. Other project staff from Westat or FDA may observe today's interview.

Your individual privacy will be maintained in all published and written data resulting from the interview. Direct quotes may be used in our final report, but you will not be individually identified and your responses will be used for research purposes only. Your answers and information will be kept secure to the extent allowable by law.

Risks: There are no known risks for participation in this research study. You may skip any item(s) that you do not want to answer in the questionnaire. You may also skip any questions that you do not wish to answer in the discussion about the study materials and/or questionnaire. All information you provide will be treated as confidential. The audio recordings will be destroyed within a year of the end of the study. 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, despite all our best efforts. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants.

Benefits: There are no direct benefits to you for participating in this study. However, you will be helping with an important research study.

Questions: If you have questions about the project, you may call the Project Director, Jennifer Berktold, at 800-937-8281, Ext. 3964. For questions about your rights and welfare as human subjects in this study, you may call the Institutional Review Board at Westat at 1-888-920-7631. Please leave a message with your full name, the name of the research study that you are calling about, i.e., the FDA Prescription Drug Advertising Study, and a phone number beginning with the area code. Someone will return your call as soon as possible.

You may also contact the FDA Institutional Review Board (IRB) at 301-796-9605 or RIHSC@fda.hhs.gov. This is a group of people at FDA who are responsible for ensuring that the rights of participants in research are protected.

You will be receive $50 cash as a token of appreciation for completing the questionnaire and interview.

If you agree to participate, please sign below.

I have read and understand the statements above. I consent to participate in this study.

_____ _____

Participant's signature Date