

For Primary Care Provider Physicians

**STUDY INFORMATION SHEET:
IN-DEPTH INTERVIEWS**

TITLE OF INFORMATION COLLECTION:

Healthcare Professional Interviews: Prescription Drug Information Processing

Sponsor: The Department of Health and Human Services (DHHS)
Principal Investigator: Kinsey Gimbel
Telephone: 571-858-3757 (24 Hours)
Address: Fors Marsh Group, LLC (FWA00011194)
1010 N. Glebe Road
Suite 510
Arlington, VA 22201

You are being asked to take part in this study because you are a practicing healthcare professional with prescriptive authority. After reading this letter, which explains the research, you may decide if you would like to participate in the study or not. Your participation is completely voluntary. If you decide to start the study and then change your mind, you can withdraw at any time. You may ask the research team questions about the study at any time.

About this Study

Fors Marsh Group is a research company partnering with the MedStar Health System and the U.S. Department of Health and Human Services (DHHS) to understand how healthcare professionals process information for newly promoted prescription drugs. We are conducting semi-structured interviews.

During this session, which will take about 60 minutes, you will be asked to view prescription drug promotional material and to share your thoughts with the moderator. During the study, we will be using an eye tracker to see and record where participants look while interacting with the materials. The eye tracker will be located at the bottom of the computer display, so you will not need to wear any equipment. There are no costs associated with your participation in this study. Researchers from DHHS and the study team may be observing the session; however, you only will be interacting with the moderator and researcher.

MedStar's Institutional Review Board (IRB) has reviewed this research. An IRB is a group of people who are responsible for ensuring that the rights of participants in research are protected.

Study Benefits:

There is no direct benefit to you. Your feedback will help us decide how information for newly promoted prescription drug products can be improved.

Incentive:

You will receive an incentive of \$150 as a token of appreciation for your participation. MedStar will issue a check to you upon completion of the interview. You will receive the incentive for your time even if you choose not to answer some questions during the interview.

Anticipated Risks:

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 of our best efforts. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants.

The data are in no way intended to evaluate the performance of personnel, and collected information will not be linked to any specific practitioner. Participants are free to opt out at any time or to decline to participate entirely, and such action will NOT be reported to any administrative or other personnel. The results will be anonymous and in no way affect evaluations or employment.

The eye tracker uses infrared light to create reflections on the eyes so they can be tracked with high accuracy. Infrared light can be found in the natural environment (e.g., candle lights, fires, the sun). The eye tracker being used has been tested and approved by certified labs according to the European standard for optical radiation hazards of lamps and lamp systems (IEC/EN 62471). All evidence has demonstrated that light emissions that meet this standard are not harmful to the human eyes; however, individuals with the following medical conditions or equipment should not participate:

- Photosensitive epilepsy – susceptibility to epileptic seizures or loss of consciousness when exposed to certain flashing lights or light patterns in everyday life.
- Medical equipment that is sensitive to infrared light (e.g., some types of pacemakers).

Please let the research staff know before you participate if you have concerns about any of these anticipated risks.

Privacy:

Everything you say during the interview can be heard by the research team. The interview will be audio recorded and transcribed for note-taking purposes. It may also be

livestreamed so that other researchers can observe remotely. By participating, you consent to being audio recorded and livestreamed during the interview, having your computer screen be recorded, as well as having your eye movements tracked and recorded. There will not be any recordings of your face. All information we collect will be stored on a password-protected computer and/or in locked cabinets that only the research team can access. After three years, all collected data will be destroyed by securely shredding documents or permanently deleting electronic information.

Your identity will not be linked to your responses. This means that no one outside of the research team will be able to link what you said back to you. Recruitment and interviews will be conducted by a sub-investigator who will represent the Human Factors Center and will not have any affiliation with your primary hospital or department of employment other than the fact that both are under the same institution, MedStar, and the potential that the representative may have worked with the department or employee for prior research studies with similar sample requirements. Everything you share will be kept private to the extent allowed by law. We will not share anything you provide with anyone outside the study unless it is required to protect you or if required by law. However, if you show a direct threat of harm to yourself or others, we have the right to take action out of concern for you and concern for others.

Results from this study may appear in professional journals or at scientific conferences. No individual participants will be identified or linked to the results. We will not disclose your identity in any report or presentation. Results also may be used in future research or shared with other researchers.

Participation and Withdrawal:

Participation in this study is completely voluntary. There are no consequences to declining to participate or opting out at any time, no evaluation is occurring, and no personally identifiable information will be linked to specific observations. You may selectively choose to not answer individual questions, without any negative impact on your overall participation. You will receive the incentive for your time in the interview even if you choose not to answer some questions. You may also cancel, interrupt, or postpone the observations at any time for any reason. You may withdraw at any time by informing the research staff in person or by contacting MedStar at Tracy.C.Kim@medstar.net (please include "HCP Interviews Study" in the subject line) or 202-243-2593.

If you have any questions or complaints about your rights as a research subject, please contact the Human Subjects Protection Specialist at the MedStar Health Research Institute Institutional Review Board, 6525 Belcrest Road, Suite 700, Hyattsville, MD 20782; Telephone 301-560-7300.

For Specialists

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Study Benefits:

There is no direct benefit to you. Your feedback will help us decide how information for newly promoted prescription drug products can be improved.

Incentive:

You will receive an incentive of \$175 as a token of appreciation for your participation. MedStar will issue a check to you upon completion of the interview. You will receive the incentive for your time even if you choose not to answer some questions during the interview.

Anticipated Risks:

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 of our best efforts. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants.

The data are in no way intended to evaluate the performance of personnel, and collected information will not be linked to any specific practitioner. Participants are free to opt out at any time or to decline to participate entirely, and such action will NOT be reported to any administrative or other personnel. The results will be anonymous and in no way affect evaluations or employment.

The eye tracker uses infrared light to create reflections on the eyes so they can be tracked with high accuracy. Infrared light can be found in the natural environment (e.g., candle lights, fires, the sun). The eye tracker being used has been tested and approved by certified labs according to the European standard for optical radiation hazards of lamps and lamp systems (IEC/EN 62471). All evidence has demonstrated that light emissions that meet this standard are not harmful to the human eyes; however, individuals with the following medical conditions or equipment should not participate:

- Photosensitive epilepsy – susceptibility to epileptic seizures or loss of consciousness when exposed to certain flashing lights or light patterns in everyday life.
- Medical equipment that is sensitive to infrared light (e.g., some types of pacemakers).

Please let the research staff know before you participate if you have concerns about any of these anticipated risks.

Privacy:

Everything you say during the interview can be heard by the research team. The interview will be audio recorded and transcribed for note-taking purposes. It may also be livestreamed so that other researchers can observe remotely. By participating, you consent to being audio recorded and livestreamed during the interview, having your computer screen be recorded, as well as having your eye movements tracked and recorded. There will not be any recordings of your face. All information we collect will be stored on a password-protected computer and/or in locked cabinets that only the research team can access. After three years, all collected data will be destroyed by securely shredding documents or permanently deleting electronic information.

Your identity will not be linked to your responses. This means that no one outside of the research team will be able to link what you said back to you. Recruitment and interviews will be conducted by a sub-investigator who will represent the Human Factors Center and will not have any affiliation with your primary hospital or department of employment other than the fact that both are under the same institution, MedStar, and the potential that the representative may have worked with the department or employee for prior research studies with similar sample requirements. Everything you share will be kept private to the extent allowed by law. We will not share anything you provide with anyone outside the study unless it is required to protect you or if required by law. However, if you show a direct threat of harm to yourself or others, we have the right to take action out of concern for you and concern for others.

Results from this study may appear in professional journals or at scientific conferences. No individual participants will be identified or linked to the results. We will not disclose your identity in any report or presentation. Results also may be used in future research or shared with other researchers.

Participation and Withdrawal:

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For NPs and PAs:

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Study Benefits:

There is no direct benefit to you. Your feedback will help us decide how information for newly promoted prescription drug products can be improved.

Incentive:

You will receive an incentive of \$100 as a token of appreciation for your participation. MedStar will issue a check to you upon completion of the interview. You will receive the incentive for your time even if you choose not to answer some questions during the interview.

Anticipated Risks:

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