INTRODUCTION

We invite you to take part in a behavioral research study called *("Healthcare Professional Interviews: Prescription Drug Information Processing")*. You were selected as a possible participant in this study because you are a practicing healthcare professional with prescriptive authority. Please take your time to read this form, ask any questions you may have and make your decision. We encourage you to discuss your decision with your family, friends and your doctors.

WHAT IS THE PURPOSE OF THIS STUDY?

This study is being done to understand how healthcare professionals, specifically primary care physicians (PCPs), specialists, physician assistants (PAs), and nurse practitioners (NPs), process information for newly promoted prescription drugs. We are conducting semi-structured interviews which will take no longer than 60 minutes, and you will be asked to view prescription drug promotional material. While you are viewing the materials, we will be monitoring the movement of your eyes. The eye tracker will be located at the bottom of the computer display, so you will not need to wear any equipment. You will be encouraged to share your thoughts with the moderator throughout the study.

There are no costs associated with your participation in this study. Researchers from the U.S. Department of Health and Human Services and the study team may be observing the session; however, you only will be interacting with the moderator and researcher.

WHAT ELSE SHOULD I KNOW ABOUT THIS RESEARCH STUDY?

It is important that you read and understand several points that apply to all who take part in our studies:

- Taking part in the study is entirely voluntary and refusal to participate will not affect any rights or benefits you normally have;
- You may or may not benefit from taking part in the study, but knowledge may be gained from your participation that may help others; and
- You may stop being in the study at any time without any penalty or losing any of the benefits you would have normally received.

The nature of the study, the benefits, risks, discomforts and other information about the study are discussed further below. If any new information is learned, at any time during the research, which might affect your participation in the study, we will tell you. We urge you to ask any questions you have about this study with the staff members who explain it to you and with your own advisors prior to agreeing to participate.

WHO IS IN CHARGE OF THIS STUDY?

The primary investigator is Kristen Miller. The research is being sponsored by the U.S. Department of Health and Human Services (DHHS) in collaboration with Fors Marsh Group (FMG). MedStar Health Research Institute is being paid by the Department of Health and Human Services (DHHS) to conduct this study with Kristen Miller as the primary investigator.

WHO CANNOT PARTICIPATE IN THIS STUDY?

You cannot be in this study if any of the following apply to you:

- If you are a minor (under the age of 18)
- If you are not a PCP, specialist, NP, or PA
- If you have participated in focus groups or individual in-depth interview research within one month prior to participation
- If you have photosensitive epilepsy or use medical equipment that is sensitive to infrared light

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 140 people will take part in this study, worldwide. Up to 60 people will be recruited at this site.

WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?

The following procedures are part of the research study during the 60-minute in-person semi-structured interview:

- Review a mock drug promotional piece, during which your eye movements will be tracked
- Complete a memory task and comprehension task to assess your recall and understanding of various types of information in the promotional piece
- Share your thoughts about the promotional materials, assessment of drug's risk and benefits, and intentions to prescribe newly promoted prescription drugs in general

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for no more than 1 hour.

The investigator may decide to take you off this study if it is believed to be in your best interest, you fail to follow instructions, new information becomes known about the safety of the study, or for other reasons the investigator or sponsor believes are important.

You can stop participating at any time.

If you suddenly withdraw from the study, there are will be no consequences and we may not be able to use any of the information gathered from your participation. You may selectively choose not to 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 study session at any time for any reason.

WHAT ARE THE RISKS AND SIDE EFFECTS OF THIS STUDY?

If you decide to participate in this study, you should know there may be risks. You should discuss these with the investigator and you are encouraged to speak with your family and friends about any potential risks before making a decision.

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, if you have any of the following medical conditions or use of medical equipment, you 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). If you are unsure if your medical equipment is sensitive to infrared light, please alert the research team before agreeing to participate.

Potential risks and side effects related to this study include:

Risks and side effects ***that rarely occur*** include:

- 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 you.
- Increased risk for people who have photosensitive epilepsy or medical equipment that is sensitive to infrared light. If you are unsure if your medical equipment is sensitive to infrared light, please alert the research team before agreeing to participate.

There may also be risks and side effects other than those listed above that we cannot predict. Many side effects go away in a short time after the study session is stopped, but, in some cases, side effects can be serious, long lasting and/or life threatening. If you have any unwanted side effects, you should ask the investigator whether there are any medications or other things that may be done to make the side effect less uncomfortable.

For more information about risks and side effects, please ask Kristen Miller.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

This study is not designed to provide direct benefits to any participants.

You may or may not get any direct benefit from being in this study. We cannot promise that you will experience any benefits from participating in this study. We hope the information learned from this study will benefit others in the future.

WHAT OTHER OPTIONS ARE THERE?

You always have the option to not be in this study or refuse to answer any questions.

WHAT ABOUT CONFIDENTIALITY?

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 (from the DHHS) can observe remotely, with only views of your computer and eye tracking screens. Observers will be in listen-only mode; only the moderator and researcher will interact with you. By signing this form, 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.

To protect your privacy, we will refer to you in this interview by your first name only. Your identity will not be linked to your responses. This means that no one outside the research team will be able to link what you said back to you. 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.

This research is covered by a Certificate of Confidentiality from DHHS to help us protect your privacy. This means that the researchers cannot disclose your name or other information that could identify you in a civil, criminal, administrative, legislative or other proceedings (like a court trial), without your consent. Information collected for this research that could identify you also cannot be used as evidence in a legal proceeding with your consent.

In addition, with the Certification for Confidentiality, researchers involved in this study generally may not provide your name, or any other information that could identify you, to anyone who is not connected with the research. However, in the following situations, the Certificate does not prevent the researchers involved in this study from disclosing study information that could identify you:

- if you consent to someone receiving your information from this study, including situations where the information is necessary for your medical treatment;
- when your study information is used for other scientific research, as allowed by federal regulations protecting research subjects;

- when information is needed by DHHS, which is funding this study, in order to audit or evaluate federally funded studies; or
- when a law otherwise requires disclosure (such as requirements to make certain reports to DHHS, if you make threats of harm to self/others; reports of child abuse) except this does not apply to disclosure in a legal proceeding.

The Certificate does not prevent you from voluntarily providing information about yourself or your involvement in this research study to 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. You will not be identified by name in any publications resulting from this study.

Your personal health information (PHI) will be kept private to the extent allowed by law. Study records identifying you will be kept confidential and will not be made publicly available.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will be paid for being in this study. **You will be receiving your payment in the form of a check mailed in the amount of $100 from Fors Marsh Group**. For security purposes, the envelope will be rather plain. Please note that payments you receive in accordance to with this evaluation are considered taxable income. If payment exceeds $600 in one calendar year, MedStar Health is required to file a 1099 form with the IRS. For amounts less than $600, you are responsible for reporting additional outcome, but no 1099 tax forms will be filed with the IRS. Receipt of your check may take up to 20 business days after your study session.

WHAT ARE THE COSTS?

You do not have to pay anything to be in this study.

WHAT IF I'M INJURED OR BECOME ILL DURING THE STUDY?

We will make every effort to prevent injuries from occurring while you are in the study. In the case of an injury, illness, or other harm occurring to you during, or resulting from, the study, you should seek medical treatment. You should also contact the study doctor as soon as possible. You or your insurance company will be charged for any continuing medical care and/or hospitalization that are not a part of the study.

No funds have been set aside, by the DHHS, the MedStar Institute for Innovation, the MedStar Health Research Institute, MedStar Health, or its affiliated entities to repay you in case of injury, illness, or other harm occurring during, or resulting from the study, and their current policies do not provide for payments for lost wages, cost of pain and suffering, or additional expenses. By agreeing to this you do not give up your rights to seek compensation in the courts.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

- You have the right to be told about the nature and purpose of the study;
- You have the right to be given an explanation of exactly what will be done in the study and given a description of potential risks, discomforts, or benefits that can reasonably be expected;
- You have the right to be informed of any appropriate alternatives to the study, including, if appropriate, any drugs or devices that might help you, along with their potential risks, discomforts and benefits;
- You have the right to ask any questions you may have about the study;
- You have the right to decide whether or not to be in the study without anyone misleading or deceiving you; and
- You have the right to receive a copy of this consent form.

By signing this form, you will not give up any legal rights you may have as a research participant. You may choose not to take part in or leave the study at any time. If you choose to not take part in or to leave the study, your regular care will not be affected and you will not lose any of the benefits you would have received normally. We will tell you about new information that may affect your health, welfare, or willingness to be in this study.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the investigator, **Kristen Miller**, at **202-243-2593**.

For questions about your rights as a research participant, contact the MedStar Health Research Institute. Direct your questions to the Office of Research Integrity at:

Address:	MedStar Health Research Institute 6525 Belcrest Rd. Suite 700 Hyattsville, MD 20782	Telephone: Toll Free: Fax	(301) 560-2912 (800) 793-7175 (301) 560-7336

SIGNATURES

STATEMENT OF CONSENT

I have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to be in this study. I am free to stop being in the study at any time without need to justify my decision and if I stop being in the study I understand it will not in any way affect my future treatment or medical management. I agree to cooperate with **Kristen Miller** and the research staff and to tell them immediately if I experience any unexpected or unusual symptoms.

_____ _____

Participant's signature Date of Signature

Printed Name of Participant _____

PERSON EXPLAINING CONSENT

I have explained the purpose, the procedures, the possible benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____ _____

Signature of Person Obtaining Consent Date of Signature

Printed Name of Individual Obtaining Consent: _____

STATEMENT OF PRINCIPAL INVESTIGATOR (or designee)

As the Principal Investigator (or designee) for this research study, I attest that I have reviewed the consent documentation and confirm requirements for obtaining informed consent have been met.

_____ _____

Principal Investigator's Signature Date of Signature

If not the principal investigator, a sub-investigator who has delegation of authority or who may adjudicate adverse events should sign for the PI; must be signed within 5 business days of consenting the participant.