



## PARTICIPANT INFORMATION SHEET

**Protocol Title:** Improving FDA Health Communications with Older Women Regarding FDA-Regulated Products

**Study No.:** Grant Scheme: Y01FD005946 Project Number: 53584-Z0071201

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**Sponsor:** Food and Drug Administration (FDA)

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### PURPOSE OF STUDY

The University of Maryland investigators are conducting this study on behalf of the U.S. Food and Drug Administration (FDA). This study does not involve an investigational drug or device. The purpose of this study is to learn from you how the FDA can improve health communications about the products that they regulate to women aged 38 and older.

You are being asked to join a research study and it is your choice to join the study. You can ask questions at any time. You are being asked to join this study because you are a woman who may receive or seek health information from the FDA or about products the FDA oversees. A total of 12 focus groups will be conducted and a total of about 120 women will participate in this study.

### PROCEDURES

If you join this study, you will be asked to participate in a focus group with 8-10 other women just like you. The focus group will last for about 1 ½ to 2 hours. We will ask for your permission to record the discussion. The reason we ask to record this is so we do not make any mistakes in our notes. After the focus groups, we will listen to the tape and type what was said into a computer file. We will record the talk only if you and all other individuals in the focus group agree to this. You will be asked to participate in the focus group one time. There is no follow-up or anything further required of you if you join this study.

### POTENTIAL RISKS/DISCOMFORTS:

The project is low risk. The potential risks with this research are no greater than risks in your normal day-to-day life.

There is a very small chance that people who are not a part of this study will see what is discussed during the focus group. This is called loss of confidentiality. This is not a serious risk and it will not threaten your safety or privacy. For your privacy, we will not use your full name or other identifying information during the discussion.

To protect you from loss of confidentiality, we will not use your name in any of our notes or what we enter into the computer from the tape-recorded discussion. Your name will not be on any of our files, aside from the signature for receipt of honoraria. We will keep this form in a locked office and in a locked cabinet. All computer files will have a code that only the research team can use.

There is a very small chance you may feel sad or stressed from talking about health-related information. This is not a serious risk. To avoid this, we will not ask you to do anything that makes you feel sad or stressed. You can leave the focus group at any time.

### **POTENTIAL BENEFITS**

There may not be any direct benefit for you by being in this study. However, your input provides much needed insights that will help the FDA improve health communication of the products it regulates. This information will be used in the future by the FDA and women just like you so that they receive information that will meet their health needs.

Receiving payment for being part of this study is not considered a benefit.

### **ALTERNATIVES TO PARTICIPATION**

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, this will in no way affect your access to healthcare or any other personal health-related issue.

### **COSTS TO PARTICIPANTS**

There is no cost to you if you join this study.

### **PAYMENT TO PARTICIPANTS**

You will receive a \$40 gift card for your time to be a part of the study.

### **CONFIDENTIALITY AND ACCESS TO RECORDS**

This study will not use your name in any of the written documents from the focus group discussion. Only the research team will be able to see any forms that have your name or telephone number. We keep this information only to contact you to schedule the focus group. The form with your name and telephone number will be kept in a locked cabinet that only the research team can use. Your name will not be used in any reports from this study. All data will be kept confidential to the fullest extent permitted by law.

Efforts will be made to limit your personal information to people who have a need to review this information. We will not collect any personal medical information from you.

We cannot promise complete secrecy. Organizations that may inspect and copy the information collected as part of this study include the Institutional Review Board (IRB) and other representatives of the University of Maryland. The FDA, which is paying for this study, may ask to see this information.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

### **RIGHT TO WITHDRAW**

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. There are no adverse effects (physical, social, economic, legal, or psychological) if you choose to leave the study. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the principal investigator: **Daniel Mullins [410-706-3839]**.

### **CAN I BE REMOVED FROM THE RESEARCH?**

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failing to follow instructions or if the person in charge feels the research is no longer in your best interest. The sponsor can also end the research study early. The research team will tell you about this and you will have the chance to ask questions if this were to happen.