AUBURN
UNIVERSITY

HARRISON SCHOOL OF PHARMACY
DEPARTMENT OF HEALTH OUTCOMES RESEARCH AND POLICY

(NOTE: DO NOT SIGN THIS DOCUMENT UNLESS AN IRB APPROVAL STAMP WITH CURRENT DATES HAS BEEN APPLIED TO THIS DOCUMENT.)

Informed Consent for a research study entitled: "Generic Drug Substitution in Special Populations"

You are invited to participate in a Food Drug Administration (FDA) funded research study to gain insight into the alignment of clinical practice and generic drug labels, including, but not limited to the communication taking place between patients and their physicians and pharmacists about drug administration, risks, and instructions that are unique to special populations. The study is being conducted by Dr. Jingjing Qian, Assistant Professor in the Auburn University Department of Health Outcomes Research and Policy and Dr. Ilene Harris, Principal Research Scientist at IMPAQ International. You were selected as a possible participant because you have prescribed or dispensed a generic medication to one or more of the target special populations [pregnant women, a parent or guardian of a child, a racial or ethnic minority group, etc.], within the last month and are age 19 or older.

As part of your participation in this research study, you will attend a focus group with up to 8 other prescribers and dispensers. One or more of our team's researchers will lead a discussion regarding your current prescribing and dispensing patterns for generic drugs, your communication about generic drugs with patients, and your desired methods of receiving information related to drug risks and instructions for special populations. Your total time commitment will be approximately 60 minutes.

The risks associated with participating in this study are minimal. Any information collected including, but not limited to, name, address, email, personal information, and responses will not be used by or disclosed to a third party. Your participation in this study will allow the study team to examine the communication taking place between patients and their physicians and pharmacists about drug risks and instructions based on the unique needs of their population group identified. To thank you for your time, by participating in this study, you will be offered an honorarium of a $275 check after the completion of the focus group.

Participant's initials _____

The Auburn University Institutional Review Board has approved this Document for use from 05/03/2017 to 05/02/2018
Protocol # 17-140 EP 1705

020 JAMES E. FOY HALL
282 WEST THACH CONCOURSE
AUBURN, AL 36849

TELEPHONE:
334-844-5152

FAX:
334-844-8307

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If you change your mind about participating, you can withdraw at any time during the study. Your participation is completely voluntary. If you choose to withdraw, your data can be withdrawn as long as it is identifiable. Your decision about whether or not to participate or to stop participating will not jeopardize your future relations with Auburn University, the Department of Health Outcomes Research and Policy, IMPAQ International, or the FDA. However, your decision to participate or withdraw may impact your receipt of the honorarium. Honorariums will only be distributed upon completion of the focus group.

If you agree, the group discussion will be recorded. However, any data obtained in connection with this study will be made anonymous as soon as possible. We will protect your privacy and the data you provide by de-identifying your data, including assigning pseudonyms and removing any identifiable information from transcripts of the audio file. Notes and transcripts from the study will be saved in password protected folders on a password and firewall protected server at IMPAQ International. Audio recordings will be destroyed immediately upon completion of the transcriptions. Even though we will emphasize to all participants that comments made during the focus group session should be kept confidential, it is possible that participants may repeat comments outside of the group at some time in the future. Therefore, we encourage you to be as honest and open as you can, but remain aware of our limits in protecting confidentiality.

Information collected through your participation may be published in governmental reports, professional journals, and/or presented at a professional meeting. As described above, notes and transcripts from the audio recordings will have no identifying information attached to them, and if information learned from this study is published, you will not be identified by name or other personal information. Also, transcriptions and written notes will have no identifying information attached to them, and will be used for analytical purposes only.

Personal information collected in connection to your honorarium will be saved in password protected folders on a password and firewall protected server at IMPAQ International. This information is being collected in order to withhold necessary tax payments on your behalf and will remain confidential.

If you have questions about this study, please ask them now or contact Jingjing Qian at (334) 844-5818 or jzq004@auburn.edu or Ilene Harris at (443) 259-5250 or iharris@impaqint.com.

If you have questions about your rights as a research participant, you may contact the Auburn University Office of Research Compliance or the Institutional Review Board by phone (334)-844 5966 or e-mail at IRBadmin@auburn.edu or IRBChair@auburn.edu.

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Should you choose to participate in this research study, you will take part in a focus group with up to 8 other older adult patients where one or more of our team's researchers will lead a discussion regarding your current medications, the communication you have had with your doctor about generic drugs, and ways you would prefer receiving information about drug risks and instructions based on the unique needs of a parent or guardian of a child 18 years of age or younger. Your total time commitment will be approximately 60 minutes.

There are few risks associated with this study. Any information you provide will remain protected and will not be used by or given to a third party. Your participation in this study will allow the study team to better understand how patients talk to their doctors and pharmacists about the drug risks and instructions. To thank you for participating in this study, you will be offered an honorarium of a $75 check after the completion of the focus group.

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There are few risks associated with this study. Any information you provide will remain protected and will not be used by or given to a third party. Your participation in this study will allow the study team to better understand how patients talk to their doctors and pharmacists about the drug risks and instructions. To thank you for participating in this study, you will be offered an honorarium of a $75 check after the completion of the focus group.

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