

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: "Educating Groups Influencing Generic Drug Use"

You are invited to participate in a research study that aims to better educate groups influencing generic drug use, based on their unique educational needs. 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. This study is funded by the U.S. Food and Drug Administration (FDA). You were selected as a possible participant because you are age 19 or older and a formulary manager, large purchaser of prescription drugs, or policymaker.

As part of your participation in this research study, you will be asked to attend a focus group (with up to 5 other participants in your group and up to 3 Auburn University researchers on the research team) at Auburn University main campus (Auburn, AL, 36849). During the focus group you will be asked to provide your thoughts on the content, format, channel, and satisfaction of one example of an educational material developed for your stakeholder group. Your total time commitment will be approximately 60 minutes.

The risks associated with participating in this study are minimal. Any information collected as part of the focus group will remain confidential and will not be shared with anyone outside of the research team. If you participate in this study, what the research team learns from you may better inform the development of educational materials regarding generic drugs. To thank you for your time spent participating in this study, you will be offered an honorarium of a \$25 check after completion of the focus group.

If you change your mind about participating, you can withdraw at any time during the study. Your participation is completely voluntary. 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.

Participant's initials _____

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

TELEPHONE:
334-844-5152

FAX:
334-844-8307

If you agree, the group discussion will be audio recorded. However, any information you share with the research team will be made anonymous as soon as possible. We will protect your privacy and the data you provide by assigning a false name and removing any recognizable information from records of the audio file. Notes and records from the study will be saved in password-protected folders on a password- and firewall-protected server at Auburn University. Audio recordings will be destroyed immediately upon completion of the study. 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 during the discussion, but remain aware of our limits in protecting confidentiality.

Information collected through your participation may be published in governmental reports, professional scientific journals, and/or presented at a professional meeting. As described above, notes and records 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.

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

If you have questions about this study, please ask them now or contact Dr. Jingjing Qian at (334) 844-5818 or jzq004@auburn.edu.

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 email at IRBadmin@auburn.edu or IRBChair@auburn.edu.

HAVING READ THE INFORMATION PROVIDED, YOU MUST DECIDE WHETHER OR NOT YOU WISH TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES YOUR WILLINGNESS TO PARTICIPATE.

Participant's Signature Date

Printed Name

Investigator's Signature Date

Printed Name

Co-Investigator's Signature Date

Printed Name

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: “Educating Groups Influencing Generic Drug Use”

You are invited to participate in a research study that aims to better educate groups influencing generic drug use, based on their unique educational needs. 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. This study is funded by the U.S. Food and Drug Administration (FDA). You were selected as a possible participant because you are age 19 or older and a patient or caregiver.

As part of your participation in this research study, you will be asked to attend a focus group (with up to 5 other participants in your group and up to 3 Auburn University researchers on the research team) at Auburn University main campus (Auburn, AL, 36849). During the focus group you will be asked to provide your thoughts on the content, format, channel, and satisfaction of one example of an educational material developed for your stakeholder group. Your total time commitment will be approximately 60 minutes.

The risks associated with participating in this study are minimal. Any information collected as part of the focus group will remain confidential and will not be shared with anyone outside of the research team. If you participate in this study, what the research team learns from you may better inform the development of educational materials regarding generic drugs. To thank you for your time spent participating in this study, you will be offered an honorarium of a \$25 check after completion of the focus group.

If you change your mind about participating, you can withdraw at any time during the study. Your participation is completely voluntary. 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.

Participant’s initials _____

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

TELEPHONE:
334-844-5152

FAX:
334-844-8307

If you agree, the group discussion will be audio recorded. However, any information you share with the research team will be made anonymous as soon as possible. We will protect your privacy and the data you provide by assigning a false name and removing any recognizable information from records of the audio file. Notes and records from the study will be saved in password-protected folders on a password- and firewall-protected server at Auburn University. Audio recordings will be destroyed immediately upon completion of the study. 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 during the discussion, but remain aware of our limits in protecting confidentiality.

Information collected through your participation may be published in governmental reports, professional scientific journals, and/or presented at a professional meeting. As described above, notes and records 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.

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

If you have questions about this study, please ask them now or contact Dr. Jingjing Qian at (334) 844-5818 or jzq004@auburn.edu.

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 email at IRBadmin@auburn.edu or IRBChair@auburn.edu.

HAVING READ THE INFORMATION PROVIDED, YOU MUST DECIDE WHETHER OR NOT YOU WISH TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES YOUR WILLINGNESS TO PARTICIPATE.

Participant's Signature Date

Printed Name

Investigator's Signature Date

Printed Name

Co-Investigator's Signature Date

Printed Name

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: “Educating Groups Influencing Generic Drug Use”

You are invited to participate in a research study that aims to better educate groups influencing generic drug use, based on their unique educational needs. 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. This study is funded by the U.S. Food and Drug Administration (FDA). You were selected as a possible participant because you are age 19 or older and a healthcare provider.

As part of your participation in this research study, you will be asked to attend a focus group (with up to 5 other participants in your group and up to 3 Auburn University researchers on the research team) at Auburn University main campus (Auburn, AL, 36849). During the focus group you will be asked to provide your thoughts on the content, format, channel, and satisfaction of one example of an educational material developed for your stakeholder group. Your total time commitment will be approximately 60 minutes.

The risks associated with participating in this study are minimal. Any information collected as part of the focus group will remain confidential and will not be shared with anyone outside of the research team. If you participate in this study, what the research team learns from you may better inform the development of educational materials regarding generic drugs. To thank you for your time spent participating in this study, you will be offered an honorarium of a \$25 check after completion of the focus group.

If you change your mind about participating, you can withdraw at any time during the study. Your participation is completely voluntary. 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.

Participant’s initials _____

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

TELEPHONE:
334-844-5152

FAX:
334-844-8307

If you agree, the group discussion will be audio recorded. However, any information you share with the research team will be made anonymous as soon as possible. We will protect your privacy and the data you provide by assigning a false name and removing any recognizable information from records of the audio file. Notes and records from the study will be saved in password-protected folders on a password- and firewall-protected server at Auburn University. Audio recordings will be destroyed immediately upon completion of the study. 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 during the discussion, but remain aware of our limits in protecting confidentiality.

Information collected through your participation may be published in governmental reports, professional scientific journals, and/or presented at a professional meeting. As described above, notes and records 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.

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

If you have questions about this study, please ask them now or contact Dr. Jingjing Qian at (334) 844-5818 or jzq004@auburn.edu.

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 email at IRBadmin@auburn.edu or IRBChair@auburn.edu.

HAVING READ THE INFORMATION PROVIDED, YOU MUST DECIDE WHETHER OR NOT YOU WISH TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES YOUR WILLINGNESS TO PARTICIPATE.

Participant's Signature Date

Printed Name

Investigator's Signature Date

Printed Name

Co-Investigator's Signature Date

Printed Name