AUBURN UNIVERSITY INSTITUTIONAL REVIEW BOARD for RESEARCH INVOLVING HUMAN SUBJECTS

RESEARCH PROTOCOL REVIEW FORM

FULL BOARD or EXPEDITED

For Information or help contact **THE OFFICE OF RESEARCH COMPLIANCE (ORC)**, 115 Ramsay Hall, Auburn University
Phone: 334-844-5966 **e-mail:** IRBAdmin@auburn.edu **Web Address:** http://www.auburn.edu/research/vpr/ohs/index.htm

Revised 2.1.2014 **Submit completed form to IRBsubmit@auburn.edu or 115 Ramsay Hall, Auburn University 36849.**

Form must be populated using Adobe Acrobat / Pro 9 or greater standalone program (do not fill out in browser). Hand written forms will not be accepted.

1. PROPOSED START DATE of STUDY: 10/1/2017

PROPOSED REVIEW CATEGORY (Check one): ☐ FULL BOARD ☑ EXPEDITED

SUBMISSION STATUS (Check one): ☑ NEW ☐ REVISIONS (to address IRB Review Comments)

2. PROJECT TITLE: Generic Drug Substitution in Special Populations

3. Jingjing Qian	Assistant Porfessor	HORP	jzq0004@auburn.edu
PRINCIPAL INVESTIGATOR	TITLE	DEPT	AU E-MAIL
038 Foy Hall, Auburn University		334-844-5818	
MAILING ADDRESS		PHONE	ALTERNATE E-MAIL

4. FUNDING SUPPORT: ☐ N/A ☐ Internal ☑ External Agency: U.S. FDA ☐ Pending ☑ Received

For federal funding, list agency and grant number (if available). U.S. FDA grant number 1U01FD005875-01

5a. List any contractors, sub-contractors, other entities associated with this project:

Sub-contractor: IMPAQ International LLC (sub-contractor PI: Ilene Harris, PharmD, PhD)

b. List any other IRBs associated with this project (including Reviewed, Deferred, Determination, etc.):

Protocol # 16-357 EX 1609 for Aim 3 of the project

PROTOCOL PACKET CHECKLIST

All protocols must include the following items:

☑ **Research Protocol Review Form** (All signatures included and all sections completed)
(Examples of appended documents are found on the OHSR website: http://www.auburn.edu/research/vpr/ohs/sample.htm)

☑ **CITI Training Certificates** for all Key Personnel.

☑ **Consent Form or Information Letter** and any Releases (audio, video or photo) that the participant will sign.

☑ **Appendix A**, "Reference List"

☑ **Appendix B** if e-mails, flyers, advertisements, generalized announcements or scripts, etc., are used to recruit participants.

☑ **Appendix C** if data collection sheets, surveys, tests, other recording instruments, interview scripts, etc. will be used for data collection. Be sure to attach them in the order in which they are listed in # 13c.

☐ **Appendix D** if you will be using a debriefing form or include emergency plans/procedures and medical referral lists (A referral list may be attached to the consent document).

☑ **Appendix E** if research is being conducted at sites other than Auburn University or in cooperation with other entities. A **permission letter** from the site / program director must be included indicating their cooperation or involvement in the project. NOTE: If the proposed research is a multi-site project, involving investigators or participants at other academic institutions, hospitals or private research organizations, a letter of **IRB approval** from each entity is required prior to initiating the project.

☐ **Appendix F** - Written evidence of acceptance by the host country if research is conducted outside the United States.

FOR ORC OFFICE USE ONLY

DATE RECEIVED IN ORC: _____ by _____ PROTOCO
DATE OF IRB REVIEW: _____ by _____ APPROVA
DATE OF IRB APPROVAL: _____ by _____ INTERVAL
COMMENTS:

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

6. GENERAL RESEARCH PROJECT CHARACTERISTICS

6A. Research Methodology

Please check all descriptors that best apply to the research methodology.

Data Source(s): ☑ New Data ☐ Existing Data

Will recorded data directly or indirectly identify participants? ☑ Yes ☐ No

Data collection will involve the use of:

- Educational Tests (cognitive diagnostic, aptitude, etc.)
- ✓ Interview
- Observation
- Location or Tracking Measures
- Physical / Physiological Measures or Specimens (see Section 6E.)
- Surveys / Questionnaires
- Internet / Electronic
- ✓ Audio
- Video
- Photos
- Digital images
- Private records or files
- ✓ Other: focus groups

6B. Participant Information

Please check all descriptors that apply to the target population.

☑ Males ☑ Females ☐ AU students

Vulnerable Populations

☐ Pregnant Women/Fetuses ☐ Prisoners ☐ Institutionalized

☐ Children and/or Adolescents (under age 19 in AL)

Persons with:

☐ Economic Disadvantages ☐ Physical Disabilities

☐ Educational Disadvantages ☐ Intellectual Disabilities

Do you plan to compensate your participants? ☑ Yes ☐ No

6C. Risks to Participants

Please identify all risks that participants might encounter in this research.

- ☑ Breach of Confidentiality*
- ☐ Coercion
- ☐ Deception
- ☐ Physical
- ☐ Psychological
- ☐ Social
- ☐ None
- ☐ Other:

*Note that if the investigator is using or accessing confidential or identifiable data, breach of confidentiality is always a risk.

6D. Corresponding Approval/Oversight

- Do you need IBC Approval for this study?
  ☐ Yes ☑ No

  If yes, BUA #_____ Expiration date _____

- Do you need IACUC Approval for this study?
  ☐ Yes ☑ No

  If yes, PRN #_____ Expiration date _____

- Does this study involve the Auburn University MRI Center?
  ☐ Yes ☑ No

  Which MRI(s) will be used for this project? (Check all that apply)
  ☐ 3T ☐ 7T

  Does any portion of this project require review by the MRI Safety Advisory Council?
  ☐ Yes ☑ No

  Signature of MRI Center Representative: _____
  Required for all projects involving the AU MRI Center

  Appropriate MRI Center Representatives:
  Dr. Thomas S. Denney, Director AU MRI Center
  Dr. Ron Beyers, MR Safety Officer

7. PROJECT ASSURANCES Generic Drug Substitution in Special Populations

A. PRINCIPAL INVESTIGATOR'S ASSSURANCES

1. I certify that all information provided in this application is complete and correct.
2. I understand that, as Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the Auburn University IRB.
3. I certify that all individuals involved with the conduct of this project are qualified to carry out their specified roles and responsibilities and are in compliance with Auburn University policies regarding the collection and analysis of the research data.
4. I agree to comply with all Auburn policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects, including, but not limited to the following:
    a. Conducting the project by qualified personnel according to the approved protocol
    b. Implementing no changes in the approved protocol or consent form without prior approval from the Office of Research Compliance
    c. Obtaining the legally effective informed consent from each participant or their legally responsible representative prior to their participation in this project using only the currently approved, stamped consent form
    d. Promptly reporting significant adverse events and/or effects to the Office of Research Compliance in writing within 5 working days of the occurrence.
5. If I will be unavailable to direct this research personally, I will arrange for a co-investigator to assume direct responsibility in my absence. This person has been named as co-investigator in this application, or I will advise ORC, by letter, in advance of such arrangements.
6. I agree to conduct this study only during the period approved by the Auburn University IRB.
7. I will prepare and submit a renewal request and supply all supporting documents to the Office of Research Compliance before the approval period has expired if it is necessary to continue the research project beyond the time period approved by the Auburn University IRB.
8. I will prepare and submit a final report upon completion of this research project.

My signature indicates that I have read, understand and agree to conduct this research project in accordance with the assurances listed above.

Jingjing Qian	Jingjing Qian Digitally signed by Jingjing Qian DN: cn=Jingjing Qian, o=Auburn University Harrison School of Pharmacy, ou=Department of Health Outcomes Research and Policy, email=jqq0004@auburn.edu, c=US Date: 2017.04.13 11:13:49 -05'00'	4/13/2017
Printed name of Principal Investigator	**Principal Investigator's Signature**	**Date**

B. FACULTY ADVISOR/SPONSOR'S ASSURANCES

1. I have read the protocol submitted for this project for content, clarity, and methodology.
2. By my signature as faculty advisor/sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol.
3. I agree to meet with the investigator on a regular basis to monitor study progress. Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
4. I assure that the investigator will promptly report significant incidents and/or adverse events and/or effects to the ORC in writing within 5 working days of the occurrence.
5. If I will be unavailable, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the ORC by letter of such arrangements. If the investigator is unable to fulfill requirements for submission of renewals, modifications or the final report, I will assume that responsibility.

Printed name of Faculty Advisor / Sponsor	**Faculty Advisor's Signature**	**Date**

C. DEPARTMENT HEAD'S ASSSURANCE

By my signature as department head, I certify that I will cooperate with the administration in the application and enforcement of all Auburn University policies and procedures, as well as all applicable federal, state, and local laws regarding the protection and ethical treatment of human participants by researchers in my department.

Richard Hansen	Richard Hansen Digitally signed by Richard Hansen DN: cn=Richard Hansen, o=Auburn University, ou, email=rwh0019@auburn.edu, c=US Date: 2017.04.13 12:30:53 -05'00'	4/13/2017
Printed name of Department Head	**Department Head's Signature**	**Date**

8. **PROJECT OVERVIEW: Prepare an abstract that includes:**
(**350** word maximum, in language understandable to someone who is not familiar with your area of study):

a) **A summary of relevant research findings leading to this research proposal:**
(Cite sources; include a "Reference List" as Appendix A.)
b) **A brief description of the methodology, including design, population, and variables of interest**

Generic drugs play an important role in controlling health care costs.[1,2] Between 2003 and 2012, generic drug use realized savings of $1.2 trillion in health care expenditures.[3] As the economic impact and the number of people using generic medicines expands, the need for ensuring generic drug safety and effectiveness is paramount. However, the current requirements for establishing bioequivalence for generic drugs may be inadequate for addressing unique characteristics of special populations, which includes subgroups such as children, pregnant women, older adults, patients taking multiple drugs with multiple comorbid conditions, and patients with impaired kidney or hepatic function. Limitations of current bioequivalence testing include small sample size and lack of direct comparison of clinical efficacy and tolerability between brand and generic drugs. [4-8] It is concerning that data from normal healthy subjects in bioequivalence studies are extrapolated to all patient populations. [9, 10] To address ongoing controversy over generic substitution of branded drugs, particularly in special populations, possible approaches include regulatory changes to the generic drug approval process or enhanced post-marketing surveillance.

This proposed project will create innovative evidence-based profiles that can be used to support FDA's regulatory science efforts to monitor and ensure successful generic substitution for special populations, as well as to provide evidence on generic drug safety and effectiveness. First, we will use systematic review to collect information on practice patterns in special populations to assess possible barriers to generic substitution (Aim 1). Then we will compare clinical practice with labeled drug administration information and conduct key informant interviews and focus group in the assessed populations to identify factors that raise issues for safety and effectiveness with generic substitution (Aim 2). Finally, we will analyze national administrative claims data to examine generic drug utilization and substitution patterns and identify the impact of product-level, patient-level, and provider-level factors on generic drug substitution among special populations (Aim 3).

9. **PURPOSE.**
a. **Clearly state the purpose of this project and all research questions, or aims.**

The purpose of the proposed research is to create innovative evidence-based profiles that can be used to support FDA's regulatory science efforts to monitor and ensure successful generic substitution for special populations, as well as to provide evidence on generic drug safety and effectiveness. Aim 1 is non-human subject research so IRB is not applicable. We already received the IRB approval for Aim 3 (Protocol # 16-357 EX 1609). In this application, we are seeking IRB approval for Aim 2 -- to compare clinical practice with labeled drug administration information and conduct key informant interviews and focus group in the assessed populations to identify factors that raise issues for safety and effectiveness with generic substitution.

Specifically, the drug labeling review portion of Aim 2 is also non-human subject research, so this IRB will cover the key informant interviews and focus group portion of the aim.

b. **How will the results of this project be used? (e.g., Presentation? Publication? Thesis? Dissertation?)**

Results from this project will be disseminated at national and international conferences. Findings will be published on peer-reviewed journals. Findings of this study will create innovative evidence-based profiles that can be used to support FDA's regulatory science efforts to monitor and ensure successful generic substitution for special populations.

10. **KEY PERSONNEL.** Describe responsibilities. Include information on research training or certifications related to this project. **CITI is required. Be as specific as possible.** (Include additional personnel in an attachment.) *All key personnel must attach CITI certificates of completion.*

Principle Investigator Jingjing Qian **Title:** Assistant Porfessor **E-mail address** jzq0004@auburn.edu

Dept / Affiliation: HORP

Roles / Responsibilities:

Dr. Qian will serve as the Principal Investigator for this project and will be responsible for overseeing all project tasks, reporting, and communication with the sponsor. She will lead analyses related to Aim 3, and contribute to study design, analysis, and interpretation for Aims 1 and 2.

Individual: Ilene Harris **Title:** Principal Rese **E-mail address** iharris@impaqint.com

Dept / Affiliation: IMPAQ International LLC

Roles / Responsibilities:

Dr. Harris will serve as another Principal Investigator on the proposed project with Dr. Qian, and will serve as PI on the IMPAQ subaward from Auburn University. She will be primarily responsible for leading the IMPAQ investigators for Aims 1 and 2 of this proposal, and will also provide support for Aim 3.

Individual: Zippora Kiptanui **Title:** Senior Resear **E-mail address** zkiptanui@impaqint.com

Dept / Affiliation: IMPAQ International LLC

Roles / Responsibilities:

Ms. Kiptanui will serve as a co-investigator on the proposed project and will support the principal investigators on project tasks, reporting, and communication with the sponsor. She will systematic review and drug laveling review in Aims 1 and 2 and also contribute to study design, analysis, and interpretation for all 3 aims.

Individual: Richard A. Hansen **Title:** Professor **E-mail address** rah0019@auburn.edu

Dept / Affiliation: HORP

Roles / Responsibilities:

Dr. Hansen will serve as co-investigator for this project, contributing his expertise in systematic review and secondary data analysis to Aims 1 and 3, and content expertise to the design, analysis, and interpretation for Aim 2.

Individual: Jennifer N. Howard **Title:** Research Asso **E-mail address** jhoward@impaqint.com

Dept / Affiliation: IMPAQ International LLC

Roles / Responsibilities:

Ms. Howard will serve as a co-investigator on the proposed project. She will primarily be responsible for the design, analysis, and interpretation of Aim 2. She also will contribute to Aims 1 and 3. Ms. Howard will consent participants and work with Baltimore Research, a marketing research firm in Maryland, to recruit participants for Aim 2.

Individual: Gavriella Frank **Title:** Research Assi **E-mail address** gfrank@impaqint.com

Dept / Affiliation: IMPAQ International LLC

Roles / Responsibilities:

Ms. Frank will assist Ms. Howard for the conduct (interviews and focus groups), analysis, and interpretation of Aim 2 for the proposed project.

11. **LOCATION OF RESEARCH. List all locations where data collection will take place.** (School systems, organizations, businesses, buildings and room numbers, servers for web surveys, etc.) **Be as specific as possible. Attach permission letters in Appendix E.**
(See sample letters at http://www.auburn.edu/research/vpr/ohs/sample.htm)

The main location for this aim will be at the IMPAQ International LLC, Columbia, MD. Research results will also be shared with the Department of Health Outcomes Research and Policy, Harrison School of Pharmacy, Auburn University, Auburn AL.

12. PARTICIPANTS.

a. **Describe the participant population you have chosen for this project including inclusion or exclusion criteria for participant selection.**

☐ **Check here if using existing data, describe the population from whom data was collected, & include the # of data files.**

For this aim, we will recruit up to 5 patients/caregivers, physicians, and pharmacists for the key informant interviews to assist in the development of the focus group guides (e.g. questions and probes) and 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.

Additionally, we will conduct three focus groups with between 18 and 27 participants, with each of the three focus groups consisting of between 6 and 9 participants. One focus group will be conducted with pharmacists and physicians. Two focus groups will be conducted with patients representing two special populations, one for older adults (65 years and older) and the other for pediatric patients/caregivers (aged 19 and younger for patients themselves or their caregivers).

The study team will work with a marketing research firm, Baltimore Research, to screen and recruit participants (American residents and speak English) with knowledge and experience in generic drug use from diverse backgrounds.

b. **Describe, step-by-step, in layman's terms, all procedures you will use to recruit participants.** *Include in Appendix B a copy of all e-mails, flyers, advertisements, recruiting scripts, invitations, etc., that will be used to invite people to participate. (See sample documents at http://www.auburn.edu/research/vpr/ohs/sample.htm.)*

A marketing research firm, Baltimore Research, will assist with recruitment and scheduling. Baltimore Research will utilize private lists to recruit physicians, pharmacists, patients, and/or caregivers.

An invitation letter or email will be sent to each potential participant to invite their participantion to the study. Participation is voluntary. The risk associated with participating in this study is minimal (no PHI will be used or disclosed). Because obtaining signed consent from phone interviewees is difficult and might slow down the process, we will use information letter instead of signed informed consent to explain the purpose, benefits, and risks of the study prior to the key informant interviews. If they agree to participate, they will schedule the date and time of interviews with Baltimore Research and IMPAQ LLC.

For focus groups, we will obtain signed consent from all participants.

c. **What is the minimum number of participants you need to validate the study?** 23

How many participants do you expect to recruit? 32

Is there a limit on the number of participants you will include in the study? ☐ No ☑ Yes – the # is 32

d. **Describe the type, amount and method of compensation and/or incentives for participants.**

(If no compensation will be given, check here: ☐)

Select the type of compensation: ☑ Monetary ☐ Incentives

- ☐ Raffle or Drawing incentive (Include the chances of winning.)
- ☐ Extra Credit (State the value)
- ☐ Other

Description:

See attached document for detailed descriptions of monetary compensation.

To compensate participant's time, we will offer one time compensation of $25-$100 to participants who participant in a key informant interview and $75-$275 to participants who participate in a focus group.

The proposed compensation or "incentive" is not a reward or salary. Rather, it is a stimulus to participate in the interview. Proposed incentive rates are in accordance with standard practice and based on several factors including education and training, level of expertise, access to participants, and willingness to participate. More specifically, incentives for subspecialties of physicians and pharmacists are based on these factors as well as the necessity to include representation from these subspecialties for their unique role in generic drug utilization among patients representing a special population. It is well documents in the research that money spent on the promotion of prescription drugs varies significantly between primary care providers and specialist, ultimately influencing their prescribing patterns.[19] Oncologists and surgeons are more likely to prescribe high cost drugs.[20] Likewise, differences in dispending policies and incentives may uniquely influence retail-based pharmacists and hospital-based pharmacists.[21] Therefore, to ensure that we capture a complete picture of the beliefs, informational needs, etc. of generic drugs among primary care providers, specialists and high cost drug prescribers, such as specialists, it is key to the success of this study that the research team is able to recruit participants from each of these subspecialties. However, all physicians and pharmacists will be provided an incentive at the specialist or hospital pharmacist rate because one focus group will consist of all four groups (physician, primary care providers and specialists; pharmacist, retail and hospital).

Incentives are based on Baltimore Research's experience. Offering an incentive below these rates may result in increased costs exceeding the amount saved with a lower incentive. Consequences of insufficient incentives include increased time and cost of recruitment, increased "no-show" rates, and increased probability of cancelled or postponed interviews and focus groups.

Table: Respondent Compensation Rate

Group	**Incentive Amount-KII**[1]	**Incentive Amount-FG**
Physicians		
• Primary Care Providers	75	275
• Specialist	100	275
Pharmacists		
• Retail	75	275

[1] Incentives are based on physician specialty, level of expertise, years in school and average salaries. The more schooling and training, the higher the incentive. Incentives are also based on willingness to participate. For example, dermatologists are very difficult to recruit because their rate is high enough that it is more beneficial to see patients than to participate in research. The $75 incentive is for retail pharmacists. The incentive for hospital pharmacists is $100. These incentives are based on the pharmacist, availability, specialty and willingness to participate. More specifically, retail pharmacists are more prevalent than hospital-based pharmacists, making hospital pharmacists more difficult to recruit.

• Hospital	100	275
Patient/Caregiver	25	75

Incentives will be distributed upon completion of the interviews. All incentives will be distributed in a check paid by IMPAQ International. No taxes will be withheld. The name and address of the recipient and date mailed will be the only information noted. All financial records will be kept confidential and stored on a secure server. Information will not be shared with anyone outside of the IMPAQ financial staff. Upon completion of this project all confidential participant information not pertinent to financial record keeping will be destroyed.

13. PROJECT DESIGN & METHODS.

a. **Describe, step-by-step, all procedures and methods that will be used to consent participants. If a waiver is being requested, check each waiver you are requesting, describe how the project meets the criteria for the waiver.**

- ☐ **Waiver of Consent (including using existing data)**
- ☑ **Waiver of Documentation of Consent (use of Information Letter)**
- ☐ **Waiver of Parental Permission (for college students)**

Because the risk associated with participating in this study is minimal (no PHI will be used or disclosed), we ask for a waiver of documentation of consent for key informant interviews (including only 5 out of the 32 participants). Instead, we will use information letter to explain the purpose, benefits, and risks of the study, as well as voluntary participation and compensation, prior to the interview. By reading the information letter, participants will understand that they are being asked to participate in a research study, that they understand the risks involved in participating, that they can refuse to answer any question that they are not comfortable with, and that the information they provide will be kept strictly confidential. We will also ask for permission to record before proceeding with the interview and focus group questions.

For focus groups, we will use signed informed consent for all participants.

b. **Describe the research design and methods you will use to address your purpose. Include a clear description of when, where and how you will collect all data for this project.** Include specific information about the participants' time and effort commitment. (*NOTE: Use language that would be understandable to someone who is not familiar with your area of study. Without a complete description of all procedures, the Auburn University IRB will not be able to review this protocol.* ***If additional space is needed for this section, save the information as a .PDF file and insert after page 7 of this form.***)

Aim 2: To compare clinical practice with labeled drug administration information and conduct key informant interviews and focus group in the assessed populations to identify factors that raise issues for safety and effectiveness with generic substitution.

We will conduct semi-structured key informant interviews with physicans, pharmacists and patients to gain an in-depth understanding of their perceptions in generic drug labeling and practice in generic substitution. Up to 5 key informant interviews will be conducted. Additionally, we will conduct 3 focus groups (1 for pharmacists and physicians and 2 for patients/caregivers) to understand their perceptions in safety and effectiveness with generic substitution. Each focus group will include 6-9 participants.

We will recruit a total of 32 participants with the expectation that due to attrition, some participants may choose not to participate in the time between agreeing to participate and the scheduled interview or are unable to participate or be located the day of the scheduled interview/focus group.

Participants will be recruited with the assistance of a marketing research firm, Baltimore Research. As part of the recruitment process, Baltimore Research will schedule a 60 minute interview (90 minutes for focus groups) with the participant and inform the study team of the scheduled interview/focus group within 24 hours. Interviews and focus groups will be audio recorded and transcribed.

13. PROJECT DESIGN & METHODS. *Continued*

c. **List all data collection instruments used in this project, in the order they appear in Appendix C.**
(e.g., surveys and questionnaires **in the format that will be presented to participants**, educational tests, data collection sheets, interview questions, audio/video taping methods etc.)

We will have a total of 6 data collection instruments of telephone key informant interview and focus group questions for the following 3 groups:

1. Patients/caregivers
2. Physicians
3. Pharmacists

d. **Data analysis: Explain how the data will be analyzed.**

The team will analyze the data using NVivo 10 software. Using NVivo 10 software, initial themes from the transcripts will be identified and then discussed until all team members agree on major themes and a final code book. Team members' coded data will be compared for variations and periodically discussed as needed until consensus is reached.

14. **RISKS & DISCOMFORTS: List and describe all of the risks that participants might encounter in this research.** ***If you are using deception in this study, please justify the use of deception and be sure to attach a copy of the debriefing form you plan to use in Appendix D.*** *(Examples of possible risks are in section #6D on page 2)*

This aim involves minimal risk. We will only collect data related to participant's perceptions about generic medications. No personal identifiable data such as name, date of birth, social security number, or other sensitive information will be collected. No PHI will be used or disclosed. Data that will be collected from key informant interviews and focus groups will be protected under IRB approval and oversight of our data and data security protocol will ensure risk (i.e., breach of confidentiality) to participants is minimized.

15. **PRECAUTIONS.** Identify and describe all precautions you have taken to eliminate or reduce risks as listed in #14. If the participants can be classified as a "vulnerable" population, please describe additional safeguards that you will use to assure the ethical treatment of these individuals. ***Provide a copy of any emergency plans/procedures and medical referral lists in Appendix D. (Samples can be found online at http://www.auburn.edu/research/vpr/ohs/sample.htm#precautions)***

All personnel involved with the project will have Human Subjects Research training. IRB approval will be obtained by all participating institutions and oversight of our data and data security protocol will ensure risk to patients is minimized. To minimize the potential for loss of confidentiality, all data collected from key informant interviews and focus groups are de-identifiable and will be stored in a de-identified format. Auburn, IMPAQ, the marketing firm Baltimore Research, and FDA will comply with safeguards for ensuring participant information is kept private to the extent permitted by law. The interviewees will be informed about how the recordings are used in the analyses, and assured that the recorded data are kept strictly confidential.

If using the Internet or other electronic means to collect data, what confidentiality or security precautions are in place to protect (or not collect) identifiable data? Include protections used during both the collection and transfer of data.

Recordings will be saved on a secure webserver prior to being stored on a secure server at the IMPAQ headquarters. Once recordings are downloaded to the IMPAQ server, they will be deleted from the webserver. Audio recordings will be transcribed, and transcriptions will be saved and stored in a de-identified format on the IMPAQ server. Verbatim quotes included in the final report will not be attributed to any individual. Recordings will be destroyed/deleted once the transcriptions are complete and have been verified for accuracy.

16. **BENEFITS.**

a. **List all realistic direct benefits participants can expect by participating in this specific study.**
(Do not include "compensation" listed in #12d.) Check here if there are no direct benefits to participants. ☑

For participants in interviews and focus groups, the extent of their perceptions regarding generic substitution will be determined and considered in developing post-marketing evaluation strategies for generic drugs in special populations.

Although no direct benefits to participant, to compensate participant's time, we will offer one time compensation of $25-$275 to participants who complete the interviews or focus groups. The range of compensation is due to different groups.

b. **List all realistic benefits for the general population that may be generated from this study.**

For the general populations represented by our participants, the extent of their perceptions regarding generic substitution will be determined and considered in developing post-marketing evaluation strategies for generic drugs in special populations.

17. PROTECTION OF DATA.

a. Data are collected:

☐ Anonymously with no direct or indirect coding, link, or awareness of who participated in the study (Skip to e)

☐ Confidentially, but without a link of participant's data to any identifying information (collected as "confidential" but recorded and analyzed as "anonymous") (Skip to e)

☑ Confidentially with collection and protection of linkages to identifiable information

b. **If data are collected with identifiers or as coded or linked to identifying information, describe the identifiers collected and how they are linked to the participant's data.**

Interviews and focus groups will be audio recorded. However, questions will only target participant's perceptions in generic labeling, communication, and substitution. No personal identifiable data such as name, date of birth, social security number, or other sensitive information will be asked or collected unless the participants tell interviewers.

c. **Justify your need to code participants' data or link the data with identifying information.**

Confidentiality will be of the utmost importance during this study. Therefore, in order to prevent the improper identification of the study participants, all audio recordings will be transcribed and transcriptions as well as other electronic documents (e.g. interview/focus group notes) will be saved with pseudonyms in lieu of study participants' real names. Pseudonyms will also be used in potential presentations and publications.

d. **Describe how and where identifying data and/or code lists will be stored.** (Building, room number?) **Describe how the location where data is stored will be secured in your absence. For electronic data, describe security. If applicable, state specifically where any IRB-approved and participant-signed consent documents will be kept on campus for 3 years after the study ends.**

A key of participant names and pseudonyms will be maintained on an on-going basis in a password-protected document saved on the secure computer connected to a secured IMPAQ International network until the completion of the study when they will be destroyed. In addition, in order to ensure participants' confidentiality is protected, audio recordings will be destroyed once transcription is complete.

e. **Describe how and where the data will be stored** (e.g., hard copy, audio cassette, electronic data, etc.), **and how the location where data is stored is separated from identifying data and will be secured in your absence. For electronic data, describe security**

Recordings will be saved on a secure webserver prior to being stored on a secure server at the IMPAQ headquarters. Once recordings are downloaded to the IMPAQ server, they will be deleted from the webserver. Audio recordings will be transcribed, and transcriptions will be saved and stored in a de-identified format on the IMPAQ server. Verbatim quotes included in the final report will not be attributed to any individual.

f. **Who will have access to participants' data?**
(*The faculty advisor should have full access and be able to produce the data in the case of a federal or institutional audit.*)

Only the IMPAQ International LLC and Auburn team personnel, per their included IRB applications.

g. **When is the latest date that identifying information or links will be retained and how will that information or links be destroyed?**
(Check here if only anonymous data will be retained ☐)

Audio recordings will be destroyed once transcription is complete. All transcriptions, pseudonyms, and notes will be destroyed by the completion of the study.

DEPARTMENT
OF HEALTH OUTCOMES
RESEARCH AND POLICY

AUBURN UNIVERSITY

HARRISON SCHOOL
OF PHARMACY

5/1/2017

Office of Research Compliance
Auburn University

Dear IRB review committee,

This memo is to support revisions of IRB protocol application #17-140, which has been submitted for Aim 2 of a U.S. FDA funded project "Generic Drug Substitution in Special Populations" (grant # 1U01 FD005875-01). The purpose of this project is to identify research needs, monitor, and improve generic drug substitution in special populations.

After the submission of the revision on 4/13/2017, we received the following feedback from Auburn IRB committee:

> *"Waiver of signed consent for phone interviews granted (use term "Information Letter at top - not informed consent).*
> *Put all consent documents (focus group and phone interviews on letterhead)"*

We thanks Auburn IRB committee's approval of waiver of signed consent for phone interviews. We've made the following changes to respond to committee's comments:

1. We corrected the "informed consent" on the top of interview information letters as "information letter";
2. We put all consent documents for both focus groups and interviews on letterhead.

Please contact me if you have any questions.

Sincerely,

Jingjing Qian, PhD
Assistant Professor
Department of Health Outcomes Research and Policy
Auburn University Harrison School of Pharmacy
Auburn, AL 36849-5506
Phone: 334-844-5818
Email: jzq0004@auburn.edu

First revision memo sent on 4/13/2017

DEPARTMENT
OF HEALTH OUTCOMES
RESEARCH AND POLICY

AUBURN UNIVERSITY

HARRISON SCHOOL
OF PHARMACY

4/13/2017

Office of Research Compliance
Auburn University

Dear IRB review committee,

This memo is to support a revision of IRB protocol application #17-140, which has been submitted for Aim 2 of a U.S. FDA funded project "Generic Drug Substitution in Special Populations" (grant # 1U01 FD005875-01). The purpose of this project is to identify research needs, monitor, and improve generic drug substitution in special populations.

After the submission, we received the following feedback from Auburn IRB committee:

> *"10 - Identify who will recruit and consent*
> *12b/13a We prefer signed consent for research which will be audio-recorded and in the case of patients could contain information on medications they are taking whether you asked it or not. Waiver for signed consent not granted.*
> *15 No need to repeat first part of Internet section - can divide info between sections with the internet part starting with "Recordings will be saved..."*
>
> *Used signed consent language at end (your heading already was for signed consent)*
> *Please add focus group confidentiality language to consent. IT can read something like the following.*
> *"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."*

Therefore, we've made the following changes to respond to committee's comments:

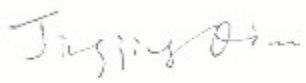
1. We identified and added the personnel who will recruit and consent for this aim in the IRB application form item 10;
2. We will use signed consent for focus groups and verbal consent (information letters) for key informant interviews, which has been revised in the IRB application form item 12b/13a as well as the supporting materials (signed consent documents for focus groups with the suggested language, and focus group protocols). We hope the committee could consider to allow us to waive for signed consent for key informant interviews because obtaining signed consent from phone interviewees will be difficult and slow down the procedure;
3. We modified language in the IRB application form item 15 as suggested.

022 Foy Hall, Auburn, AL 36849-5506; Telephone: 334-844-5152; Fax: 334-844-8307

www.auburn.edu

We hope that we have addressed the committee's comments. Please contact me if you have any questions.

Sincerely,



Jingjing Qian, PhD
Assistant Professor
Department of Health Outcomes Research and Policy
Auburn University Harrison School of Pharmacy
Auburn, AL 36849-5506
Phone: 334-844-5818
Email: jzq0004@auburn.edu