AUBURN
UNIVERSITY

HARRISON SCHOOL OF PHARMACY

DEPARTMENT OF HEALTH OUTCOMES RESEARCH AND POLICY

Informed Consent
For a research study entitled
Enhancing a sustainable pharmacy-based immunization program in two states

Study Investigator: Salisa Westrick, PhD

Study invitation. You are invited to participate in a research study about enhancing the provision of pharmacy-based pneumococcal and herpes zoster vaccination services. This study involves pharmacies in Alabama and California. Approximately 32 pharmacies in these states will serve as intervention pharmacies and 32 pharmacies will serve as control pharmacies. Each participating pharmacy will have a pharmacist-technician pair who will participate in study activities. Your pharmacy manager has agreed to allow the pharmacy to participate, however your participation is completely voluntary. Your decision whether to participate will not affect your evaluations as a staff member in this pharmacy, nor will it affect your future relations with Auburn University or the Keck Graduate Institute.

What is the purpose of the study?
The purpose of this study is to enhance current immunization activities in community pharmacies through targeting the two most commonly available non-seasonal vaccines in community pharmacies: pneumococcal vaccine and herpes zoster vaccine. Comparing the intervention with control pharmacies will allow us to know whether training and support from immunization experts can sustainably increase the number of pneumococcal and herpes zoster vaccinations.

What will my participation involve?
If you agree to participate in the study, your pharmacy will be randomly assigned to either receive the intervention or to participate as a control pharmacy. You will complete a brief 10-15 minute baseline survey online. If your pharmacy is assigned as an intervention pharmacy, you will participate in a series of 3 online continuing education webinars at the start of the study. The three webinar topics will be: 1) immunization update, 2) enhanced immunization delivery, and 3) pharmacy practice change. During the 6 month intervention period, you will be required to use a vaccine recommendation form when interacting with patients regarding pneumococcal or herpes zoster vaccine. In addition, either a pharmacist or a pharmacy technician will complete brief 5 minute online questionnaires each month related to implementation of immunization activities. Clinical support and provider feedback will be provided to your pharmacy based on the information we receive. You will also complete two follow-up surveys either online or by phone at 6 months. Either a pharmacist or pharmacy technician will complete a survey at 12 months after the start of the study. Each survey will take approximately 5-10 minutes. Lastly, you may be selected to complete a 30-60 minute phone interview with a member of the research team at the conclusion of the 6-month intervention period.

If your pharmacy is assigned as a control pharmacy, you will receive only the immunization update webinar at the beginning of the study and will complete monthly questionnaires as described above. You will not get feedback or clinical support, but you will be able to receive the other two webinars at the end of the study. In addition, your pharmacy will provide an immunization report to the study investigators, detailing the number of pneumococcal and herpes zoster vaccinations administered during the study period.

Are there any benefits?
There are no direct benefits to you individually for participating in this study. Indirect benefits to you include the professional development and support programs that will be provided at no cost as part of the study. Benefits for your pharmacy include enhancing your current vaccination services, increasing the number of administered vaccines, and receiving the patient's normal payment for each vaccine administered over and above your current level. Your community and patients also receive the benefit of having more individuals who are protected from pneumonia and herpes zoster.

Will my pharmacy be compensated?
Your pharmacy will be modestly reimbursed for its time and effort by receiving $150 after the baseline survey and pre-intervention vaccination reports are submitted at the start of the study. Your pharmacy will also be compensated $100 after submitting the 6-month post intervention vaccination report, and an additional $100 after submitting the 12-month report. The total direct compensation is $350.

Are there any costs?
The main cost involved in your participation in this study is time – time to complete the training program and to complete baseline, monthly, and follow-up surveys and an in-depth phone interview.

If I decide to start the study, can I change my mind?
Your decision to participate in this research is entirely voluntary. You may choose not to participate. If you do decide to participate, you may change your mind at any time without penalty or loss of benefits that you had prior to the study.

Will my confidentiality be protected?
No information about individual respondents, pharmacies, or patients will be released. Staff surveys will be conducted online. Your responses will be assigned a code number which will allow us to monitor responses and to follow-up, if any questions arise. All codes will be stored in a secured file and kept separate from the information collected. Upon completion of the study, lists with names and code numbers will be destroyed. Study results will be presented in aggregate form only.

What if I have questions?
If you have questions about this research, please contact the study coordinator, Salisa Westrick, or the study coordinator in your state:

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For more information regarding your rights as a research participant you may contact the Auburn University Office of Human Subjects Research or the Institutional Review Board by phone (334)-844-5966 or e-mail at hsubjec@auburn.edu or IRBChair@auburn.edu.

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

Name of Participant	Signature	Date

Name and Location of Pharmacy

Printed Name and Signature of Investigator Obtaining Consent	Date