Increase Vaccine Uptake in Adolescent in Rural South (INVEST)

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Duke University Health System

Consent to Participate in a Research Study
Stakeholder Interviews
INVEST: A tailored school-based INtervention to increase VaccinE uptake among adoleScenTs in the rural south

CONCISE SUMMARY

This is a research study to investigate if a school-based intervention can increase HPV vaccination rates among middle schoolers in rural counties in North and South Carolina.

Schools in each rural county will be assigned (like flipping a coin) to one of two groups. Schools in Group 1 will have school nurses receive study training, an orientation packet with vaccination and overall health information, health newsletters, and other vaccine related information to distribute to caregivers of middle schoolers. School nurses will provide information on which materials were distributed. Schools in Group 2 will not receive these materials. School wide HPV vaccination information will be collected from both groups. Stakeholders from Group 1 will have the chance to answer questions about their experience with the training and materials.

The risks for this study are considered minimal and equal to risks in daily life.

You are being asked to take part in this research study because you are a stakeholder in a rural county in North or South Carolina involved with adolescent vaccination. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As a study staff member discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Emmanuel Walter will conduct the study and it is funded by Centers for Disease Control and Prevention (CDC). The CDC will pay Duke University to perform this research, and these funds may reimburse part of Dr. Walter's salary.

WHY IS THIS STUDY BEING DONE?
The Human Papilloma Virus (HPV) vaccine is recommended for middle schoolers as a way to prevent cervical cancer and other cancers of the head and neck. The purpose of this study is to understand reasons why middle schoolers living in rural areas are less likely to be vaccinated than those in urban. We want to test if INVEST, a school-based intervention, to see if it can improve HPV vaccination rates. In particular, the study will ask about challenges that middle schoolers and their families and stakeholders face when trying to access the Human Papilloma Virus (HPV) vaccine.

Why AM I BEING ASKED TO PARTICIPATE IN THIS STUDY?
You may be able to help us understand the effects of the vaccine promotion materials, the reach of the materials to caregivers, and the effects of the materials in your community because you are:

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- A local health provider in a practice which provides vaccines to teenagers, or
- A community-based stakeholder (e.g., school principal or board member, members of community organizations etc.) who closely interacts with teenagers or their families

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 30 health providers and stakeholders from two rural counties in North and South Carolina can be enrolled.

WHAT IS INVOLVED IN THE STUDY?

The study involves an interview that will last for about 30 minutes for individual interviews and 90 minutes for group interviews. If you choose to participate in the study, we will ask you to indicate your choice by signing and dating this consent form. During the interview:

1. An interviewer will ask you questions such as your perceptions and involvement in the INVEST intervention. You may be asked how the intervention was received in your area, which pieces of the intervention were useful and how to change the intervention in the future.
2. Your interview responses will be recorded on audiotape, and will be downloaded and stored on a secure Duke network. The baseline questionnaire responses will be recorded on paper or digitally in an electronic survey software called REDCap. The data entered in REDCAP will be stored on a secure Duke network. Only authorized personnel working on this study or who have Duke University's permission to review this information will know what you said.

HOW LONG WILL I BE IN THIS STUDY?

The interview will last between 30 and 90 minutes. Your participation in the study will end once you complete the interview. You can leave the interview at any time without penalty or loss of any benefits to which you are entitled. Your job will not be affected in any way if you decide to stop. We will use any information that you have already given us, but not collect any further information from you.

WHAT ARE THE RISKS OF THE STUDY?

There are no physical risks to participants in this study. There is a potential risk of loss of privacy in any study involving participant information; however, every effort will be made to protect participants' confidentiality as described below.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You may not receive any personal benefits from participating in the study, but your participation may lead to knowledge that will help others.

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WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

To protect your identity, all identifying information collected from you will be kept confidential and accessed only by authorized study staff. Your name will only be listed on this consent form which tells us that you agreed to participate in the study (and with your contact information so we can reach you during the study). We will not write your name or other personal information on notes or other study documents but will instead use a unique identification number. In addition, when we report to others what we learn from the study, we will not use your name.

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Any data collected on paper will be stored in locked rooms, and any electronic data containing identifiable information will be kept on password-protected, encrypted and/or secure devices or drives on Duke servers. The audio recordings will be stored on encrypted devices, as mentioned above, and will only be accessed by authorized study staff. Identifiable information will be removed from notes we make from the audio-recording.

Study documents and data containing identifiable information will be kept for at least six years after the study is completed. Audio files will be deleted once all analyses have been completed and published. All other data may be retained indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.
If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
There are no costs to you to participate in this study.

WHAT ABOUT COMPENSATION?
You will be reimbursed up to $50 for your expenses related to your participation (parking, gas, and time) except if you report having current employment, which prohibits you from receiving the payment (examples could include government officials, school superintendents, local providers, etc.) To process the payment, we will need to collect your social security number (SSN). SSNs will be stored under double lock (locked PI office and locked cabinet). The SSNs will be destroyed by shredding as soon as the payment is processed.

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WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

If you do decide to withdraw, we ask that you contact Dr. Walter in writing and let him know that you are withdrawing from the study. His mailing address is 27 Parmer Way, Durham, NC, 27703.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have complaints, concerns or suggestions about the research, contact Dr. Walter at 919-620-5346 during regular business hours and at 919-970-5720 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time