Official Title: Cohort Study to Determine the Effect of an Educational Intervention Focusing on Herd Immunity to Enhance Vaccination Uptake Rates
NCT04568590
IRB-Approved Date: 9/13/2021

Wake Forest®
School of Medicine

Department of *Pediatrics*

COHORT STUDY TO DETERMINE THE EFFECT OF AN EDUCATIONAL INTERVENTION FOCUSING ON HERD IMMUNITY TO ENHANCE VACCINATION UPTAKE RATES

Informed Consent Form to Participate in Research

Elizabeth Halvorson, MD, co-Principal Investigator
David Kram, MD, co-Principal Investigator
Steven Giles, PhD, co-Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to see whether increasing individuals' awareness of the benefits of herd immunity, specifically to the local pediatric oncology community, can improve vaccination uptake rates. You are invited to participate in this study because your child is eligible for the seasonal influenza vaccine and you are at your doctor's office during influenza season when the vaccine is available. As part of this study, you will be asked to complete three to four (3-4) questionnaires. The first questionnaire asks basic demographic information; the second is 20 questions asking the frequency at which you engage in helping behaviors primarily for strangers; and the third is 8 questions asking about your beliefs regarding vaccination. This may be the entire intervention for some participants. Following completion of these three questionnaires, selected participants will also be asked to listen to a brief education intervention which will center on a study volunteer orienting you to and giving you an informational pamphlet to read. This informational handout, sponsored by the Pediatric Oncology Section at Wake Forest Baptist Health, focuses on the herd immunity benefit that pediatric cancer patients receive from healthy children receiving vaccines for vaccine-preventable diseases. The pamphlet also addresses several common myths on which much vaccine concern is based. Following the educational intervention, you will again fill out the same 6-question questionnaire asking about your beliefs regarding vaccination. You may remain in this study for only 1 day, after which the investigators will have access to the answers to the questions you provided. You may also be contacted in the future (no greater than one year) to participate in a short phone or video interview concerning your experiences as a study participant. Participation in this interview is entirely voluntary.

All research studies involve some risks. There is very little risk with participating in this study. We may ask you questions that you do not want to answer. If this happens you may choose not to answer. We could also ask questions that could make you feel uncomfortable or anxious. There is always a risk of breach of confidentiality. However, we have put safeguards in place to protect your identity. We do not expect that you will benefit from participating in this study. We do hope that the information gained will help pediatric cancer patients who are at heightened risk of

contracting vaccine-preventable diseases and also help inform practices to enhance overall vaccine uptake rates.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. Your other option is to not participate. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The persons in charge of this study are Dr. Elizabeth Halvorson, Dr. David Kram, and Dr. Steven Giles (co-Principal Investigators). If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, Dr. Halvorson's contact information is [redacted] and Dr. Kram's contact information is [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, you should contact the Chairman of the Institutional Review Board at [redacted] or the Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because your child is eligible for the seasonal influenza vaccine today. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to figure out if increasing individuals' awareness of the benefits of herd immunity, specifically to the local pediatric oncology community, can improve vaccination uptake rates.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We estimate that 500 people at Wake Forest Baptist Health pediatric practices will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

You will be asked to answer three questionnaires at first. The first contains 7 demographic questions, including your race/ethnicity, your marital status, the number of children in your household, the number of people in your household, your household annual income, your highest education level in the household, and your political affiliation. The second contains 20 questions about the frequency at which you engage in helping behaviors for strangers in your community. The third includes 8 questions about your opinions regarding the flu vaccine. These three

questionnaires should take less than 10 minutes to complete. Participants who are selected to continue in the study will then undergo a brief educational encounter by a study volunteer focusing on the benefits that pediatric cancer patients receive by vaccine-eligible children receiving their recommended vaccines, and how this contributes to protective herd immunity. The educational session takes about 5 minutes to complete. Following the education session, either immediately, or after your scheduled doctor's appointment, you will be asked again to answer 8 questions about your opinions regarding the flu vaccine. This will take approximately 3 minutes. You may be contacted in the future (no greater than one year) to participate in a short phone or video interview concerning your experiences as a study participant. Participation in this interview is entirely voluntary. In total, we estimate this involvement in this study will take 10-20 minutes of your time; 30-40 minutes in total if you agree to participate in the interview.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for one day, after which we will study the answers that you have provided.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. There are no anticipated side effects from leaving the study early.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff.

During the question-answering sessions and/or education session, you could get tired and become frustrated with the questions. As part of this study, you will be asked questions about your education, income, political affiliation, behaviors, and beliefs about vaccines. You could feel that the questions make you anxious or uncomfortable. You may decide that you do not want to answer the questions.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

There are no costs associated with this study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will be offered a $5 Target Gift Card as compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University Health Science. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**

Name
Date of birth
Medical Record Number
Date of clinic evaluation
Contraindications to the Flu Vaccine

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations. We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products. Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the

extent permitted by other applicable laws.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

You can tell Drs. Elizabeth Halvorson or David Kram that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Elizabeth Halvorson, MD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your Protected Health Information for this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to

continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigators, Dr. Halvorson at [redacted] and/or Dr. Kram at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed): _____

Subject Signature:_____ Date:_____ Time:_____ am pm

Person Obtaining Consent (Printed): _____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm