DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study

A Prospective, Randomized, Open-label Clinical Trial to Assess the Safety and Immunogenicity of Simultaneous versus Sequential Administration of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis (Tdap) Vaccine and Inactivated Influenza (Flu) Vaccine in Pregnant Women – Pilot (Infant Consent)

We are asking you to allow your child to take part in a research study because you participated in the main portion of the study while you were pregnant and received the Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis (Tdap) and Inactivated Influenza (Flu) vaccines. 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. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Please ask the study doctor or study staff to explain anything that you do not clearly understand. In addition, tell the study doctor or study staff if your child is taking part in another research study.

[redacted] will conduct the study and it is funded by the Centers for Disease Control and Prevention (CDC). The sponsor of this study, the CDC, will pay Duke University to perform this research, and these funds may pay part of [redacted] salary.

WHO WILL BE MY CHILD'S DOCTOR ON THIS STUDY?

If you decide to take part, [redacted] will be your child's doctor for the study. [redacted] will be in contact with your child's regular health care provider while your child is in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

Vaccines work by causing the body to make proteins called antibodies that fight and protect against infection. Vaccination is the most effective way to prevent infections such as tetanus, diphtheria, pertussis (whooping cough), and influenza (flu). As part of your participation in the main portion of this study, you received both Tdap and flu vaccines either simultaneously (both vaccines on the same day) or sequentially (the flu vaccine at one visit, and a few weeks later the Tdap vaccine).

This part of the study is looking to see if the level of antibodies to pertussis (whooping cough) is different in infants born to mothers receiving these vaccines simultaneously versus sequentially.

HOW MANY CHILDREN WILL TAKE PART IN THIS STUDY?

Approximately 20 children will take part in this study, with 10 children taking part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?

If you agree for your child to be in this study, you will be asked to sign and date this consent form. A member of the study staff will ask you questions regarding your child's health (feedings, illnesses, medications, and vaccinations). Prior to your infant receiving his/her recommended 2-month vaccines, they will have a heel stick performed to obtain a small amount of blood (approximately 0.5mL or less than one-tenth a teaspoon). Blood samples from your child will be sent to the research laboratories at the CDC to look for the proteins (antibodies) that fight pertussis. If there are extra blood samples remaining at the end of the study, it will be discarded.

HOW LONG WILL MY CHILD BE IN THIS STUDY?

If you agree for your child to take part in this study, your child's involvement may last for approximately 1 day. You can choose for your child to stop participating at any time without penalty or loss of any benefits to which your child is entitled.

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WHAT ARE THE RISKS OF THE STUDY?
Risks associated with collecting blood from your child's heel (heel stick) include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely. Staff will apply direct pressure to the blood draw site to reduce any bruising. Sterile techniques will be used to prevent infection at the site where blood will be drawn.

There is also the potential risk of loss of confidentiality about information obtained as part of this study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree for your child to take part in this study, there is no direct medical benefit to your child. Information learned from this study may also help researchers learn how to perform future studies of vaccination during pregnancy and how they affect infants' immune systems and protect against infections in the first few months of life.

WILL MY CHILD'S INFORMATION BE KEPT CONFIDENTIAL?
Study records that identify your child will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, your child will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, your child will be assigned a unique code number. The key to the code will be kept securely at DUHS.

As part of the study, [redacted] and [redacted] study staff will report the results of your child's study-related procedures to the sponsor. Results from any test done solely for this research study will not be included in your child's medical record.

In addition, your child's records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the CDC and the DUHS Institutional Review Board, or domestic governmental regulatory agencies. If your child's research record is reviewed by any of these groups, they may also need to review your child's entire medical record.

The study results will be retained in your child's research record for six years after the study is completed or until your child reaches the age of 21 years, whichever is longer. At that time either the research information not already in your child's medical record will be destroyed or information identifying your child will be removed from such study results at DUHS. Any research information in your child's medical record will also be kept indefinitely. Research information may be further disclosed by the sponsor of this study, CDC. If disclosed by the sponsor, the information is no longer covered by the 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 the 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 child's identity will not be revealed.
If you decide not to sign this consent form, your child will not be able to participate in the study.

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A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT ARE THE COSTS?

There will be no additional costs to you as a result of your child being in this study. However, any routine medical care (care your child would have received whether or he/she were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further. In order to make sure that tests and studies done solely for research purposes are charged correctly, we will carefully monitor your Duke Hospital and Clinic charges as long as your child is participating in this study. These tests and studies are not a part of routine care, and people who are not part of the study do not usually have them performed. Please ask the study staff if you would like to know more about which tests and studies are being done solely for research purposes.

WHAT ABOUT COMPENSATION?

You will be reimbursed up to $75 for your expenses related to your child's participation (parking, gas, and time).

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that your child is injured as a result of his/her participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your child's Duke physicians or the study sponsor, the CDC, to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact [redacted] during regular business hours and at [redacted] after hours and on weekends and holidays. The Perinatal Research team can also be reached at [redacted] during regular business hours.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

Your decision to allow your child to be in this study is voluntary. You may choose to withdraw your child from the study at any time. If your child withdraws from the study, no new data about your child will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study.

If such an adverse event occurs, we may need to review your child's entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision for your child not to participate or to withdraw your child from the study will not involve any penalty or loss of benefits to which he/she are entitled, and will not affect their access to health care at Duke. If you decide to withdraw your child from the study, we ask that you contact [redacted] in writing and let her know that your child is withdrawing from the study. Her mailing address is [redacted]. You may also contact the study team to notify them of your decision to withdraw from the study by

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calling [redacted] during regular business hours. However, the study doctor may continue to use and share your health information that was collected before you stopped your consent.

The study doctor or sponsor may withdraw your child from this study for any reason at any time even without your consent. This could occur, for example, if the study doctor decides that it is in your child's best interest. We will tell you about new information that may affect your child's health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if your child has problems, or you have concerns, questions or suggestions about the research, contact [redacted] or use the 24-hour pager number at [redacted]. For general questions about the study or if you have complaints, concerns or suggestions about the research, you may also contact the Perinatal Research team at [redacted] during regular business hours. For questions about your child's 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 [redacted]

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 for my child to be in this study, with the understanding that I may withdraw my child at any time. I have been told that I will be given a signed and dated copy of this consent form."

Signature of Parent or Legal Guardian	Date	Time

Signature of Person Obtaining Consent	Date	Time