



A Prospective, Randomized, Clinical Trial to Compare Adverse Birth Outcomes in Pregnant Women Receiving Quadrivalent Recombinant Influenza Vaccine (RIV4) versus Quadrivalent Inactivated Influenza Vaccine (IIV4)

**CONCISE SUMMARY**

The purpose of this study is to learn more about the safety of Recombinant Inactivated Influenza vaccine (RIV) in pregnant women and their babies. RIV is a type of flu vaccine that is made using an egg-free process. In 2016, the CDC Advisory Committee on Immunization Practices (ACIP) included RIV as one of the flu vaccines that can be given to pregnant women. This study will compare the safety of RIV to a flu vaccine that is made using an egg-based process (IIV); egg-based flu vaccines have been in use for decades. What we learn from this study may help doctors better understand if there is a difference in side effects or health benefits from the two vaccines during pregnancy.

Participants in this study will be randomly assigned (like flipping a coin) to receive either RIV or IIV. Through the course of the study you will have two in-person study visits and up to four phone/email/text visits. Participation is complete once you have delivered your baby and the study team has reviewed both you and your baby's charts for any medical occurrences approximately 90 days after birth.

Risks include that of taking blood and receiving the Flu vaccine.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this study because you are at least 18 years old, you are less than or equal to 34 weeks pregnant with one baby, and you are planning to receive the Influenza (Flu) vaccine as recommended for routine prenatal care during flu season. 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 your study doctor or study staff 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 healthcare provider, 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.

Please tell the study doctor or study staff if you are taking part in another research study.

Through a contract from the Centers for Disease Control and Prevention (CDC), the CDC will support this research study. The CDC will pay a portion of Dr. Geeta Swamy's and Dr. Emmanuel Walter's and their research team's salaries to conduct the study.

**WHO WILL BE MY DOCTOR ON THIS STUDY?**

If you decide to participate, Dr. Geeta Swamy will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are 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 infection. Vaccination is the most effective way to prevent infections such as influenza (flu). The Advisory Committee on Immunization Practices (ACIP) and the American College of Obstetrics and Gynecology (ACOG) currently recommend the Flu vaccines for pregnant women to protect both mothers and their babies from the flu. Flu vaccines that are licensed in the United States and recommended for use in pregnant women, are routinely given to women who are pregnant during flu season.



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The influenza virus causes influenza or "flu", an infection of your breathing tubes and your lungs. Flu is a disease caused by different types of influenza viruses. Usually the influenza viruses are similar from year-to-year but there are small changes in the circulating viruses that require getting a flu vaccine each year. Flu is spread from person-to-person mainly through coughing and sneezing. Each winter, the flu causes illness with symptoms that include fever, sore throat, cough, runny nose and fatigue. Pregnant women who get the flu are more likely than women who are not pregnant to be hospitalized for flu or have serious complications from the infection, such as pneumonia (infection of the lungs).

In 2013 the Food and Drug Administration (FDA) approved a recombinant inactivated influenza vaccine (RIV) called FluBlok® and in 2016 the FDA approved a similar RIV vaccine call Flublok® quadrivalent. In 2016, ACIP included RIV as one of the flu vaccines that can be given to pregnant women. Compared to other flu vaccines that are licensed and recommended for pregnant women, RIV is made using an egg-free process.

A number of studies show FluBlok® is safe to give to non-pregnant women. Although there are no studies that have looked to see if this is also the case in pregnant women, information in a registry that tracks pregnancies after RIV has not shown any concerning side effects.

The purpose of this study is to learn more about the safety of RIV in pregnant women and their babies. The study will compare the safety of RIV to a flu vaccine made using an egg-based process (IIV); IIV vaccines made with the egg-based processed have been used for decades. The study will also look at how much antibody (proteins in the blood that protect against the flu) the body makes after receipt of RIV compared to a flu vaccine that is made using an egg-based process.

What we learn from this study may help doctors better understand if there is a difference in side effects or health benefits from the two vaccines during pregnancy.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

Approximately 430 pregnant women will be enrolled in this study overall, with approximately 200 pregnant women to take part at Duke.

**WHAT IS INVOLVED IN THE STUDY?**

If you agree to participate, you will be asked to sign and date this consent form. We ask that you:

- Follow the instructions you are given.
- Come to the study center for both visits with the study doctor or study staff.
- Record your health information for the first 8 days after vaccination
- Tell study staff about any changes in your health or the way you feel, especially any colds or respiratory (lung) infections.
- Sign a medical release to permit us to review medical records for you and your baby, if needed for the hospital where you are planning to deliver.

**Screening visit (clinic visit):** Study staff will review this consent form with you as well as the study criteria to make sure you qualify. Additionally, study staff will ask you about your health and any medicines you are taking. If you agree to participate, you will be asked to sign and date this consent form.



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**Visit 1 (clinic visit) Study Day #1:** Study staff will review the study criteria with you and ask about your health and any medicines you are taking to make sure that you still qualify for the study. Study staff will take your vital signs (temperature, blood pressure, respiratory rate, and heart rate). A blood sample of 15 mL (~3 teaspoons) will be taken to test for flu antibody levels. Study staff will then use a computer system to randomly (like flipping a coin) assign you to receive either the IIV or RIV flu vaccine. The study is blinded which means neither you nor the study team will know which vaccine you will get. Only the study staff giving you the vaccine will know which vaccine you will get.

The vaccine will be administered by licensed study staff. You will need to stay in the clinic for at least 20 minutes after that to be watched for any reactions. Your arm and the site of the injection will be looked at before you leave. You will be given a Memory Aid form, ruler and thermometer, and shown how to use them for the study. You will be asked to write down your temperature and any symptoms that you have daily from the evening of the day you got the vaccine to seven days after you receive the vaccine. You should also write down any new medicines you take during this time, even over-the-counter medicines like Tylenol. You will also be asked to measure (with the ruler) the spot where you received your vaccine if the area gets red or swollen.

You have the choice of filling out the Memory Aid either on paper or online, using the study's web-based system, "REDCap."

You will be given the Centers for Disease Control and Prevention (CDC) Flu Vaccine Information Statement for your records. You will also receive documentation of receipt of influenza vaccine (without specification of whether it was RIV or IIV vaccine) in case this is required for your place of work.

You should contact the study staff if you have any severe reactions (explained on the Memory Aid form you will receive) in the week after the vaccine.

**Visit 2 (phone call/email/Text follow-up) Study Day #4:** If you choose to use the paper Memory aid, a member of the study staff will contact you to review your symptoms and medications. If you choose to enter your Memory aid information in the web-based system (that is REDCap), study staff will review your entries online. If the study team sees that you have not entered any information, the study team will contact you by phone, email, or text to get this information from you. The study team may also contact you if more information is needed regarding the details you entered in REDCap.

If you have a severe reaction to the vaccine, you will be encouraged to follow up with your obstetrician or primary care provider. You may be asked to return to clinic for an unscheduled visit where you will have an evaluation by the study doctor.

**Visit 3 (phone call/email/Text follow-up) Study Day #9:** Visit 3 will be the same as visit 2.

**Visit 4 (clinic visit) Study Day 29:** About 29 days after the first visit you will return to the clinic for another in-person visit. You will be asked about and changes to your health and any medicines you are taking. A blood sample of 15 mL (~3 teaspoons) will be taken to test for flu antibody levels.

**Visit 5 (phone call/email/Text follow-up) Study Day #43:** About 43 days after vaccination you will be contacted by the study team to collect any new/changes in conditions or medications since your last clinic visit.



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**Visit 6 (hospital visit/chart review):** During your admission for the birth of your baby, a blood sample of 15 mL (3 teaspoons) will be taken from you to test for flu antibody levels. The study team will work with your care providers to have this drawn when you are having other blood drawn for part of your care (for example when your IV is placed). If this is not possible, a member of the study team will draw your blood for the study before you go home from the hospital.

After the birth of your baby, the medical personnel charged with the delivery will collect approximately 15 mL (3 teaspoons) of umbilical cord blood (the blood that remains in the placenta after delivery), if feasible, in order to evaluate your antibodies levels. This blood sample will be collected after the umbilical cord is cut so that there is no risk for the baby. Also, this will not affect your ability to donate the remaining umbilical cord blood if you so wish.

Study staff will review your and your baby's medical records until your baby is 90 days old in order to complete research questions. After you deliver, study staff will review your labor and delivery medical records to collect additional information on the delivery and the health of you and your baby during your hospital stay. If you do not deliver at Duke University Medical Center, study staff will obtain records from these health care providers (after you have signed a medical record release form for you and your baby). Study staff will review your medical record up to 90 days after the birth of your baby to see if you develop any new or worsening medical problems.

**Visit 7 (phone call/email/Text follow-up) Study Day #90:** Study staff will contact you to record any unexpected medical events that occurred in you or your baby. Information will also be collected on hospital admissions, emergency room visits and unanticipated visits to the primary care pediatrician or a specialist. This information will be verified by reviewing medical records.

**Unscheduled Visit:** Unscheduled visits may occur at any time during the study. If you experience a severe reaction to the vaccine, the study team will recommend that you follow up with your healthcare provider. Should you come in for an unscheduled visit, the study team will take your vital signs (just like in Visit 1) and you will be asked about any changes in your health or medications you are taking. Depending on the severity of the reaction, the study doctor may refer you to your primary care or pregnancy doctors for assessment and possible treatment.

#### **HOW LONG WILL I BE IN THIS STUDY?**

You will be in this study for 2-7 months, depending on how far along you are in your pregnancy when you enroll and when you deliver. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

#### **WHAT ARE THE RISKS OF THE STUDY?**

The flu vaccines used in the study are licensed by the FDA, and CDC routinely recommends their use in pregnant women in any stage of pregnancy. There may be some risks from being in the study including side effects that are not yet known.

#### **Blood draws**

Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely. Staff will apply direct pressure to the



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blood draw site to reduce any bruising. Sterile techniques will be used to prevent infection at the site where blood will be drawn.

**Flu vaccine**

Possible risks with receiving the Flu vaccine include:

- redness, swelling, tenderness, or pain where the vaccine was given
- fever, chills, body aches, headache, or fatigue
- nausea
- cough or hoarseness
- sore, red or itchy eyes
- itching

Guillain-Barré syndrome is a rare but serious condition that can occur after certain infections or after receiving certain vaccines such as the flu vaccine. There is a small increased risk of Guillain-Barré syndrome (about 1 or 2 additional cases per million people vaccinated) after vaccination with flu vaccine. Guillain-Barré syndrome causes inflammation and damage to the nerves in your body. Minor symptoms such as muscle tiredness or more severe symptoms, such as paralysis (weakness, or inability to move certain parts of the body) may occur.

Very rarely, occurring in about 1 in 1 million vaccine doses, there can be a serious allergic reaction to any vaccine. These reactions can cause skin rash (hives), difficulty breathing, swelling around the mouth, throat, or eyes, a fast pulse, sweating, or loss of blood pressure, and would happen within a few minutes to a few hours after the vaccination. If these reactions occur, they can usually be stopped by the study staff giving emergency medications. If you experience these reactions away from the study site, you should get immediate medical care and then contact the study doctor.

Some people get severe pain in the shoulder and have difficulty moving the arm where a vaccine was given. This happens very rarely. As with any vaccine or medication, there is a very small chance of a fatal reaction, although researchers do not expect this to occur.

**Other potential risk**

There may be risks to you or your baby, discomforts, drug interactions or side effects that are not yet known. There may be other unknown risks to you or your baby that may be unforeseen. Study staff will update you in a timely way about any new information that may affect your decision to stay in the study.

Because e-mail and text messaging do not provide a completely secure and confidential means of communication, please let us know if you would prefer the study team to only communicate with you through regular channels like the telephone.

**WHAT ABOUT RESEARCH RELATED INJURIES?**

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians 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 Dr. Swamy at 919-681-5220 during regular business hours and at 919-970-6606 (pager) after hours and on weekends and holidays.



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**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

The benefits are expected to be the same as they would be if you were receiving flu vaccine as part of your usual prenatal care. There may be direct medical benefit to you and your baby, but this cannot be guaranteed. By participating in this study, you will receive the recommended Flu vaccination during your pregnancy. As with any licensed vaccine, protection may not occur in 100% of vaccinated persons. However, you may develop protective antibodies against the flu. Flu vaccine given during pregnancy has been shown to prevent flu in both mothers and their babies (up to 6 months of age). Information learned from this study may also help researchers learn more about the risk and benefits of flu vaccine during pregnancy.

**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.

This study is supported by the Centers for Disease Control and Prevention (CDC). Because of this support, your study information is protected by a Certificate of Confidentiality.

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.

Your records may be reviewed in order to meet federal or state regulations or local regulations. Reviewers may include representatives from the Duke University Health System Institutional Review Board, as well as the CDC and its affiliates, and the Food and Drug Administration (FDA) as appropriate. If one of these groups reviews your research record, they may also need to review your entire medical record. This information may be further disclosed by the sponsor of this study, the Centers for Disease Control and Prevention. If disclosed by the



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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.

Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share your and your baby's private information with anyone not involved in the study, the federal law designed to protect your child's 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.

The study results will be retained in your research record for at least six years after the end of the study. At the end of this retention period, either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

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

A description of this clinical study will be available on <http://www.ClinicalTrials.gov>. This Web site will not include information that can identify you. 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?**

You will receive the Flu vaccine at no cost. There are no additional costs to you associated with this study. However, you or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Swamy. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services. 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 you are participating in this study. Please ask Dr. Swamy if you would like to know more about which tests and studies are being done solely for research purposes. If your phone data plan includes charges for text messaging that you do not want to pay, discuss this with study staff.

**WHAT ABOUT COMPENSATION?**

All study participants will be compensated \$50 for randomization, \$25 after completing each blood draw visit, \$25 for completing each study phone call, \$25 after completing the memory aid, with a total of up to \$225 for all completed study visits. Subjects will only be compensated for successful completion of each study visit.

If an unscheduled visit is needed to assess any adverse reactions to the vaccine(s), you will receive an additional \$50 for completion of that visit.



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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 unless the data concerns an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your 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.

If you do decide to withdraw, we ask that you contact Dr. Swamy in writing and let her know that you are withdrawing from the study. Her mailing address is 2608 Erwin Road Suite 210 Durham, NC 27705. Once you withdraw consent, you can no longer take part in the study. You may also contact the study team to notify them of your decision to withdraw from the study by calling (919) 613-9630 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.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke including receiving the Flu vaccine outside of the study. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

The study doctor may decide to take you off this study if she determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include changes in medical practice, or problems with the study. If this occurs, you will be notified.

**CONSENT FOR STORAGE OF BLOOD AND FUTURE TESTING**

Your blood samples will be stored and labeled only by a unique study subject number and will not be labeled with any identifying information such as your name or initials. Samples will be kept confidential to the best of our ability within state and federal law. After all study tests are done, we would like to keep any remaining samples to use in possible future research studies. These studies may test for antibodies against other bacteria or viruses, markers of inflammation, or used in research on the health of mothers and infants. No human genetic tests will be performed on your samples. Your coded samples will be linked to the information (including personally identifiable information) that you have provided to this study.

You will not receive results of any future testing that is done on these samples. Your decision regarding future research will not affect your participation in this study.

If you agree to allow your blood to be kept for future research, you are free to change your mind at any time. We ask that you contact Dr. Swamy in writing and let her know you are withdrawing your permission for your blood to be used for future research. Her mailing address is 2608 Erwin Road Suite 210 Durham, NC 27705. You may also choose to contact the study team at (919) 613-9630 to inform them of your decision to withdraw your permission for your blood to be used for future research. At that time, we will ask you to indicate in writing if you want the unused blood destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.



## DUKE UNIVERSITY HEALTH SYSTEM

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**PLEASE INITIAL** your decision about permission for us to use your leftover samples for future research (indicate only ONE option):

\_\_\_\_\_ YES, I agree to allow my *coded* samples to be stored and tested in the future. My samples may be used in new or different laboratory tests, or for further research into vaccines. If I decide later to cancel my consent to storage and future testing, I will write a letter to the study doctor at the address listed on page 8 of this form.

\_\_\_\_\_ YES, I agree to allow my *de-identified* samples to be stored and tested in the future. My samples may be used to in new or different laboratory tests, or for further research into vaccines. I cannot decide to cancel my consent to storage and future testing because there will be no way to link me to my samples.

\_\_\_\_\_ No, I DO NOT agree to allow my samples to be stored and tested in the future. My decision will not affect my ability to participate in the study. My samples collected for this study will be destroyed at the end of this study.

### CONTACT FOR FUTURE STUDIES

We may want to contact you in the future to ask if you or your child would like to participate in other studies. If you agree, we would like to keep your name, address, phone number and email address on file. This information will be kept confidential and will not be shared with other research groups. If you agree to be contacted for a future study, you will be asked to sign a separate consent form for that study. Your decision regarding future research contact will not affect your participation in this study.

**PLEASE INITIAL** your decision about permission for us to use contact you for future research studies(indicate only ONE option):

\_\_\_\_\_ YES, I agree to be contacted for possible participation in future research studies.

\_\_\_\_\_ No, I DO NOT agree to be contacted for possible participation in future research studies.

### WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or if you have problems, concerns or suggestions about the research, contact Dr. Swamy at 919-681-5220 during regular business hours and at 919-970-6606 (pager) after hours and on weekends and holidays. The study team can also be reached by calling 919-613-9630 during regular business hours.

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.



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**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