# Randomized study of the immunogenicity and duration of antibody response against circulating SARS-CoV-2 variant and influenza viruses following concomitant versus sequential administration of mRNA COVID-19 vaccine and quadrivalent cell culture-based influenza vaccine among children and adults

**NCT: NCT06020118**

**05Oct2023**

Form
M0345

[Enter your institution's header here, if applicable]

**Consent to Participate in a Research Study**
**ADULT**

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***Version 2.0 05Oct2023***

**CONCISE SUMMARY**
This research study is designed to address key questions related to the prevention and control of influenza and COVID-19. The goal is to understand the amount of protection your body receives from flu and COVID-19 vaccines. We will give you two vaccines (Flucelvax [flu vaccine, ccIIV4] and Moderna mRNA COVID-19 vaccine), and you will be randomized to receive the vaccines either at the same time or 28 days apart, perform up to 6 blood draws, measure your height and weight, and look at your medical history, including your vaccination history. Both vaccines have been either approved or authorized by the Food and Drug Administration for safe use in humans and are regularly given to people in the United States each year. We will also ask you to respond to a weekly electronic survey about any acute respiratory symptoms you experience until May 2024 or your last follow-up visit, whichever occurs first. If you experience acute respiratory symptoms during the study, we may collect a nasal swab for testing.

If you agree to take part in this study, your involvement will last up until May 2024 or your last follow-up visit, whichever occurs first. The risks involved in this study include risks from a blood draw (mild discomfort or slight pain during blood draw) and risks from vaccination (soreness, redness, swelling, or pain where the shot was given, fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, fever, and feeling unwell). In rare cases, blood draw may cause bruising, prolonged bleeding, or infection at the site of the draw and fainting can occur in association with administration of injectable vaccines. You may be at risk of delayed vaccination and may be exposed to flu or COVID-19 before you are fully vaccinated.

If you agree to participate in this study, you will receive both a flu and COVID-19 vaccine, which can prevent flu and COVID-19 infection, respectively.

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

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 the 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 family and friends before you decide to take part in this

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research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

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

This study is being done by ***[SITE]***. ***[PI Name]*** will conduct the study and it is funded by the Centers for Disease Control and Prevention (CDC). The sponsor of this study, CDC, will pay [**insert Institution**] to perform this research, and these funds may reimburse part of [***PI Name's]*** salary.

**WHY IS THIS STUDY BEING DONE?**
The purpose of this research study is to learn more about flu and COVID-19. The researchers hope to learn the following:

- If getting the flu and COVID-19 vaccines at the same time or 28 days apart changes how your body's immune system responds to each vaccine,
- How the immune system responds to flu and COVID-19 infection, and
- How many people are getting sick with flu and COVID-19-like illnesses following vaccination.

To answer these questions, we will collect health information from adults and children agreeing to participate in this research study at ***[SITE]***.

**WHAT ARE INFLUENZA AND COVID-19?**
Influenza (also called *the flu*) is caused by a virus that can affect adults and children. Symptoms of the flu can include fever, cough, sore throat, runny or stuffy nose, muscle or body aches, headaches, tiredness, and an upset stomach. COVID-19 is a disease caused by a virus called SARS-CoV-2 that can affect adults and children. Symptoms of COVID-19 are similar to the flu. Most people don't get very sick from the flu or COVID-19 but sometimes they can lead to serious sickness, hospitalization, or even death. CDC recommends influenza and COVID-19 vaccines for everyone 6 months and older.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**
Approximately 800 people will take part in this study at 4 locations across the United States during this flu season. About 150-250 people will participate in this study at ***[SITE]*** during this flu season.

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## WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. You will first need to answer a few questions to make sure that you are eligible to participate:

### Interview

First, we will ask you some questions about your health and medical history, and if you got the seasonal flu vaccine and/or the COVID-19 vaccine in previous years. The interview should take about 10 minutes. We will record your answers in a secure electronic database. You may skip any question you don't want to answer and you may end the interview at any time.

### Height and Weight Measurement

Your height and weight will be obtained at one of the first three study visits.

### Blood draw

To help us understand how your body responds to flu and/or COVID-19 and whether you could have had flu and/or COVID-19 in the past, we need to collect a blood sample at 4 visits throughout the study (today, 28 days after enrollment, 56-120 days after enrollment, and 180 days after enrollment). If you develop influenza-like or COVID-19-like symptoms during the study, we may ask you to provide a nasal swab and 2 additional blood samples (3 weeks apart). It will take between 15–30 minutes for each visit and the blood sample will be collected by a needle from a vein in the arm (venipuncture). This blood draw will be performed by study personnel. We will collect up to 34 mL of blood from you at each visit. To minimize risk of prolonged bleeding and/or infection, we will swab the site of puncture with alcohol to disinfect the area, use a disposable needle, and apply pressure to the puncture site following sample collection to minimize bruising. We will cover the puncture with an appropriate dressing and provide you with information on how to monitor for signs of infection.

Even if you give permission now to participate in each blood draw, you can change your mind later and ask us to destroy your blood specimen. You will not receive results of research testing of your blood specimens. If you do not want to provide a blood specimen, you should not participate in this study.

### Flu and/or COVID-19 vaccination

After the blood draw today, we will randomly assign you to one of three vaccine groups (like drawing numbers from a hat):

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**Group #1:** You will receive both the flu (Flucelvax) and COVID-19 mRNA vaccines today (Visit 01)
**Group #2:** You will receive the flu (Flucelvax) vaccine today (Visit 01) and the COVID-19 mRNA vaccine in 28 days (Visit 02)
**Group #3:** You will receive the COVID-19 mRNA vaccine today (Visit 01) and the flu (Flucelvax) vaccine in 28 days (Visit 02)

For every four participants, two will be randomly assigned to vaccine group #1, one will be randomly assigned to group #2, and one to group #3. Once you have been randomized, we will administer the flu (Flucelvax) and/or COVID-19 mRNA vaccines. Both vaccines have been either approved or authorized by the Food and Drug Administration for safe use in humans and are regularly given to people in the United States each year. If you are randomized to receive both vaccines today, we will administer them in separate arms.

**Medical records**
We will look at your medical records including your vaccination records at ***[SITE]*** to learn more about your health and medical history (including HIV infection status, history of flu and COVID-19 infections and other chronic health conditions). We will review your medical records through the end of the flu season to look for possible flu and COVID-19 infections after vaccination. We will enter the information into a secure computer database.

**Post-vaccination Survey**
Three days after each vaccination visit, we will contact you via email or text message with a follow-up survey that will ask you questions about how you are feeling after receiving the vaccine(s) and if you have experienced any symptoms common to flu or COVID-19 illness such as coughing or sore throat. Your answers will be submitted directly into a secure electronic database. The survey should take about 5–10 minutes to complete.

**WEEKLY SURVEILLANCE**

**Weekly Survey**
We will contact you weekly via email or text message with a follow-up survey that will ask you questions about how you are feeling after receiving the vaccine(s) and if you have experienced any symptoms common to flu or COVID-19 illness such as coughing or sore throat. Your answers will be

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submitted directly into a secure electronic database. The survey should take about 2 minutes to complete. You will receive this survey for the remainder of the flu season (until May 2024) or your last follow-up visit, whichever occurs first.

If you agree to take part in this study, we will either send you automated text messages or emails throughout this study. In order to send text messages, we use a web-based system, called Twilio, which uses your phone number to send you messages. We plan to use this feature to send you text message survey reminders. As long as you agree and are a member of the study, we will contact you this way up to 45 times during the study. If you change your mind about the messages or if your contact phone number changes, please contact the study team. These messages are one-way only, so you cannot reply. If you have questions or concerns about information in a message, contact your study team. If you would like to stop receiving text messages, please call [(XXX-XXX-XXXX)].

**Flu and COVID-19 test**
If you report having respiratory symptoms during your weekly surveys, we may do a lab test to determine if you have the flu and/or COVID-19. We may provide one of the following for flu and/or COVID-19 testing:

- Clinical or research testing at ***[SITE]*** by placing a soft swab (like a Q-tip) in your nose.
- Clinical or research testing at ***[SITE]*** by placing a soft swab (like a Q-tip) in your throat.
- Self-collected nasal swab by placing a soft swab (like a Q-tip) in your nose that you send to/drop off at ***[SITE]*** for clinical or research testing.
- Self-collected throat swab by placing a soft swab (like a Q-tip) in your throat that you send to/drop off at ***[SITE]*** for clinical or research testing.
- At-home testing via a testing kit provided to you to complete at your home and report results to study staff.

**Final steps**
During the study, researchers at ***[SITE]*** will combine your information from the questions, medical records, vaccine records, and weekly surveys with information from other people in the study and enter it into a research database maintained at the Networking Coordinating Center (NCC). After we remove personal health information that could identify you, such as your name and contact information, the data will be shared with CDC and investigators at the other study sites for analysis.

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**SPECIMEN STORAGE FOR FUTURE USE**
Your specimens may be stored for future testing to discover new ways to identify causes of illness. We will keep your blood and respiratory samples for future analyses of SARS-CoV-2, influenza, and other respiratory viruses and bacteria. We will create a repository for your specimens and data that other researchers can use to study respiratory infections. Your specimens will be identified with only a unique study code. However, this code will be linked to identifying information held at **[SITE]** or at Duke, which manages the secure database where some identifying information is held for the study. Your specimens will never be sold or used directly to produce commercial products. No human genetic tests will be performed on your samples. Researchers will only be allowed to use your data and specimens if their research is approved by the lead study investigator and if they receive approval from an institutional review board.

**HOW LONG WILL I BE IN THIS STUDY?**
Your participation in this study will last until May 2024 or 180 days after your first vaccination visit, whichever comes first. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. Clinically relevant results of this research will be communicated with you for any result of FDA-approved laboratory tests used for study purposes, including those from SARS-CoV-2 or influenza positive tests. Results of tests done for measuring immunity or other research test results will not be returned to you.

**WHAT ARE THE RISKS OF THE STUDY?**
You may experience one or more of the risks indicated below from being in this study. The potential risks of participating in this study are those related with having blood drawn, having respiratory swabs collected, and receiving flu or COVID-19 vaccines.

**Risks Related to Vaccination**
Flucelvax risks include minor problems such as soreness, redness, swelling, or pain where the shot was given, hoarseness, sore, red or itchy eyes, cough, fever, aches, headache, itching, fatigue, all of which usually occur within 1-2 days of vaccination and are self-limiting. More serious problems including a small increased risk of Guillain-Barré Syndrome can occur, although rarely.

Side effects that have been reported with mRNA COVID-19 vaccines include both injection site reactions as well as general side effects. Injection site reactions include: pain, tenderness, and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness at the injection site. General side effects include: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting,

fever and feeling unwell. Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received mRNA COVID-19 vaccine. In most of these people, symptoms began within a few days following vaccination. The chance of having this occur is very low. You should seek medical attention right away if you have chest pain, shortness of breath or difficulty breathing, or feelings of having a fast-beating, fluttering, or pounding heart.

After any vaccine, you may get severe pain in the shoulder and have difficulty moving the arm where a shot was given. Syncope (fainting) can occur in association with administration of injectable vaccines. Sitting or lying down when space is available for about 15 minutes can help prevent fainting, and injuries caused by a fall, as recommended in the ACIP General Recommendations on Immunization. You should inform your doctor if you feel dizzy or have vision changes or ringing in the ears.
There is a small possibility that either an mRNA vaccine or a flu vaccine could cause a severe allergic reaction occurring shortly after getting a dose of vaccine. Occasionally, people have allergic reactions to vaccines which may require medical treatment. A severe allergic reaction could be life-threatening. Examples of an allergic reaction include: a rash; shortness of breath; wheezing; difficulty breathing; sudden drop in blood pressure; swelling around the mouth, throat, or eye; fast pulse; and sweating. You should get immediate medical help and contact the study doctor if you have any of these or any other side effects during the study. Medicines are immediately available to treat such an allergic reaction should you have one.

You may be at risk of delayed vaccination if randomized to groups 2 and 3 (sequential vaccination, 28 days apart) and may be exposed to flu or COVID-19 before you are fully vaccinated. You may receive your second vaccine earlier if risk of flu or COVID-19 is high based on local surveillance.

**Risks Related to Obtaining Respiratory Samples (Nasal Swabs and Throat Swabs)**
Getting respiratory samples may cause some discomfort. There may be brief soreness while the nose and throat swab are being taken. Obtaining a nasal swab can cause you to sneeze, have watery eyes, or cough at the time of collection. Once in a while, a small nosebleed may occur. If this should happen, we will treat it right away. Swabbing the throat may cause you to gag.

**Risks of Drawing Blood:**
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.

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**Risks of Allowing Twilio to be Used for Text Message Reminders:**
Many companies and applications on your smartphone commonly work with text platforms and cloud-based companies to send and receive information. We use Twilio to send you text messages. Text messaging does not provide a completely secure and confidential means of communication, and the messages are unencrypted. Twilio does encrypt your information on their servers, but no system is completely safe. If they decide to share these data, it may no longer be covered under the privacy protections. Information that identifies you, such as your phone number, may be sent to and permanently kept by Twilio and their business associates. Information disclosed to these companies or their business partners, may no longer be covered under the privacy protections. Because text messaging does not provide a completely secure and confidential means of communication, if you wish to keep your communication completely private, please let us know and we will communicate with you only through regular channels like the telephone or email.

**Risks of Loss of Privacy:**
There is also the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed.

**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**
You will receive both a flu and COVID-19 vaccine which can prevent flu and COVID-19 infection, respectively. You may also be provided with flu and COVID-19 testing throughout the flu season. We hope that in the future the information learned from this study will benefit other people needing flu and COVID-19 vaccination.

**WILL MY INFORMATION BE KEPT CONFIDENTIAL?**
CDC and ***[SITE]*** are committed to protecting your personal health information (like your name and medical history) and the risk of disclosure is minimal. We cannot guarantee absolute confidentiality.

To protect your confidentiality, we will use a number instead of your name on all forms and we will store your data in password protected files located on secure computers. The risk of loss of confidentiality/disclosure is minimal. Any information that could identify you will be destroyed when the study is finished. If information from this study is shown publicly or published in a journal, you will not be mentioned by name, picture, or in any other way that could identify you.

If you complete an online survey, it is possible, although unlikely, that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person's everyday use of the

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Internet. If you complete and submit an anonymous survey and later request your data be withdrawn, this may or may not be possible as the researcher may be unable to extract anonymous data from the database.

The researchers in this study will be looking at your personal health information and will need to disclose it to CDC for the purposes of lab testing, data analysis, and preparing articles for publication. We will not disclose any information that could identify you, such as your name, contact information, or health record number. Your personal information collected for this research will be kept as long as it is needed to conduct this research. Once your participation in the research is over, your information will be stored in accordance with applicable policies and regulations. Your permission to use your personal data will not expire unless you withdraw it in writing. You may withdraw or take away your permission to use and disclose your information at any time. You do this by sending written notice to the Principal Investigator at the following address: ***[SITE ADDRESS]***. If you have concerns about the use or storage of your personal information, you have a right to lodge a complaint with the data supervisory authority in your country.

A copy of this consent form will be placed in your medical record. The results of the tests performed for this study will not be placed in your medical record and will not be shared with your health care provider. Because of this, it is unlikely that others within the clinic, an insurance company, or an employer will ever learn of such results.

This research project has a Certificate of Confidentiality from CDC. Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena. There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the

research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.

The Certificate of Confidentiality will not be used to stop reporting as required by federal, state, or local law such as child abuse and neglect, or harm to self or others, communicable disease reporting.

The Certificate of Confidentiality will not be used to stop sharing your information for any purpose you have consented to in this informed consent document, such as including research data in the medical record.

**HOW DOES HIPAA APPLY TO THIS STUDY?**
Your health information is protected by a federal privacy law called HIPAA. Our institution must follow this privacy law. According to HIPAA, the information collected by the researchers for this study is part of that protected health information (PHI). By giving your written consent to participate in this study, you are giving us your permission to allow researchers to collect, use and share the following information with the CDC and our research collaborators:

1. Your answers to the questionnaires
2. Your medical record information as described to you above.
3. Your specimens and results from the laboratory tests.

With the exception of the NCC, when we share this study information with outside researchers, no names, medical record ID numbers, or patient contact information (address, phone, email) will be included. All study information will be identified only by a unique study code. We have agreements in place with all our research partners that require them to keep research information private. It is possible that staff, the CDC, or the FDA may look at our records for study oversight. We will not share information we collect with anyone else except as required by law. The HIPAA privacy law does not always apply to those who are given PHI. Once we have given out PHI, the person who receives it may re-disclose it. Privacy laws may no longer protect the information. This permission for the researchers to obtain your health information for this study ends on July 31st, 2028, when we will destroy any records that include your name or other identifying information.

**WHAT ARE THE COSTS TO YOU?**
There is no cost to you for taking part in this study; The study sponsor CDC has agreed to pay for services and procedures that are done solely for research purposes.

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**WHAT ABOUT COMPENSATION?**
You will be compensated up to **$[ ]** for your participation in the study. ***[INSERT SITE SPECIFIC COMPENSATION SCHEME]***

***[IF APPLICABLE AT SITE]*** To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not tell them what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

**WHAT ABOUT RESEARCH RELATED INJURIES?**
Immediate necessary medical care is available at ***[SITE]*** in the event that you are injured as a result of your participation in this research study. However, there is no commitment by ***[SITE]*** to provide monetary compensation or free medical care to you in the event of a study-related injury.

**WHAT IF NEW INFORMATION BECOMES AVAILABLE ABOUT THE STUDY?**
During the course of this study, we may find more information that could be important to you. We will notify you as soon as possible if such information becomes available. The study team/study will not cover the costs of any follow-up consultations or actions.

**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 concern 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.

This study is completely voluntary. 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 ***[SITE]***. If you do decide to withdraw, we ask that you notify the study team as soon as you can. ***[PROVIDE STUDY TEAM CONTACT INFORMATION]***

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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 you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact ***[PI's Name]*** at [***PI's Number with Area Code]*** during regular business hours and at [***PI's 24-hour Number with Area Code]*** 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."

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