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Consent to Participate in a Research Study
ADULT

Measuring Immunity Against Circulating Influenza Viruses: Randomized Immunogenicity Study Among US Adults Aged 18-64 Years Comparing Two Approved Influenza Vaccines

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KEY INFORMATION SUMMARY

This research study is designed to address key questions related to the prevention and control of influenza. The goal is to understand the amount of protection your body receives from flu vaccines. We will give you one flu vaccine (Flucelvax [ccIIV], Flublok [RIV], or Fluzone [IIV]) at the first visit, perform up to 5 blood draws, and look at your medical history, including your vaccination history. These flu vaccines have been approved 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 2025 or your last follow-up visit, whichever occurs first. If you experience acute respiratory symptoms during the study, we may collect a nasal or throat swab or provide an at-home test for testing.

If you agree to take part in this study, your involvement will last up until May 2025 or your last follow-up visit, whichever occurs first. The risks involved in this study are minimal. These include risks from a blood draw (mild discomfort or slight pain during blood draw), 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), and risks from a nasal or throat swab (soreness, sneezing, watery eyes, cough, gagging, or a nosebleed). 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.

If you agree to participate in this study, you will receive a flu vaccine, which can prevent the flu.

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

Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about 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 and will be reviewed with you by the study team.

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

[PI Name] will conduct the study. The study is funded by the Centers for Disease Control and Prevention (CDC), who will pay ***[SITE]*** to perform this research. 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. The researchers hope to learn the following:

- How the immune system responds to the flu vaccine,
- How the immune system responds to flu infection, and
- How many people are getting sick with flu following vaccination.

To answer these questions, we will collect health information from adults agreeing to participate in this research study at ***[SITE]***. We will also give them a flu vaccine which has been FDA approved. This will involve giving either the Flucelvax vaccine or one of two other flu vaccines: Flublok or Fluzone.

Approximately 150 people will take part in this study at ***[SITE]*** during the flu season and about 600 people will take part in total from five participating sites across the United States.

WHAT IS INFLUENZA?
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. Most people don't get very sick from the flu, but it sometimes can lead to serious

sickness, hospitalization, or even death. CDC recommends influenza vaccination for everyone 6 months and older.

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.

Blood draw
To help us understand how your body responds to flu and whether you could have had flu in the past, we need to collect a blood sample at 3 visits throughout the study (today, 28 days after enrollment, and 180 days after enrollment). If you develop influenza-like symptoms during the study, we may ask you to provide a nasal or throat 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 44 mL (approximately 9 teaspoons) 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 vaccination
We will randomly assign you to one of two vaccine groups (like a flip of the coin), with a 50% chance to receive one of the following flu vaccines:

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1. You will receive the Flucelvax vaccine today (Visit 01) or
2. You will receive a comparator flu vaccine today (Flublok or Fluzone, Visit 01)

Once you have been randomized and after the blood draw, we will administer the flu vaccine. All study vaccines have been approved by the Food and Drug Administration for safe use in humans and are regularly given to people in the United States each year.

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 history of flu infections and other chronic health conditions including HIV infection status). We will review your medical records through the end of the flu season to look for possible flu infections after vaccination. We will enter the information into a secure computer database.

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 if you have experienced any symptoms common to flu-like illness such as coughing or sore throat. Your answers will be 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 2025) 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 26 times during the study. If you do not respond to the survey you may receive up to 3 additional reminders per survey. 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)].

Testing

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 or throat.
- Self-collected nasal or throat swab by placing a soft swab (like a Q-tip) in your nose or throat that you send to/drop off at ***[SITE]*** for clinical or research testing.

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) at Duke University. 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.

Will I be given research results that may affect my medical care?

Clinically relevant results of this research will be communicated with you ***[SITE to insert if applicable]***

How long will I be in this study?

Your participation in this study will last until May 2025 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.

You can stop participating at any time without penalty. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

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What are the risks of the study?
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

Risks Related to Vaccination: may cause some, all or none of the side effects listed below.

More likely

- soreness, redness, or swelling where the shot was given
- hoarseness
- sore, red or itchy eyes
- cough, fever, aches, headache, itching, fatigue

These usually occur within 1-2 days of vaccination and are self-limiting.

Less Likely

- syncope (fainting) can occur in association with administration of injectable vaccines. If you feel dizzy or have vision changes or ringing in the ears, you should inform your doctor
- severe pain in the shoulder and difficulty moving arm
- a small increased risk of Guillain-Barré Syndrome can occur, although rarely
- a severe allergic reaction occurring shortly after getting a dose of vaccine. Medicines are immediately available to treat such an allergic reaction should you have one.

Risks of Drawing Blood:
The risks of drawing blood include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

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 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. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

Are there benefits to taking part in the study?
If you agree to take part in this study, there may be direct medical benefit to you. You will receive a flu vaccine which can prevent flu infection. You may also be provided with flu testing throughout the flu season.

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. 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. 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. 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 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. Your personal information may also be given out if required by law.

As part of the study, results of any study-related tests or procedures may be shared with CDC and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include:

- representatives from the Food and Drug Administration,
- representatives and affiliates of CDC,
- the Duke University Health System Institutional Review Board,
- ***[SITE IRB]***,
- Other participating study sites

If any of these groups review your research record, they may also need to review your entire medical record.

All of the procedures (blood draw, nasal swab, throat swab, and vaccination) are being done only because you are in this study. The study results will not be provided to you OR sent to your personal healthcare provider.

The study results will be retained in your research record for at least six years after the study is completed. At that time, either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at ***[SITE]***. Any research information in your medical record will be kept indefinitely.

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This information may be further disclosed by the sponsor of this study or to outside reviewers for audit purposes. If disclosed by the sponsor or outside reviewers, the information is no longer 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 ***[SITE]***, we cannot guarantee that it will remain confidential. If you decide to share your 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.

The Centers for Disease Control (CDC) has issued a Certificate of Confidentiality (CoC) for this study. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings, like a court order.
There are some important things that you need to know about the CoC:

It DOES NOT stop reporting required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

It CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs, including when the Food and Drug Administration (FDA) requires it.

It DOES NOT prevent your information from being used for other research if allowed by federal law.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers,

medical providers or any other people not connected with the study. The CoC does not stop you from willingly releasing information about your involvement in this study. It also does not prevent you from having access to your own information.

Will it cost me anything to be in the study?
There is no cost to you for taking part in this study.

The study sponsor (CDC) has agreed to pay for study activities and procedures that are done only because you are in this study. Please talk with your study doctor/study team about the specific procedures that the sponsor will pay for, and the ones for which you or your insurance will be responsible.

CDC will provide the study vaccination free of charge to you.

Will I be paid to be in the study?
You will receive up to $( ) for your expenses related to your participation (parking, gas, and time). You will only be paid for the visits you complete. In order to issue your payment, ***[SITE]*** may need to collect your name, mailing address, and social security number for tax reporting purposes. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.

What about research related injuries?
[Insert site-specific RRIL here]

- For questions about the study or research-related injury, 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.

What if I want to withdraw from the study?
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.*

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

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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 contact Dr. ***[PI Name]*** in writing and let them know that you are withdrawing from the study. Their address is ***[SITE mailing/email address]***.

Dr. ***[PI Name]*** may decide to take you off this study if it is determined that it is no longer in your best interest to continue. Reasons why this might occur include that you are unable to return for follow-up blood draw visits, if not enough blood is able to be collected, or if you develop a new health condition that arises that prevents future participation. If you withdraw (or are withdrawn) from this study, the data, blood, respiratory, and saliva samples collected before the date of withdrawal may still be used and shared with other researchers and CDC. The sponsor or regulatory agencies may stop this study at any time. If this occurs, you will be notified and ***[PI Name]*** will discuss other options with you.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Specimen Storage for Future Use:
By agreeing to participate in this study, your samples will be stored for potential future use. If you do not want your samples to be used in future research, you should not sign this consent form.

Your blood, saliva, and respiratory specimens will be stored for future analyses to further study illness caused by 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 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.

Your blood, saliva, and respiratory samples will be kept for future research with identifying information that could link your sample to you. You are free to change your mind at any time. We ask that you contact Dr. ***[PI Name]*** in writing and let

them know you are withdrawing your permission for your identifiable samples to be used for future research. Their address is ***[insert whichever appropriate, mailing/email address, MyChart]***. At that time, we will ask you to indicate in writing if you want the unused identifiable samples destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.

Your samples and data may be stored and shared for additional future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

A description of this clinical trial will be available on https://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 should 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 Dr. ***[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.

You can call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have question about your rights as a research participant
- You wish to discuss problems related to the research
- You have any concerns or suggestions related to the research

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

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- **Want to obtain information or offer input about the research**

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