IRB APPROVED
AS MODIFIED
Sep 11, 2025

RESEARCH PARTICIPANT CONSENT FORM

TITLE:	A Phase 3/3b, Randomized, Observer-blind, Multicenter Clinical Study to Evaluate the Efficacy, Safety and Immunogenicity of Fluad and Fluad Quadrivalent Compared to a Non-adjuvanted Influenza Vaccine in Adults ≥65 Years of Age
PROTOCOL NO.:	V118_24 WCG IRB Protocol #20252087
SPONSOR:	Seqirus UK Limited
INVESTIGATOR:	Awawu E. Igbinadolor, MD 343 Venus Street Monroe, North Carolina 28112 United States
STUDY-RELATED PHONE NUMBER(S):	704-283-7359 (24 hours)

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you agree to take part in this study, you will be asked to sign this consent form. By signing this form, you will not be giving up any legal rights to which you are entitled as a participant in a research study.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

How long will I be in this research?

We expect that your taking part in this research will last approximately 6-8 months.

Why is this research being done?

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This research study is being conducted to learn more about the safety, immune response, and efficacy (protective effect) the study vaccine has on older adults.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, you will be asked to visit the clinic 3 times, receive either the study vaccine or comparator vaccine, provide a nasal swab, and will receive 1 follow-up telephone call during the entire study period.

Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include pain at the injection site, fatigue, and headache. A full list of side effects is located later in this document

Will being in this research benefit me?

The most important benefits that you may expect from taking part in this research is that you may be protected against the Flu, a highly contagious (infectious) disease caused by a virus, or you may have an improved ability to fight against this season's Flu. However, there may not be a direct medical benefit to you as a result of taking part in this study. The information collected may benefit others in the future.

What other choices do I have besides taking part in this research?

Other vaccines against the Flu are available. You should discuss with the study doctor other options that may be right for you.

What else should I know about this research?

Other information that may be important for you to consider so you can decide whether to take part in this research is:

There is a possibility that your deidentified information or biospecimens may be used or distributed for future research studies without your additional informed consent.

DETAILED RESEARCH CONSENT

You are being invited to take part in a medical research study sponsored by Seqirus UK Limited, a CSL company (hereinafter "Seqirus" or "Sponsor") investigating a vaccine for the prevention against influenza (also called the 'Flu'). A person who takes part in a research study is called a research participant.

Before making your decision to be part of this study, please take your time to read this information sheet carefully. If there is anything in this information sheet that you do not understand, please ask the study doctor or study staff for clarifications.

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Why is this research being done?

This study is being conducted to learn more about the safety, immune response, and efficacy (protective effect) the investigational MF59-Adjuvanted Vaccine has on older adults.

A vaccine (also known as a "vaccination" or "shot") is a type of medicine that helps protect you against getting a specific disease. For the season in which you are participating, trivalent flu vaccines (aTIV/TIV) will be used. A trivalent study flu vaccine contains 2 inactivated (killed) influenza A types and 1 influenza B type.

Immune response refers to your body's defense system producing substances (antibodies) to fight off germs after you have been in contact with them. Germs are microorganisms like bacteria, viruses and parasites that can cause diseases.

The aim of this research study is to understand if and how well the study vaccine helps to produce antibodies that specifically recognize and fight off germs causing the Flu. This will be done by measuring the antibody levels and will be assessed outside USA, in countries that are selected to participate in this research.

Efficacy refers to studies that show how well a vaccine works by comparing how many people develop the disease or signs of the disease after receiving the study vaccine to people who did not get the study vaccine or who receive a different flu vaccine.

Influenza, commonly called the Flu, is a highly contagious (infectious) disease caused by a virus. Influenza is a major health concern and is one of the leading causes of death in the world. The flu virus causes disease in all age groups, but causes more serious illnesses in children, older adults (over 65 years of age) and people of any age with chronic medical conditions or with a weakened body's defense system.

It has been recognized that older adults are at greater risk of serious complications from the Flu, such as lung and heart diseases, compared with young, healthy adults. This is because human immune defenses become weaker with age. So, influenza can be a very serious disease for older adults.

Vaccination is the most common way to prevent influenza disease and its complications. A vaccine is a type of medicine which is designed to "fool the immune system" to respond as if you were exposed to the influenza virus without giving you the actual disease. It should protect you against diseases caused by a live influenza virus later on.

Among older adults, the flu vaccine may be less effective. One possible explanation may be a weaker body's defense system compared with younger adults. One way to make the immune response to the vaccine stronger is by adding a substance to the vaccine; this substance is called an "adjuvant".

There are two flu vaccines used in this study and you will receive one of them. There is a study flu vaccine called adjuvanted inactivated influenza vaccine and a control flu vaccine which does not contain the adjuvant.

The study started in 2023 and participants received either the study flu vaccine or the control flu vaccine, containing 4 inactivated (killed) types of the flu virus: 2 influenza A types and 2 influenza B types. Because the vaccines contain 4 inactivated types of the flu virus, they are referred to as "quadrivalent" inactivated influenza vaccines.

In 2024, the World Health Organization (WHO) recommended flu vaccines, containing 3 inactivated types of the flu virus be used, referred to as "trivalent" inactivated influenza vaccines, because one of the influenza B type viruses is no longer circulating within the flu seasons.

Because the study is being conduct over multiple flu seasons, study participants receive either quadrivalent or trivalent formulations of the influenza vaccines.

For the season in which you are participating, trivalent flu vaccines (aTIV/TIV) will be used.

For the 2025-2026 influenza season, you will receive a trivalent influenza vaccine.

aTIV (Fluad) is a Seqirus adjuvanted trivalent flu vaccine that is approved for use in your country. The vaccine has been developed to prevent infection from the flu virus. It contains 3 inactivated (killed) types of the flu virus; 2 influenza A types and 1 influenza B type, and it contains an "adjuvant" named MF59®. The adjuvant is added to make your immune response to the vaccine stronger. MF59® has been tested in various research studies and is used in flu vaccines licensed for elderly in many countries worldwide. The quadrivalent and trivalent adjuvanted influenza vaccines have been given to over 310 million people 65 years of age and older.

TIV (Fluarix) is the control vaccine. In this study, the group that is not assigned to the adjuvanted flu vaccine, will receive TIV that contains 3 inactivated (killed) types of the flu virus; 2 influenza A types and 1 influenza B types (so also "trivalent"), but it does not contain an "adjuvant". This trivalent vaccine is approved for use in the United States.

Approximately 35,800 participants of 65 years of age and older in approximately 25 countries will take part in this study.

How long will I be in this research?

We expect that your participation in this research will last approximately 6-8 months, and will involve 3 clinic visits and 1 follow-up telephone call during the entire study period.

What happens to me if I agree to take part in this research?

Study Methods and Study Procedures

This is a randomized, observer-blind, flu vaccine controlled, multicenter clinical study. The full study will be conducted over more than one influenza season.

Randomized: means you will be assigned by chance (like flipping of a coin) to receive either the study vaccine or the control vaccine. (e.g., 50% chance of receiving either the study vaccine or the control vaccine). Assignment to one of these groups is done by a computer. Neither you nor the study doctor can choose what group you will be assigned. During the research, you (or you and the study doctor) will not know which group you are in. (Your study doctor can find out in case of an emergency).

Control: means a shot that is given that may protect against the flu but does not have "adjuvant".

Observer-blind: means that neither the person getting the vaccine, nor the study doctor will know which of the two vaccines is given. Only the person who will give the injection will know which vaccine was given. However, the study doctor will be able to find out this information if needed in an emergency.

Influenza Season: means the recurring time period each year, usually during the cold or wet months, when flu viruses cause outbreaks of illness or disease.

Older adults that meet the requirements and volunteer to participate in the study, will be assigned by chance to receive one dose of the study flu vaccine or one dose of the control vaccine at the start of the study. Approximately half of the participants will receive the study flu vaccine and the other half the control flu vaccine.

You will be asked to contact your study physician immediately if you experience flu-like respiratory symptoms with sore throat, cough, production of phlegm or mucus in the lungs, wheezing or difficulty breathing, concurrent with one or more of the following: temperature of more than 99◦F, chills, tiredness, headaches, or muscle pain. The study physician will schedule a clinic or home visit with you, during which a sample from your nose (nasopharyngeal swab) will be collected. In addition, you will be asked to start filling out the influenza-like illness (ILI) e-booklet. You will also have a follow-up visit approximately 14 days after your nasal swab sample was collected to see how you are doing.

Handling of Samples Left Over After the Study

Future Use of Samples Related to the Purpose of this Study:

If samples (nasal swabs) are left over after testing, these may be stored in a freezer at a global Seqirus or Seqirus contracted facility for up to fifteen (15) years, for purposes limited to additional analyses related to this study that Seqirus may need to conduct at Seqirus or other companies working for Seqirus in the future to further understand the body's response to the vaccine or to the disease (Flu) or to further understand other pathogens causing infection/disease.

Future Use of Samples Not Related to the Purpose of this Study:
We ask for your consent to your leftover samples being used for future research not related to this study. The future use of your samples may result in new discoveries that are important to the understanding of the vaccine(s) or disease. However, the results of these additional research studies will not be shared with you.

The leftover samples that are stored will not be used for genetic testing.

If you decide to be part of this study but do not agree to your leftover samples being used for future research not related to this study, please indicate this on the consent form.

What are my responsibilities if I take part in this research?

If you volunteer to participate in the study, you agree to:

- receive study flu vaccine (aTIV) or control flu vaccine (TIV)
- not have any plans to receive another vaccine to prevent the Flu until you have completed participation in this study
- travel to the clinic for the scheduled visits (or be available for home visits) and be available for the planned telephone call
- have a nasopharyngeal (back of the nose) sample collected from you preferably within 48 hours of the onset of flu-like symptoms
- respond to weekly phone messages designed to remind you of reporting symptoms that you are requested to report
- complete the electronic flu-like illness booklet in the event that you experience flu-like symptoms
- follow the study doctor's and study staff's directions and instructions
- tell the study doctor and study staff about any changes in your health
- tell the study doctor about any medicines and other vaccines taken during the study, and
- allow the study doctor to perform some tests to assess your health for participation in the research study.

If the study doctor is not your regular doctor, you and/or the study doctor can inform your primary physician of your study participation unless you do not wish to do so. Later in this document, you will be asked to confirm your decision as to whether you agree or do not agree to inform your primary physician.

In addition, you will receive a message on a smartphone device every week to remind you to contact the study doctor as soon as possible if you are experiencing any flu-like symptoms until approximately 6 months after vaccination or until the end of the flu season, whichever is longer. In case you experience flu-like symptoms, you will have 2 extra clinic visits for every occurrence of a flu-like illness.

In exceptional circumstances, such as a public health emergency, declaration of a pandemic, natural disasters and/or in other special cases, where visits at the clinic may not be possible, the site staff may ask to come to your home to perform the physical examination and draw blood or perform other study assessments. You will be notified by the study staff if this is the case and you will be informed on how the home visit will be conducted.

A list of all activities that will be performed during the study is presented in the **Attachment 1** to this document.

As the study is to be conducted over multiple influenza seasons, completion of the entire study may be longer than your participation by one or more years.

Could being in this research hurt me?

There are possible risks or side effects listed below that you might experience from participating in this study. Also, there may be other risks and side effects that are not yet known.

All risks and side effects will be monitored throughout the study. For this reason, please contact the study doctor immediately if you think you are having side effects or experiencing a change in your health condition.

Study Flu Vaccine Related Risks:

The following side effects are *very commonly* reported (more than 1 out of every 10 people):

- pain at the injection site,
- fatigue, and
- headache.

Common side effects (more than 1 out of every 100 people but less than 1 out of every 10 people) include:

- loss of appetite,
- diarrhea,
- nausea,
- joint pain,
- muscle pain,
- redness at the injection site,
- hardening of the skin at the injection site,
- bruising at the injection site, and
- shivering.

Most of these side effects are mild or moderate and last for 3 days or less.

With any medicine, including vaccines, there is a chance of getting reactions. These are usually mild and go away on their own, but serious reactions are also possible. Most people who get a flu shot do not have any problems with it. The following adverse events have been reported by consumers who received an MF59® adjuvanted trivalent or quadrivalent flu vaccines. Because these events are reported outside of a clinical trial, it is not possible to reliably estimate their frequency or establish if the events that occurred were caused by taking the vaccine:

- reduction in the number of certain types of particles in the blood called platelets; a low number of these can result in excessive bruising or bleeding; swelling of the glands in the neck, armpit or groin
- influenza-like illness (ILI)
- swelling, pain and redness at the injection site extending to more than 4 inches (10 cm) and lasting more than one week
- extensive swelling of injected limb lasting more than one week
- allergic reactions:
    - sudden fall in blood pressure that in rare cases can lead to failure of the circulatory system to maintain adequate blood flow to the different organs (shock)
    - swelling, most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body
- pain in the extremity, muscular weakness
- pain situated on the nerve route, anomalies in the perception of touch, pain, heat and cold, fits, fainting, feeling faint, neurological disorders that may result in stiff neck, confusion, numbness, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of part or all the body
- skin reactions that may spread throughout the body including itchiness of the skin, rash
- severe skin rash
- blood vessel inflammation which may result in skin rashes and in very rare cases in temporary kidney problems

As for all vaccines, severe allergic reactions may occur. These kinds of reactions are usually rare, however can be life-threatening. Medications are available at the clinical study site in order to treat the possible allergic reactions.

MF59® (adjuvant) Related Risks: This vaccine contains an adjuvant called MF59®. An adjuvant is a substance which may make your immune response to the vaccine stronger. Rarely, adults and children who have received vaccines with MF59 or a related adjuvant have developed illnesses called autoimmune diseases. However, adults and children who did not receive vaccines or have received vaccines without MF59 adjuvant may also develop autoimmune diseases. These diseases develop when immune cells, that normally protect you from illness, attack your own organs instead. Autoimmune diseases can be serious and can also be lifelong. They can involve your liver, kidneys, skin, joints, eyes, and brain, as well as other parts of the body. Since no one knows for sure whether this adjuvant causes autoimmune diseases, Seqirus monitors the safety of MF59 continuously.

Control Flu Vaccine Related Risks: The following side effects are very commonly reported (more than 1 out of every 10 people):

- pain at the injection site,
- fatigue, and
- muscle pain.

Common side effects (more than 1 out of every 100 people but less than 1 out of every 10 people):

- headache,
- nausea,
- vomiting,
- diarrhea,
- abdominal pain,
- sweating,
- joint ache,
- injection site redness,
- injection site swelling,
- shivering,
- fever, and
- injection site hardness.

The following side effects occurred occasionally during general use of Fluarix and/or Fluarix Quadrivalent:

- allergic reactions:
    - leading to medical emergency with a failure of the circulatory system to maintain adequate blood flow to the different organs (shock) in rare cases;
    - swelling most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body (angioedema) in very rare cases;
- skin reactions that may spread throughout the body including itchiness (pruritus, urticaria) and redness (erythema) of the skin;
- neurological disorders that may result in stiff neck, confusion, numbness, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of part or all the body (encephalomyelitis, neuritis, Guillain-Barré syndrome);
- temporary swelling of the glands in the neck, armpit or groin (transient lymphadenopathy);
- flu-like symptoms, generally feeling unwell (malaise).

Further details on the control vaccine can be found in the most recent Patient Information Leaflet for Fluarix.

Guillain-Barré Syndrome is a progressive weakness starting in the limbs and moving up the body. It is a condition that has been reported after infectious illnesses and also rarely after receiving vaccines, including influenza vaccines. If you have ever been diagnosed with this disease or other demyelinating disease you should let the study doctor know immediately and you will not be able to take part in this study.

If you have had allergic reactions in the past after vaccinations, or you are allergic to eggs or egg products, chicken feathers, influenza viral protein, neomycin, or polymyxin you must tell the study doctor or site staff and you will not be able to take part in this study.

Risks Related to Swab Sample Collection: A swab sample from the upper portion of your nose will be taken if you have flu-like symptoms. Although the chance is small, there is a possibility that you may experience a nose bleed as a result of swab sample collection via the nose

Other Risks:
Any visit to a clinic or a hospital has the risk of potential exposure to you, which may result in a clinic or hospital-acquired infection. The site will follow local requirements to ensure that infection control measures are in place to minimize this risk.

Will it cost me money to take part in this research?

There is no cost involved to participate in this study. There will be no cost to you for the visits or supplies.

You will receive the study flu vaccine or the control flu vaccine at no cost (provided by the sponsor).

Will being in this research benefit me?

There may not be a direct medical benefit to you as a result of taking part in this study, however you may be protected against the Flu or you may have an improved ability to fight against this season's Flu.

In addition, data from this study may help to determine whether the vaccine that is being studied (aTIV) is effective and safe for older adults which may benefit others in the future.

What other choices do I have besides taking part in this research?

Taking part in this study is voluntary. You are free to refuse or discontinue your participation in the study without giving any reason at any time. Your decision not to participate or to stop taking part will not affect the care that you would normally receive from your doctor.

What other options do I have if I do not join this study: Other vaccines against the Flu are available. You should discuss with the study doctor other options that may be right for you.

If you agree to take part in this study, you will be asked to sign this consent form. By signing this form, you will not be giving up any legal rights to which you are entitled as a participant in a research study.

If you agree to participate in this study, you should not receive a flu vaccine this year outside of this study. There is medication available to treat the Flu if you experience flu-like symptoms. If you do become sick with the Flu during this study inform your study doctor immediately so your doctor can use these medications to treat you.

Study procedures will only be performed after you have signed this informed consent form.

A copy of the signed and dated informed consent form will be given to you to keep.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor. Sponsor may share study data with other companies within its group, with its service providers, its contractors, with researchers and with research institutions
- Government agencies, such as the Food and Drug Administration (FDA)
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Collection and Treatment of Personal Data During the Study and HIPAA Authorization

By signing this form, you consent to the study doctor and his or her study site staff collecting and using personal data (including special types of personal data) about you for the study. This includes the following categories of personal data: contact and identification information and demographic information (such as date of birth and gender). It also includes the following categories of sensitive personal data: health data and medical history, ethnic origin, race and sex life, if applicable. Providing your personal data is necessary to participate in the study. If you do not provide the requested personal data, you cannot participate in the study. Your authorization to the use of study data does not have a specific expiration date, but you may withdraw your authorization at any time by notifying the study doctor.

In California and any other state that requires an expiration date, the authorization will expire 50 years after you sign this authorization document.

To revoke your authorization, you must notify the study doctor in writing. If you withdraw your consent, the study doctor will no longer collect study data after you withdraw your consent. Seqirus will still use study data that was collected before you withdrew your consent. If you revoke your authorization, you may no longer be allowed to participate in the research study described in this document.

To ensure that your personal information is kept confidential, your name, and any other information that allows you to be identified, will not be entered on the electronic systems/paper forms or included in any records or samples the study doctor provides to Parexel (an organization that will be involved in parts of the study on behalf of Seqirus) or Seqirus. Instead, you will only be identifiable by a code key, which is a number specific to you. The study doctor is in control of the code, which is needed to connect the study data to you. An individual appointed by Seqirus, health authorities, such as the US Food and Drug Administration (FDA), or other supervisory bodies may review any study data held by the study doctor.

The study doctor will use study data to conduct the study. Seqirus may use study data to analyze the study, to support the maintenance of the vaccine marketing authorization, and for research related to the development of vaccines, diagnostics or medical aids and promotional activities.

The study site and Seqirus are each responsible for handling study data in accordance with applicable data protection law(s).

Seqirus may share study data with other companies within its group, with its service providers, its contractors, government agencies, such as the FDA, with researchers and with research institutions for purposes of carrying out the Study. In addition, representatives from government agencies, ethics committees (EC), institutional review boards (IRB), Seqirus or its agents (e.g., study auditors, monitors) and Parexel may consult your medical and study participation records for the purpose of verifying completeness and correctness of the information collected for the purposes of this research Study, without violating your confidentiality. By signing the informed consent form, you authorize this access and use.

Your medical files may be reviewed remotely (outside of the study center), but only for temporary and exceptional circumstances. Review will be done by Sponsor or its representatives in order to check the information and verify the clinical study procedures, without breaking your confidentiality. If your medical files are reviewed remotely, the records will be shared via secured methods and will include your study subject number, gender and date of birth, but will not include your name or other directly identifiable information, unless these records will be reviewed directly through the study center's secure electronic medical records portal.

Documents generated as part of this study will be stored on paper in physical archives under the custody of Seqirus. Your pseudonymized personal information will also be transferred, stored or processed in electronic databases owned and/or operated by Seqirus companies or other companies working for Seqirus. These databases may be located in the United States, or any other country where Seqirus conducts business. Seqirus, its corporate affiliates, service providers, government agencies and collaborators may transfer study data to countries outside of the United States for the purposes described in this document.

Please be aware that some countries may not offer the same level of privacy protection as you are used to in the United States and may not stop study data from being shared with others. All study data that is transferred will be coded.

Please note, the results of the study may be published in accordance with applicable laws and in medical literature. If the results of this study are published in medical publications or presented at a meeting, nothing will identify you. You will not be named, and no one will be able to tell that you were in the study from the publication or presentation.

A description of this clinical trial will be available on https://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.

When the study is completed, the summary of its results will be made available to you by your study site or on: *http://www.trialsummaries.com*.

By signing this form, you authorize the study doctor to disclose (release) your health information for the purposes of this study. Those individuals that receive your health information may not be required by federal privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. You are not required to sign this form, but if you do not, you will not be allowed to participate in the study.

You have the right to request information about your study data held by the study doctor and Seqirus. You also have the right to request that any inaccuracies in such data be corrected. If you wish to make a request, then please contact the study doctor, who can help you contact Seqirus if necessary. If you wish to complain about our use of your personal data, you can contact the competent data protection authority.

Your records (including your personal data as described above) will be kept for at least ten (10) years, or longer if required by applicable law for maintaining the marketing authorization.

If you have any questions in relation to how we process your personal data, please contact Seqirus' Data Protection Officer using the contact information provided below. By signing this form, you consent to the use of study data as described in this document.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number(s) listed in this document.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may contact them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research participant.

If you have any medical or study related questions or feel you have been hurt or injured as a result of taking part in the study and in case of any symptoms or illnesses that require hospitalization, emergency room visit or visit to/by a health care provider during the entire study period you should contact the study doctor or site staff.

If you have questions about the results of the study generally, your study data (i.e., the study results that are specific to your participation in the study) or whether you received the study flu vaccine or the control flu vaccine during your participation in the study, such information will only be disclosed to you by your study doctor upon completion of the full study unless there are reasonable health and safety concerns that require early disclosure. Because this study is to be conducted over multiple Influenza Seasons, access to your study data may be delayed by several years after your individual participation. Please contact your study doctor for more information.

If you have any questions in relation to how we process your personal data or your rights under United States law, please contact Seqirus' Data Protection Officer by using the contact information provided below.

Seqirus' data protection officer may be reached by email at *privacy@cslbehring.com* or postal mail to CSL – Privacy and Data Protection, CSL Behring GmbH, Philipp-Reis-Str. 2, 65795 Hattersheim, Germany.

What if I am injured because of taking part in this research?

Seqirus has insurance to cover any study-related physical injuries. If any physical injury is directly caused by your participation in the study, Seqirus will pay for the reasonable costs of your medical treatment to the extent permitted by the laws of the United States if:

- You received the study flu vaccine or control flu vaccine as directed by the study doctor;

- Your injury was not deliberately caused;
- The study doctor was immediately notified about your injury; and
- The medical advice of the study doctor was followed.

Seqirus will not pay any expenses related to injuries caused by a clinic- or hospital-acquired infection. You have not waived any of your rights to legal recourse in the event of research-related injury.

Can I be removed from this research without my approval?

At any time during the study, it is also possible that the study doctor or the study sponsor may end your participation in the study. This may happen if:

- You develop an illness which may negatively affect your health
- You require a medication or vaccine that is not allowed during the study
- You do not follow the study instructions given by the study staff
- Seqirus decides to suspend or terminate the study or the participation of this site in the study
- Other unanticipated circumstances

Communication of New Information on this Vaccine

Any new important information or findings that relate to, for example, the safety of the study vaccine, that develop during the conduct of the study will be made available to you in a timely manner as these new findings may influence your willingness to remain in the study.

What happens if I agree to be in this research, but I change my mind later?

Withdrawal From the Study After Signing the Informed Consent

At any time during the study you can withdraw your consent to participate in the study without any negative consequences on your medical care. If you decide to withdraw from the study, please tell the study doctor or member of the study staff right away and let them know of any medical problems you experienced or medications you have taken since the last study contact. If you withdraw your consent, you will be asked to come to the clinic for a final study visit and return the electronic device, if applicable. If a clinic visit is not possible, you may be asked if site staff can visit you at home or have a safety phone call.

After you have told your study doctor or a member of the study staff to stop your participation in the study, no further new data will be collected from you, but any information collected before that time will remain a part of the study data. This also applies for any future use of samples already collected from you, if you withdraw your consent, Seqirus (and/or any of its affiliate companies) will only keep and use the research results from the testing of your samples up to the date that you withdrew consent. In any case, these results are pseudonymous (i.e., not associated with your name or identity) and you cannot be identified from them.

Will I be paid for taking part in this research?

You will be compensated a flat fee of $150.00 after each completed site visit, which is inclusive of travel fees, and $37.50 for each completed safety phone call.

In the case you experience any flu-like symptoms, you will be compensated a flat fee of $150.00 for the deep nasal swab and end of episode visit, which is inclusive of travel fees, and $37.50 for each completed start of episode visit.

Beyond this compensation, you will not receive any additional payments relating to this study. If you have any questions regarding your compensation for participation, please contact your study doctor.

The results from this study may lead to new commercial products or tests. If this happens you will not receive any additional compensation.

Your study doctor and study site will be compensated to conduct the work on the study.

IRB APPROVED
AS MODIFIED
Sep 11, 2025

Informed Consent Form Subject Number: _____

My signature indicates that I agree to participate in the research study mentioned above and that:

- The study procedures have been explained to me.
- I have read and understood the written study information and study procedures. I have been given enough time to ask questions and all my questions have been answered satisfactorily.
- I consent to take part in the study. I am aware that my participation in the study is entirely voluntary and that I am free to withdraw participation at any time, without giving any reason, and without my medical care or legal rights being affected.
- I am aware that other individuals or entities, as mentioned in the Informed Consent, may have access to my personal data, including remote access to my personal data.
- I am aware that if I decide to withdraw from this study, data collected about me before my withdrawal, including personal data and study data, will be used in the analysis of the study results.
- I agree that data collected from me during this study, including personal data and study data, may be transferred to other countries as described in this Informed Consent.
- I consent that my personal data as set out in this consent form, including data relating to my physical or mental health or condition, and race or ethnic origin, may be used by Seqirus and the study site as described in this consent form, including transfer to countries outside of the United States which may not provide the same level of data protection as in the United States.
- I can withdraw my consent at any time. Such a withdrawal will not affect the processing of my personal data prior to the withdrawal of my consent and Seqirus and the study site will continue processing my personal data that was collected before I withdrew my participation from the study.
- I acknowledge that I have received a copy of this informed consent form (ICF).

Left over samples to be used in future research (related). Please tick one box. ☐ I agree to my leftover samples (nasal swabs) being used in future research related to this study. ☐ I **do not** agree to my leftover samples (nasal swabs) being used in future research related to this study.
Left over samples to be used in future research (not related). Please tick one box. ☐ I agree to my leftover samples (nasal swabs) being used in future research **not** related to this study. ☐ I **do not** agree to my leftover samples (nasal swabs) being used in future research **not** related to this study.
Primary Physician to be informed about study participation. Please tick one box. ☐ I would like my Primary Physician to be informed about my participation in this study. ☐ I **would not like** my Primary Physician to be informed about my participation in this

study.
I **do not** have a Primary Physician.

Permission to request medical records. Please tick one box.

☐ I give permission to request my medical records from my Primary Physician.
☐ I **do not** give permission to request my medical records from my Primary Physician.

Permission for a home visit. Please tick one box please.

☐ I give permission for a home visit to occur if during the course of the study due to exceptional circumstances, visits to the study clinic are not allowed.
☐ I do not give permission for a home visit to occur if during the course of the study due to exceptional circumstances, visits to the study clinic are not allowed.

Section only to be completed by the participant

NAME PARTICIPANT (printed name)	NAME OF INDEPENDENT WITNESS SIGNING[1]	DATE (DD MMM YY) TIME (24 HOUR CLOCK)	SIGNATURE
		Date: _ _ _ _ _ _ _ _ Time: _ _ : _ _	

1) I as independent witness declare that by signing this document, the written information has been read out to the participant and to the best of my knowledge is understood by the participant and consent to participate has been given voluntarily.

Only applicable if the participant is not able to read this written information, however does understand the language.

This section is only to be completed by the person obtaining the Informed Consent

I declare that the participant/person signing mentioned above has been fully informed, both verbally and in writing, and all her/his questions about participation in this study have been answered. If new information becomes available during the study that might influence the participant/person signing earlier consent I will inform her/him about this as soon as possible.

NAME (printed name)	DATE (DD MMM YY) TIME (24 HOUR CLOCK)	SIGNATURE
	Date: _ _ _ _ _ _ _ _ Time: _ _ : _ _	

NOTE: To be signed at the same time by the participant/delegate and person obtaining the Consent form

IRB APPROVED
AS MODIFIED
Sep 11, 2025

Attachment 1: Study Related Procedures and Time & Events

The following activities will be performed during the study to make sure you are able to participate and that you can continue to participate until the end of the study. These activities will also be used to assess your safety and any side effects after you have received one of the study vaccines. You will be provided with a paper card with the study details and contact information in case of an emergency.

General Information and Medical History: You will be asked to provide general information about yourself, your medical history and to describe all medications (and vaccinations) including prescription medications and non-prescription (over the counter [OTC]) medications, you are currently taking and may have taken recently in the past. You may be requested to get medical records from other doctors.

Physical Exam: You will be given a physical exam during your first visit (and it may be repeated during additional visits), which may include examination of head, neck, thyroid, ears, eyes, nose, throat, chest, lungs, heart, lymph nodes, abdomen, skin, muscles and skeleton, nervous system and other if needed, as per your study doctor's judgement.

Body temperature, *Height and Weight*: During the first visit, your temperature and your height and weight will be measured.

Laboratory: At different study visits the following clinical specimens will be obtained from you

- Nasopharyngeal swabs (behind your nose, above the back of your throat), which will be collected from you during an ad hoc clinic or home visit when you experience flu-like symptoms. The swab should be collected as soon as possible, but not more than 10 days after you start experiencing these symptoms. The swab will be used for evaluation of the presence of influenza virus.

Vaccination: You will be given the study flu vaccine or control flu vaccine that was assigned to you by chance at visit 1. A member of the site staff will inject the vaccine into the upper muscle of preferably the arm you use the least.

After Vaccination (Post Injection Side Effects): After *the* injection, you will have to stay in the clinic for approximately 30 minutes so that the study doctor or his/her staff can observe whether you have any side effects from the injection. During this time, the staff will observe you and may examine you. The site will also provide you with instructions for what to do after you leave the clinic and when to return to the clinic next.

Safety Telephone Call: At Day 91 after your vaccination, the study staff will call you in order to review general safety information with you, such as any visits to the doctor for any new and/or serious health problems since the last visit to the study center.

Flu-like Illness Reminder Messages: These messages will be sent to you electronically via a smartphone application. The purpose of this message is to remind you to contact the study doctor or his/her staff as soon as possible when you are experiencing any flu-like symptoms. If so, an ad hoc clinic or home visit to collect a nasopharyngeal swab will be scheduled. You will receive a *message* every week until approximately 6 months after vaccination or until the 31st of May 2026, whichever is longer.

Flu-like symptoms: You will be asked to contact your study physician immediately if you experience flu-like respiratory symptoms with sore throat, cough, production of phlegm or mucus in the lungs, wheezing or difficulty breathing, concurrent with one or more of the following: temperature of more than 99◦F, chills, tiredness, headaches or muscle pain. The study physician will schedule a clinic or home visit with you, during which a sample from your nose (nasopharyngeal swab) will be collected. In addition, you will be asked to start filling out the influenza-like illness (ILI) e-booklet. You will also have a follow-up visit approximately 14 days after your nasal swab sample was collected to see how you are doing.

Flu-like symptoms Booklet: You will be asked to report certain information when you experience flu-like symptoms on a flu-like symptoms Booklet (also called ILI Booklet). The ILI Booklet used in this study is an electronic device.

The site staff will provide you with a device that has an application pre-installed or will help you to install the application on your own device and also will explain to you how to use it and make entries for as long as your symptoms last or for a maximum of 10 days after your symptoms have started. You will also be asked to:

- Measure your body temperature by mouth
- Keep all the packages of any medications that you started taking after your symptoms started and bring them with you to your next visit
- Call the site staff if you experience symptoms that concern you or require you to visit a doctor or medical professional

Table 1: Schedule of Study Related Procedures and Time & Events

Clinic Visit 1 (Day 1)	**Clinic Visit 2 (Day 22)[1]**	**Phone Call *(#3)* (Day 91)**	**Clinic Visit 4 (end of flu season, approximately 180 days after vaccination)**
Medical History		Call to assess your safety	Study Completion
Physical Exam	Safety assessment		Physical Exam & Safety assessment
Body temperature, height and weight			

Vaccination with aTIV or flu control			
Safety assessment: Stay at the clinic for 30 minutes after receipt of vaccine for observation			
Training on the electronic ILI Booklet			
Flu Reminder messages (weekly)[2]			

[1]*In the exceptional case that the site staff is not able to see subjects at the clinic, the site staff may request to come to your home to perform the safety assessment. You will be notified by the study staff if this is the case and additional information detailing how the home visit will be conducted, will be provided to you before the visit occurs.*

[2]*You will receive a message every week until approximately 6 months after vaccination or until the 31st of May 2026, whichever is longer.*

Table 2: Ad Hoc (as needed) Schedule When Experiencing Flu-Like Symptoms

Clinic or Home Visit (as soon as possible)	**Electronic ILI Booklet completion**	**Follow-up Visit (approx.14 days after flu-like symptoms started)**
Assessment or review of symptoms	Daily completion of the Booklet as long as your symptoms last (with a maximum of 10 days after your symptoms started)	Assessment of final diagnosis and possible complications
Nasal Swab		Physical exam, if needed
		Collection of information on healthcare use
		Collection of information on use of medication