IRB Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
AS MODIFIED
Apr 10, 2023

INFORMED CONSENT FORM

TITLE:	A Randomized, Double-blind, Placebo-controlled, First-in-human Phase 1/2a Study to Evaluate Safety, Reactogenicity and Immunogenicity of a Universal Influenza (Uniflu) Vaccine with INFLUENZA G1 mHA in Healthy Adults
PROTOCOL NO.:	VAC21148FLZ1001 WCG IRB Protocol #20226057
SPONSOR:	Janssen Vaccines & Prevention B.V.
Represented by	Janssen Research & Development, LLC 920 US Route 202, Raritan, NJ 08869
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Phone Number Phone Number (24 hours) [24-hour number is required]

Taking part in this research 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 have any 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.

You are kindly invited to be in a research study.

Here are a few things to know as you learn more:

- Taking part in a research study is voluntary and is not part of your regular health care
- Before you decide, please read this form carefully so you know why the study is being done and what it involves
- Take your time to decide – you may take an unsigned copy of this form home to read again and discuss with your other doctors, family, and friends
- Ask the study doctor or staff your questions

Thank you for taking the time to consider this study.

Information in this Informed Consent Form may be confidential to the Sponsor. The Sponsor is sharing this information with you for the purpose of inviting you to make an informed decision about participating in the research study. We kindly ask you to consider this sensitive information when discussing details about the research study with people other than your healthcare provider(s), family and friends.

STUDY CONSENT SUMMARY

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

What should I know about this study?

- Someone will explain this study to you.
- Taking part in this study is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this study?

We expect that your taking part in this study will last about 12 months.

Why is this study being done?

The purpose of this study is to test a new experimental vaccine to help doctors and scientists learn how to prevent influenza virus infection. Further details are included in the STUDY OVERVIEW section of this consent.

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

If you decide to take part in this study, the general procedures include informed consent, collecting your demographics [your name, address, date of birth, and health data (information about your health)], physical exam, vital signs, sample collection (including blood, urine and nasal swab), study vaccine injections in your upper arm on Day 1 and Day 57, completion of a paper diary for 7 days after each vaccination, completion of questionnaires, collection of nasal swab samples during an influenza-like illness, and monitoring your health condition and medications during the study. Further details are included in WHAT IS DONE AT THE STUDY VISITS section of this consent.

Could being in this study hurt me?

All vaccines can cause side effects. This will be the first study for this vaccine in humans, therefore there is no human data available yet. General risks and possible side effects associated with vaccination may be arm discomfort, pain, soreness, bruising, swelling or redness at the site of injection. It is also possible that you will get a fever, chills, rash, body aches and pains, muscle pain, nausea, headache, and fatigue (feeling tired). These side effects usually last 48 to 72 hours. Rarely, there can be a small amount of bleeding or infection at the site of injection. It is rare, but you could have an allergic reaction to the vaccine, such as a rash, hives, difficulty breathing, itching, and swelling of lips, tongue, or face. Allergic reactions can be life-threatening.

Guillain-Barré Syndrome (GBS) is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. Previous seasonal influenza vaccines on the market have included GBS as a potential risk. As this is the first study for this influenza vaccine in humans, there is no evidence or data regarding a possible link of GBS and this study vaccine.

Further details are included in WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS OF PARTICIPATING section of this consent. You should inform the study doctor immediately if you experience any symptoms.

Will being in this study benefit me?

There is no direct medical benefit to you from being in this study since the study vaccine has not yet been proven to be effective. You may benefit from clinical testing and physical examination. Others may benefit from the knowledge that they may aid in the development of a universal influenza vaccine. A universal influenza vaccine is designed to create an immune response which can provide protection against different strains of the influenza virus present every season and hopefully replace the need to get a new influenza vaccine every year. Your participation may help prevent other people from getting influenza in the future. This is also stated in COMMON QUESTIONS ABOUT JOINING THE STUDY section of this consent.

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

Instead of taking part in this study, you may choose to take other seasonal influenza vaccines that are approved and available. There may also be other clinical studies for other experimental influenza vaccines. The study doctor will explain to you the benefits and risks. This is also stated in STUDY VACCINE/OTHER MEDICATIONS section of this consent.

What else should I know about this study?

TO PARTICIPATE IN THE STUDY, YOU MUST FOLLOW A LIST OF THINGS TO DO AND NOT DO IN THE STUDY RULES SECTION OF THIS CONSENT. IF YOU ARE FEMALE WITH CHILDBEARING POTENTIAL, YOU SHOULD PRACTICE AN ACCEPTABLE EFFECTIVE METHOD OF CONTRACEPTION AS DETAILED IN THE CAUTIONS SECTION OF THIS CONSENT.

STUDY OVERVIEW

Why is this study being done?

The experimental vaccine in this study is called VAC21148 (Universal Influenza [Uniflu] Vaccine) which contains JNJ-67920320 (INFLUENZA G1 mHA) with or without aluminum hydroxide. A vaccine is a type of medicine to prevent certain diseases by causing the human body to form a defensive response against the disease. This defensive response is called the immune response, and it is your body's way to fight infections.

The influenza virus is usually common in the winter months, and can cause symptoms such as cough, sore throat, headache, fatigue, and fever. Influenza is a worldwide public health problem, responsible for making lots of people ill, causing death in some cases and health care costs are high. In a typical year, about 3 to 5 million people become severely ill with about

290,000 to 650,000 deaths worldwide. About 90% of influenza-associated deaths occur among adults aged 65 years and older. Seasonal influenza vaccine effectiveness is generally variable and current seasonal vaccines may not cover all circulating strains in a season. Furthermore, seasonal vaccines must be adapted to current circulating strains (often yearly) based on World Health Organization (WHO) recommendations. Seasonal vaccines also need to be adapted to the strains circulating in the Northern and Southern hemispheres.

Despite the high disease burden, no effective universal influenza vaccine is available for the influenza virus, which would be especially important for populations that are at risk for severe disease like the elderly.

In this study, some participants will get a placebo instead of the study vaccine. A placebo looks just like the study vaccine and is given the same way but has no active vaccine in it. The placebo in this study will consist of a sterile solution of Sodium Chloride.

All references to the word “study vaccine” can mean JNJ-67920320 with or without aluminum hydroxide, as well as placebo.

This study will test a new experimental vaccine to help doctors and scientists learn how to prevent infections of influenza virus. The main purpose of this study is to see:

- If the study vaccine components are safe
- If the study vaccine causes any side effects
- How well the study vaccine is tolerated by participants
- What the best dose of the study vaccine is

Doctors and scientists will also measure:

- How the body reacts to the study vaccine (the immune response)
- How well the study vaccine works against the influenza virus
- How long the effects of the study vaccine last
- How the study vaccine acts on the body

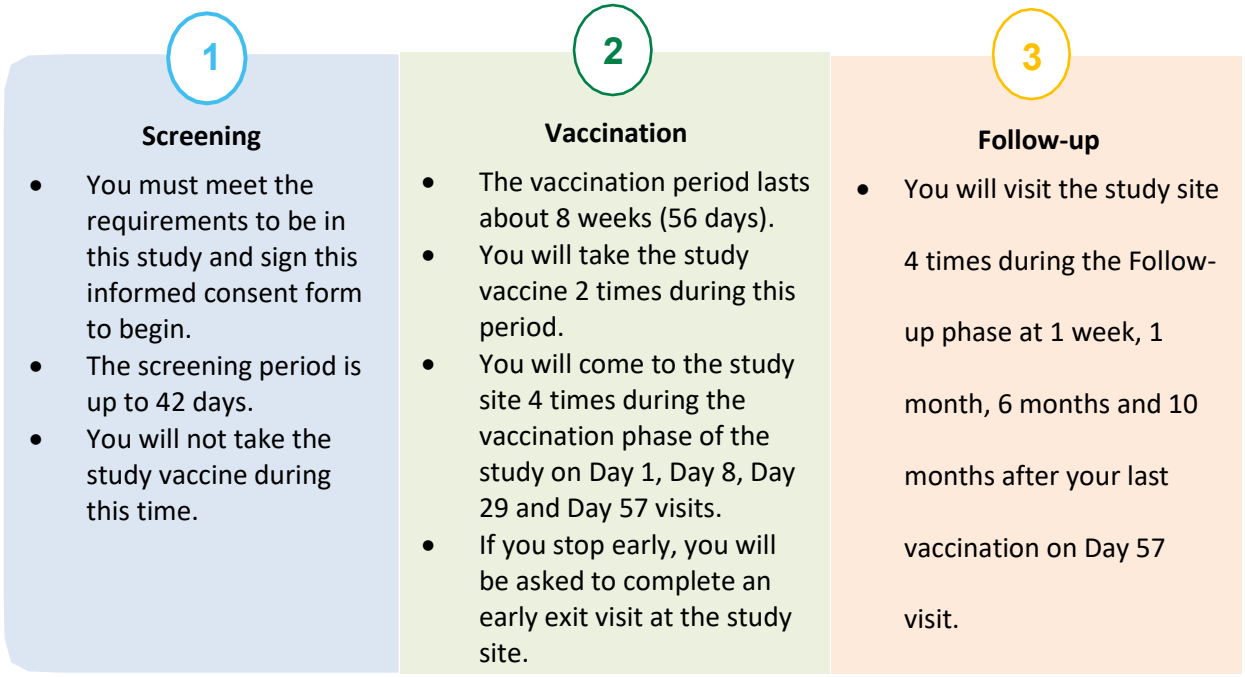
General Information about the study

About 170 male and female participants aged 18 to 45 will take part in this study within the United States of America. If you join the study, you will be in it for about 12 months.

Sometimes during a study, the sponsor may learn new information about the research study vaccine, the risks, or something else. Your doctor/staff will tell you in a timely manner if there is any new information that might make you change your mind about being in the study.

WHAT HAPPENS DURING THE STUDY?

The study is divided into 3 parts.



WHAT IS DONE AT THE STUDY VISITS?

Study procedures and activities

This table describes all the procedures you can expect to have during the study. Not all procedures will be done at every visit. The study doctor or study staff will discuss this with you in more detail.

Procedure	What is it?	When is it done?
Informed consent	The study doctor or staff will talk to you about the study and you'll decide if you want to join.	Screening visit
Collect demographics information	The study doctor or staff will collect your demographics information, such as race, age, and gender.	Screening visit
Review medical history	You will discuss your current and past health with the study doctor or staff.	Screening visit and throughout the study
Review of medicines	You will talk with the study doctor or staff about your medicines.	Screening visit and throughout the study
Physical exam	The study doctor or staff will check your body for general health.	Screening visit. There may be additional exam(s) during the study if the study doctor deems them as needed.
Vital signs	The study doctor or staff will take your blood pressure, pulse, breathing rate, and body temperature.	Screening visit, Vaccination period, and Follow-up period
Sample collection to check for eligibility for the study	Study staff will take blood samples from you for testing to see if you can join the study. Your remaining samples may also be used as described in the "Samples collected for Scientific Research" section below.	Screening visit
Urine sample	Your urine will be used to check for pregnancy, if you are a female who	On the same day prior to study vaccination

	could get pregnant. Sometimes you may need to repeat a urine pregnancy test.	
Blood draw/tests	The study doctor or staff will draw blood from a vein in your arm. You may get a bruise or irritation at the place where the needle goes into your skin. Some participants may faint and, in rare cases, can get an infection. A total of about 1 cup (1 cup = about 250 ml) of blood will be drawn during the entire study. Sometimes you'll need to repeat a blood test. Your blood will be used to check for: • Your general health • Signs of influenza • How your body reacts to the study vaccine • Pregnancy (if you are a female who could get pregnant) The study doctor or staff will discuss with you the test results that are medically important.	Screening visit, Vaccination period, and Follow-up period
Sample collection for scientific research	Your blood and nasal swab sample will be collected for scientific research as described in the "Samples collected for scientific research" section below.	Visits during vaccination period and follow-up period

	You will be informed if testing on your samples for this study will change.	
Study vaccination and 30-minute post-vaccine observation	You will receive study vaccine and will be monitored for at least 30 minutes at the study site after study vaccination. The study doctor or staff will let you know when you may leave the study site.	Day 1 visit and Day 57 visit
Diary	You will be given a diary and an explanation of how to use it. You will report information on a daily basis, starting from the day of each study vaccination, and for the 7 days afterwards. Staff will show you how to note: • Daily symptoms, such as tiredness, headache, nausea, and muscle pain • Pain or tenderness, redness, and swelling at the site of the injection (using a ruler at home) • Your daily body temperature using a thermometer at home (you should measure your temperature at the same time each day) You must bring the diary with you to the study doctor or staff at the next visit after study vaccination.	Daily for 7 days after each study vaccination
Review of risks and possible side effects of vaccines	At each visit, the study doctor/staff will ask about any side effects. All vaccines can cause side effects.	Vaccination period and Follow-up period

	Problems that are not expected may arise and they may be life-threatening.	
Influenza-like illness monitoring	The study doctor or staff will contact you via phone calls or other means of communications every 2 weeks during influenza season. You should notify the study doctor or staff immediately when you have influenza-like illness symptoms during influenza season, such as cough, sore throat, headache, nasal congestion, feeling feverish, body aches and pains, tiredness, neck pain, interrupted sleep, and loss of appetite. You will be monitored by the study doctor or staff until you are fully recovered.	When you have influenza-like illness symptoms during influenza season
Nasal swab sample collection for influenza-like illness	Nasal swabs will be used to check for the presence of the influenza virus and/or any other respiratory virus by the study site. During the influenza season, if you develop any influenza-like illness symptoms, you should take a nasal sample at home 12 to 24 hours after onset of symptoms or the day thereafter (Days 1-2). The sample should be stored in the refrigerator and brought to the study site within 4 days (preferably) after collection. Materials and instructions for nasal swab sample collection and transportation will be distributed to	Days 1-2 and Days 3-5 after onset of influenza-like illness symptoms during influenza season

	you by the study doctor or staff. An additional nasal swab will be taken at the study site by the study staff, ideally between 2 and 4 days after symptom onset (influenza-like illness Days 3-5).	
Temperature monitoring for influenza-like illness	You must measure your body temperature daily around the same time each day (preferably in the evening) from the onset of influenza-like illness symptoms until you are fully recovered. You must document your temperature and any medication(s) used on the paper form provided to you, and bring the completed form to the study doctor or staff.	Daily from the onset of influenza-like illness symptoms during influenza season until you are fully recovered
Influenza Intensity and Impact Questionnaire (Flu-iiQ™) for influenza-like illness	Study staff will give you an Influenza Intensity and Impact Questionnaire (Flu-iiQ™) to answer questions about how you're feeling. This will be a paper form. These questions will give the study sponsor important information about how you're doing in the study, so it's important to complete these questions as your study doctor, staff, nurse, or coordinator instructs you. It will take about 5-10 minutes to complete the daily questionnaire.	Daily from the onset of influenza-like illness symptoms during influenza season until you are fully recovered
Blood test for influenza-like illness	About 1.5 teaspoons of blood will be collected from you to confirm infection of influenza virus.	Days 3-5 and Day 29 after the onset of influenza-like illness

		symptoms during influenza season
Clinical Assessment for influenza-like illness	The study doctor or staff will take your blood pressure, pulse, breathing rate, body temperature, and oxygen saturation.	Days 3-5 and Day 29 after the onset of influenza-like illness symptoms during influenza season

Study rules

To participate in the study, you must follow this list of things to do and not do:

Overall study rules	
Do	**Do not**
• Give correct information about your health history and health condition. • Tell the study doctor and staff about any health problems you have during the study including any pre-planned surgery/procedures. • Complete the diary, study form and questionnaire and bring them to the study site as instructed. • Inform the study doctor or staff on any influenza-like illness symptoms immediately during influenza season, and complete nasal swab sample collection as instructed. • Inform the study doctor or staff immediately if you develop symptoms such as: shortness of breath, chest pain, leg pain or swelling, abdominal pain that does not go away, severe headache or a headache that does not get better,	• Do not take part in any other medical research studies within 30 days before the first study vaccination for this study and during the course of this study. • Do not receive any other experimental vaccine within 6 months before the first study vaccination for this study and during the course of this study. • Do not receive any Licensed Live Attenuated vaccines within 28 days before or after planned study vaccination(s). • Do not receive any Other Licensed (not live) vaccines (not including seasonal influenza vaccines) - within 14 days before or after planned study vaccination(s). • Do not receive Seasonal Influenza Vaccine within 4 months before planned study vaccination(s) until the end of the

blurred vision, or other vision changes, mental status changes or seizures (fits), increased skin bruising, tiny blood spots under the skin other than at the site of vaccination or easy bleeding. • Come to all study visits. • You will be given a participant wallet card including study information. You should carry this card with you for the duration of the study.	study. • Do not get pregnant or cause your partner to become pregnant. • Do not donate eggs during the study, if you are a female. • Do not donate blood during the study until at least 3 months after the last study vaccination.
Medicines	
Do	**Do not**
• Tell the study doctor and staff about any new medicine or drug you take during the study, including over-the-counter drugs (for example, to prevent or treat side effects of the study vaccine) and any vaccines. Also tell the study doctor and staff about any changes to your medicines or drugs.	• Do not get or plan to get any other vaccines during the study unless the study doctor and staff have approved them beforehand. • Do not start any new medication including over-the-counter ones unless the study doctor and staff have approved them beforehand.

STUDY VACCINE/OTHER MEDICATIONS

What is the study vaccine?

The INFLUENZA G1 mHA vaccine contains a modified protein, called a mini hemagglutinin, which is made from the outer part of the influenza virus. This mini hemagglutinin protein is produced from something called a cell line. This is a continuously dividing set of cells that come from a single cell. The INFLUENZA G1 mHA protein is collected and purified from the cell line.

When the study vaccine is injected, it will deliver the INFLUENZA G1 mHA protein into the human body. The scientists are looking to see if after getting the vaccine, a person's body will

develop an immune response to the protein of the influenza virus. An immune response is your body's way to fight infections.

For some study participants, the INFLUENZA G1 mHA vaccine is taken with aluminum hydroxide, Al(OH)3, which is an "enhancer" (called an adjuvant). A vaccine adjuvant is a substance that is added to the vaccine to increase or "enhance" the body's immune response to the vaccine.

The study vaccine has already been studied in test tubes and in animals. This is the first time that the study vaccine will be used in humans. The study vaccine is not approved for use by any Regulatory Authority in any country, such as the FDA (Food and Drug Administration). Therefore, it can only be used in a research study such as this one.

What treatment will I receive?

Not everyone in the study will get INFLUENZA G1 mHA.

You will either get INFLUENZA G1 mHA with or without aluminum hydroxide, $Al(OH)_{3,}$, or placebo at different predefined concentrations. You will randomly (by chance) be put into the active vaccine or placebo group.

There are 8 groups in this study. About 20 participants will receive placebo and about 150 participants will receive 1 dose or 2 doses of the active vaccine (see table below).

Cohort	Group	Number of Participants per group	Day 1	Day 57
1	1	25	INFLUENZA G1 mHA [redacted]	INFLUENZA G1 mHA [redacted]
	2	25	INFLUENZA G1 mHA [redacted] /$Al(OH)_3$	INFLUENZA G1 mHA [redacted] /$Al(OH)_3$
	3	10	Placebo	Placebo
2	4	25	INFLUENZA G1 mHA [redacted]	INFLUENZA G1 mHA [redacted]
	5	25	INFLUENZA G1 mHA [redacted] /$Al(OH)_3$	INFLUENZA G1 mHA [redacted] /$Al(OH)_3$
	6	25	INFLUENZA G1 mHA [redacted]	Placebo
	7	25	INFLUENZA G1 mHA [redacted] /$Al(OH)_3$	Placebo

8	10	Placebo	Placebo
TOTAL:	170		

$Al(OH)_3$ = aluminum hydroxide; G1= Group 1; mHA= mini hemagglutinin (protein vaccine).

During the study, neither you nor the study staff will know which vaccination group you're in (this is called double-blinded). But if needed for a medical emergency, the study doctor and staff can quickly find out which vaccine group you're in.

How is the study vaccine given?

If you decide to take part in the study, you also agree to have the study vaccine(s) given as directed by the study staff.

The study vaccine is an injection. The needle is put into a muscle in your arm (preferred) or in other body parts per the study doctor. This will be done at Day 1 and Day 57 visits.

What other options are there outside of this study?

Instead of taking part in this study, you may choose to take other seasonal influenza vaccines that are approved and available. There may also be other clinical studies for other experimental influenza vaccines. You may choose to not take a seasonal influenza vaccine. The study doctor will explain to you the benefits and risks of these other options.

What about my current medicines?

You must tell the study doctor and staff about all your prescription and over-the-counter medicines. This includes vitamins and herbal supplements.

You can continue to take your medication(s) while you are in this study as long as the study doctor has approved them.

WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS OF PARTICIPATING?

Potential Discomforts, Side Effects, and Risks Associated with Uniflu Vaccine VAC21148

All vaccines can cause side effects. Problems that are not expected may happen and can be life-threatening. If you have any side effects or problems during your participation in this study, please tell your study doctor right away. There may be risks with the use of this vaccine that are not yet known. This will be the first study for this vaccine in humans, therefore there is no human data available yet.

Sometimes during a study, the sponsor learns new facts about the study vaccine. It is possible that this information might cause you to change your mind about being in the study. If new information is discovered, your study doctor will tell you about it right away.

General Risks and Possible Side Effects Associated with Vaccination

There may be arm discomfort, pain, soreness, bruising, swelling or redness at the site of injection. These reactions can occur with all types of injections. It is also possible that you will get

- a fever,
- chills,
- rash,
- body aches and pains,
- muscle pain,
- nausea,
- headache,
- and fatigue (feeling tired).

These side effects usually last 48 to 72 hours. Rarely, there can be a small amount of bleeding or infection at the site of injection. Some people may experience more severe side effects that limit their normal activities or make them go to the doctor. If you have any redness, swelling and/or pain at the site of injection which is worsening or not going away over time, you should promptly contact the study doctor.

It is rare, but you could have an allergic reaction to the vaccine, such as a rash, hives, difficulty breathing, itching, and swelling of lips, tongue, or face. **Allergic reactions can be life-threatening**. For this reason, the study staff will watch you for at least 30 minutes after you receive each study injection. You should tell your study doctor if you have ever had a bad reaction to any injection or vaccine. Medications are available in the clinic to treat serious allergic reactions. If you think you are having a severe allergic reaction after you leave the study site, contact the 24-hour emergency number on page 1, and seek medical attention immediately.

Risks Related to Aluminum in Vaccinations

Aluminum is one of the most common metals found in nature and is present in air, food, and water. Aluminum salts, such as aluminum hydroxide, aluminum phosphate, and aluminum potassium sulphate have been used safely in vaccines for more than 70 years. A few studies have reported that rarely vaccines containing an aluminum adjuvant, which is an ingredient used in some vaccines that helps create a stronger immune response, can cause a small firm lump to form at the injection site. Two studies examining infant exposure to aluminum from both diet and vaccines concluded that aluminum adjuvants at the levels included in vaccines are well within a safe range. Additionally, in 2017, a review of studies using aluminum adjuvants found that currently there is no evidence to support that aluminum-containing vaccines cause autoimmune disorders (which are medical conditions where your immune system attacks healthy cells in your body by mistake).
Adjuvanted vaccines can cause more skin reactions (such as redness, swelling, and pain at the injection site) and more systemic reactions (such as fever, chills, and body aches) than vaccines without adjuvants.

Guillain-Barré Syndrome

Guillain-Barré Syndrome (GBS) is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. Previous seasonal influenza vaccines on the market have included GBS as a potential risk. The 1976 swine influenza vaccine was associated with an elevated risk of GBS. It is unclear whether other influenza vaccines cause GBS or not. GBS has also been reported following infection with influenza.

As this is the first study for this influenza vaccine in humans, there is no evidence or data regarding a possible link of GBS and this study vaccine. Furthermore, it is important to note that the modified protein design of this study vaccine is different from other seasonal influenza vaccines of the past.

Please seek immediate medical attention and inform the study doctor if you experience any of the following symptoms after vaccination with the Uniflu vaccine:

- double vision or difficulty moving eyes
- difficulty swallowing, speaking, or chewing
- coordination problems and unsteadiness
- difficulty walking
- tingling sensations in the hands and feet
- weakness in the limbs, chest, or face
- problems with bladder control and bowel function

Please inform the study doctor if you have previously experienced GBS as you are not allowed to enroll in this clinical trial.

Side Effects from Tests

- Blood draw: Taking blood may cause bruising at the place where the needle goes into the skin. Fainting, and in rare cases, infection, may occur.
- Collection of nasal swabs: You may experience some slight discomfort or tickling in the nose while this procedure is being done. It may also cause a nosebleed.

COMMON QUESTIONS ABOUT JOINING THE STUDY

Will I be paid?

You will not be paid for taking part in this study. You will be reimbursed for local travel, study visits, and parking [insert other conditions for reimbursement as applicable, e.g., meals, etc.].

Who pays for the study vaccine and tests?

The sponsor will pay the study doctor and / or the institution depending on the agreement for the study vaccine and tests that are part of the study.

The sponsor will not pay for doctor visits, treatments, or tests that are not part of this study. The sponsor will not pay for co-medications or other treatments described in the protocol and informed consent form.

This means that you, your insurance company, or your government health plan are responsible for paying for co-medications or other treatments that will not be paid for by the sponsor.

To Be Completed by Investigator: Disclose any conflict of interest. Include financial relationships or interests associated with the study e.g., the source of funding and funding arrangements for the conduct and review of the study or information about a financial arrangement or interest of an institution or an investigator such as stock in the sponsor or patent on the investigational product. State if the investigator has no financial relationships or interests associated with the study.

Can the study staff remove me from the study?

Yes, the study doctor/staff and the study sponsor have the right to remove you from the study at any time, with or without your agreement. These decisions will be made if:

- It is in your best medical interest to stop
- You need treatment not allowed in this study
- You do not follow the study staff's instructions
- You become pregnant
- The study is canceled
- You no longer meet the eligibility criteria

The study doctor/staff will discuss with you the reasons for removing you from the study, other treatment or research options, and plans to follow up with you for side effects, if needed.

Can I change my mind about participating?

Your participation in this study is voluntary. You don't have to be in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your regular care or the benefits to which you are otherwise entitled. If you agree to participate in the study and later change your mind, call [name] at [number].

What happens if I stop the study early?

If you stop the study early, the study doctor/staff may continue to monitor your health until the study is officially completed. This is to make sure that you are followed and monitored for your safety. This information will be added to your study record. If you do not want the study doctor to continue monitoring your health after you stop taking the study vaccine, you will be asked to indicate this clearly.

If the study doctor/staff is unable to contact you by conventional means (e.g., clinic/practice visit, telephone, e-mail, fax, or certified mail), he/she may also contact you by other means (for example, consult with family members, contacting your other physicians, medical records, database searches, use of locator agencies at study completion, as permitted by local regulations, to find out about your health status. By signing this consent form, you agree that this information can be obtained and added to your study record unless you indicate otherwise. Should you continue to be unreachable, you will be considered to have withdrawn from the study.

If you have side effects after you stop the study early, the study doctor/staff may contact your other doctors who you see regularly. By signing this consent form, you agree that this information can be obtained and added to your study record unless you indicate otherwise.

If you stop the study early and withdraw your consent at any time, you agree not to limit the use of information collected about you for the purpose of the study up to the point of your consent withdrawal. The Sponsor will continue to collect information from you as described in other sections of this Informed Consent Form (see “Samples Collected for Scientific Research,” “Samples Used for Future Research,” and “What happens if I stop the study early?”). The Sponsor will not collect any new information from you for any parts of the study from which you have withdrawn.

Can I take the study vaccine after the study is over?

After you complete the trial, you will no longer receive the study vaccine. Your study doctor/staff will discuss your future medical care options with you.

What are the benefits of joining this study?

There is no direct medical benefit to you from being in this study since the study vaccine has not yet been proven to be effective. You may benefit from clinical testing and physical examination. Others may benefit from the knowledge that they may aid in the development of a universal influenza vaccine. Your participation may help prevent other people from getting influenza in the future.

What about my regular doctors?

The study doctor or staff may let your regular doctors know that you are in this study and may report any side effects. It is important for your other doctors to know that you may be taking a research study vaccine.

WHAT IF SOMETHING GOES WRONG?

If you need medical care because of something that happened to you as a result of being in this study, medical care will be provided to you. **Janssen Vaccines & Prevention B.V.**, as the Sponsor of the study, agrees to reimburse the reasonable medical expenses necessary to diagnose and treat an injury caused by the proper administration of the study vaccine or the proper performance of a procedure required only for the study's research purposes. The Sponsor will not pay the costs to diagnose or treat a condition or injury that is not a result of the study vaccine or procedure, or for expenses related to the normal progression of a preexisting medical condition or an underlying disease. For those costs that are Sponsor's obligation, you or your health insurance won't be billed and in no event will Sponsor pay for coinsurance, copayments or deductibles. It is very important to follow all study directions.

Before or after paying for treatment, **Janssen Vaccines & Prevention B.V.**, or its representatives, may need to collect certain personal information about you such as your name, date of birth, gender, social security number, and Medicare identification number (if you have one) in order to comply with a Medicare reporting requirement. This information may be collected directly from you, or from researchers, physicians, or other health care providers who treated your problem or injury. This information and also information about your injury or other health problem may be shared with others, including the Centers for Medicare & Medicaid Services (the federal agency responsible for administering the Medicare program).

The above statements do not limit your legal rights.

CAUTIONS

Birth control and pregnancy during the study

Effects of the study vaccine(s) on sperm, egg, conception, pregnancy, an unborn child, or a breastfed infant have not been studied. There is currently no information on possible effects of the study vaccine(s) in these cases.

If you are pregnant or breastfeeding or planning to become pregnant, you are not allowed to participate in the study. If you are pregnant or breastfeeding, there may be risks to you and your baby that are not known at this time.

If you or your partner become pregnant during the study, you must tell the study doctor immediately. If you are a woman and become pregnant, you will not receive further injections of the study vaccine. If you or your partner become pregnant, the study doctor will advise you/your partner about medical care and will ask you/your partner to allow him/her to collect information about your pregnancy and the health of your baby.

Female Participants

Before being included in the study, volunteers who were born female must be either:

a. **Not of childbearing potential defined as:**

i. Premenarchal: *a premenarchal state is one in which menarche (menstrual periods) has not yet occurred.*

ii. postmenopausal: *amenorrhea (no menstrual periods) for at least 12 months without alternative medical cause.*

iii. permanently sterile: *permanent sterilization methods include hysterectomy (removal of the womb), bilateral salpingectomy (surgical removal of the fallopian tubes), and bilateral oophorectomy (surgical removal of both ovaries).*

b. **Of childbearing potential and**

i. practicing an acceptable effective method of contraception. Acceptable methods for this study include:

- hormonal contraception
- intrauterine device (IUD)
- intrauterine hormone-releasing system (IUS)

- bilateral tubal occlusion/ligation procedure
- vasectomized partner (the vasectomized partner should be the sole partner for that participant)
- sexual abstinence* (*Sexual abstinence is considered an effective method **only** if defined as refraining from heterosexual intercourse from signing the informed consent until 3 months after the last dose of study vaccine)*

ii. agree to remain on an effective method of contraception from signing the informed consent until 3 months after the last dose of study vaccine. No egg donation is allowed during the study. Use of hormonal contraception should start at least 28 days before the first administration of study vaccine.

Note: if the childbearing potential changes after start of the study (eg, a premenarchal woman experiences menarche) or the risk of pregnancy changes (eg, a woman who is not heterosexually active becomes active,) a woman must begin an acceptable effective method of contraception, as described above.

All female participants of childbearing potential must agree to:

a. Have a blood pregnancy hormone (β-human chorionic gonadotropin (β-hCG)) test at screening which demonstrates that you are not pregnant

b. Have a urine β-hCG pregnancy test immediately prior to each study vaccine administration which demonstrates that you are not pregnant

Male Participants

Pregnancies in partners of male participants must be reported. If your partner becomes pregnant during the study, you must tell the study doctor immediately. The study doctor will advise your partner about medical care and will ask your partner to allow him/her to collect information about the pregnancy and the health of the baby.

SAMPLES COLLECTED FOR SCIENTIFIC RESEARCH

What happens to the samples collected from me?

Scientific research is done to help improve the development of vaccines and understand the disease better. The sponsor may use any of your samples collected during this study for scientific research to help scientists understand:

- Influenza
- How to identify which people may respond differently to the study vaccine component(s)
- How the study vaccine components may work, or why it/they may cause side effects if any
- Why people may respond differently to placebo
- How to develop tests for study vaccine components and for influenza
- To better understand and develop vaccines for influenza or other respiratory diseases

Scientific research also involves ribonucleic acid (RNA) testing. RNA provides instructions to cells to make proteins. This happens all day long in all living cells in your body. The amount of RNA made by a gene can differ from person to person, and changes under different conditions. The testing that will be performed on your blood samples is to see what the changes in your RNA are after study vaccinations. For example, the characteristics of RNA may be investigated in cells that fight off influenza. Because your RNA information is unique to you, there is potential for someone to identify you or your close biological relatives from your RNA information. The risk of this happening is very small but may increase in the future as technology improves. In the unlikely event that another company will complete the RNA testing, they will also have the data. If RNA information is known by another company, applicable laws may not fully protect you or your family from judgements based on RNA information. If you do not want your blood samples to be used for RNA research, you cannot participate in this study.

The results of tests done on these samples are only for scientific research. They will not be used for your medical care. They will not be used to make a diagnosis about your health. Therefore, these results will not be given to you or the study doctor/staff.

Your collected samples will continue to be analyzed as described in this form unless you specifically ask for your samples to be destroyed. This is to protect the quality of the study.

Samples Used for Future Research

Future Research Testing: Any samples leftover after they are used for the main study will be stored for future use (up to 15 years or defined by local regulations). Testing will depend on the available technology at the time of testing.

You have the option to opt out of future use of your samples and can withdraw your consent at any time during or after the study by notifying your study doctor. If you withdraw consent for future use of your samples, your samples will be destroyed after they are no longer required for the main study. This will not affect your access to the care, medicine, and equipment you would otherwise be getting. This can be done at any time and for any reason. You will need to do this before 15 years since the study doctor/staff will discard the medical records that link your name to your study number at least 2 years after the last approval of a marketing application and until there are no pending or contemplated marketing applications or until at least 2 years have elapsed since the formal discontinuation of clinical development of the study vaccine.

The sponsor plans to keep the samples securely in Laboratory Corporation of America in the United States of America. The samples may be re-located at any time by the sponsor.

To protect your privacy, your samples will be labeled with the study number and your participant number. No personal identifiers (such as name, initials, social security number) are used. The scientists doing the research will not know your identity.

Your samples may be sent to other members of the Johnson & Johnson group of companies, to contractors working for them and to regulatory authorities.

Your samples may also be shared with research partners for scientific research purposes. Your samples will not be sold, loaned or given to any other independent groups for their own use. Research partners working with the sponsor are not allowed to share samples with anyone who is not authorized by the sponsor. The sponsor will manage what is done with your samples.

You will not be paid for any use of your samples, results, or inventions made from research on them. You are providing your samples, for use by the sponsor. The sponsor (and research partners, where applicable) plan(s) to own the use of the results, treatments, or inventions that can be made from this research.

HOW IS MY PRIVACY PROTECTED?

The Study Staff and the Sponsor will manage your personal data (information about you) in compliance with Health Insurance Portability and Accountability Act as described in this consent form.

What personal data will the study staff collect?

If you join this study, the study doctor/staff will collect and use your personal data to do the research. This personal data may include, among other items, your name, address, date of birth, and health data (information about your health). Health data includes past medical records and data collected during this study, including data collected when analyzing your biological samples as described in "What is Done at the Study Visits?".

Sensitive data such as racial or ethnic origin, lifestyle, sex life or sexual orientation will also be collected, as it is necessary for the evaluation of the study results.

Who will have access to your personal data?

Your personal data may be stored in paper files and electronic databases which have limited access. The study doctor/staff will have access to these paper files and databases. Other people may also need direct access to this information to ensure that the research study is being conducted properly, in accordance with laws and ethical requirements.

Monitor(s), auditor(s), institutional review board (IRB)/institutional ethics committee (IEC), and regulatory authorities, such as the FDA (Food and Drug Administration), will be granted direct access to your original medical records for verification of clinical study procedures and/or data, without violating your confidentiality, to the extent permitted by the applicable laws and regulations. By signing this informed consent form, you authorize such access.

Records identifying you will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, your identity will remain confidential.

Your PHI (Personal Health Information) is not disclosed by Janssen. Only Coded data is shared. If your PHI is re-disclosed by the study doctor/staff to others, it may no longer be protected by federal privacy laws.

Remote access to your records at the study site, if applicable

Representatives of the sponsor (i.e., auditors; monitors) may use an electronic tool to access your personal data remotely. This electronic tool provides a secure electronic gateway between

the study doctor and staff's computer system and the computer of the representatives of the sponsor, who may be located outside of your country of residence. This minimizes the risk that anyone else might be able to access the information.

How will your personal data be protected?

Your personal data will be labeled with the study number and your participant number ("Your Coded Data") before it is reported to the sponsor. No direct personal identifiers such as your name, initials, date of birth, or social security number are included in Your Coded Data.

How will Your Coded Data be used?

Your Coded Data is needed for the sponsor to learn about the study vaccine, get permission to introduce and keep it on the market, monitor its safety and get it covered by health insurances and health service providers. Therefore, they will be used as planned in this study as well as within related research activities in order to:

- understand how the study vaccine and similar medicines work in the body;
- better understand influenza and associated health problems;
- develop diagnostic tests;
- learn from past studies to plan new studies or improve scientific analysis methods;
- publish research results in scientific journals or use them for educational purposes.

How will Your Coded Data be shared and transferred?

The sponsor may share Your Coded Data with its affiliates, regulatory authorities such as the FDA (Food and Drug Administration), authorized service providers and, with select investigators and scientists conducting scientific research, which is compatible with research related to this study including statistical purposes. Your Coded Data may also be shared with scientific journals so the study results can be reviewed by independent scientists and to ensure the accuracy of results. Your identity will not be revealed in any of these cases.

The Sponsor will protect Your Coded Data as far as the law allows and will keep and supervise the information collected about you only for as long as needed.

Sharing of your anonymized data

The Sponsor believes that access to study data advances clinical science and medical knowledge and is in the best interest of public health, provided that the participant's privacy is protected. Therefore, the Sponsor may generate and share with some researchers, contractual partners or institutions an anonymized set of your study data. This means Your Coded Data will be stripped of your participant number as well as of any other information that could indirectly identify you such as your exact height or weight or exact dates of treatment. This anonymized study data set may be shared only for scientific research as allowed by applicable law.

How long will my personal data be stored?

Records containing your personal data will be retained at the study site for 15 years. In addition, the Sponsor will retain Your Coded Data for time periods as allowed per applicable laws for the identified uses.

What rights do I have concerning my personal data?

If you would like to review, correct, delete personal data, or make other requests concerning your personal data in accordance with the laws in your country, you should contact your Study Doctor at [number].

Please note that you may not be able to review some of the data until after the end of the study, and a request to delete your personal data cannot be fulfilled where regulations and laws that apply to clinical research require your personal data to be retained.

You can request your study doctor to forward any questions, concerns or complaints you may have to the Sponsor or its representative.

What if I change my mind and do not want my information used or disclosed?

The permission to use or disclose your protected health information for this study does not have an expiration date. If you no longer want to share your protected health information, you may cancel your permission at any time by writing to the study staff and/or the Study doctor at the address below:

[Name] [Address]

If you cancel your permission after you have started in the study, the study staff and the Study doctor will stop collecting your health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study or receive any treatment as part of the study. This is because the study staff and/or the Study doctor would not be able to collect the information needed to evaluate the study vaccine.

If the study doctor or Sponsor ends your participation, or if you decide not to continue, you will be asked to return to the study doctor or study site to have all of the final clinical evaluations and laboratory tests done.

Protections for Genetic Information

A Federal law, called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

GENERAL STUDY INFORMATION

Who do I contact for information?

If you have any questions about the study, please contact:
[name] at [number] (24 hours)

If you feel that this study has caused you any harm, please contact:
[name] at [number]

Show your Clinical Study Participant Card to any doctor who treats you.

If you have any questions, concerns, or complaints about the study or about your rights as a research participant, please contact the study doctor/staff or WCG IRB.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or e-mail researchquestions@wcgirb.com.

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 sitewill include a summary of the results. You can search this Web site at any time.

YOUR AGREEMENT TO PARTICIPATE

If you consent, please read and then sign below.

- I have read and understood this information.
- It has been written in a language that I can read and understand.
- This study has been explained to me.
- All my questions about the study, the study vaccine, and possible risks and side effects have been answered to my satisfaction.
- I give permission for my doctors, other health professionals, hospitals, or labs to release information to [institution/clinic name] / [investigator name] about my health for the purposes of this study. I understand this information will remain confidential.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study.
- I understand that I will be given a signed copy of this document to keep.

Based on this information, I volunteer to take part in this study.

- I have been informed that the study doctor/staff may inform my other doctors, if any, about my participation in this study, and I agree to this.

Check Yes, No, or Not applicable:

Yes ☐ No ☐ Not applicable, I have no other doctors ☐

- I agree to the use of my blood and nasal swab samples for future research as described in section "Samples Collected for Scientific Research".

Check Yes or No:

Yes ☐ No ☐

You will receive a copy of this signed Informed Consent Form.

_____
Printed name of participant in full

_____
Signature of participant Date (dd/MON/yyyy)

_____
Printed name of person obtaining consent

_____
Signature of person obtaining consent Date (dd/MON/yyyy)