INFORMED CONSENT FORM

TITLE: A Phase 3, Randomized, Observer-Blinded, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1™ Adjuvant in Adult Participants ≥ 18 Years

PROTOCOL NO.: 2019nCoV-301
IRB Protocol # 20202703
20-2768

SPONSOR: Novavax, Inc.

INVESTIGATOR: Cynthia Leigh Gay, MD, MPH
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(919) 966-4131 (24 hours – Ask for ID Fellow on call)

STUDY CONTACT: Erin Hoffman

NOTICE: Due to the ongoing COVID-19 (Coronavirus) outbreak, there may be changes in how this study is done. These changes may affect you directly. For example, these changes can include doing study visits online or by phone, and completing study questionnaires online. There could also be other changes needed. Some blood samples may be drawn using local lab services. The sponsor may arrange home health services if you cannot come into the study site. The study staff will tell you about any new changes how the study is done.

KEY INFORMATION

This section summarizes basic information about the study. More detailed information is later in the document. Ask us any questions you may have. We want you to understand this study fully before deciding whether you want to take part. If you have questions at any time later, the contact information for the study doctor is below.

You are being asked to join this COVID-19 vaccine research study because you have not had COVID-19, but you may be at high risk of catching the infection or having more serious complications if you get it. The purpose of this study is to test a study vaccine made by Novavax, Inc. called “SARS-CoV-2 rS with Matrix-M1™ Adjuvant”. Because

this vaccine is not made using infectious virus, it cannot give you COVID-19, the disease caused by the SARS-CoV-2 virus. Study vaccine means the vaccine is not approved by the U.S. Food and Drug Administration (FDA). You will receive either the study vaccine or a placebo. A placebo does not contain any active ingredient. The study has 8-10 required visits and will last about 26 months. The first four visits will occur within the first 3 months, then approximately one visit every 6 months for the rest of the study. About 30,000 people, mostly in the U.S., are planned to take part in this study.

Currently, there is no approved vaccine for COVID-19, but this may change at any time. There may be other research studies in your area to join. The choices for you to consider are to not take part in this study, or to take part in another research study. The study staff will talk about these choices, risks, and possible benefits of participating in this study with you. If you decide not to take part, or stop the study at any time, there will be no penalty, and you will not lose any benefits or medical care to which you are otherwise entitled.

The procedures in this study include:

- two injections given 3 weeks apart into your upper arm
- swabs of your nose (nasal swabs) if you develop symptoms of COVID-19
- keeping records of your body temperature and symptoms of COVID-19 (if any)
- blood tests

We will ask you to monitor your health for signs of COVID-19 by keeping records of your body temperature and symptoms of possible COVID-19 infection daily in your electronic diary. You may have side effects from the injections. The most common side effects seen in people who got this study vaccine in other research studies were pain or tenderness at the injection site, tiredness, muscle pain, headache or “feeling unwell”.

We do not know if the vaccine will prevent you from getting sick if you are exposed to the SARS-CoV-2 virus. You may not benefit from being in this research study. Your participation may benefit others in the future by helping researchers understand this virus and the illness it causes.

Introduction
You are being asked to take part in a research study. It is up to you to decide if you want to join. Before you decide, we want you to understand why the research is being done and what it will involve for you.

Please read this consent form carefully and ask the study staff to explain anything you do not understand. You can take time to talk about the study with your friends, family, your personal doctor, and other people you trust. You can take as much time as you like to make your decision.

What is the purpose of the study?
This is a research study of an investigational vaccine called "SARS-CoV-2 rS with Matrix-M1™ Adjuvant". You will receive either the investigational vaccine or a placebo. A placebo does not contain any active ingredient. In the rest of this document, "study injection" will mean either the investigational vaccine or the placebo. The study vaccine is investigational because it is not approved by any health authority, including the U.S. FDA. The vaccine is designed to prevent the disease called COVID-19, which is caused by the virus called SARS-CoV-2. Throughout the rest of this document, we will call this virus, "coronavirus".

There is currently no approved vaccine to prevent or act against the coronavirus. Novavax, Inc. (the sponsor of this study) has developed a vaccine that may help the body to fight against coronavirus infection.

There have been two previous studies of this study vaccine in people to test its safety and the best dose. This study will help us understand whether the study vaccine works to prevent COVID-19 disease and whether it is safe to use in a large number of people. The main study questions are:

- To determine whether the vaccine prevents COVID-19 disease
- To see if the study vaccine continues to be safe for people to use, and whether it may cause side effects
- To see what different types of immune responses are stimulated by the study vaccine

We will also collect data about your health care utilization and how your life is affected by coronavirus infection. If that occurs, we will request additional permission to collect the information from you.

Do I have to join?
Joining this research study is voluntary and entirely up to you. If you choose to join, you will need to sign and date this consent form. We will give you a copy of the signed and dated consent form to keep. No study tests or procedures will be performed until after the informed consent is signed.

If you join, you can change your mind and withdraw at any time. If you decide not to join or later to leave the study, there will be no penalty, and you will not lose any medical benefits to which you are otherwise entitled.

Please tell us if you decide to leave the study. To help you leave the study safely, we may ask you to have more tests. If you have an unresolved health problem when you withdraw from the study, we may ask to collect information about your health until the problem improves or goes away. If you decide to withdraw from this study, you are encouraged to stay in the follow-up part of the study for safety and COVID-19 data collection.

How long will I be in the study?
You will be in this study for about 2 years and 2 months. You will have about 8-10 study visits.

We will ask you to come to the study site for extra (unscheduled) visits, if needed. If you develop symptoms of COVID-19, we will ask you to come to the study site for a visit to assess your health. This visit is called the Acute Illness visit and it will be scheduled only if, after Day 4 of the study, you develop symptoms that may be COVID-19 and which last for 2 days or more. If at your Acute Illness visit, you are tested and found to have COVID-19, you will be asked to return to the study site about a month later for another extra visit called the Convalescent visit. At any other time during the study, you may be asked to come to the study site if you have a medical issue or side effect that the study doctor wants to check on. This type of 'extra visit' is called the General visit.

How many people will be in the study?
About 30,000 participants will take part in the study at about 125 study sites, mostly in the U.S. At least 25% of participants will be age 65 or older and at least 25-40% of participants will be persons of color or those with high risk conditions.

As this study is expected to enroll participants quickly, a delay in your first study injection may result in your not taking part in the study. If most of the target number of participants have already started the study, the study staff may cancel your participation even if you wanted to participate.

Study Vaccine and placebo
Study participants will be assigned randomly (by chance, like drawing straws) to get either the study vaccine or the placebo.

You will have about a 2 in 3 (66%) chance to get the study vaccine. This means you have a 1 in 3 (33%) chance to get the placebo. Neither you nor the study staff can choose or know which you will get. This is done to make sure the results of the study cannot be influenced by anyone. However, if needed for a medical emergency, we can quickly find out what you received.

We will give you an injection into your upper arm 2 times during this study, on the first day and 21 days later (about 3 weeks).

What will happen during the study?
Study visits will normally take place at the study site unless other plans are required by the pandemic. Other plans, with your permission, may include study visits at your home. We will let you know if or when study visits need to be done at your home.

There are 3 stages to this study: Screening, Injection Period, and Surveillance Follow Up.

SCREENING
If you sign the consent form, we will do the screening procedures below to see if you are eligible to join this study. In most cases, screening will occur on the same visit as the initial injection, the first day of the study which is called “Day 0”. You will be asked:

- your date of birth, gender (sex), and race or ethnic background.
- your medical and social (your living and working or school environment as it relates to possible exposure to the coronavirus) history, including any recent confirmed coronavirus infection or COVID-19 hospitalizations.
- If you are able to become pregnant, we will do a urine pregnancy test. The result must be negative for you to join the study.
- If you are able to become pregnant, you must agree not to be sexually active in ways that could result in a pregnancy, OR you must agree to consistently use a medically acceptable method of preventing pregnancy from at least 28 days before enrollment until 3 months after the last study injection. We will tell you which contraception methods you may use during this study. You cannot take part in this study if you are breast feeding or planning a pregnancy within 3 months after the last study injection.
- To undergo a physical examination including height and weight.
- To have your vital signs (blood pressure, heart rate, breathing rate, and body temperature) measured.

If you are not able to take part in the study, your study staff will explain the reason. If you do qualify for this study after screening and would like to join it, you will enter the Injection Period. You will be given a Participant Wallet Card, which contains emergency contact information and information about your study commitments.

INJECTION PERIOD
This period will last approximately 90 days, beginning on the first day (Day 0). You will come to the study site for 3 more study visits at approximately 3 weeks (Day 21), 5 weeks (Day 35) and 3 months during the Injection Period. You will receive your first injection on Day 0 and your second injection on Day 21.

Enrollment or First Injection Day
On Day 0, you will receive a physical examination and have your vital signs (blood pressure, heart rate, breathing rate, and body temperature) measured. You will also be asked about your health and about any medicines you are taking or have taken in the past 3 months, including prescription and non-prescription medicines, vaccines, vitamins, supplements and herbal remedies. You will have a nasal swab to see if you currently have coronavirus infection without symptoms. You will also be trained on how to do a nasal swab at home. You will be given a kit of 3 swabs to swab your nose at

home, instructions for how to use them if you develop symptoms of possible COVID-19 and how to send the kits to the central laboratory. Additionally, the following will occur:

- A blood draw of about 20 mL or 4 teaspoons of blood will be needed for immune system tests.
- If you are able to become pregnant, we will do a urine pregnancy test. The result must be negative for you to receive the injection.
- Randomly assign you to the study vaccine group or the placebo group.
- You will be given the first study injection into your upper arm (deltoid muscle). We will ask you to stay at the study site for at least 30 minutes after the injection, so that we can see whether you have any immediate reactions to the study injection that need medical attention.
- You will be asked to install a mobile application ("app") on your smart phone for use during the study. If you do not have a device or cannot use your own device, the staff will provide you with a device to use during the study. We will help you learn how to use the app, which we call the "eDiary". You will be given the phone number to a Help Desk which is available 24 hours a day, 7 days a week in case you need technical assistance with the eDiary app. If you have data entry issues, please contact the study site.

Second Injection Day
On Day 21, you will receive a physical examination and have your blood pressure, heart rate, breathing rate, blood oxygen level and body temperature measured. You will be asked about your health and about any medicines you are taking, including prescription and non-prescription medicines, vaccines, vitamins, supplements and herbal remedies. Additionally, the following will occur:

- If you are able to become pregnant, we will do a urine pregnancy test. The result must be negative for you to join the study.
- A blood draw of about 20 mL or 4 teaspoons of blood will be needed for immune system tests.
- You will be given the second study injection into your upper arm (deltoid muscle). We will ask you to stay at the study site for at least 30 minutes after the injection, so that we can see whether you have any immediate reactions to the study injection that need medical attention.

Day 35 and Month 3
On the Day 35 and Month 3 visits, you will be asked about your health and about any medicines you are taking, including prescription and non-prescription medicines, vaccines, vitamins, supplements and herbal remedies. You may receive a physical examination, if needed.

A blood draw of about 20 mL or 4 teaspoons of blood will be needed for immune system tests.

During the Injection Period
At home:

- You will record your body temperature in your eDiary daily.
- The eDiary contains a list of symptoms that you may have after each study injection. You will answer the first day's question in the eDiary in the evening on the day of your first and second injections. The same questions will appear in the eDiary for you to answer on each of the next 6 days (total of 7 days) to record any reactions to the study injection. We will give you a measuring tape to measure any swelling or redness on your arm where the study injection was given, and we will show you how to use it. We will also provide an oral thermometer and show you how to use it.
- In the 7 days after each injection, we will ask you to tell us of any medications, other vaccinations, doctor visits, or other illnesses you have that are not included in the eDiary.
- You will be reminded daily to record any symptoms you have from this list in the eDiary.

COVID-19 SURVEILLANCE AND FOLLOW-UP

- You will record your body temperature and record any of these symptoms of COVID-19 daily:

    - cough worse than has been typical for you
    - fever or chills
    - sore throat
    - new onset of difficulty breathing or shortness of breath
    - fatigue that limits your activity
    - new muscle or body aches, not limited to one part of body
    - headache
    - new loss of taste or smell
    - congestion (feeling 'stuffed up') or a runny nose
    - nausea (feeling like you might throw up) or vomiting (throwing up)
    - diarrhea

- If you have any of these symptoms that last for 2 days or more and occur on Day 4 or later, contact the study site immediately so that an Acute Illness visit can be arranged. In the meantime, you will:

    - Obtain your first nasal swab using 1 of the swabs in your 3-swab kit and repeat daily for a total of 3 days.

  - Start to complete the FLU-PRO questionnaire once a day in your eDiary. This questionnaire asks you about your symptoms and how serious they are. The questionnaire will be completed for 10 days after the start of any possible COVID-19 symptoms, or until you have 2 days with no symptoms. This questionnaire is easy and takes about 4 minutes to complete.

- If you are sick or think you are sick with COVID-19, we may be able to help you come to your study visits. We may offer to arrange free transport for you to the clinic and back home with a service called Ride Health. We will need to provide your name and pick-up location in order to schedule a ride.
- At the Acute Illness visit, you will:

  - Be asked about your health.
  - Be asked about any medicines and supplements you are taking for these symptoms.
  - Undergo a physical examination, which includes measuring your blood oxygen level using a pulse oximeter. A pulse oximeter is a small device used to monitor the level of oxygen in your blood. It clamps gently on your fingertip and no blood or skin prick is required. Your blood oxygen level will be tested at rest and after mild exercise.
  - Have a nasal swab taken by study staff.
  - Have a blood draw of about 20 mL or 4 teaspoons of blood for immune system tests.
  - Be trained on the use of a portable pulse oximeter. The pulse oximeter will be provided to you to record your blood oxygen level daily in your eDiary at home. You will record your oxygen saturation daily (seated at rest and following mild exercise, like walking around the room for a minute). You will continue to do this for 10 days or until you have 2 days with no symptoms.

- If 1 or more of your 4 nasal swabs (3 obtained at home and 1 obtained at the Acute Illness visit) are positive for coronavirus, your study site will contact you to arrange a Convalescent visit. The Convalescent visit will occur about a month or so after your Acute Illness visit. At the Convalescent visit, you will:

  - Be asked about your health.
  - Be asked about any medicines and supplements you are taking for these symptoms.
  - Undergo a physical examination, if needed.
  - Be asked about your experience with coronavirus.
  - Have a blood draw of about 20 mL or 4 teaspoons of blood for immune system tests.
  - Return the pulse oximeter to the study site.

- At the Months 6 and 12 visits after the last study injection, you will be asked about your health, any new significant health problems that you have experienced since your last visit and any medicines you have taken since you last visit. You may receive a physical examination, if needed. Also, will do a blood test using about 20 mL or 4 teaspoons of blood to check your immune response to the study vaccine and possible exposure to the coronavirus.
- At Months 18 and 24 visits after the last study injection, you will be asked about your health, any new significant health problems that you have experienced since your last visit and any medicines you have taken since your last visit. Also, we will do a blood test using about 20 mL or 4 teaspoons of blood to check your immune response to the study vaccine and possible exposure to the coronavirus.
- During the time period from Month 12 to Month 24 after the last study injection, you will receive monthly phone calls, text messages or emails from the study staff to check on your health.

If you are hospitalized during this study for COVID-19, the study team will ask for a nasal swab sample, if permitted. This sample will be sent to the sponsor's central lab. The table below provides more information about the timing of all tests and procedures in this study.

Study Period:	**Screening**	**Injection**				**Unscheduled Visits**			**Months Following Last Vaccination**			
						Acute Illness	**Convalescent**	**General**				
Study Day:	**–30 to 0**	**0**	**21**	**35**	**Month 3**	**–**	**–**	**–**	**Month 6**	**Month 12**	**Month 18**	**Month 24**
Study Visit:	**Screening**	**1**	**2**	**3**	**4**	**Acute Illness**	**Convalescent**	**General**	**5**	**6**	**7**	**EoS**
Informed consent	X											
Medical and social history	X											
Date of birth, gender (sex), race, ethnic background	X											
Medication review		X	X	X	X	X	X	X	X	X	X	X
Vital signs	X	X	X									
Pregnancy test (if able to become pregnant)	X	X	X									
Physical examination	X	X	X	X	X	X	X	X	X	X		
Coronavirus blood test		X		X	X	X	X		X	X	X	X
Study vaccine injection		X	X									
Monitoring reactions to study vaccine		X	X									

Study Period:	Screening	Injection				Unscheduled Visits			Months Following Last Vaccination			
						Acute Illness	Convalescent	General				
Study Day:	–30 to 0	0	21	35	Month 3	–	–	–	Month 6	Month 12	Month 18	Month 24
Study Visit:	Screening	1	2	3	4	Acute Illness	Convalescent	General	5	6	7	EoS
Blood test to check immune response		X	X	X	X	X	X		X	X	X	X
COVID-19 surveillance			From 4 days after initial vaccination using eDiary									
Nasal swabs by study staff		X				X						
Nasal swabs by participant		Starting on Day 4, if any possible symptom of COVID-19 lasts 2 days or more, you will obtain your first nasal swab and repeat once a day for a total of 3 days										
Blood oxygen level			At Acute Illness visit, blood oxygen levels will be measured using a pulse oximeter and you will be trained on the use of this device at home for 10 days or until you have 2 days with no symptoms									
Checking your health		X	X	X	X	X	X	X	X	X	X	X
Review of coronavirus experience							X					

When you notify your study site that you have COVID-19-like symptoms, you will be asked to come to the study site to be evaluated, have a nasal swab and blood test, be informed about the use of the pulse oximeter and provided guidance for seeking additional healthcare. You may be asked to return to the study site, or to go to your regular care provider or other urgent/emergent care facilities. The study staff can also provide guidance with respect to self-isolation, informing your close contacts and employer, etc. Your study staff will collaborate with any other healthcare providers who become part of your care to ensure that health information needed to complete the safety profile of the study vaccine is collected.

End of Study (EoS)

When you complete the last study visit about 2 years after the last study injection or if you stop the study early, you will have the End of Study (EoS) visit (may be conducted remotely if necessary) to check your health, including COVID-19-like symptoms. If the EoS visit is conducted in-person at the study site, a blood sample will be obtained to test for long-term immunity.

If a smart phone was provided for you to use for the eDiary, we will ask you to return it and the pulse oximeter, if you received one, at the EoS visit, or at an early discontinuation of study and follow-up visit. Instructions on how to return these devices at no cost to you will be given to you by your study site.

Collecting study samples

A total of 20 mL (4 teaspoons) of blood will be collected at each visit on Days 0, 21, and 35, and Months 3, 6, 12, 18 and 24 for a total of 160 mL (about 11 tablespoons). Two additional blood draws of 20 mL each will be collected at the Acute Illness and

Convalescent visits if you experience symptoms of COVID-19 and test positive for coronavirus. Therefore, a maximum of 200 mL (about 13 tablespoons) of blood can be collected throughout the study.

All samples will be labelled with your unique study participant number and will not contain any personal information that can identify you. Blood samples and nasal swabs collected will be sent for testing your immune responses to sponsor-approved laboratories. These samples will be stored securely at the University of Washington.

If you withdraw from the study, you can ask in writing for your samples to be destroyed at any time. However, data already obtained from your samples will continue to be kept and used for the purposes described in this form. Your data will be protected by a code that will not allow Novavax, Inc., or its partners to know your identity. If you decide to leave the study at any time but do not ask for your samples to be destroyed, Novavax, Inc., may continue to use your samples for the purposes described in this form. For further information on how your personal information will be handled, see the section on Confidentiality and Data Protection.

Blood samples may be stored frozen by Novavax, Inc. or companies working for Novavax, Inc. for up to 25 years. Your stored samples may also be used alone or mixed with other participants' samples for other purposes, such as:

- Making standard samples that can be used to make sure the coronavirus antibody tests always work the same way, or
- Developing new vaccines or new or improved tests related to the coronavirus or other diseases.

If any of your samples are used in these other ways, the information linking those samples to you personally will be permanently destroyed.

Your samples will only be used for the purposes described in this consent document. If additional analyses are proposed, your consent and the review of the Institutional Review Board (IRB) will be required. An IRB is an independent group of people who review research studies to protect the rights, dignity, safety and well-being of people participating in research studies.

You will not be paid for any information and inventions derived from your participation in the study, including information derived from your biological samples. These are considered the property of Novavax, Inc.

Future Research

Any leftover samples or nasal swab samples for COVID-19 detection collected from you during the study will be retained by the central laboratory for up to 25 years and with your permission may be used for future unspecified research. Genetic material from SARS-CoV-2 found in nasal swabs may be tested for possible genetic mutations in the

virus. Testing for virus mutations may help to explain some time in the future why the vaccine works the way it does. No test will be performed on your genetic material (DNA or RNA). After 25 years, all samples will be destroyed. The virus material may be stored at the University of Washington for future testing, but will not be linked to your personally identifiable information.

Your study data will be used for the purpose of optional exploratory research on other current or future research involving the same vaccine, the same or related therapeutic area, or for other relevant health research that is within the scope of the current study. In addition, your study data may be used to support domestic or foreign regulatory filings. You will have the opportunity to document your decision later in this form. If you choose not to take part in this optional exploratory research, you may still take part in the main research study.

What are the risks and possible discomforts of being in this study?
All medicines, including vaccines, can have some risks or cause certain side effects and discomforts, although not everybody experiences them. Side effects are any unwanted or sometimes unpleasant reactions that may happen after getting injections.

The known risks, side effects, and discomfort when people receive any vaccine are injection site reactions, which result in redness, itching, or a painful sensation at the place of the injection.

Possible Risks Due to Study Vaccine Administration
While the SARS-CoV-2 rS vaccine is quite new (because the virus only appeared in December, 2019), there has been considerable experience with investigational vaccines intended for other infections based on the same manufacturing methods. To date, over 14,000 adult participants, including pregnant women and people aged up to 85 years, in clinical studies done by Novavax, have received vaccines prepared with the same type of manufacturing methods as the study vaccine. The nanoparticle protein vaccines have been given to over 4,200 participants in different clinical research studies conducted by the sponsor for testing vaccines against different viruses and other germs. About 2,500 participants received Matrix-M1 adjuvant (an ingredient used in some vaccines that helps create a stronger immune response to make the vaccine work better), and 2,985 participants received the nanoparticle protein + Matrix-M vaccines, mostly adults and people up to 85 years of age.

Side effects experienced by participants who received any of the vaccines with the Matrix-M1 adjuvant include:

- Pain, redness, bruising, and swelling at the injection site
- Headache
- Fatigue (feeling tired)
- Muscle pain
- Malaise (feeling unwell)

- Diarrhea
- Joint pain
- Chills
- Nausea
- Vomiting
- Fever

These are symptoms that can occur with vaccines in general but can be more apparent when the vaccine contains an adjuvant. So far, no serious health concerns have been identified as being related to receiving the Matrix-M1 adjuvant.

Autoimmune diseases may be a potential side effect of any vaccines or adjuvants. These are serious diseases that can occur in the general population who do not get vaccines. Autoimmune diseases involve the immune system attacking the body's own tissues. Autoimmune disease can affect the heart, skin, blood health, metabolism, nervous system, thyroid, muscles, joints, liver, and/or kidneys. There is no evidence that the technology used to prepare the study vaccine, or the use of Matrix-M1 adjuvant, is associated with an increased risk of autoimmune disease. However, for your safety, you will be monitored and regularly checked during the study for any side effects that you may have after receiving the study injections.

A total of 131 participants in an ongoing study have received the study vaccine or placebo using doses that are being used in this study. No serious adverse events have been reported in that study. The most common injection site side effects were pain and tenderness, and these were mostly mild and side effects generally lasted less than two days. The most common general symptoms after vaccination were headache, tiredness and muscle aches, and these effects were generally mild and of short duration. Vaccination side effects were more likely after the second study vaccine was given. No participants stopped taking the second study vaccine dose due to side effects related to the study vaccine. At least 3 other studies that currently involve more than 2000 people are currently being conducted. They have been enrolling for too short a time to provide much information, but no serious side effects have been reported.

Risk of testing positive for SARS-CoV-2 antibodies
Antibodies to fight or prevent infection are stimulated by most vaccines as a way of preventing infection. Your body may make antibodies to SARS-CoV-2 because you received a study vaccine. Because of this, the study vaccine may cause you to test positive on some SARS-CoV-2 antibody blood tests, even if you do not have it. This is called vaccine-induced seropositivity (VISP).

For this reason, we recommend that you avoid getting antibody blood tests outside of this study. If you need to get tested outside of this study, we will give you information to help you be sure that you receive a test that will avoid this problem.

If you test positive for SARS-CoV-2 antibodies, we don't know if they will protect you.

If you become pregnant during or after the study and have VISP, we do not know if the antibodies could be passed to your baby. We know that this happens with other vaccines, like tetanus vaccine. For most babies, antibodies passed from the mother last for about six months.

Placebo risk
Some participants in this study will receive a placebo. Taking a placebo is the same as not taking any active medicine.

Unknown Risks
Because this study vaccine has only been given to 131 participants in other studies, there may be other risks that are unknown. Sometimes allergic reactions to vaccines occur and if untreated could become life threatening. Some signs of an allergic reaction are as follows:

- Rash
- Difficulties in breathing
- Wheezing with breathing
- Sudden change in blood pressure that can cause dizziness or fainting
- Swelling around the mouth, throat, or eyes
- Fast pulse
- Sweating

You should get medical help and contact the study doctor or staff if you have any of these or any other side effects during the study.

Most side effects begin soon after the study injection and last for a few days. However, sometimes side effects can be serious, long lasting, or life-threatening, and can result in death. If a severe side effect or reaction occurs, your study doctor may need to stop your participation in the study. Your study doctor will discuss the best way of managing any side effects with you.

You may also get other unwanted effects or discomforts with the study tests such as the following:

- **Blood Draw:** Collecting blood may cause bruising at the place where the needle is inserted. Fainting, and in rare cases infection, may occur.
- **Nasal Swabs:** During collection of swabs, you may have sneezing, eye tearing, or gagging. There is also the potential for those people that are susceptible to nosebleeds to have one.

Are there any reproductive risks?
If you are able to become pregnant, there is important information for you to know about the pregnancy risk precautions for this study before you sign and date this form.

It is not known whether the study vaccine may affect an unborn child or an infant that is breast-feeding. If you are breast-feeding, pregnant or plan to become pregnant during the study period, then you may not take part in this study.

If you are capable of becoming pregnant, you must agree to be heterosexually inactive from at least 28 days prior to enrollment and until 3 months after the last study injection OR agree to consistently use a medically acceptable method of contraception from at least 28 days prior to enrollment until 3 months after the last study injection.

If you become pregnant during this study, immediately inform the study staff. You will not receive any more study injections, but you may be able to continue with other study visits and procedures. We would like to collect data and information about your pregnancy. The study staff will discuss the risks of continuing with the pregnancy and the possible effects on the fetus. Monitoring of your pregnancy will continue until the outcome is known.

Will I be told if I have a positive coronavirus test from samples collected during the study?
Yes, but this result may take some time. Samples collected for COVID-19 tests are for the purposes of the research study. The test results may not be available in an immediate time frame, so should not be relied upon to confirm a diagnosis of COVID-19 or direct your medical management. The tests conducted in the study are approved for research and diagnostic purposes. If you have a suspected COVID-19 illness, you should follow local testing guidelines. You should discuss with your research site or your regular healthcare provider local guidelines for potential positive COVID-19 cases, that usually includes self-isolation along with your close contacts until a confirmatory test can be done according to local guidelines.

Your study staff will discuss the best medical management of your illness and may, with your consent, involve discussions with your regular treating doctor. You will get results of tests that are clinically relevant to your health (for instance nasal swab coronavirus results) when they are available. During other parts of this study, you will not get information from tests that are done purely for research (for instance, coronavirus research antibody test results).

Positive coronavirus test results, when available, will be reported to health authorities as required by local law.

Will I be informed if new information becomes available during the study?
Sometimes during a study, new information becomes available about a study vaccine. If this happens, we will tell you about it as soon as possible. We will discuss with you whether you want to continue in the study.

If you decide to continue in the study after learning about the new information, or if new procedures need to be performed during the study, we may ask you to sign an updated consent form.

Benefits
There may be no direct benefit to you for participating in this study. We do not know if this study vaccine will protect you against SARS-CoV-2 infection or COVID-19 illness. That is the research question that this study is intended to answer. Even if the study does not help you directly, taking part in this study may help other people in the future by helping us learn more about COVID-19 and the virus that causes it.

Are there any alternatives to joining this study?
There is no vaccine currently approved by the FDA available to prevent coronavirus infection. If one of the several vaccines under study (including this one) are approved, recommended, and available, while you are in this study, you may be offered the chance to be unblinded to see if you received placebo. If you were on placebo, the research staff will discuss your options and you may be able to get the new active vaccine outside of this protocol. We will ask you to continue the safety follow-up for COVID-19 disease in this study if you choose to get the new vaccine. The study staff will tell you how to get the new approved vaccine.

What happens if you change your mind?
Taking part in this study is voluntary. You do not have to take part, and you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to leave the study before the last study visit, tell us and follow our instructions.

In addition, we or the sponsor may remove you from the study for your own safety, even if you wish to continue to take part. For example, this could happen:

- If receiving the study injections would be harmful to you
- If you experience a serious reaction or unacceptable side effects
- If you do not follow the study rules or it is discovered that you do not meet the requirements for taking part in the study
- If the study is cancelled because of decisions made by the sponsor or by local government agencies or health authorities
- If you become pregnant (only if you have not received the second injection).

If you stop the study early, we will ask you to complete the end-of-study phone call as a final health check for your safety and blood sample, if possible. We may ask you if you would consider being contacted for further safety follow-up but not for further study procedures.

What are the costs of taking part?
There are no costs for you if you take part. You will receive the study injections and study-related tests or procedures at no cost to you.

You or your insurance company will be responsible for the costs of any standard medical care that is not required for this study, including any care related to diagnosis, treatment or hospitalization for COVID-19. You may talk to the study staff and your insurance company about what is covered.

Is there a payment if you take part in the study?
You will receive $100 for each of the two visits during which you receive an injection. You will receive $70 at each of the other visits including screening, follow ups and unscheduled illness visits. You will be compensated additionally for each of the eDiaries that you complete, up to $590 for completing them all. You will receive these funds within 30 days of your visit by a pre-paid card.

If you travel greater than 50 miles one-way to the visit, we will provide additional reimbursement based on the distance traveled to help with your travel expense. We will consider additional hardships related to travel on a case-by-case basis.

IRS regulations require that individuals receiving $600 or more from the institution during a calendar year must have the total amount of the payments reported to the IRS on Form 1099.

Payment for Injury Related to the Study
All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill or the National Institute of Allergy and Infectious Diseases (NIAID) have not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care.

The Sponsor of the study, Novavax, Inc., LLC., has agreed to pay all reasonable necessary medical expenses for the treatment of reactions, illnesses or injuries related to the use of the study drug, defects in the manufacture of the study drug, or as a direct result of properly performed study tests and/or procedures, except to the extent such expenses are due to the negligence of the study staff or due to your current disease or condition unless it is made worse because you are taking part in this study.

The sponsor has no plans to provide additional financial compensation for lost wages or any other losses or expenses. Any costs for medical expenses not paid by the Sponsor will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

A new public health declaration, called the Public Readiness and Emergency Preparedness Declaration (PREP), was issued by the Department of Health and Human Services on March 10, 2020. This declaration limits the legal rights of a subject participating in a COVID-19 clinical study that uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19. This includes the study drug, SARS-CoV2 rS, used in this study. Subjects using SARS-CoV2 rS used in this study will have limits on their right to sue the manufacturers, the study sponsor, healthcare providers and others for significant injuries and adverse reactions. Under some circumstances, compensation may still be available under the PREP Declaration for certain patients who sustain injuries. To find out more, go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

If you think you have been injured from taking part in this study, call the study doctor at the telephone number listed on the first page of this form. They will let you know what you should do.

Alternatives to Site Visits if there are Restrictions on Travel or 'Lockdown'
The study staff may hire another company to provide home care services. The home care staff will be given your name, address, telephone number, and study medical information that is strictly necessary to conduct home visits. All parties are required to respect your confidentiality at all times. If you sign and date this consent form for procedures in the study, you are giving permission to the study site and the sponsor to give your contact information to the hired company for the purposes of providing home care services. There will be no cost to you for these services. Any information collected by the third party company will be transferred to the study site.

Your study site will provide the appropriate kit(s), labels and instructions to collect and transport your nasal swabs to the designated laboratory.

Confidentiality and Data Protection
We will do our best to protect your private information.

Your study records and samples will be kept in a secure location. Study staff will label all of your samples and most of your records with a code number, not your name or other personal information. We will not share your name with anyone who does not need to know it.

Your records may also be reviewed by groups who watch over this study. These groups include:

- Novavax, Inc., and its study monitors
- The CoVPN (the COVID-19 Prevention Network) and people who work for it

- Some government agencies:
    - The US National Institutes of Health
    - The US Food and Drug Administration
    - The US Office for Human Research Protections
    - Operation Warp Speed partners
    - Any regulatory agency that reviews research studies
- Some committees that make sure we protect your rights and keep you safe:
    - The Data and Safety Monitoring Board
    - The Institutional Review Board (IRB)

These people may look at your records to make sure the study has been done the right way. They also want to make sure that your health information has been collected the right way, or for other reasons that are allowed under the law.

Your health information may be further shared by the groups above. All reviewers will take steps to keep your records private.

We cannot guarantee absolute privacy. If you are found to have a medical condition that we are required to report by law, then some of your information may be shared. At the study site, we have to report the following information:

- SARS-CoV-2
- Pneumonia

We have a Certificate of Confidentiality from the US government to help protect your privacy. With the certificate, we do not have to release information about you to someone who is not connected to the study, such as the courts or police. Sometimes we can't use the certificate. Since the US National Institutes of Health funds this research, we cannot withhold information from it.

We will not share your name or information that can identify you with the CoVPN (the COVID-19 Prevention Network). The CoVPN may share information from this study with other researchers. Researchers may publish the results of this study. You will not be identified in any published information.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You will be asked to sign a separate form ("HIPAA Authorization") to allow researchers to review your medical records.

Risks to Confidentiality and Privacy for eDiary ("app")
As part of this research study you will need to use Medidata's Patient Cloud Application. You may be asked to download the app to your smartphone or researchers may provide you with an eDiary device. In order to use the app, you will be asked to agree to the Terms of Use and Privacy Policy which will appear on your mobile device's screen when you first start using the app. If you decide that you do not want to agree, then you should not participate in the research.

While using the app, data about you including personal health information, other communication data, and internet usage will be collected and transmitted to the researchers and to the app developer. A complete description of this data collection and sharing is found in the Privacy Policy. Transmission of information via the internet is not completely secure, so there is a small risk of unintentional release of your information and safeguards are in place to protect your personal information.

If you do not agree with the data collection and sharing identified in the Privacy Statement, or do not want your information transmitted via the internet, then you should not participate in the research. If you choose to participate, notwithstanding anything to the contrary in the Terms of Use or Privacy Statement, you do not release the investigator, sponsor, institution, or their agents from their responsibilities to you under this research study, including their obligations related to protection of your personal information, whether provided through the app or otherwise.

What do I have to do?
When deciding whether to take part in this study, consider whether you are able and willing to do the following:

- To follow the instructions of the study doctor and the study team because it is important for your own safety.
- To commit to the time required to attend study site visits described above.
- To tell the study staff truthfully about your complete medical history.
- To tell the study staff truthfully about your working or occupation details in order to check whether you are working in a high-risk environment with exposure to coronavirus.
- To report any new problems, illnesses, or side effects that you are having. If you have experienced a cough, sore throat, fever, or breathing difficulty in the past few days, please tell the study staff. This is important because these symptoms are often seen in patients with COVID-19 disease. If you have any of these symptoms, the study staff will arrange for you to have an in-person visit and inform you about the necessary steps and procedures to be taken.
- To allow the study doctor and/or the study team to collect blood samples, nasal swabs, or other samples from you for testing.
- To take nasal swabs samples by yourself as directed, and to provide these samples to the study staff as instructed.

- To report changes in medication(s) or new medication(s), including supplements or any vaccinations that you are taking during the study. In addition, you must inform the study staff about taking any medicine for prevention of COVID-19 disease. You should not take any new vaccines or medications without asking the study doctor first.
- To record any symptoms of COVID-19 in the eDiary.
- To remain in touch with the study staff and to let them know if you have changes to your contact information (address or telephone number) or if you no longer wish to take part in the study.
- To provide an emergency contact in case the study staff cannot reach you.

Funding and contact information
Novavax, Inc. (a vaccine company) produces the study vaccine and is the sponsor. The US Government, is involved in organizing and funding this study. The US government will pay your study doctor and/or the study site to cover their costs of conducting this study. If applicable, your study doctor will disclose to you any financial links or other interests that he/she may have to the sponsor.

To protect your safety, rights, wellbeing and dignity, all research is reviewed by an independent group of people called an Institutional Review Board. You may talk to them at 855-818-2289 or researchquestions@wcgirb.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 subject.

If you have any questions, concerns or complaints about the research or your rights as a participant, or any injury or if you are unwell, please contact the study doctor at the phone number(s) listed above on the first page.

Signature Page

I have read and understand the information in this informed consent form. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to take part in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent form. I will receive a copy of this signed and dated informed consent form.

Primary Care Physician / Specialist notification option
Please indicate below by ticking the box alongside the appropriate line whether you want us to notify your primary care physician or your specialist of your participation in this study.

- ☐ Yes, I want the study doctor to inform my primary care physician / specialist of my participation in this study.
- ☒ No, I do not want the study doctor to inform my primary care physician / specialist of my participation in this study.
- ☐ I do not have a primary care physician / specialist.
- ☐ The study doctor is my primary care physician / specialist.

They requested selecting 2 or 3 to make it easier for them

The sponsor would like your permission to collect and use extra blood for immune testing that looks at how some types of your white blood cells (cells of the immune system) respond following study injection. The extra blood volume (about 50 mL [less than 4 tablespoons]) will be collected before the first study injection, Day 21 after the 2nd study injection and then again at about Day 35. It is possible that we will not collect this extra blood from every participant who agrees to it.

- ☒ **(tick box)** Yes, I agree to have extra blood collected and my blood sample(s) used for white blood cell testing.
- ☐ **(tick box)** No, I do not agree to have extra blood collected and my blood sample(s) used for white blood cell testing.

Ask them if I was chosen for this?

I agree that a copy of the signed and dated informed consent form (whether signed by electronic or manual means) will be securely transmitted to and stored by ICON/Firecrest Clinical (South County Business Park, Leopardstown, Dublin 18, Ireland). The copy held may be reviewed by regulatory authorities, Institutional Review Boards/ethics committees, my study doctor and auditors. I understand that by signing this consent form electronically or manually I am giving my permission for this to happen.

Joseph Puccio
Joseph Puccio (Jan 20, 2021 13:32 EST)

Signature of participant

01/20/21

Date of Signature

JOSEPH PUCCIO

Printed name of participant (CAPITALS)

PERSON OBTAINING CONSENT
I have fully informed the participant about all aspects of the study and answered all of the participant's questions.

Tanailly Smith (Jan 20, 2021 13:34 EST) 1/20/21

Signature of person obtaining consent | Date of Signature

TANAILLY G. SMITH, RN

Printed name of person obtaining consent (CAPITALS)

INFORMED CONSENT FORM ADDENDUM FOR OPTIONAL EXPLORATORY RESEARCH ON BIOLOGICAL SAMPLES

Consent to Use Samples for Future Medical Research		Participant to initial
I consent to the use of left-over samples from this study being retained for exploratory medical research, now or in the future.	Yes ☒ No ☐	JP
I have been informed that if I do not consent to donate left-over samples for exploratory research, I can still take part in this study.	Yes ☒ No ☐	JP

By signing below, I confirm I have read the section titled “Future Research” and have expressed my choice. I understand I can change my mind at any time, for any reason.

Joseph Puccio
Joseph Puccio (Jan 20, 2021 13:32 EST)

Signature of participant

01/20/21
Date of Signature

JOSEPH PUCCIO
Printed name of participant (CAPITALS)

Tanailly Smith (Jan 20, 2021 13:34 EST)

1/20/21

Signature of person conducting the informed consent discussion

Date of Signature

TANAILLY G. SMITH, RN

Printed name of person conducting the informed consent discussion (CAPITALS)

IRB Approved at the
Study Level
Nov 01, 2020
#29071214.0

University of North Carolina at Chapel Hill
HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

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IRB Study # 20-2768
Title of Study: Novavax 2019nCoV-301 A Phase 3, Randomized, Observer-Blinded, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1™ Adjuvant in Adult Participants

Principal Investigator: Cindy Gay, MD, MPH
Mailing Address for UNC-Chapel Hill Department: 130 Mason Farm Road CB 7030 , Suite 2112 Bioinformatics, Chapel Hill, NC 27599-7030 , USA

This is a permission called a "HIPAA authorization." It is required by the "Health Insurance Portability and Accountability Act of 1996" (known as "HIPAA") in order for us to get information from your medical records or health insurance records to use in this research study.

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1. If you sign this HIPAA authorization form, you are giving your permission for the following people or groups to give the researchers certain information about you (described below):

Any health care providers or health care professionals or health plans that have provided health services, treatment, or payment for you such as physicians, clinics, hospitals, home health agencies, diagnostics centers, laboratories, treatment or surgical centers, including but not limited to the UNC Health Care System and its members and affiliates (collectively, "UNCHCS"), health insurance plans, and government health agencies.

2. If you sign this form, this is the health information about you that the people or groups listed in #1 may give to the researchers to use in this research study:

Any information in your medical records that relates to your participation in this research. These records might include information about mental health, drug or alcohol use, HIV/AIDS or other communicable diseases, or genetic testing.

3. The HIPAA protections that apply to your medical records will not apply to your information when it is in the research study records. Your information in the research study records may also be shared with, used by or seen by collaborating researchers, the sponsor of the research study, the sponsor's representatives, and certain employees of the University of North Carolina at Chapel Hill or other affiliated entities conducting the research, or government agencies (like the FDA) if needed to oversee the research study. HIPAA rules do not usually apply to those people or groups. If any of these people or groups reviews your research record, they may also need to review portions of your original medical record relevant to the situation. The informed consent document describes the procedures in this research study that will be used to protect your personal information. You can also ask the researchers any questions about what they will do with your personal information and how they will protect your personal information in this research study.

If study participant payments are described in the consent form, payments may be paid through a partner financial institution or its vendor. By participating in this Study, you authorize the disclosure of limited protected health information to a financial institution or its vendor to facilitate such payments or for tax reporting purposes.

4. If this research study creates medical information about you that will go into your medical record, you may not be able to see the research study information in your medical record until the entire research study is over.

5. If you want to participate in this research study, you must sign this HIPAA authorization form to allow the people or groups listed in #1on this form to give access to the information about you that is listed in #2. If you do not want to sign this HIPAA authorization form, you cannot participate in this research study. However, not signing the authorization form will not change your right to treatment, payment, enrollment or eligibility for medical services outside of this research study.

6. This HIPAA authorization will not stop unless you stop it in writing.

7. You have the right to stop this HIPAA authorization at any time. You must do that in writing. You may give your written stop of this HIPAA authorization directly to Principal Investigator or researcher or you may mail it to the department mailing address listed at the top of this form, or you may give it to one of the researchers in this study and tell the researcher to send it to any person or group the researcher has given a copy of this HIPAA authorization. Stopping this HIPAA authorization will not stop information sharing that has already happened.

8. You will be given a copy of this signed HIPAA authorization.

Joseph Puccio
Joseph Puccio (Jan 20, 2021 13:32 EST)

Signature of Research Subject

01/20/21

Date

Joseph Puccio

Print Name of Research Subject

For Personal Representative of the Research Participant (if applicable)

Print Name of Personal Representative: _____
Please explain your authority to act on behalf of this Research Subject:

_____

I am giving this permission by signing this HIPAA Authorization on behalf of the Research Participant.

_____ _____

Signature of Personal Representative Date