Participant Information Sheet/Consent Form

PART 2 OF THE STUDY

Alfred Project Number:	151/20
Full Study Title:	A 2-Part, Phase 1/2, Randomized, Observer-Blinded Study to Evaluate the Safety and Immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With or Without Matrix-M™ Adjuvant in Healthy Subjects
Protocol Number:	2019nCoV-101
Test Drug Code:	SARS-CoV-2 rS
International Sponsor:	Novavax, Inc.
Local Sponsor:	PPD Australia Pty Ltd.
Coordinating Principal Investigator:	Dr Paul Griffin
Principal Investigator:	Dr Susan Thackwray
Location:	USC Clinical Trials Level 1, 9 Ochre Way Sippy Downs QLD 4556

Part 1 What does my participation involve?

1 Introduction

You are invited to participate in a clinical research study (hereafter, called the “study”). This is a study of an experimental vaccine against a new type of virus called SARS-CoV-2. As you are probably aware, this virus has caused a global outbreak of an illness called coronavirus disease-19 (called “COVID-19”) around the world.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to have the tests and treatments that are described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this study?

Coronaviruses are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS), which are flu-like illnesses.

An outbreak of COVID-19 caused by the new type of coronavirus (SARS-CoV-2) began in Wuhan, Hubei Province, China in December 2019 and has spread to many countries worldwide. In COVID-19, patients have flu-like symptoms such as fever, coughing, sore throat, fatigue, and shortness of breath. Serious cases of COVID-19 can progress to pneumonia (infection of the lungs) and death. COVID-19 is dangerous for elderly people, those with chronic diseases affecting the heart and lungs, and patients with an impaired immune system. As we learn more about SARS-CoV-2 and COVID-19, it appears that younger people with COVID-19 can also experience the more severe form of this disease, although at a lower rate.

So far, there are no approved vaccines available to prevent or act against SARS-CoV-2. Novavax, Inc. (Sponsor) is developing a vaccine that aims to prevent this virus from infecting people and/or preventing serious illness if infection occurs. Vaccines are substances used to try to create resistance (or immunity) to a disease. The name of the study vaccine in this study is SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine with Matrix-M adjuvant (hereafter, called the "study vaccine").

This study is being conducted in 2 parts (Part 1 and Part 2).

Part 1 of the study was the first time the study vaccine was given to humans. In Part 1, 131 healthy male and female participants between the ages of 18 and 59 years (inclusive) received up to 2 doses of study vaccine with or without a vaccine ingredient called Matrix-M adjuvant. An adjuvant is a substance that increases the body's immune response to a vaccine. Early results from Part 1 showed no immediate safety concerns. An independent safety group and the US Food and Drug Administration (US FDA) reviewed the Part 1 safety results and agree that the Part 2 of the study can begin. The independent safety group is called a Safety Monitoring Committee (SMC). The SMC is made up of doctors not working for the Sponsor.

As a result, Part 2 is being conducted.

You are being invited to join Part 2 of the study. About 750 to 1,500 healthy men and women between the ages of 18 and 84 years will take part in Part 2. About half of the participants will be 60 years of age and older. Part 2 will be conducted in either Australia or the United States, or in both countries.

More information is needed to understand whether the study vaccine works and whether it is safe to use in a larger number of people. Therefore, the main purpose of Part 2 of this study is to continue to collect more information about the study vaccine:

1) To see if the study vaccine continues to be safe for people to use and whether it may cause further side effects;
2) To find out the best dose of the study vaccine for adults younger than, and older than, 60 years;
3) To see what different types of immune responses the study vaccine produces; and
4) To also find out the dose or doses of the study vaccine that can be used for future research studies or emergency use.

Other purposes of the study include measuring the immune system responses over time, whether a booster dose is needed, and to see if the study vaccine may reduce the chance of people being diagnosed with COVID-19 illnesses.

This informed consent form explains Part 2 of the study and your possible role as a participant in it if you agree to participate in the study.

3 What does participation in this study involve?

If you decide to take part in this study, you will be in the study for up to 62 weeks (around 15 months). You will have to visit the study site (i.e. clinic) at least 7 times. If your study site can study the effect of the study vaccine on cells related to the immune system, then you will need to attend 2 additional visits on Days 7 and 28. The study team will inform you accordingly. All visits will involve only day visits to the study site. An additional last 2 appointments (Days 273 and 357) will be performed by telephone, and you will not have to visit the study site. The Day 357 visit is the final visit or End-of-Study Visit. You may have to attend unscheduled (extra) visits for safety reasons.

Study visits will normally take place at the study site, unless your study site staff make other plans. However, due to COVID-19, local guidelines may prevent you from going to the study site. Therefore, some of the study visits may be done at your home.

You will be asked to read and sign this form before you have any study tests. If you want to participate in this study, then your study doctor will first check whether this study is right for you. This is called screening. This visit will take up to 3 hours. Screening must be completed no more than 45 days before you receive the study vaccine.

If your study doctor says you can be in the study, you will be assigned by chance (like flipping a coin) to 1 of 5 treatment groups on Day 0 (the day on which you receive the first injection of study vaccine). Four of these groups will receive study vaccine and one group will receive placebo as shown below. A placebo is a substance that looks like the study vaccine but does not have contain any vaccine product in it; the placebo in this study contains only water and sodium chloride (salt). You have an 80% chance of receiving the study vaccine. A computer program will randomly decide which treatment you will receive. Participants in all 5 groups will follow the same study procedures. You will not know what treatment group you are in until after the study ends.

This study will test 2 different strengths of study vaccine, a lower strength vaccine (5 µg study vaccine + 50 µg Matrix-M adjuvant) and a higher strength vaccine (25 µg study vaccine + 50 µg Matrix-M

adjuvant). The following table shows the treatment groups (study vaccine or placebo) you may be assigned by chance to receive in the study.

Treatment Group	Number of Subjects	Day 0	About Day 21	About Day 189
		Study Vaccine or Placebo	Study Vaccine or Placebo	Study Vaccine or Placebo
A	150-300	Placebo	Placebo	Placebo
B	150-300	5 µg + 50 µg	5 µg + 50 µg	Placebo
C	150-300	5 µg + 50 µg	Placebo	5 µg + 50 µg
D	150-300	25 µg + 50 µg	25 µg + 50 µg	Placebo
E	150-300	25 µg + 50 µg	Placebo	5 µg + 50 µg

Note: The first value represents the amount SARS-CoV-2 vaccine and the second value represents the amount of Matrix-M adjuvant. For example, 5 µg + 50 µg represents 5 µg SARS-CoV-2 rS + 50 µg Matrix-M adjuvant. µg is unit of measure that is 1 millionth of a gram.

For the remainder of this document, when we use “study vaccine”, this refers to vaccination with either the investigational vaccine product or placebo you will receive according to your treatment group.

After you have been assigned by chance to a treatment group, you will be given the study vaccine as an injection into the muscle in your upper arm (the deltoid muscle) on Day 0. About 3 weeks later, on around Day 21, you will get a second injection of the study vaccine that was assigned to you by chance. The third injection of the study vaccine (called the booster dose) will be given about 6 months after the second injection on around Day 189. The injections on Day 0 and on or around Day 21 will be given in the opposite arm of the previous injection, as long as there are no issues with the use of both arms for injection. The study doctor or study team will observe you for at least 30 minutes after you receive the study vaccine. This is to check whether you experience any major side effects or immediate reactions to the injected study vaccine.

If, on the day of the planned vaccinations, you are unwell, have fever, or have high blood pressure, then the vaccination may be delayed to a later date. You should be well for at least 3 days before returning to the study site for the vaccination. As COVID-19 studies rapidly enroll participants over a short period of time (1-2 weeks), there is a chance a delay in your vaccination may result in you not taking part in the study. If the target number of participants have already started the study just as you are about to start, the study doctor can cancel your participation without your consent.

This study is “observer-blinded.” This means that you and your study doctor will not know whether you have received the study vaccine or placebo. However, if needed for a medical emergency, your study doctor can quickly find out what you received. Only certain members of the study team will know whether you are receiving either the study vaccine or placebo.

After your first vaccination, you will visit the study site at least 5 times. The number of study site visits includes the second and the third vaccination visits on Day 21 and Day 189, respectively. Each visit will last about 1 to 2 hours. The main reason for these visits is to check you for any health changes or problems. If you become ill with symptoms that could be SARS-CoV-2 infection, you may be asked to collect samples at home to test for the virus that causes COVID-19 using sample kits that will be provided to you.Two extra visits are planned on Day 7 and Day 28 (for a total of 7 visits) if your site can study how some types of your white blood cells (cells of the immune system) respond following vaccination. You will need to give consent for collecting these extra blood samples by checking the appropriate box at the end of this consent form.

You may also be asked to attend the site for extra study visits. At these visits, nasal swabs or other samples may be collected to test for the virus that causes COVID-19. There is also a possibility that

due to COVID-19, you or the study doctor may not be able to visit the study site following the exact schedule for a visit. In such cases, you may be contacted using telemedicine (telephone or video) visits to check your general health. The study staff may also visit your home to collect samples or carry out other procedures. Further details about telemedicine visits and home visits are provided later in this document.

Key Tests and Assessments

This part of the informed consent form presents a list of the key procedures and assessments that will be done during the study. There is also information and a table provided later in this section to show what happens at each visit. If you do not understand these procedures and assessments or want to know more, please ask your study doctor to explain.

- **Demographics and Medical History**: The study doctor (or a study staff member the study doctor has allowed to do so) will ask questions about you, including your age, date of birth, and sex. You will be asked about your race and ethnicity. This is because the Sponsor does not know whether the effects of the study vaccine are influenced by race or ethnicity. You will be asked about your medical history including any recent infection with SARS-CoV-2 and any medications that you have taken recently, including any vaccinations. At later visits, you will be asked about any new signs and symptoms, and any new medications or vaccinations that you took or are taking after joining this study. You should inform your study doctor if you change any of your medications or start taking new medications for other reasons.
- **Physical Examination**: A limited physical examination will be done at screening. This will include assessments of the skin, lungs, heart, neck, lymph nodes, arms, legs, and abdomen. During the Screening Visit, your height and body weight will be measured. At the other 5 visits, you will have a physical examination based on any symptoms you may have and that the study doctor indicates is needed. This may not include an exam of all body parts. This examination will be done before the vaccination injection is given to you.
- **Vital Sign Measurements**: This will involve looking at your body temperature (taken either by mouth, or by a different method that the site uses), pulse rate, and blood pressure. Vital signs will be taken before the vaccination injection is given to you. Should there be any abnormal results, the vaccination will be rescheduled until the results return to normal.
- **Blood Tests**: During your visits to the site you will be asked to provide blood samples. A needle will be used to collect blood from a vein in your arm at 7 visits. Two extra blood collections may be done on Day 7 and Day 28 if your study site can study how some types of your white blood cells (cells of the immune system) respond following vaccination. You will need to give consent for these extra blood samples.

  During the time you are in the study, the total amount of blood taken from you should be no more than 350 mL (about 70 teaspoons) for most subjects. If you are taking part at a study site which is taking additional blood for immune tests at 3 timepoints (you will give an additional consent for these additional blood samples if they apply to you), approximately another 150 mL (about 30 teaspoons) will be collected. You should not fast before having blood drawn. Blood will be collected for the following reasons:

  - To check your health status.
  - To check different types and number of cells and levels of certain substances in your blood. This is done to check your general health, including the health status of your immune system.

- To check whether there are antibodies to study vaccine in your blood and to see whether this response may protect you from getting infected with SARS-CoV-2 in the future.
- Extra blood may be taken during the study should repeat laboratory tests or further analyses be needed.
- If you are a woman who has stopped getting menstrual periods, then a blood test may be done to confirm that status.
- To study how some types of your white blood cells (cells of the immune system) respond following vaccination. This test will be done on a subgroup of participants in the study and if you are planned to be in this subgroup, you will give additional consent for this to happen.
- Blood may also be collected at the unscheduled visits to check whether there are antibodies (blood proteins produced in response to a foreign substance in your blood that fight the substance) to the study vaccine in your blood.

Results of the safety laboratory tests will be reviewed by your study doctor. If any results are concerning, you will have further testing if needed.

- **Pregnancy Tests:** If you are a woman who is able to have children, then you will need to have a pregnancy test, which must be negative for you to take part and then continue taking part in the study. A urine sample will be taken to test whether you are pregnant or not. In addition, a blood sample may also be collected at screening for pregnancy testing. If the results are positive for pregnancy at any point during the study, then further study vaccine will not be given to you, but you may continue in the study.
- **Vaccination:** You will be given the study vaccine that was assigned to you by chance. After the vaccination, you will be asked to stay in the study site for at least 30 minutes so that the study doctor or member of the study team can observe whether you have any major immediate reactions to the study vaccine.
- **Electronic Diary (eDiary):** You will be asked to download a mobile application (“app”) on your smart phone. If you cannot use your own device, the staff may be able to provide you with a device to take home for use during the study. You will be trained by the site staff on how to use the “app” (which will be referred to as an eDiary) for the following procedures:
  - **Vaccination reactions:** The eDiary contains a list of symptoms that you may develop after each vaccination. You will record any symptoms present on this list that you experience in the eDiary. You will be asked to make your first entry in the eDiary in the evening on Day 0 and for 6 days following vaccination. Your health will be monitored using the eDiary. You will be provided a tool to measure any swelling or redness at the injection site and a thermometer to take your temperature orally. You will be asked to inform your study doctor of any medications, vaccinations, doctor visits, or additional illnesses not included in the eDiary.
  - **Research COVID-19 Monitoring:** Your health will also be monitored using the same eDiary used to record reactions to the study vaccine. From 4 weeks after you are first vaccinated on the study, the following Potential COVID-19 symptom forms will start to become available in the eDiary:

- Routine Monthly Self-Sample Collection Form - to be completed every month after you complete 4 weeks in the study. You will also be asked to collect samples on 2 days consecutively, even if you have had no symptoms.
- Assessment for Interim Self-Sample Collection Form - To be completed every 14 days after you have completed the routine monthly self-sample collection form. Sample collection would only be required for 2 consecutive days if you report symptoms that suggest samples should be collected.
- New Illness Symptoms Report Form - This form may be completed at any time you have a new illness (as close as possible to the symptom start) after you complete 4 weeks in the study. Sample collection would only be required for 2 consecutive days if you report symptoms that suggest samples should be collected. You may also be asked to start completing an additional form called the Flu-PRO form, which collects information about symptoms daily for up to a total of 10 days. This form, and some additional questions within the app should also be completed in the evening each day it is available, since the form will disappear after midnight each day and be replaced by the form for the next day.

- **Self-Sample Collection for COVID-19 Confirmation:** You will be instructed on how to take nasal or saliva samples to test for SARS-CoV-2 at home using sample kits that will be provided to you. You will be informed on whether to collect a nasal or saliva sample by the study site staff. Nasal or saliva samples will need to be collected 2 days in a row every 28 days if you are not having any symptoms of COVID-19 and within 3 days but not more than 14 days when you have symptoms of COVID-19. It is important that these samples are taken as explained in this section. These samples will be sent to a testing center to check if you have SARS-CoV-2 infection. Sometimes the study site may instruct you to attend the study site if this is possible, and nasal swabs or saliva samples for COVID-19 testing may be collected at the site, or the site may provide other instructions.

  These samples may be stored by Novavax, Inc. (vaccine company) or companies working for Novavax, Inc. for up to 25 years.

- **COVID-19 Diagnosis and Public Health Management:** Samples collected for COVID-19 tests as described above are for the purposes of research. As there may be long delays until the results of the tests are available, these samples cannot be used to confirm a diagnosis of COVID-19 if you are unwell. Therefore, having samples collected in the study does not mean that you should not also follow local guidelines and test procedures for COVID-19. These local guidelines and test procedures should get results faster as the tests are approved for diagnosis and not for research purposes, and positive results will directly link into the public health system and associated actions, such as isolation and close-contact monitoring. Your study site staff can help alert you to local options as needed. Your study staff site will only notify you if one of your swab samples (from the study) tests positive for SARS-CoV-2 infection. In case a positive result has not been given to you by other tests you may have had through local guidelines. As there is the possibility that nasal swabs or other samples that are positive to SARS-CoV-2 could at times show false-positive results, your study doctor may advise that you should be retested through local test procedures, or may recommend retesting if there is a negative result and they believe COVID-19 remains a possibility. Your study doctor may need to discuss your illness with your regular treating doctor (if permission is given) or other doctors to ensure your illness is appropriately managed within the way the health system is operating if COVID-19 disease is widespread.

- **Health and Medications**: You should inform the study doctor if you change any of your medications or start taking new medications or have received any other vaccinations since you started in the study, including any supplements for other reasons at any time during the study. Throughout the study, you will be asked about how well you are feeling or whether you have experienced any side effects or immediate reactions after receiving the study vaccine. Inform the study doctor immediately if you experience any reaction or a side effect after vaccination and visit your primary physician or local doctor for consultation and/or treatment or a hospital visit.

The following section provides a list of tests performed at the study visits.

Screening Visit

At screening (your first visit), the following tests will be done to determine whether you are eligible to take part in this study:

- Discussion of this study with the study doctor and review and signing of this form. You will be given enough time to make a decision.
- Recording of your demographic information, including age, date of birth, sex, and race/ethnicity.
- Review of your medical history, vaccinations, and any medications you are taking or have taken recently.
- Physical examination and vital sign measurements.
- Urine will be taken for laboratory testing. If you are a woman who is able to have children, then you will be tested for pregnancy using a urine sample. A blood sample may also be taken for pregnancy testing at this visit.
- Blood samples will be taken to check your health status. Some of your blood will be tested for human immunodeficiency virus, hepatitis B, and hepatitis C. The study doctor may be required by law to report the result of these tests to the local health authority.
- If you are a woman who is no longer having menstrual periods, you may have a blood test to assist the study doctor in determining if you may be able to become pregnant.

First Vaccination Visit (Day 0)

Note: If the Screening Visit and Day 0 Visit are completed on the same day, procedures from screening will not be completed twice.

If the screening tests show that you can take part in the study, the following tests will be done at this visit before you receive first injection of the study vaccine:

- You will be asked again about any medications you have been taking, including any vaccinations, and surgical procedures.
- Review of your health and a check to see whether you have any side effects or have had any new doctor or hospital visits.
- Review of the entry conditions to check if this study is still right for you.
- Physical examination and vital sign measurements.
- If you are a woman who is able to have children, then you will be tested for pregnancy using a urine sample.

- Blood samples will be taken to measure your body's immune response to the study vaccine.
- Blood samples will be taken to study how some types of your white blood cells (cells of the immune system) respond following vaccination. This test will be done on a subgroup of participants in the study and your study doctor will inform you if you are to be included in this subgroup.
- Sample collection for COVID-19 tests.
- You will be assigned by chance to 1 of 5 treatment groups (which selects which dose of study vaccine or placebo you will get at different time points). This assignment will be done at Day 0 only.

A number of blood samples will be collected from you during the course of the study at later study visits.

After completion of these tests, the study staff will give you the first injection of study vaccine. After you receive the study vaccine, you will be observed for at least 30 minutes after the injection to check whether you have any immediate major reactions to the study vaccine.

The study team will also provide you with instructions on what you should do after you leave the study site and when you should return to the study site. You should record any reactions to the study vaccine in the eDiary.

Second and Third Vaccination Visits (Day 21 and Day 189)

About 3 weeks after the first vaccination (ie, on around Day 21), you will get a second injection of the study vaccine assigned to you by chance. On around Day 189, you will get a third injection of the study vaccine assigned to you by chance (this is the booster dose).

- You will be asked again about any medications you have been taking, including any vaccinations.
- Review of your health and a check to see whether you have any side effects or have had any new doctor or hospital visits.
- Review of the entry conditions to check if this study is still right for you.
- Physical examination of some body parts (not all) and vital sign measurements.
- If you are a woman who is able to have children, then you will be tested for pregnancy using a urine sample.
- Blood samples will be taken to measure your body's immune response to the study vaccine.

After completion of these tests, the study staff will give you the second or third injection of study vaccine. After you receive the study vaccine, you will be observed for at least 30 minutes after the injection, as you were after the first vaccination. You should record any reactions to the study vaccine in the eDiary. The study staff will train you on how to collect nasal or saliva samples on your own for COVID-19 confirmation and will remind you to complete Research COVID-19 Monitoring Forms as stated above.

Starting from Day 28 and up until Day 217, you will collect nasal or saliva samples 2 days in a row if you do not have any symptoms of COVID-19 every 28 days. If you have symptoms of COVID-19 and record them in the eDiary, then you will take these samples within 3 days but not more than 14 days from the start of the symptoms.

Visits on Days 35, 105, and 217

On other visits, the following procedures will be done:

- You will be asked again about any medications you have been taking, including any vaccinations.
- Review of your health and a check to see whether you have any side effects or have had any new doctor or hospital visits.
- Physical examination will be performed.
- Blood samples will be taken to check your immune response to the study vaccine.

Telephone Visits (Days 273 and 357)

The last 2 visits (Days 273 and 357) will be performed by telephone, and you will not have to visit the study site. The Day 357 Visit is the final visit or End-of-Study Visit. If the study is stopped for other reasons or if you withdraw from the study, then the tests/procedures planned for the Day 357 Visit will be conducted on your last study day. On Days 273 and 357, the study doctor or a designated member of the study team will contact you via telephone and ask for the following details:

- You will be asked again about any medications you have been taking, including any vaccinations.
- Review of your health and a check to see whether you have any side effects that you may have experienced since your last study visit or a have had any new doctor or hospital visits.
- An End-of-Study Form will be completed with your feedback.

Unscheduled Visit(s)

In addition to the scheduled visits, you may have unscheduled (extra) visits for safety reasons or to assess and investigate if you may have COVID-19. Unscheduled visits will be performed in case you experience any unusual symptoms or side effects or if the study doctor identifies any abnormality in the test results that requires your health to be followed more closely and if further evaluations are needed.

At an unscheduled visit, the following procedures will be done:

- You will be asked again about any medications you have been taking, including any vaccinations.
- Review of your health and a check to see whether you have any side effects or have had any new doctor or hospital visits.
- Physical examination and vital sign measurements, if required.
- Blood sample for laboratory testing may be collected or organized if the study doctor feels it is important for your safety. The blood sample collected may also be used to test for antibodies to SARS-CoV-2 if the study doctor suspects that you may have been exposed to SARS-CoV-2.
- A nasal or saliva sample may be collected by the site staff.

The following table is a summary of the study tests. Please ask your study doctor if you would like more information.

What will be done?	Screening Visit	Day 0	*Day 7**	Day 21	*Day 28**	Day 35	Day 105	Day 189	Day 217	Telephone Contact: Day 273	Telephone Contact: Final Study Visit/End of Study Visit Day 357	Unscheduled Visit
Site Visit Number	-	**1**	***2***	**3**	***4***	**5**	**6**	**7**	**8**	**9**	-	-
Informed consent	X	-	-	-	-	-	-	-	-	-	-	-
Checking that the study is right for you	X	X	-	X	-	-	-	X	-	-	-	-
Demographics and medical history	X	-	-	-	-	-	-	-	-	-	-	-
Physical examination	X	X	-	X	-	X	X	X	X	-	-	X
Vital signs measured	X	X	-	X	-	-	-	X	-	-	-	X
Blood tests	X	X	-	X	-	X	X	X	X	-	-	X
Blood test at sites studying how some types of your white blood cells (cells of the immune system) respond following vaccination	-	-	X	-	X	-	-	-	-	-	-	-
Pregnancy test (if you are a woman who is able to have children)	X	X	-	X	-	-	-	X	-	-	-	-
Vaccination	-	X	-	X	-	-	-	X	-	-	-	-
The following tests will be done after vaccination												
Checking to see if you have any immediate reaction to the study vaccine	-	X	-	X	-	-	-	X	-	-	-	-
Recording any immediate reactions for 7 days, including the day of vaccination using the electronic device	-	X	-	X	-	-	-	X	-	-	-	-
Monitoring for COVID-19 disease	-	-	-	-	Day 28 through Day 217					-	-	-
Nasal swab or saliva sample collection for COVID-19 detection		X	Self-collected from Day 28 onwards as needed, and every month, or site collected if needed from Day 7 onwards								-	X
Check of your health (includes any side effects that you may have experienced)	-	X	-	X	-	X	X	X	X	X	X	X
You will be asked questions about any medications you are taking	X	X	-	X	-	X	X	X	X	X	X	X
End of Study Form	-	-	-	-	-	-	-	-	-	-	X	-

* Day 7 and Day 28 visits are only for participants from sites collecting extra blood samples for white blood cell testing.

The study team will discuss the exact schedule of these visits with you. The visit schedule is a little flexible, but it is important that you follow the given schedule as closely as possible. You should try to not miss any visits. You should contact the study doctor as soon as possible if you need to change the date or time of any study visit.

There is also a possibility that due to the ongoing global outbreak of COVID-19, including in Australia, you or the study doctor may not be able to visit the study site following the exact schedule for a visit. In such cases, you may be contacted using telemedicine (telephone or video) visits to check your general health. If blood tests are to be carried out, the study staff may use local clinics or test centers or may visit your home to collect samples. Arrangements may include a member of the study staff, home healthcare provider, or a nurse visiting you at home and performing the required tests and/or procedures. Injections of study vaccine may also be given to you in local clinics or at your home but under trained supervision. You will be informed by the study team in a timely manner of any changes to the timing of study tests, procedures, and visits. For any supplies (eg, ruler, thermometer, nasal swab kits) needed during the conduct of this study, alternative arrangements will be made to provide

these supplies directly to you at your home if you are unable to visit the study site. You will be informed by the study staff of these details.

Proper care will always be taken to ensure your safety throughout your participation in the study. In addition, all precautions to establish participants' safety in the study as stated in the local Ethics Committee (EC) and national regulatory authority health guidance documents will be implemented.

If you are not familiar with any of these procedures, then please ask your study doctor to explain how they are performed.

Any leftover blood and/or urine samples or nasal swab or saliva samples for COVID-19 detection collected from you during the study will be retained by the central laboratory for up to 25 years and thereafter will be destroyed.

Will you be informed if you have a positive SARS-CoV-2 test from study-collected samples?

Yes, however this result may take some time. The tests conducted in the study are approved for research purposes and not to confirm SARS-CoV-2 infection. If you have a suspected COVID-19 illness, you should follow local testing guidelines. If you have taken a test outside the study, you may have already received a confirmed SARS-CoV-2 infection result. If you have not been advised of a positive SARS-CoV-2 infection result from other testing when contacted by the study staff, you should follow local guidelines for potential positive COVID-19 cases, which would usually include self-isolation along with your close contacts until a test can be done through local guidelines using approved diagnostic tests to confirm whether you have a positive test result.

Your study doctor will discuss the results of your test and any follow-up, which may involve discussions with your regular treating doctor with your consent.

Positive study SARS-CoV-2 infection results may be reported to health authorities as required by local law.

4 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 doctor truthfully about your complete medical history.
- To tell the study doctor truthfully about your working or occupation details in order to check whether you are working in a high-risk environment with exposure to SARS-CoV-2.
- 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 doctor. This is important because these symptoms are often seen in patients with COVID-19 disease. If you exhibit any of these symptoms, the study doctor will 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, possibly nasal swabs, or other samples from you for laboratory testing.

- To take nasal swabs or collect saliva samples by yourself 2 days in a row within 3 days and not more than 14 days of your starting to see any symptoms often observed in patients with COVID-19 disease, and to provide these samples to the study staff as instructed.
- To take nasal swabs or collect saliva samples by yourself every 28 days (for 2 days in a row) when prompted by the “app” (or electronic device).
- 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 doctor about taking any medicine for prevention of COVID-19 disease.
- To record any reactions to the study vaccine or any medication you received in the evening of Day 0 through Day 6 (first vaccination), around Day 21 through Day 27 (second vaccination), or around Day 189 through Day 195 in the “app” (or electronic device).
- To record any symptoms of COVID-19 in the “app.”
- To remain in touch with the study doctor and to let them know if you have changes to your contact information (address or telephone number) or if you no longer wish to participate in the study.

You will be given a Participant Card, which contains emergency contact information and information about your study commitments. You must carry the Participant Card with you at all times until the end of the study.

5 Other relevant information about the research project

This study is being conducted at USC Clinical Trials in Australia.
A representative of Novavax, Inc. (study sponsor) may be present for inspections in the unit during the study.

Reimbursement

You will be reimbursed $100 per visit for participating in this study. The study vaccine will be made available to you at no charge and you will not be required to pay for any study-related tests or procedures. You may be also be reimbursed for any reasonable travel expenses (bus/train/taxi fares) incurred as a result of taking part in this study if you provide a receipt. If you withdraw from the study before the final visit you will receive a partial reimbursement according to the number of visits you have attended.

Should you withdraw from the study before the final visit you will receive a partial reimbursement according to the number of visits you have attended.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with USC Clinical Trials.

7 What are the alternatives to participation?

There are no vaccines currently authorized and available to prevent SARS-CoV-2 infection. However, there are many vaccines under development, and some vaccines may start to become available during the period you are on the study. If other COVID-19 vaccines do become available in your country, and you may be eligible and recommended to receive them, then the study doctor will consult with the Sponsor and advise you on the options available for you. This may involve your withdrawing from the study, and your being told if you received the study placebo. In this case you could benefit from receiving a newly authorized COVID-19 vaccine available in your country, but this will not be provided to you as part of the study. Rather it will be provided through whatever routine guidelines are in place in your country.

Recently, a medicine called Remdesivir has been approved by European Medicines Agency (EMA) and the US FDA to treat adults and children with severe COVID-19. However, this is a treatment medication and not a vaccine and can be used if you have contracted SARS-CoV-2. There are many potential treatments for COVID-19 being studied currently, and there may be new treatments becoming available while you are on the study. If you become ill and you test positive to SARS-CoV-2 infection, then your study doctor will discuss treatment options with you if you have or exhibit symptoms of COVID-19 prior to joining or during the study.

8 What are the possible benefits of taking part?

Taking part in this study may be of no direct benefit to you. However, the information we receive from you during this study may help doctors learn more about the study vaccine, and this may benefit others in the future.

9 What are the possible risks and disadvantages of taking part?

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 result from taking a medicine, including a vaccine.

The study vaccine is an experimental vaccine, and in Part 1 of this study 131 participants were enrolled, and side effects have been monitored for up to 2 doses of study vaccine. Therefore, at the moment there is limited information about all the risks or side effects that may occur. However, after review of safety data from Part 1 by an independent safety committee and the US FDA, Part 2 of the study can now be started.

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

The current vaccine is prepared by the Sponsor in a way similar to other vaccines (used against different viruses such as influenza, Ebola, and respiratory syncytial virus) using a method called "nanoparticle technology." To date, over 14,000 adult participants, including pregnant women and people aged up to 85 years, have received nanoparticle vaccines prepared with this type of technology in clinical studies conducted by the Sponsor. The adjuvant being evaluated in this study is called Matrix-M. It has been given to over 4200 participants in different clinical research studies conducted by the Sponsor for testing vaccines against different viruses and other germs, and of these, about 2,500 participants received Matrix-M adjuvant with nanoparticle vaccines, mostly in adults and in people up to 85 years of age.

Side effects experienced by participants who received any Sponsor-prepared vaccine with the Matrix-M adjuvant in other studies conducted by the Sponsor to date include pain, redness, bruising, and swelling at the injection site, as well as headache, fatigue, muscle pain, diarrhea, joint pain, chills, nausea, vomiting, and fever. These are symptoms that can occur with vaccines in general but can be more apparent with an adjuvant. So far, no serious health concerns have been identified as being related to receiving the Matrix-M adjuvant.

Autoimmune diseases are a potential side effect of vaccines and adjuvants. These are serious diseases that can occur in the general population as well (without administration of a vaccine). 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-M adjuvant is associated with an increased risk of autoimmune disease. However, for your safety, you will be observed and regularly checked during your time in the study for any side effects that you may have experienced after receiving the study vaccine.

Unforeseen Risks

Because the study vaccine has only been given to 131 participants in the Part 1 study, 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

Most side effects begin soon after the vaccination 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.
- **Blood Pressure:** The blood pressure cuff used to take your blood pressure may cause discomfort or bruising to your upper arm.
- **Nasal Swabs:** During collection of swabs, you may experience sneezing, eye tearing, or gagging. There is also the potential for those people that are susceptible to nosebleeds to experience one.
- **Saliva Collection:** During saliva collection, you may experience a bad taste in your mouth.

Unexpected Medical Findings

It is possible that the study tests could detect a medical problem that is unrelated to the purpose of this study that was previously unknown. If the study tests uncover findings that may be important for you to know about, such as the possibility of a previously unknown medical condition, you will be informed by a member of the study team. You may authorize the release and communication of the findings to your primary physician. These findings may necessitate extra testing or treatment. The cost of any extra tests or related treatment will be your responsibility.

Pregnancy Risk

Female participants: If you are a woman and are able to have children, there is important information for you to know about the pregnancy risk precautions for this study before you sign this form.

It is not known whether the study vaccine may affect an unborn child or nursing infant. For this reason, 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 use an acceptable method of birth control throughout the entire study. Acceptable forms of birth control will be reviewed with you at the beginning of the study and continued use will be monitored at scheduled visits.

If you become pregnant during your participation in the study, immediately inform the study doctor; your participation in the study may be stopped. However, data and information about your pregnancy may be collected. The study doctor 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. If required by country regulations, you and your partner may be requested to sign a separate informed consent form prior to collection of data about the outcome of the pregnancy for scientific or security reasons.

10. What will happen to my test samples?

The blood and urine samples (information on collection of urine samples is provided later in this consent form) collected for the assessment of your health status (eg, liver and kidney function tests) will be processed by a central pathology laboratory. These samples will be labelled with your unique study participant number, your initials, and date of birth, and will not contain any information that can identify you personally. These samples will be destroyed following analysis.

Blood samples collected for tests of your immune response, including cells related to your immune system, will be sent to various Sponsor-approved laboratories in Australia, Singapore, the United States, and/or other countries. These samples will be labelled with your unique study participant number and will not contain any information that can identify you personally. These samples will be stored at secure locations.

If you withdraw consent to participate after the start of the study, all samples collected from you up to that time will be stored and used for testing, unless you request the collected samples be destroyed.

By agreeing to take part in this study, you agree that your blood samples may be used to measure your body's immune response to the study vaccine.

Blood samples may be stored frozen by Novavax, Inc. (Sponsor, a vaccine company) 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 SARS-CoV-2 antibody tests always work the same way, or
- Developing new or improved tests related to SARS-CoV-2 or other germs or vaccines.

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

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied.

Your study doctor will inform you or your legal representative, in a timely manner, of any new information learned during the study that may affect your willingness to continue participating.

12 Can I have other treatments during this research project?

It is important to tell your study doctor and the study staff, at each clinic visit, about any treatments or medications you may have taken, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments.

13 What if I withdraw from this research project?

Your participation in this study is voluntary. You do not have to take part, and you may discontinue your involvement 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 the study doctor and follow their instructions. It may be helpful if you could explain your reasons. You may receive standard treatment, and no prejudice will be shown toward you regarding medical care or participation in future research.

If your participation in the study is stopped early, then you will be asked to complete the end of study procedures (such as a final health check and blood sample collected for laboratory testing) for your own safety. If you are not able to visit the study site, then information about your health will be collected by contacting you via telephone.

Any laboratory samples collected prior to your withdrawal from the study may still be stored for up to 25 years and analysed during this time. If you do not want this to happen, you may ask for them to be destroyed. If they can still be linked back to you via your participant number (i.e., they have not been fully anonymised), this request will be respected. You are not required to give a reason for this request.

14 Could this research project be stopped unexpectedly?

The study doctor or the Sponsor may withdraw you from the study for your own safety, even if you wish to continue to participate, for example, under the following circumstances:

- If receiving the study vaccine 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 study requirements for taking part in the study
- If the study is cancelled because of decisions made in the commercial interests of the Sponsor or by local government agencies/health authorities
- If you become pregnant

If your participation in the study is stopped early, then you will be asked to complete the end-of-study procedures (such as a final health check and blood sample collected for laboratory testing) for your own safety. If you are not able to visit the study site, then information about your health will be collected by contacting you via telephone. You may be asked if you would consider being contacted for further safety follow-up but not for further study procedures.

15 What happens when the research project ends?

The study doctor will contact you via telephone at the end of the study on Day 357 and perform the tests described in the summary of study tests. If the study is stopped for other reasons or if you withdraw from the study, then the activities planned for the Day 357 visit will be conducted on your last study day.

Your study doctor will tell you whether extra follow-up is needed and whether you need to visit the study site again.

The study data will be analysed, and a final report provided to the study doctor, who will share the results with you when requested. The disclosure and/or any published results will be available to you when requested. It is usual for a number of years to elapse before definitive results of this type of study are available. These may be published in medical journals that are available to the public. You should feel free to ask the study staff about this.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

The study site staff will record basic personal details about you, including your name, contact details, gender, height, weight, and racial origin, as well as information on your medical history and any clinical data collected about your participation in the study. The following people may also access these records:

- Study monitors and auditors, who may work for Novavax Inc., PPD Australia, Pty Ltd, or its authorized representatives, who check that the study is being performed correctly and that the information collected about you is accurate;

- Other employees or students of PPD Australia, Pty Ltd or its authorized agents and Novavax Inc., who may accompany study monitors and auditors for quality and training purposes;
- The IRB/EC that approved this study and ensures that your rights and well-being are safeguarded;
- National and international regulatory authorities involved in keeping research safe for participants.

All members accessing your records are required to respect your confidentiality at all times.

The Sponsor or designees has contracted the following vendor, which will know your real identity, although the vendor will only be informed about your medical condition if absolutely necessary, to perform the service:

- World Courier or any Courier Vendor contracted for this study will collect your nasal swabs or saliva samples

To ensure your privacy, your name and other directly identifying information will not be attached to records or samples released for research purposes. Only the study doctor and authorised study team members will be able to connect this code to your name, with a list that will be kept securely by the study site. Your date of birth and initials may also be recorded to help identify your study record.

Your coded data will be forwarded to PPD Australia, Pty Ltd and its service providers for activities related to the study, e.g., laboratory analysis. The data will be transferred into a computer database and processed to allow the results of this study to be analysed and reported or published. If the results of the study are published, then your identity will remain confidential.

In accordance with relevant Australian and/or Queensland privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information. However, in order to protect the scientific integrity of the study, the treatment (i.e., study vaccine or placebo) that you received needs to remain unknown until the study data are analysed, unless otherwise required to be made known by law or regulation.

Recipients of your information may be in countries that do not have data protection safeguards and rights. PPD Australia, Pty Ltd and its authorised representatives, Novavax, Inc. and its authorised representatives, and regulatory authorities shall, in all cases, seek to maintain confidentiality within the limits of local laws.

If you should withdraw from the study, then data collected prior to your withdrawal may still be processed along with other data collected as part of the study. Normally, no new information will be collected for the study database unless you specifically consent to that. However, the law does require that any side effects that you experience are documented and reported. You have the right to require that any previously retained samples are destroyed.

If you are not satisfied with how your personal information has been handled (as laid out in the Privacy Act, 1988), then you can make a complaint to the Office of the Australian Information Commissioner (OAIC). It is free to lodge a complaint and you do not need a lawyer, however if you do decide to hire

a lawyer, you must pay for the lawyer yourself. You can choose to withdraw your complaint at any time. Please refer to http://www.oaic.gov.au/privacy/privacy-complaints for more information.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this research study, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

There are two avenues that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this research project:

- The pharmaceutical industry has set up a compensation process, with which the Sponsor, PPD Australia, Pty Ltd, of this research project has agreed to comply. Details of the process and conditions are set out in the Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial. In accordance with these Guidelines, the sponsor will determine whether to pay compensation to you, and, if so, how much. The research staff will give you a copy of the Guidelines together with this Participant Information and Consent Form. If you have any questions about the Guidelines, please ask to speak to Lucas Litewka, on 07 5456 3797.
- You may be able to seek compensation through the courts.

18 Who is organising and funding the research?

This study is being conducted at USC Clinical Trials and sponsored in Australia by PPD Australia, Pty Ltd (Local Sponsor). PPD Australia, Pty Ltd is a contract research organization. As part of its role, PPD Australia, Pty Ltd will be responsible for the management of the study in Australia and overseeing the study site. The Sponsor 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.

The vaccine company providing the study vaccine in the study is Novavax, Inc. (Global Sponsor).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of [Name of institution].

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on [phone number] or any of the following people:

Clinical contact person

Name	Georgina Street
Position	Clinical Operations Manager
Telephone	07 5456 3797
Email	CTC@usc.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Office of the Chief Operating Officer
Address	University of the Sunshine Coast, Sippy Downs QLD 4556
Telephone	07 5459 4789

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Alfred Hospital Ethics Committee
HREC Executive Officer	Governance Officer, Ethics and Research Governance, Alfred Health
Telephone	(03) 9076 3619
Email	research@alfred.org.au

A description of this clinical study will be available on http://www.ClinicalTrials.gov and/or https://australianclinicaltrials.gov.au (Australia law). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Consent Form - *Adult providing own consent*

Part 2 of the Study

Alfred Project Number:	151/20
Full Study Title:	A 2-Part, Phase 1/2, Randomized, Observer-Blinded Study to Evaluate the Safety and Immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With or Without Matrix-M™ Adjuvant in Healthy Subjects
Protocol Number:	2019nCoV-101 Version 5
Test Drug Code:	SARS-CoV-2 rS
International Sponsor:	Novavax, Inc.
Local Sponsor:	PPD Australia Pty Ltd.
Coordinating Principal Investigator:	Dr Paul Griffin
Principal Investigator:	Dr Susan Thackwray
Location:	USC Clinical Trials Level 1, 9 Ochre Way Sippy Downs QLD 4556

Declaration by Participant

- I have read and understand the statements in this informed consent form.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had the opportunity to ask questions, and I am satisfied with the explanations provided.
- I voluntarily agree to take part in this study.
- I understand that my blood samples will be used for additional, non-genetic testing that may help understand more about my disease:
- I understand that the authorised representatives of PPD Australia, Pty Ltd, the Ethics Committee, and inspectors for regulatory authorities may review my medical information by directly accessing my medical records.

- I understand that study data, including my coded medical information, may be used and shared for legitimate study and scientific purposes, including, if I do not object future use in medical or pharmaceutical research.
- I understand that I will receive a copy of this signed and dated written consent form.

If the study doctor is not your family doctor, then your family doctor may be told about your taking part in this study and asked for medical information about you. Please check the appropriate check box to indicate your decision.

☐ Yes, I agree that if the study doctor is not my family doctor, then my family doctor may be told about my taking part in this study and can be asked for medical information about me.

☐ No, I do not agree to my family doctor being informed about my taking part in this study and being asked for medical information about me.

The Sponsor would like your permission to use the remaining samples collected during this study for future research purposes not involving genetic testing to further understand COVID-19. Please check the appropriate check box to indicate your decision.

☐ Yes, I agree to the use of any of my remaining samples for future research purposes and non-genetic testing as described in this information sheet.

☐ No, I do not agree to the use of any of my remaining samples for future research purposes and non-genetic testing as described in this information sheet.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - Adult providing own consent

Alfred Project Number:	151/20
Full Study Title:	A 2-Part, Phase 1/2, Randomized, Observer-Blinded Study to Evaluate the Safety and Immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With or Without Matrix-M™ Adjuvant in Healthy Subjects
Protocol Number:	2019nCoV-101
Test Drug Code:	SARS-CoV-2 rS
International Sponsor:	Novavax, Inc.
Local Sponsor:	PPD Australia Pty Ltd.
Coordinating Principal Investigator:	Dr Paul Griffin
Principal Investigator:	Dr Susan Thackwray
Location:	USC Clinical Trials Level 1, 9 Ochre Way Sippy Downs QLD 4556

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with .

Name of Participant
(please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project, and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.