Eastern Health

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Box Hill Hospital

Study Title:	Phase 3, Randomized, Observer Blinded Study to Evaluate the Safety and Immunogenicity of Two Booster Doses of the NVX-CoV2515 and Bivalent SARS CoV-2 rS Vaccines in Adults Previously Vaccinated with Other COVID-19 Vaccines
Short Title:	Phase 3 Boosting Study for the SARS-CoV-2 rS Vaccines
Protocol Number:	2019nCoV-311
Project Sponsor:	Global Sponsor: Novavax, Inc. Local Sponsor: ICON Clinical Research Pty Ltd.
Coordinating Principal Investigator/ Principal Investigator:	CPI: Dr. Eugene Athan PI: Professor Christopher Gilfillan
Location *(where CPI/PI will recruit)*:	Box Hill Hospital – Arnold Street, Box Hill VIC 3128, Australia

NOTICE: You are likely aware of the ongoing COVID-19 (Coronavirus) pandemic and the growing emergency measures that are being put in place to limit the spread of the virus, including government and institutional restrictions. These restrictions may affect how the study is conducted during this time. Please be aware of possible changes, which could impact you directly. These changes can include, for example, use of available technology for remote monitoring/data collection, "virtual" study visits, electronic completion/transmission of study-related questionnaires, and/or any other changes (telephone, email or text message contact, alternative location for assessment, including local laboratories or home visits) deemed necessary until the pandemic and associated government/institutional restrictions are lifted. Some blood samples may be taken using local laboratory services, and the sponsor may arrange home health services if site visits cannot occur. Your study doctor/study team will inform you in a timely manner about any new information and the need to make changes to any part of the study as described in this Informed Consent Form.

Part 1 What does my participation involve?

1. Introduction

You are invited to take part in this research study. This is because you have already been vaccinated with 2 or 3 doses of an approved mRNA COVID-19 vaccine (Moderna and/or

Pfizer/BioNTech COVID-19 vaccines). This research study is testing 3 vaccines to be given as booster doses to prolong your immunity against the disease called COVID-19, which is caused by the virus called SARS-CoV-2.

This Participant Information Sheet/Consent Form tells you about the research study. It explains the tests and study vaccines 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 study, 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 study
- Consent to have the tests and study vaccines 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.

Please discuss taking part with your friends and family and your general practitioner, if you wish.

2. What is the purpose of this research?

This is a research study to test 3 vaccines to be given as booster doses to prolong your immunity against 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". 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. 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. Recently, a new strain of coronavirus has been discovered around the world that is different from the original Wuhan strain. This new strain is called "omicron". Current vaccines are proving to be less efficient at being protective against the omicron strain. It is hoped that the booster vaccine will improve the protection you have from your first 2 or 3 doses of the COVID-19 vaccines and prevent you from getting severely ill with COVID-19.

The purpose of this study is to assess the immune response (how your body's defence system reacts) of an investigational vaccine against the omicron strain of coronavirus, called NVX-CoV2515 and a bivalent (NVX-CoV2373 + NVX-CoV2515 vaccine against the Wuhan and

omicron strains. The study will see how safe the investigational vaccines are and whether they cause any side effects. The study will also compare the immune response generated by the study vaccine NVX-CoV2515 and a bivalent (NVX-CoV2373 + NVX-CoV2515 to that generated by the investigational vaccine for the original Wuhan strain (the initial SARS-CoV-2 virus discovered in Wuhan) called NVX-CoV2373 (trade name: Nuvaxovid, generic name: SARS-CoV-2 rS with matrix M adjuvant).

NVX-CoV2373 (Nuvaxovid, SARS-CoV-2 rS with matrix M adjuvant) is an approved COVID-19 vaccine in Australia and has also been approved as a booster in people aged 18 and over where an mRNA vaccine is not suitable. However, NVX-CoV2373 (Nuvaxovid, SARS-CoV-2 rS with matrix M adjuvant), NVX-CoV2515 and a bivalent (NVX-CoV2373 + NVX-CoV2515 are considered 'investigational' vaccines in this study because they have not been approved as booster vaccines by the Therapeutic Goods Administration, the health authority that gives approval for new medications to be prescribed in Australia.

This research is being conducted by Novavax, Inc. and sponsored in Australia by ICON Clinical Research Pty Ltd.

How long will I be in the study?

You will be in this study for about 10 months. You will need to visit the research site about 9 times during the study.

3. What does participation in this research involve?

You will be assigned randomly by chance, like flipping a coin, to receive one of the following:

- Group A: patients who have already received 2 doses of a COVID-19 vaccine will receive 2 doses of the study vaccine NVX-CoV2515, against the omicron strain
- Group B: patients who have already received 2 doses of a COVID-19 vaccine will receive 2 doses of the study vaccine NVX-CoV2373 (Nuvaxovid, SARS-CoV-2 rS with matrix M adjuvant), against the original Wuhan strain
- Group C: patients who have already received 3 doses of a COVID-19 vaccine will receive 2 doses of the study vaccine NVX-CoV2515, against the omicron strain
- Group D: patients who have already received 3 doses of a COVID-19 vaccine will receive 2 doses of the study vaccine NVX-CoV2373 (Nuvaxovid, SARS-CoV-2 rS with matrix M adjuvant), against the original Wuhan strain
- Group E: patients who have already received 3 doses of a COVID-19 vaccine will receive 2 doses of the bivalent (NVX-CoV2373 + NVX-CoV2515) vaccine, against the original Wuhan and omicron strains

The following table shows the study vaccine you may receive in this research study:

Group	Previous vaccine	Doses received	Number of study vaccine booster doses	Study vaccine	Number of participants
A	Moderna and/or Pfizer-BioNTech	2	2	NVX-CoV2515	130
B			2	NVX-CoV2373 (Nuvaxovid, SARS-CoV-2 rS with matrix M adjuvant)	130
C		3	2	NVX-CoV2515	360
D			2	NVX-CoV2373 (Nuvaxovid, SARS-CoV-2 rS with matrix M adjuvant)	360
E	Moderna and/or Pfizer-BioNTech	3	2	Bivalent Vaccine (NVX-CoV2373 + NVX-CoV2515)	360

If you have received 2 doses of Moderma and/or Pfizer-BioNTech, you will have a 50% (1 in 2) chance of receiving each of the 2 monovalent (NVX-CoV2373 or NVX-CoV2515) study vaccines. If you have received 3 doses of Moderna and/or Pfizer-BioNTech, you will be randomly assigned to one of the 3 study vaccines. Neither you nor your study doctor can choose the group you will be in.

All study vaccines will be given as intramuscular injections in your upper arm. You will be asked to stay at the study site for at least 30 minutes after each injection to monitor your health.

You will be participating in an observer-blinded study. This means that neither you nor your study doctor will know to which study vaccine group you have been assigned. This is done to make sure the results of the study cannot be influenced by anyone. However, in certain circumstances requiring an urgent need, your study doctor can find out quickly which study vaccine you are receiving.

This research study has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

What will happen during the research study?

There are different stages to this study:

- Screening visit
- Vaccination visits
- Non-vaccination visits and
- An End of Study (EOS) visit.

Screening

Screening will last no more than 14 days. If you provide informed consent by signing the consent form, you will have the screening procedures listed below to see if you are eligible to take part in this study. Screening may occur on the same visit as the initial study injection, the first day of the research study which is called “Day 0”. If the Screening visit and Day 0 visit occurs on the same day, all procedures noted for each visit below will be performed only once. Several visits to the research site may be needed.

- Information will be recorded about your year of birth, gender, race and ethnicity (demographic data).
- Your medical history including any significant surgical procedures, alcohol abuse or drug addiction history will be reviewed.
- You will be asked about any medications you are taking including non-prescription medications, vaccines, including COVID-19 vaccination. If you are able to become pregnant, the study doctor will tell you which birth control methods you should use during this study. You cannot take part in this study if you are breastfeeding, or planning on becoming pregnant in the near future.
- You will be asked about your health and any changes in your health.
- A physical examination will be done.
- Your vital signs (blood pressure, pulse rate, temperature, breathing rate and the amount of oxygen in your blood) will be measured. Your blood oxygen will be measured using an oximeter; a device that clips onto a finger.
- If you are a woman of childbearing potential, a pregnancy test will be done on your urine. The result must be negative for you to be in the study.

With your permission your General Practitioner will be informed of your participation in this study.

If you are not able to take part in the study, your study doctor will explain the other options that are available to you, for example, additional injections of approved vaccines that may be available for you to prevent COVID-19 or other research studies.

Vaccination visits, Day 0 and Day 90

If you meet all the criteria to take part in the study, you will be assigned to one of the study vaccine groups and you will receive the first dose of the assigned study vaccine on Day 0.

You will be given 2 single doses of the study vaccine at visit 2 (Day 0) and visit 5 (Day 90).

During these study visits some of the procedures already done during the screening will be repeated. In addition, you will have the following assessments:

- You will be given an electronic diary (eDiary) to record any symptoms you may experience after the vaccination and for 6 additional days after each vaccination (Day 0 to Day 6 and Day 90 to Day 96). The study team will show you how to fill out the eDiary.
- Blood will be collected from you to test your immune response and to test for natural immunity to COVID.
- You will be asked to provide a nasal swab sample to test for coronavirus infection using PCR (Polymerase Chain Reaction) testing.

Non-vaccination visits

You will have 3 study visits after the first study vaccination (Day 7, 14 and 28), another 2 study visits after the second study vaccination (Day 104 and 189), and one telephone visit at Day 118. During these study visits you will be asked about your health and any changes in your health and some of the procedures already done will be repeated.

End of Study (EOS) and Unscheduled Visits

On Day 270 you will have the last study visit called the End of Study (EoS) visit. During this visit some of the test and procedures already explained will be repeated.

If you stop the study early for any reason, you will be asked to return to the study site one more time to complete all of the tests and procedures that are described in Table 1 below. If you refuse to come to the study site, the study team will call you to check your health status.

If you experience any general health issues at any time during the study, you may be asked to come to the research site for extra visits if the study doctor decides that extra tests and procedures are needed for your safety.

At any time during the study, if you have symptoms that are compatible with COVID-19, you will be asked to notify the study team immediately. The study team will arrange a telehealth (phone call) visit within 3 days of developing your COVID-19 symptoms. At that visit you will be asked about your symptoms and if you're taking any new medication. The study staff will also provide guidance on how to collect a nasal swab sample to test (PCR test) for coronavirus infection and provide for shipment to the testing laboratory. If you test positive for coronavirus infection and have symptoms, you will be referred to your primary care provider for management.

Please see Table 1 towards the end of this document for details of the study procedures that will be done during the study.

Additional Costs

There are no additional costs associated with participating in this research study, nor will you be paid. All tests required as part of this research study will be provided to you free of charge.

Reimbursement

You may be reimbursed for any reasonable travel and parking associated with the research project visit.

You will not receive any payment for taking part in this research study.

4. What do I have to do?

During this study, you will be asked to do the following:

- You will be asked to carry a participant wallet card, which contains emergency contact information and information about your study commitments.
- Provide accurate and complete information about your medical history and your present conditions.
- Keep all scheduled study appointments at the research site. Please inform the study team in advance if you cannot attend an appointment.
- Tell the study team about all prescribed and non-prescribed medications and vaccines you are using before and during the study. You cannot use some treatments during the study. Please check with the study doctor before using any new prescribed or non-prescribed medications and vaccines.
- Tell your study doctor about any change in your health. Report any changes in your health to your study doctor between visits to the site. The contact number for your study doctor is provided at the beginning of this document. If you have symptoms consistent with suspected COVID-19, please notify the study team immediately.
- You must not take part in any other research study that involves another investigational vaccine or treatment against COVID-19 while you are taking part in this study. If during your participation in this study you are hospitalised with COVID-19, participation in research studies with investigational treatments is permitted.
- If you are a female, able to become pregnant, and heterosexually active, you must use a medically acceptable method of birth control, from at least 28 days before enrolment and through the end of the study.
- Provide an emergency contact in case the study team cannot reach you.

5. Other relevant information about the research project

Approximately 1340 participants will take part in the study at, up to, 20 research sites in Australia.

Please note that investigational vaccines may not be recognized by the Australian or international authorities as contributing to a person's vaccination status.

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.

6. Do I have to take part in this research study?

Participation in any research study 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 Eastern Health.

If you choose to take part, you can change your mind and withdraw at any time without giving a reason. If you decide not to take part or to leave the study, you will not lose any medical benefits to which you are otherwise entitled.

Please inform the study doctor if you decide to leave the study. To help you leave the study safely, your study doctor may ask you to have more tests and procedures. If you have an unresolved health problem when you withdraw from the study, if you agree, the study doctor may need to collect information about your health until the problem resolves. This can be done by telephone contact.

7. What are the alternatives to participation?

You do not have to take part in this research study to receive a booster vaccine at this hospital.

While there are vaccines approved by the Therapeutic Goods Administration (TGA) in Australia, there is no vaccine available to completely prevent coronavirus infection.

If you are offered the opportunity to get provisionally approved booster vaccines outside of this research study, we will ask you to continue the safety follow-up in this research study if you choose to get the new booster vaccine. Your study doctor will discuss these options with you before you decide whether or not to take part in this research study. You can also discuss the options with your local doctor.

8. What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research study. You may or may not benefit from taking part in this study. However, in the future other people may benefit from this research.

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 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

The original SARS-CoV-2 vaccine made by Novavax (NVX-CoV2373, Nuvaxovid, SARS-CoV-2 rS with matrix M adjuvant) has been given to approximately 45,000 adults 18 to 85 years of age, with the first doses given in 2020. The amount of vaccine given was the same or higher than that being given in this research study and most people got two doses of the vaccine.

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.

The study vaccine against the omicron variant NVX-CoV2515 and the bivalent (NVX-CoV2373 + NVX-CoV2515 vaccine are made using a similar manufacturing process to the original Novavax vaccine so the potential side effects are expected to be similar. However, this will be the first research study that looks at the side effects of this vaccine so it might be different.

There are also symptoms that can occur with vaccines in general but can be more apparent when the vaccine contains an adjuvant (something used to help increase the immune response to the vaccine). The vaccines in this research study contain an adjuvant. So far no serious health concerns have been identified as being related to the 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 vaccines, or that use of the adjuvant, is associated with an increased risk of autoimmune disease. However, for your safety, you will be monitored and regularly checked during the research study for any side effects that you may have after receiving the study vaccinations.

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 tests, even if you do not have COVID-19.

For this reason, we recommend that you avoid getting antibody blood tests for coronavirus outside of this research study. If you need to get tested outside of this research 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 research study, we do not know if the antibodies could be passed to your baby. We know that this happens with other vaccines, like the tetanus vaccine. For most babies, antibodies passed from the mother last for about 6 months.

Very common side effects (greater than or equal to 10%):

- Pain
- Tenderness
- Headache
- Tiredness
- Muscle aches
- Nausea or vomiting

Common side effects (greater than or equal to 1% but less than 10%):

- Injection site redness
- Injection site swelling
- Fever
- Chills
- Pain in the extremities (arm, hand, leg or foot)

Uncommon side effects (greater than or equal to 0.1% but less than 1%)

- Rash
- Redness
- Itching and injection site itching
- Urticaria (red, raised, itchy rash)
- Swollen lymph nodes

Unknown Risks

Rare side effects such as blood clots with a decrease in platelets (small blood cells that play a role in the formation of blood clots) and inflammation of the heart have been linked to some of the COVID-19 vaccines made by other manufacturers. Although no serious risks have been identified from ongoing research studies of the Novavax vaccines, there may be other risks with the study vaccines that are currently unknown. You will be monitored for any side effects while you are participating in the study.

Symptoms of myocarditis and pericarditis

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the outer lining of the heart) were reported in the clinical trials in subjects who received vaccine and who received placebo (an inactive substance). No causal link between vaccine and myocarditis and pericarditis has been established.

Symptoms of myocarditis or pericarditis include:

- Sudden onset of chest pain or pressure
- Heart racing
- Shortness of breath or shoulder/upper back pain

If you experience these symptoms, seek medical help and contact your doctor.

Sometimes allergic reactions to vaccines can occur and if untreated could become life threatening. These allergic reactions may be serious, including anaphylaxis. While the occurrence of anaphylaxis is possible with the administration of any vaccine, whether licensed or in development, no such reactions have been observed in any of the research studies of the Novavax vaccines to date.

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 research 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 research 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 sample collection:** 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 research study before you sign and date this form.

It is not known whether the study vaccines 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 research study.

If you are a woman of childbearing potential, you must agree to be heterosexually inactive from at least 28 days prior to enrolment and until the end of the research study OR agree to consistently use a medically acceptable method of birth control listed below from at least 28 days prior to enrolment until the end of the research study:

- Condoms (male or female)
- Diaphragm
- Cervical cap
- Intrauterine device (IUD)
- Oral or patch contraceptives
- Contraceptive implant, contraceptive injection e.g. Depo-Provera®
- Abstinence, as a form of contraception, is acceptable if it's in line with your lifestyle

NOTE: Periodic abstinence (e.g. calendar, ovulation, sympto-thermal, post-ovulation methods) and withdrawal method are not acceptable methods of contraception.

If you become pregnant during this research study, immediately inform the study staff. You will not receive any more study vaccines, but you will be required to remain in the study and be followed for safety. You will be asked to provide information about the outcome of your pregnancy. The study staff will discuss the risks of continuing with the pregnancy and the possible effects on the fetus.

If you are a male participant, you must use highly effective methods of contraception for the duration of the study.

Will I be told if I have a positive coronavirus test from samples collected during the research study?

A nasal swab will be collected at Day 0 to check for COVID-19.

Your study staff will discuss the best medical management of your illness and may, with your consent, involve discussions with your general practitioner. You will not get information from tests that are done purely for research (for instance, coronavirus research antibody test results).

10. What will happen to my test samples?

This study involves the collection of biological samples, such as blood, urine (if applicable) and nasal swab samples. These biological samples will be used for study analyses.

A total of no more than 75 mL (approximately 15 teaspoons) of blood will be required for all the screening tests. No more than 75 mL (approximately 15 teaspoons) of blood will be collected on any study visit day after screening.

Urine samples (if applicable) will be analysed locally, at your research site, and then destroyed once all the required laboratory tests have been completed.

Nasal swabs and blood samples to test the immune response will be sent, analysed and stored in a central laboratory until the report of the research study is final. Then they will be either destroyed or stored for unspecified research use if you agree to it. The central laboratory receiving your samples, with the exception of one blood sample, in this study is Sonic Clinical Trials, 14 Giffnock Ave, Macquarie Park, NSW 2113, Australia. Sonic Clinical Trials will distribute your samples to pre-identified laboratories in Australia and the United States of America for further analysis. One of your blood samples will be sent to 360biolabs for analyses, 85 Commercial Road, Melbourne, 300, Australia.

Your samples will only be used for the purposes described in this consent document. If additional analyses are proposed, Ethics Committee approval will be taken followed by your consent.

Information and inventions derived from your participation in the study including information derived from your biological samples are the property of the sponsor.

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 document.

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 research 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 section 16.

Blood samples may be stored frozen by Novavax, Inc. or companies working for Novavax, Inc. for up to 25 years. If needed, your stored blood samples may be used to look for changes in your blood cell counts or blood chemistries to learn about the safety of the study vaccines, including the evaluation of a health event. 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.

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

Future Research

Any leftover blood samples collected from you during the research study will be sent and stored at the following central laboratory for up to 25 years and with your permission may be used for future unspecified research: SriSai Biopharmaceutical Solutions, LLC 320 Montevue Ln. Frederick MD 21702, United States. The future unspecific research may include, 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 research study.

Allowing your leftover blood samples to be used for exploratory research is optional. If you choose not to take part in this optional exploratory research, you may still take part in the main research study. You will have the opportunity to document your decision in the consent form.

Any future research will be conducted in accordance with applicable regulations and guidances including those pertaining to Human Research Ethics Approval.

11. What if new information arises during this research project?

Sometimes during the course of a research study new information becomes available that may affect your decision to continue to take part in the study. If this happens, your study doctor will tell you about it in a timely manner time and discuss with you whether you want to continue in the study. If you decide to continue in the study after reading the new information or if new procedures need to be performed during the study, you may be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research study. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12. Can I have other treatments during this research study?

It is important to tell your study doctor and the study staff about any treatments or medications you may be taking. You should also tell your study doctor about any changes to these during your participation in the research study. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research study.

While participating in this study, it is advised that you not get an alternative vaccine, available outside of this study visit. If for some reason you should need a non-study vaccine while enrolled in the study, please contact your site for guidance.

13. What if I withdraw from this research study?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research study, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research study can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research study results. If you do not want them to do this, you must tell them before you join the research study.

14. Could this research study be stopped unexpectedly?

Your participation is voluntary. There are approved COVID-19 vaccines that may be available to you as a booster dose. The public health officials in your area will inform the public on how to get the available vaccine(s).

In addition, our study doctor or the Sponsor may remove you from the study for your safety, without your consent at any time. For example, this could happen if:

- your study doctor does not consider it to be in your best interest to continue
- you experience a serious illness
- you do not comply with the study requirements

- you become pregnant
- the study is stopped by the research site, the sponsor, an Ethics Committee/Institutional Review Board, or a health authority

The sponsor may stop the study at any time for any reason. If for any reason your participation in the study is stopped, the reason will be explained to you. For your own safety, you will be asked to return to the research site for final health checks as part of an EOS visit. Your study doctor will discuss any medical issues that may arise with you and will also discuss any alternative booster vaccines with you.

15. What happens when the research study ends?

On Day 270 you will have the last study visit called the End of Study (EoS) visit. During this visit some of the test and procedures already explained will be repeated.

If you stop the study early for any reason, you will be asked to return to the study site one more time to complete all of the tests and procedures that are described in Table 1 below. If you refuse to come to the study site, the study team will call you to check your health status.

Part 2 How is the research study being conducted?

16. What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research study. Any information obtained in connection with this research study that can identify you will remain confidential.

Confidentiality and Data Protection

The study information will be recorded in your medical records. The collection and use of your information is based on your written consent and applicable laws and regulations, for example, on research studies and patient safety. By consenting to participate in the study you acknowledge that certain personal data (information which is capable of identifying you), in particular health data and other data, which may be sensitive, such as year of birth, race, ethnicity and sex will be collected and processed electronically for research purposes in connection with this study.

Medical records

The records identifying you, including your medical records, remain at the study doctor's site and will be kept confidential by those reviewing them.

Your personal data, including your medical records will be controlled by the institution running the research study, which will act as data controller of such data for the purposes of data protection legislation. Direct access to relevant sections of your medical records will be required by authorised representatives of the sponsor, to check health related information collected for the study is correct and complete.

In certain limited circumstances, it may be necessary to provide direct access to the records identifying you (including your original medical records) by authorised personnel of the research sponsor and its agents, collaborators, research partners, assignees or designees; regulatory authorities; or other persons required by law. Your medical records will be reviewed at the study doctor's site, or through "remote monitoring", which is when study documents can be accessed electronically (e.g., e-mail, secure website or portal, etc.). This access is required to verify that the research study is conducted appropriately. In exceptional circumstances, such access to your personal data may also be required if for example the sponsor and/or its research partners were subject to legal proceedings or a regulatory investigation. Any such processing of personal data will always be in accordance with applicable data protection law.

The team monitoring the study accesses your uncoded personal data while at the research site, but the monitoring and access to your personal data could also be carried out remotely. In remote monitoring, your data would be accessed electronically from outside the research site using a secure platform.

Remote monitoring is used only in certain circumstances, such as during government and/or institutional restrictions related to an emergency situation (for example, COVID-19 pandemic). When remote monitoring is necessary, there is a slightly increased risk to your confidentiality.

However, study monitors will use a secure server for all correspondence and transmission of your personal information.

Study Data

Any personal data which is capable of identifying you will be replaced with a unique code referred to as a Participant Identification Number (PID). All data collected about you for this study, and data obtained from your tests and samples, will be identified using this PID number. This means that your personal identifying information, such as your name and address, will be removed and replaced with your PID number before your information leaves the research site. Your personal data is coded in this way to protect your privacy. We refer to this coded information as study data. Your name and identifying information will remain with the research site and will remain confidential at all times otherwise than in exceptional circumstances as set out above.

Your study doctor is responsible for keeping a code list which makes it possible to link your assigned number to your name. This will be kept in a safe place to ensure that in case of an emergency you can be identified and contacted. The code list will be kept at least 15 years after the end of the study.

The sponsor will act as data controller in relation to your study data. All your study data will be protected in accordance with national legislation for Australia. However, your data might be transferred to a country that may not have the same level of personal data protection as your country. If your data is transferred outside of your country the sponsor will ensure that your information and samples will be handled in accordance with Australian or equivalent privacy laws at all times.

Your data protection rights

You have the right to access your study data and request the correction of any errors. In certain circumstances, you have the additional rights to object to how your study data is being handled, request deletion of your study data, restrict certain uses of it or ask for a copy of your study data to be provided to you. However, to ensure proper evaluation of study results some of these rights may not be available until after the study has been completed.

Right to withdraw consent

You have the right to withdraw your consent to participate in the study at any time by contacting your study doctor. You can discuss this further with your study doctor, who will be your primary contact person for your rights, or you can contact the data protection officer of the study doctor's institution for further information. You should contact your study doctor initially for all queries relating to this study. In addition, if you are of the opinion that your study data is being used in violation of applicable data protection laws, you have the right to bring a complaint to the [Insert Supervisory Authority for privacy in local country].

Your information will only be used for the purpose of this research study and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research study.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, Novavax Inc. and ICON Clinical Research Pty Ltd., the institution relevant to this Participant Information Sheet, Eastern Health, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

Information about your participation in this research study may be recorded in your health records.

In accordance with relevant Australian and/or Victorian 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.

Any information obtained for the purpose of this research project *and for the future research described in Section 10* that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

Retention

The sponsor will retain your study data for 15 years in accordance with research study rules. The retention time may be longer if your study data is included in filings used to obtain approvals.

The results of this study will be published, though you will not be identified in any report or publication.

17. Complaints and compensation

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 ICON Clinical Research 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. A copy of the Guidelines is available to you from the research staff on request. If you have any questions about the Guidelines, please contact the Manager of Eastern Health Office of Research & Ethics on (03) 9895 3398.

- You may be able to seek compensation through the courts.

18. Who is organizing and funding the research?

This research study is being conducted and funded by Novavax, Inc. and sponsored in Australia by ICON Clinical Research Pty Ltd.

Novavax, Inc. may benefit financially from this research study if, for example, the project assists them to obtain approval for a new vaccine.

By taking part in this research study you agree that samples of your blood (or data generated from analysis of these materials) may be provided to Novavax, Inc.

Novavax, Inc. may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

You will not benefit financially from your involvement in this research study even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to Novavax, Inc.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Novavax, Inc. the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

Eastern Health will receive a payment from Novavax, Inc. for undertaking this research study.

No member of the research team will receive a personal financial benefit from your involvement in this research study (other than their ordinary wages).

19. Who has reviewed the research study?

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 Monash Health Human Research Ethics Committee

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2018)*. 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?

If you suffer any complications as a result of this research study, please contact us as soon as possible. In case of an emergency, contact 000.

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 (03) 9092 6753 or any of the following people:

Clinical contact person

Name	Kerrie Peacock
Position	Trial Coordinator
Telephone	03 9095 2421
Email	Kerrie.Peacock@monash.edu

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	Eastern Health Office of Research and Ethics
Position	Manager
Telephone	(03) 9895 3398
Email	ethics@easternhealth.org.au

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 name	*Monash Health Human Research Ethics Committee*
HREC Executive Officer	*HREC Executive Officer*
Telephone	*(03) 9594 4611*
Email	*research@monashhealth.org*

Reviewing HREC approving this research and HREC Executive Officer details

Table 1. Study Procedures

Study Visit	Screening	1	2	3	4	5	6	7	8	EOS	Unscheduled Visit	
Study Day	**-14 to 0**	**0**	**7**	**14**	**28**	**90**	**104**	**118 Phone Visit**	**189**	**270**	**Gen**	**Sp[a]**
Demographics and medical history	X											
Physical examination	X	X				X				X	X	
Vital signs measured	X	X				X				X	X	
Urine pregnancy test (if you are a woman who is able to have children)	X	X				X						
Vaccination		X				X						
Nasal swab sample collected for COVID-19	X	X				X						X
Blood sampling to test for natural immunity to COVID		X[b]				X[b]						
Blood samples for immune response testing		X	X	X	X	X	X		X	X		
Recording any immediate reactions for 7 days, including the day of vaccination using the eDiary		X				X						
Check of your health (includes any side effects that you may have experienced)	X	X	X	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	X	X

EOS = end of study; Gen = Unscheduled Visit due to a general medical issue; Sp = Unscheduled Visit due to suspected COVID-19 symptoms

a) In situations where the Unscheduled Visit is due to suspected COVID-19 symptoms, the visit will be conducted as a telehealth visit in keeping with local health regulations.

b) Performed prior to study vaccination

Eastern Health

Consent Form - *Adult providing own consent*

Study Title:	A Phase 3, Randomized, Observer Blinded Study to Evaluate the Safety and Immunogenicity of Two Booster Doses of the NVX-CoV2515 and Bivalent SARS CoV-2 rS Vaccines in Adults Previously Vaccinated with Other COVID-19 Vaccines
Short title:	Phase 3 Boosting Study for the SARS-CoV-2 rS Vaccines
Protocol Number:	2019nCoV-311
Project Sponsor:	Global Sponsor: Novavax, Inc. Local Sponsor: ICON Clinical Research Pty Ltd.
Coordinating Principal Investigator / Principal Investigator:	CPI: Dr. Eugene Athan PI: Professor Christopher Gilfillan
Location *(where CPI/PI will recruit)*:	Box Hill Hospital – Arnold Street, Box Hill VIC 3128, Australia

Declaration by Participant

I am 18 years of age or older.

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Eastern Health concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received. I know whom to contact if I have any further questions.

I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the research study without affecting my future health care.

I understand that relevant sections of my medical records will be reviewed by the Sponsor representatives, Ethics Committees, Auditors and National and foreign regulatory authorities where it is relevant to my taking part in the study. I give permission for these individuals to have access to my medical records at the study doctor's site or through remote monitoring.

I agree to the transfer of my study related data including year of birth, gender, race, ethnicity, information about my health and my sex life, to the sponsor and to regulatory authorities both within and outside Australia. I understand that my coded personal data identified only by my PID number may be sent to countries that do not have the same level of data protection as Australia.

I understand that I will be given a signed copy of this document to keep.

Consent for my treating General Practitioner / Physician		Participant to initial
I consent to my treating General Practitioner / Physician to be informed of my participation in this study.	Yes ☐ No ☐	

Consent to Use Samples for Future Medical Research		Participant to initial
I consent to left-over samples from this research study being retained for further exploratory medical research. I understand this additional unspecified research may be conducted, either now or in the future, and may not be solely in relation to this research study.	Yes ☐ No ☐	
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 research study.	Yes ☐ No ☐	

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 study.

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

Eastern Health

Form for Withdrawal of Participation - *Adult providing own consent*

Study Title:	A Phase 3, Randomized, Observer Blinded Study to Evaluate the Safety and Immunogenicity of Two Booster Doses of the NVX-CoV2515 and Bivalent SARS CoV-2 rS Vaccines in Adults Previously Vaccinated with Other COVID-19 Vaccines
Short title:	Phase 3 Boosting Study for the SARS-CoV-2 rS Vaccines
Protocol Number:	2019nCoV-311
Project Sponsor:	Global Sponsor: Novavax, Inc. Local Sponsor: ICON Clinical Research Pty Ltd.
Coordinating Principal Investigator/ Principal Investigator:	CPI: Dr. Eugene Athan PI: Professor Christopher Gilfillan
Location *(where CPI/PI will recruit)*:	Box Hill Hospital – Arnold Street, Box Hill VIC 3128, Australia

Declaration by Participant

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

Name of Participant (please print) _____

Signature _____ Date _____

I wish to withdraw my consent to have my residual (left-over) samples stored and used for future research.

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 study 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 study.

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