Momentum Clinical Research

PARTICIPATION INFORMATION SHEET (PART 2 PARTICIPANTS ONLY)

Lay title:	Phase 3 Study of the Safety and Immune Response of a COVID-19 and Flu Combination Vaccine and a Standalone Flu Vaccine
STUDY TITLE:	A Phase 3, Randomized, Observer-Blinded, Active-Controlled Study to Evaluate the Safety and Immunogenicity of a COVID-19 Influenza Combination Nanoparticle Vaccine and a Standalone Trivalent Nanoparticle Influenza Hemagglutinin Vaccine in Participants ≥ 65 years of Age
STUDY NUMBER:	CIC-E-301
STUDY SPONSOR	Novavax, Inc. 700 Quince Orchard Road Gaithersburg, MD 20878 United States
STUDY DOCTOR:	Dr Nine Smuts 205 Hastings Street South, Hastings 4122 T: 64 (6) 824 3070
ETHICS REFERENCE:	2024 AM 19922

You are invited to participate in a clinical research study (hereafter, called the “study”). This is a study of an experimental vaccine against the virus that causes COVID-19 disease (SARS-CoV-2) and the seasonal influenza (“flu”) virus. This experimental vaccine is a combination of 2 individual experimental vaccines, 1 vaccine against flu and 1 vaccine against COVID-19. This study will also evaluate a vaccine against flu when administered on its own. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide

you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document with the study Doctor. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 22 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Taking part in this study is voluntary. This means that you can choose if you want to take part in the study. You can leave the study at any time, without any reason. Doing so will not change your health care or your rights. If you do not want to join the study, you can talk to the study Doctor about your health care.

WHAT IS THE PURPOSE OF THE STUDY?

Novavax, Inc. (the "Sponsor") is developing a combination vaccine that aims to prevent serious illness or infection of both the flu virus and COVID-19 virus in people who are at least 65 or more years old. Instead of needing 2 separate vaccines, this one combination vaccine targets prevention of both viruses. The goal of this study is to see if the new combined **Trivalent Nanoparticle Influenza Hemagglutinin Vaccine (tNIV) and SARS-CoV-2 rS Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M™ Adjuvant** (further referred to as "Combination Study Vaccine") is safe.

Vaccines contain substances called antigens that cause your immune system to make special proteins called antibodies (this is called an immune response). Antibodies help your body remember how to fight off an illness/infection if you are exposed to these viruses in the future. Your immune response helps you to become more resistant to viruses and have a better chance of staying healthy.

The Sponsor also wants to see how safe Novavax's tNIV vaccine (further referred to as "Flu Study Vaccine") is.

The **SARS-CoV-2 rS** (COVID-19) component of the Combination Study Vaccine contains the 2024/2025 recommended strain, likely to be JN.1, and is designed to prevent COVID-19 infection and/or to prevent serious illness if infection with COVID-19 does occur. COVID-19 was caused by an outbreak of SARS-CoV-2. It began in Wuhan, Hubei Province, China in December 2019 and has spread worldwide. People with COVID-19 may 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.

Novavax's tNIV is also part of the Combination Study Vaccine. It is an experimental flu vaccine that contains the recommended 2024/2025 antigens to 3 different strains (types) of flu and the Matrix-M adjuvant to prevent infection with the flu and/or serious

illness if infection does occur. The Flu Study Vaccine has been tested as a single dose treatment in over 330 people 65 years of age and older in clinical research studies. In these studies, the Flu Study Vaccine was considered safe, well tolerated and shown to produce immune responses similar to, or better than, those of authorised flu vaccines.

Matrix-M Adjuvant - the Combination Study Vaccine and Flu Study Vaccine also contains an adjuvant which is a substance added to a vaccine to make the immune response greater and to increase the vaccine's effectiveness

The authorised vaccine to which the Combination Study Vaccine OR Flu Study Vaccine will be compared is called the "Active Comparator." If you are selected to get the Active Comparator, you will receive the authorised flu vaccine **Fluzone High Dose (HD)**. Fluzone HD is not licensed in New Zealand but is registered in Australia and the US, hence it is considered investigational in New Zealand and has been included in the study application to Medsafe, the authority responsible for the regulation of therapeutic products in New Zealand.

From this point, the term "study treatment" will be used to refer to any of the vaccines administered in this study (Combination Study Vaccine, Flu Study Vaccine, and Active Comparator).

HOW IS THE STUDY DESIGNED?

About 9,320 adults, 65 years of age and older will take part in this study with 7,020 participating in Part 1 and 2,300 in Part 2. All participants will automatically be enrolled into Part 1 until the total of 7,020 is reached, and then participants will be automatically enrolled into Part 2 until 2,300 is reached.

You are being enrolled into Part 2. This study will be run at approximately 59 sites located in Australia and New Zealand. About 700-800 adults in New Zealand will be enrolled in Part 2 of the study.

As a participant in the Part 2 study you will be given one of the following study treatments:

- **A Combination Study Vaccine, the Flu Study Vaccine, OR the Active Comparator.**

If you decide to take part in this study, you will be in the study for around 12 months. You will have to visit the study site (clinic) at least 2 times (Day 0 and Day 182) and have six study visits by telephone on Days 7, 28, 84, 135, 275 & 364 (also called the End of Study [EoS]). You may have to attend unscheduled (extra) study visits for safety reasons.

Study visits are expected to take place at the study site. 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, on the phone, or via video call.

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 study screening visit may take up to 3 hours. Screening and Day 0 (the day on which you receive the Combination Study Vaccine, Flu vaccine or Comparator will be combined and completed on the first study visit unless the study doctor identifies a reason that the dose needs to be delayed). All participants will receive 1 vaccination, in the arm, on the first day of the study (Day 0).

There are 3 vaccine groups overall in Part 2 of this study. If your study doctor says you can be in the study, you will be assigned by chance to 1 of the 3 treatment groups on Day 0. A computer program will randomly decide which vaccine you will receive. This means that there is a 50% of being assigned to the Combination Study Vaccine; a 40% chance of being assigned to the Flu Study Vaccine; and a 10% chance of being assigned to the Fluzone HD vaccine. Participants in all 3 groups will follow the same study procedures. You will not know what vaccine group you are in until after the study ends.

The study will compare the safety across all treatment groups. The following table shows the treatment groups you may be assigned to by chance during the study:

Vaccine Group	Treatment and Route of Administration
Combination Study Vaccine	1 IM dose of CIC (180 µg HA [60 µg per strain], 35 µg rS, and 75 µg Matrix-M)
Flu Study Vaccine	1 IM dose of tNIV (containing 180 µg HA [60 µg per strain] and 75 µg Matrix-M)
Active Comparator	1 IM dose of Fluzone High-Dose (containing 180 µg HA [60 µg per strain])

All participants are asked to remain on the study for the safety data collection through Day 364 EoS.

The study doctor or study team will observe you for at least 15 to 30 minutes after you receive the injection of study treatment. This is to check whether you experience any side effects or immediate reactions to the injected study treatment.

If, on the day of the planned vaccination, you are unwell, have fever, or high blood pressure, the vaccination may be delayed up to 7 days. As the study is planned to rapidly enrol participants over a short period of time (about 3 to 4 weeks), there is a chance that should your vaccination be delayed, you may end up not taking part in the

study. If the target number of participants have already started the study when you are about to begin participation, the study doctor can cancel your participation without your consent prior to you receiving the study vaccination.

You and your study doctor will not know which treatment group you are assigned to in the study. 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 the study treatment.

After your vaccination, you will visit the study site at least 1 additional time (Day 182 and possible unscheduled visits if needed). Each additional study visit will last about 1 hour. The main reason for these study visits is to check you for any health changes or problems."

WHO CAN TAKE PART IN THE STUDY?

You are being asked to join this study because you have completed at least one vaccination series against COVID-19 with an authorised COVID-19 vaccine; your second or last COVID-19 vaccine dose was more than 8 weeks ago; and you are considered medically stable based on history and physical examination by a qualified medical doctor at this site.

There are further criteria to determine if it is safe for participants to take part in the study, these will be assessed at the Screening visit.

What is expected from you?

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 all study visits described above.
- To tell the study Doctor truthfully about your complete medical history and current health.
- To report any new problems, illnesses, or side effects that you are having. This is particularly important if you experience symptoms of myocarditis or pericarditis, such as **new onset of chest pain, shortness of breath, heart palpitations (a "racing heart"), or fainting, which must be reported to your study Doctor IMMEDIATELY so that you may be given instructions to seek the appropriate medical care for this potentially serious condition**. 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. If you exhibit any of these symptoms, the study Doctor will inform you about the necessary steps and procedures to be taken.

- 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 or treatment of COVID19.
- Agree to use of the eDiary “app” and “app” Privacy Policy.
- Do not eat or drink anything 10 minutes prior to taking temperature for vaccine reactions.
- To record any reactions to the study treatment for 7 days or any medication you received after vaccination received in the “app” (or electronic diary).
- 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.
- During your time in this study it is asked that you agree to not post or discuss confidential information about this study either verbally or on any social media to maintain confidentiality until the study is confirmed complete by your study Doctor.
- Report to your study Doctor if you would like to take a COVID-19 authorised vaccine outside of the study, agree to wait to receive it until after your Day 28 phone call; and if the COVID-19 vaccine is received indicate the date received to your study Doctor.
- Agree to not take part in any other clinical research study for 90 days before starting the study or during the study, unless for treatment of COVID-19 during the study.

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

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

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 study 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) will ask questions about you, including your age, date of birth, and gender. You will be asked about your race and ethnicity. This is because the Sponsor does not know whether the effects of the Study Vaccine, Flu Study

Vaccine or Active Comparator are influenced by race or ethnicity. You will be asked about your medical history, including any recent infection with COVID-19, any preventive vaccinations you may have taken already for COVID-19 and any medications that you are currently or previously have taken, including any other vaccinations. You will be asked to provide documentation to confirm that you have received and the date(s) you received an authorised COVID-19 vaccine(s). At later study 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.

- **Physical Examination**: A physical examination will be done at screening before vaccination. This will include assessments of the head, eyes, ears, nose, throat, lungs, heart, neck, lymph nodes, arms, legs, and abdomen. During the screening, your height and body weight will be measured. At the other study visits, you will have a physical examination based on any symptoms you may have and that the study doctor indicates is needed (further referred to as a "symptom-directed physical examination"). This may not include an exam of all body parts.
- **Vital Sign Measurements**: This will involve looking at your body temperature (taken either by mouth, forehead, or ear), pulse rate, pulse oximetry (measures oxygen level in your blood), and blood pressure. On the day of vaccination (Day 0), vital signs will be taken before the vaccination is given to you. Vital signs will also be taken 15 to 30 minutes after vaccination. Should there be any abnormal results, the vaccination may be rescheduled until the results return to normal. At all remaining visits, vital signs may be taken at the discretion of the study doctor.
- **Electrocardiogram**: An electrocardiogram (ECG) measures the heart's electrical activity and can help the study doctor tell how your heart is working and identify any problems. An ECG will be performed on Day 0, before the vaccination is given to you.
- **Vaccination:** You will be given the study treatment that was assigned to you by chance. After the vaccination, you will be asked to stay in the study site for at least 15 to 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 treatment.
- **Electronic Diary (eDiary):** You will be asked to download a mobile application ("app") on to your smart phone. If you cannot use your own device, the staff will be able to provide you with a device to take home for use during the study. This "app" is referred to as an eDiary. The eDiary allows you to record any local and all over (systemic) reactions you may have during the study. It can be accessed on your personal device, or a device provided to you by the study. The information you enter in the eDiary is available electronically for the study doctor and study staff to review. The study staff will regularly check the eDiary to make sure all the information is complete. You will be trained by the site staff on how to use the eDiary for the following procedures:

- **Recording Vaccination reactions:** The eDiary contains a list of symptoms that you may develop after Day 0 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 additional 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 should not eat or drink anything for 10 minutes prior to taking your temperature. You will be asked to inform your study doctor of any medications, vaccinations, doctor visits, or additional illnesses not included in the eDiary. If you have a vaccination reaction at the injection site including swelling, redness (erythema), hardness (induration), pain or itch at or near the injection site, or other symptoms that are significantly impacting your daily activities, you should contact the study doctor immediately. If you have a significant local reaction, you will be asked to take non identifying photos with your smartphone to help document your vaccination reactions and to send them to the study staff either via the eDiary app or by email or text; or study staff may take a photo of your vaccination reaction at the study site visit. Photos of your vaccination reactions will be used to monitor your reaction and shared with the Sponsor.
- **eDiary Review with site staff:** The site staff will review the eDiary responses and may have additional questions following their review which require a response from you.

  The study staff will receive an email every morning to check if you have missed entering in the eDiary from the previous day. If you happen to miss entering in your eDiary, the study staff will contact you on the next working day and ask you to complete it before a certain time. If you miss the deadline, the study staff will talk to you about any symptoms you may have experienced. Once the specific time window is over, you won't be able to enter into your eDiary for the previous day.

- **Prior/concomitant 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 treatment. You will have a phone visit on Days 7, 28, 84,135, 275 & 364 [EoS]. During this visit, the study doctor or the study staff will check up on your overall health and record any medication that you have taken, or you are taking over the phone or through other forms of telemedicine contact, such as web chat, video calls, or FaceTime. 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.

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

The following table is a summary of the study tests and the timepoints in which key study procedures will be completed. Please ask your study doctor if you would like more information.

Study Day:	**Day 0**	**Day 7**	**Day 28**	**Day 84**	**Day 135**	**Day 182**	**Day 275**	**Day 364**
Visit Type	**Clinic**	**Phone**	**Phone**	**Phone**	**Phone**	**Clinic**	**Phone**	**Phone**
Approximate Study Visit Duration:	**3 hr.**	**15-30 mins**	**15-30 mins**	**15-30 mins**	**15-30 mins**	**1-2 hr.**	**15-30 mins**	**15-30 mins**
Study Visit:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Informed consent	X							
Medical history	X							
Inclusion/exclusion criteria	X							
Assignment to vaccine group	X							
Demographics	X							
Prior/concomitant medications	X	X	X	X	X	X	X	X
Adverse Events (Side effects/reactions)	X	X	X	X	X	X	X	X
Vital signs measurements	X							
Physical examination	X					X		
Baseline ECG	X							
Study Vaccination	**X**							
Record vaccine reactions in eDiary	X							
Review eDiary with Staff		X						

Abbreviation: ECG = electrocardiogram; hr.=hour(s); mins =minutes

WHAT HAPPENS TO THE BLOOD SAMPLES COLLECTED FROM YOU?

There will be no planned blood samples taken from you in this study.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

All medicines, including vaccines, can cause effects that are not wanted. These are called side effects.

Possible Risks Due to Study Vaccine Administration

People who received **components** of the Study Vaccine in the past have most often told the Sponsor about the following side effects:

Trivalent Nanoparticle Influenza Hemagglutinin Vaccine (tNIV)t component: The most common (greater than 1/100 people) injection site side effects were pain, swelling, redness, and bruising, which were generally mild or moderate. The most common general side effects after vaccination were muscle pain, headache, fatigue, joint pain, chills, cough, diarrhoea, sore throat, nausea, hoarseness, and wheezing; these side effects were generally mild or moderate.

SARS-CoV-2 rS Nanoparticle Vaccine component: (Novavax COVID-19 Vaccine)

The most common (greater than 1/100 people) injection site side effects were pain, tenderness, pain, redness, and swelling, which were mostly mild and generally lasted less than 2 days. The most common general side effects after vaccination were fatigue, headache, muscle aches, vague feeling of being unwell (malaise), joint pain, nausea//vomiting, and fever, which were generally mild and of short duration. Vaccination side effects were more likely to occur after receiving the second Novavax COVID-19 Vaccine when given the initial primary series vaccination.

Myocarditis/Pericarditis

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) have been seen in a small number (less than 1 in 10,000 vaccine recipients) of participants in clinical trials of the NVX-CoV2373 (Novavax COVID-19 Vaccine). Whether these conditions were caused by the vaccine is unknown. Based on information from people receiving mRNA vaccines, these side effects are seen more often in male adolescents and young adults after the second dose of vaccine. However, they have also been seen in women and older adults, and after the first dose. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine including chest pain, shortness of breath or feelings of having a fast-beating, fluttering, or pounding heart.

Matrix-M Adjuvant: 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, diarrhoea, joint pain, chills, nausea, vomiting, and fever. These are symptoms that can occur with vaccines in general but can be up to 2 times 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 believed to be 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 study vaccines, 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

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.

Risks identified in post-authorisation Use

Side effects that have been reported in post-authorisation use with the Novavax COVID-19 Vaccine include severe allergic reactions; inflammation of the heart muscle (myocarditis); inflammation of the lining outside the heart (pericarditis); an unusual feeling in the skin such as tingling or a crawling feeling (paraesthesia); a decreased feeling or sensitivity, especially in the skin (hypoesthesia); and tinnitus, ringing in the ears.

Possible Risks Due to Active Comparator Administration

Fluzone HD: In adults at least 65 years of age, the most common side effect (greater than 10%) was injection site pain (41.3%). The most common systemic (all over your body) side effects were muscle aches (myalgia) (22.7%), headache (14.4%), and lack of energy (malaise) (13.2%).

Study Procedure Risks

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

- **Blood Pressure:** The blood pressure cuff used to take your blood pressure may cause discomfort or bruising to your upper arm.

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, a member of the study team will inform you. If any clinically significant abnormal findings are noted by the study team, your GP will be advised of these findings. These findings may necessitate extra testing or treatment. The cost of any extra tests or related treatment will be your responsibility.

If any of these side effects happen to you or you notice a side effect not mentioned here, tell your study doctor.

Risks to Confidentiality and Privacy for eDiary ("app")

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

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

While the Terms of Use may include statements limiting your rights if you are harmed in this study, you do not release the study Doctor, Sponsor, institution, or agents from responsibility for mistakes, and these statements do not apply to the use of the app in this research study.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

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 Combination Study Vaccine and Flu Study Vaccine and this may benefit others in the future.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

Instead of taking part in this study, you may choose to receive vaccines for prevention of flu and/or COVID-19 that are approved in New Zealand. Your study doctor can

provide information on the list of available preventive vaccines and will explain the risks and benefits of these other treatments before you decide if you want to take part in the study.

WILL ANY COSTS BE REIMBURSED?

Taking part in this study will not cost you anything. You will not be charged for the study treatment or any of the tests that are part of the study.

Will you receive any payment if you take part in the study?

You will be reimbursed for participating in this study. You will also be reimbursed for any reasonable travel expenses (bus/train/taxi fares), or lodging incurred as a result of taking part in this study. If you withdraw from the study before the final study visit you will receive a partial reimbursement according to the number of study visits you have attended.

If you are eligible to enter the study, you will be reimbursed $210 for an in-clinic visit (includes travel), and $52.50 for a follow-up phone call, for taking part in this study. The total reimbursement for participants who complete the entire study will be $735.00 (before tax).

WHAT IF SOMETHING GOES WRONG?

As this research study is for the principal benefit of Sponsor, if you are injured as a result of taking part in this study you **won't** be eligible for compensation from ACC.

However, Novavax, Inc. has satisfied the Central Health and Disability Ethics Committee that approved this study that it has up-to-date insurance for providing participants with compensation if they are injured as a result of taking part in this study.

New Zealand ethical standards require compensation for injury to be at least ACC equivalent. Compensation should be appropriate to the nature, severity and persistence of your injury and should be no less than would be awarded for similar injuries by New Zealand's ACC scheme.

Some sponsors voluntarily commit to providing compensation in accordance with guidelines that they have agreed between themselves, called the Medicines New Zealand Guidelines (Industry Guidelines). These are often referred to for information on compensation for commercial clinical trials. There are some important points to know about the Industry Guidelines:

- On their own they are not legally enforceable and may not provide ACC equivalent compensation.

- There are limitations on when compensation is available, for example compensation may be available for more serious, enduring injuries, and not for temporary pain or discomfort or less serious or curable complaints.
- Unlike ACC, the guidelines do not provide compensation on a no-fault basis:
- The Sponsor may not accept the compensation claim if:
    - Your injury was caused by the study Doctor, or;
    - There was a deviation from the proposed study research plan, or;
    - Your injury was caused solely by you.

An initial decision whether to compensate you would be made by the Sponsor and/or its insurers.

If they decide not to compensate you, you may be able to take action through the Courts for compensation, but it could be expensive and lengthy, and you might require legal representation. You would need to be able to show that your injury was caused by participation in the trial.

You are strongly advised to read the Industry Guidelines and ask questions if you are unsure about what they mean for you.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study, the study Doctor and other Site staff will record information about you and your study participation. This includes the results of any study assessments. If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). The following groups may have access to your identifiable information:

- Site staff (to complete study assessments)
- Your GP will be notified of your participation in this study.
- Study monitors, to make sure the study is being run properly and that the data collected is accurate.
- The Sponsor and its representatives, if you make a compensation claim for study-related injury. Identifiable information is required in order to assess your claim.

- The Sponsor, ethics committees, or government agencies from New Zealand or overseas, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.
- Your GP, if a study test gives an unexpected result that could be important for your health or well-being. This allows appropriate follow-up to be arranged.
- Rarely, it may be necessary for the study doctor to share your information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of you or another person OR if the information is required in certain legal situations.

To ensure your privacy, your identifiable information will not be attached to records or samples released for research purposes. Any photos you may provide as documentation of vaccination reactions will become a part of your study data record. In case photographs include your face, birth marks, or other items that could identify you, every effort will be made to make sure that such information is removed or blurred before the photographs are shared with the Sponsor. The Sponsor and the study staff will not use your vaccination reaction photos for any reason, other than those stated in this consent form, without your written permission. Your information and samples, including photos, will only be identified by a code. 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 for 15 years. Your date of birth and initials may also be recorded to help identify your study record at the study site.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by Novavax, Inc. and any study information sent to the sponsor. Instead, you will be identified by a code. The study site will keep a list linking your code with your name, so that you can be identified by your coded data if needed. 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.

The following groups may have access to your coded information [which may be sent and stored overseas]:

- The Sponsor, for the purposes of this study.
- People and companies working with or for the Sponsor, for the purposes of this study (e.g. Medidata).
- Regulatory or other governmental agencies worldwide.

Security and Storage of Your Information.

Your identifiable information is held at Momentum Clinical Research during the study. After the study it is transferred to a secure archiving site and stored for at least 15 years, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Your coded information is being sent overseas. Other countries may have lower levels of data protection than New Zealand. There may be no New Zealand representation on overseas organisations which make decisions about the use of your information. There is a risk that overseas researchers may work with information in a way that is not culturally appropriate for New Zealanders.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and safety tests during the study. You may access other study-specific information before the study is over, but it is requested that due to the nature of the proprietary information, you may be asked to wait until it is released so as not to compromise the purpose of the study and sharing of data. If you request the results, they will be provided to you by your study doctor and explained to you for proper interpretation. You may also be asked to keep the information shared with you until the treatment groups are revealed after the study.

If you have any questions about the collection and use of information about you, you should ask study Doctor.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing your study Doctor.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

Ownership Rights.

Information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to any such discoveries and inventions will belong to Sponsor. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

Use of New Technologies

Information collected via the eDiary App will be shared with the Sponsor and its service providers. The data collected will be encrypted and stored in an electronic case report form and sent through a secure server to the Sponsor. Any photos shared through the App will also be shared through a secure server to the Sponsor. Your data will not be shared with any third parties except as otherwise stated and agreed upon herein. There is no cost to you for using the App.

Māori Data Sovereignty

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga:

- We have consulted with Laurie Te Hāpuku Te Nahu about the collection, ownership, and use of study data.
- We allow Māori organisations to access de-identified study data, for uses that may benefit Māori.
- We apply the principles of whakapapa, whanaungatanga, rangatiratanga, kotahitanga, manaakitanga, and kaitiakitanga throughout the study, to ensure that the data generated from this research is protected and may benefit now and into the future.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

What happens at the end of the study?

You will receive a phone call from the study site on Day 364 where you will be asked about any changes in your health and medications. If the study is stopped for other reasons or if you withdraw from the study early, then the activities planned for the Day 364 study visit will be conducted on your last study day if you agree. You will not be able to get Study Vaccine after the study is over.

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

Will you be informed if new information becomes available during the study?

Your study Doctor will inform you, in a timely manner, of any new information learned during the study that may affect your willingness to continue participating in the study. You will be informed about the new facts. You can then decide if you want to still participate in the study. If you leave the study, there will be no penalty and you will not lose any benefits to which you are entitled. Leaving the study will not affect the quality of the health care you are given.

What happens if you change your mind?

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. If you choose to leave the study, your standard medical care will not be affected, and no prejudice will be shown toward you regarding medical care or participation in future research.

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

- If receiving the study treatment would be harmful to you
- If you experience a serious health concern, 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 including but not limited to decisions made by local government agencies/health authorities
- If you receive a COVID-19 authorised vaccine during the study period that is not given as part of a study treatment

If the study vaccination is not administered, you will no longer be in the study.

If your participation in the study is stopped early, then you will be asked to complete the end-of-study procedures for Day 364 (such as a final health check for your own safety). If you are not able to visit the study site, then information about your health may 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.

Following the end of the study or after you have left the study early, your study Doctor (or staff) may seek to follow your long-term health for safety-related follow-up up until the end of the study, by looking at your hospital records if permission is given or publicly available sources such as national registries, newspaper obituaries, and social networking websites. Attempts may also be made to contact you or your relatives whom you have authorised for contact for information. If you do not want this information about you to be collected, you may tell your study Doctor at any time.

CAN I FIND OUT THE RESULTS OF THE STUDY?

A description of this clinical trial will be available at http://www.ClinicalTrials.gov. 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.

After this study is over, a brief report of the overall results will be prepared for the general public. The study results may also be shared with scientific journals and the scientific community. Whenever the results of the study are shared or published, your identity will remain private.

WHO IS FUNDING THE STUDY?

The Sponsor is the drug company that will run and pay for this study. The study doctor is paid by Novavax, Inc. to conduct this study.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Central HDEC has approved this study.

The scientific aspects of this study have been approved by the Standing Committee on Therapeutic Trials (SCOTT), which is part of Medsafe.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns, or complaints about the study at any stage, you can contact:

Name, position: Crawford Davidson Lead Study Coordinator
Telephone number: +64 (6) 824 3070
Email: Crawford.davidson@momentumclinicalresearch.co.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

For Māori cultural support please contact:

Name, position: Laurie Te Hāpuku Te Nahu,
Pou Whakaruruhau Matua (Senior Cultural Advisor to Executive Leadership Team), Te Whatu ora o Matau-a-Māui Hawkes Bay
Telephone number: +64 27 704 9665
Email: Laurie.tenahu@hawkesbaydhb.govt.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Email: hdecs@health.govt.nz
Phone: 0800 400 569 (Ministry of Health general enquiries)

Momentum Clinical Research

CONSENT FORM

Phase 3 Study of the Safety and Immune Response of COVID-19 and Influenza Combination Vaccine

If you need an INTERPRETER, please tell us.

By signing this consent form, you are agreeing to:

I have read the Participant Information Sheet or have had it read to me in a language I understand, and I fully comprehend what it says.
I have been given sufficient time to consider whether or not to participate in this study.
I have had the opportunity to use a legal representative, whanau/family support or a friend to help me ask questions and understand the study.
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
I consent to the research staff collecting and processing my information, including information about my health.
I consent to my information being sent overseas.
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.

I agree to my non-identifying photos being used to assess my vaccination reactions, if I have a significant local reaction, as described in the Participant Information Sheet.

I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.

I understand the compensation provisions in case of injury during the study.

I know who to contact if I have any questions about the study in general.

I understand my responsibilities as a study participant.

I understand that if I selected 'No' to the above question that the Sponsor can use publicly available records to obtain information about me.

Please tick to indicate your consent to:

I wish to receive a summary of the results from the study	Yes ☐	No ☐
If I withdraw from the study early I agree to the long term surveillance of my hospital records, until the end of the study	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name:

Signature: Date: (dd-mmm-yyyy) Time:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date: (dd-mmm-yyyy) Time: