MAIN PARTICIPANT INFORMATION SHEET AND CONSENT FORM- UK

NAME OF STUDY:	A Phase 3, Randomised, Observer-Blinded, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1™ Adjuvant in Adult Participants 18-84 Years of Age in the United Kingdom
STUDY NUMBER:	2019nCoV-302
IRAS ID:	288793
IRAS SHORT TITLE:	A trial to evaluate SARS-CoV-2 Recombinant Nanoparticle vaccine
STUDY SPONSOR:	Novavax, Inc. 21 Firstfield Road Gaithersburg, MD 20878 United States
STUDY DOCTOR (INVESTIGATOR):	Dr Andrew Higham Royal Lancaster Infirmary, Ashton Road Lancaster LA1 4RP Office Tel: 01524 583311 Out of hours: 01524 65944

Invitation

You are being asked to consider whether you would like to participate in a clinical research study (hereafter, called the "study"). This is a study of an experimental vaccine against a new type of virus called SARS-CoV-2. As you are probably aware, this virus has caused a global outbreak of an illness called coronavirus disease-2019 (called "COVID-19") around the world.

The following information describes the study and your role as a participant. Please read this information carefully and do not hesitate to ask your study doctor any questions to ensure that you are able to make an informed decision as to whether to participate. You are under no obligation to take part in this study.

What is the purpose of this clinical research study?

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

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

So far, there are no approved vaccines available in the United Kingdom to prevent or protect against SARS-CoV-2. Novavax, Inc. (Sponsor) has developed a vaccine that aims to prevent this virus from infecting people and/or preventing serious illness if infection occurs. Vaccines are substances used to try to create resistance (or immunity) to a disease. The name of the study vaccine in this study is SARS-CoV 2 Recombinant(r) Spike (S) Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M adjuvant (hereafter, called the "study vaccine"). Because this vaccine is not made using infectious virus, it cannot give you COVID-19, the disease caused by SARS-CoV-2.

About 15,000 male and female participants between the ages of 18 and 84 years with and without the presence of additional medical problems will take part in this study. The study will be conducted in areas expected to have high levels of the disease (up to 18 regions) in the United Kingdom (UK). About 1 in 4 of the participants will be 65 years of age and older. The study will be conducted in areas expected to have high levels of the disease (approximately 28 sites) in the United Kingdom (UK).

The main purpose of the study is:

1. To see if the study vaccine continues to be safe for the general population
2. To see if the vaccine is effective in preventing symptoms of COVID-19 and more severe COVID-19
3. To see what different types of immune responses the study vaccine produces

In addition to the main study, you may also be asked to participate in a separate part of the study (a sub-study). This will depend on which hospital/clinic you visit. Your study doctor will explain which, if any, sub-studies are running at your hospital/clinic. If your hospital/clinic is participating in any of the sub-studies and you are willing to participate, a separate consent explaining all necessary information about the sub-study will be provided that you will be asked to sign.

This informed consent form explains your possible role as a participant if you agree to participate in this main study.

Do I have to take part?

No. It is up to you to decide. Your participation in this study is voluntary and you may refuse to participate or withdraw from the trial at any time without penalty or loss of benefits to which you are otherwise entitled. If you do decide to participate you will need to read this information sheet and sign a consent form to show you have agreed to take part.

What procedures are involved?

If you decide to take part, you will be in the study for approximately 1 year after your second (and final) study vaccination (including screening). You will have to visit the study site (i.e., clinic) at least 6 times. All visits will involve only day visits to the study site. You may have to attend unscheduled (extra) visits if you develop COVID-19-like symptoms in order to see if you have COVID-19.

If you pass the screening visit, the study vaccination will be given on Day 0 and Day 21. You will then attend the study site for follow-up visits on Day 35 (14 days after second study vaccination) and at 3, 6, and 12 months after the last study vaccination.

Study visits will normally take place at the study site, unless your study site staff make other plans.

You will be asked to read and sign this form before you have any study tests. If you want to participate in this study, then your study doctor will first check whether this study is right for you. This is called screening. This visit will take up to 3 hours. Screening must be completed no more than 30 days before you receive the study vaccine. If your study doctor confirms you are suitable for the study, and you agree, it may be possible to do both the screening and Day 0 visits on the same day. A nose/throat swab will be taken before the first vaccine dose.

In this study, the active vaccine will be compared to a placebo. A placebo is a substance that looks like the active vaccine but does not have any vaccine product in it; the placebo in this study contains only water and sodium chloride (salt). If your study doctor says you can be in the study, you will be assigned by chance (like flipping a coin) to either active vaccine or placebo as an injection into the muscle in your upper arm (the deltoid muscle) on Day 0 (the day on which you receive the first injection of study vaccine), and on Day 21. You have a 50% chance of receiving the active vaccine. A computer program will randomly decide which treatment you will receive. You will not know what treatment group you are in until after the study ends.

For the remainder of this document, when we use "study vaccine", this refers to vaccination with either 'SARS-CoV-2 rS with Matrix-M adjuvant' or 'placebo'.

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

If, on the day of the planned vaccinations, you are unwell, have fever, cough or other symptoms such as very elevated blood pressure, then the vaccination may be delayed to a later date. You should be well for at least 3 days before returning to the study site for the vaccination. As COVID-19 studies rapidly enrol participants over a short period of time (3-4 weeks), there is a chance a delay in your vaccination may result in you not taking part in the study. If you tested positive for SARS-CoV-2 before your participation in the study (by being asymptomatic), the study doctor can cancel your participation without your consent.

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

After your first vaccination, the number of study site visits includes the second vaccination visit on Day 21 followed by follow-up visits on Day 35 and at 3, 6, and 12 months after second study vaccination. Each visit will last about 1-2 hours. The main reason for these visits is to check you for any health changes or problems.

If you become ill with symptoms that could be due to COVID-19, you will be asked to collect samples at home to test for the SARS-CoV-2 using sample kits that will be provided to you. You will also be asked to complete a COVID-19 Symptom eDiary (FLU PRO) daily for a minimum of 10 days. You

should contact your study site within 24 hours with the help of contact information mentioned on your Study Identification (ID) card. Your Study ID card will be provided to you on Day 0 (first study vaccination).

If you have COVID-19 symptoms, you will also be asked to attend the site for 2 extra study visits. At the first visit the study staff will assess your illness and a follow-up visit, about 7 days later will be scheduled to evaluate any worsening of your symptoms. There is also a possibility that due to COVID-19, you or the study doctor may not be able to visit the study site following the exact schedule for a visit. The study staff may also visit your home depending on local procedures. After the second visit, you will be contacted every week by the study staff to ask about your symptoms, until they go away. As the study is using Public Health England (PHE) tests, PHE will contact you within several days with your COVID-19 test results and instructions.

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 about what happens at each visit. If you do not understand these procedures and assessments or want to know more, please ask your study doctor to explain.

- **Demographics and Medical History**: The study doctor (or a study staff member the study doctor has allowed to do so) will ask questions about you, including your age, full date of birth, and sex. You will be asked about your race and ethnicity (only for clinical research purposes). This is because the Sponsor does not know whether the effects of the study vaccine are influenced by race or ethnicity. You will be asked about your medical history including any recent infection with SARS-CoV-2 and any medications or herbals, vitamins, and supplements, that you have taken recently, including any vaccinations. At later visits, you will be asked about any new signs and symptoms, and any new medications or vaccinations that you took or are taking after joining this study. You should inform your study doctor if you change any of your medications or start taking new medications for other reasons.
- **Physical Examination**: A limited physical examination will be done at screening. This will include assessments of the skin, head, ears, eyes, nose, throat, thyroid, lungs, heart, neck, lymph nodes, arms, and abdomen. During the Screening Visit, your height and body weight will be measured. At the remaining visits, you will have a physical examination based on any symptoms you may have and that the study doctor indicates is needed. This examination will be done before the study vaccine injection is given to you.
- **Vital Sign Measurements**: This will involve looking at your body temperature (taken either by mouth, or by a different method that the site uses), respiratory rate (number of breaths taken per minute), pulse rate, blood pressure and pulse oximetry (monitoring of oxygen saturation level). Vital signs will be taken before the vaccination injection is given to you and 15 to 30 minutes after study vaccination. Should there be any significant abnormal results, the vaccination may be rescheduled until the results return to normal.
- **Pregnancy Tests:** If you are a woman who is able to have children, then you will need to have a pregnancy test, which must be negative for you to take part and then continue taking part in the study. A urine sample will be taken to test whether you are pregnant or not. If the results are

positive for pregnancy at any point during the study, then further study vaccine will not be given to you, but you may continue in the study.

- **Testing for the SARS-CoV-2 virus:** A nose/throat sample will be taken at screening to test for SARS-CoV-2 if you have had symptoms of COVID-19 or have been in close contact with someone who has symptoms. If the result is positive, you will not be able to take part in the study. Samples will be collected from the nose/throat at Day 0 to determine if you are infected with SARS-CoV-2. If you do experience COVID-19 symptoms at any time during the study, you will be required to self-sample daily starting about 24 hours after the symptoms start, for up to 3 days. You will be taught by study staff on Day 0 how to self-sample.
- **Blood Tests**: During your visits to the site you will be asked to provide blood samples. A needle will be used to collect blood from a vein in your arm. During the time you are in the study, the total amount of blood taken from you should be no more than 20 mL (about 4 teaspoons). Blood will be collected to check if you have any antibodies in your blood that suggests you have been infected with SARS-COV-2 even though you do not show symptoms. If your study site is participating in a sub-study that requires additional blood samples, you will be provided with another information sheet that will explain more about why the samples are being taken. The study doctor will ask you to sign a separate consent form to agree to have additional samples taken.

  Some of the blood sample will be sent to the Sponsor company, Novavax, Inc.21 Firstfield Road Gaithersburg, MD 20878 United States, where they will be stored, frozen, for up to 25 years and used for additional research into SARS-COV-2.

  These samples will be labelled with your unique study participant number and will not contain any information that can identify you personally. These samples will be destroyed following analysis. If any of your samples are used in these other ways, the information linking those samples to you personally will be permanently destroyed. A full list of laboratories being used to process your samples can be found at the end of this section.

  If you withdraw consent to participate after the start of the study, all samples collected from you up to that time will be stored and used for testing, unless you request the collected samples be destroyed.
- **Vaccination:** You will be given the study vaccine that was assigned to you by chance. After the vaccination, you will be asked to stay in the study site for at least 30 minutes so that the study doctor or member of the study team can observe whether you have any immediate reactions to the study vaccine.
- **COVID-19 Symptom Electronic Diary (FLU-PRO eDiary):** If you have COVID-19 symptoms you will be asked to complete the COVID-19 Symptom eDiary (FLU PRO). You should start the COVID-19 Symptom eDiary on your first day of symptoms and complete this diary daily for a minimum of 10 days, even if symptoms have resolved. You should continue to complete the eDiary beyond 10 days if you have any ongoing symptoms and should continue to complete the eDiary until all symptoms have been resolved. You will be asked to download a mobile application ("app") on your smart phone to allow you to complete the COVID-19 Symptom eDiary **(**FLU-PRO). You will be trained by the site staff on how to use the app. eDiary for FLU-PRO is a mobile application containing study-related information such as patient symptoms

whether patients have sought medical attention and the like. The eDiary for FLU-PRO is a product of Medidata Solutions, Inc. (hereinafter "Medidata"). Data from the app will flow to Medidata RAVE Electronic Data Capture (EDC) system. Email addresses, on the other hand, are not stored in the Rave EDC and cannot be accessed by the study team, site staff or Medidata staff. Any data collected pursuant to the use of the application or desktop version will be subject to Medidata's Privacy Policy available at your request.

- **Monitoring of COVID-19:** Your health will be monitored throughout the study to record any new symptoms or health concern related to infection with SARS-CoV-2. A Study ID Card will be provided to you with details on study participation, study site contact information, and assessment of COVID-19 symptoms. You can contact the study team on the 24 hours a day/7 days a week telephone number provided to you at the time of study entry. You should contact the study team at this number within 24 hours if you observe any COVID-19 symptoms. Newly discovered symptoms can cause a COVID-19 illness check-in visit. If you have COVID-19 symptoms, you will be asked to complete the COVID-19 Symptom eDiary daily for a minimum of 10 days. You will also be monitored for any COVID-19-related complications that require hospitalisation (like pneumonia, respiratory disease, renal disease or any infection).
- **Self-Sample Collection for COVID-19 Confirmation:** You will be instructed on how to take a nose/throat sample at home to test for the SARS-CoV-2 virus on Day 0. You will be given 3 sample collection kits to take home with you. You will be individually informed on whether or not to collect samples by the study site staff. Samples will need to be collected for 3 days in a row if you experience any new symptom related to COVID-19, and you will need to provide these samples to the study staff as instructed. It is important that these samples are taken as explained in this section. These samples will be sent to a testing centre to check if you have COVID-19.
- **Health and Medications**: You should inform the study doctor if you change any of your medications, or start taking new medications, or have received any other vaccinations since you started in the study, including herbals, vitamins and any supplements for other reasons at any time during the study. Throughout the study, you will be asked about how well you are feeling or whether you have experienced any side effects or immediate reactions after receiving the study vaccine. Inform the study team immediately if you experience any reaction or a side effect after vaccination and if you visit your GP or local doctor for consultation and/or treatment or a hospital visit.

  You will be provided a thermometer to take your temperature by mouth. You will be asked to inform your study doctor of any medications, vaccinations, doctor visits, or additional illnesses during the study.

Your samples (mentioned above in detail) will be sent to special laboratories listed below:

PPD Global Central Labs - GCL-EUROPE
19 Kleine Kloosterstraat
Zaventem, B-1932
Belgium

Lighthouse labs (various locations)

Milton Keynes:
Units 2 & 3, Java
Park, Bradbourne
Drive, Tilbrook,
MK7 8AT, UK

Cheshire:
Alderley Park
Congleton Road
Nether Alderley
Macclesfield
SK10 4TG

Glasgow:
University of Glasgow, Queen Elizabeth University
Hospital Campus, 1345 Govan Road
Govan
G51 4TF
Glasgow

Cambridge:
The Anne McLaren Laboratory for Regenerative Medicine
Addenbrooke's Hospital
Hills Road Cambridge
CB2 0SZ

Antrim, Northern Ireland:
55 Diamond Road,
Crumlin,
County Antrim,
BT29 4QY,

Newport:
Imperial Park,
Dyffryn Lane,
Newport
NP10 8ul

Loughborough: Charnwood Campus Bakewell Road Loughborough LE11 5RB
Oxford Immunotec ***(Used for the cell mediated testing sub-study)*** 143 Park Drive, Milton Park, Abingdon, OX14 4SE
Public Health England ***(Used for the Neutralisation assay substudy and Haemagglutination Inhibition assay sub-study)*** Porton Down Salisbury SP4 0JG United Kingdom
Nexelis laboratories (Used for the ***Anti S protein serology substudy)*** 525 Cartier West Blvd Laval QC H7V 3S8 Canada

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

Screening Visit

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

- Discussion of this study with the study doctor and review and signing of this form. You will be given enough time to make a decision.
- Recording of your demographic information, including age, date of birth, sex, race/ethnicity, weight, and height.
- Review of your medical history, surgical procedures, vaccinations, and any medications you are taking or have taken recently.
- Physical examination and vital sign measurements.
- If you are a woman who is able to have children, then you will be tested for pregnancy using a urine sample.
- Nose/throat samples to test for SARS-CoV-2, **only if you have any COVID-19 symptoms.**
- Review of your health and a check to see whether you have any side effects or have had any new doctor or hospital visits.

First Study Vaccination Visit (Day 0)

If the screening tests show that you can take part in the study, the following tests will be done at this visit before you receive first injection of the study vaccine (most subjects should be able to combine the Screening visit and the Day 0 visit in which case the tests will NOT be done twice):

- You will be asked again about any medications you have been taking, including any vaccinations, and surgical procedures.
- Review of your health and a check to see whether you have any side effects or have had any new doctor or hospital visits.
- Review of the entry conditions to check if this study is still right for you.
- Physical examination of some body parts (not all).
- Vital sign measurements before and after study vaccination.
- If you are a woman who is able to have children, then you will be tested for pregnancy using a urine sample before study vaccination.
- Blood samples will be taken before study vaccination:
    - To measure if you have previously been exposed to SARS-CoV-2.
    - Other blood tests may be taken if your study site offers a sub-study. You will be asked to give additional consent for this to happen.
- Monitoring for any immediate reaction to the study vaccine (reactogenicity).
- Nose/throat samples to test for SARS-CoV-2 (this will not be repeated if it was done as screening). You will be taught how to collect this sample at home.
- Monitoring for any symptoms related to COVID-19.
- You will be assigned by chance to a treatment group (which selects whether you will receive active vaccine or placebo). This assignment will only be done at Day 0.

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

The study team will also provide you with instructions on what you should do after you leave the study site and when you should return to the study site.

Second Vaccination Visits (Day 21)

About 3 weeks after the first vaccination (i.e., on Day 21), you will get a second injection of the study vaccine as assigned to you by chance on Day 0.

- You will be asked again about any medications you have been taking, including any vaccinations.
- Review of your health and a check to see whether you have any side effects or have had any new doctor or hospital visits.
- Review of the entry conditions to check if this study is still right for you.

- Physical examination of some body parts (not all).
- Vital sign measurements before and after study vaccination.
- If you are a woman who is able to have children, then you will be tested for pregnancy using a urine sample before study vaccination.
- Blood samples will be taken only if you are in one of the sub-studies.
- Monitoring for any immediate reaction to the study vaccine (reactogenicity).
- Nose/throat samples to test for SARS-CoV-2, **only if you have any COVID-19 symptoms between Day 0 and Day 21.**
- Monitoring for any symptoms related to COVID-19.

After completion of these tests, the study staff will give you the second (and final) injection of study vaccine. After you receive the study vaccine, you will be observed for at least 30 minutes after the injection to check whether you have any immediate reactions to the study vaccine, as you were after the first vaccination.

Day 35 Follow-up Visits

The following procedures will be performed:

- You will be asked again about any medications you have been taking, including any vaccinations.
- Review of your health and a check to see whether you have any side effects or have had any new doctor or hospital visits.
- Physical examination of some body parts (not all).
- Blood samples will be taken:
    - To measure if you have been exposed to SARS-CoV-2.

      Other blood tests may be taken if your study site offers a sub-study. You will be asked to give additional consent for this to happen.
- Monitoring for any symptoms related to COVID-19. If you test positive for COVID-19, you will be asked to complete a COVID-19 Symptom eDiary (FLU PRO) daily and start taking your temperature at home for a minimum of 10 days.

COVID-19 Illness Visits (Unscheduled)

In addition to the scheduled visits, you may have unscheduled (extra) visits for safety reasons or to assess and investigate if you may have COVID-19. In case you experience any new symptoms, you should contact the study team immediately, start your COVID-19 Symptom eDiary (FLU PRO), start taking your temperature at home and begin your self-testing. You will be asked to attend visits, "Initial COVID-19 Illness Visit" and "Follow-up Visit".

Initial COVID-19 Illness Visit: This visit will be performed at the study site (or home) and will occur as soon as possible within about 1-3 days of experiencing new symptom. During this visit, you will undergo the following procedures:

- You will be asked again about any medications you have been taking, including any vaccinations.

- Review of your health and a check to see whether you have any side effects or have had any new doctor or hospital visits.
- Physical examination of some body parts (not all).
- Vital sign measurements.
- Monitoring for any symptoms related to COVID-19. If you test positive for COVID-19, you will be asked to complete a COVID-19 Symptom eDiary (FLU PRO) daily for a minimum of 10 days, start taking your temperature at home for a minimum of 10 days and begin your self-testing.

Follow-Up Visit: This visit will occur about 7 days after the first visit (initial COVID-19 illness visits) to evaluate possible progression of COVID-19 symptoms. During this visit, you will undergo the following procedures:

- You will be asked again about any medications you have been taking, including any vaccinations.
- Review of your health and a check to see whether you have any side effects or have had any new doctor or hospital visits.
- Physical examination of some body parts (not all).
- Vital sign measurements.
- Monitoring for any symptoms related to COVID-19. If you test positive for COVID-19, you will be asked to complete a COVID-19 Symptom eDiary (FLU PRO) daily for a minimum of 10 days, start taking your temperature at home for a minimum of 10 days and begin your self-testing.
- After the Follow-Up Visit, you will continue to receive telephone contacts about every week for checking of any COVID-19 symptoms status until symptoms have been resolved.

3 Months After Second Study Vaccination
This visit will occur about 3 months after your second study vaccination. During this visit, you will undergo the following procedures:

- You will be asked again about any medications you have been taking, including any vaccinations.
- Review of your health and a check to see whether you have any side effects or have had any new doctor or hospital visits.
- Blood samples will be taken to measure if you have been exposed to SARS-CoV-2.
- Reminder about monitoring for any symptoms related to COVID-19. If you have new symptoms that could be due to COVID-19, you will be asked to complete a COVID-19 Symptom eDiary (FLU PRO) daily for at least 10 days, start taking your temperature at home for a minimum of 10 days and begin your self-testing.

6 Months After Second Study Vaccination
This visit will occur about 6 months after your second study vaccination. During this visit, you will undergo following procedures:

- You will be asked again about any medications you have been taking, including any vaccinations.
- Review of your health and a check to see whether you have any side effects or have had any new doctor or hospital visits.
- Blood samples will be taken to measure if you have been exposed to the SARS-CoV-2 virus.
- Reminder about monitoring for any symptoms related to COVID-19. If you have new symptoms that could be due to COVID-19, you will be asked to complete a COVID-19 Symptom eDiary (FLU PRO) daily for at least 10 days, start taking your temperature at home for a minimum of 10 days and begin your self-testing.

12 Months After Second Study Vaccination
This visit will occur about 12 months after your second study vaccination. During this visit, you will undergo following procedures:

- You will be asked again about any medications you have been taking, including any vaccinations.
- Review of your health and a check to see whether you have any side effects or have had any new doctor or hospital visits.
- Blood samples will be taken to measure if you have been exposed to the SARS-CoV-2 virus.

Study Vaccination Stopping Rules:
Your study vaccination will be paused if you experience serious side effects and any immediate reaction to the study vaccine. These will be monitored throughout the study for your own safety. Final decision to stop vaccination will be taken by your study doctor or the Sponsor after discussing with an independent Safety Monitoring Committee (SMC) made up of doctors and scientists. You will be informed by your study doctor if vaccination is stopped.

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 study site visits described above.
- To tell the study doctor truthfully about your complete medical history.
- To tell the study doctor truthfully about your working or occupation details in order to check whether you are working in a high-risk environment with exposure to SARS-CoV-2.
- To report any new problems, illnesses, or side effects that you are having. If you have experienced a new cough, sore throat, fever, breathing difficulty, fatigue, muscle or body aches, headache, loss of taste or smell, congestion, runny nose; or nausea, vomiting or diarrhoea 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 allow the study doctor and/or the study team to collect blood samples and nose/throat swabs for laboratory testing.

- To take nose/throat samples by yourself 3 days in a row if you experience any new symptom related to COVID-19, and to manage these samples as instructed by the study staff.
- To report changes in medication(s) or new medication(s), including supplements or any vaccinations that you are taking during the study. In addition, you must inform the study doctor about taking any medicine for prevention of COVID-19.
- To record any symptoms of COVID-19 in the app when symptoms begin
- To not take any vaccines during the study as instructed by the study doctor.
- To not take any medication that reduces the strength of the body's immune system within 3 months of first study vaccination until the last study visit.
- To not take continuous medication that inhibits your blood's ability to clot.
- To remain in touch with the study doctor and to let him or her know if you have changes to your contact information (address or telephone number) or if you no longer wish to participate in the study.

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

What will happen at the end of the study?
If the study is stopped for other reasons or if you withdraw from the study, then the activities planned for the 12-month follow-up visit will be conducted on your last study day. The study doctor will contact you via telephone at the end of the study on the 12-month follow-up visit to arrange the following tests:

- You will be asked again about any medications you have been taking, including any vaccinations.
- Review of your health and a check to see whether you have any side effects or have had any new doctor or hospital visits.
- A blood sample will be taken to confirm if you have any antibodies to SARS-CoV-2.
- Monitoring for any symptoms related to COVID-19. If you test positive for COVID-19, you will be asked to complete a COVID-19 Symptom eDiary (FLU PRO) daily for a minimum of 10 days.
- You will be asked to complete the End-of-Study Form to record your feedback.

Following the end of the study, or after you have withdrawn from the study before its conclusion, your study doctor will tell you whether additional follow-up is needed and whether you need to visit the study site again

What are the potential risks and discomforts?
All medicines, including vaccines, can have some risks or cause certain side effects and discomforts, although not everybody experiences them. Side effects are any unwanted or sometimes unpleasant reactions that may result from taking a medicine, including a vaccine.

The study vaccine is an experimental vaccine and at the moment there is limited information about all the risks or side effects that may occur from the vaccine.

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. Others have reported fever, headache, fatigue, and body aches.

Possible Risks Due to Study Vaccine Administration

The current vaccine is prepared by the Sponsor in a way similar to other vaccines (used against different viruses such as influenza) using a method called "nanoparticle technology." To date, over 14,800 participants, including pregnant women and people aged up to 85 years of age, have received vaccines prepared with this type of technology in clinical studies conducted by the Sponsor. The adjuvant (vaccine boosting agent) being evaluated in this study is called 'Matrix-M1'. It has been given to over 4311 participants in different clinical research studies conducted by the Sponsor for testing vaccines against different viruses and other germs, and of these, about 2600 participants received Matrix-M1 adjuvant with nanoparticle vaccines, mostly in adults and in people up to 85 years of age.

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

Autoimmune diseases are a potential side effect of vaccines and adjuvants. These are serious diseases that can occur in the general population as well (without administration of a vaccine). Autoimmune diseases involve the immune system attacking the body's own tissues. Autoimmune disease can affect the heart, skin, blood health, metabolism, nervous system, thyroid, muscles, joints, liver, and/or kidneys. There is no evidence that the technology used to prepare the study vaccine, or the use of Matrix-M adjuvant is associated with an increased risk of autoimmune disease. However, for your safety, you will be observed and regularly checked during your time in the study for any side effects that you may have experienced after receiving the study vaccine.

In the Phase 1 study of this vaccine, involving 131 volunteers, reported symptoms after vaccination were generally mild, and vaccinations were well tolerated. Pain and tenderness at the injection site were the most common local finding with headache, fatigue, and muscle pain being the most common overall symptoms. No participants sought medical attention or refused second vaccination dose due to symptoms and no serious adverse events were reported through 2 weeks after the second dose.

Unforeseen Risks

Sometimes allergic reactions to vaccines occur and if untreated could become life-threatening. Some signs of an allergic reaction are as follows:

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

- Fast pulse
- Sweating

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

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

- **Blood Collection:** Collecting blood may cause bruising at the place where the needle is inserted. Fainting, and in rare cases infection, may occur.
- **Blood Pressure:** The blood pressure cuff used to take your blood pressure may cause discomfort or bruising to your upper arm.
- **Nose/Throat Samples:** During collection of nose/throat samples, you may experience sneezing, eye tearing, or gagging. There is also the potential for those people who are susceptible to nosebleeds to experience one.

Are there any reproductive risks?

Women: It is not known whether the study vaccine may affect an unborn child or nursing infant. For this reason, if you are breast-feeding or pregnant or plan to become pregnant within 3 months following the last study vaccination, you cannot participate in this study. If you are capable of becoming pregnant, you must avoid sex or use an acceptable method of birth control (see below) from at least 28 days prior to participation in the study through 3 months after the last study vaccination

Pregnancy (female participant): If you become pregnant during your participation in the study, you should inform the study doctor and you will not receive any more study vaccinations. However, data and information about your pregnancy may be collected. Pregnancies must be reported to the Sponsor within 2 weeks of you becoming aware. Monitoring of your pregnancy will continue until the outcome (including miscarriage, termination, normal birth, or any abnormality) is known. If required by country regulations, you and your partner may be requested to sign a separate informed consent form prior to collection of data about the outcome of the pregnancy for scientific or security reasons.

Men: If your partner becomes pregnant, she may be requested to sign a separate informed consent form for the collection of data about the pregnancy and the outcome of the pregnancy.

Birth Control: Birth control methods considered acceptable for this study include:

- Sexual abstinence (avoid sex), is acceptable as a form of contraception if this is in line with your usual lifestyle. Other approaches to abstinence are not acceptable).
- Condom
- Adding spermicide (a contraceptive substance that destroys sperm) to your diaphragm or cervical cap before it is inserted into the vagina prior to intercourse to prevent pregnancy.
- Birth control pills or birth control skin patch.
- Birth control implants inserted into the uterus such as Intrauterine devices (IUD) or Intrauterine hormone-releasing system (IUS).

It is important that you tell the study doctor immediately if you or your partner becomes pregnant during the study. The study doctor will talk with you about what you should do.

What are the possible benefits of taking part in the 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 study vaccine, and this may benefit others in the future.

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

There are many potential treatments for COVID-19 being studied currently, and there may be new treatments becoming available while you are on the study. If you become ill and you test positive for SARS-CoV-2 infection, then your study doctor will discuss treatment options with you if you have or exhibit symptoms of COVID-19 prior to joining or during the study.

Will you be informed if you have a positive SARS-CoV-2 test from study-collected samples?
Yes, this result will be available as early as 24 to 48 hours. This study is using the Public Health England (PHE) test kits and laboratories. PHE will provide you with your test results and instructions.

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

Who can you contact with further questions?
You may ask questions about this consent form or the study at any time (before or during the course of the study). If you have additional questions or experience a research-related injury, contact the study doctor using the details provided in the table on the first page of this information sheet.

For any questions about your rights as a research participant, please direct enquiries to:
Patient Advice and Liaison Service (PALS) on **tel: 01539 716621** or email pals@mbht.nhs.uk

A description of this clinical study will be available on https://www.clinicaltrialsregister.eu/, as required by EU regulations. 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.

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. If you decide to leave the study before the last study visit, tell the study doctor and follow their instructions. It may be helpful if you could explain your reasons. You

may receive standard treatment, and no prejudice will be shown toward you regarding medical care or participation in future research.

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

- If receiving the study vaccine would be harmful to you.
- If you experience a serious reaction or unacceptable side effects.
- If you do not follow the study rules or it is discovered that you do not meet the study requirements for taking part in the study.
- If the study is cancelled because of decisions made in the commercial interests of the Sponsor or by local government agencies/health authorities.
- If you become pregnant.

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

Are there any costs if you decide to participate?
You will not receive payment for participating in this study, but the study drugs will be made available to you at no charge and you will not be required to pay for any study procedures. You may be reimbursed for any reasonable travel expenses (bus/train/taxi fares) incurred as a result of taking part in this study if you provide a receipt.

Who is funding this research?
Novavax, Inc. (a pharmaceutical company) will be organising and funding this study. Novavax, Inc. will pay your study site to cover their costs of conducting this study. If applicable, your study doctor will disclose to you any financial links or other interests that he/she may have to the Sponsor.

What if there is a problem?
Complaints
If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions on **Tel: 01524 512134**. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. We recommend that you obtain a copy of your hospitals complaints procedure or policy if you intend to make a complaint.

Harm
Novavax, Inc. will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI).

Novavax, Inc. will pay compensation where the injury probably resulted from:
- A drug being tested or administered as part of the trial protocol
- Any test or procedure you received as part of the trial

Any payment would be without legal commitment. (Please ask if you wish more information on this)

Novavax, Inc. would not be bound by these guidelines to pay compensation where:

- The injury resulted from a drug or procedure outside the trial protocol
- The protocol was not followed.

Copies of these guidelines are available from your study doctor on request.

How will your confidentiality be respected and the privacy of your personal information maintained?

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

- Study monitors and auditors, who may work for Novavax or its authorised agents, who check that the study is being performed correctly and that the information collected about you is accurate;
- Ethical committee that approved this study and ensures that your rights and well-being are safeguarded;
- National and international regulatory authorities involved in keeping research safe for participants;
- Clinical trial recruitment company if you were referred to the study by such a company, for analytical purposes and so they may be compensated.

To ensure privacy, your name and other directly identifying information will not be attached to records or samples released to Novavax and its service providers for research purposes. Instead, you will only be identified by a code. Only the study doctor and authorised personnel will be able to connect this code to your name, by a list that will be kept securely by the study site for 15 years. Your date of birth may also be recorded to help identify your study record. Your coded data will be forwarded to Novavax and its service providers for activities related to the study e.g. laboratory analysis. A list of companies to whom your coded information is transferred is available from Novavax via your study doctor.

Under the Data Protection Act 2018, the Novavax, Inc. makes important decisions on how your information collected for the research project are used and disclosed and is responsible as 'controller' for ensuring that the rules of this law are followed. **Novavax has appointed PPD Global Ltd as its 'representative' to fulfil its obligations under this law.** The study site will have similar responsibility in respect to the handling of data in your medical files at site.

To the extent there is no conflict with the purpose of the study, you have the right to access, through your study doctor, all the information collected about you and, if applicable, ask for corrections. You may have the additional rights to object to how your information is being handled, request deletion of your data, restrict aspects of the processing of your information or ask for a copy of your data to be provided to you, or a third party, in a digital format. Note however, in order to

protect the scientific integrity of the study, the treatment you receive in this study needs to remain unknown (= blinded) until the study data is analysed.

You also have the right to complain about how your information is handled to a supervisory authority that is responsible for enforcing data protection law. In the UK, this is the Office of the Information Commissioner.

Recipients of your information may be in countries that do not provide the same standard of legal protection for your information as in the United Kingdom, raising the risk that you will not be able to enforce the above rights and recipient organisations may not be legally required to fully secure your data. Certain international recipients of your information may have signed special contracts to provide legal protection for your transferred information (e.g. so called "Standard Data Protection Clauses"). In any event, all parties involved in the study are required to maintain your confidentiality.

Your information is collected, used and disclosed in the interest of Novavax conducting scientific research. You are asked to consent to various uses and disclosures of your information at the end of this form.

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

This study may only be performed by collecting and using personal information on study participants as described in this form, therefore you may only participate in the study if you agree to the collection and use of your information as described here.

If you have any questions, comments or complaints about how your information is handled in this study, or wish to obtain a copy of the Standard Data Protection Clauses, you should firstly contact your study doctor who will be able to direct your query where appropriate to staff responsible for data protection at the Novavax or site, including the site Data Protection Officer.

Has the study received medical or ethical approval?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by the North West - Greater Manchester Central Research Ethics Committee.

Do not sign this consent form unless you have had the chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this information sheet and consent form for your records. Thank you for taking the time to read this information.

Consent Form

Principal Investigator: Dr Andrew Higham **Participant Initials:**

Participant Number: **IRAS ID: 288793**

Short Title: A trial to evaluate SARS-CoV-2 Recombinant Nanoparticle vaccine

Statement of Consent:	**Please initial box:**
I confirm that I have read and understood the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and I am satisfied with the explanations provided.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected.	
By signing this form, I provide specific consent for the following in regards to my data: • The authorised representatives of Novavax, Inc, the NHS Trust my site resides in, the ethics committee, and regulatory authorities' inspectors may have direct access to my medical records. • Study data, including my coded medical information, may be retained and later used for further research into my medical indication, unless I object. • Study data may be transferred to other countries for study purposes, including countries not providing the same standard of legal protection for my personal information as in the European Union.	
I specifically agree to my personal information and blood samples collected during the study being sent outside the European Union as described in this information sheet	
I agree to allow my blood samples to be collected for future testing and analysis	
I understand that I will receive a copy of this signed and dated Participant Information Sheet and Informed Consent Form.	
I voluntarily agree to take part in this study.	

Consent Form- continued

Principal Investigator: Dr Andrew Higham **Participant Initials:**

Participant Number: **IRAS ID: 288793**

Short Title: A trial to evaluate SARS-CoV-2 Recombinant Nanoparticle vaccine

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Participant
Printed Name Signature Date

Witness (if applicable)
Printed Name Signature Date

- I have presented the study and answered the participant's questions.
- I will give the participant a copy of this signed and dated informed consent.

Presenter (Investigator)
Printed Name Signature Date

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.