Duke University Health System

Consent to Participate in a Research Study

A Phase I, dose-escalation study to assess the safety, reactogenicity, and immunogenicity of two doses of an adjuvanted novel pancoronavirus vaccine (Cov-RBD-scNP-001) in 18 through 55 year-old healthy participants
DMID 24-0009
Version 2.0; 17JUL2025

KEY INFORMATION SUMMARY

This is a research study to understand what happens when a person receives one of three dose levels of an investigational pancoronavirus vaccine (Cov-RBD-scNP-001) designed to fight multiple different coronaviruses including the virus that causes COVID-19. This study will help us learn how the body responds to the dose of vaccine received. Participation in this research is voluntary. To do this research, 17 participants will be enrolled into each group to receive either a low dose (50 microgram [mcg]), medium dose (100 mcg), or high dose (150 mcg) of the investigational vaccine. Dosing will start at the 50 mcg dose level and only increase to the next level if no concerning side effects are found. All study vaccines will be administered in the upper arm. We will draw blood (varying from 1 tablespoon to about 5 tablespoons at select study visits) from the arm to monitor the safety of the vaccine and to measure the levels of protection in the body against multiple coronaviruses that are present both before and after receiving the vaccine. We will also obtain samples from the nose using a filter paper to test for levels of antibody against multiple coronaviruses. If you develop a COVID-19-like illness, we will collect a nasal swab to test for the presence of the SARS-CoV-2 virus.

Blood and nasal samples will be stored for future research to further the understanding of coronavirus infection. Providing these samples is required for participation in this study. If you do not want to provide these samples, you should not agree to participate in this study. No genetic testing will be performed on samples collected during this study.

Participation in this study will last approximately 14 months, including a screening visit to determine eligibility, two vaccination visits and nine follow up research clinic visits.

The risks involved in participating in this study are described in detail below. Some of the more common risks to receiving Cov-RBD-scNP-001 are similar to other vaccines and include fatigue, headache, muscle and joint pain, chills, nausea,

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vomiting, diarrhea, along with redness, swelling, and pain at the injection site. Risks associated with COVID-19 vaccines that are also possible in this study include myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart). These events are rare and have occurred particularly in adolescents and young adult males after the second dose of COVID-19 mRNA vaccine. Risks associated with blood draws include discomfort, bruising and fainting. Nasal sampling can cause mild discomfort, a gag reflex, bleeding from the nose, and watery eyes.

If you are interested in learning more about this study, please continue reading below.

Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below and will be reviewed with you by the study team.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Emmanuel "Chip" Walter will conduct the study. The study is funded by the National Institute of Allergy and Infectious Diseases (NIAID), which is part of the National Institutes of Health (NIH). NIAID will pay Duke University to perform this research. These funds may reimburse part of Dr. Walter's salary.

Who will be my doctor on this study?
If you decide to participate, Dr. Emmanuel "Chip" Walter will be your doctor for the study. He will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

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Why is this study being done?

The purpose of this study is to explore the safety of and your body's response to an investigational pancoronavirus vaccine. This pancoronavirus vaccine is being developed to protect against a group of coronaviruses, which includes both SARS-CoV-1 which caused the 2003 outbreak of SARS and SARS-CoV-2 which caused the COVID-19 pandemic, as well as other related coronaviruses. In some people, COVID-19 is associated with a relatively mild or moderate illness with fever, cough, and headache, but sometimes COVID-19 can be more severe, resulting in pneumonia and, in some cases, death. Although there are several approved or authorized vaccines for SARS-CoV-2, there are currently no vaccines approved to prevent diseases caused by multiple different coronaviruses. There is a need to develop improved COVID-19 vaccines that last longer and can help protect against severe disease caused by current SARS-CoV-2 variants strains and as well as other SARS-related viruses that may cause a future outbreak.

This investigational vaccine being tested in this study is named Cov-RBD-scNP-001. The vaccine is a protein-based vaccine made up of a small portion of the SARS-CoV-2 virus spike protein called the receptor binding domain (RBD). To make the vaccine, the RBD protein has been linked to a another protein called ferritin, which has been derived from bacteria. Linking the RBD with the ferritin creates a very small particle, called a nanoparticle, which displays multiple copies of the RBD protein on its surface. Nanoparticle (NP) vaccines are thought to create a better immune response for protection from viruses. The investigational vaccine also includes another vaccine component called an adjuvant, which increases the immune response to the protein in the vaccine to provide better protection from viruses. The investigational adjuvant in this vaccine is called 3M-052-AF. Cov-RBD-scNP-001 vaccine is given by injection into the upper arm muscle using a needle. This study will test the Cov-RBD-scNP-001 vaccine at three different dose levels (amounts of vaccine).

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The three different doses of the Cov-RBD-scNP-001 vaccine being tested include: a low dose of 50 micrograms (mcg), a medium dose of 100 mcg, and a higher dose of 150 mcg. Dosing will start at the lowest dose (50 mcg) and only increase to the next highest dose if it is determined that there are no concerning side effects. Up to 17 participants will receive each dose level. All study injections will be given into the muscle of the upper arm.

We will evaluate the level of protection and side effects that participants experience following receipt of the Cov-RBD-scNP-001 vaccine in people receiving different dose levels of the vaccine. Blood samples will be collected to measure levels of antibodies and immune cells in the blood before and after the injections, and the safety and side effects of the vaccine will be evaluated. We will also collect samples from your nose using a filter paper as well as saliva to measure the levels of antibodies in the nose and saliva in future studies. The results of these tests will not be shared with you.

Up to 100 people may be consented into this study taking place at Duke University to ensure that 51 participants are enrolled and vaccinated in the study.

What is involved in the study?
If you agree to be in this study, you will have 12 scheduled in-person study visits lasting between 30 minutes and 2 hours, and possibly more if an unscheduled visit is needed. An unscheduled visit may be needed if certain labs need to be repeated or if you become ill during your participation in this study. You will receive the vaccine at two separate in-person study visits.

Ten visits will include a blood draw, and four visits will include a nasal absorption specimen and collection of saliva. The total amount of blood drawn throughout the entire study period of one year is approximately 540 mL (2.2 cups). The amount of blood drawn at each visit will vary between 20 mL (4 teaspoons) to 75 mL (5 tablespoons). Each study visit is detailed below.

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Visit 0 - Screening Visit
The first visit will be a screening visit to help determine if you are eligible to participate. At this visit, you will be asked to sign and date this consent form. No study activities will occur until you decide that you want to participate and sign/date the form.

Once you sign/date this consent form, the following screening procedures will be done to see if you are eligible for the study.

- We will review criteria to make sure that you are eligible to participate in this study.
- We will collect your demographic information such as sex, age, ethnicity, and race.
- We will review and document your medical history and recent medications taken within the last 90 days.
- We will collect a history of any medication allergies, including a hypersensitivity to any components of the study products.
- We will ask if you are participating in another clinical trial or plan to enroll in another clinical trial during the study period.
- We will document your full COVID-19 vaccination history.
- We will obtain vital signs: oral temperature, heart rate, and blood pressure.
- We will measure your height and weight.
- You will have a physical exam.
- We will collect approximately 18.5 mL (about 4 teaspoons) of blood from a vein in your arm for screening lab tests, including blood counts and blood chemistry. This will also include tests to see if you are infected with hepatitis B, hepatitis C, or HIV, the virus that causes AIDS. Hepatitis B and C cause liver damage and liver failure.
    - You will be notified of the results of the testing, and counseled as to the meaning of the results, whether they are positive or negative. We are required to report all positive hepatitis B, hepatitis C and HIV results to the North Carolina Division of Public Health. The test results will be kept confidential to the extent permissible under the law. If the test indicates that you are infected with hepatitis B or C or HIV, you

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will receive additional counseling about the significance of your care and possible risks to other people.
    - If you do not want to be tested for hepatitis B and C or HIV, then you should not agree to participate in this study. The study doctor or study staff will provide pre-test counseling for the HIV/AIDS tests so you will have information about the risks and benefits of being tested.
    - In rare cases, an HIV test result may be 'indeterminate', which means that it is not possible to say if it is positive or negative. This can occur for several reasons and most people with indeterminate tests do not have HIV. Indeterminate tests are not notifiable conditions and this information is not reported to the local health department.
    - If the hepatitis B or C or HIV tests are positive or if other tests are outside an acceptable range, you will not be able to continue in the study. Abnormal results will be provided to you for follow-up with your provider.
- We will obtain a nasal swab to perform a test for COVID-19 infection.
- If you are a woman of childbearing potential you will have a blood pregnancy test at this visit and will be counseled to practice true abstinence or use at least one primary form of contraception from 28 days prior to receipt of the study vaccine until 60 days after receipt of the last study vaccine.
- If you are a person who could potentially father children, you will be counseled to refrain from sperm donation and abstain from sexual intercourse or use male condoms from the date of receipt of the study vaccine until 90 days after receipt of the last study vaccine.

The screening visit may take up to 2 hours. If the evaluations obtained at the screening visit confirm that you are eligible, the vaccination visit will be scheduled within 28 days of the screening visit.

Visit 1 – First Vaccination Visit

This visit will take approximately 2 hours and will include the following activities:

- We will review and confirm that you are still eligible to participate in this study.
- We will review your medical history and update if needed.

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- We will review your current medications and COVID-19 vaccination history.
- We will obtain vital signs: oral temperature, heart rate, and blood pressure.
- A physical exam will only be obtained if the study investigator thinks it is necessary, for instance, if you have a new symptom.
- The site where you will receive the vaccine will be assessed.
- Approximately 75 mL (5 tablespoons) of blood will be collected from your arm to test for blood counts, blood chemistry, and immune testing to determine your body's baseline level of protection from coronaviruses including COVID-19.
- At this visit, women of childbearing potential will have a urine pregnancy test. Those with a positive test will not be able to continue in this study. You will also be counseled to continue the method of birth control discussed at the screening visit.
- If you are a sexually active man, you will be counseled to refrain from sperm donation and abstain from sexual intercourse or use condoms from the date of receipt of the study vaccine until 90 days after receipt of the last study vaccine.
- We will obtain a nasal swab to perform a test for COVID-19 infection.
- We will obtain a nasal absorption sample by placing a small synthetic filter paper material into both sides of your nasal passage.
- We will obtain additional nasal swab/s and a saliva sample to test for your body's response to coronaviruses.
- Depending on what dose level the study is evaluating at time of vaccination visit, you will receive either the low dose (50 mcg), medium dose (100 mcg), or high dose (150 mcg) into the muscle of your upper arm. You will need to stay at the study clinic for at least 30 minutes after your injection to be watched for study injection reactions. Study staff will look at your arm and the site of the shot before you leave.
- A study staff member will give you a paper memory aid, a ruler and thermometer, and will show you how to use them for the study. You will be asked to write down your temperature and any symptoms that you experience every day, starting the evening of the study vaccination, and continuing for the next 7 days. You should also write down any drugs or medicines you take during this time, even over-the-counter medicines such

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as Tylenol®. You should contact the study staff if you have any severe reactions in the week after the study injection. These reactions are described later in this form.

Follow up visits will take approximately 30 minutes and will consist of:

Clinic Visit 2 (Day 4 +/- 1 days)

- We will review your COVID-19 vaccination history, medications, any new or worsening medical problems, and the Memory Aid diary with you.
- The site where you received the vaccine will be assessed.
- Study staff will obtain vital signs.
- A physical exam may be performed.
- Persons of reproductive potential will receive abstinence and contraception counseling.

Clinic Visit 3 (Day 8 +/- 2 days)

- We will review your COVID-19 vaccination history, medications, any new or worsening medical problems and the Memory Aid diary with you.
- The site where you received the vaccine will be assessed.
- Study staff will obtain vital signs.
- A physical exam may be performed.
- Approximately 30 mL (2 tablespoons) of blood will be taken from your arm for safety and to determine the response in your body from coronaviruses including COVID-19.
- Persons of reproductive potential will receive abstinence and contraception counseling.

Clinic Visit 4 (Day 15 +/- 2 days)

- We will review your COVID-19 vaccination history, medications, and any new or worsening medical problems with you.
- Study staff will obtain vital signs.
- A physical exam may be performed.
- Study staff will obtain a nasal absorption, nasal swab, and saliva samples.
- Approximately 60 mL (4 tablespoons) of blood will be taken from your arm to determine your body's response to coronaviruses including COVID-19.

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- Persons of reproductive potential will receive abstinence and contraception counseling.

Clinic Visit 5 (Day 29 +/- 3 days)

- We will review and confirm that you are still eligibile to receive they study vaccination.
- We will review your COVID-19 vaccination history, medications, and any new or worsening medical problems with you.
- Study staff will obtain vital signs.
- The site where you will receive the second dose of vaccine will be assessed.
- A physical exam may be performed.
- We will obtain a nasal swab to perform a test for COVID-19 infection.
- Study staff will obtain a nasal absorption and saliva samples.
- Approximately 75 mL (5 tablespoons) of blood will be taken from your arm for safety and to determine the response in your body from coronaviruses including COVID-19.
- At this visit, women of childbearing potential will have a urine pregnancy test. Those with a positive test will not be able to receive additional vaccination in this study.
- Persons of reproductive potential will receive abstinence and contraception counseling.
- Depending on what dose level you received at Visit 1, you will receive the second dose at the same level of either the low dose (50 mcg), medium dose (100 mcg), or high dose (150 mcg) into the muscle of your upper arm. You will need to stay at the study clinic for at least 30 minutes after your injection to be watched for study injection reactions. Study staff will look at your arm and the site of the shot before you leave.
- A study staff member will give you a paper memory aid, a ruler and thermometer. You will be asked to write down your temperature and any symptoms that you experience every day, starting the evening of the study vaccination, and continuing for the next 7 days. You should also write down any drugs or medicines you take during this time, even over-the-counter medicines such as Tylenol®. You should contact the study staff if you have

any severe reactions in the week after the study injection. These reactions are described later in this form.

Clinic Visit 6 (Day 32 +/- 1 day)

- We will review your COVID-19 vaccination history, medications, and any new or worsening medical problems with you.
- The site where you received the vaccine will be assessed.
- Study staff will obtain vital signs.
- A physical exam may be performed.
- Persons of reproductive potential will receive abstinence and contraception counseling.

Clinic Visit 7 (Day 36 +/- 2 days)

- We will review your COVID-19 vaccination history, medications, and any new or worsening medical problems with you.
- The site where you received the vaccine will be assessed.
- Study staff will obtain vital signs.
- A physical exam may be performed.
- Approximately 30 mL (2 tablespoons) of blood will be taken from your arm for safety and to determine the response in your body from coronaviruses including COVID-19.
- Persons of reproductive potential will receive abstinence and contraception counseling.

Clinic Visit 8 (Day 43 +/- 2 days)

- We will review your COVID-19 vaccination history, medications, and any new or worsening medical problems with you.
- Study staff will obtain vital signs.
- A physical exam may be performed.
- Approximately 60 mL (4 tablespoons) of blood will be taken from your arm to determine the response in your body from coronaviruses including COVID-19.
- Persons of reproductive potential will receive abstinence and contraception counseling.

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Clinic Visit 9 (Day 57 +/- 3 days)

- We will review your COVID-19 vaccination history, medications, and any new or worsening medical problems with you.
- Study staff will obtain vital signs.
- A physical exam may be performed.
- Study staff will obtain a nasal absorption and saliva samples.
- Approximately 75 mL (5 tablespoons) of blood will be taken from your arm for safety and to determine the response in your body from coronaviruses including COVID-19.
- Persons of reproductive potential will receive abstinence and contraception counseling.

Clinic Visit 10 (Day 209 +/- 14 days)

- We will review your COVID-19 vaccination history, medications, and any new or worsening medical problems with you.
- A physical exam may be performed.
- Approximately 65 mL (4 tablespoons) of blood will be taken from your arm to determine the level of protection in your body from coronaviruses including COVID-19.

Clinic Visit 11 (Day 394 +/- 14 days)

- We will review your COVID-19 vaccination history, medications, and any new or worsening medical problems with you.
- A physical exam may be performed.
- Approximately 60 mL (4 tablespoons) of blood will be taken from your arm to determine the response in your body from coronaviruses including COVID-19.

Unscheduled/Illness Visit

You may be asked to come back to the study clinic at other times if needed to review your health. This visit may be conducted by phone or telehealth if an in-person visit is not possible. Study personnel will determine what activities will be

needed after reviewing any symptoms that you are having. This visit may consist of:

- Reviewing COVID-19 vaccination history, medications, and any new or worsening medical problems
- Collecting vital signs: oral temperature, heart rate and blood pressure
- A physical exam
- Collecting a nasal swab to test for COVID-19.
- Obtaining blood for safety and immune testing

Early Withdrawal Visit

If you stop taking part in this study for any reason, you may be asked to return to the study center for a final visit. You will be asked about any reactions, illnesses, or any new or worsening medical problems you may have had since your last clinic visit. You also may be asked about any medications you may have taken or if you received a COVID-19 vaccine since your last study clinic visit. A brief physical examination may be done and blood samples may be taken along with vital signs. Persons of reproductive potential may receive abstinence and contraception counseling.

Blood and nasal sample storage for future use

As part of this study, we are obtaining blood and nasal samples from you for this study and extra samples for the Duke Human Vaccine Institute repository (a place that stores samples). At the time of screening, eligible participants will be required to sign a separate consent form for the separate biorepository protocol, for the storage and use of extra nasal samples as well as leftover blood samples and associated data (information) in future research. If you do not want your leftover samples to be used for future research, you should not agree to participate in this study.

Secondary research is research that is not part of this study but will be performed in the future. You will not be told about the secondary research or any results. Types of research include new or different immunological laboratory tests to provide information for the development of new vaccines, or to better understand SARS-CoV-2 virus or other coronavirus infections. No genetic testing, including

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DNA testing, will occur. The tests we might want to use to study your blood and nasal samples may not even exist at this time.

After enrollment, you may withdraw your consent for the collection and storage of samples for secondary research at any time by providing written notice to the investigator or study staff. If you withdraw consent, no "extra samples" will be collected. Samples collected and to be analyzed for this vaccine study may not be destroyed. However, samples collected or stored for secondary research may be destroyed after the vaccine study is completed. Samples released for secondary research before you withdrew consent may not be able to be destroyed.

The samples will not be sold or used directly for production of any commercial product. However, the research studies in the future could indirectly lead to a commercial product that protects against viral infection or disease. Although the results of any future research may be patentable or have commercial profit, you will not receive payment if this happens.

Will I be given research results that may affect my medical care?
Results of this research that could affect your health will be communicated with you as the study team receives these results. A member of the study team will contact you by telephone with the results.

How long will i be in this study?
Your participation in this study will last up to approximately 394 days (13 months), not including the screening period that will take place up to 28 days prior to Visit 1.

You can stop participating at any time without penalty. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

What are the risks of the study?
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

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Study risk is minimized by slowly increasing the dose being tested and by first testing each dose of vaccine in just four participants and pausing before enrolling the remaining participants receiving that dose.

This investigational pancoronavirus vaccine, Cov-RBD-scNP-001, has never been tested in humans. There may be risks that we do not know about, which include your health getting worse or even death.

Cov-RBD-scNP-001 and Risks: may cause some, all, or none of the side effects listed below.

More likely

- Pain at the site of injection
- Tenderness at the site of injection
- Swelling at the site of injection
- Hardness at the site of injection
- Redness at the site of injection
- Swelling of the lymph nodes on the same arm of the injection
- Difficulty moving your arm where you received the injection
- Fatigue
- Headache
- Muscle pain
- Joint pain
- Chills
- Nausea
- Vomiting
- Diarrhea
- Fever
- Feeling unwell
- Dizziness

Less likely

- Difficulty breathing
- Facial and throat swelling

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- Rapid or irregular heartbeat
- Body rash
- Dizziness
- Weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received COVID-19 vaccines. These events have occurred particularly in adolescents and young adults after the second dose.

In a population-based cohort study the incidence of acute myocarditis was noted to be almost 6 per 1 million individuals after the second dose. Myocarditis reporting rates after second doses of mRNA COVID-19 vaccines range from less than 1 to as many as 106 cases per million individuals vaccinated with the largest number of cases reported in males 16-17 years of age. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is low. Symptoms include:

- Chest pain
- Shortness of breath
- Palpitations (fast beating or fluttering heart)

If you have any symptoms of myocarditis and/or pericarditis during this study, you should seek immediate medical attention and also notify study site staff if any of these symptoms occur following vaccination. Contact Dr. Walter at (919) 620-5346 during regular business hours and at (919) 970-5720 after hours and on weekends and holidays. A member of the study team may also be contacted at (919) 971-5649.

Because this vaccine includes an iron carrying ferritin protein from the *H. pylori* bacteriium, it is theoretically possible that your body could respond by making antibodies against human ferritin. Anti-ferritin antibodies have not been observed in animals receiving *H. pylori* ferritin. Study participants will be closely monitored via blood draws for levels of iron, ferritin, and anti-ferritin antibodies.

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There may be other possible unknown side effects of Cov-RBD-scNP-001 vaccines. Serious and unexpected side effects may also occur. Should a severe allergic reaction occur immediately following vaccination, medications to treat such a reaction will be immediately available for administration according to standard guidelines at the study site.

Risks associated with 3M-052-AF
Risks of receiving a vaccine with the investigational adjuvant 3M-052-AF may include headache, feeling unwell or tired, body aches, and/or chills.

If I Catch COVID-19, Could the Antibodies Produced Following Vaccination Make It Worse?
For other vaccines tested in animals against similar viruses, there have been reports of the illness being more severe in the animals that received the product than in those animals that did not. This has not been reported with current COVID-19 vaccines and data from animals receiving Cov-RBD-scNP-001 suggests that this will not happen with this vaccine. However, it remains important for you to contact your the study team if you develop symptoms that might be caused by COVID-19 (for example, fever, tiredness, shortness of breath).

Reproductive risks and Contraception:
Pregnancy can affect the body's response to vaccines. In addition, the effects of Cov-RBD-scNP-001 on a pregnant woman, developing pregnancy, or breastfeeding infant are not known, and it may be present in semen and transmitted to a partner during sexual activity. For these reasons, women who are pregnant, planning to become pregnant or father a child, or breastfeeding are not allowed to participate in this study. Pregnancy testing and contraception requirements for people able to become pregnant or father a child are described in detail above.

If you or your partner should become pregnant while you are in this study, you should report this immediately to the study staff. With your permission and additional consent from the pregnant person, the study doctor or study staff will ask about your health and the outcome of the pregnancy. The study doctor may share this information with the sponsor and the Institutional Review Board (IRB), a

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group of people who review research studies to protect the rights and welfare of research participants. If additional consent is not provided by your pregnant partner, the pregnancy outcome and date of delivery may be requested from you.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

Risks related to Nasal Absorption, Nasal Swab, or Saliva Sampling:
Obtaining a nasal absorption, nasal swab, or saliva sample can cause discomfort in the nostrils, a nosebleed, tickling in the throat, coughing, sneezing, or watery eyes at the time of collection.

Risks of Drawing Blood:
The risks of drawing blood include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Are there benefits to taking part in the study?
If you agree to take part in this study, no direct medical benefit is expected. As this is a first-in-person trial, it is unknown whether the study product, Cov-RBD-scNP-001, will help to protect participants from coronaviruses including COVID-19 disease or, if it does, how long that protection may last.

We hope that in the future the information learned from this study will benefit other people.

Will my information be kept confidential?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

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DMID 24-0009
Version 2.0; 17JUL2025

As part of the study, results of any study-related tests or procedures may be shared with NIAID and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include:

- Representatives from the Food and Drug Administration,
- Representatives and affiliates of NIAID,
- The Duke University Health System Institutional Review Board (IRB),
- and others as appropriate

If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you may be asked to have certain tests and/or procedures performed. Some of these tests and/or procedures may be been done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. Your information may be shared with representatives from the FDA, representatives and affiliates of NIAID, the Duke University Health System IRB, and others as appropriate.

Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time, either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record (e.g., signed consent form, results of clinical lab tests) will be kept indefinitely.

If you choose to be in this study, data collected from you that can be used for future research will be stored long-term in a repository following the completion of the study. Any personal information that could identify you will be removed or changed before files are stored in this repository for use by other researchers or results are made public. The removal of this information allows your data to be

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used without anyone knowing which person in the study it comes from. As an additional layer of protection, the repository where the data will be stored requires researchers to formally apply to use the data and obtain approval prior to gaining access.

This information may be further disclosed by the sponsor of this study or to outside reviewers for audit purposes. If disclosed by the sponsor or outside reviewers, the information is no longer covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain confidential. If you decide to share your information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

The National Institutes of Health (NIH) has issued a Certificate of Confidentiality (CoC) for this study. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings, like a court order.

There are some important things that you need to know about the CoC:

> It DOES NOT stop reporting required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

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It CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs, including when the Food and Drug Administration (FDA) requires it.

It DOES NOT prevent your information from being used for other research if allowed by federal law.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other people not connected with the study. The CoC does not stop you from willingly releasing information about your involvement in this study. It also does not prevent you from having access to your own information.

Will it cost me anything to be in the study?
There are no additional costs to you for participating in this study. You and your insurance company will not be billed for your participation.

Will I be paid to be in the study?
You will receive up to $1300 for your expenses related to your participation (parking, gas, and time). You will receive $100 for the screening visit, $150 for the vaccination visits, and $100 for each of the follow up in-person visits. You will also receive $70 per visit if additional visits are needed. You will only be paid for the visits you complete. In order to issue your payment, Duke University may need to collect your name, mailing address, and social security number for tax reporting purposes. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.

Payment received as compensation for participation in research is considered taxable income to the research participant. Research participant payments to a non-employee of Duke University adding up to $600 or more during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the Internal Revenue Service (IRS).

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What about research related injuries?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. In addition, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the Federal government.

A Declaration under the Public Readiness and Emergency Preparedness (PREP) Act was issued by the Secretary of the United States Department of Health and Human Services on March 10, 2020. This Declaration limits the legal rights of a subject participating in clinical studies utilizing COVID-19 countermeasures used in this study. Because this study is covered by the Prep Act Declaration, covered persons, such as the manufacturers, study sponsor, researchers, healthcare providers and others have liability immunity (that is, they cannot be sued by you or your family under the laws of the United States).

If you believe that you may have been harmed as a result of this research study, certain claims for serious injury or death caused by the countermeasure may be eligible for compensation through the Countermeasures Injury Compensation Program. This is a program set up by the United States Government. Information about this program can be found at https://www.hrsa.gov/cicp/about/index.html or by calling 1-855-266-2427. If you are eligible for this program, you must file a claim within one year of the administration or use of the covered countermeasure.

For questions about the study or research-related injury, contact Dr. Walter at (919) 620-5346 during regular business hours and at (919) 970-5720 after hours and on weekends and holidays.

What if I want to withdraw from the study?
If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the

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study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Walter in writing and let him know that you are withdrawing from the study.

His mailing address is:
Emmanuel Walter MD, MPH
DVTU-RTP
Duke University
PO BOX 106008
Durham, NC 27710

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include:

- You are unable or unwilling to follow the instructions of the study;
- Participant becomes pregnant prior to study product dosing;
- The study doctor decides that the study is not in your best interest or that you are no longer eligible to be in the study; or
- The study is stopped by the study sponsor, an institutional review board (IRB), or by a government or regulatory agency.

If this occurs, you will be notified and your study doctor will discuss other options with you.

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We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

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

Whom should i call if I have questions or problems?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Walter at (919) 620-5346 during regular business hours and at (919) 970-5720 after hours and on weekends and holidays. A member of the study team may also be contacted at (919) 971-5649.

You can call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have question about your rights as a research participant
- You wish to discuss problems related to the research
- You have any concerns or suggestions related to the research
- Want to obtain information or offer input about the research

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____ _____
Signature of Subject Date Time

_____ _____
Signature of Person Obtaining Consent Date Time