INFORMED CONSENT FORM
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION
for Main Cohort,
Immediate Vaccination and Standard of Care Groups

Sponsor / Study Title:	**National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (DHHS) / "A randomized controlled study to assess SARS CoV-2 infection, viral shedding, and subsequent potential transmission in individuals immunized with Moderna COVID-19 Vaccine"**
Protocol Number:	**CoVPN 3006**
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Thank you for your interest in our research study. It is called CoVPN 3006. This informed consent form will tell you more about the study. Please read it carefully as you decide if you want to join. If you have questions, please ask us. At the end, we will ask you to answer a few questions to make sure you understand the study.

If you decide to join this study, we will ask you to sign and date this form. We will offer you a copy of this form to keep.

CoVPN 3006 is a research study. Research is not the same as medical care. The purpose of a research study is to answer scientific questions. We hope that what we learn will help people in the future.

Key information

- Joining this research study is voluntary. It is your choice.
- Our scientific questions are: Does the vaccine protect people from getting infected with a coronavirus called SARS-CoV-2? Does the vaccine prevent people from transmitting SARS-CoV-2 to others?
- If you join, your participation in this study will last for about 5 months.
- If you join, we will ask you to answer questionnaires, get injections, give blood, and take daily swabs of your nose.

Here are the risks of taking part:

- The most common risk is symptoms such as muscle aches or headaches after getting the injection.
- There is a risk of loss of your personal information.
- There are other, less serious risks. We will tell you more about them later in this consent form.

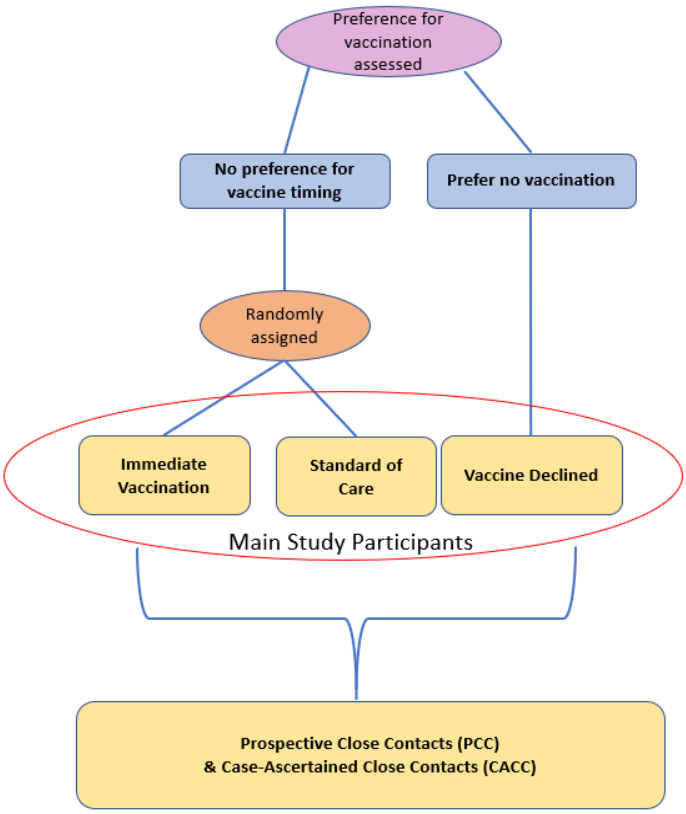
About the study

The COVID-19 Prevention Network (CoVPN) is doing a study to test a vaccine against SARS-CoV-2. SARS-CoV-2 is the virus that causes the disease called COVID-19. We want to know if the vaccine is able to protect people from getting infected and if getting the vaccine will affect the amount of virus that is in your nose. We also want to know if getting the vaccine will prevent transmitting SARS-CoV-2 to others.

Many young adults will take part in this study around the US. This study has 5 groups. The first 3 groups, called the Immediate Vaccination, Standard of Care, and Vaccine Declined groups, will be in the Main Study.

- The Immediate Vaccination and Standard of Care groups will have about 12,000 people that will get vaccine injections either immediately or 4 months later. In this study, “standard of care” refers to all federal, state, and local recommendations regarding COVID-19 prevention, including COVID-19 vaccination, masking, social distancing, isolation and quarantine.
- The Vaccine Declined group will have about 6,000 people who prefer not to be vaccinated and will be followed for 4 months.
- The last two groups are close contacts of the Main Study: the Prospective Close Contact (PCC) group will have up to 36,000 people, and the Case-ascertained Close Contact (CACC) group will have up to 2250 people. These close contact groups will help

researchers determine if the vaccine prevents transmission of the SARS-CoV-2 virus to others. We will explain more about this later in this form.



You have indicated that you are agreeable to getting vaccinated for COVID-19 as recommended by the Centers for Disease Control and Prevention (CDC) and have no preference as to the timing of vaccination.

The researcher in charge of this study at this clinic is called the study doctor. The US National Institutes of Health is paying for this study (Sponsor).

1. This study's vaccine has an Emergency Use Authorization (EUA) for individuals 18 and older.

The vaccine we will use in this study is called the Moderna COVID-19 Vaccine. The vaccine has been given to over 15,000 people in other research studies and over 100 million people under EUA. We will give you the most up-to-date "Fact Sheet for Recipients and Caregivers" with more information about the Moderna COVID-19 Vaccine. The person giving you the vaccine can answer any questions you might have about what is in this fact sheet.

We already know that the vaccine can prevent serious COVID-19 disease, but we do not know if the vaccine will work to prevent SARS-CoV-2 infection in others. That is what we are testing in this study.

The Moderna COVID-19 Vaccine is not approved for sale in the United States by the US Food and Drug Administration (FDA).

Although the vaccine is not approved, it has an Emergency Use Authorization (EUA) from the FDA based on its success at preventing disease symptoms from SARS-CoV-2 in other studies to date. During a public health emergency, like the COVID-19 pandemic, the FDA can issue an EUA to get vaccines to people faster. When the FDA issues an EUA, they continue to monitor safety.

The vaccine was developed by ModernaTX, Inc. Typical vaccines for viruses are made from a weakened or killed virus, but the Moderna COVID-19 Vaccine is not made from the SARS-CoV-2 virus. The vaccine includes a short segment of messenger ribonucleic acid (mRNA). The mRNA is a genetic code that tells cells how to make a protein. This mRNA is made in a laboratory. When injected into the body, the mRNA vaccine causes some cells to make that viral protein, which can trigger the immune system. Your immune system protects you from disease. If a person is later infected, their immune system remembers the protein from the vaccine which may help it to fight the virus. It is impossible for the vaccine to give you SARS-CoV-2 or COVID-19 infection.

Risks of the Moderna COVID-19 Vaccine:

To date, more than 100 million people have already received the Moderna COVID-19 Vaccine. In clinical trials, most people who got the vaccine had some reaction after their injections, especially after the second injection. Most of these people said they had pain in the arm where they got the injection. These people also felt tired, had headaches, muscle and joint pain, and chills. A much smaller number of these people said they had redness or swelling where the needle went in their arm. Some people had swelling of the lymph nodes in the same arm of the injection.

The risks of the study vaccine seen so far are the same as what have been seen with most vaccines. Generally, vaccines can cause:

- Fever
- Chills
- Rash
- Aches and pains
- Nausea
- Headache
- Dizziness
- Feeling tired

Vaccines can also cause pain, redness, swelling, or itching where you got the injection. Most people can still do their planned activities after getting a vaccine. Rarely, people have side effects that limit their normal activities or make them go to the doctor.

Rarely, a vaccine can cause you to have an allergic reaction. You might have a rash, hives, swelling of your face and throat, a fast heartbeat, dizziness and weakness, or trouble breathing. Allergic reactions can be life-threatening. Tell us if you have ever had a bad reaction to any injection or vaccine.

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) have occurred in some people who got mRNA COVID-19 vaccines like the Moderna COVID-19 vaccine. They have been more common in young adults than in older people. In most of these people, symptoms began within a few days after the second dose of the vaccine. Almost all people have responded well to medications and rest, and their symptoms improved quickly. The chance of having this inflammation occur is very low.

You should seek medical attention right away if you have any of the following symptoms after getting the Moderna COVID-19 vaccine:

- Chest pain
- Shortness of breath
- Having a fast-beating, fluttering, or pounding heart.

There may be other risks that we don't yet know about, even serious ones. We will tell you if we learn about any new risks.

Joining the study

2. You will receive the vaccine immediately or later.

Some people will get the vaccine immediately. Other people will get the vaccine 4 months later.

We will compare the results from people who got the vaccine immediately with results from people who got the vaccine later. In this way, we will be able to tell if the vaccine can prevent SARS-CoV-2 infection.

You have a 50/50 chance of getting the vaccine immediately or later. Whether you get the vaccine immediately or a little later is completely random, like flipping a coin.

We have no say in whether you get the vaccine immediately or later.

3. It is completely up to you whether or not to join this study.

Take your time in deciding. If it helps, talk to people you trust, such as your personal doctor, friends, or family. If you decide not to join this study, or if you leave it after you have joined, it will not change your healthcare. If you do join, you do not give up your legal rights.

You cannot be in this study while you are in another study where you get a study product.

If you choose not to join this study, you may be able to join another study.

If you have a preference to be vaccinated immediately, you have the option to not join the study and instead receive vaccination outside of the study right away.

If you have a preference to not be vaccinated at all, you have the option to join the "Vaccine Declined" observational group.

If you are an employee or relative of an employee of the study site, you are under no obligation to participate in this study. You may withdraw from the study at any time and for any reason, and your decision will not have any effect on your/your family member's performance appraisal or employment at the study site. You may refuse to participate or you may withdraw from the study at any time without penalty or anyone blaming you.

If you are a student, your participation will not place you in good favor with the study doctor or other faculty (for example, receiving better grades, recommendations, employment). Also, not participating in this study will not adversely affect your relationship with the study doctor or other faculty.

4. If you want to join this study, after you sign and date this consent, you will download an electronic diary (eDiary) app and take questionnaires in it.

We will send you information about how to download the eDiary app onto your phone or tablet. We can help you download the app and show you how to use it.

To find out if you are eligible to join the study, you will answer questionnaires in the eDiary. Some of the questions will ask about your health history, what medications you take, your age, race, and ethnicity, and where you live. Your answers will tell us about some aspects of your health and if you may be eligible to join the study. It should only take about 10 minutes to complete the questionnaires.

Your answers to the questions may show you are not eligible to join the study, even if you want to. We might contact you to ask some more questions to further evaluate whether you can join the study.

In order to use the app you will be asked to agree to the Terms of Use and Privacy Policy which will appear on your mobile device's screen when you first start using the app. If you decide that you do not want to agree, then you should not participate in the research. While using the app, data about you including personal health information, other communication data, and internet usage will be collected and transmitted to the researchers and to the app developer. A complete description of this data collection and sharing is found in the Privacy Policy. Transmission of information via the internet is not completely secure, so there is a small risk of unintentional release of your information and safeguards are in place to protect your personal information. While the Terms of Use may include statements limiting your rights if you are harmed in this study, you do not release the investigator, sponsor, institution, or agents from responsibility for mistakes, and these statements do not apply to the use of the app in this research study.

Being in the study

If you want to join and you are eligible, here is what will happen:

You will be in the study about 5 months.

Visits can be done in-person or remotely depending on the type of procedures that need to be done. Visits where you get injections must be done in person. Remote visits will be done whenever possible to reduce potential SARS-CoV-2 exposure.

You may have to come to the clinic if you have a lab or health issue.

At your first visit, we will give you nasal swab kits and instructions so that you can take daily swabs of your nose. Once you receive your first kit, and for four months of the study, you will swab your nose every day, and you will be prompted by text or email to scan the barcode on the swab. In all, you will swab both of your nostrils every day for about 4 months. You can ask us questions if you need help. You will return your swabs using drop-off location(s) specified by the clinic or by mail.

If you are in the immediate vaccination group, we will take blood samples in the clinic at your first injection visit and 2 more times, two months and four months later. When we take blood, the amount will depend on the lab tests we need to do. Each time we take your blood, the total amount we will take will not be more than two tablespoons (30 mL). If for some reason you cannot come to the clinic, you may be asked to self-collect blood using a small device called the Tasso-SST OnDemand. Each time you collect your own blood, the amount will be less than one teaspoon (1 mL). We will give you everything you need to take the blood and return it to us. We will be looking at how your body responds to the vaccine and if you been exposed to the SARS-CoV-2 virus.

If you are in the Standard of Care group (the later vaccination group), we will take blood samples in the clinic at the first visit, 2 more times, two months and four months later. Each time we take your blood, the total amount we will take will not be more than one teaspoon. If for some reason

you cannot come to the clinic, you may be asked to self-collect blood using a small device called the Tasso-SST OnDemand. Each time you collect your own blood, the amount will be less than one teaspoon. We will give you everything you need to take the blood and return it to us. We will be looking to see if you been exposed to the SARS-CoV-2 virus.

The self-collection device called the Tasso-SST OnDemand sticks to the skin with a light adhesive. When the button is pressed, a vacuum forms and the device will prick the surface of the skin. The vacuum draws blood out of the capillaries and into a sample pod attached to the bottom of the device.

You will also take questionnaires in the eDiary that ask about the results of any SARS-CoV-2 tests you may have had. The questionnaires will take about 5 minutes to complete. You will also take an End of Study questionnaire in the eDiary.

5. We will give you the vaccine on a schedule.

You will be in one of 2 groups: The Immediate Vaccination group or the Standard of Care group. In the Standard of Care group, you will be offered vaccine at Month 4 and 5 if you have not received a vaccine already by then. Regardless of which group you are in, you will get 1 injection into your upper arm at 2 separate visits during the study.

We will ask you to sign up for v-safe to report any reactions to the study vaccine. V-safe is a smartphone-based tool from the Center for Disease Control (CDC) that uses text messaging and web surveys to check in with you after your COVID-19 vaccination.

Procedures for Immediate Vaccination group	**Screening visit(s)**	**First injection visit**	**1st month**	**2nd month**	**4th month**
Injection		√	√		
Medical history questionnaire	√	√			
SARS-CoV-2 testing questionnaire		About 2x per week			
eDiary app	√	About 2x per week through month 4			
Blood drawn		√		√	√
Nasal swab		Daily through month 4			

Procedures for Standard of Care group	**Screening visit(s)**	**1st Day**	**2nd month**	**First injection visit (4th month)**	**5th month**
Injection				√	√
Medical history questionnaire	√	√			
SARS-CoV-2 testing questionnaire		About 2x per week			
eDiary app	√	About 2x per week through month 4			√
Blood drawn		√	√	√	
Nasal swab		Daily through month 4			

6. We will compensate you for your participation.

You will receive $180 per visit, with a total of 4 visits, for a possible total compensation of $720. Depending on your group assignment, you will be compensated on the following schedule:

- The immediate vaccination group will have visits on Days 1, 29, 57, and 113.
- The standard of care group will have visits on Days 1, 57, 113, and 141.

You will be paid after each visit.

There will be no charge to you for your participation in this study. The study vaccine, study-related procedures, and study visits will be provided at no charge to you or your insurance company.

7. In addition to giving you the vaccine:

We will ask you to give a referral code to people with whom you expect to be in frequent close physical proximity during the study, like a roommate or co-worker. We want to ask these people to enroll in another part of this study that will help us find out if the vaccine prevents transmission of the SARS-CoV-2 virus. We may also ask you to provide us with their contact information so that we can reach out to them directly. We are calling this group the Prospective Close Contact group or PCC.

As part of their study participation, they will be asked to complete questionnaires like the ones you completed in the eDiary. If you become infected with SARS-CoV-2, we will ask you to share your status with your PCCs. Then your PCC participants will be asked to fill out additional questionnaires for 2 weeks as well as take nasal swabs and self-collect blood samples.

When considering who to ask to be your PCC, you should think about whether you feel comfortable or safe sharing your infection status with them if you get SARS-CoV-2. If you don't feel comfortable sharing this information with them, you should not ask them to participate as a PCC.

It is possible that someone you know may also be participating in the Main part of the study and might identify you as a close contact. They will not know you are also participating in the study unless you choose to tell them. If someone else identifies you as a close contact, they will give you their referral code. It is okay to be enrolled in both the Main part of the study and the PCC group.

We may also ask you for the name of someone who can tell us how you are doing if we can't reach you or if you are unable to talk. We may contact you after the main study ends (for example, to tell you about the study results).

We will ask you to continue to follow any school or employer program for SARS-CoV-2 testing and contact tracing, if applicable. If you test positive for SARS-CoV-2, based on any SARS-CoV-2 testing you receive, please tell us as soon as possible.

8. The CoVPN will test your samples to see how your body, including your immune system, responds to the Moderna COVID-19 vaccine.

We will send your samples to labs approved by the CoVPN. Your samples will not be labeled with your name or other identifying information.

Researchers may also do genetic testing related to this study on your samples. Your genes are passed to you from your birth parents. Differences in people's genes can help explain why some people get a disease while others do not. The genetic testing will only involve some of your genes, not all of your genes (your genome). The researchers will study only the genes related to the immune system and coronavirus, and genes that may affect how people get coronavirus.

If you get SARS-CoV-2, the researchers may look at all of the virus' genes that are in your samples. The researchers will use this information to learn more about SARS-CoV-2 and how the virus is impacted by the study vaccine.

The tests the researchers do on your samples are for research purposes, not to check your health. However, the nasal swab testing you do as part of this study may tell us if you are SARS-CoV-2 positive. Nasal swab test results from the study will be provided to the sites and be made available to you. You may be asked to get a confirmatory test. For all other lab tests, we will not provide the results to you or the site.

When your samples are no longer needed for this study, the CoVPN will continue to store them.

9. We will do our best to protect your private information.

We will keep your study records and samples in a secure location. We will label all of your samples and most of your records with a code number, not your name or other personal information. We will not share your name with anyone who does not need to know it.

Your records may also be reviewed by groups who watch over this study. These groups include:

- Study monitors
- The CoVPN, people who work for it, and companies that help it with this study
- Some government agencies:
    - The US National Institutes of Health
    - The US Office for Human Research Protections
    - Any regulatory agency that reviews research studies
- Some committees that make sure we protect your rights and keep you safe:
    - The Independent Data Monitoring Committee
    - Advarra Institutional Review Board (IRB)

All reviewers will take steps to keep your records private.

We cannot guarantee absolute privacy. If you are found to have a medical condition that we are required to report by law, then some of your information may be shared with local health authorities.

At this clinic, we have to report the following information:

- SARS-CoV-2
- Pneumonia
- After receiving the vaccine, we are required to report any of the following that may occur to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors
- Serious reaction after receiving the vaccine (for example that results in death, hospitalization, a life-threatening reaction, a birth defect, or other important medical event)
- A condition called "Multisystem Inflammatory Syndrome"
- Cases of COVID-19 that result in hospitalization

We have a Certificate of Confidentiality from the US government to help protect your privacy. With the certificate, we do not have to release information about you to someone who is not connected to the study, such as the courts or police. Sometimes we can't use the certificate. Since the US National Institutes of Health funds this research, we cannot withhold information from it. Also, you can still release information about yourself and your study participation to others.

The CoVPN may share information from this study with other researchers. Researchers may publish the results of this study.

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

10. We may take you out of the study at any time.

We may take you out of the study if:

- You do not follow instructions,
- We think that staying in the study might harm you,
- The study is stopped for any reason.

11. If you get COVID-19, we will ask you to do several things.

If you find out that you have COVID-19, please let us know right away. We will ask you to quarantine per local guidelines. By agreeing to join this study, you also agree to share any SARS-CoV-2 test results with us.

We will ask you to tell anyone with whom you have recently had close physical contact that they may have been exposed to COVID-19. We will give you a referral code to give to these contacts so that they can decide if they would like to join the Case Ascertained Close Contact group (CACC). We may also ask you to provide us with their contact information so that we can reach out to them directly. You may remember at the beginning of this form that we told you that about 2,250 people will be enrolled in the CACC group. The CACC group will help us learn if people who got the study vaccine are less likely to give SARS-CoV-2 to someone else. When considering who to ask to be your CACC, you should think about whether you feel comfortable

or safe sharing your infection status with them if you get SARS-CoV-2. If you don't feel comfortable sharing this information with them, you should not ask them to participate as a CACC.

It is possible that someone you know may also be participating in the Main part of the study and might identify you as a close contact. They will not know you are also participating in the study unless you choose to tell them. If someone else identifies you as a close contact, they will give you their referral code. It is okay to be enrolled in both the Main part of the study and the CACC group.

If you find out that you have COVID-19, you will be directed to contact the clinic, and we will ask you to either come to the clinic to have your blood drawn or we will ask you to self-collect less than one teaspoon of blood and complete one additional eDiary questionnaire. It is important that you give the blood sample as soon as possible after finding out the you have COVID-19. The study doctor may be required by law to report the result of these tests to the local health authority.

We will ask you to track your COVID-19 symptoms using the eDiary daily for 2 weeks or until the symptoms go away.

After you get better, we will ask you to continue your study participation so that we can monitor your health and safety for the rest of the study.

If you are hospitalized, we will pause your participation. We will ask for your medical records and results from tests you might have received at the hospital. It is unlikely that you will be hospitalized, but to prepare for this, we will ask you to sign and date a medical release of information so we can get records from your doctor or view your hospital records. When you are released from the hospital, please let us know. We will ask you to resume your study participation so that we can continue to monitor your health and safety for the rest of the study.

We will not pay for any of your COVID-19 care directly.

12. If you receive an EUA or licensed COVID-19 vaccine outside the study we will stop your on-study vaccinations but you may continue in the study.

If you receive an EUA or licensed COVID-19 vaccine outside the study, please let us know. We will ask you to tell us what vaccine you received and when you received it. You may continue to participate in follow-up visits and procedures like swabbing your nose and completing eDiary entries. Your continued participation is valuable to help us meet our study goals.

If you are in the Standard of Care group and receive COVID-19 vaccination outside the study prior to your Month 4 visit, that Month 4 visit will be your last visit and can happen remotely. At this visit, we will ask you for a final blood sample (the sample can be self-collected using Tasso-SST OnDemand) and to complete an End of Study questionnaire.

Other Risks

13. There are other risks to being in this study.

This section describes the other risks and restrictions we know about. There may also be unknown risks, even serious ones. We will tell you if we learn anything new that may affect your willingness to stay in the study.

Risks of routine medical procedures:

In this study, we will do some routine medical procedures. These are taking blood and giving injections. These procedures can cause bruising, pain, fainting, soreness, redness, swelling, itching, a sore, bleeding, and (rarely) muscle damage or infection where you got the injection.

Risks of swabbing your nose:

The feeling of having a small, soft-tipped swab inserted into your nostril and twirled around may be a little uncomfortable, but it should not be painful. There is a small chance there could be some bleeding, but this is unlikely.

Risks to your personal information:

We will take several steps to protect your personal information. Although the risk is very low, it is possible that your personal information could be given to someone who should not have it. If that happened, you could have stress or anxiety.

Risks of genetic testing:

It is unlikely, but the genetic tests done on your samples could show you may be at risk for certain diseases. If others found out, it could lead to discrimination or other problems. The results are not part of your study records and are not given to you.

In the very unlikely event that your genetic information becomes linked to your name, a federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect you. GINA keeps health insurance companies and employers from seeing results of genetic testing when deciding about giving you health insurance or offering you work. GINA does not help or protect you against discrimination by companies that sell life, disability or long-term care insurance.

Risk of anxiety/emotional stress:

You may feel anxiety or emotional stress if you experience any of the risks described here. You may feel worried if tests show that you have SARS-CoV-2. Some of the questions we will ask you may make you feel uncomfortable.

Risk of delaying COVID-19 vaccine:

COVID-19 vaccines are highly effective at preventing COVID-19 illness. The Centers for Disease Control and Prevention (CDC) recommend that you receive a COVID-19 vaccine if it is made available to you. By agreeing to potentially delay getting the vaccine, you may be at risk for serious illness if you get SARS-CoV-2 infection.

Unknown risks:

The vaccine has been shown to prevent adults from getting COVID-19 for at least 6 months after their injection, but we do not know if it will protect them for any longer. If you get COVID-19, we do not know how the vaccine might affect your illness. It is also unknown if the vaccine will prevent you from giving the virus to someone else. If you get COVID-19, we do not know how the vaccine might affect your illness.

We do not know if getting this vaccine will affect how you respond to any future SARS-CoV-2 vaccines.

We do not know if getting the vaccine will affect pregnancy or breastfeeding, and there may be unknown risks to yourself, or to your fetus or infant. If you have concerns, we recommend that you discuss this with a health care provider.

While you are in this study, you should still follow federal, state, and local guidelines for SARS-CoV-2 prevention, which may include wearing a mask and keeping physical distance from others. If you get sick, you should follow COVID-19 precautions and isolate or self-quarantine.

Benefits

14. This study may not benefit you.

COVID-19 vaccination helps protect people from getting sick or severely ill with COVID-19. This study may help researchers find out if the vaccine is able to prevent infection with SARS-CoV-2. COVID-19 vaccination is an important tool to help stop the COVID-19 pandemic. The CDC recommends you get a COVID-19 vaccine as soon as one is available to you.

If the vaccine later becomes approved and sold, there are no plans to share any money with you.

If you decide not to join this study, you could get the Moderna COVID-19 vaccine or another COVID-19 vaccine in your community. You can also continue to follow federal, state, and local guidelines for SARS-CoV-2 prevention. You do not have to join this research study if you don't want to.

Your rights and responsibilities

15. If you join the study, you have rights and responsibilities.

You have many rights that we will respect. You also have responsibilities. We list these in the Bill of Rights and Responsibilities for Research. We will give you a copy of it.

Leaving the study

16. Tell us if you decide to leave the study.

You are free to leave the study at any time and for any reason. If you want to leave, you will need to tell us. Your care at this clinic, your standing at your school, and your legal rights will not be affected.

Previously collected information about you will remain in the study records and will be included in the analysis of results. Your information can not be removed from the study records.

We may ask you to give a final blood sample or nasal swab.

We believe these steps are important to protecting your health, but it is up to you whether to complete them.

Injuries

17. If you get sick or injured during the study, contact us immediately.

Your health is important to us. We will tell you about the care that we can give here. For the care that we cannot provide, we will explain how we will help you get care elsewhere.

Nebraska Medicine and UNMC have no plans to pay for any required treatment or provide other compensation. If you have insurance, your insurance company may or may not pay the costs of medical treatment. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay for the medical treatment.e

This research study is covered by a US government program that may provide compensation for a serious injury or death. We will give you a handout with more information about this program. The National Institutes of Health (NIH) does not have a mechanism to provide direct compensation for research related injury.

Some injuries are not physical. For example, you might be harmed emotionally by being in this study. Or you might lose wages because you cannot go to work. However, there are no funds to pay for these kinds of injuries, even if they are study related.

You always have the right to use the court system if you are not satisfied.

The US Government has issued an order (the Public Readiness and Emergency Preparedness Declaration; PREP) that limits your legal rights if you are injured by the Moderna COVID-19 Vaccine in this study. You will be limited in your right to sue the maker of the drug, the sponsor of the research, and the investigators if you are injured. If you are injured you may be able to apply for benefits through the Countermeasures Injury Compensation Program (CICP). Ask the investigator if you have questions. You can also get information at https://www.hrsa.gov/cicp/about/index.html or by calling 1-855-266-2427.

In no way does signing and dating this consent form waive your legal rights nor does it relieve the investigators, Sponsor or involved institutions from their legal and professional responsibilities.

18. When samples are no longer needed for this study, the CoVPN wants to use them in other studies and share them with other researchers.

The CoVPN calls these samples "extra samples". The CoVPN will only allow your extra samples to be used in other studies if you agree to this. You will mark your decision at the end of this form.

Do I have to agree? No. You are free to say yes or no, or to change your mind after you sign and date this form. At your request, the CoVPN will destroy all extra samples that it has. Your decision will not affect your being in this study.

Where are the samples stored? Extra samples are stored in a secure central place called a repository. Your samples will be stored in the CoVPN repository in the United States.

How long will the samples be stored? There is no limit on how long your extra samples will be stored.

Will I be paid for the use of my samples? No. Researchers may make scientific discoveries or products using your samples. If this happens, there is no plan to share any money with you.

Will I benefit from allowing my samples to be used in other studies? Probably not. Results from these other studies are not given to you, this clinic, or your doctor. They may help other people in the future.

Will the CoVPN sell my samples and information? No, but the CoVPN may share your samples with other researchers. Once the CoVPN shares your samples and information, it may not be able to get them back.

What information is shared with researchers? The samples and information will be labeled with a code number which will not be removed. The key to the code will stay at this clinic. However,

some information that the CoVPN shares may be personal, such as your race, ethnicity, sex, and health information from the study.

What kind of studies might be done with my extra samples and information? The studies will be related to vaccines, the immune system, coronavirus, and other diseases. Researchers may also do genetic testing on your samples.

If you agree, researchers may compare all of your genes (your genome) to the genomes of many other people. Researchers look for common patterns of genes to help them understand diseases. The researchers may put the information into a protected database so that other researchers can access it. Your name and other personal information will not be included.

Usually, no one could connect your genome to you as a person. There are rules against this. It's also really difficult to do. But there is a risk that someone could combine information from your genome and other public information about you and identify you. If others found out, it could lead to discrimination or other problems. The risk of this happening is very small.

Who will have access to my information in studies using my extra samples? People who may see your information are:

- Researchers who use your extra samples and information for other research
- Government agencies that fund or monitor the research using your extra samples and information
- The researcher's Institutional Review Board or Ethics Committee
- Any regulatory agency that reviews research studies
- The people who work with the researcher

All of these people will do their best to protect your information. If they publish their research, they will not use your name or identify you personally.

Questions

19. Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00049375.

20. Authorization To Disclose Health Information

You have rights regarding the privacy of your medical information collected before and during this research. This medical information is called "protected health information" (PHI). PHI used in this study may include your medical record number, address, birth date, medical history, the results of physical exams, blood tests, x-rays as well as the results of other diagnostic medical or research procedures. Only the minimum amount of PHI will be collected for this research. Your research and medical records will be maintained in a secure manner.

By signing and dating this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at Nebraska Medicine and UNMC

Your PHI will be used only for the purpose(s) described in the main consent form.

You are also allowing the research team to share your PHI, as necessary, with other people or groups listed below.

- the Institutional Review Board (Advarra IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that your information may be shared with these groups:
- HHS Office for Human Research Protections (OHRP)
- The Food and Drug Administration (FDA)

- National Institutes of Health (NIH)

The HIPAA Privacy Rule requires the following groups to protect your PHI:

- Your health insurance company

Your PHI may also be shared with the following groups. However, these organizations do not have the same obligation to protect your PHI:

- National Institute of Allergy and Infectious Diseases (NIAID), which sponsors this research and provides funds to Nebraska Medicine/UNMC to conduct this research
- Fred Hutchinson which has been hired by the sponsor to coordinate this study
- Data and safety Monitoring Committee (DSMC)

You are authorizing us to use and disclose your PHI for as long as the research study is being conducted. This authorization has no expiration date, unless and until you revoke it.

You may cancel your authorization for further collection of PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.

The results of clinical tests and therapy performed as part of this research may be included in your medical record. The information from this study may be published in scientific journals or presented at scientific meetings but your identity will be kept strictly confidential.

Your permissions and signature

21. In Section 18, we told you above about possible other uses of your extra samples and information outside this study. Please choose only one of the options below and write your initials in the box next to it. Whatever you choose, the CoVPN keeps track of your decision about how your samples and information can be used. You can change your mind after signing and dating this form.

☐ I allow my extra samples and information to be used for other studies related to vaccines, the immune system, coronavirus, and other diseases. This may include genetic testing.

OR

☐ I agree to the option above *and* also to allow my extra samples and information to be used in studies that look at my whole genome.

OR

☐ I do not allow my extra samples to be used in any other studies. This includes not allowing genetic testing, or studies that look at my whole genome.

22. If you agree to join this study, you will need to sign and date below. Before you sign and date, make sure of the following:

- You have read this consent form.
- You feel that you understand what the study is about and what will happen to you if you join. You understand what the possible risks and benefits are.
- You have had your questions answered and know that you can ask more.
- You agree to join this study.

You will not be giving up any of your rights by signing and dating this consent form.

Participant's Name (Print)	Participant's Signature	Date
Clinic Staff Conducting Consent Discussion (Print)	Clinic Staff Signature	Date