**INFORMATION AND CONSENT FORM TO SUBJECTS**
**AND**
**AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION**
**FOR SUBJECTS IN PART C**

| | |
|---|---|
| **Sponsor / Study Title:** | **ModernaTX, Inc. / "A Phase 2a, Randomized, Observer-Blind, Placebo-Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older"** |
| **Protocol Number:** | **mRNA-1273-P201** |
| **Principal Investigator: (Study Doctor)** | **«PiFullName»** |
| **Telephone:** | **«IcfPhoneNumber»** |
| **Address:** | **«PiLocations»** |



**Why are you receiving this information?**

You are being invited to take part in a clinical research study, sponsored by ModernaTX, Inc. Please read this informed consent form carefully and ask the study staff to explain words or information that you do not clearly understand. It is important that you know the following:

- Your participation is voluntary.
- You may or may not benefit from participating in this study. However, your participation may help others in the future as a result of knowledge gained from this study.
- You may choose to leave the study at any time.
- If you choose not to take part or if you leave the study, it will not harm your relationship with your study doctor or the research center.

This informed consent form describes the things you will be asked to do before, during, and after the study. It also describes the risks and possible benefits of the study. Please read this form carefully and ask any questions that might help you decide whether you would like to take part in this clinical research study. If you decide to take part in this study after reading this form, you will be asked to sign and date this consent form. A copy of this signed and dated form will be given to you to keep.

Before any study procedures are performed, you will be asked to review and sign and date this informed consent form. Signing and dating this consent form indicates that you understand your involvement in the study and the risks of participating in the study and that you agree to take part in the study.

**What is the purpose of this clinical research study?**

Coronaviruses (CoV) 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-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). Coronaviruses are zoonotic, meaning they are transmitted between animals and people.

An outbreak of the coronavirus disease (COVID-19) caused by the 2019 novel coronavirus SARS-CoV-2 began in Wuhan, Hubei Province, China in December 2019 and by February 2020 had spread throughout China and to more than 31 other countries and territories, including the United States.

In December 2020, the United States Food and Drug Administration (FDA) granted Emergency Use Authorization (also called "EUA") to multiple COVID-19 vaccines, including Moderna's mRNA-1273 vaccine. This means that the mRNA-1273 vaccine has a special authorization by the FDA to be used outside of clinical trials in a health emergency like the current pandemic. This authorization was granted after the FDA's review of both safety and efficacy (how well the vaccine protects against infection) data we have observed to date.

There is an urgent need for vaccination strategies that provide broader protection against strains (types) of SARS-CoV-2, such as the South African B.1.351. The 2-dose regimen of the Moderna COVID-19 vaccine is expected to be protective against new strains detected to date. Moderna is developing a modified mRNA vaccine (mRNA-1273.351 and a combination of mRNA-1273.351 and mRNA-1273) that is similar to the mRNA-1273 vaccine available under the EUA, but which would help protect against this new B.1.351 strain.

**How many people will participate in this part of the study?**

This is an open-label part of the main study. That means that subjects will know the vaccine they receive. Approximately 60 people from Moderna's mRNA-1273-P301 COVE Study will take part in this part of the study. There will be 3 different dosing groups.

Of the 60 subjects who will exit the COVE Study and enter this study, 20 of the subjects will receive mRNA-1273.351 20 µg (microgram), 20 subjects will receive mRNA-1273.351 50 µg, and 20 subjects will receive a mixture of mRNA-1273 25 µg and mRNA-1273.351 25 µg (50 µg total). Subjects will be enrolled sequentially to receive the study vaccine as follows. First, 20 subjects will be enrolled and will receive mRNA-1273.351 (50 µg), followed by 20 subjects enrolled who will receive a mixture of mRNA 1273 and mRNA-1273.351 (50 µg total). Upon enrollment completion of the previous group, 20 subjects will be enrolled and will receive mRNA-1273.351 20 µg. Each subject will receive a single injection at Visit 1 (Open Label [OL] - Day 1). An additional dose may be added approximately 56 days after the first boost at OL-Visit 1. Your study doctor will notify you in advance if this additional booster dose will be added.

Both you and your study doctor will know which study treatment you receive.

If the target number of subjects is reached just as you are about to start, you will be asked not to participate by the study site staff.



**What procedures are involved?**

If you decide to participate in this study, you will complete a total of 6 in-person visits. You will be asked to complete your electronic diary for 7 days, following vaccination. There will also be about 8 safety follow-up questionnaires via your electronic diary or telephone calls by the study site. There may be times when in-person clinic visits are not possible due to travel restrictions. If so, the study doctor or designee may ask to visit your home in order to perform the scheduled assessments. The total length of your participation in this sub-study is approximately 6 months. The first visit where you will receive your study vaccine (Visit OL-1) will take approximately 90 minutes. Each follow-up in person clinic or home visit will take approximately 30 to 90 minutes, and each telephone contact will take approximately 20 minutes.

**Information about the study vaccine:**

Vaccines serve to prepare your immune system for fighting illnesses. Certain cells of the immune system produce antibodies (special proteins) that recognize viruses and other pathogens (things that cause

disease) and make them harmless. The mRNA-1273.351 study vaccine is intended to boost the immune system to produce enough antibodies against the new variant B.1.351 of SARS-CoV-2 so, in case of an infection, the virus becomes harmless.

The experimental study vaccine, mRNA-1273, is an investigational drug. An investigational drug is not approved for sale in the United States by the U.S. Food and Drug Administration (FDA). It can only be given to people in an investigational study.

The mRNA-1273 study vaccine is made using a new process that allows for a much faster vaccine production than older methods. Typical vaccines for viruses are made from a weakened or killed virus, but the mRNA-1273 study vaccine is not made from the SARS-CoV-2 virus. It includes a short segment of mRNA (messenger Ribonucleic Acid).

The mRNA is a genetic code that tells cells how to make a protein. This mRNA is entirely made in a laboratory. When injected into the body, the mRNA causes some cells to make that viral protein, which can trigger an immune response.

If the person is later infected, their immune system remembers the protein from the prior vaccination which may help it to fight the invading virus. The mRNA vaccine degrades naturally and does not persist in the body.



**Study Procedures**

The following activities will be performed to make sure that you are able to take part in the study. These activities will also be used to evaluate the safety and the effect of the study vaccine. The procedures and activities that will be performed are described below.

**Demographic and Medical History:** As you were a subject in Moderna's COVE Study immediately prior to your decision to enroll in this new part of Moderna's mRNA-1273-P201 study, your medical history and medications will be automatically linked between the 2 studies. You may still be asked to confirm all medications including prescription medications, non-prescription (over the counter) medications, dietary supplements, vitamins, and herbal medications that you are currently taking and may have taken recently in the past.

**Physical Examination, Height, and Weight:** At the screening visit, Visits OL-1, OL-4, and OL-5 you will be given a symptom-directed physical examination by the study doctor or designated staff and your height and weight will be measured. A full physical examination will be performed at the last study visit, OL-6. At other study visits, a symptom-directed physical examination may be performed as needed.

**Vital Signs:** During study visits your blood pressure, body temperature, heart rate (beat), and breathing rate may be measured.

**Pregnancy Test:** If you are a Woman of Childbearing Potential (WOCBP), that is, a woman who can become pregnant, you will be asked to provide a urine sample at screening to confirm that you are not pregnant. Additional urine samples will also be collected at OL-Day 1, prior to you receiving the study vaccination, to confirm you are not pregnant. Your study doctor may choose to do a blood pregnancy test at any of these visits, in addition to or in place of the urine pregnancy test.

**Birth Control:** Women of Childbearing Potential who are sexually active will be asked to use birth control for at least 28 days prior to the first study vaccination and for 3 months after the last study

vaccination. This is approximately 5 months from the time that you sign and date this informed consent form. Acceptable forms for birth control include:

- Barrier method (condom, diaphragm, or cervical cap) with spermicide
- Intrauterine Device (IUD)
- Hormonal contraceptives in the form of a pill or patch
- Medroxyprogesterone injection (Depo-Provera®)
- Etonogestrel implant (Nexplanon®)
- Sterilization of the male partner of a female subject before entry into the study

If you are a male subject with a female partner who can become pregnant, you must agree to practice adequate contraception from the first study vaccination through 3 months after the last study vaccination. Adequate contraception for male subjects is defined as:

- Monogamous relationship with a female partner using an intrauterine device or hormonal contraception (described above)
- Use of barrier methods and spermicide
- History of surgical sterilization

**Blood Tests:** During your study visits, you will be asked to provide blood samples. Blood samples collected during the course of this clinical trial will be sent to the Sponsor or external laboratories for further testing for immune response (how your body reacts to foreign substances) to vaccination against SARS-CoV-2 and other viruses in the same family.

Additional tests include the following:

- Hepatitis B surface antigen, hepatitis C virus antibody, and HIV virus (types 1 and 2) antibody at Screening. Please note that a positive result for any of these tests may be required by law to report to the local health authority.
- If not documented in a female subject's medical records, a follicle-stimulating hormone test may be performed at the Screening Visit, as necessary and at the discretion of the study doctor, to confirm postmenopausal status.

The total amount of blood collected from you during each visit will not exceed 20 mL, which is approximately 2 tablespoons. Overall, approximately 120 mL or 8.5 tablespoons of blood will be collected over the 6-month duration of the study. This is less than a typical blood donation (470 mL taken at one time).

If you are confirmed to have SARS-CoV-2 infection during the course of the study, you will be asked to return to the clinic after you feel better approximately 28 days after diagnosis for an additional blood collection of approximately 50 mL (about a little more than 3 tablespoons). This blood sample will be used to help understand more about the body's immune response after infection by the virus.

**Nasopharyngeal Swabs:** During study visits or if you become sick, you will be asked to provide 1 nasopharyngeal swab. Nasopharyngeal swab is a method for collecting a test sample of nasal secretions from the back of the nose and throat to test for COVID-19. You may feel discomfort but it should not be painful. Nasopharyngeal swabs collected throughout the study will be sent to the laboratory for SARS-CoV-2 testing to see if you are infected. Results of the swabs will be shared with you when they are available.

**Study Vaccination:** You will receive an injection of the study vaccine that was assigned to you at OL-Visit 1. An additional booster may be given at Visit OL-D5, following data review. After each injection, you will remain in the clinic for an observation period of approximately 30 minutes. During this time, the study doctor or his/her staff will assess you for any potential reactions to the study vaccine by asking you

questions and taking your vital signs. The study site will also provide you with instructions on what you should do after you leave the clinic and information about your next study visit.

**Electronic Diary (eDiary):** You will be asked to report symptoms you might experience after the study vaccination and certain information about your health using an electronic diary. This diary is an app that will be downloaded onto your smartphone. If you do not have a smartphone, an electronic diary device will be provided to you. You will be trained on how to complete the eDiary. You will have to complete the diary every day for 7 days after the study vaccination.

In addition, about 2 weeks after Visit OL-5, you will be asked to use the eDiary to respond to a questionnaire every 4 weeks for the next almost 4 months.

To fill out the electronic diary (eDiary) after vaccination visits, you will also be asked to do the following:

- Look at your arm where you received the study vaccine and measure specific reactions you may see.
- Check for underarm gland swelling or tenderness on the same arm where you were vaccinated
- Describe reactions that are sometimes seen after vaccination.
- Measure your temperature (an oral thermometer will be provided to you).
- Enter any medications that you take.
- Describe any other types of reactions or illnesses that you may experience.

To fill out the electronic diary (eDiary) during the safety follow up period, you will be asked to do the following:

- Respond to questions regarding your health.
- Measure your temperature (an oral thermometer will be provided to you).
- A calendar with the days of safety dairy completion dates and safety call dates marked will be provided to you.

**Home Visits:** The study visits consist of both in person and telephone contacts. Ideally, all in person visits will take place at the study site. However, there may be circumstances in which you are not able to visit the clinic in person due to travel restrictions or other limitations as a result of the COVID-19 pandemic. If this occurs, the study site staff may ask if they or a representative may come to your home in order to perform the scheduled assessments.

If any in person visits must be performed at your home, the site will notify you before the visit takes place. A home visit will only take place if verbally agreed upon and approved by you prior to the visit. Procedures that may take place during a home visit are outlined in the table below; however, study vaccination will only take place on-site at the clinic.

A detailed description of the procedures for each study visit and telephone call is presented in the table below:

| Visit | When | What Will Be Done |
|---|---|---|
| **Open Label Visit –Day 1 (in clinic)** | Completed for all subjects | • Review study information as part of informed consent<br>• Medication review and discussion of any changes in your health since your last study contact |

| Visit | When | What Will Be Done |
|---|---|---|
| | | • Blood sample collection<br>• 1 nasopharyngeal swab for SARS-CoV-2 testing<br>• Confirmation that you will receive vaccine after review of inclusion/exclusion criteria<br>• Symptom-directed physical examination (including vital signs)<br>• Pregnancy test<br>• Study vaccination with mRNA-1273.351 (20 or 50 μg) or mixture of mRNA-1273 and mRNA-1273.351 (50 μg total) booster<br>• 30-minute observation after study vaccination<br>• eDiary app download and training; the eDiary will be used to record any changes in your health starting the day of your study vaccination for a total of 7 days following your vaccination |
| **Open Label Visit – Day 8 (in clinic)** | Approximately 7 days after the study vaccination. | • Review of eDiary<br>• Blood sample collection<br>• Medication review and discussion of any changes in your health since your vaccination |
| **Open Label Visit – Day 15 (in clinic)** | Approximately 2 weeks after the study vaccination. | • Blood sample collection<br>• Medication review and discussion of any changes in your health since your last visit |
| **Open Label Visit – Day 29 (in clinic)** | Approximately 1 month after the study vaccination | • Medication review and discussion of any changes in your health since your last visit<br>• Symptom-directed physical examination (including vital signs)<br>• 1 nasopharyngeal swab for SARS-CoV-2<br>• Blood sample collection |
| **Open Label Visit – Day 57 (in clinic)** | Approximately 2 months after study vaccination | • Medication review and discussion of any changes in your health since your last visit<br>• Symptom-directed physical examination (including vital signs)<br>• 1 nasopharyngeal swab for SARS-CoV-2 testing |

| Visit | When | What Will Be Done |
|---|---|---|
| | | • Blood sample collection<br>• If a second booster is needed based on data evaluation in this part of the study, your study doctor will notify you. |
| **Open Label eDiary Safety Follow-up** | Starting 2 weeks after Open Label Visit 5/Day 57, eDiary questionnaires will require responses every 4 weeks until Open Label Visit 6 (Day 181) | • Discussion of any changes in your health since the last visit<br>• COVID-19 exposure and symptoms<br>• Medical attention received<br>• The responses to some of these questions may need a phone follow-up with the clinic and/or further clinical evaluation. |
| **Open Label Safety Calls** | Starting 4 weeks after Open Label Visit 5/Day 57, safety calls will be performed monthly until Open Label Visit 6 (Day 181) | • Medication review and discussion of any changes in your health since the last visit<br>• COVID-19 exposure and symptoms<br>• Medical attention received |
| **End-of-Study Open Label Visit – Day 181 (in clinic)** | Approximately 6 months after study vaccination | • Discussion of any changes in your health since your study vaccination<br>• Symptom-directed physical examination (including vital signs)<br>• Blood sample collection |
| **Illness Visit** | Anytime during this part of the study, if you experience signs and symptoms of COVID-19 or have been in contact with someone confirmed to be infected with SARS-CoV-2, you will be asked to schedule a visit within 24 hours or as soon as possible with the study doctor. Your study doctor will discuss with you the current signs and symptoms of COVID-19 (per CDC website: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html) | • Vital signs<br>• Physical examination<br>• Blood sample collection<br>• 2 nasopharyngeal swabs (one swab per each nostril) for SARS-CoV-2 |

Per local regulations, if you are confirmed to have the SARS-CoV-2 infection, the study site staff will notify you, your primary care physician, and the local health authority of the diagnosis, as soon as results are available. Additionally, the study site staff will schedule an illness visit for evaluation, blood sample collection, and nasopharyngeal swabs. A follow-up visit will be scheduled in approximately 28 days after the diagnosis to be evaluated by the study doctor and to collect a blood sample to better understand your body's immune response after SARS-CoV-2 infection.

If you are not familiar with any of the above procedures, please ask your study doctor to explain how they are performed.

**How will the Study Data and Samples be Used?**

Results of your blood samples taken throughout the study will be used for research purposes only. You will not receive your results of the tests.

Your blood samples will be sent to special laboratories to test the response of your body's immune system to the study vaccine. Blood samples obtained in the study will be labeled with a code and will not contain any information that could identify you. The blood samples will be stored in a freezer until the tests analyzing your immune response to the study vaccine are performed. The blood samples may be stored for up to approximately 20 years by the Sponsor or designee. Additional laboratory tests may be performed in the future to further understand immune responses to the study vaccine or for further research. The future use of your blood samples may result in new discoveries that are important to the understanding of the study vaccine(s) or disease.

Any leftover blood may be used for future research after this study is over. These leftover blood samples will still be coded. This may be performed at the discretion of the Sponsor to further understand the immune response to SARS-CoV-2, additional assay (new lab tests) development, and the immune response across coronavirus.

You may request that your samples, if they can be identified, be destroyed at any time. Any data already collected from those samples will still be used for the study. The samples will remain the property of ModernaTX, Inc. and may be shared with other researchers as long as confidentiality is maintained. No testing of your DNA will be performed. You will not be told of additional tests, nor will you receive results of any of these tests.

The Sponsor may continue using the coded study data and samples after the study is over. You are allowing the Sponsor to use the information and samples in the research and development of mRNA-1273 and other medicines and diagnostics. You will not own any of the information or samples collected.



**What is expected from you?**

When deciding whether to participate, consider whether you are able and willing to do the following:

- To follow the study instructions you are given by your study doctor
- To commit the time required to keep appointments
- To accurately disclose your complete medical history
- To promptly report any new problems, illnesses, or changes in medication during the study
- To complete your electronic diary (eDiary) for 7 days following each study vaccination, including the day of the vaccination.

**What will happen at the end of the study?**

After completing all your study specific visits, you will be discharged from the study at the discretion of the study doctor.

**What are the potential risks and discomforts?**

If you choose to take part in this study, you are at risk for the side effects listed in this section. You should discuss these with the study staff and if you choose, with your regular doctor. You will be monitored for risks and side effects throughout your participation in the study. You should contact the study doctor if you think you are having side effects or experiencing a change in your medical condition.

Following injectable vaccines, redness, swelling, pain, tenderness, and/or fever may occur. These reactions normally last no more than 48 hours. Headache and malaise (general discomfort or illness), muscle aches, joint aches, chills, and feeling tired have also been reported in ongoing studies with similar vaccines.

If you had an allergic reaction after being vaccinated in the past or if you are allergic to any product(s), then you must tell the study doctor or site staff before you decide to sign and date this informed consent form. Some symptoms of allergic reactions are rash, wheezing and difficulty breathing, dizziness and fainting, swelling around the mouth, throat or eyes, a fast pulse or sweating.

If you have an allergy to some products, then you will not be able to take part in this study. Serious allergic reactions can be life-threatening.

To date more than 15,400 subjects, in this study and other ongoing studies, have received at least 1 dose of the mRNA-1273 vaccine with most getting 2 doses. Data gathered from these subjects to date have been analyzed.

The most frequent side effects that we have seen so far typically occur in the week after receiving a dose mRNA 1273 (50 µg or 100 µg) and are as follows:

- Pain at the injection site
- Headache
- Fatigue (tiredness)
- Muscle aches or pain
- Joint aches or pain

Other side effects that we have seen include the following:

- Fever
- Redness and hardness of the skin at the injection site
- Nausea/vomiting
- Chills
- Underarm gland swelling on the side of study vaccination

Not every study subject experienced these side effects, and they have been generally mild to moderate in severity. They have been reported more often after the second dose of the mRNA-1273 vaccine, and when they do occur, they typically last 2 to 3 days. Although the mRNA-1273.351 variant vaccine has not been tested in humans yet, it is nearly identical to the original mRNA-1273 therefore the risks associated with mRNA-1273.351 are expected to be similar to those seen for mRNA-1273 (described above). At approximately the same time as your participation in this study, a separate study will be conducted by the US Government Division of Microbiology and Infectious Diseases (DMID) to further evaluate the mRNA-1273.351 vaccine.

There may be possible side effects of the study vaccine that are not fully known.

Brief increases in some laboratory tests were noted in previous clinical studies with similar mRNA vaccines. These increases were observed without physical symptoms or signs, and generally returned to levels observed before study vaccination. The significance of these observations is unknown.

Blood collection may be associated with temporary discomfort, light-headedness, or a bruise at the needle site. Infection may occur at the needle stick site where blood is collected, but this is very rare.

You may experience moderate discomfort, and, in rare instances, nosebleeds can occur as a result of nasopharyngeal swab collection. You may experience watery eyes and/or coughing, but only for the short duration of the swab.

You may have emotional stress if you experience any of the side effects listed above or from keeping to the study visit schedule. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may stop taking part in the study at any time.

***Experience Post Emergency Use Authorization***

There is a very small chance that mRNA-1273 could cause a severe allergic reaction called anaphylaxis shortly after vaccination (minutes to about 1 hour after receiving a dose). Symptoms of a severe reaction might include difficulty breathing, low blood pressure, a bad rash all over your body, dizziness and weakness, or swelling of your face and throat.

It is important you tell your study doctor if you have a known allergy or have had previous episodes of severe reactions.

Another very uncommon side effect after vaccination with mRNA-1273 is inflammation of the heart or lining around the heart that is called myocarditis and pericarditis. Myocarditis or pericarditis have been reported in greatest numbers in males under the age of 30 years following the second dose, but cases have been reported in older males and in females as well, and also following the first dose.

Symptoms of myocarditis or pericarditis include chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart, with onset of symptoms most commonly reported within a few days following vaccination. Study subjects should seek medical attention and also notify study site staff if any of these symptoms occur following vaccination.

While some severe cases have been reported, most cases have been associated with full resolution of symptoms in the short term. However, long-term follow-up is limited.

It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of the vaccine (for example, following a booster dose).

Anaphylaxis, myocarditis and pericarditis have been reported following administration of mRNA-1273 vaccine in the general public after emergency use authorization.

**Are there any reproductive risks?**

**Women:** It is not known if the study treatment may affect an unborn child or nursing infant. For this reason, if you are breastfeeding, pregnant, or plan to become pregnant, then you may not participate in this study. Female subjects must be at least 1 year postmenopausal, surgically sterile (such as hysterectomy [uterus removed], bilateral tubal [both tubes] ligation, or bilateral oophorectomy [both ovaries removed]), or practicing a medically approved and highly effective method of contraception from 28 days prior to the first study vaccination through 3 months after the last study vaccination. Such methods include diaphragm with spermicide, cervical cap with spermicide, intrauterine device, oral or patch contraceptives, Depo-Provera, Nexplanon, or other FDA approved contraceptive method that is designed to protect against pregnancy. Periodic abstinence for the duration of the study and withdrawal are not acceptable methods of contraception. You should discuss with the study doctor your chosen method of birth control to determine whether it is acceptable for your participation in this study.

**Pregnancy:** If you become pregnant during your participation in the trial, then your participation in the study may be stopped. However, information about your pregnancy may be collected. 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.

**Men:** It is not known whether the study vaccine may affect your sperm or an unborn child. For this reason, you must use an acceptable method of birth control from the first study vaccination through 3 months after the last study vaccination. In addition, you must agree to refrain from sperm donation from the time of first study vaccination until 3 months after the last study vaccination. Periodic abstinence withdrawal are not acceptable methods of contraception.

**Could there be any other risks?**

There could be other risks to you (or to a pregnancy, embryo, or fetus, if you or your partner become pregnant) that are currently unforeseeable.

**What are the advantages and disadvantages of participation in the study?**

When this study started, we did not know if the vaccine would work to protect people from getting sick with COVID-19, which is why we're conducting this study.

In a larger Phase 3 study by Moderna, as planned, all subjects were followed closely after 2 doses of either placebo or mRNA-1273 (100 µg) to see if they became sick with COVID-19. In November 2020, the data was analyzed by Moderna and reviewed by an independent group of safety experts. It was determined that the vaccine was approximately 94% effective at preventing COVID-19 (this is also called "vaccine efficacy"). This means that for every 100 people exposed to the virus, the vaccine should prevent about 94 of them from getting sick with COVID-19. This result means that the study achieved its main goal to show that the mRNA-1273 vaccine can protect people from getting sick with COVID-19.

Receiving 2 doses of the mRNA-1273 vaccine as part of the study, we believe that you now have the benefit of protection against getting sick with COVID-19. However, it is important for you to understand that there are some limitations and that we are still learning about the vaccine including the following:

- The vaccine is not 100% effective, and a few people who have received the vaccine have still gotten sick with COVID-19.
- The vaccine has only been studied so far to show whether it can protect people from getting sick with COVID-19. We don't know yet if people who received the vaccine and become infected can still carry the virus and pass it to other people around them.
- We don't know how long the mRNA-1273 vaccine protects you from getting sick, which means your protection could wear off at any time and we don't know when this might happen.
- Finally, we don't know the immunogenicity of mRNA-1273 vaccine against this new strain of the virus.

Therefore, we strongly encourage you to still follow all instructions from your study doctor and local guidance around limiting your exposure to the virus (for example, social distancing, mask wearing, and hand washing).



**Are there any alternative treatments?**

While there are no COVID-19 vaccines that are yet approved with a full license and broadly available in the United States, the FDA has granted EUA to multiple COVID-19 vaccines in December 2020, including the mRNA-1273 vaccine. COVID-19 vaccines are initially limited in supply under EUA. Therefore, they are available only to some people in the general public that are considered to be at high risk of exposure to the virus or at risk of poor outcomes if they get sick. We expect that COVID-19 vaccines will be extended to more people on a rolling basis through the first half of 2021, when more vaccine is available.

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

Your study doctor will inform you in a timely manner of any new information learned during the study that may affect your willingness to continue your participation in this study.

**Can you share information about the study?**

If you participate in this study, you should feel free to discuss the study with your family and with other people who are close to you.

It is recommended to tell your health care provider about your participation in the study. However, to help make sure that the information from the study is as accurate and reliable as possible, please do not discuss information about the study in public places while the study is in progress. Public places include things like social media (Facebook, Instagram, Twitter), blogging, and speaking to the media.

**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 subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
- or call **toll free**:
- or by **email**:

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

**What happens if you change your mind?**

Your participation in the study is voluntary. You may decide not to participate, or you can leave the study at any time. You will not be punished if you decide not to participate or leave the study before the last study visit. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you decide to leave the study before the last study visit, please notify a member of the research team and follow their instructions. It may be helpful if you could explain your reasons. You will receive standard treatment and no prejudice will be shown towards you for medical care or participation in future research.

If you withdraw consent during the study, the study doctor and study staff will not collect additional personal information from you. Personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with the law. Data collected by the Sponsor up to the time you withdraw will form part of the research project results.

In addition, your participation in the study can be terminated by your study doctor or the Sponsor, even if you wish to continue, for example:

- If you experience a severe adverse reaction
- If you do not follow the study rules
- If it is discovered that you do not meet the study requirements
- If the study is cancelled

- For administrative reasons, including completion of enrollment

If your participation in the study is stopped early or you decide to leave the study before the last study visit, you may be asked to complete end-of-study procedures (such as a final medical examination and laboratory tests) for your safety.

**Can you continue getting the study vaccine after the study?**

If you choose to withdraw from the study or are taken out of the study, you will not continue receiving the study vaccine. Also, if the study is terminated early, or when the study is ended, the Sponsor will not continue providing the study vaccine.

[redacted]

**Will you receive compensation if you are injured as a result of the study?**

If you become sick or injured as a direct result of a study procedure or properly administered study vaccine, call the 24-hour telephone contact number listed on the first page of this consent form. Additionally, appropriate medical care for the treatment of the illness or injury will be provided to you. The Sponsor may pay for the reasonable and necessary costs associated with this care. Provision of medical care does not imply any fault or wrongdoing on the part of Sponsor, your study doctor, or the study center. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes, except as noted below under the Public Readiness and Emergency Preparedness Declaration.

To pay medical expenses, the Sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the Sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

A new federal public health declaration, called the Public Readiness and Emergency Preparedness Declaration (PREP), was issued by the Department of Health and Human Services on March 10, 2020. This declaration limits the legal rights of a subject participating in a COVID-19 clinical study that uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19. This includes the study vaccine mRNA-1273 used in this study. Subjects using mRNA-1273 in this study will have limits on their right to sue the manufacturers, the study sponsor, healthcare providers and others for significant injuries and adverse reactions. The limits on a subject's right to sue do not apply in the case of willful misconduct resulting in death or serious bodily injury.

**Will the personnel involved in the study receive any payment?**

The study doctor receives payment from ModernaTX, Inc., who is the Sponsor of this study.

**Confidentiality**

This research study will be performed only by collecting and using your medical information. Your study records will be kept as confidential as possible. Only a number will be used to identify you. You will not be personally identified in any reports or publications that may result from this research study.

Because of the research goals of this study, however, your study records cannot be kept completely confidential. The Sponsor of this study is ModernaTX, Inc.

The study personnel, the Sponsor and its agents, and Pharmaceutical Product Development, LLC (PPD) will need to review the medical information collected from you for use in this study to accurately record information for this study. In addition, to review the study findings, the FDA, other government agencies, and the IRB will be able to inspect and copy confidential study-related records that identify you by name. This means that absolute confidentiality cannot be guaranteed. Representatives of the Sponsor and government agencies may also observe a study visit to check that study staff are conducting the study correctly.

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.

**Statement of Consent**

- I have read and understand the statements in this informed consent form.
- I have had the opportunity to ask questions, and I am satisfied with the explanations provided.
- I voluntarily agree to take part in this study.
- I understand that I will receive a copy of this signed and dated written consent form.
- For men: I agree to utilize an acceptable method of birth control with my partner as outlined in this informed consent form AND agree to not donate sperm from the time of first study vaccination until 3 months after the last study vaccination.
- For women of childbearing potential: I agree to utilize an acceptable method of birth control as outlined in this informed consent form. Should I become pregnant during my participation in the trial, I agree to provide information on my pregnancy and birth outcome as part of the safety follow-up.
- I agree that the blood samples provided by me during this study will be used as described in this informed consent form.
- I understand that if I am confirmed to have the SARS-CoV-2 infection, the study doctor will inform my primary care doctor of the test results.



| **Subject** | Signature | Date |
|---|---|---|
| Printed Name | | |

I presented the study and answered the subject's questions.

I will give the subject a copy of this signed and dated informed consent.

| **Presenter (Study Doctor/Delegate)** | Signature | Date |
|---|---|---|
| Printed Name | | |

## AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

The following sections provide a specific description of how your protected health information ("PHI") will be used and disclosed if you participate in this research study. By signing and dating this authorization, you are authorizing such access. If you do not sign and date this form to authorize access, then you will not be able to participate in this research study.

The medical information that will be collected from you, if you participate in the study, includes the following:

- Information obtained from procedures to determine your eligibility to participate in the study, including routine medical history, physical examination, blood and urine tests, and nasopharyngeal swabs.
- Information that is created or collected from you during your participation in the study, including the results of the blood and urine tests and any other procedures performed during the study.
- Information contained in your underlying medical records related to your medical history and treatment.

The above information may identify you by name, address, telephone number, social security number, health plan number, study number, date of birth, dates relating to various medical procedures, and/or other identifying information.

If you sign and date this form and participate in the study, then the study personnel will be authorized to use the information described above to carry out the purposes of the research study. The study personnel will also be authorized to disclose the relevant information described above to the following parties involved in the research study:

- ModernaTX, Inc., PPD, or other agents designated by ModernaTX, Inc. to collect or review study data for verification of study procedures, adverse event reporting, and any other purpose.
- The IRB that oversees the research study at your site.
- Government regulatory agencies, including the FDA.

- Clinical trial recruitment company: If you were referred to the study by such a company, then once your information is disclosed to the study Sponsor, its agents, the IRB, or government agencies as described above, there is a potential that your medical information will be redisclosed and will no longer be protected by U.S. federal privacy regulations. In addition to disclosures to the entities identified above, PPD may further electronically disclose your coded health information to others involved in the research study, such as:
    - To laboratories or offsite testing facilities for clinical tests for safety and immune responses as required by study protocols.
    - To approved offsite storage facilities or cloud service providers to meet study record retention and storage requirements.
    - To study Sponsor, ModernaTX, Inc., who directs the medical research studies.
    - To other third parties contracted by PPD and/or ModernaTX, Inc., to provide services related to studies.

The study data may be transferred to other countries for processing, including countries not covered by data protection legislation. The laws of your state may provide further protection.

While the study is in progress, your access to your study records will be temporarily suspended. You will be able to access your information when the research study is completed. However, note that in order to protect the scientific integrity of the study, the study treatment you receive needs to remain unknown (blinded) until the study data are analyzed.

You have the right to see and copy the medical information collected from you in the course of the study for as long as that information is maintained by the study personnel and other entities subject to federal privacy regulation.

Study data, including your coded medical information, may be used and shared for pharmaceutical research purposes related to this study. This authorization will expire 50 years from the date you sign and date it unless you revoke (cancel or withdraw) sooner. In signing and dating this form, you authorize the use and disclosure of your information for purposes of the study at any time in the future.

You may withdraw your authorization at any time by sending a written request to the study doctor listed on page one of this informed consent. If you withdraw your authorization, then data collected prior to your withdrawal may still be processed along with other data collected as part of the study.

Generally, no new information will be collected for the study database unless you specifically authorize that. However, the law does require that any side effects that you experience be documented and reported. To complete the study findings, your long-term health status may also be obtained from public sources.

You have the right to refuse to sign and date this authorization, which would result in your inability to participate in the study. You will receive a copy of this authorization after you sign and date it.

**Subject Authorization to Use and Disclose PHI**

_____

Printed Name of Subject

_____

Signature of Subject Date

**Person Obtaining Authorization to Use and Disclose PHI**

- I presented the Authorization above and answered the subject's questions.
- I will give the subject a copy of this signed and dated Authorization.

_____

**Presenter (Study Doctor/Delegate)** Signature Date
Printed Name