16.1.3 List of IECs and IRBs (Plus the Name of the Committee Chair if Required by the Regulatory Authority) and Representative Written Information for Participant and Sample Consent Forms

Central IRB/IEC services were provided by:

Advarra, Inc. (b) (6)
6100 Merriweather Drive
Suite 600
Columbia, MD 21044
United States

Advarra, Inc. (Previous)
6940 Columbia Gateway Drive
Suite 110
Columbia, MD 21046
United States

The following sample informed consent forms are provided on the following pages:

Main Informed Consent Form dated 31 Jul 2020

Informed Consent Form Addendum to Master ICF dated 04 Jan 2021

Informed Consent Form Addendum version 2.0 dated 25 Mar 2021

INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**ModernaTX, Inc / "A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS -CoV-2 Vaccine in Adults Aged 18 Years and Older"**
Protocol Number:	**mRNA-1273-P301**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

Key Information

The purpose of this study is to test an experimental study vaccine that may protect people from a viral infection called the coronavirus disease (also called, "COVID-19") caused by the 2019 novel coronavirus (the virus is also called, "SARS-CoV-2"). There is currently no vaccine to protect people from SARS- CoV-2 infection. The mRNA-1273 study vaccine is intended to boost the immune system to produce enough antibodies against SARS-CoV-2; so, in case of an exposure, the virus does not cause illness.

You are being asked to take part in this research study. Your participation in this study is voluntary and you can change your decision at any time. The study team members will explain the study to you and will answer any questions you may have. The study length is 25 months and includes approximately 6 visits to the clinic and 25 phone calls. In addition, if you are diagnosed with COVID-19, you will have 2 additional clinic or home visits and daily telemedicine visits by videoconference or telephone daily for 14 days after illness visit or until your symptoms have resolved, whichever is later. If you chose to participate in this study, you will receive 2 injections of study vaccine or placebo given about 1 month apart. Placebo is an injection that does not have the active ingredient. You will use an electronic diary (eDiary) to record side effects that you experience after dosing and also monitor for COVID-19 symptoms. During some of the clinic or home health visits, blood samples and nasopharyngeal or nasal swabs or saliva samples will be taken. Your samples, which will be coded with a unique number that does not contain your personal information (data), will be tested to learn how your body reacts to the study vaccine. You can contact the study site at any time with questions.

Like all medicines and vaccines, the study vaccine and the other ingredients in the formulation may cause side effects, although not everyone gets them. The most likely side effects you may have from the study vaccine are pain, redness, and swelling where the shot is given, headache, muscle pain, joint pain, fever, feeling tired, nausea/vomiting, underarm gland swelling on the side of the vaccination, and shivering. In addition to side effects from the study vaccine, you may feel faint or have mild pain, bruising, irritation, or redness where the blood samples are taken.

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 what 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 and SARS-CoV. Coronaviruses are zoonotic, meaning they are transmitted between animals and people.

An outbreak of COVID-19 caused by the 2019 novel coronavirus SARS-CoV-2 began in Wuhan, Hubei Province, China in December 2019 and has spread throughout China and to over 200 other countries and territories, including the United States.

There is currently no vaccine that has been shown to be effective against SARS-CoV-2. Therefore, there is an urgent public health need for rapid development of novel interventions to prevent the spread of this disease. This study is testing the mRNA-1273 study vaccine at a dose of 100 micrograms (µg).

The main purpose of this study is to understand if mRNA-1273 can prevent COVID-19 and to understand the safety of the mRNA-1273 study vaccine.

How many people will participate in this study?

Approximately 30,000 people will take part in this study in around 80 - 100 study sites in the United States. The total number of subjects may differ depending on the infection rate of SARS-CoV-2, which is not known.

All subjects will be randomly assigned to receive two doses of 100 µg [microgram] of an experimental study vaccine called “mRNA-1273” or a placebo (a saline injection that contains no active ingredients). Each subject will receive an injection of mRNA-1273 100 µg [microgram] or placebo at Visit 1 (Day 1) and at Visit 2 (Day 29). This random assignment (like flipping a coin) will be a 1:1 ratio. That is, around 15,000 of the subjects will receive two doses of saline placebo and around 15,000 subjects will receive two doses of 100 µg of mRNA-1273. Neither you nor your study doctor will know which study treatment you receive throughout the two-year duration of this study. However, your study doctor can find out which group you are in if there is an emergency.

What procedures are involved?

If you decide to participate in this study, you will complete a total of 6 scheduled in-person visits, and about 25 safety telephone calls over approximately 25 months. 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. In addition, if you are diagnosed with COVID-19, you will have 2 additional clinic or home visits and daily telemedicine visits by videoconference or telephone daily for 14 days after your illness visit or until your symptoms have resolved, whichever is later. The total length of your participation in this study is approximately 25 months. The 2 visits where you will receive your study vaccine (Visit 1 and Visit 2) will take approximately 90 to 120 minutes, each follow-up in-person clinic or home visit will take approximately 30 to 90 minutes, and each telemedicine visit will take approximately 10 - 20 minutes.

Information about the study vaccine

Vaccines serve to prepare your immune system for fighting infection and preventing 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 study vaccine is intended to boost the immune system to produce enough antibodies against SARS-CoV-2; so, in case of an infection, the virus does not cause illness. To date, no effective vaccine to prevent SARS-CoV-2 has been produced.

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 messenger ribonucleic acid (mRNA). 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.

Because mRNA is a recent technology for making vaccines, there are no approved mRNA vaccines for any diseases, including COVID-19. We don't know if the technology will work. Several mRNA vaccines, like this one, are in human testing right now against other diseases. At the moment, over 300 subjects have received at least one dose of mRNA-1273 since March 2020 in two other clinical trials that are still ongoing. There have been no serious safety concerns observed to date and early laboratory tests on a small subset of these subjects suggest the vaccine might trigger an immune response that can fight the SARS-CoV-2 virus, which is why we are moving forward this new study. This study will now help us understand if the mRNA-1273 vaccine can protect people from getting infected with the SARS-CoV-2 virus or getting sick with COVID-19.

The following activities will be performed to determine if 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.

Study Procedures

Demographics, Medical History, and Medications: During your first clinic visit, you will be asked to provide information about your medical history and where you typically receive medical care. You will be asked to provide contact information for your Primary Care physician and may be requested to provide personal medical records from your doctor(s).

This is really important information for your study doctor to have to ensure the best care for you in the event you become sick during the study. The study doctor or designee may need to review your medical records for additional information. To prepare for this, they will ask you to sign and date a medical release of information so we can get your records from your Primary Care physician or view your hospital records. They will also ask you to provide the name of a person who can provide information for you if you are unable to do it yourself, such as if you are admitted to the hospital.

You will be asked about 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: A full physical examination, including vital signs, height, and weight will be performed at Screening and Day 1 (Visit 1) by the study doctor or designated staff.

A symptom-directed physical examination by the study doctor or designated staff will be performed on Day 29 and Day 57 and thereafter at the discretion of the study doctor during clinic visits.

If you become sick with COVID-19 there will be 2 additional full physical examinations at the visit to confirm your diagnosis of COVID-19 and 28 days after your diagnosis.

Vital Signs: During study Visits, Screening, Visit 1 (Day 1) and Visit 2 (Day 29) your blood pressure, body temperature, heart rate (beat), and breathing rate will be measured.

If you become sick with COVID-19 there will be 2 additional vital signs collected at the visit to confirm your diagnosis visit and 28 days after your diagnosis.

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 Day 1 and Day 29, 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. If you are pregnant, you cannot receive the study vaccine.

Birth Control: WOCBP 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

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 responses (how your body reacts to foreign substances) to vaccination against SARS-CoV-2 and other viruses in the same family. You will not be told the results of these test of your immune system until the study ends.

The total amount of blood collected from you during each visit will not exceed 75 mL, which is approximately 5 tablespoons. Overall, approximately 400 mL or 27 tablespoons of blood will be

collected over the 25-month duration of the study. This is less than a typical blood donation (470 mL taken at one time).

Nasopharyngeal Swab: During study visits or if you become sick, you will be asked to provide nasopharyngeal swabs. 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 have minor bleeding and you may feel discomfort, but this 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. An additional swab will be collected at illness to look for other respiratory illnesses such as influenza. Results of the swabs will be shared with you when they are available. The nasopharyngeal swab is the best way to diagnose COVID- 19 but if the study doctor or his/her staff can't collect this from you, an alternative sample collected from the nose or a saliva sample will be sufficient.

Study Vaccination: You will receive an injection of the study vaccine or placebo that was assigned to you by chance at Visit 1 and Visit 2. 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 site will also provide you with instructions on what you should do after you leave the clinic and information about your next study visit.

eDiary: You will be asked to report on about 17 symptoms you might experience after each study vaccination and certain information about your health using an eDiary. This diary is an application (or "app") that will be downloaded onto your smartphone. If you do not have a smartphone, an eDiary device can be provided to you based on availability. You will be trained on how to complete the eDiary. You will have to complete the diary every day (preferably at the same time each day in the evenings) for 7 days after each of the 2 study vaccinations. Completion of the daily symptoms should take about 5-10 minutes each day.

To fill out the eDiary, you will also be asked to do the following:

- Look at your arm where you received the study vaccine and measure any specific reactions you may see (a ruler will be provided to you to measure injection site reactions).
- 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). You must not eat or drink anything hot or cold within 10 minutes of taking your temperature.
- Note if you take any medications.
- Confirm if you have seen another healthcare provider for any illness or symptoms.

Starting at about 1 month after the second study vaccination you will also receive weekly (approximately every 7 days) prompts in the eDiary through the end of the study to follow your health status. These prompts will ask you to confirm the presence or absence of about 17 symptoms that are associated with COVID-19. It should take no longer than 5 minutes to complete this weekly assessment.

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 site study 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:

Visit	When	What will be done
Screening (in clinic)	Before you enter the study	• Informed consent review • Demographic data • Medical history review (including any medications you take) • Physical examination (including vital signs) • Pregnancy testing • Inclusion/exclusion criteria review to determine if you are eligible to participate in the study
Visit 1 (in clinic)	Day 1 (first study vaccination)	• Confirmation that you may participate in the study after review of inclusion/exclusion criteria • Medication review and discussion of any changes in your health since the last visit • Physical examination (including vital signs) • Pregnancy test • Blood sample collection • Nasopharyngeal swab for SARS-CoV-2 • First study vaccination (mRNA-1273 or placebo) • A 30-minute observation after study vaccination • 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 study vaccination and to record any COVID-19 symptoms throughout the study • Distribute participant card, oral thermometer and ruler
Visit 2 (in clinic)	Approximately 1 month after the first study vaccination (second study vaccination)	• Medication review and discussion of any changes in your health since your vaccination • Physical examination (including vital signs) • Pregnancy test • Blood sample collection • Nasopharyngeal swab for SARS-CoV-2 • Second study vaccination with the same treatment you received at the first dose • eDiary app review to record any changes in your health starting the day of your study injection for a total of 7 days following your study vaccination • A 30-minute observation after study vaccination
Visit 3 (in clinic)	Approximately 2 months after the first study vaccination	• Medication review and discussion of any changes in your health since your study vaccination • Physical examination • Blood sample collection

		• Activation of weekly eDiary prompts for COVID-19 symptoms
Visit 4 (in clinic)	Approximately 7 months after the first study vaccination	• Medication review and discussion of any changes in your health since your study vaccination • Physical examination • Blood sample collection
Visit 5 (in clinic)	Approximately 13 months after the first study vaccination	• Medication review and discussion of any changes in your health since your study vaccination • Physical examination • Blood sample collection
Safety Calls	Safety calls will be performed 7, 14, and 21 days after each study vaccination in addition to monthly calls if no in clinic visit	• Medication review and discussion of any changes in your health since the last visit, including presence of any COVID-19 symptoms
eDiary Safety Prompts	Weekly starting after Visit 3 (1 month after second vaccination)	• Monitoring your health for COVID-19 symptoms
End-of - Study Visit 6 (in clinic)	Approximately 25 months after the first study vaccination	• Medication review and discussion of any changes in your health since your study vaccination • Physical examination • Blood sample collection

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

"Illness Visits' to test for SARS-COV-2 infection: During your participation in the study you will be asked to monitor your health for about 17 possible symptoms of COVID-19 to include:

- Fever (Temperature greater than or equal to 38ºC/100.4ºF)
- Cough
- Shortness of breath
- Difficulty breathing
- Fatigue
- Muscle aches
- Body aches
- Chills
- Headache
- New loss of taste
- New loss of smell
- Sore throat
- Congestion
- Runny nose
- Nausea
- Vomiting
- Diarrhea

If you experience Fever, Cough, Shortness of Breath or Difficulty Breathing you are asked to immediately contact your study doctor and they will schedule an "illness visit" within 72 hours or as soon as possible. The other symptoms listed should be present for at least 48 hours (2 days) before your study doctor will schedule an "illness visit".

At the "Illness Visit" you will be physically examined and have nasopharyngeal swabs collected to see if you have been infected by the SARS-CoV-2 virus or other respiratory infections. Additionally, the study doctor will collect approximately 20 mL (about a little more than 3 tablespoon) of blood to

evaluate your immune response. If you cannot make it to the clinic for any reason for the illness visit, and if you agree to it, a medically qualified staff member from the clinic can conduct a home visit as soon as possible to collect the nasopharyngeal swab, blood sample and check on your health status.

You will be also be given an instruction card listing possible COVID-19 symptoms, a thermometer to record your temperature, a device to measure your oxygen level and saliva collection tubes. You will be trained on how to use the thermometer, the device to record your oxygen level, and how to take saliva specimens. The study team will arrange daily telemedicine visits via videoconference or phone so they can monitor your health. You will be asked to review the COVID-19 symptoms at each telemedicine visit so it will be important that you keep this with you for these visits.

The results of your nasopharyngeal swabs could take several days to come back from the laboratory. When you study doctor receives the results, they will communicate them to you right away.

If your nasopharyngeal swab and blood test is negative for SARS-CoV-2, the telemedicine visits will stop and you will continue with regular study visits and procedures.

If you are confirmed positive for SARS-CoV-2, you will be followed up for 28 days which will include daily telemedicine visits via phone or video will continue for 14 days or until your symptoms resolve, whichever is later. Because it takes a few days to get your result, the telemedicine visits will start the day after your illness visit. During the telemedicine visits, you will be asked to report the severity of each symptom, your highest body temperature, your lowest oxygen level for that day, and be reminded to collect your own saliva on Days 3, 5, 7, 9, 14, and 21 days after the initial illness visit. Arrangements will be made by the study team to retrieve these samples from your home the same days you collect them to be returned to the study site.

Based on availability, and only if you agree, there may an option to have a telemedicine "app" downloaded to your smartphone. This would be another option for you to manage the daily telemedicine visits. The "app" provides a secure video connection and allows another way for you to communicate with the study team. Your study doctor will be able to tell you if it is available. At 28 days after the illness visit, you will be asked to come into the clinic for a follow-up visit.

You will be physically examined; a saliva sample will be taken and approximately 20 mL (about a little more than 3 tablespoons) of blood sample will be collected to help understand more about your body's immune response after infection by the virus.

If you cannot make it to the clinic for any reason for the 28 day follow-up visit, and if you agree to it, a medically qualified staff member from the site can conduct a home visit as soon as possible to collect the blood and saliva samples, as well as check on your health status.

If you are hospitalized during this 28- day period, a medically qualified site staff will try to obtain medical records and SARS-CoV-2 results from tests you might have received at the hospital. Clinic study staff may also try to collect a nasopharyngeal or saliva specimen (or respiratory sample) for the study while you are in the hospital, if possible. If you are discharged from the hospital during this 28-day period, the telemedicine visits will resume.

If you are confirmed to have SARS-CoV-2 infection, the study staff will notify your primary care doctor of the diagnosis as soon as results are available. If you do not have a primary care doctor, your study doctor can help you to find one.

Your study doctor will also advise you on any additional steps you must take with respect to local quarantine requirements and ensure that you understand your options for access to medical care. Frequent and close communication with your study doctor, your primary care doctor, and/or other healthcare institutions will be important to ensure you are well cared for if you are confirmed infected.

If you are confirmed to have SARS-CoV-2 infection before receiving your second dose, you will not be eligible to get this dose.

Visit	When	What will be done
Illness Visit – Day 1	During the study, if you experience any of the 17 signs and symptoms of COVID-19 you will be asked to schedule a visit within 72 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 Centers for Disease Control [CDC] Website: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html)	• Medication review and discussion of any changes in your health since your study vaccination • Physical examination (including vital signs) • Blood sample collection • 1 nasopharyngeal swab for SARS-CoV-2 testing • 1 additional nasopharyngeal swab for respiratory illness testing • Distribute oxygen saturation monitor, saliva home collection kits, oral thermometer, and instruction card for symptom review at telemedicine visits
Telemedicine Visits After Illness Visit Day 1	Daily Telemedicine Visit via phone or video for 14 days after Illness visit until symptoms resolve whichever is longer	• During the telemedicine visits (by phone or video), you will be asked to report the severity of your symptoms, including your highest body temperature and lowest oxygen level for that day. • You will be reminded to collect your own saliva on day 3, 5, 7, 9, 14, and 21 after the Illness Visit
Illness Visit – Day 28 (in clinic)		• Medication review and discussion of any changes in your health since your study vaccination • Physical examination (including vital signs) • Blood sample collection • Saliva Sample

How will the study data and samples be used?

Results of your serum (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 15 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 or nasopharyngeal/nasal swab or saliva specimens may be used for future research after this study is over. These leftover blood samples will still be coded. ModernaTX, Inc. will always retain the identifying codes for any samples provided to special laboratories for future research. This research may be performed at the discretion of the Sponsor to further understand the immune response

to SARS-CoV-2, additional assay (new laboratory tests) development, and the immune response across coronavirus. Your samples will not be used for commercial profit.

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 and may be shared with other researchers as long as confidentiality is maintained, and 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 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, including any potential COVID-19 symptoms
- To complete your eDiary for 7 days following each study vaccination, including the day of study vaccination

What will happen at the end of the study?

After completing all of 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?

The mRNA-1273 vaccine is being studied in two ongoing studies in the United States. The first study (also called "Phase 1") was started in March 2020 and the second study was started in May 2020 (also called "Phase 2"). Multiple dose levels of the study vaccine, including the one to be used in this study, are being evaluated in these studies.

To date, over 300 adult subjects have received at least 1 dose of the mRNA-1273 study vaccine.

There have been no serious side effects observed or reported by subjects in these studies. The majority of side effects that are reported by subjects to date have been mild to moderate in severity.

If you would like to learn more about these studies, you can find information at *www.clinicaltrials.gov* under study identification #NCT04283461 (Phase 1) and #NCT04405076 (Phase 2).

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

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.

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 study 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 may not be able to take part in this study. Serious allergic reactions can be life- threatening.

In other studies of people receiving similar study vaccines like mRNA-1273, the most common side effects are listed below. You will be asked about these side effects during this study.

- Fever
- Pain at the injection site
- Redness and hardness of the skin at the injection site
- Headache
- Muscle aches or pain
- Joint aches or pain
- Fatigue (tiredness)
- Nausea/vomiting
- Chills
- Under arm gland swelling on the side of study vaccination

Most of these side effects occurred within the first few days after study vaccination and went away within a few days. Not everyone has had these side effects and those who experienced them did not necessarily experience them after every dose. These side effects were usually reported as mild or moderate but were occasionally severe.

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, lightheadedness, or a bruise at the needle site. Infection may occur at the needlestick 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 or nasal 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.

Are there risks if you become infected with the coronavirus after getting study vaccine?

There are currently no vaccines approved for use to protect against SARS-CoV-2 virus infection. Receipt of this experimental mRNA-1273 study vaccine may affect your response to future vaccines against the SARS-CoV-2 virus. It is unknown if the mRNA-1273 study vaccine will protect you from getting infected or if it will prevent you from developing illness from the infection. Sometimes vaccines are not protective. Rarely they can cause you to have more severe illness after virus exposure. Based on all available data about this study vaccine and prior animal studies with similar types of vaccine, we do not think this study vaccine should increase your risk of severe illness. It is also unknown how long an immune response may last. If you receive placebo (the inactive substance) as part of this study, you will not have any additional protection against the infection.

To help monitor for infection, we will give you a reminder card to call your study clinic if you develop signs or symptoms of COVID-19, or if you come in contact with someone with the novel coronavirus infection (SARS-CoV-2). Again, your study doctor will discuss with you the current signs and symptoms of COVID-19 per the CDC guidelines. If you develop these symptoms or come

in contact with an infected person, we will schedule you to come in and be checked for coronavirus infection, including nasopharyngeal swab and blood collection.

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 vaccination through 3 months after the last vaccination with the study vaccine. Such methods include diaphragm with spermicide, cervical cap with spermicide, IUD, oral or patch contraceptives, Depo-Provera, Nexplanon, or another U.S. Food and Drug Administration (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 (you will not receive any further doses of the study vaccine) but you will be asked to stay in the study and be followed-up for safety. Details about your pregnancy will be collected until Month 25. It is important that you tell the study doctor immediately if you become pregnant during the study. The study doctor will talk with you about what you should do.

Periodic abstinence and withdrawal are not acceptable methods of contraception.

Risk of testing positive for SARS-CoV-2 antibodies:

The body makes antibodies to fight or prevent infection. Most vaccines cause the body to make antibodies as a way of preventing infection. Your body may make antibodies to coronavirus because you received a coronavirus study vaccine. Because of this, the study vaccine may cause you to test positive on coronavirus antibody tests, even if you do not have coronavirus. This is called vaccine-induced seropositivity (VISP).

VISP means that after you get the study vaccine, some coronavirus antibody tests may say you have been infected with the coronavirus, even if you haven't. For this reason, the study doctor or designee doesn't recommend getting tested outside of the study. If you need to get tested outside of this study, there are tests you can get that will avoid this problem. The study doctor or designee will give you information to help you if you need to get tested outside of the study. As a reminder, if you test positive for coronavirus antibodies, scientists don't know if these antibodies will protect you.

If you become pregnant during or after the study and have VISP, scientists don't know if the antibodies could be passed to your baby. This happens with other vaccines, like the tetanus vaccine. For most babies, antibodies from the mother last for about six months.

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?

You may not personally benefit from your participation in this study. However, by taking part, you will help to provide new scientific information that will benefit patients in the future.

Are there any alternative treatments?

Your alternative is to not participate in this vaccine study.

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 I 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:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
  - or call **toll free**: 877-992-4724
  - or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00044270.

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 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.

Are there any costs if you decide to participate?

The study vaccine will be made available to you at no charge, and you will not be required to pay for any study procedures. You or your insurance company may be billed for any standard medical care that is not required for the research study.

Is there a payment if you decide to participate?

«Compensation»

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.

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 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.

What will happen to your data?

This research study may 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.

If you use your personal mobile device for the electronic Diary, your data could be shared by your device manufacturer or third parties outside of this study according to your end-user license agreement or terms of service.

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 in order to accurately record information for this study. In addition, in order to review the study findings, the US FDA and other regulatory agencies may review your medical records. 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.

There might be circumstances where it is difficult or impossible for study monitors, auditors and those other individuals mentioned in the ICF to access the study site to check that the study is being performed correctly and that the information collected about you is accurate. Remote solutions may be adopted to allow the study to continue in these circumstances. Such solutions will involve your personal information collected for the study being handled and disclosed in new ways. These solutions may include the following:

- Information from your medical file may be "redacted" and forwarded by email, fax, or secure portal to remote based study monitors, auditors and other individuals. Redaction means that your identifying information will be removed and replaced with your Subject ID.

In all cases, the study site and the study monitors, auditors and other individuals will implement technical and organizational controls to ensure that your confidential personal information is protected from unauthorized access or loss. Full details on the how your privacy is respected in the study, and the rights you have in respect to your study data, are set out in the main study informed consent form.

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.

NIH Sites Only:

<<Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about

yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.>>

Primary health care provider notification option

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

❒**YES** (If yes, please complete the information below)

❒**NO**

Name and address of family doctor or primary health care provider:	Name: Address:
Telephone and Fax Number:	Tel: Fax:

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 women who are able to get pregnant: I agree to utilize an acceptable method of birth control as outlined in this informed consent form for at least 3 months after the last study vaccination. 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 sample and nasopharyngeal or nasal swab or saliva specimens 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.

Participant		
Printed Name	Signature	Date

Witness (if applicable)		
Printed Name	Signature	Date

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

Presenter (Study Doctor/Delegate)		
Printed Name	Signature	Date

AUTHORIZATION FOR USE OR DISCLOSURE OF HEALTH INFORMATION

This research study may 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 PPD will need to review the medical information collected from you for use in this study in order to accurately record information for this study. In addition, in order to review the study findings, the U.S. Food and Drug Administration (FDA) and other regulatory agencies may review your medical records.

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, 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:

- Information obtained from procedures to determine your eligibility to participate in the study, including a 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, 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 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 and/or adverse event reporting.
- Clinical trial recruitment companies for analytical purposes and so that they may be compensated. These companies may also contact you periodically with appointment reminders, study instructions, and other important study updates, unless you choose to opt out.
- The institutional review board (IRB) that oversees the research study at your site.
- Government regulatory agencies including the FDA.

Once your information is disclosed to the study sponsors, its agents, the IRB or government agencies as described above, there is a potential that your medical information will be re-disclosed 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 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.

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 expires 50 years from the date this form is signed. After that date, your health care provider is no longer authorized to disclose your medical information for this study unless a new authorization is signed.

You may withdraw your authorization at any time by sending a written request to the study doctor listed on the first page of the main informed consent. If you withdraw your authorization, data collected prior to your withdrawal may still be processed along with other data collected as part of the study. Normally no new information will be collected for the study database unless you specifically authorize that. However, the law does require that any side effects you may suffer are 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.

Participant's Statement Authorization

- I have read and understand the statements in this authorization 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 form.

Participant

Printed Name Signature Date

INFORMED CONSENT FORM ADDENDUM to MASTER ICF

Sponsor / Study Title:	**ModernaTX, Inc. / "A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older"**
Protocol Number:	**mRNA-1273-P301**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

In the Informed Consent Form you signed when you agreed to take part in this study, you were told you would be informed if there was new or updated information about the study. The purpose of this additional form, called an "Informed Consent Form Addendum," is to provide you with new information since the last Informed Consent Form you signed.

In December 2020, the United States Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) to multiple vaccines for the coronavirus disease (COVID-19), 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 the safety and efficacy (how well the vaccine protects against COVID-19) data that has been observed to date.

Although the study has had initial success, it is not completed, and we continue to gain valuable information from your participation. In this document, we want to provide you with additional information about the safety and efficacy data of the study and the changes to the study visits and procedures.

This Addendum includes updates to the following sections from your original Informed Consent Form:

What are the potential risks and discomforts?

This section is being updated because since you agreed to take part in the study more than 15,600 participants in this study, and other ongoing studies have received at least one dose

of the mRNA-1273 vaccine, with most participants in all studies combined receiving two doses. Data gathered from these participants to date have been analyzed.

The most frequent common side effects that we have seen so far typically occur in the week after receiving a dose of mRNA-1273 and are the following:

- Fever
- Pain at the injection site
- Redness and hardness of the skin at the injection site
- Headache
- Muscle aches or pain
- Joint aches or pain
- Fatigue (tiredness)
- Nausea/vomiting
- Chills
- Under arm gland swelling on the side of study vaccination

Not every study participant experienced all of these side effects, which have been generally mild to moderate in severity. These side effects have been reported more often after the second dose of the mRNA-1273 vaccine and as typically lasting 2 to 3 days in duration anytime they occurred.

While we have not seen this in the studies so far, there is a very small chance that the mRNA-1273 could cause a severe reaction, also called “anaphylaxis”, shortly after vaccination (within minutes to about one hour after receiving a dose). Symptoms of a severe reaction might include difficulty breathing, a fast heartbeat, a bad rash all over your body, dizziness, weakness, or swelling of your face and throat.

Anaphylaxis has been reported following administration of mRNA-1273 vaccine in the general public after emergency use authorization. It is important that you tell your study doctor if you have a known allergy or have had previous episodes of severe reactions.

Are there risks if you become infected with the coronavirus after receiving the study vaccine?

To date, we have observed that there have been fewer cases of severe COVID-19 in participants who received the mRNA-1273 vaccine compared to those who received placebo. This continues to reassure us currently that the vaccine does not increase your risk for severe illness. We will continue to monitor this closely and let you know if that changes.

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

In this study, we followed all participants closely after two doses of either placebo or mRNA-1273 to see if they became sick with COVID-19. In November 2020, the data were 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 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 if the mRNA-1273 vaccine can protect people from getting sick with COVID-19.

If you received two 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 there are some limitations and aspects of the vaccine that we are still trying to learn more about which are listed below:

- The vaccine is not 100% effective and a few people who have received the vaccine have still gotten sick with COVID-19.
- We do not know yet if people who received the vaccine and became infected can still carry the virus and pass it to other people around them.
- If you only received one dose of mRNA-1273 vaccine during the study, you might have some level of protection but likely not as much as those who received two doses. We have not fully studied how well the vaccine works with just one dose, and we think the best protection against becoming sick with COVID-19 starts about two weeks after receiving your second dose.
- Lastly, we do not know for how long our vaccine protects you from getting sick, which means your protection could wear off at any time, and we do not know when this might happen.

Therefore, even if you think you received the vaccine, we strongly encourage you to still follow all instructions from your study doctor and local guidance around limiting your exposure to the virus (e.g., social distancing, mask wearing, and hand-washing).

The study team is very thankful for your dedication to this study. Although we have learned a lot about this vaccine based on your contributions so far, your continued participation in the study will help provide additional scientific information that will benefit the general population in the future.

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 doses become available.

As an alternative to continued participation, you may be able to receive a COVID-19 vaccine outside the study based on the current recommendations by the government on populations that are prioritized to receive the vaccine. This will vary based on your status (e.g., age, occupation, and health status), as well as availability of any COVID-19 vaccines in your region. If you receive a COVID-19 vaccine outside of the study, you will not be able to continue your participation.

Your study doctor will be able to tell you specifically about the availability of COVID-19 vaccines under EUA in your local area. Your study doctor will also talk to you about options for receiving the mRNA-1273 vaccine (if you received placebo or only 1 dose of mRNA-1273) through your continued participation in this study.

Study Procedures

All participants were originally selected for this study because they were at high risk for exposure to the severe acute respiratory syndrome coronavirus 2 (SARs-CoV-2; the virus that causes the disease called COVID-19) and, in some cases, also at high risk for worse outcomes if they became sick with COVID-19. As we have shown the vaccine to be effective protecting people from getting sick with COVID-19, we are changing the design to offer participants options for continuing in the study based on this new information:

1. You can remain “blinded” (not know what treatment you received) and continue participation as originally planned.

2. You can request to be “unblinded,” which means learning if you received the mRNA-1273 vaccine or placebo and continue study participation.

If you choose option #1, we would like to collect an additional blood sample and nasopharyngeal swab at the time of this visit. The blood sample will be approximately 20mL (or about 4 teaspoons). You will then continue with your study visits as originally planned.

If you choose option #2, we would like to invite you to continue participation following the original study schedule with the potential for up to 3 extra clinic visits and 2 additional safety calls based on whether you received mRNA-1273 or placebo. We call this new set of study activities "Study Part B - Open Label," and it is completed in addition to your original plan of study procedures and visits. Details for each of the visits and what will occur at each visit are provided in the table below:

STUDY PART B – OPEN LABEL

Visit	When	What Will Be Done
Open Label Visit – Day 1	Completed for all participants	• Review updated study information as part of informed consent • Medication review and discussion of any changes in your health since your last study contact • Blood sample collection • 1 nasopharyngeal swab for SARS-CoV-2 testing • Unblinding (if you choose): You are told whether you received placebo or mRNA-1273. **Two-Dose mRNA-1273 Participants ONLY**: • Receive documented confirmation of vaccine receipt **Placebo or Single-Dose mRNA-1273 Participants ONLY**: • mRNA-1273 offered • Confirmation that you may receive vaccine after review of inclusion /exclusion criteria • Symptom-directed physical examination (including vital signs) • Pregnancy test • Study vaccination with mRNA-1273 • 30-minute observation after study vaccination
Open Label – Day 8 Safety Call	Safety call is performed approximately 8 days after the 1st study vaccination.	• Medication review and discussion of any changes in your health since the last visit, including presence of any COVID-19 symptoms

Visit	When	What Will Be Done
	(ONLY if mRNA-1273 Received at OPEN LABEL DAY 1)	
Open Label Visit – Day 29	Approximately 1 month after the first study vaccination (second study vaccination) **(ONLY if mRNA-1273 Received at OPEN LABEL DAY 1)**	• Medication review and discussion of any changes in your health since your vaccination • Symptom-directed physical examination (including vital signs) • Pregnancy test • Blood sample collection (*only for participants who get 1 dose of mRNA-1273 in Study Part B*) • Second study vaccination with mRNA-1273 (if previously received 2 placebo vaccinations) • 30-minute observation after study vaccination
Open Label – Day 36 Safety Call	Safety call is performed approximately 8 days after the 2nd study vaccination. **(ONLY if mRNA-1273 Received at OPEN LABEL DAY 29)**	• Medication review and discussion of any changes in your health since the last visit, including presence of any COVID-19 symptoms
Open Label Visit – Day 57	Approximately 2 months after the first study vaccination **(ONLY if mRNA-1273 Received at OPEN LABEL DAY 29)**	• Medication review and discussion of any changes in your health since your study vaccination • Symptom-directed physical examination (including vital signs) • Blood sample collection

If you find out you received two doses of mRNA-1273 vaccine, you only need to complete the Open-Label Day 1 activities as described in the above table. You will then continue to be followed in the study according to your original schedule. Your study doctor can also provide you documentation that you received the vaccine.

If you find out you have received placebo and your study doctor determines that you still meet the criteria for participation in the study, you will have the option to receive two doses of the mRNA-1273 vaccine, with each dose given approximately one month apart. When you receive your first dose you will be given a vaccination card to bring back when you return for your second dose. We ask that you then come back to the clinic for an extra visit about 1 month after the second dose to evaluate your health and collect a follow-up blood sample of

approximately 20mL (or about 4 teaspoons). After that visit, you will continue with the original study schedule for weekly eDiary prompts and monthly safety calls to monitor your health, including the presence of potential COVID-19 symptoms. If you have COVID-19 symptoms, you will have an illness visit for evaluation and a nasopharyngeal swab to test for the virus.

If you only received one dose of mRNA-1273 during the study for any reason your study doctor will offer you an opportunity to receive an additional dose if you meet criteria to receive mRNA-1273. You will follow the visit schedule above except you will not receive a second dose at the Day 29 visit and you do not need to complete the Day 36 phone call and Day 57 visit. You will still need to come to the clinic at Day 29 to be evaluated and have a blood sample drawn of approximately 20mL (or about 4 teaspoons).

If the additional visits (clinic visit or phone call) for the Study Part B overlap with already planned visits for the study, they may be combined and you will only have study procedures done once. Your study doctor can tell you if this will happen.

If you received placebo or only one dose of mRNA-1273 and you became sick with COVID-19 during the study, you are still eligible to receive mRNA-1273 in this new part of the study based on your study doctor's evaluation of your health. We do not know for sure, but we think there is the potential that the vaccine can provide you added protection, so this option is offered to you. The types and rates of side effects are similar between those participants who received the vaccine after being infected with the SARs-CoV-2 virus and those who had never been infected before they receive the mRNA-1273 vaccine.

You do not need to commit to receiving the vaccine to know what you originally received in the study. You may unblind and discover that you received placebo, but then decide not to receive the mRNA-1273 vaccine for any reason. This is okay and does not impact your ability to continue in the study. However, if you receive a COVID-19 vaccine outside of this study, you will not be able to continue in the study.

You will continue to be followed to your original end-of-study visit approximately 25 months after you originally entered the study and received either mRNA-1273 vaccine or placebo.

Is there a payment if you decide to participate in the Study Part B - Open Label period of the study?

You may be compensated for your time and effort in accordance with the visits and amounts listed in the consent you previously signed. Please discuss this with the study staff for more information.

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

  6940 Columbia Gateway Drive, Suite 110

  Columbia, MD 21046

- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00044270.

Conclusion

This Addendum does not replace the most recent version of the Informed Consent that you already signed. It simply adds updated information to it.

By signing this Addendum, you confirm that you received updated information about study mRNA-1273-P301, and you agree to continue taking part in the study.

As you have been told, taking part in this study is voluntary. This means that you can choose whether you want to continue in the study after receiving this updated information.

You can choose to stop being in the study at any time and for any reason. If you decide to stop taking part in the study, there will be no penalty and you will not lose any benefits you are supposed to receive. Choosing to no longer take part in the study will not affect the quality of the health care you are given.

Statement of Consent

- I have read and understand the statements in this Informed Consent Form Addendum.
- I have had the chance to ask questions, and I am satisfied with the answers given to me.
- I agree to continue taking part in this study of my own free will.
- I understand that I and/or my legal representative will receive a copy of this signed and dated Addendum.
- Based on the new information shared in this Informed Consent Addendum, I would like to continue in the study in the following manner (check the appropriate boxes):

☐ I wish to continue participation in the study and know my treatment assignment. (check one box below)

☐ If I find out that I received placebo, I wish to receive the mRNA-1273 vaccine.

☐ If I find out that I received placebo, I do not want to receive the mRNA-1273 vaccine.

☐ I wish to continue participation in the study without unblinding my treatment assignment.

☐ I do not wish to continue participation in the study and I wish to know my treatment assignment.

_____

Printed Name of Participant, in full

_____

Signature of Participant **Date (DD-Mmm-YYYY)**

- I have presented the study updates and answered the participant's questions.
- I will give the participant/legal representative a copy of this signed and dated Informed Consent Form Addendum.

_____

Printed Name of Person Obtaining Consent (Study Doctor/Delegate), in full

_____

Signature of Person Obtaining Consent **Date (DD-Mmm-YYYY)**

If required,

_____

Printed Name of Legally Authorized Representative or Legal Guardian (if participant is a minor), in full

_____

Signature of Legally Authorized Representative or Legal Guardian (if participant is a minor) ***Date (DD-Mmm-YYYY)***

If required,

_____

Printed Name of Impartial Witness, in full

_____

Signature of Witness **Date (DD-Mmm-YYYY)**

Informed Consent Form Addendum

INFORMED CONSENT FORM ADDENDUM V.2 25Mar2021

Note: Addendum V.2 25Mar2021 is for Participants that have not returned for their Participant Decision Visit or have previously had their Participant Decision Visit and chose not to be unblinded.

STUDY TITLE:	ModernaTX, Inc. / "A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older"
PROTOCOL NUMBER:	mRNA-1273-P301
CLIENT:	Moderna
STUDY DOCTOR:	[Investigator Name] [Site Address] [Office Hours Tel] [Out of Hours Tel]
ETHICS COMMITTEE or INSTITUTIONAL REVIEW BOARD:	[EC/IRB Name] [EC/IRB Address] [Office Hours Tel]

In the Informed Consent Form you signed and dated when you agreed to take part in this study, you were told that you would be informed if there was new or updated information about the study.

The purpose of this additional form called an addendum is to provide you with new information that has become known since the last Addendum that you signed.

This addendum includes the following updates:

In the Study Procedures section of the informed consent form (ICF), the Participant Decision visit in Part B of this study is still a key visit for Part B and is now important to complete as it is mandatory that you become unblinded during this visit to understand what you received in Part A (mRNA-173 or placebo). Therefore, at the Participant Decision Visit, you will be told if you received mRNA-1273 or placebo. However, the choice to receive mRNA-1273 (if you received placebo) is no longer an option because study vaccine is no longer available. At the Participant Decision visit you will have a nasopharyngeal swab and blood test, be unblinded, and then you will remain in the study and continue participation as originally planned.

Informed Consent Form Addendum

We would also like to inform you that at the time of the first database lock, we will unblind any remaining participants that have not been unblinded to confirm what they received in Part A of the study (mRNA-1273 or placebo). This information will be provided to your study site and your site will share the information with you if you have not previously received it.

Once you know your Part A treatment assignment, if you choose to receive a vaccine outside the study, you will need to be discontinued from the study.

This addendum does not replace the most recent version of the Informed Consent that you already signed. It simply adds updated information to it.

By signing this addendum, you confirm that you received updated information about study mRNA-1273-P301 and you agree to continue taking part in the study.

As you have been told, taking part in this study is voluntary. This means that you can choose whether or not you want to continue in the study after receiving this updated information.

You can choose to stop being in the study at any time and for any reason. If you decide to stop taking part in the study, there will be no penalty and you will not lose any benefits you are supposed to receive. Choosing to no longer take part in the study will not affect the quality of the health care you are given.

Informed Consent Form Addendum

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 Drive, 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: Pro00044270.

Informed Consent Form Addendum

Statement of Consent

- I have read and understand the statements in this Informed Consent Form Addendum.
- I have had the chance to ask questions, and I am satisfied with the answers given to me.
- I agree to continue taking part in this study of my own free will.
- I understand that I and/or my legal representative will receive a copy of this signed and dated Addendum.

_____

Printed Name of Patient, in full

_____

Signature of Patient **Date (DD-Mmm-YYYY)**

<PIFullName>

Informed Consent Form Addendum

- I have presented the study updates and answered the participants's questions.
- I will give the participant/legal representative a copy of this signed and dated Informed Consent Form Addendum.

_____

Printed Name of Person Obtaining Consent (Investigator/Delegate), in full

_____

Signature of Person Obtaining Consent **Date (DD-Mmm-YYYY)**

If required,

_____

Printed Name of Impartial Witness, in full

_____

Signature of Witness **Date (DD-Mmm-YYYY)**

<PIFullName>