INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR PARENT/LEGAL GUARDIAN OF PARTICIPANTS (Children 12 –17 years) AND FOR PARTICIPANTS REACHING THE AGE OF MAJORITY PARTICIPATING IN PART 3

Sponsor / Study Title:	**ModernaTX, Inc. / "A Phase 2/3, Randomized, Observer-Blind, Placebo-Controlled, Study to Evaluate the Safety, Reactogenicity, and Effectiveness of mRNA-1273 SARS-CoV-2 Vaccine in Healthy Adolescents 12 to < 18 years of age"**
Protocol Number:	**mRNA-1273-P203**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

If you are a participant reaching the age of majority, your parent/legal guardian previously signed and dated this consent. Since you are now of age, if you wish to continue participating in this study, you also need to read, sign, and date this consent. When "your child" appears in this form, it refers to you.

Your child is being invited to take part in a research study, sponsored by ModernaTX, Inc. (Moderna). Please read this 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:

- Your child's participation is voluntary, which means you can choose whether or not you want them to participate in the study. Your child may or may not benefit from participating in this study. Your child's participation may help others in the future as a result of knowledge gained from this study.
- If you choose to have your child take part in the study and then change your mind, your child will be free to leave the study at any time.
- If you choose not to have your child join the study, or if you decide to have your child leave the study, your child's future care and your relationships with your child's doctor or with the research center staff will not change.
- Being in this study does not replace your child's regular medical care.

This informed consent form explains the things you and your child will be asked to do before, during, and after this study. It also explains the risks and possible benefits of the study.

Please read this form carefully and ask any questions that might help you decide if you would like your child to take part in this clinical research study. If you decide that you want your child to take part in this study, you will be asked to sign and date this consent. A copy of this signed and dated consent form will be given to you to keep.

An Institutional Review Board (IRB) has reviewed this study to make sure that your child's rights and welfare are protected after your child joins this study. This committee will watch over this study while you are in it.

DISCLOSURE OF SPECIAL INTERESTS OF YOUR CHILD'S STUDY DOCTOR

The Sponsor of this study is a company named Moderna. This means that Moderna planned the study, is responsible for the products that will be tested, will collect and analyze the information gained in the study, and will pay for the study. The study doctors and study centers will be paid for conducting the study.

INFORMATION ABOUT THIS STUDY

WHAT IS THE DISEASE AND WHAT IS THE STUDY VACCINE?

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.

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

The mRNA-1273 vaccine containing the original SARS-CoV-2 virus strain was studied in thousands of people, including children down to the age of 6 months to determine if it is safe and effective at preventing COVID-19.

Approvals or authorizations have been issued in many countries for mRNA-1273 as 2-dose 100 µg primary series or as a 50 µg booster dose in individuals 12-17 years of age. Moderna variant-containing bivalent booster vaccines (mRNA-1273.214 and mRNA-1273.222) have also received approvals or authorizations in many countries for use in the adolescent population. On 11 September 2023, the U.S. Food and Drug Administration (FDA) approved Spikevax® (mRNA-1273.815) containing the updated form of the SARS-CoV-2 virus (XBB.1.5) for ages 12 years and above as a single dose regimen. Global regulatory filings for the updated COVID-19 vaccine have also been initiated.

Part 3 is testing a variant-containing vaccine, called the mRNA-1273.222 study vaccine, that targets 2 different forms of the SARS-CoV-2 virus (the original strain, called Wuhan-Hu-1, and Omicron BA.4/BA.5). It is given at a dose of 50 µg in 1 or 2 doses, 6 months apart, in individuals who haven't received any doses of COVID-19 vaccine before. The main purpose of this study is to understand if the bivalent mRNA-1273.222 can prevent people from getting infections due to different strains of COVID-19 and to understand the safety of the mRNA-1273.222 study vaccine in individuals from 12 to up to 18 years of age.

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-1273.222 study vaccine is intended to boost the immune system to produce enough antibodies against SARS-CoV-2 (the original strain called Wuhan-Hu-1 and the Omicron BA.4/BA.5) to ensure that in case of an infection, the virus does not cause illness.

The mRNA-1273.222 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-1273.222 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 study vaccine degrades naturally and does not persist in the body.

Why is this study being done?

Your child is being asked to take part in this study because the Sponsor of this study, Moderna, is studying a vaccine for the prevention of COVID-19 in children. The study vaccine is called mRNA-1273.222. This study is being conducted to learn about any side effects and how your child's body responds to the study vaccine (the "immune response").

Part 1 of this study has been completed, which includes Part 1A, Part 1B, Part 1C-1, and Part 1C-2. Part 2 and Part 3 are ongoing.

You are being asked to participate in Part 3 if you have not yet received a COVID-19 vaccination.

Approximately 300 participants will take part in Part 3 from up to 16 study sites.

Your child's immune response to the study vaccine will be measured by testing their blood for natural proteins called antibodies. These antibody levels help us to understand how well the study vaccine is working.

Your child's study doctor, the study staff, an IRB, and Moderna will closely evaluate your child's safety and the safety of others participating in this study.

From this point on, any references to the word "study vaccine" will mean mRNA-1273.222.

What will happen during the study?

Part 3 is an open-label study in healthy children, 12 years to less than 18 years of age.

Open-label: You and the study doctor will know the study treatment your child receives.

Part 3 participants in the United States of America are getting 1 dose (Day 1) of mRNA-1273.222 primary series (50 µg [micrograms]) or 2 doses (Day 1 and Day 180) 2 doses of mRNA-1273.222 6 months apart.

It was communicated to you previously, in a letter dated October 6, 2023, that due to new information, the study staff decided to hold the second dose of the study vaccine, as well as certain blood draws, clinic visits, virtual calls, and/or safety calls related to it. The decision has now been made not to provide the second dose and to provide an explanation of what changes will occur for the remainder of your participation.

Participants who receive 1 dose of mRNA-1273.222 in Part 3, will be in the study for approximately 6 months including 1 week for Screening, 1 day for dosing (Day 1), and 6 months of follow-up after Dose 1. You will have:

- Up to 7 clinic visits
- Approximately 1 virtual call (Visit 3/Day 8)
- Approximately 2 brief telephone calls:
    - Approximately 2 calls between Month 3 and Month 6
        - D99 = Call 1
        - D141 = Call 2
- There will be total of up to 5 blood draws (blood collections). During the study, blood draws will be performed at:
    - Day 1
    - Day 3*
    - Day 29
    - Day 85
    - Day 181

Participants who receive 2 doses of mRNA-1273.222 in Part 3, will be in the study for approximately 7 months including 1 week for Screening, 6 months for receiving the 2 doses of study vaccines and 1 month of follow-up after dose 2. You will have:

- Up to 9 clinic visits

- Approximately 2 virtual calls (Visit 3/Day 8, and Visit 9/Day 188)
- Approximately 2 brief telephone calls:
    - Approximately 2 calls between Month 3 and Month 6
        - D99 = Call 1
        - D141 = Call 2

There will be total of up to 7 blood draws (blood collections). During the study, blood draws will be performed at:

- Day 1
- Day 3*
- Day 29
- Day 85
- Day 181
- Day 184*
- Day 209

*Biomarker plasma and biomarker serum samples will be stored for potential future biomarker assessment (i.e., signs of inflammation and/or proteins in blood that can indicate heart damage or heart disease).

On the day of each study vaccination (approximately 30 minutes after injection) and for at least 6 days after, you will record your child's temperature and symptoms you might observe in an electronic diary (eDiary). Alternatively, if your child is capable of completing their own eDiary entries, they may do so, however if your child decides to be responsible for completing the eDiary on their own they must complete the eDiary entries for the entirety of their participation. You and your child will be trained on how to complete the diary. It is very important that you or your child enter the data into the diary. If you miss a day, you or your child will receive an electronic prompt.

Your child's health status will be checked at each clinic visit and reviewed during the telephone calls.

There may be times when in-person clinic visits are not possible due to travel restrictions or other limitations such as the COVID-19 pandemic. If so, the study doctor or a member of his or her study staff may ask to visit your home to perform the scheduled assessments.

WHAT WILL MY CHILD AND I BE ASKED TO DO?

Before any study tests and procedures are performed, you will be asked to read, sign, and date this consent form.

Signing and dating this consent form indicates that you understand your child's involvement in the study and the risks of participating in the study, and that you agree to have your child take part in the study.

The following activities will be done to make sure your child is able to take part in the study. There is also a table later in this form to show what happens at each visit. If you do not know these tests or want to know more, please ask your study doctor to explain.

These activities will also be used to evaluate your child's safety and the effect of the study vaccines. The procedures and activities that will be performed are described below:

- **Demographic and Medical History:** During your child's first clinic visit, you will be asked to provide information about your child's medical history. You may be requested to get medical records from your child's doctor(s). You will be asked about your child's vaccination history and all medications your child is currently taking and may have taken recently in the past. Also, during this visit, the study staff will collect demographic information including your child's age, sex, race, and ethnicity.
- **Physical Examination, Height, and Weight:** During several of the visits to the clinic, your child will be asked to give a physical examination, which may include check of head, neck, ears, eyes, nose, throat, chest, lungs, heart, glands, stomach, skin, muscles, nervous system, lymph nodes (part of the body that contain white blood cells, which fight infection) and others, if needed. Your child's height and weight will be measured, and their body mass index will be calculated.
- **Pregnancy Test:** If your child was assigned female at birth, a pregnancy test may be performed at the Screening Visit (Day 0) and before each study vaccine dose.
- **Vital Signs:** During several of the visits to the clinic, your child's heart rate (beat), breathing rate, blood pressure, and body temperature will be measured.
- **Blood Tests:** For Part 3, the total amount of blood collected from you during each visit will not exceed approximately 25 mL, which is slightly more than 5 teaspoons.

  Overall, a total of 125 mL, which is slightly more than 25 teaspoons, of blood will be collected over the 7 months of the study.

- **Nasal / Nasopharyngeal Swab:** During study visits or if your child becomes sick, your child may be asked to provide a nasal and/or nasopharyngeal swab. The swab is a method for collecting a test sample of nasal secretions from inside the nostrils or the upper part of the throat behind the nose to test for COVID-19. Your child may feel some discomfort. These swabs collected throughout the study will be sent to a laboratory for SARS-CoV-2 testing to see whether your child is infected. Results of the swabs will be shared with you when they are available.
- **Study Vaccination:** Your child will be given the mRNA-1273.222 study vaccine. After each study vaccination, you and your child will be asked to stay in the clinic for at least 30 minutes so that the study doctor or his/her study staff can observe whether your child has any immediate reactions to the study vaccine. While your child is being observed, the study staff will ask questions, measure vital signs,

and may physically examine your child. Before you and your child leave the clinic, the study staff will also provide you with instructions on when to return to the clinic and what you should do after you leave the clinic including:

- To call the study clinic if your child has a fever above 100.4°F/38°C.
- To call the study clinic if your child experiences any symptoms within 7 days of receiving the study vaccination that you observe as severe and/or symptoms for which your child receives medical care.

- **Electronic Diary (eDiary):** While you and your child are in the clinic on the day of study vaccination, you will be trained on how to complete the eDiary. Alternatively, if your child can complete their own eDiary entries, they will be trained to do so. You or your child will be asked to enter into the eDiary symptoms your child might experience after the study vaccination and certain information about your child's health into the eDiary. You or your child will be asked to make the first entry in the eDiary 30 minutes after injection before you leave the clinic. You or your child will make the next entry that same evening and for 6 days following the day of study vaccination. If your child has symptoms on Day 7, you or your child may be asked to continue making entries into the eDiary until the symptoms resolve. The eDiary will be accessed through an app on your phone or on your child's phone. The information you or your child enters the app will be captured in the study database and reviewed by the study staff. If you cannot or do not want to use your own device or your child's device, the study staff may be able to provide you with a device to take home for use during the study.

  <u>To fill out the electronic diary, you or your child will be asked to:</u>

  - Look at the place on your child's body where the study vaccine was received and measure specific reactions you may see.
  - Describe reactions that are sometimes seen after study vaccination.
  - Measure your child's temperature (a thermometer will be provided to you).
  - Write down any medications your child takes.
  - Describe any other types of reactions or illnesses that you may observe.

  The following items will be given to you to take home and you will use them to check your child's temperature and take any required measurements:

  - Metric Ruler: for measuring specific reactions
  - Thermometer: for measuring your child's temperature.

- **Home Visits:** This study consists 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 such as 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 visits will only take place on site at the clinic.

An unscheduled visit or convalescent (the gradual recovery of health and strength after illness or injury) visit may be necessary because of new or ongoing side effects, reaction issues or COVID-19 illness visits. Depending on the reason for the visit, a nasal swab sampling to ascertain the presence of SARS-CoV-2 and/or a blood sample may be collected as well as other clinical evaluations at the discretion of your child's study doctor.

Depending on the date you sign this informed consent form, it might mean that you are at a different stage of the study than what was explained earlier.

- If you are at a stage that needs more follow-ups, your study doctor will let you know if there are any extra assessments that need to be done.

If you are at a time point, when the follow-up period has been completed, your study doctor will ask you to return to the clinic to complete the study.

What happens to the samples collected from your child?

Your child's samples will be sent to the following laboratories to be tested for the response of his or her body's immune system to the study vaccines. You will not be told your child's specific results from these tests.

Name	Address
PPD Central Laboratory (NA/LA)	2 Tesseneer Drive Highland Heights, KY, 41076

Blood samples and nasal swab or saliva specimens obtained in the study will be labeled with your child's code, but not his or her name.

The samples will be stored in a freezer until the tests analyzing your child's immune response to the study vaccine are performed.

If you withdraw consent for your child to participate after the start of the study, all samples collected from your child up to that time will be stored and used for testing,

unless you request the collected samples be destroyed. By agreeing to have your child take part in this study, you agree that your child's blood samples may be used to measure your child's body's immune response to the mRNA-1273.222 study vaccine.

Any of your child's leftover blood or nasal swab samples may be used for future research after this study is over. 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 coronaviruses. The blood samples may be stored for up to approximately 20 years by the Sponsor.

Your samples will not be used for commercial profit. The future use of your child's blood samples may result in new discoveries that are important to the understanding of the vaccine(s) or disease.

The results of the study of your child's serum samples will be used for research purposes only and you will not be told the results of the tests.

During and after the study, you and your child will keep the right to have the samples destroyed if you contact your child's study doctor, as long as your child's samples are still coded and can be found. If your child leaves the study, your child's samples may not be destroyed. If you and your child want your child's samples to be destroyed, you will have to ask your child's study doctor. All the samples and test data collected before your child left the study will still be used for study purposes. After your child leaves this study, no new samples or test data will be taken from your child for the study.

What is expected from you and your child?

Having your child take part in this study is your choice. Taking part in a study can disrupt your and your child's daily life.

Please consider the time needed for study visits (possibly including travel away from home) and responsibilities when you are deciding to have your child take part in the study. Your responsibilities will include the following:

- Follow the instructions you are given by the study doctor
- Give correct and accurate information about your child's medical history and current conditions
- Tell the study doctor about any problems, medication changes, and vaccinations your child has during the study
- Your child should not eat or drink anything hot or cold 10 minutes before their oral temperature is taken
- Keep and attend all the study visit appointments
- Complete the electronic diary for the 7 days following each study vaccination, including the day of study vaccination

What will happen at the end of the study or if you stop your participation early?

Upon conclusion of the study or early withdrawal, the study staff may contact you and your child to follow-up on illnesses or conditions that were present when your child stopped participating in the study or may establish your child's survival status from public available sources including the internet or by trying to make contact up until resolution of the illnesses or conditions, unless the parent/legal guardian decline additional contact.

Your child's study doctor will also tell you if additional follow-up is needed and if you and your child need to visit the study site again. Your child will not be able to get study vaccine after the study is over.

Your child's study doctor and/or Moderna may also learn new information during the study that might make you want to stop your child from taking the study vaccine or leave the study. You will be told about the new facts. You can then decide if you want your child to still be in the study. If your child leaves the study, there will be no penalty and you and your child will not lose any benefits you are entitled to. Leaving the study will not affect the quality of the health care you or your child are given.

The study doctor may stop the study vaccine or end your child taking part in this study for any of the following reasons:

- Staying on study vaccine or in the study would be harmful for your child.
- If your female child becomes pregnant or is breastfeeding.
- Your child needs treatment that is not allowed in this study.
- Your child did not follow instructions about what to do in the study.
- The study is cancelled, or your child's study treatment group is stopped.

The study doctor will tell you the reason(s) why your child should stop being in the study.

OUR RIGHT TO STOP THE STUDY

The study doctors at the study site have the right to stop your child from taking part in this study if they determine that your child no longer qualifies to continue, that it would be dangerous for your child to continue, or if you do not follow the study procedures as listed in this consent form. Moderna may stop the study at any time.

BENEFITS AND RISKS

Are there any possible benefits of being in the study?

By receiving one or two 50 µg doses of the mRNA-1273.222 study vaccine as part of the study, your child may 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 study vaccine including the following:

- The study vaccine is not 100% effective, and a few people who have received the study vaccine have still gotten sick with COVID-19.
- The study 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 study 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-1273.222 study vaccine protects your child from getting sick, which means your child's protection could wear off at any time and we don't know when this might happen.
- Finally, we are still evaluating the immunogenicity of mRNA-1273.222 study vaccine against this new strain of the virus. Therefore, we strongly encourage you and your child to still follow all instructions from your study doctor and local guidance around limiting your child's exposure to the virus (such as, social distancing, mask wearing, and hand washing).

Information learned from the study may help other people in the future.

What are the potential risks and discomforts?

This is the first time that the investigational (study) vaccine, mRNA-1273.222 will be tested in children.

If you choose to have your child take part in this study, they 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 child's regular doctor.

The most common side effects seen in the first portion of this study, involving 3726 participants aged 12 years through 17 years of age who received at least one dose of 100 µg mRNA-1273 (N=2486) or placebo (N=1240) included the following:

- Pain, swelling or erythema (redness) at the injection site
- Headache
- Fatigue (tiredness)
- Muscle aches or pain
- Joint aches or pain
- Chills
- Swelling/tenderness of the lymph node under the arm on the side of study vaccination
- Nausea/vomiting
- Fever

Other side effects in clinical trials in adults that have been reported rarely (occurring in 1 person out of a thousand or even fewer than that) include the following:

- Swelling of the face in adult participants with a history of dermatological fillers
- Anaphylaxis and hypersensitivity (allergic reactions explained in detail below)
- Weakness or paralysis of facial muscles

Not every study participant experienced all 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 study vaccine and typically lasted for 2 to 3 days.

There is a very small chance that the mRNA-1273 study vaccine could cause a severe allergic reaction called “anaphylaxis”, shortly after study vaccination (within minutes to about one hour after receiving a dose). Symptoms of this reaction might include wheezing, difficulty breathing, a fast heartbeat, sweating, a bad rash all over your child’s body, dizziness, weakness, fainting, or swelling of your child’s face and throat or eyes.

If your child has a known allergy or has had an allergic reaction after being vaccinated or to other medicines in the past, you must tell the study doctor or study staff before you decide to sign and date this informed consent form. If your child has an allergy to some products, he or she will not be able to take part in this study. Serious allergic reactions can be life-threatening.

Another very rare side effect after vaccination with mRNA-1273 is inflammation of the heart (myocarditis) or inflammation of the lining around the heart (pericarditis). Myocarditis or pericarditis have been reported mostly in young males, 18 through 24 years of age. The conditions mostly occurred within 7 to 14 days after receiving study vaccine and more often following the second dose, but cases have been reported in older males and in females as well, and also following the first dose. In this study, one child experienced symptoms of chest pain which could have been due to myocarditis. The symptoms got better after about a week, and there were no signs of any heart problems 5 months after the event.

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. If your child experiences any of these symptoms following vaccination, you should seek medical attention with your child and notify study staff.

While some severe cases have been reported, including some cases requiring intensive care support and fatal cases, most cases are mild and have been associated with full resolution of symptoms within a few days or weeks. However, long-term follow-up is limited in terms of whether there are sides effects we don’t know about. It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of the study vaccine (for example, following a third/booster dose) although some information indicates that this is not the case.

In previous studies with the mRNA-1273 study vaccine, a small number of adult participants experienced Bell’s palsy, a form of facial paralysis that recovers over time. This occurred slightly more often in the group that received mRNA-1273 compared to the group that received placebo (an inactive substance). It is unclear if mRNA-1273

causes this form of facial paralysis. Facial swelling was also seen after mRNA-1273 injection in a small number of adult participants who had a history of receiving cosmetic skin fillers.

Brief increases in some laboratory tests were noted in previous clinical studies with similar vaccines in adults. These increases were observed without physical symptoms or signs and returned to near baseline levels. 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.

Additional side effects that may occur are:

- Tenderness at the injection site
- Allergic reaction to the study vaccination
- Fainting triggered by anticipation of or pain from the injection

If your child experiences emotional stress from participating in any part of the study, such as struggling to keep the study visit schedule or if he or she have any side effects listed above, you should tell the study doctor. Some of the questions we will ask you about your child as part of this study may make you feel uncomfortable. Your child may stop taking part in the study at any time.

Your child will be monitored for the risks and side effects throughout his or her participation in the study. You should contact the study doctor if you think your child is having side effects or experiencing a change in his or her medical condition.

Blood Samples

Taking a blood sample involves insertion of a needle into your child's arm and withdrawing blood.

Your child may be offered a numbing cream before the collection of blood samples, if available with your study doctor, but this is not guaranteed. Your child may have pain, redness, irritation, or bleeding where the needle is inserted, and some people may have a brief feeling of faintness.

Your child may have pain or bruising for up to a few days where the needle was inserted after the blood draw. There is a rare possibility of infection where the needle is inserted.

Nasal Swabs:

During the collection of swabs, your child may feel some discomfort. Your child may also experience watery eyes, coughing, sneezing, or bleeding during or after the swab.

Unknown Risks

Your child may experience some side effects that have not been experienced before. This could be an allergic reaction or interaction with another drug. Medical treatment will be given to your child in case of an allergic reaction to the study vaccine. It is important that you tell the study doctor about any changes in your child's health.

Are there any reproductive risks?

Participants assigned female at birth: It is not known if the study treatment may affect an unborn child or nursing infant. For this reason, if your child is breastfeeding, pregnant or plans to become pregnant, they may not participate in this study.

- Participants of nonchildbearing potential may be enrolled in the study. Nonchildbearing potential is defined as premenarche (has not started menstrual periods), or surgically sterile [history of bilateral tubal ligation (tubes tied), bilateral oophorectomy (both ovaries removed), hysterectomy (uterus removed)].
- Participants of childbearing potential may be enrolled in the study if the participant fulfills all the following criteria:
    - Has a negative pregnancy test at Screening (Day 0), on the day of the first injection (Day 1), and on the day of the second injection (Day 181) to rule out pregnancy before receiving the study vaccine, or at any point as deemed necessary by the study doctor or staff.
    - Has practiced effective contraception or has abstained from all activities that could result in pregnancy for at least 28 days prior to the first injection (Day 1).
    - Has agreed to continue effective contraception or abstinence through 3 months following the last study vaccination dose.

Effective contraception is defined as consistent and correct use of an approved contraception method, for example:

- Condoms (male or female) with spermicide, diaphragm with spermicide, cervical cap with spermicide
- Intrauterine device (IUD)
- Oral or patch contraceptives, Nexplanon, Depo-Provera, or other approved contraceptive method that is designed to protect against pregnancy

Your child can also agree to practice abstinence from the start of the study through 3 months following the last study vaccination dose. Withdrawal is not an acceptable method of contraception. You and your child should discuss with the study doctor the proposed method of birth control to ensure they understand all the options and how to be consistent and compliant with the agreed upon method.

Pregnancy: If your child becomes pregnant during their participation in the study, their participation in the study may be stopped. However, information about their pregnancy, its outcome, and the health of the child after birth will be collected. It is important that

you tell the study doctor immediately if your child or your child's partner become pregnant during the study. The study doctor will talk with you and your child about what you should do.

Are there any other treatments?

Having your child take part in this study is your choice. Your other option is not to have your child take part in this study. If you decide to opt out of the study, you also have the option to have your child receive an alternative authorized/approved COVID-19 vaccine for use in people aged 12 years and older. Your study doctor will explain the risks and benefits of these other treatments before you decide if you want to take part in the study.

WHAT IF THERE IS NEW INFORMATION ABOUT THIS STUDY TREATMENT DURING THIS STUDY?

The 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 child's participation.

COSTS AND COMPENSATION FOR STUDY PARTICIPATION

Are there any costs if you decide to take part in the study?

There will be no charge to you for your child's participation in this study. The study vaccine, study-related procedures, and study visits will be provided at no charge to you or your child's insurance company. You or your child's insurance company may be billed for any standard medical care that is not required for the study.

Will you receive any payment if you take part in the study?

«Compensation»

You will be paid up to a total of $xx.xx if you complete this study. You will be paid for the visits you complete according to the following schedule:

- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid _____ ***["after each visit," "annually," "bi-weekly," etc.]***

If you have any questions regarding compensation for your child's participation, please contact the study staff at the telephone number listed on the first page of this consent form.

Will your child receive compensation for injury resulting from the study?

If your child becomes sick or injured as a direct result of a study procedure or properly administered study vaccine, get the medical care that your child needs right away. You should also 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 your child. 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, the study doctor, or the study site. 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 your child like name, date of birth, and Medicare Beneficiary Identifier. 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 someone 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-1273.222 used in this study.

Participants using mRNA-1273.222 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 participant's right to sue do not apply in the case of willful misconduct resulting in death or serious bodily injury.

CONFIDENTIALITY

What happens to the data collected about your child?

The information below explains how your child's health records and the study data we get from the samples collected from your child during the study may be used and shared with others.

Persons working on the behalf of Moderna such as the study staff at the study clinic and under certain circumstances, the U.S. FDA and the IRB (Institutional Review Board) will be able to inspect and copy confidential study-related records which identify your child by name.

If the results of this study are published or presented at meetings, your child will not be identified by name.

There is a possibility that information that identifies your child will be given to the study site's oversight officials or to officials of the Department of Health and Human Services and the U.S. FDA. This information may be used for audits or evaluations, or to ensure that research work is being done correctly. If this should happen, these officials are also obliged to protect your child's privacy.

Your child's private health information will be kept confidential. To the extent permitted by the applicable laws and/or regulations it will not be shared without your permission. However, it is possible that your child taking part in this study could result in this occurring.

All study data, including your child's coded medical information, will be sent to the study Sponsor. This data may be used for purposes of the study and may be used and shared for future pharmaceutical research and development purposes.

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. The blood samples may be stored for up to approximately 20 years by the Sponsor or designee.

Finally, the study staff at the study site can take steps, including reporting to authorities as required by law, to prevent serious harm to your child or others.

If this does happen, it could create a problem for you or your child depending upon what kind of information is shared. In some situations, you could be at risk for problems with the law, your financial standing, your child's health care, your job or your child's schooling, or your child's ability to get access to health care or other insurance.

If you tell your child's regular doctor about your child taking part in this study, it is possible that it could be written in your child's medical record, and an insurance company might think that it means that your child may be at risk for a certain condition. If this should happen, it might hurt your child's ability to get health care or other insurance.

All study staff with access to your records are required to keep your data private.

While evert effort will be made to protect the confidentiality of your child's information, absolute confidentiality cannot be guaranteed.

Risks to confidentiality and privacy

As part of this study, you and your child will need to use the Medidata's Patient Cloud Application. You and your child may be asked to download the app to your smartphones or researchers may provide you and your child with an eDiary device. To use the app, you and your child will be asked to agree to the Terms of Use and Privacy Policy, which will appear on your mobile device's screen when you and your child first start using the app. If you and your child decide that you do not want to agree, then your child should not participate in the study.

While using the app, data about you and your child including personal health information, other communication data, and internet usage will be collected and transmitted to the researchers and to the app developer. A complete description of this data collection and sharing is found in the Privacy Policy. Transmission of information

via the internet is not completely secure, so there is a small risk of unintentional release of your information and safeguards are in place to protect your personal information.

While the Terms of Use may include statements limiting your rights if your child is harmed in this study, you do not release the study doctor, Sponsor, institution, or agents from responsibility for mistakes, and these statements do not apply to the use of the app in this study.

What if you change your mind and do not want your data to be used or disclosed?

You may choose to not have your child take part in this study at all. If your child begins the study, you may stop having him or her take part for any reason without penalty or loss of benefits to which your child is otherwise entitled and without any effect on your child's future medical care.

If you decline further study vaccination for your child after the first dose, your child will be asked to continue safety visits/calls until approximately 6 months after his or her first study vaccination. If your child leaves the study early, we may ask for your child to have some final testing for his or her safety.

If your child leaves the study early, data obtained while your child was in the study may still be kept with other data obtained as part of the study. No new data will be obtained for the study unless you clearly agree to that.

Will information about this study be publicly available?

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.

After this study is over, a brief report of the overall results will be prepared for the general public. The study results may also be shared with scientific journals and the scientific community. Whenever the results of the study are shared or published, your identity will remain private.

CONTACTS

Whom to contact about this study

During the study, if your child experiences any medical problems, suffers a research-related injury, or if you 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 for your child, or hospitalization is required, alert the treating physician that you are participating in this study.

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

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

Please reference the following number when contacting the Study Subject Adviser: Pro00047942.

APPENDIX 1: TABLE OF STUDY EVENTS

The detailed description of procedures for each study visit, virtual visit, and phone call are presented below:

Part 3

Visit	Who	When	What will be done
Screening (In clinic)	All participants	Before your child receives study vaccination (may occur on same day as Day 1)	• Informed consent and assent • Confirmation that your child may participate in the study • Medical history review • Demographic data • Medication review • Physical examination • Vital signs (including height & weight) • Pregnancy testing (if applicable)
Day 1 (In clinic)	All participants	Within 7 days of Screening (may occur on same day as Screening)	• Confirmation that your child may participate in the study • Physical examination and vital signs (including height & weight) • Pregnancy testing (if applicable) • Blood sample for study vaccine immunogenicity • Nasal swab sample for SARS-CoV-2 • Receive the first study vaccination • 30-minute observation after study vaccination • Surveillance for COVID-19 • Instruction from study staff on how to complete the electronic diary (eDiary) • eDiary activation and completion of first eDiary entry • Recording of adverse events (side effects) • Medication review

Visit	Who	When	What will be done
Day 3 (in clinic)	All participants	3 days (-2 days) after the first injection	• Blood sample for biomarker analysis • Surveillance for COVID-19 • Recording of adverse events • Medication review
Day 8 (virtual visit)	All participants	7 days (+3 days) after the first study vaccination	• Surveillance for COVID-19 • Review eDiary data • Recording of adverse events • Medication review
Day 29 (in clinic)	All participants	28 days (+7 days) after the first study vaccination	• Physical examination and vital signs (including height & weight) • Nasal swab sample for SARS-CoV-2 • Blood sample for study vaccine immunogenicity • Surveillance for COVID-19 • Recording of adverse events • Medication review
Day 57 (in clinic)	All participants	56 days (+3 days) after the first study vaccination	• Surveillance for COVID-19 • Recording of adverse events • Medication review
Day 85 (in clinic)	All participants	84 days (+7 days) after the first study vaccination	• Blood sample for study vaccine immunogenicity • Nasal swab sample for SARS-CoV-2 • Surveillance for COVID-19 • Recording of adverse events • Medication review

Day 99 to Day 141
(phone call)
	All participants	Every 6 weeks (±3 days) between month 3 and month 6	• Safety follow-up phone call to capture:
			  ○ Surveillance for COVID-19
			  ○ Recording of adverse events
			  ○ Medication review

Visit	Who	When	What will be done
Day 181 (in clinic)	Participants receiving 2 doses	180 days (+7 days) after the first study vaccination	• Physical examination and vital signs (including height & weight) • Pregnancy testing (if applicable) • Receive the second study vaccination • 30-minute observation after study vaccination • Blood sample for study vaccine immunogenicity • Nasal swab sample for SARS-CoV-2 • Surveillance for COVID-19 • eDiary activation and completion of first eDiary entry • Recording of adverse events • Medication review
Day 181 (in clinic)	Participants receiving 1 dose	180 days (+7 days) after the first study vaccination	• Physical examination and vital signs (including height and weight) • Blood sample for study vaccine immunogenicity • Nasal swab sample for SARS-CoV-2 • Surveillance for COVID-19 • Recording of adverse events • Medication review
Day 184 (in clinic)	Participants receiving 2 doses	3 days (-2 days) after the second study vaccination	• Blood sample for biomarker analysis • Surveillance for COVID-19 • Recording of adverse events • Medication review
Day 188 (virtual call)	Participants receiving 2 doses	7 days (+3 days) after the second study vaccination	• Surveillance for COVID-19 • Review eDiary data • Recording of adverse events • Medication review

Visit	Who	When	What will be done
Day 209 (in clinic)	Participants receiving 2 doses	28 days (+7 days) after the second study vaccination	• Physical examination and vital signs (including height & weight) • Nasal swab sample for SARS-CoV-2 • Blood sample for study vaccine immunogenicity • Surveillance for COVID-19 • Recording of adverse events • Medication review

STATEMENT OF CONSENT

- I have read and understand the statements in this informed consent form.
- I have had the chance to ask questions, and I am satisfied with the answers given to me.
- I understand that this study may only be performed by collecting and using my child's health data. Therefore, by signing this form, I specifically give permission for my child's data to be checked, transferred, and processed as follows:
    - The authorized representatives of Moderna, the institutional review board, and inspectors for regulatory authorities may review my child's health data by directly accessing my child's health records.
    - Study data, including my child's coded health data, may be used and shared for legitimate study and scientific purposes.
- I agree to have my child take part in this study of my child's own free will.
- I understand that I will receive a copy of this signed and dated written informed consent form.

Printed Name of Participant, in full

Signature of Participant **Date (dd-Mmm-yyyy)**

- I have presented the study and answered the participant's questions.
- I will give the participant/parent(s) or legal guardian a copy of this signed and dated informed consent form.

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

Signature of Person Obtaining Consent **Date (dd-Mmm-yyyy)**

Printed Name of Parent(s)/ Legal Guardian(s) (if participant is a minor), in full

Signature of Parent(s)/ Legal Guardian(s) (if participant is a minor) **Date (dd-Mmm-yyyy)**

FOR CHILDREN WHO BECOME ADULTS

I have been told that my parents/legal guardian agreed for me to participate in this study as a minor. I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to continue to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

Participant's Printed Name

Participant's Signature Date

Printed Name of the Person Conducting the Consent Discussion

Signature of the Person Conducting the Consent Discussion Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

The following sections provide a specific description of how your child's information will be used and disclosed if he or she participates in this research study. By signing and dating this form, you are authorizing such access. If you do not sign and date this form to authorize access, your child will not be able to participate in this research study.

This research study may be performed only by collecting and using your child's medical information. Your child's study records will be kept as confidential as possible. Only a number and your child's initials will be used to identify your child. Your child 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 child's study records cannot be kept completely confidential. The Sponsor of this study is ModernaTX, Inc.

The study staff, the Sponsor, its agents and PPD will need to review the medical information collected from your child for use in this study in order to accurately record information for this study. In addition, in order to review the study findings, the FDA, the IRB, and other regulatory agencies may review your child's medical records.

The medical information that will be collected from your child if he or she participates in the study includes:

- Information obtained from procedures to determine your child's eligibility to participate in the study, including a routine medical history, physical examination, and blood and urine tests.
- Information that is created or collected from your child during his or her 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 child's underlying medical records related to his or her medical history and treatment.

The above information may identify your child 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 your child participates in the study, the study staff will be authorized to use the information described above to carry out the purposes of the research study. The study staff will also be authorized to disclose the relevant information described above to the following parties involved in the research study:

- Moderna, PPD or other agents designated by Moderna, to collect or review study data for verification of study procedures and/or adverse event (bad side effect) reporting.
- The IRB that oversees the research study at your site.
- Government regulatory agencies including the FDA.
- Clinical trial recruitment company, if your child was referred to the study by such a company, for analytical purposes and so they may be compensated.

Once your child's information is disclosed to the study sponsors, its agents, the IRB or government agencies as described above, there is a potential that your child's medical information will be re-disclosed and will no longer be protected by US federal privacy regulations. In addition to disclosures to the entities identified above, PPD may further electronically disclose your child's 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 plans.
- To approved offsite storage facilities or cloud service providers to meet study record retention and storage requirements.
- To study Sponsor Moderna, who directs the medical research studies.
- To other third parties contracted by PPD and/or Moderna, 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 state where your child lives may provide further protection.

While the study is in progress, your access to your child's study records will be temporarily suspended. You will be able to access your child's information when the research study is completed.

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

Study data, including your child's coded medical information, may be used and shared by the Sponsor. This authorization does not have an expiration. In California and any other state that requires and expiration date, this authorization expires 50 years from the date this form is signed.

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. You have the right to require that any previously retained samples are destroyed. 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 your child may suffer are documented and reported. To complete the study findings, your child's long-term health status may also be obtained from public sources.

I understand that I have the right to refuse to sign and date this authorization, which will result in my child's inability to participate in the study. You will receive a copy of this authorization after you have signed and dated it.

Printed Name of Participating Child

Printed Name of Parent/Legal Guardian

Relationship to Participating Child

Signature of Parent/Legal Guardian

Date

FOR CHILDREN WHO BECOME ADULTS

I have been told that my parents/legal guardian agreed to the use and disclosure of my Protected Health Information as outlined in this document. I have read and understand the information in this authorization. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I continue to authorize the use and disclosure of my Protected Health Information. I will receive a copy of this signed and dated authorization.

Participant's Printed Name

Participant's Signature

Date