INFORMED CONSENT FORM FOR PARENT/LEGAL GUARDIAN OF PARTICIPANTS (Children 6 months to less than 12 years) AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Note: Only newly enrolled participants or re assenting participants on Part 1 & 2 opting for the booster will need to sign this form.

Sponsor / Study Title:	**ModernaTX, Inc. / "A Phase 2/3, Three-Part, Open-Label, Dose-Escalation, Age De-escalation and Randomized, Observer-Blind, Placebo-Controlled Expansion Study to Evaluate the Safety, Tolerability, Reactogenicity, and Effectiveness of mRNA-1273 SARS-CoV-2 Vaccine in Healthy Children 6 Months to Less Than 12 Years of Age"**
Protocol Number:	**mRNA-1273-P204**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

INTRODUCTION

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

- Your child's participation is voluntary, which means that 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 relationship with your child's regular doctor or with the research center staff will not change.
- Being in this study does not replace your child's regular medical care.

This form explains the things you and your child will be asked to do before, during and after the 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 form. A copy of this signed and dated consent form will be given to you to keep.

DISCLOSURE OF SPECIAL INTERESTS OF YOUR CHILD'S STUDY DOCTOR

The Sponsor of this study is a company named ModernaTX. This means that ModernaTX 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.

WHAT IS THE DISEASE AND WHAT IS THE VACCINE?

Coronaviruses (CoV) are a large family of viruses that cause illnesses ranging from cold-like illnesses to more severe diseases. These include Middle Eastern Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS).

An outbreak caused by the 2019 novel coronavirus known as SARS-CoV-2 began in Wuhan, Hubei Province, China in December 2019. It spread throughout China and the world, including the United States and Canada. It has been declared a global pandemic by the World Health Organization. The illness caused by SARS-CoV-2 is called COVID-19.

Vaccines prepare your immune system to fight infection and prevent illness. Certain cells of the immune system produce antibodies (special proteins) that recognize viruses and prevent them from causing sickness. The mRNA-1273 study vaccine is intended to boost the immune system to produce SARS-CoV-2 antibodies. Then, after exposure to SARS-CoV-2, antibodies may prevent the SARS-CoV-2 virus from making your child sick.

The mRNA-1273 study vaccine is made using a new method that allows for much faster vaccine production than older methods. Typical vaccines for viruses are made from a weakened or killed virus. 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 set of instructions that tell cells how to make a protein. This mRNA is made entirely in a laboratory. When injected into the body, the mRNA in the study vaccine causes some cells to make the spike protein found in SARS-CoV-2. This then triggers an immune response. If the person is later infected by SARS-CoV-2, their immune system remembers the protein from the prior vaccination. This could help the body to fight the invading virus. The mRNA study vaccine is degraded by the body naturally. It does not persist.

To date, over 30,000 adults and 1,500 children older than 12 years have received at least 1 dose of mRNA-1273 since March 2020 in 4 other ongoing clinical trials. This study will now help us understand if the mRNA-1273 study vaccine can protect children from 6 months to less than 12 years of age from getting infected with the SARS-CoV-2 virus or getting sick from it.

On 23 August 2021, the Pfizer-BioNTech COVID-19 vaccine, Comirnaty, was approved by the United States Food and Drug Administration (FDA) for the prevention of COVID-19 disease in individuals 16 years of age and older. On 26 October 2021, the same vaccine received emergency use authorization at a lower dose for children 5 to less than 11 years of age but is still investigational for individuals less than 5 years old. The Moderna mRNA-1273 vaccine, SPIKEVAX, has been approved by the FDA on the 31 January 2022 for adults 18 years of age or older. The mRNA-1273 vaccine is investigational, which means it has not been approved for children ages 6 months to less than 12 years old by the FDA for use outside of research studies like this one.

This study is testing the mRNA-1273 study vaccine at a dose of 10, 25, 50, or 100 micrograms (µg) in children ages 6 months to less than 12 years old. The main purpose of this study is to understand the safety and immune response of the mRNA-1273 study vaccine and if it can prevent COVID-19.

This study is being conducted during an ongoing pandemic resulting in SARS-CoV-2 infection (COVID-19) in children as well as adults. If the FDA approves the mRNA-1273 study vaccine for emergency use in children, as they have in adults, the study will allow those in the placebo group to receive mRNA-1273 and those who received a lower dose of mRNA-1273 to be given a booster/third dose with the optimal dose for the given age group. If the FDA approves another COVID-19 vaccine before mRNA-1273 is approved for emergency use in children, those in the placebo group may withdraw from the study and seek the alternative vaccine or receive the mRNA-1273 study vaccine with the dose being tested for the given age group.

WHAT IS THIS STUDY ABOUT?

Your child is being asked to take part in this study because the Sponsor of this study, ModernaTX, is studying the mRNA-1273 vaccine for the prevention of COVID-19 in children. This study is being conducted to learn about the safety, any side effects, and how your child's body responds to the study vaccine (the "immune response"). Your child's immune response to the study vaccine may be measured by testing their blood for antibodies. Further, antibody levels after the third or booster dose will be measured and compared to antibody levels in young adults.

The mRNA-1273 study vaccine is fully licensed by the U.S. FDA for adults ages 18 and older. At this time, this study vaccine can only be given to people under the age of 18 years in research studies in the United States and Canada. It is being tested before it can be approved by health officials for widespread use in children. It has been approved for Emergency Use Authorization in children 6 to 11 years old in Australia and in the European Union. Information from this study will be shared with the FDA.

Your child's study doctor, the study staff, an independent committee called an institutional review board (IRB), and ModernaTX will closely evaluate your child's safety and the safety of others participating in this study.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?
Approximately 13,575 children will take part in this study from approximately 75 to 100 study sites. If the target number of participants have already started the study when your child is ready to start, the study site can cancel your child's participation without your consent.

WHAT HAPPENS IN THE STUDY?
This is a three-part, open-label, dose-escalation, age de-escalation and randomized, observer-blind, placebo-controlled study in healthy children, 6 months to less than 12 years of age.

Open-Label: If your child is enrolled during the open-label part of the study, they will be given the mRNA-1273 study vaccine. The study doctor will be able to tell you which dose your child will receive.

Dose-Escalation: The study will start with a lower dose of the study vaccine. Once it is determined to be safe and tolerable, the study may move on to a higher dose level.

Age De-Escalation: The study will be done first in the older age group and then move on to the lower age groups.

Randomized: Your child will be assigned by chance (like flipping a coin) to receive the investigational mRNA-1273 study vaccine or placebo. You will not be able to choose the study vaccine group to which your child will be assigned.

Observer-blind: Neither you, your child, nor the study doctor will know if your child receives the investigational mRNA-1273 study vaccine or placebo. Only the persons who prepare and give the injection will know what your child receives. However, the study doctor will be able to find out in an emergency.

Placebo-controlled: If your child is randomized to receive placebo, it will be given to him or her the same way as the study vaccine, but it does not contain active vaccine. The placebo used in this study will be salt water. Placebos are used to help us understand the true effects of the mRNA-1273 study vaccine.

The study will enroll approximately 13,575 children aged 6 months to less than 12 years. The study is divided into 3 parts. Parts 1 and 2 will be divided into 3 age groups. The 3 age groups are as follows:

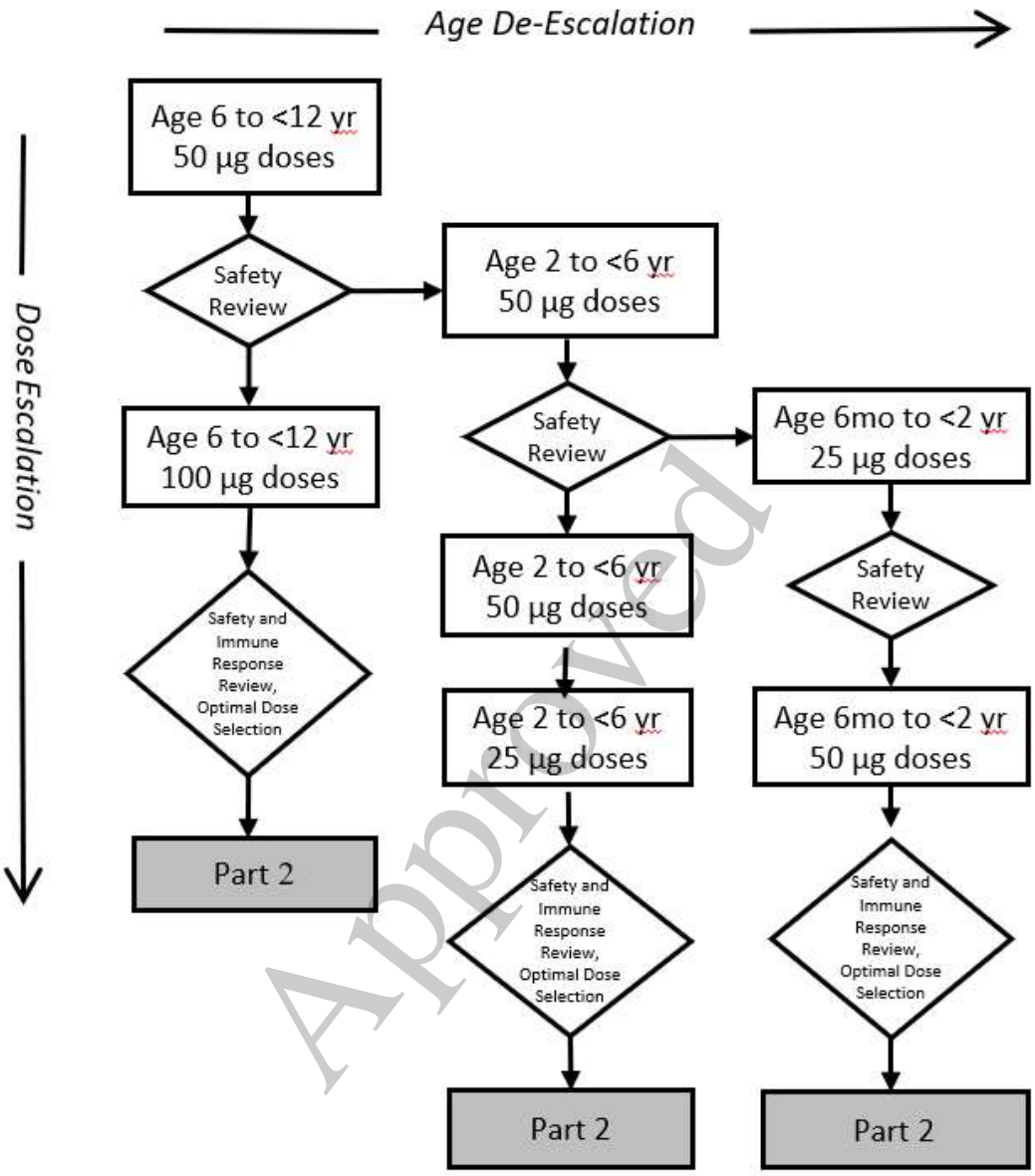
- 6 years to under 12 years
- 2 years to under 6 years
- 6 months to under 2 years

Part 3 will enroll one age group: 6 years to under 12 years.

The purpose of Part 1 is to identify the optimal (safest and most effective) dose level for each age group. Part 1 is an open-label, dose-escalation, age de-escalation, study. This means that all participants will receive 2 doses of the mRNA-1273 study vaccine about one month apart, and the first participants may receive a lower dose of the study vaccine than later participants. In addition, an optional booster dose will be offered to all participants in Part 1 (all age groups) of this study, at least 6 months after their second dose. 1,128 children participated in Part 1. For each age group, a team will review the safety data of the lower dose before proceeding with a higher dose. Also, lower age groups will not begin the study until a team reviews initial safety data of older age groups.

The purpose of Part 2 is to study the optimal (safest and most effective) dose from Part 1 to see how well it works to prevent COVID-19. Part 2 is a placebo-controlled, observer-blind study. This means that participants will be given 2 doses of the mRNA-1273 study vaccine or 2 doses of placebo. The probability of your child receiving the active study vaccine is 3 out of 4 chances. The 2 doses will be administered about one month apart. The study team will be able to tell you which dose level was selected in your child's age group for Part 2, but you and your child and the study doctor will not know which one (vaccine or placebo) has been administered. An optional booster dose will be offered to all participants ages 6 to 12 years old in Part 2 at least 6 months after their second dose. Approximately 12,000 participants will participate in Part 2.

The purpose of Part 3 is to study a lower dose of mRNA-1273 for the oldest age group. mRNA-1273 will be given as 2 doses open-label followed by a third dose. The 2 doses will be administered a month apart and the third dose will be given 3 to 5 months after the second dose. Approximately 300 participants will participate in Part 3.



Part 3, Arm 14:
6 to < 12 years; N = up to 300; mRNA-1273 - 25µg

*Subcohort F only
**Subcohort G only

Part 1 (Total of 1,275 participants to receive study vaccine)

	Age Group	Dose Level (# participants)	Dose schedule
1	6 years to less than 12 years	Arm 1: 50 µg (micrograms) (375 participants) or Arm 2: 100 µg (375 participants) Arm 1 and 2: Booster Dose: 25 µg (optional)	Day 1 and 29
2	2 years to less than 6 years	Arm 3: 50 µg (75 participants) or Arm 4: 100 µg (75 participants) or Arm 7: 25 µg (75 participants) Arms 3, 4 and 7: Booster Dose: 10 µg (optional)	Day 1 and 29
3	6 months to less than 2 years	Arm 5: 25 µg (150 participants) or Arm 6: 50 µg (150 participants) Arm 5 and 6: Booster Dose: 10 µg (optional)	Day 1 and 29

Part 2 (Total of approximately 12,000 participants to receive study vaccine or placebo 3:1 ratio)

	Age Group	Dose Level (# participants)	Dose schedule
1	6 years to less than 12 years	Selected dose level (50 µg or 100 µg) (3,000 participants) or placebo (1,000 participants) Booster Dose: 25 µg (optional)	Day 1 and 29
2	2 years to less than 6 years	Selected dose level (25 µg or 50 µg) (approximately 3,000 participants) or placebo (approximately 1,000 participants)	Day 1 and 29
3	6 months to less than 2 years	Selected dose level (25 µg or 50 µg) (approximately3,000 participants) or placebo (approximately 1,000 participants)	Day 1 and 29

Part 3 (Total of approximately 300 participants to receive study vaccine)

	Age Group	Dose Level (# participants)	Dose schedule
1	6 years to less than 12 years	Selected dose level (25 µg) (approximately 300 participants) Three doses	Day 1 and 29 followed by third dose 4 months after Dose 2

All participants will be in the study for approximately 17 months (without booster dose) or approximately 24 months (with booster dose). Depending on your child's enrollment assignment, he/she will have up to 8 clinic visits, approximately 3 telemedicine visits, and approximately 11 brief telephone calls. Participants enrolled in selected sites will have an additional clinic visit on Day 43. For participants with a booster dose, up to 4 clinic visits, and 7 brief telephone calls.

Participants in Part 1, without a booster dose, will have up to 4 blood draws (blood collection). During the study, blood draws will be performed at the Day 1, Day 57, Month 7 (Day 209), and Month 13 (Day 394) visits. For participants with a booster dose, up to 4 additional blood draws may be required.

Participants in Part 2, without a booster dose, will have up to 4 blood draws (blood collection). Participants in each age group will be divided into 5 cohorts. During the study, blood draws will be performed at the Day 1, Day 29, Day 30, Day 43, Day 57, Month 7 (Day 209), and/or Month 13 (Day 394) visits depending on your child's cohort assignment or if your child is enrolled at a selected study site. No child will be scheduled for more than 4 blood draws as part of the study, unless they receive a booster dose. Your study team will be able to tell you which cohort your child will be in at the time of study enrollment. For participants with a booster dose, up to 4 additional blood draws may be required.

Part 2- (each age group)

Cohort	Study Vaccine	Placebo	Blood Draw Time points
Cohort A	132	44	D1, D29, D57
Cohort B	132	44	D1, D57, D209
Cohort C	132	44	D1, D57, D394
Cohort D	Remainder of the age group		D1, D30
Cohort E (only selected study sites)	18	6	D1, D43, D209, and D394

Participants in Part 3 will have up to 5 blood draws (blood collection). During the study, blood draws will be performed at the Day 1, Day 57, Day 149, one month after the third dose at Day 177, Day 329 (first 150 participants), and Day 514 (next 150 participants).

On the day of each study vaccination and for at least 6 days after, you will record your child's temperature and symptoms you observe in an electronic diary (eDiary). It is very important that you enter the data into the eDiary. If you miss a day, you will receive an electronic reminder.

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 staff may ask to visit your home or conduct a telemedicine visit, in order to perform the scheduled assessments.

WHAT WILL MY CHILD AND I BE ASKED TO DO?

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

Signing and dating this consent form shows 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. These activities will also be used to evaluate your child's safety and the effect of the study vaccine. 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 asked to get medical records from your child's regular 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/Length, and Weight: During each clinic visit your child may be given a physical examination, which may include a check of the head, neck, ears, eyes, nose, throat, chest, lungs, heart, lymph nodes, stomach, skin, muscles, nervous system, and others, if needed. Your child's length/height and weight will be measured at the first visit. Body Mass Index will be calculated.

Pregnancy Test: If your child is female, and has had her first period, a pregnancy test may be performed at the Screening Visit (Day 0) and before each study vaccine dose.

Vital Sign: At each clinic visit your child's body temperature may be measured.

Blood Tests: For up to 5 of the visits to the clinic, your child will provide blood samples to see how your child's immune system responds to the study vaccine, if no booster dose is taken. For participants with a booster dose, up to 5 additional blood draws may be required. In addition, the blood sample collected on Day 30 (within 4 days of Dose 2) was requested by the FDA in order to have an additional blood sample in storage for testing in case there are any unexpected adverse events (bad side effects) after your child receives Dose 2. There is currently no testing planned for samples collected on Day 30. If your child is enrolled at one of the selected study sites, blood will be collected to look at how different cells of your child's immune system help to fight the virus. **If we cannot obtain an acceptable amount of blood on Day 1, then your child can only participate in the study if they return to have blood drawn within 28 days of**

their first study visit. If your child is screened for Part 1 and we cannot obtain an acceptable amount of blood on Day 1, they will be eligible to screen again for Part 2 or Part 3. The study team can tell you which part of the study is enrolling.

Blood Tests Details
If your child is enrolled in Part 1, Part 2, or Part 3 the overall total volume of blood collected could range from 4 mL (1 teaspoon) to 104 mL (21 teaspoons) over the duration of the study. The total amount of blood collected from your child during each visit will depend on their age as detailed below.

6 months to less than 2 years: approximately 4 mL (about 1 teaspoon)
2 to less than 6 years: approximately 16 mL (slightly more than 3 teaspoons)
6 to less than 12 years: approximately 24 mL (slightly less than 5 teaspoons)

If your child is enrolled in cohort E at the selected study sites, the overall total volume of blood collected could range from 36 mL (8 teaspoons) to 68 mL (14 teaspoons) over the 14 months of the study.

The total amount of blood collected from your child if enrolled in cohort E during each visit for the study will depend on their age as detailed below.

6 months to less than 2 years: approximately 9 mL (about 2 teaspoons)
2 to less than 6 years: approximately 9 mL (about 2 teaspoons)
6 to less than 12 years: approximately 17 mL (about 4 teaspoons)

Nasal Swab: During study visits or if your child becomes sick, your child will be asked to provide a nasal swab. The swab is a method for collecting a test sample of nasal secretions from the front of the nose to test for COVID-19. Your child may feel some discomfort. Nasal swabs collected throughout the study will be sent to a laboratory for SARS-CoV-2 testing to see if your child is infected. Results of the swabs will be shared with you when they are available. If a positive result for COVID-19 is found, your study doctor may inform the local public health authorities, as required by law.

Study Vaccination: Your child will be given the study vaccine or placebo that will be assigned to him/her by chance. After the 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 temperature, and may physically examine your child. Before you 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.

- 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 are in the clinic on the day of the study vaccination, you will be trained on how to complete the eDiary. You will be asked to enter symptoms your child might experience after the study vaccination and certain information about your child's health into the eDiary. You will be asked to make the first entry in the eDiary before you leave the clinic. You will make the next entry that same evening and for 6 days after the day of study vaccination. If your child has symptoms on Day 7, you 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. The information you enter into the app will be saved into the study database and reviewed by the study staff. If you cannot or do not want to use your own device, the 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 will be asked to</u>:

- Look at the place on your child's body where he or she received the study vaccine and measure specific reactions you may see (a metric ruler will be provided to you).
- Describe reactions that are sometimes seen after study vaccination.
- Measure your child's temperature (a thermometer will be provided to you); The child must not eat or drink anything hot or cold within 10 minutes of taking their temperature by mouth.
- Write down any medications your child takes.
- Describe any other types of reactions or illnesses that you may observe.
- Confirm if your child has seen another healthcare provider for any illness or symptoms.
- Starting at about 6 weeks after the second study vaccination you will also receive prompts every 4 weeks in the eDiary through the end of the study to follow your child's health status. These prompts will ask you to confirm the presence or absence of about 18 symptoms that are associated with COVID-19. It should take no longer than 5 minutes to complete this weekly assessment.

Home Visits: This study consists of both in-person, telemedicine, 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 1 and 3 will only take place on site at the clinic.

The detailed description of procedures for each clinic visit, telemedicine visit, and phone call are presented below for all Part 1 participants without a booster dose. Procedures and study visits may be slightly different for each cohort assignment (with or without a booster/third dose) in Part 2 and Part 3.

Visit	When	What will be done
Screening/Day 0 (in clinic)	Before your child enters the study (may occur on same day as Visit 1/Day 1)	• You will be asked to provide informed consent • Your child will be asked to provide assent (if applicable) • Inclusion and exclusion criteria will be reviewed to determine if your child is eligible to participate in the study • Medical history review • Demographic data will be obtained • Medication review • Full physical examination • Height/weight/BMI (body mass index) • Pregnancy testing (if applicable)
Visit 1/ Day 1 (in clinic)	Within 28 days of Screening (may occur on same day as Screening)	• Confirmation that your child may participate in the study • Medication review and discussion of any changes in your child's health since Screening/Day 0 • Targeted physical examination (full if not done at screening) • Body temperature • Pregnancy testing (if applicable) • Blood sample for antibody levels (all participants in Part 1 and if applicable for Part 2 cohort assignment) • Nasal swab sample for SARS-CoV-2 • First study vaccination • 30-minute observation after study vaccination • You will receive instructions from the study staff on how to complete the electronic diary • Completion of first eDiary entry and for 6 days after first study vaccination • Distribute participant card, oral and/or tympanic thermometer and ruler • Blood for cell-mediated immune response (only for Part 2 at selected sites). Cell-mediated immunity tests measure how certain immune cells respond to a virus instead of just measuring the amount of antibodies in the blood.

Visit	When	What will be done
Visit 2/Day 8 (telemedicine visit)	7 days (+3 days) after the first study vaccination	• Review your child's health for COVID-19 symptoms • Review of eDiary • Medication review and discussion of any changes in your child's health since your child's study vaccination
Visit 3/ Month 1/ Day 29 (in clinic)	28 days (+7 days) after the first study vaccination	• Medication review and discussion of any changes in your child's health since your child's study vaccination • Targeted physical examination (if applicable) • Body temperature • Pregnancy testing (if applicable) • Blood sample for antibody levels (only if applicable for Part 2 cohort assignment) • Nasal swab sample for SARS-CoV-2 • Review your child's health for COVID-19 symptoms • Second study vaccination • 30-minute observation after study vaccination • Completion of first eDiary entry and for 6 days after second study vaccination
Visit 3A/Day 30 (in clinic)	1 day (+3 days) after the second study vaccination	• Medication review and discussion of any changes in your child's health since your child's study vaccination • Blood sample for storage and future testing only if needed to study unexpected side effects as requested by the FDA (only if applicable for Part 2 cohort assignment)
Visit 4/Day 36 (telemedicine visit)	7 days (+3 days) after the second study vaccination	• Medication review and discussion of any changes in your child's health since your child's study vaccination • Review your child's health for COVID-19 symptoms • Review of eDiary
Visit 4S/Day 43 ***(in clinic-only for selected sites)***	*14 days (±2 days) after the second study vaccination*	• Medication review and discussion of any changes in your child's health since your child's study vaccination • Body temperature may be taken • Targeted physical examination (if applicable) • Nasal swab sample for SARS-CoV-2 • Monitoring your child's health for COVID-19 symptoms • Blood sample for cell-mediated immunity (only for Part 2 at selected sites)
Visit 5/ Month 2/ Day 57 (in clinic)	28 days (+7 days) after the second study vaccination	• Medication review and discussion of any changes in your child's health since your child's study vaccination • Targeted physical examination (if applicable) • Body temperature may be taken • Blood sample for antibody levels (some participants in Part 1 and if applicable for Part 2 cohort assignment). If your child is enrolled in Arms 1 or 2 during Part 1, collection of this blood sample may be optional. • Nasal swab sample for SARS-CoV-2 • Monitoring your child's health for COVID-19 symptoms
Safety Follow-Up via eDiary Questionnaire	Every 4 weeks (±3 days)	• Medication review and discussion of any changes in your child's health

Visit	When	What will be done
Days 71, 99, 127, 155, & 183 (eDiary entry)	beginning on Day 71	• Monitoring your child's health for COVID-19 symptoms • eDiary questionnaire
Safety Call Days 85, 113, 141, 169, & 197 (phone call)	Every 4 weeks (±3 days) beginning on Day 85	• Monitoring your child's health for COVID-19 symptoms • Medication review and discussion of any changes in your child's health • Brief telephone call
Visit 6/ Month 7/ Day 209 (in clinic)	180 days (±14 days) after second study vaccination	• Medication and discussion of any changes in your child's health • Targeted physical examination (if applicable) • Body temperature may be taken • Nasal swab sample for SARS-CoV-2 • Blood sample for antibody levels (all participants in Part 1 and if applicable for Part 2 cohort assignment) • Monitoring your child's health for COVID-19 symptoms • Blood sample for cell-mediated immunity (only for Part 2 at selected study sites)
Safety Follow-Up via eDiary Questionnaire Days 223, 251, 279, 307, 335, & 363 (eDiary entry)	Every 4 weeks (±3 days) beginning on Day 223	• Medication and discussion of any changes in your child's health • Monitoring your child's health for COVID-19 symptoms
Safety Call Days 237, 265, 293, 321, 349, & 377 (phone call)	Every 4 weeks (±3 days) beginning on Day 237	• Monitoring your child's health for COVID-19 symptoms • Medication review and discussion of any changes in your child's health
Visit 7/ Month 13/ Day 394 (in clinic)	365 days (±14 days) after second study vaccination	• Medication review and discussion of any changes in your child's health • Targeted physical examination (if applicable) • Body temperature • Nasal swab sample for SARS-CoV-2 • Blood sample for antibody levels (all participants in Part 1 and, if applicable, for Part 2 cohort assignment) • Review your child's health for COVID-19 symptoms • Blood sample for cell-mediated immunity (only for Part 2 at selected study sites)

Visit	When	What will be done
Illness Visits Day 8 to end of Study	Anytime your child has possible symptoms of COVID-19 or was exposed to someone with COVID-19	During your child's participation in the study you will be asked to monitor his/her health for possible symptoms of COVID-19. If your child experiences any of the COVID-19 symptoms that last for 48 hours or more (except for fever and/or respiratory symptoms), you will be asked to immediately contact your study doctor to schedule an "Illness Visit" for your child within 72 hours. If your child is in close contact with someone who has confirmed COVID-19, you will be asked to schedule an "Illness Visit" approximately 7 days after your child's exposure to a diagnosis of COVID-19 in a household, even if your child has no symptoms. At this visit, your study doctor will take a nasal swab to confirm the diagnosis of SARS-CoV-2. Your study doctor will be informed of all test results performed at the Illness Visit.
Convalescent Visit Day 36 to end of Study	May be conducted approximately 28 days after the Illness Visit if your child has a confirmed diagnosis of COVID-19	If, during your child's participation in the study, they return to the clinic for an Illness Visit and the resulting test confirms a diagnosis of COVID-19, your child may be asked to return to the clinic for a Convalescent Visit which may include the following: • Blood sample to test for antibodies to SARS-CoV-2 • Nasal swab sample for SARS-CoV-2

If the FDA approves the mRNA-1273 study vaccine or another COVID-19 vaccine for emergency use in a certain age group, the study doctor will be able to tell you which study vaccine your child received. If the FDA approves the mRNA-1273 study vaccine, those who received a lower dose of mRNA-1273 during Part 1 will be offered a booster with the optimal dose for the given age group at an unscheduled visit and will continue to follow the study procedures listed in the table above. If the FDA approves the mRNA-1273 study vaccine or another COVID-19 vaccine, those who received the placebo and choose to receive the mRNA-1273 study vaccine may follow the procedures presented in the table below.

Study Visit	When	What will be done
Cross-Over Day 1 (in clinic)	After mRNA-1273 or another COVID-19 vaccine becomes available	• First Cross-Over study vaccination • 30-minute observation after study vaccination • Collection of adverse events

Study Visit	When	What will be done
	outside of the study	
Cross-Over Day 29 (in clinic)	28 days after the first Cross-Over vaccination	• Second Cross-Over study vaccination • 30-minute observation after study vaccination • Collection of adverse events
Cross-Over Day 36 (telephone call)	7 days after the second Cross-Over vaccination	• Collection of adverse events
Cross-Over Day 57 (telephone call)	28 days after the second Cross-Over vaccination	• Collection of adverse events
Remaining Study Visits	Through Day 394	• Collection of adverse events

Additional schedule for Optional Booster Dosed for Part 1 and Part 2 Participants

Visit	When	What will be done
Booster Dose 1 (in clinic)	Minimum 6 months after second dose.	• Confirmation that your child may participate in the study • Medication review and discussion of any changes in your child's health since Screening/Day 0 • Physical examination (as directed by your study doctor) • Body temperature may be taken • Pregnancy testing (if applicable) • Nasal swab sample for SARS-CoV-2 • Third study vaccination • Review your child's health for COVID-19 symptoms • 30-minute observation after study vaccination • You will receive instructions from the study staff on how to complete the electronic diary • Blood for cell-mediated immune response (only for Part 2 at selected sites). Cell-mediated immunity tests measure how certain immune cells respond to a virus instead of just measuring the amount of antibodies in the blood
Booster Dose 2 (telephone call)	7 days after booster dose (±3 days)	• Review your child's health for COVID-19 symptoms • Brief telephone call • Review of eDiary
Booster Dose 3 (in clinic)	28 days after booster dose (-3/+14 days)	• Physical examination (as directed by your study doctor) • Blood sample for antibody levels

		• Review your child's health for COVID-19 symptoms • Nasal swab sample for SARS-CoV-2 • Review of eDiary
Safety Follow-Up via eDiary Questionnaire Days 43, 71, 99, 127 & 155 (eDiary entry)	Every 4 weeks beginning on Day 43	• Review your child's health for COVID-19 symptoms
Safety Call Days 57, 85, 113, 141, & 169 (phone call)	Every 4 weeks beginning on Day 57	• Review your child's health for COVID-19 symptoms
Boost Dose 4 (in clinic)	180 days after booster dose (-3/+14 days)	• Physical examination (as directed by your study doctor) • Blood sample for antibody levels • Review your child's health for COVID-19 symptoms • Nasal swab sample for SARS-CoV-2
Booster Dose 5 (telephone call)	270 days after booster dose (+3 days)	• Review your child's health for COVID-19 symptoms • Brief telephone call
Booster Dose 6 (in clinic)	365 days after booster dose (-3/+14 days)	• Physical examination (as directed by your study doctor) • Blood sample for antibody levels • Review your child's health for COVID-19 symptoms

Part 3

Visit	When	What will be done
Screening/Day 0 (in clinic)	Before your child enters the study (may occur on same day as Visit 1/Day 1)	• You will be asked to provide informed consent • Your child will be asked to provide assent (if applicable) • Inclusion and exclusion criteria will be reviewed to determine if your child is eligible to participate in the study • Medical history review • Demographic data will be obtained • Medication review • Full physical examination • Height/weight/BMI (body mass index) • Body temperature • Pregnancy testing (if applicable)

Visit	When	What will be done
Visit 1/ Day 1 (in clinic)	Within 28 days of Screening (may occur on same day as Screening)	• Confirmation that your child may participate in the study • Medication review and discussion of any changes in your child's health since Screening/Day 0 • Targeted physical examination (full if not done at screening) • Body temperature • Pregnancy testing (if applicable) • Blood sample for antibody levels • Nasal swab sample for SARS-CoV-2 • First study vaccination • 30-minute observation after study vaccination • You will receive instructions from the study staff on how to complete the electronic diary • Completion of first eDiary entry and for 6 days after first study vaccination • Distribute participant card, oral and/or tympanic thermometer and ruler
Visit 2/Day 8 (telemedicine visit)	7 days (+3 days) after the first study vaccination	• Review your child's health for COVID-19 symptoms • Review of eDiary • Medication review and discussion of any changes in your child's health since your child's study vaccination
Visit 3/ Month 1/ Day 29 (in clinic)	28 days (+7 days) after the first study vaccination	• Medication review and discussion of any changes in your child's health since your child's study vaccination • Targeted physical examination (if applicable) • Body temperature • Pregnancy testing (if applicable) • Nasal swab sample for SARS-CoV-2 • Review your child's health for COVID-19 symptoms • Second study vaccination • 30-minute observation after study vaccination • Completion of first eDiary entry and for 6 days after second study vaccination
Visit 4/Day 36 (telemedicine visit)	7 days (+3 days) after the second study vaccination	• Medication review and discussion of any changes in your child's health since your child's study vaccination • Review your child's health for COVID-19 symptoms • Review of eDiary
Visit 5/ Month 2/ Day 57 (in clinic)	28 days (+7 days) after the second study vaccination	• Medication review and discussion of any changes in your child's health since your child's study vaccination • Targeted physical examination (if applicable) • Body temperature • Blood sample for antibody levels • Nasal swab sample for SARS-CoV-2

Visit	When	What will be done
		• Monitoring your child's health for COVID-19 symptoms
Safety Follow-Up via eDiary Questionnaire Days 71, 99, 127, 155, & 183 (eDiary entry)	Every 4 weeks (±3 days) beginning on Day 71	• Medication review and discussion of any changes in your child's health • Monitoring your child's health for COVID-19 symptoms
Safety Call Days 85, 113, 141, 169, & 197 (phone call)	Every 4 weeks (±3 days) beginning on Day 85	• Monitoring your child's health for COVID-19 symptoms • Medication review and discussion of any changes in your child's health
Visit 6/ Month 5/ Day 149 (Booster Dose [BD]-D1) (in clinic)	120 days (±28 days) after second study vaccination	• Review of inclusion and exclusion criteria • Pregnancy test • eDiary activation for recording solicited adverse reactions (7 days) • Medication review and discussion of any changes in your child's health • Targeted physical examination (if applicable) • Body temperature • Nasal swab sample for SARS-CoV-2 • Blood sample for antibody levels • Third study vaccination • Monitoring your child's health for COVID-19 symptoms
Visit 6A/ D156 (BD-D8) (phone call)	127/7 (BD) days (±3 days)	• Medication review and discussion of any changes in your child's health • Collection of Adverse Events • Collection of concomitant medications and non-study vaccinations • Surveillance for COVID-19 • Review of eDairy data
Visit 6B/ D177 (BD-D29) (in clinic)	148/28 (BD) days (±7 days)	• Medication review and discussion of any changes in your child's health • Blood sample for antibody levels • Nasal swab sample for SARS-CoV-2 • Monitoring your child's health for COVID-19 symptoms • Collection of Adverse Events • Collection of concomitant medications and non-study vaccinations
Safety Follow-Up via eDiary Questionnaire	Every 4 weeks (±3 days) beginning on	• Medication review and discussion of any changes in your child's health

Visit	When	What will be done
Day 191 (BD-D43) – D303 (BD-155) (eDiary entry)	Day 191 (BD-D43)	• Monitoring your child's health for COVID-19 symptoms
Safety Call Day 205 (BD-D57)-D317 (BD-169) (telemedicine visit)	Every 4 weeks (±3 days) beginning on Day 205	• Monitoring your child's health for COVID-19 symptoms • Medication review and discussion of any changes in your child's health
Visit 7/ Month 11/ Day 329 (BD-D181) (in clinic)	305/180 (BD) days (±14 days) after third study vaccination	• Targeted physical examination (if applicable) • Body temperature • Nasal swab sample for SARS-CoV-2 • Blood sample for antibody levels (based on cohort assignment) • Review your child's health for COVID-19 symptoms • Collection of Adverse Events • Collection of concomitant medications and non-study vaccinations
Visit 8/ Month 17/ Day 514 (BD-D366) (in clinic)	485/365 (BD) days	• Targeted physical examination (if applicable) • Body temperature • Nasal swab sample for SARS-CoV-2 • Blood sample for antibody levels (based on cohort assignment) • Review your child's health for COVID-19 symptoms • Collection of Adverse Events • Collection of concomitant medications and non-study vaccinations
Illness Visits Day 8 to end of study	Anytime your child has possible symptoms of COVID-19 or was exposed to someone with COVID-19	During your child's participation in the study, you will be asked to monitor his/her health for possible symptoms of COVID-19. If your child experiences any of the COVID-19 symptoms that last for 48 hours or more (except for fever and/or respiratory symptoms), you will be asked to immediately contact your study doctor to schedule an "Illness Visit" for your child within 72 hours. If your child is in close contact with someone who has confirmed COVID-19, you will be asked to schedule an "Illness Visit" approximately 7 days after your child's exposure in the household, even if your child has no symptoms.

Visit	When	What will be done
		At this visit, your study doctor will take a nasal swab to confirm the diagnosis of SARS-CoV-2. Your study doctor will be informed of all test results performed at the Illness Visit.
Convalescent Visit Day 36 to end of study	May be conducted approximately 28 days after the Illness Visit if your child has a confirmed diagnosis of COVID-19	If during your child's participation in the study, they return to the clinic for an Illness Visit and the resulting test confirms a diagnosis of COVID-19, your child may be asked to return to the clinic for a Convalescent Visit which will include the following: • Blood sample to test for antibodies to SARS-CoV-2 • Nasal swab sample for SARS-CoV-2

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

Upon conclusion of the study or if your child withdraws before the study is complete, the study staff may contact you to follow-up on illnesses or conditions that were present when you ended your child's participation or may establish how well your child is doing from publicly available sources including the internet or by trying to make contact up until resolution of the illnesses or conditions, unless you decline additional contact.

Ask the study doctor for your child's estimated recovery time from the study vaccine or procedures done during your child's participation in this study.

YOUR CHILD'S PARTICIPATION IN THE STUDY

Having your child take part in this study is your choice. Taking part in a research 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. Your responsibilities will include the following:

- Follow the instructions you are given by the study doctor
- Tell the truth 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
- Keep and attend all the study visit appointments
- Complete the electronic diary following each study vaccination, the day of study vaccination, and during the safety follow-up period.

ARE THERE ANY REPRODUCTIVE RISKS?

It is not known if the study vaccine may affect an unborn child or nursing infant. For this reason, female participants who have reached menarche (that is, started having periods) may be required to take a pregnancy test prior to receiving a study injection. Your child may be asked if they are sexually active. Female participants who are

sexually active must be practicing a medically approved and highly effective method of contraception from 28 days before the first study vaccination through 3 months after the last study vaccination. If your child is sexually active, please discuss this with the study staff.

Adequate contraception is defined as consistent and correct use of an FDA-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 FDA-approved contraceptive method that is designed to protect against pregnancy
- **Declaration of abstinence for the duration of the study**

Periodic abstinence and withdrawal are not acceptable methods of contraception. If applicable, you and your child should discuss with the study doctor the proposed method of birth control to be used during this study to determine if it is acceptable for participation in this study.

Pregnancy

If your child becomes pregnant during their participation in the trial, their participation in the study may be stopped. However, information about their pregnancy may be collected. It is important that you tell the study doctor immediately if your child becomes pregnant during the study. The study doctor will talk with you and your child about what you should do.

ARE THERE ANY POSSIBLE RISKS OR DISCOMFORTS IF MY CHILD TAKES PART IN THIS STUDY?

This is the first time that this investigational vaccine will be tested in children less than 12 years old.

If you choose to have your child take part in this study, he or she is 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 we have seen in studies of adults who received the mRNA-1273 vaccine included the following:

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

Other side effects that we have seen, include the following:

- Fever
- Redness and hardness of the skin at the injection site
- Nausea/vomiting
- Chills
- Swelling of the lymph node under the arm on the side of study vaccination
- Swelling of the face in adult participants with a history of dermatological fillers

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 2 to 3 days in duration anytime they occurred.

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.

It is important that you tell your child’s study doctor if your child has a known allergy or has had previous episodes of severe allergic reactions.

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

Symptoms of myocarditis or pericarditis include chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart, with onset of symptoms most commonly reported within a few days following vaccination. 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, most cases have been associated with full resolution of symptoms in the short term. However, long-term follow-up is limited. It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of the vaccine (for example, following a third/booster dose).

Anaphylaxis, myocarditis and pericarditis have been reported following administration of mRNA-1273 vaccine in the general public after Emergency Use Authorization.

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.

Additional side effects that may occur are as follows:

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

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

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 has 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.

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 children 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 and there is a rare possibility of infection.

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.

Placebo Risk

If your child receives placebo (the inactive substance), he or she will not develop any antibodies following the injection but may experience similar side effects to those listed above.

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. We will also be

watching for any signs of too much inflammation in your child, a condition called MIS-C (multisystem inflammatory syndrome due to COVID-19). This is a rare illness that has been seen in some children after being exposed to someone with COVID-19. We do not expect the study vaccine to cause MIS-C; however, we will be watching closely to monitor for this condition.

Risks to Confidentiality and Privacy

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

While using the app, data about your child's 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 Terms of Use and 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 and Privacy Policy 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 research study.

ARE THERE ANY POSSIBLE BENEFITS IF MY CHILD TAKES PART IN THIS STUDY?

Children who receive the study vaccine may be protected from COVID-19 disease. Information learned from the study may help other people in the future.

WHAT ARE MY OTHER OPTIONS?

Having your child take part in this study is your choice. This research study is for research purposes only. Your other option is not to have your child take part in this study.

WHAT IF THERE IS NEW INFORMATION ABOUT THIS STUDY VACCINE 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.

VOLUNTARY PARTICIPATION / WITHDRAWAL

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. There is no guarantee that your child will continue to receive the study vaccination when your child has finished taking part 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. ModernaTX may stop the study at any time.

ARE THERE ANY COSTS TO ME?

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 research study.

IS THERE A PAYMENT IF I DECIDE MY CHILD CAN TAKE PART IN THIS STUDY?

«Compensation»

You will be paid up to a total of $xx.xx if your child completes every visit required by this study. You will be paid for the visits your child completes according to the following schedule:

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

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

[OR]

You will not receive any monetary compensation for your child's participation in this study.

We will reimburse you for the cost of ***[describe: e.g., traveling to your study visits]***. You will be reimbursed approximately ***[e.g., 2 weeks, 1 month, etc.]*** after you submit your travel receipts to the study staff.

WHAT IF MY CHILD IS INJURED DURING THIS 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 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 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 your child like his/her 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 participant 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 mRNA-1273 study vaccine used in this study.

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

WHAT WILL HAPPEN TO MY CHILD'S INFORMATION THAT IS COLLECTED DURING THIS STUDY?

Persons working on the behalf of ModernaTX such as the study staff at the study clinic and under certain circumstances, the U.S. FDA and the IRB 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. These data may be used for the 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 nor will you benefit financially from any developments.

Finally, the 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. The site staff may be required to report confirmed COVID-19 infections or positive test results to public health authorities as required by applicable local laws and regulations.

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.

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 your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WILL MY CHILD'S SAMPLES BE USED FOR ANYTHING ELSE?

Some of your child's blood will be sent to special laboratories and tested for the response of his or her body's immune system to the study vaccines. In addition, some of your child's blood will be stored for possible testing in the future in case there are any unexpected adverse events after your child receives Dose 2 at the request of the FDA. You will not be told your child's specific results from these tests.

Blood samples and nasal swab specimens obtained in the study will be labeled with your child's code, but not his or her name. The samples (except samples collected for cell-mediated immunity (CMI) at the selected sites) will be stored in a freezer at PPD Global Clinical Laboratories (located at 2 Tesseneer Drive, Highland Heights, Kentucky USA 41076) until the tests analyzing your child's blood samples are performed.

If you or your child withdraw consent 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, and they can be identified, be destroyed. By agreeing to have your child take part in this study, you agree that your child's blood samples may be used for future research and to measure your child's body's immune response to the mRNA-1273 study vaccine.

Any of your child's leftover blood or nasal swab samples may be used for future research after this study is over. Your child's blood or nasal swab samples collected during the study will be retained by the Sponsor for 20 years or as allowed per local regulations and then will be destroyed. This research may be performed at the discretion of the Sponsor to further understand the immune response to SARS-CoV-2, any side effects potentially related to the mRNA-1273 study vaccine if such events occur, additional assay (new laboratory tests) development, and the immune responses to other coronaviruses. Your child's 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 study 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. Your child's individual results will not be available to you or your regular doctor and will not be placed in your child's medical record.

CAN I SHARE INFORMATON ABOUT THE STUDY?

If you agree for your child to participate in this study, you should feel free to discuss the study with family and with other people who are close to them. It is recommended to tell your child's health care provider about their 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 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 your child is 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 child's rights as a research participant, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Advisor
  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 Advisor: Pro00049112.

PRIMARY DOCTOR NOTIFICATION

Please indicate below whether it is allowable for us to notify your child's primary doctor about his or her participation in this study, if necessary.

_____ Yes, I allow the study doctor to tell my child's primary doctor that he or she is taking part in this study, as needed.

_____ No, I don't want the study doctor to tell my child's primary doctor that he or she is taking part in this study.

_____ My child does not have a primary doctor.

_____ The study doctor at the study site is my child's primary doctor.

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

CONSENT

I have read and understood all the pages of this informed consent form. I was able to ask questions, and all of my questions have been answered. I understand that I am free to ask more questions at any time. If I believe my child has been harmed by this study, I can contact the study doctor listed on page one of this consent. I am aware that this is a research study and that unforeseen side effects may occur.

I voluntarily agree to have my child participate in this study until I decide otherwise without penalty, loss of benefits, or prejudice to the quality of care which my child will receive.

I acknowledge that no guarantees have been made regarding the results of the study vaccine involved in this study, and I consent to have my child participate in the study. I will receive a copy of this signed and dated consent form.

I agree to allow the Sponsor to use my child's blood and nasal swab samples for future research that may help them understand more about the immune response to SARS-CoV-2 or side effects related to the mRNA-1273 study vaccine.

_____
Name of Participating Child

_____ _____
Parent/Legal Guardian's Printed Name Relationship to Child

_____ _____
Parent/Legal Guardian's Signature Date

_____ _____
Parent/Legal Guardian's Printed Name Relationship to Child
(if required by local jurisdiction for 2 legal guardian signatories)

_____ _____
Parent/Legal Guardian's Signature Date
(if required by local jurisdiction for 2 legal guardian signatories)

☐2nd Parent/2nd LAR Signature not required per local jurisdiction

Second parent permission not documented, reason (person obtaining consent will initial and check all that apply):

Initials of person obtaining consent

☐2nd Parent is deceased: _____

☐2nd Parent is unknown: _____

☐2nd Parent is incompetent: _____

☐2nd Parent does not have legal custody: _____

☐2nd Parent "Not Reasonably Available": _____

- ☐ 2nd Parent Not available by telephone
- ☐ 2nd Parent Not available by email
- ☐ 2nd Parent Not available by mail
- ☐ 2nd Parent Not available by fax

_____

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 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 personnel, 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 U.S. 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 personnel will be authorized to use the information described above to carry out the purposes of the research study. The study personnel will also be authorized to disclose the relevant information described above to the following parties involved in the research study:

- ModernaTX, PPD, or other agents designated by ModernaTX, to collect or review study data for verification of study procedures and/or adverse event (bad side effect) reporting.
- Third parties contracted by the study site to provide services related to the study.
- The IRB or Independent Ethics Committee (IEC) 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/IEC 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 U.S. 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 protocols.
- To approved offsite storage facilities or cloud service providers to meet study record retention and storage requirements.
- To study Sponsor ModernaTX, who directs the medical research studies.
- To other third parties contracted by PPD and/or ModernaTX, to provide services related to studies, and reporting of confirmed COVID-19 infections or test results to public health authorities.

The study data may be transferred to other countries for processing, including countries not covered by data protection legislation. The laws of the 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 personnel and other entities subject to federal privacy regulation.

Study data, including your child's 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 child's health care provider is no longer authorized to disclose your child's 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 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 child's 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.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my child's health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____
Printed Name of Participating Child

_____
Printed Name of Parent/Legal Guardian Relationship to Participating Child

_____ _____
Signature of Parent/Legal Guardian Date

_____
Printed Name of Parent/Legal Guardian Relationship to Participating Child
(if required by local jurisdiction for 2 legal guardian signatories)

_____ _____
Signature of Parent/Legal Guardian Date
(if required by local jurisdiction for 2 legal guardian signatories)

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

_____
Presenter (Study Doctor/Delegate) Signature Date

ASSENT FORM FOR SUBJECTS AGED 10 TO 11 YEARS OLD

Note: Only newly enrolled participants or re assenting participants on Part 1 & 2 opting for the booster will need to sign this form.

Sponsor / Study Title:	**ModernaTX, Inc. / "A Phase 2/3, Three-Part, Open-Label, Dose-Escalation, Age De-escalation and Randomized, Observer-Blind, Placebo-Controlled Expansion Study to Evaluate the Safety, Tolerability, Reactogenicity, and Effectiveness of mRNA-1273 SARS-CoV-2 Vaccine in Healthy Children 6 Months to Less Than 12 Years of Age"**
Protocol Number:	**mRNA-1273-P204**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

What is a research study?

Research studies help us learn new things. We can test new ideas. First, we ask a question. Then we try to find the answer.

This paper talks about our study and the choices that you have before you take part in it. We want you to ask us any questions that you have. You can ask questions any time. We will give you a copy of this paper to keep.

Important things to know…

- You get to decide if you want to be in the study.
- You can say 'No' or you can say 'Yes'.
- No one will be upset if you say 'No'.

- If you say 'Yes', you can always say 'No' later.
- You can say 'No' at any time.
- We would still take good care of you no matter what you decide.

Being in this study is your choice. You can choose not to be in this study.

Before you decide if you would like to be in the study, it is important for you to know about this study and why we are doing it.

You can take a copy of this sheet with you. Take your time to read this sheet and discuss it with your parent(s)/or the adult(s) taking care of you before you decide if you want to be in this study.

Please ask us questions at any time, if there are words that you do not understand or things that you want us to tell you more about; we will try to answer your questions. If you have a question later, you can call us or ask us the next time you visit.

We will tell you and your parent(s)/or the adult(s) taking care of you about any new information that we find out about the study vaccine (mRNA-1273) so you can decide whether you want to stay in the study.

Why are we doing this study?

There is a new virus called SARS-CoV-2. This virus causes a sickness called Coronavirus Disease-19 (COVID-19). You have probably heard of this.

One of the best ways we have for preventing virus infections is to develop a vaccine. Vaccines are shots. Vaccines help train your immune system to fight viruses. They may prevent you from getting sick. We are doing this study to find out more about a new vaccine called mRNA-1273. This vaccine is made to try to protect people from getting sick from COVID-19. It has been previously tested in studies in adults. After testing, it has been made available to adults for preventing COVID-19. It has also been studied in children older than 12 years of age.

In this study, we are trying to understand if the mRNA-1273 vaccine will be safe and help prevent kids younger than 12 years of age from getting sick from COVID-19.

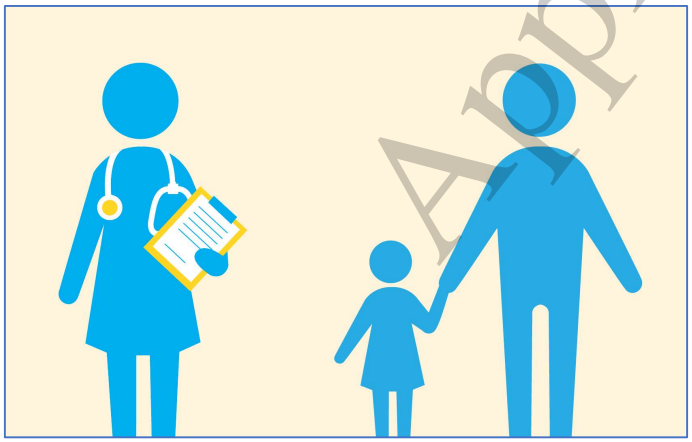
This study will be done in approximately 13,575 kids from ages 6 months to under 12 years old.

This study may or may not prevent you from getting sick from COVID-19. It may help us to know more about how to prevent COVID-19. It may stop some kids from getting sick with COVID-19.

What will happen to you during the study?

If you want to be in this study with two shots, you will spend about 17 months in the study; you will get one shot today or one shot the next time you come to the study site. You will also get a second shot about a month later. If you receive the booster shot, you will be in this study about 2 years, and you will get this shot after 6 months of your second shot. You will have to visit the study site about 8 times. If you get two shots, you will have 3 visits by video and 11 brief (short) telephone calls. If you get the booster shot, you may have to do 4 additional (extra) visits and 7 brief (short) telephone calls. You may miss some school or other activities during those visits.

After you and your parent(s)/or the adult(s) taking care of you have agreed that it is okay for you to be in the study, then we will:



- Ask you and your parent(s)/or the adult(s) taking care of you some questions about your health.
- Measure how tall you are and how much you weigh.
- Listen to your heart.
- Take your temperature.

Some of these questions and steps will help us decide if you can be in the study.

There are 3 parts (Part 1, Part 2, and Part 3) to this study. The study team can tell you whether you will be in Part 1, Part 2 or Part 3.

You will get one vaccine at your first or second visit, a second vaccine about a month later, and a third vaccine about 4 months after the second vaccine. You can ask your study doctor for more information.

If you get two shots, you will have a small amount of blood drawn from your arm at up to 5 of your study site visits. If you get the booster shot, up to 4 additional (extra) blood draws may be needed. The team will tell you when you must have blood taken. Your blood will help us learn more about how to protect kids and other people from getting sick from COVID-19.

The study doctor will also use a nose swab to take some stuff from inside your nose. This nose swab will be tested to see whether you have COVID-19.

The study doctor will also ask how you are feeling and whether you have experienced any bad things after you got the vaccine.

During the study, you will have to follow some rules such as:

- Do not take any other medicines without talking about it with us first.
- Come to the visits and have the tests or checks done as planned.
- Do not post or discuss the study on social media.
- Tell your parent(s) or the adult(s) taking care of you right away if you feel sick.

What are things that might not make you feel good?

Some of the tests might make you uncomfortable or the questions we ask might be hard to answer. We will try to make sure that no bad things happen.

The needle poke to test your blood may hurt, but it should not last long. You could get a bruise.

The nose swab might be uncomfortable, but it should not last too long.

Vaccines may or may not prevent people from getting sick, and they may cause things that are not wanted. These are called side effects. Not everyone gets all side effects,

and we usually do not know who will have them. That is why it is important to tell us and your parent(s) or the adult(s) taking care of you right away if you feel sick or something feels wrong.

After you get the vaccine, you may have side effects. These could include:

1. Symptoms at the site where you got the vaccine. This includes pain, redness, or hardness of the skin and swelling
2. Other symptoms from your body responding to the vaccine. This includes fever
3. Feeling cold or hot
4. Headache
5. Sore muscles or pain
6. Tummy ache or throwing up
7. Aches or pain in your bones
8. Feeling tired
9. Swelling

Other people who have received the vaccine have had some of these things happen within the first few days after they got their shots. Most of them went away after a few days and they were usually not serious.

Very rarely, other more serious things that could happen are:

1. Trouble breathing or breathing with a whistling or rattling sound in your chest
2. Fast heartbeat
3. Bad rash
4. Dizziness, weakness, or fainting
5. Swelling of your face, throat or eyes
6. Pain in your chest

It is very important to tell us and your parent(s) or the adult(s) taking care of you if you feel sick, or if something does not feel right.

Girls Should Know:

The vaccine used in this study might hurt you or hurt a baby if you get pregnant. You will be asked questions to see if you can get pregnant. If you can get pregnant, you may be tested to see if you are pregnant. You may be asked if you are having sexual activity. You may be asked if you want this discussed with your parent(s) or adult(s) taking care of you.

What are the good things that might happen?

If the new vaccine works, you may or may not be protected from getting sick from COVID-19. By being in the study, the information obtained from you may help to prevent other kids from getting sick.

What happens if you change your mind?

Remember that you do not have to be in this study if you do not want to, even if your parent(s) or adult(s) taking care of you have agreed to it. You can say "yes" now and change your mind later; it is okay. You will still receive medical care.

How will your information be kept secret?

Your name and other personal details will be kept private and will not be shared with people who are not part of the study unless required by law. We will not tell other people that you are in this study or share information about you. Instead of sharing your name with people outside the study site, we will replace your name with a number. That way, people will not know that the information belongs to you. All people working with your information will make sure it is treated with care.

Will you get paid for being in the study?

Your parents or the adult(s) taking care of you will be paid because of the time and effort needed to take part in this study.

DO YOU WANT TO PARTICIPATE IN THIS STUDY?

1. I have read this information sheet and someone has explained the study to me.
2. The study doctor or another team member from his/her study staff has answered my questions. I understand this information.
3. I had enough time to decide whether I want to join the study. I know that I do not have to be in the study if I do not want to.
4. I understand what the study is about and what will happen to me during the study.
5. I understand that if I have more questions, I can ask for more information at any time.
6. I understand that if I have any health problems, I must tell the study doctor.
7. I understand that I can stop being in the study at any time without giving a reason, and it will not affect my future treatment in any way.

Your parent(s)/or the adult(s) taking care of you must also sign the main informed consent form. If you want to be in the study, then write your name and today's date. Thank you!

Your name: _____

Today's date: _____

PERSON OBTAINING ASSENT:

I, the undersigned, have explained the relevant details of this study to the child named above. I certify that the participant is either capable of reading the assent form and has signed above as documentation of assent to take part in this study, or the participant is not capable of reading the assent form, but the information was verbally explained to him/her and the participant signed above as documentation of assent to take part in this study.

Printed name of Investigator/Delegate

Signature of Investigator/Delegate Date (dd-mmm-yyyy)

WITNESS:

(Only needed in case the child has his/her reading ability impaired, e.g., by disease, or is not knowledgeable or proficient enough in the assent language.)

Printed name of witness

Relationship of the child to the witness *(e.g., nurse)*

Signature of witness Date (dd-mmm-yyyy)

ASSENT FORM FOR SUBJECTS AGED 7 TO 9 YEARS OLD

Note: Only newly enrolled participants or re assenting participants on Part 1 & 2 opting for the booster will need to sign this form.

Sponsor / Study Title:	**ModernaTX, Inc. / "A Phase 2/3, Three-Part, Open-Label, Dose-Escalation, Age De-escalation and Randomized, Observer-Blind, Placebo-Controlled Expansion Study to Evaluate the Safety, Tolerability, Reactogenicity, and Effectiveness of mRNA-1273 SARS-CoV-2 Vaccine in Healthy Children 6 Months to Less Than 12 Years of Age"**
Protocol Number:	**mRNA-1273-P204**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

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This paper talks about our study and the choices that you have before you take part in it. We want you to ask us any questions that you have. You can ask questions any time. We will give you a copy of this paper to keep.

Important things to know…

- You get to decide if you want to be in the study.
- You can say 'No' or you can say 'Yes'.
- No one will be upset if you say 'No'.
- If you say 'Yes', you can always say 'No' later.
- You can say 'No' at any time.
- We would still take good care of you no matter what you decide.

Before you decide if you would like to be in the study, it is important for you to know about this study and why we are doing it.

Please ask us questions at any time if there are words that you do not understand or things that you want us to tell you more about. We will try to answer your questions. If you have a question later, you can call us or ask us the next time you visit.

Why are we doing this study?

There is a new virus called SARS-CoV-2. This virus causes a sickness called Coronavirus Disease-19 (COVID-19). You have probably heard of this.

One of the best ways we have of preventing viruses from making us sick is to develop a vaccine. Vaccines are shots. Vaccines help train your immune system to fight viruses. They may prevent you from getting sick.

We are doing this study to find out more about a new vaccine called mRNA-1273. This vaccine is made to try to protect people from getting sick from COVID-19. It has been previously tested in studies in adults. After testing, it has been made available to adults for preventing COVID-19. It has also been studied in kids older than 12 years old.

In this study, we are trying to understand if the shot we give you is safe and will help prevent you and other kids from getting sick from COVID-19. This study is being done in approximately 13,575 kids from ages 6 months to under 12 years old. This study may or may not prevent you from getting sick from COVID-19. It may help us to know more about how to prevent COVID-19. It may also help other kids.

What will happen to you during the study?

If you want to be in this study with two shots, you will spend about 17 months in the study; you will get one shot today or one shot the next time you come to the study site. You will also get a second shot about a month later. If you receive the booster shot, you will be in the study about 2 years, and you will get this shot 6 months after your second shot. You will have to visit the study site about 8 times. If you get two shots, you will have 3 visits by video and 11 brief (short) telephone calls. If you get the booster shot, you may have to do 4 additional (extra) visits and 7 brief (short) telephone calls. You may miss some school or other activities during those visits.

After you and your parent(s) or the adult(s) taking care of you have agreed that it is okay for you to be in the study, we will:

- Ask you and your parent(s) or the adult(s) taking care of you some questions about your health.
- Measure how tall you are and how much you weigh.
- Listen to your heart.
- Take your temperature.

Some of these questions and steps will help us decide if you can be in the study.

There are 3 parts (Part 1, Part 2, and Part 3) to this study. The study team can tell you whether you will be in Part 1, Part 2 or Part 3.

If you participate in the study, you will get one shot at your first or second visit, a second shot about a month later, and a third shot about 4 months later.

If you get two shots, the study doctor will take some blood from your arm using a needle at up to 5 of your study site visits. If you get a booster shot, up to 4 additional (extra) blood draws may be needed. The team will tell you when you must have blood taken. Your blood will help us learn more about how to protect kids and other people from getting sick from COVID-19.

The study doctor will also use a nose swab (like a Q-tip) to take some stuff from inside your nose. This nose swab will be tested to see if you have COVID-19.

Will it hurt you?

Some of the tests might make you uncomfortable or the questions we ask might be hard to answer. We will try to make sure that no bad things happen.

The needle to take your blood may hurt a little, but it should not last long. You could get a bruise.
The nose swab might be uncomfortable, but it should not last too long.

After you get the vaccine some of the things below may happen:

1. Fever
2. Feeling cold or hot
3. It might hurt where you got the shot
4. Red spots or bumps on the skin where you got the shot
5. Headache
6. Sore muscles or pain
7. Aches or pain in your bones
8. Feeling tired
9. Tummy ache or throwing up
10. Swelling

Other people who have got the shot have had some of these things happen within the first few days after they got their shots. Most of them went away after a few days and they were usually not serious.

Very rarely, other more serious things that do not happen as much include:

1. Trouble breathing or breathing with a whistling or rattling sound in your chest

2. Fast heartbeat
3. Bad rash
4. Dizziness, weakness or fainting
5. Swelling of your face, throat or eyes
6. Pain in your chest

It is very important to tell us and your parent(s) or the adult(s) taking care of you if you feel sick, or if something does not feel right.

Do you have to be in this study?

You do not have to be in this study if you do not want to, even if your parent(s)/or the adult(s) taking care of you said yes to it. It is up to you.

DO YOU WANT TO PARTICIPATE IN THIS STUDY?

1. We have told you about this study and what will happen to you during it. You have been able to ask questions about the study.

2. Your study doctor has spoken with your parent(s) or the adult(s) taking care of you about this study.

If you want to be in the study, then write your name and today's date. Thank you!

Your name: _____

Today's date: _____

Your parent(s)/or the adult(s) taking care of you must sign the main consent form.

PERSON OBTAINING ASSENT:

I, the undersigned, have explained the relevant details of this study to the child named above. I certify that the participant is either capable of reading the assent form and has signed above as documentation of assent to take part in this study, or the participant is not capable of reading the assent form, but the information was verbally explained to him/her and the participant signed above as documentation of assent to take part in this study.

Printed name of Investigator/Delegate

Signature of Investigator/Delegate Date (dd-mmm-yyyy)

WITNESS:

(Only needed in case the child has his/her reading ability impaired, e.g., disease, or is not knowledgeable or proficient enough in the assent language.)

Printed name of witness

Relationship of the child to the witness *(e.g., nurse)*

Signature of witness Date (dd-mmm-yyyy)