University of California, Los Angeles
Consent to Participate in Research
Phase I/II, Open-Label Dose-Finding Trial of High-Dose mRNA-1273 Booster for Lung Transplant Recipients

Protocol Number:	COVID-19
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Sponsor/Investigator:	Yusaku Michael Shino, MD
Funding Organizations:	Pending
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UNIVERSITY OF CALIFORNIA LOS ANGELES

CONSENT TO PARTICIPATE IN RESEARCH

Sponsor / Study Title:	**ModernaTX, Inc** / "Phase I/II, Open-Label Dose-Escalation Trial of High-Dose mRNA-1273 Booster for Lung Transplant Recipients"
Short Title:	Evaluation of the Safety and Immune Response of a Higher-dose mRNA-1273 Vaccine Dose Among Lung Transplant Recipients
Protocol Number:	V4, 06/07/22
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INTRODUCTION:
Dr. Yusaku Michael Shino, and associates from the Departments of Pulmonary and Critical Care and Infectious Disease at the University of California, Los Angeles are conducting a research study. The study is being funded by the David Geffen School of Medicine.

KEY INFORMATION:
The Moderna mRNA-1273 vaccine has been approved by the U.S. Food and Drug Administration (FDA) to help provide protection from a viral infection called "COVID-19" caused by the 2019 novel coronavirus (the virus is also called "SARS-CoV-2") in individuals 18 years of age and older and is authorized for a booster dose. The purpose of this study is to test the safety of higher booster doses of the Moderna mRNA-1273 vaccine among lung transplant recipients. The mRNA-1273 study vaccine is intended to boost the immune system to produce enough antibodies against SARS-CoV-2; so, in case of an exposure, the virus does not cause severe illness. Lung transplant recipients have had weaker responses to the vaccine, and we are studying the safety of higher vaccine doses that are not FDA approved.

WHY AM I BEING INVITED TO TAKE PART IN THIS RESEARCH STUDY?
You are being invited to take part in this UCLA clinical research study, conducted in partnership with ModernaTX, Inc, because you have received a lung transplantation and have received at least three doses of the Moderna mRNA-1273 or Pfizer BNT162b2 vaccine after your lung transplantation.

WHAT SHOULD I KNOW ABOUT THIS RESEARCH STUDY?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.
- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.

WHY IS THIS RESEARCH BEING DONE?

An outbreak of COVID-19 caused by the 2019 novel coronavirus SARS-CoV-2 began in Wuhan, Hubei Province, China in December 2019 and has spread throughout the world, including the United States. Vaccines serve to prepare your immune system for fighting infection and preventing illnesses. Certain cells of the immune system produce antibodies (special proteins) that recognize viruses and other pathogens (things that cause disease) and make them harmless. Moderna's mRNA-1273 vaccine is intended to boost the immune system to produce antibodies against SARS-CoV-2; so, in case of an infection, the virus does not cause severe illness.

However, lung transplant recipients, due to their immune suppressing medications, have had a weaker response to the COVID-19 vaccines including mRNA-1273 and remain at higher risk of severe disease. This study is testing the mRNA-1273 vaccine at a higher booster doses of 100 micrograms (ug) and 200 ugs compared with the standard booster dose of 50 ug. The FDA has approved the use of the standard 50 ug booster dose, but not the 100 ug or 200 ug doses. The main purpose of this study is to understand the safety and antibody response after these higher doses of mRNA-1273 vaccine among lung transplant recipients who previously received at least three doses of the Moderna mRNA-1273 or Pfizer BNT162b2 vaccine, with the last dose received at least four months prior to study enrollment.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 6 months. You will be asked to complete 3 visits to the clinic and 3 telephone calls. If you chose to participate in this study, you will receive 1 booster injection of study vaccine at either the standard-dose, mid-dose or high-dose at your first visit at the study center. You will be told which dose you will receive but you or your doctor will not be able to choose the dose. You will be asked to keep a daily diary to record side effects that you experience for the first 7 days after your booster dose. During your 3 in-person visits to the study center, blood samples and a short physical exam will be required. More detailed information about the study procedures can be found under the section "WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY".

Since we are studying antibody responses to vaccine doses, we ask that you do not receive any antibody infusions or injections for COVID-19 prophylaxis, including Evusheld monoclonal antibodies until 30 days after you receive the study vaccine. The standard of care recommendation is that Evusheld can be given 2 weeks after vaccination, but if you choose to participate in this study, we will ask you to wait until after your 30 day study visit (which includes the last study blood draw) before receiving Evusheld. If you become sick with COVID-19, you would not be limited from receiving any treatments including antibody infusions but we defer your treatment to your lung transplant or primary care doctor.

WHAT KINDS OF RISKS OF DISCOMFORTS COULD I EXPECT?

The most common side effects associated with receiving the vaccine include: injection site pain, swelling of the lymph nodes in the injection arm, fatigue, headache, muscle pain, fever, and chills. In addition to side effects from the study vaccine, you may feel faint or have mild pain, bruising, irritation, or redness where the blood samples are taken. A very uncommon side effect after vaccination with mRNA-1273 is inflammation of the muscle of the heart, called myocarditis, or lining around the heart that is called pericarditis. This has been reported more in young men under 30 years of age after the second dose of vaccine; however, it has been reported in older males and in females as well after the first dose. Symptoms of myocarditis and pericarditis include chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart, syncope or fainting with onset of symptoms most commonly reported within a few days following vaccination. You should seek medical attention and notify study site staff if any of these symptoms occur following vaccination. Most cases are mild and the patients recover fully. However, long-term follow-up information is limited. It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of the vaccine. More detailed information about the risks of this study can be found under the section “WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT? (Detailed Description)” on page 9.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

You may directly benefit if the higher booster dose is effective in preventing COVID-19 infection or severe disease from COVID-19 infection. Also, by taking part, you will help to provide new scientific information that will benefit patients in the future.

WHAT OTHER CHOICES DO I HAVE IF I DON’T WANT TO PARTICIPATE?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your decision to participate or not will not affect your medical care at UCLA or your relationship with your doctor. An alternative treatment would be to receive the currently FDA approved booster dose (50 ugs) of the mRNA-1273 vaccine or another vaccine. Another alternative treatment is Evusheld, which is a monoclonal antibody for COVID-19 prevention. Evusheld received an FDA Emergency Use Authorization for moderate to severely immunocompromised individuals, but its efficacy has not yet been well evaluated.

DISCLOSURE STATEMENT:

Your health care provider may be an investigator of this research protocol, and as an investigator, is interested in both your clinical welfare and in the conduct of this study. You are not under any obligation to participate in any research project offered by your clinician.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Sixty participants from UCLA will take part in this study.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?
All participants will be assigned to receive either: 50 ug “standard-dose”, 100 ug “mid-dose” or 200 ug “high-dose” of the mRNA-1273 booster vaccine. There is no placebo (inactive) doses given in this study. You will receive either the 50 ug, 100 ug or 200 ug dose and will be told which dose you will receive, but you will not be able to choose the dose that you receive. The first two participants in the “mid-dose” and “high-dose” groups will be observed for 7 days. The remaining participants will only receive these higher doses if it is well tolerated in these initial participants.

WHAT PROCEDURES ARE INVOLVED?
If you decide to participate in this study, you will complete a total of 3 scheduled in-person visits, and 3 safety telephone calls over 6 months. The first visit where you will receive your study vaccine (Visit 1) will take approximately 60 to 90 minutes, each follow-up in-person visit will take approximately 30 minutes, and each telephone visit will take approximately 10 - 15 minutes. If you experience severe symptoms between the time you receive the study vaccine and 6 months after you receive the study vaccine, you will be asked to immediately contact your study doctor for a telephone “safety check” as soon as possible. As part of the “safety check”, you may be asked to come to the study center or your doctor’s office for further evaluation and additional blood draw depending on the severity.

STUDY PROCEDURES:
The following activities will be performed as part of the study:

Demographics, Medical History, and Medications: During your first clinic visit, you will be asked to provide information about your medical history. Contact information for your primary care and lung transplant doctors and may be requested to provide personal medical records from your doctor(s).

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

You will be asked about all medications including prescription medications, non-prescription (over-the-counter) medications, dietary supplements, vitamins, and herbal medications that you are currently taking and may have taken recently in the past.

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

A symptom-directed physical examination by the study doctor or designated staff will be performed on Day 7 and Day 30 and thereafter at the discretion of the study doctor.

Pregnancy Test: If you are a woman of childbearing potential (WOCBP), that is, a woman who can become pregnant, you will be asked to provide a urine sample at screening to confirm that you are not pregnant, prior to you receiving the study vaccination.

Your study doctor may choose to do a blood pregnancy test at any of these visits, in addition to or in place of the urine pregnancy test. If you are pregnant, you cannot receive the study vaccine.

Birth Control: WOCBP who are sexually active will be asked to use birth control for at least 28 days prior to the study vaccination and for 3 months afterwards. Acceptable forms for birth control include:

- Barrier method (condom, diaphragm, or cervical cap) with spermicide
- Intrauterine device (IUD)
- Hormonal contraceptives in the form of a pill or patch
- Medroxyprogesterone injection (Depo-Provera®)
- Etonogestrel implant (Nexplanon®)
- Sterilization of the male partner of a female subject before entry into the study
- Female subject is at least 1 year postmenopausal

Periodic abstinence for the duration of the study and withdrawal method are not acceptable methods of contraception. You should discuss with the study doctor your chosen method of birth control to determine whether it is acceptable for your participation in this study.

Blood Tests: During your study visits, you will be asked to provide blood samples. Blood samples collected during the course of this clinical trial will be sent to the clinical and research laboratories for further testing for immune responses (antibody levels) to the study vaccine. You will not be told the results of these test of your immune system.

The total amount of blood collected from you during each visit will not exceed 25 mL, which is approximately 2 tablespoons. Overall, approximately 75 mL or 6 tablespoons of blood will be collected over the 3-month duration of the study. This is less than a typical blood donation (470 mL taken at one time).

Nasopharyngeal Swab: During study visits or if you become sick, you may be asked to provide nasopharyngeal swabs at the study center. Nasopharyngeal swab is a method for collecting a test sample of nasal secretions from the back of the nose and throat to test for COVID-19. You may have minor bleeding and you may feel discomfort, but this should not be painful. Nasopharyngeal swabs collected throughout the study will be sent to the laboratory for SARS-CoV-2 testing to see if you are infected. An additional swab will be collected at illness to look for other respiratory illnesses such as influenza. Results of the swabs will be shared with you when they are available.

Study Vaccination: You will receive an injection of the study vaccine ("standard-dose", "mid-dose" or "high-dose") that was assigned to you at Visit 1. After the injection, you will remain in the clinic for an observation period of approximately 30 minutes. During this time, the study doctor or his/her staff will assess you for any potential reactions to the study vaccine by asking you questions and taking your vital signs. The site will also provide you with instructions on what you should do after you leave the clinic and information about your next study visit.

Daily Diary: For the first week after your study vaccine, you will be asked to report on symptoms you might experience using a diary notebook. You will be trained on how to complete the diary. You will have to complete the diary every day (preferably at the same time each day in the evenings) for 7 days after the study vaccinations. Completion of the daily symptoms should take about 5-10 minutes each day.

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

- Look at your arm where you received the study vaccine and measure any specific reactions you may see (a ruler will be provided to you to measure injection site reactions).
- Check for underarm gland swelling or tenderness on the same arm where you were vaccinated.
- Describe reactions that are sometimes seen after vaccination.
- Measure your temperature (an oral thermometer will be provided to you). You must not eat or drink anything hot or cold within 10 minutes of taking your temperature.
- Note if you take any medications.
- Confirm if you have seen another healthcare provider for any illness or symptoms.

Home Visits: The study visits consist of both in-person and telephone contacts. Ideally, all in-person visits will take place at the study site. However, there may be circumstances in which you are not able to visit the clinic in person due to travel restrictions or other limitations as a result of the COVID-19 pandemic. If this occurs, the site study staff may ask if they or a representative may come to your home in order to perform the scheduled assessments. If any in-person visits must be performed at your home, the site will notify you before the visit takes place. A home visit will only take place if verbally agreed upon and approved by you prior to the visit. Procedures that may take place during a home visit are outlined in the table below; however, study vaccination will only take place on site at the clinic.

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

Visit	When	What will be done
Screening (Telephone)	Before you enter the study	• Informed consent review • Medical history review (including any medications you take and vaccination history). If you choose to move forward with enrolling in the study, we will plan Visit 1 to be at least 4 months after your last dose of an mRNA COVID-19 vaccine.
Visit 1 (in clinic)	**Day 1** (study vaccination)	• Informed consent review and signature • Confirmation that you may participate in the study after review of inclusion/exclusion criteria • Medication review and discussion of any changes in your health since the last visit • Physical examination (including vital signs) • Pregnancy test • Blood sample collection • Study vaccination • A 30-minute observation after study vaccination • Receive daily diary notebook: the diary will be used to record any changes in your health starting the day of your study vaccination for a total of 7 days following your study vaccination. • Receive oral thermometer and ruler
Safety Call (Telephone)	**Day 3** (Safety Check)	• Review any symptoms which may have developed from the study vaccine. • Review daily diary. • This telephone call will take 10-15 mins.
Visit 2 (in clinic)	**Day 7**	• Review any symptoms which may have developed from the study vaccine. • Review daily diary. • Physical examination (including vital signs) • Blood sample collection

Visit 3 (in clinic)	**Day 30**	• Review any symptoms which may have developed from the study vaccine. • Physical examination (including vital signs) • Blood sample collection
Safety Call (Telephone)	**Day 90** (Safety Check)	• Review any symptoms which may have developed from the study vaccine. • This telephone call will take 10-15 mins.
Safety Call (Telephone) / End of Study	**Day 180** (Safety Check)	• Review any symptoms which may have developed from the study vaccine. • This telephone call will take 10-15 mins.

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

"Safety Check" after study vaccination: During your participation in the study you will be asked to monitor your health for possible symptoms associated with the vaccine including:

- Pain, redness and swelling at injection site.
- Pain, redness and swelling in the armpit of the injection arm.
- Fatigue
- Headache
- Muscle pain
- Joint pain
- Fever (Temperature greater than or equal to 38ºC/100.4ºF)
- Chills
- Nausea and vomiting
- Rash

If these symptoms are severe, you are asked to immediately contact your study doctor for a telephone "safety check" as soon as possible. You may be asked to come to the study center or your doctor's office for further evaluation, depending on the severity. At your first study visit, you will be given a daily diary notebook listing these symptoms with severity rating and thermometer. You will be trained on how to use the thermometer and daily diary.

You will also be asked to monitor your health for symptoms of COVID-19 including:

- Fever (Temperature greater than or equal to 38ºC/100.4ºF)
- Chills
- Sore throat
- Nasal congestion or runny nose
- Coughing
- Chest congestion
- Fatigue
- Headache

- Body aches
- Nausea and vomiting
- Diarrhea
- Loss of smell or taste

If you develop symptoms that may indicate COVID-19 infection during the 6-month study period, we request that you notify your lung transplant and/or primary care doctor immediately. We also request that you contact the study team as well. We will make sure that your lung transplant doctor and/or primary care doctor are aware of your symptoms, and that you can receive testing and medical care under their direction. If you become sick or are hospitalized during the first 30 days after the study vaccine, a medically qualified site staff may try to obtain additional medical records, information, and possibly a blood test at your home or hospital. Your lung transplant or primary care doctor will advise you on any additional steps you must take with respect to local quarantine requirements and ensure that you understand your options for access to medical care.

WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT? (Detailed Description)

Known Risks and Discomforts:
The mRNA-1273 vaccine has been found to be safe and effective in large clinical trials. However, like all medicines and vaccines, the study vaccine may cause side effects, although not everyone gets them. The most likely side effects you may have from the study vaccine are pain, redness, and swelling where the shot is given, headache, muscle pain, joint pain, fever, feeling tired, nausea/vomiting, underarm gland swelling on the side of the vaccination, and shivering. In addition to side effects from the study vaccine, you may feel faint or have mild pain, bruising, irritation, or redness where the blood samples are taken.

There is a remote chance that the mRNA-1273 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (swelling of the heart) and pericarditis (swellingaround the heart) have occurred in some people who have received the Moderna COVID-19 Vaccine, more commonly in males under 30 years of age. In most of these people, symptoms began within a few days following receipt of the second dose of the Moderna COVID-19 Vaccine. The chance of having this occur is very low. It is estimated at 3.5 cases per

million doses after second dose mRNA among all adults, and 24.3 cases per million among individuals 12 to 29 years of age. Several studies have also found that the risk of myocarditis and pericarditis after vaccination is significantly lower than the risk of developing these conditions after COVID-19 infection. However, if you receive the higher doses of the vaccine (mid-dose or high-dose) as part of the study, the risk of myocarditis and pericarditis (swelling in and around the heart) may be higher, especially for male participants under the age of 30.

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

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported during post-authorization use of the Moderna COVID-19 Vaccine include:

- Severe allergic reactions
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Fainting in association with injection of the vaccine

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials. If you choose to take part in this study, you are at risk for the side effects listed in this section. If you receive the higher doses of the vaccine (mid-dose or high-dose), you may be at increased risk for these side effects or more severe adverse effects than with the standard dose. You should discuss these with the study staff and if you choose, with your regular doctor. You will be monitored for risks and side effects throughout your participation in the study. You should contact the study doctor if you think you are having side effects or experiencing a change in your medical condition.

If you had an allergic reaction after being vaccinated in the past or if you are allergic to any product(s), then you must tell the study doctor or study staff before you decide to sign and date this informed consent form. Some symptoms of allergic reactions are rash; wheezing and difficulty breathing; dizziness and fainting; swelling around the mouth, throat, or eyes; a fast pulse; or sweating. If you have an allergy to some products, then you may not be able to take part in this study. Serious allergic reactions can be life-threatening.

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

- Fever
- Pain at the injection site
- Redness and hardness of the skin at the injection site
- Headache
- Muscle aches or pain
- Joint aches or pain

- Fatigue (tiredness)
- Nausea/vomiting
- Chills
- Under arm gland swelling on the side of study vaccination

Most of these side effects occurred within the first few days after study vaccination and went away within a few days. Not everyone has had these side effects and those who experienced them did not necessarily experience them after every dose. These side effects were usually reported as mild or moderate and not severe. Brief laboratory tests abnormalities including lipase elevation and hemoglobin decrease were noted in previous clinical studies with similar mRNA vaccines. These increases were observed without physical symptoms or signs, usually within the first week and generally returned to levels observed before study vaccination. The significance of these observations is unknown, but the major side effects associated with the vaccine are listed above.

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

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

Are there risks if you become infected with the coronavirus after getting study vaccine?
Receipt of this experimental mRNA-1273 study vaccine may affect your response to future vaccines against the SARS-CoV-2 virus, as well as a SARS-CoV-2 infection. The mRNA-1273 booster vaccine has been shown to be highly effective in protecting against severe disease. You will receive either the “standard dose” (50 ug), “mid-dose” (100 ug) or “high-dose” (200 ug) vaccine. There will be no placebo (inactive) doses given as part of this study. It is not known how long the immune response or COVID-19 protection from the study vaccine may last.

If you develop symptoms concerning for COVID-19 during the 6-month study period, we request that you notify your lung transplant and/or primary care doctor immediately. We also request that you contact the study team as well. We will make sure that your lung transplant doctor and/or primary care doctor are aware of your symptoms, and that you can receive testing and medical care under their direction.

Unknown Risks and Discomforts:
The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

Are there any reproductive risks?

Women: It is not known if the study treatment may affect an unborn child or nursing infant. For this reason, if you are breastfeeding, pregnant, or plan to become pregnant, then you may not participate in this study. Please refer to contraception requirements in page 5.

Pregnancy: If you become pregnant during your participation in the trial, then your participation in the study may be stopped, but you will be asked to stay in the study and be followed-up for safety. You will be asked to sign a separate consent for the collection of pregnancy follow up data. It is important that you tell the study doctor immediately if you become pregnant during the study. The study doctor will talk with you about what you should do.

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

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Because this study involves the treatment of a medical condition and/or medical procedures, a copy of this consent form will be placed in your medical record. This will allow the doctors that are caring for you to obtain information about what medications and/or procedures you are receiving in the study and treat you appropriately.

Use of personal information that can identify you:
This research study may be performed only by collecting and using your medical information. After completion of the study, your study data and clinical samples (including blood, nasopharyngeal / nasal swabs) will only contain a de-identified code. UCLA will keep the study code – personal identification link confidential and take every precaution to ensure that it remains confidential. All study data will be physically and electronically secured. You will not be personally identified in any reports or publications that may result from this research study.

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

following:

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

In all cases, the study site and the study monitors, auditors and other individuals will implement technical and organizational controls to ensure that your confidential personal information is protected from unauthorized access or loss.

Information from this study (without your personal identifying information) may be given to authorized study collaborators. “Collaborator” includes any persons or companies which are contracted by UCLA to have access to the de-identified research information during and after the study. De-identified study information will also be given to the U.S. FDA, as well as other governmental agencies in other countries where the study drug may be considered for approval.

The research team, authorized UCLA personnel, ModernaTX Inc (the vaccine manufacturer), and regulatory agencies such as the Food and Drug Administration(FDA), may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name. Representatives of ModernaTX and government agencies may also observe a study visit to check that the study staff are conducting the study correctly. Absolute confidentiality cannot be guaranteed because of the need to give information to these parties.

USE OF DATA AND SPECIMENS FOR FUTURE RESEARCH:
Results of your serum (blood) samples taken throughout the study will be used for research purposes only. You will not receive your results of the tests. Your blood samples and nasopharyngeal / nasal swabs (if collected) will be sent to special laboratories to test the response of your body’s immune system to the study vaccine. Samples obtained in the study will be labeled with a code and will not contain any information that could identify you. These samples will be stored in a freezer until the tests analyzing your immune response to the study vaccine are performed. These samples may be stored for up to approximately 15 years by UCLA.

Additional laboratory tests may be performed in the future to further understand immune responses to the study vaccine or for further research. This research may be performed at the discretion of the study investigators to further understand the immune response to SARS-CoV-2, additional assay (new laboratory tests) development, and the immune response across coronaviruses. The future use of your samples may result in new discoveries that are important to the understanding of the study vaccine(s) or disease. Any leftover samples (including blood, nasopharyngeal / nasal swabs) may be used for future research after this study is over. These leftover samples will be labeled with a code and will not contain any identifying information. UCLA will keep the study code – personal

identification link confidential. The samples will remain the property of UCLA and may be shared with collaborators including ModernaTX Inc. as long as confidentiality is maintained. You are allowing the UCLA to use the information and samples in the research and development of mRNA- 1273 and other medicines and diagnostics. Any specimens (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the University of California. Once you provide the specimens you will not have access to them. The University may share your specimens in the future with other researchers or outside institutions. Information that identifies you will not be shared with anyone outside of UCLA. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

How long information from the study will be kept?
The UCLA and the study collaborators may continue using the deidentified study data and samples after the study is over for up to approximately 15 years.

WHAT IS EXPECTED FROM YOU?

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

- To follow the instructions, you are given by your study doctor
- To commit the time required to keep appointments
- To accurately disclose your complete medical history
- To promptly report any new problems, illnesses, or changes in medication during the study, including any potential COVID-19 symptoms
- To complete your daily diary for 7 days following the study vaccination.

WHAT WILL HAPPEN AT THE END OF THE STUDY?

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

WILL YOU BE INFORMED OF NEW INFORMATION THAT BECOMES AVAILABLE DURING THE STUDY?

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

CAN I SHARE INFORMATION ABOUT THIS STUDY?

If you participate in this study, you should feel free to discuss the study with your family and with other people who are close to you. It is recommended to tell your health care provider about your participation in the study. However, to help make sure that the information from the study is as accurate and reliable as possible, please do not discuss

information about the study in public places while the study is in progress. Public places include things like social media (Facebook, Instagram, Twitter), blogging, and speaking to the media.

ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?
The study will pay for the cost of supplying and administering the study drug, and all required study items and services as described in this consent form.

WILL I BE PAID FOR MY PARTICIPATION:
For your time and inconvenience related to your participation in this study, you will be paid up to a total of $300 in the form of Amazon gift cards if you complete this study. You will be paid according to the following schedule after each visit. If you do not complete the study, you will only be paid for the study visits that you completed. The study team will provide parking vouchers for the study visits.

Visit:	**Amount:**
Clinic Visit 1: Vaccination	$100 Amazon gift card
Clinic Visit 2: Day 7	$100 Amazon gift card
Clinic Visit 3: Day 30	$100 Amazon gift card

If you have any questions regarding your compensation for participation, please contact the study doctor at the telephone number listed on page one of this consent document.

Specimens collected (e.g., blood, nasopharyngeal / nasal swabs (if collected) obtained for the purposes of this study may be provided to study collaborators. These specimens will not include information that identifies you directly. Once you provide the specimens you will not have access to them. The specimens will be used for research and such use may result in discoveries that could become the basis for new products or therapeutic agents. In some instances, these discoveries may be of potential commercial value. You will not receive any money or other benefits derived from such a product.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Principal Investigator of the study listed below. If you need emergency care, or hospitalization is required, please call 911 and alert the treating physician that you are participating in this research study.

Principal Investigator: Yusaku Michael Shino, MD
Department of Medicine, Division of Pulmonary and Critical Care
Pager: 310-206-6766 – ask to page Dr Shino
Email: mshino@mednet.ucla.edu

Other study contact: S. Sam Weigt, MD
Department of Medicine, Division of Pulmonary and Critical Care
Pager: 310-206-6766 – ask to page Dr Weigt
Email: sweigt@mednet.ucla.edu

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

- By mail:
  Office of the Human Research Protection Program (OHRPP)
  10889 Wilshire Blvd, Suite 830
  Los Angeles, CA 90095-1406
- or call: 310-825-5344
- or by email: webIRBHelp@research.ucla.edu

PUBLIC INFORMATION ABOUT THIS STUDY:
ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on *http://www.ClinicalTrials.gov* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT HAPPENS IF I BELIEVE I AM INJURIED BECAUSE I TOOK PART IN THIS STUDY?
It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researchers in person or call them at the number(s) listed above.

If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or billed to you or your insurer just like other medical costs, depending on a number of factors. The University of California does not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-825-5344 or send an email to mirb@research.ucla.edu.

You will not lose any of your legal rights or release UCLA, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing this consent document. The federal government also has a program that may provide compensation to you or your family if you experience serious physical injuries or death and these costs are not covered by other payors. To find out more about this "Countermeasures Injury Compensation Program" go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

Due to the coronavirus public health crisis, the federal government has issued an order

that may limit your right to sue and recover for losses if you are injured or harmed while participating in this COVID-19 clinical study. If the order applies, it limits your right to sue and recover for losses from the researchers, healthcare providers, any study sponsor or manufacturer or distributor involved with the study. However, the order does not limit your right to seek compensation for injuries that result from conduct or activities of the researchers, health care providers, study sponsors, manufacturers and distributors that is unrelated to the study.

VOLUNTARY PARTICIPATION AND WITHDRAWAL:
Your participation in the study is voluntary. You may decide not to participate, or you can leave the study at any time. You will not be punished if you decide not to participate or leave the study before the last study visit. Your decision will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with UCLA or UCLA Medical Center.

If you decide to leave the study before the last study visit, please notify a member of the research team and follow instructions. It may be helpful if you could explain your reasons.

You will receive standard treatment and no prejudice will be shown towards you for medical care or participation in future research.

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

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

- If you experience a severe adverse reaction
- If you do not follow the study rules
- If it is discovered that you do not meet the study requirements
- If the study is cancelled
- For administrative reasons, including completion of enrollment

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

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?
Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from UCLA.

- If you decide to take part, you can leave the study at any time.
- If you decide to stop being in this study you should notify the research team right away. The researchers may ask you to complete some procedures in order to protect your safety.
- If you decide not to take part, you can still get medical care from UCLA.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you want to participate in this study you should sign and date below. You have been given a copy of this consent form and the Research Participant's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

SIGNATURE LINES:

Participant
Printed Name

Signature Date (MM/DD/YYYY)

Consenter
Printed Name

Signature Date (MM/DD/YYYY)

Primary health care provider notification option

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

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

□ **NO**

Primary Health Care Provider Information:

Name:	
Address:	
Telephone:	