INFORMED CONSENT **FORM**

Sponsor / Study Title:	National Institute of Allergy and Infectious Diseases / "SARS-CoV-2 Immune Responses after COVID-19 Therapy and Subsequent Vaccine"
Protocol Number:	A5404
Principal Investigator: (Study Doctor)	«PiFullName»
Telephone:	«IcfPhoneNumber»
Address:	«PiLocations»

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participant cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative) who is signing and dating this form for the participant. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant, and the participant offered the ability to leave the study if desired.

SUMMARY

PURPOSE

This is a research study and your participation in this study is voluntary. The purpose of this study is to evaluate the safety and efficacy of mRNA COVID-19 vaccines in:

- People with prior COVID-19 (SARS-CoV-2 infection) who were in the ACTIV-2/A5401 study.
  And
- People who have never had COVID-19 (SARS-CoV-2 infection).

VACCINE

Study-provided Moderna mRNA-1273 COVID-19 vaccine, or

Community-provided mRNA COVID-19 vaccine (from a local clinic or vaccination site, for example).

NUMBER OF PARTICIPANTS

This study **planned to** enroll 70 people who were in ACTIV-2/A5401 from each ACTIV-2/A5401 study treatment group, and up to 70 people who have never had COVID-19 per each ACTIV-2/A5401 study treatment group. **Enrollment into this study closed on February 25, 2022, due to slow enrollment. A total of 43 participants were enrolled.**

LENGTH OF STUDY

You will be on this study for up to 730 days, which is about 2 years.

REQUIRED ACTIVITIES

If you enter the study before you have the first **vaccination**, you will have blood drawn from a vein in your arm before your first **and second** mRNA COVID-19 **vaccinations**. **If you enter the study before you have the second vaccination, you** will have blood drawn before your second mRNA COVID-19 **vaccination**. **If you enter the study after you have two doses of vaccine, you will have blood drawn on the day you enroll in the study.** This blood will be used to measure immune and genetic (determined by inherited factors) responses to your initial SARS-CoV-2 (the virus that causes COVID-19) infection and to the mRNA COVID-19 vaccine.

If you are receiving study-provided Moderna mRNA-1273 COVID-19 vaccine, the study vaccine will be given by needle into the muscle of your arm on study days 0 and 28.

Phone Visits 7 to 14 Days after Vaccinations

If you enter the study before your first or second mRNA COVID-19 vaccination, you will be contacted by phone by the study team **between 7 and 14 days after each vaccine** to see whether or not you have had any new symptoms or medical events. If you **enter the study** more than 14 days after your first **vaccination**, you will only be contacted after the second vaccine. **If you enter the study more than 14 days after your second vaccination, you will not have a scheduled phone visit.**

Study Visits 2 Months, 5 Months, 1 Year, and 2 Years After Your First mRNA COVID-19 Vaccine

You will have blood drawn. This blood will be used to measure immune responses to your study-provided or community-provided mRNA COVID-19 vaccine.

RISKS

Taking blood may cause some discomfort, bleeding, or bruising where the needle enters the body, lightheadedness, and in rare cases, fainting or infection.

If You Are Receiving **the** Study-Provided Moderna mRNA-1273 COVID-19 Vaccine

Side effects that have been reported with the Moderna mRNA-1273 COVID-19 vaccine include:

- Injection site reactions: pain, itching, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling and hardness around the injected area, and redness.
- General side effects: fatigue (tiredness), headache, muscle pain, joint pain, chills, nausea and vomiting, fever, and mild abdominal pain.
- Other: facial flushing (redness), generalized itching, tingling of face or extremities, runny nose, sneezing, hypotension (low blood pressure), hives, and pruritus (itching).
- **There is increased risk of myocarditis and pericarditis. Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the lining outside the heart.**

There is a very small chance that the study-provided Moderna mRNA-1273 COVID-19 vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after being vaccinated. For this reason, you will be asked to stay at the study site for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing or swallowing
- Chest tightness
- Shortness of breath
- Coughing
- Wheezing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Vomiting
- Abdominal pain
- Dizziness and weakness
- Fainting (loss of consciousness), convulsions (like a seizure)

<u>If You are Receiving Community-Provided mRNA COVID-19 Vaccine</u>
This is an observational study of the community-provided mRNA COVID-19 vaccine that you are receiving locally, so the risks of taking those vaccines are not part of this study. Your medical provider or vaccine administrator should give you that information.

<u>BENEFITS</u> There is increasing evidence that COVID-19 vaccination has the potential of direct benefit because it offers high levels of protection against future COVID-19 (SARS-CoV-2 infection), whether you have been infected previously or not.

<u>OTHER CHOICES</u> Instead of being in this study, you have the choice of obtaining a COVID-19 vaccine **in the community**, obtaining an experimental COVID-19 vaccine in another study, if you qualify, or no vaccination.

INTRODUCTION

You are being asked to take part in this research study because you**:**

1. Have previously had COVID-19 (SARS-CoV-2 infection) and received an experimental treatment, placebo (a look-alike product that has no active substance), or a standard of care COVID-19 treatment (the usual care for COVID-19 at the time) in a clinical trial known as ACTIV-2/A5401.

   Or

2. You have not previously been diagnosed with a COVID-19 (SARS-CoV-2 infection) infection and have not previously been vaccinated for COVID-19.

The current study is sponsored by the National Institutes of Health (NIH). The study doctor in charge of this study at this site is listed on the first page of this form. Before you decide if you want to be a part of this study, we want you to know about the study.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study, you will be asked to sign and date this consent form. You will get a copy to keep.

WHY IS THIS STUDY BEING DONE?

SARS-CoV-2 is a recently identified virus that has caused a widespread outbreak of an illness called COVID-19. New treatments and vaccines are being developed for this virus. Some of these treatments and vaccineshave received Emergency Use Authorization (EUA) from the FDA. This means that they became available for use more quickly than usual. **The Moderna mRNA-1273 vaccine received full FDA approval.** Some of these treatments and vaccines are being evaluated in clinical trials, **such as** ACTIV-2/A5401 and this study (A5404).

People who have previously experienced SARS-CoV-2 infection can get it again, and it is not known if active viral infection generates a weaker immune response than what can be elicited by a COVID-19 vaccine.

This study is for people who had COVID-19 and participated in ACTIV-2/A5401 and received either experimental treatment, a standard of care COVID-19 treatment, or placebo. This study is also for people who have not previously had a COVID-19 infection. The study is designed to evaluate how the immune system responds to mRNA-COVID-19 vaccines in these participants. The safety of mRNA COVID-19 vaccines in persons with prior COVID-19 who did and did not receive prior experimental treatment for COVID-19 will be explored. Prior infection with or without treatment could increase, decrease, or have no significant effect on the response to mRNA COVID-19 vaccines, as well as the risk of side effects from these vaccines. Immune responses of participants who have not previously been infected with COVID-19 will be compared to those who have previously had COVID-19.

Enrollment for this study closed on February 25, 2022, due to slow enrollment. Vaccine responses will be studied in the 43 participants enrolled. Your continued participation is appreciated.

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?

Location of Study Visits

Your study visits will take place in person or remotely. You and the **study** staff at your **study** site will discuss the location for each visit.

- In-person visits will take place at the clinic, at your home, or at another non-clinic location.
- Remote visits will take place over the phone or via telemedicine systems approved for use at your **study** site.

Information Collected at Screening

There is some information that we collect on everyone who is screened for an AIDS Clinical Trials Group (ACTG, part of the National Institute of Allergy and Infectious Diseases, an institute

of the NIH) study. As part of your screening visit, some demographic (for example, age, gender, race) and clinical (for example, disease condition, diagnosis) information will be collected from you. We also collect information on whether you use (or have used) injection drugs.

We will collect this information even if you do not enroll in this study. This information is collected so that ACTG researchers may determine whether there are patterns and/or common reasons why people do not join a study.

Blood Drawn
The study site staff can tell you how much blood will be collected at any particular visit.

Screening Visit
If you would like to be in this study, after you have read, signed, and dated this consent form, you will have a screening visit to make sure you meet the requirements for joining the study. This visit will take about 1 hour. You may come to the clinic, or if it is possible or necessary, this visit might be done remotely (for example, by telephone).

At this visit:
- Study staff will tell you more about the study.
- If you will receive **the** study-provided Moderna mRNA-1273 COVID-19 vaccine, then study staff will tell you about that **study** vaccine.
- If you are receiving **a** community-provided mRNA COVID-19 vaccine, then study staff will ask you which vaccine (for example, Pfizer or Moderna) you are getting and when you received or are scheduled to receive your first **and (if applicable) second** vaccine dose**s**.
- If you were a participant in the A5401/ACTIV-2 study: Study staff will review your history and confirm your participation in ACTIV-2/A5401.
- You will be asked about any symptoms you are experiencing.
- Study staff will ask you about your allergy history, any health conditions you have, and questions about your health in general.
- Study staff will ask you about your medication history and any medications you are taking.
- You may have a brief physical exam if your screening visit takes place at the clinic.

Entry Visit
If you qualify for the study, you will have an entry visit. This visit might occur on the same day as your screening visit.

- You will have a physical exam and answer questions about your medical and allergy history and any medications you are taking or have taken in the past.
- **If you have already received a community-provided mRNA COVID-19 vaccine dose before the Entry visit, you will be asked to bring your vaccine card to this visit.**
- **If you have already received a community-provided mRNA COVID-19 vaccine dose before the Entry visit, you will be asked to bring your vaccine card to this visit.**
- If you were a participant in the A5401/ACTIV-2 study, your information collected from A5401/ACTIV-2 will also be used in this trial.
- If you were a participant in the A5401/ACTIV-2 study, you will be asked some questions about ACTIV-2/A5401 experimental treatment and about your interest in this study.
- You will be asked about symptoms you are experiencing.
- You will have a pregnancy test, if applicable.
- You will have blood collected. This blood will be tested to measure any responses that your genes and immune system have had to your previous SARS-CoV-2 infection.

- If you are receiving **the** study-provided Moderna mRNA-1273 COVID-19 vaccine, you will receive the first dose of the vaccine. You will be asked to remain at the clinic for approximately 30 minutes for monitoring after you receive the Moderna mRNA-1273 COVID-19 vaccine.
- If you are receiving **both** COVID-19 vaccine **doses outside of the study ("in the community") and enroll prior to receiving the first or second dose, you should have your entry visit within 72 hours prior to receiving the dose. If you enroll after receiving the second dose, you must have blood collected within 14 days of that second dose.**
- **If you are receiving the first vaccine dose outside of the study, and the second dose through the study (this is for people who receive Moderna mRNA-1273 vaccine only), and enroll prior to receiving the first dose, you should have your entry visit within 72 hours prior to receiving that first dose. If you enroll after receiving the first vaccine dose, you must have blood collected within 72 hours prior to the second dose you receive through the study.**

Phone Visits 7 to 14 Days after Vaccinations

If you enter the study before your first or second mRNA COVID-19 vaccination, between 7 and 14 days after **the** vaccine**(s)**, you will be contacted by phone by the study team to see whether or not you have had any new symptoms or medical events. If you **enter the study** more than 14 days after your first **vaccination**, then you will only be contacted after the second vaccine. **If you enter the study more than 14 days after your second vaccination, then you will not be contacted.**

Study Visit on Day of 2nd Dose of Vaccine

- If you are receiving **the** study-provided Moderna mRNA-1273 COVID-19 vaccine, you will return to the clinic a**round** 28 days (about 4 weeks, or 1 month) after your first vaccine dose to receive your second dose. You will be asked to remain at the clinic for approximately 30 minutes for monitoring after you receive the vaccine. If you do not receive the second dose of the vaccine at this time (and you still want to receive it), you may still get the second dose through the study up to 140 days after your first vaccine dose. You will still be contacted by phone 7 to 14 days after you receive the vaccine.
- If you are receiving **the** community-provided mRNA COVID-19 vaccine **and enter the study before receiving your second dose**:
  - If you received the Moderna mRNA-1273 COVID-19 vaccine, **you will receive your second dose** about 28 days after your first dose. If you received the Pfizer-BioNTech **BNT162b2** mRNA COVID-19 vaccine, **you will receive your second dose** about 21 days after your first dose. You will be asked to bring your vaccine card to this visit.
  - If you received the Moderna mRNA-1273 COVID-19 vaccine for your first dose, you may be able to get the second dose of the Moderna mRNA-1273 COVID-19 vaccine through the study, if you want to.
- If you do not receive your 2nd dose of **the** vaccine, you may still remain on the study and have the remaining study visits performed.
- **If you enter the study after receiving both doses of mRNA COVID-19 vaccine in the community, then you will not have this visit.**
- **If your first community-provided mRNA-based COVID-19 vaccine dose occurred after entry, you will be asked to bring your vaccine card to this visit.**

At this visit:
- You will have a physical exam and answer questions about current medications you are taking.
- You will have a pregnancy test, if applicable.
- You will be asked about symptoms you are experiencing.
- You will have blood collected. This blood will be tested to measure any responses that your genes and immune system have had to your previous SARS-CoV-2 infection.

Study Visit 8 Weeks (56 days, or about 2 months) after Your First mRNA COVID-19 Vaccine Dose
You will have a physical exam and answer questions about medications you are currently taking. You will have blood drawn. This blood will be used to measure immune responses to the vaccine you took. If you think you may be pregnant, you will have a pregnancy test. If you **received the second** community-provided mRNA COVID-19 vaccine **dose after entering the study**, you will be asked to bring your vaccine card to this visit. **If you enroll more than 56 days after your first mRNA COVID-19 vaccine dose, you will not have this visit. If you enroll between 56 and 63 days after your first mRNA COVID-19 vaccine dose, then this study visit may be combined with your entry visit.**

Study Visit 20 Weeks (140 days, or about 5 months) after Your First mRNA COVID-19 Vaccine Dose
You will have a physical exam and answer questions about medications you are currently taking. You will have blood collected. This blood will be tested to measure immune responses to the vaccine you took. If you think you may be pregnant, you will have a pregnancy test.

If you enroll between 133 and 139 days after your first mRNA COVID-19 vaccine dose, then this study visit may be combined with your entry visit.

Study Visit 1 Year (365 days) after Your First mRNA COVID-19 Vaccine Dose
You will have a physical exam and answer questions about medications you are currently taking. You will have blood collected. This blood will be tested to measure immune responses to the vaccine you took. If you think you may be pregnant, you will have a pregnancy test.

Study Visit 2 Years (730 days) after Your First mRNA COVID-19 Vaccine Dose – FINAL VISIT
You will have a physical exam and answer questions about medications you are currently taking. You will have blood collected. This blood will be tested to measure immune responses to the vaccine you took. If you think you may be pregnant, you will have a pregnancy test.

Additional Study Visit
If you think you have contracted COVID-19, you will be asked to come in for an extra study visit.

At this visit:
- You will have a physical exam.
- Diagnosis and documentation of new active SARS-CoV-2 infection with an antigen or nucleic acid test (these tests that can detect active SARS-CoV-2 infection from your nose or throat) will be done or you will be referred to a site that can do this testing
- If you are found to have an active SARS-CoV-2 infection, you may have nasopharyngeal swabs (**for example,** deep nasal swabs) collected by a study staff person as early as possible within 14 days after your symptoms begin. Your current medications will also be reviewed.

- You will be asked about symptoms you are experiencing.
- You will have blood drawn. This blood will be stored for future study-required testing.
- You will have a pregnancy test, if applicable.

Genetic Testing

Your body, like all living things, is made up of cells. Cells contain deoxyribonucleic acid, also known as "DNA." DNA is like a string of information put together in a certain order. Parts of the string make up "genes." Genes contain instructions on how to make your body work and fight disease. These genes direct the cells to make particular sequences or types of ribonucleic acid, also known as "RNA." Differences or changes in DNA and RNA explain some of the physical differences among people. These differences partly explain why some people get diseases **such as** cancer or diabetes while others do not. Genetic testing looks at the differences in people's DNA and RNA. This testing also looks at how differences affect health and the body's response to disease, treatment, and vaccination.

If you agree, some of your blood that is collected will be used to study whether there are genetic differences in how people respond to study drugs. This genetic testing might include whole genome sequencing (WGS) for DNA and gene expression for RNA. "Sequencing" is looking at the order of a person's genes to see how this order is different from the order of other people to see if these differences are associated with different disease states or immune responses. You must agree to participate in this genetic testing in order to participate in this study.

Please put your initials below to indicate your choice:

_____ (initials) I understand and I agree to this use of my samples.
OR
_____ (initials) I understand but I do not agree to this use of my samples**,** and I understand that this means I cannot participate in this study.

CAN I CHOOSE THE TYPES OF RESEARCH THAT MY SAMPLES AND INFORMATION ARE USED FOR?

Your information and samples from ACTIV-2/A5401 and data generated from your information and samples from ACTIV-2/A5401 will be used for this study. Some of your blood will be stored and used for study-required testing.

Your samples and any private information that has been collected about you **will be coded**. This means that no one looking at the labels or at other information will be able to know that the samples or information came from you.

The tests described above are required by this study. If you do not agree to the storage or testing that has been described above, you should not join this study. Your samples may be used for commercial profit and you will not share in this commercial profit.

Please refer to **the separate consent at the end of this document** to consent for use of your samples in other studies.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

This study **planned to** enroll 70 people who were in ACTIV-2/A5401 from each ACTIV-2/A5401 study treatment group, and up to 70 people who have never had a COVID-19 infection per each ACTIV-2/A5401 study treatment group. **In total, the study enrolled 43 participants.**

HOW LONG WILL I BE IN THIS STUDY?

You will be in this study for about 730 days.

WHY WOULD THE DOCTOR TAKE ME OFF THIS STUDY EARLY?

The study doctor may need to take you off the study early without your permission if:
- The study is stopped or cancelled.
- You are not able to attend the study visits as required by the study.
- You do not receive the first dose of mRNA COVID-19 vaccine, or other community–provided mRNA vaccine**, such as** the Pfizer BioNTech **BNT162b2 mRNA** COVID-19 vaccine.

If you received **the** study- or community-provided Moderna mRNA-1273 COVID-19 vaccine for your first dose:
- You may still be able to get the second dose of the Moderna mRNA-1273 COVID-19 vaccine through the study (up to 140 days after your first dose) at the premature study discontinuation visit if you are taken off of the study early.

If you are receiving **the** study-provided Moderna mRNA-1273 COVID-19 vaccine, the study doctor may need to take you off the Moderna mRNA-1273 COVID-19 vaccine without your permission if:
- Continuing the Moderna mRNA-1273 COVID-19 vaccine may be harmful to you.
- You are not able to take the Moderna mRNA-1273 COVID-19 vaccine as required by the study.

If you must stop taking the Moderna mRNA-1273 COVID-19 vaccine before the study is over, the study doctor may ask you to continue to be part of the study and return for some study visits and procedures.

If you leave the study early, you will have a physical exam, pregnancy test (if applicable), and blood collection.

<u>If I have to permanently stop taking study-provided Moderna mRNA-1273 COVID-19 vaccine, or once I leave the study, how would the Moderna mRNA-1273 COVID-19 vaccine be provided?</u>

During the study:
If you must permanently stop receiving study-provided Moderna mRNA-1273 COVID-19 vaccine before your study participation is over, the study staff will discuss other options that may be of benefit to you.

WHAT ARE THE RISKS OF THE STUDY?

The study-provided Moderna mRNA-1273 COVID-19 vaccine used in this study may have side effects, some of which are listed below. Please note that these lists do not include all the side effects seen with this vaccine. These lists include the more serious or common side effects with a known or possible relationship. If you have questions concerning the additional Moderna mRNA-1273 COVID-19 vaccine side effects please ask the medical study staff at your site.

There is a risk of serious and/or life-threatening side effects when non-study medications are taken with the Moderna mRNA-1273 COVID-19 vaccine. For your safety, you must tell the study doctor or nurse about all medications you are taking before you start the study and also before starting any new medications while on the study. Also, you must tell the study doctor or nurse before enrolling in any other clinical trials while on this study.

Since we do not fully understand the Moderna mRNA-1273 COVID-19 vaccine's effectiveness in participants who have previously had COVID-19, it is recommended that you continue to take general precautions (**for example**, physical distancing, wearing a mask) to reduce the risk of infection.

Risks of **the** Study-provided Moderna mRNA-1273 COVID-19 Vaccine
There are risks to taking part in any research study.

There is a risk that the study-provided Moderna mRNA-1273 COVID-19 vaccine may not stop you from acquiring COVID-19.

Additionally, if you have previously had COVID-19 and received an experimental treatment, placebo, or a standard of care COVID-19 treatment in the ACTIV-2/A5401 study:

- The study-provided Moderna mRNA-1273 COVID-19 vaccine has received **full FDA approval. It** has been shown in a clinical trial to be effective in preventing COVID-19 following two doses given at least 1 month apart, but it is not known if it is effective in people who have had COVID-19 previously and if being treated with experimental treatment has any effect.

Side effects that have been reported with the study-provided Moderna mRNA-1273 COVID-19 vaccine include:

- Injection site reactions: pain, itching, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness) redness, and formation of an ulceration (a break in the skin) or infection.
- General side effects: fatigue (tiredness), headache, muscle pain, joint pain, chills, nausea, vomiting, fever, and mild abdominal pain.
- Other: facial flushing (redness), generalized itching, tingling of face or extremities, runny nose, sneezing, hypotension (low blood pressure), hives, and pruritus (itching).

There is a very small chance that the study-provided Moderna mRNA-1273 COVID-19 vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the study-provided Moderna mRNA-1273 COVID-19 vaccine. For this reason, you will be asked to stay at the study site where you received your vaccine for about 30 minutes after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing or swallowing
- Chest tightness
- Shortness of breath

- Coughing
- Wheezing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Vomiting
- Abdominal pain
- Dizziness and weakness
- Fainting (loss of consciousness), convulsions (like a seizure)

There is an increased risk of myocarditis and pericarditis after getting the study-provided Moderna mRNA-1273 COVID-19 vaccine. Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the lining around the heart. In both cases, the body's immune system is causing inflammation in response to the vaccine. Symptoms can include chest pain, shortness of breath, or palpitations. Symptoms usually start within a few days after receipt of the Moderna mRNA-1273 COVID-19 vaccine. Most individuals who have sought medical care have responded well to medications and rest, and symptoms have resolved for most persons who experienced this side effect. It is not known if either myocarditis or pericarditis from the vaccine causes long-term health effects.

Myocarditis and pericarditis have been reported in greatest numbers in males under the age of 40 years following a second dose of mRNA vaccines (including the COVID-19 vaccine), but cases have been reported in older males and in females as well, and also following other doses. Risk for myocarditis and pericarditis has been observed to be highest in males between 12 to 17 years of age. While some cases required intensive care support, data suggests that symptoms got better in most people with some management. Information is not yet available about the potential long-term affects of myocarditis and pericarditis in these people. While there is limited data on the risk of myocarditis and pericarditis in children younger than 12 years old (especially compared to the risk data that is available in adolescents and adults), it is an area of science that is currently being studied.

Please let a member of the study staff know if you experience any of the following symptoms of myocarditis or pericarditis, following vaccination provided through the study:
- **Chest pain**
- **Shortness of breath**
- **A fast heartbeat, fluttering, or pounding heart**

Study staff will provide you with appropriate contact information so that you can reach out should you experience any of these symptoms.

You should not get the study-provided Moderna mRNA-1273 COVID-19 vaccine if you:
- Had a severe allergic reaction after a previous dose of this vaccine.
- Had a severe allergic reaction to any ingredient of this vaccine.

Serious and unexpected side effects may also occur.

Risks of Blood Collection
Having blood collected may cause some discomfort, bleeding, bruising, and/or swelling where the needle enters the body, and in rare cases it may result in fainting. There is a small risk of infection.

ARE THERE RISKS RELATED TO PREGNANCY AND BREASTFEEDING?

Pregnancy
If at any point during the study you think you may be pregnant, you should let the staff at your site know so that a pregnancy test can be done.

If you become pregnant after the first dose of the mRNA COVID-19 vaccine but prior to the second dose, you are eligible to receive the second dose. If you choose not to receive the second dose of the vaccine, you will be encouraged to continue on study and complete the study.

At the end of the pregnancy, study staff will contact you to ask about the pregnancy outcome.

If you have completed the study or choose to discontinue from the study before the end of the pregnancy, then **study** staff will request permission to contact you regarding pregnancy outcomes at the end of pregnancy.

If you are receiving **the** study-provided Moderna mRNA-1273 COVID-19 vaccine:
There is limited data regarding the use of mRNA COVID-19 vaccines in people who are pregnant. The American College of Obstetrics and Gynecology (ACOG suggests offering vaccination in pregnant and breastfeeding individuals if they are at risk for COVID-19 if they meet the criteria for vaccination based on the Advisory Committee on Immunization Practices (ACIP) recommending priority groups for vaccination. The Centers for Disease Control and Prevention (CDC) has recently classified pregnant and breastfeeding individuals at increased risk of severe illness or death from COVID-19. Therefore, pregnant individuals are eligible to participate in this study.

The study-provided Moderna mRNA-1273 COVID-19 vaccine may involve risks to you (or to the embryo or fetus, if you or your partner become pregnant), which are currently unforeseen.

Breastfeeding
If you are receiving **the** study-provided Moderna mRNA-1273 COVID-19 vaccine: It is not known if the Moderna mRNA-1273 COVID-19 vaccine is safe to use in people who are breastfeeding; however, you are eligible to receive this vaccine if you are breastfeeding.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

There is increasing evidence that COVID-19 vaccination has the potential of direct benefit because it offers high levels of protection against future COVID-19 (SARS-CoV-2 infection), whether you have been infected previously or not.

WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?

Instead of being in this study you have the choice of:
- Obtaining a COVID-19 vaccine **in the community**.
- Obtaining an experimental COVID-19 vaccine, if you qualify.
- No vaccination.

Please talk to your doctor about these and other choices available to you. Your doctor will explain the risks and benefits of these choices.

WHAT ABOUT CONFIDENTIALITY?

For sites in the US

We will do everything we can to protect your privacy. In addition to the efforts of the study staff to help keep your personal information private, we have gotten a Certificate of Confidentiality from the US Federal Government. This certificate means that researchers cannot be forced to tell people who are not connected with this study, such as the court system, about your participation. Also, any publication of this study will not use your name or identify you personally. **Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study. Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to yourself or others, we will be required to tell the proper authorities.**

Your records may be reviewed by the US Food and Drug Administration (FDA), the ACTG, the US Office for Human Research Protections (OHRP), or other local, US, and international regulatory entities as part of their duties, Advarra IRB institutional review board (a committee that protects the rights and safety of participants in research), National Institutes of Health (NIH), study staff, study monitors, drug companies supporting this study, and their designees. Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study.

All information collected about you as part of the study will be sent securely to the ACTG Statistical and Data Management Center in the United States for combining with information from other study participants and statistical analysis of study results. Your name and other personal identifiers will not be sent. Your research site is responsible for sending your information in accordance with the laws, regulations, and policies of your country and research site.

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.

For sites outside the US

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Any publication of this study will not use your name or identify you personally.

Your records may be reviewed by the US Food and Drug Administration (FDA), the ACTG, the US Office for Human Research Protections (OHRP), or other local, US, and international regulatory entities as part of their duties, (insert name of site) institutional review board (IRB) or

Ethics Committee (a committee that protects the rights and safety of participants in research), National Institutes of Health (NIH), study staff, study monitors, drug companies supporting this study, and their designees.

All information collected about you as part of the study will be sent securely to the ACTG statistical and data management center in the United States for combining with information from other study participants and statistical analysis of study results. Your name and other personal identifiers will not be sent. Your research site is responsible for sending your information in accordance with the laws, regulations, and policies of your country and research site.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time

WHAT ARE THE COSTS TO ME?

Taking part in this study may lead to added costs to you and your insurance company. In some cases, it is possible that your insurance company will not pay for these costs because you are taking part in a research study.

WILL I RECEIVE ANY PAYMENT?

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

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

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

You will be paid _____ *["following each completed visit," "monthly," "quarterly," "at the end of your participation in the research study," "following each completed visit or at the end of your participation in the research study, whichever you prefer"]*.

If you have any questions regarding your compensation for participation, please contact the study staff.

[OR]

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

WHAT HAPPENS IF I AM INJURED?

If you are injured as a result of being in this study, you will be given immediate treatment for your injuries. The US National Institutes of Health (NIH) does not have a mechanism to provide direct compensation for research-related injury.

[For sites outside the US: Please modify (if necessary) and insert one of these two statements, as appropriate to your site. If your site is required to carry CTI, this must be indicated in the informed consent.

- *This site has clinical trials insurance. This insurance will allow the site to provide you with monetary compensation if you suffer harm as a result of participating in this research study. OR*
- *The cost for this treatment will be charged to you or your insurance company. There is no program for compensation either through this institution or the NIH].*

The US federal government 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.

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

Due to the coronavirus public health crisis, the US 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. Review the Public Readiness and Emergency Preparedness Act (PREP): https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.
You will not be giving up any of your legal rights by signing and dating this consent form.

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. Your decision will not have any impact on your participation in other studies conducted by NIH and will not result in any penalty or loss of benefits to which you are otherwise entitled.

We will tell you about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you want the results of the study, let the study staff know. Clinically relevant research results, including individual research results, will not be provided to you. If applicable, pregnancy test results will be provided to you.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants.

[Sites: Select the contact information of your IRB below.]

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

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

Please reference the following number when contacting the Study Subject Adviser: Pro00050357.

[OR]

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

- **Name or title of person on the Institutional Review Board (IRB) or other organization appropriate for the site.**
- **T**elephone number of above.

SIGNATURE PAGE

If you have read this consent form (or had it explained to you), all your questions have been answered, and you agree to take part in this study, please sign your name below and date it.

Printed Name of Participant

Signature of Participant **Date**

Printed Name of Legally Authorized Representative (As Appropriate)

Signature of Legally Authorized Representative **Date**

Printed Name of Study Staff Conducting Consent Discussion (print)

Signature of Study Staff Conducting Consent Discussion **Date**

Printed Name of Witness (As Appropriate)

Signature of Witness **Date**

CONSENT FOR **OPTIONAL** USE OF **EXTRA** SAMPLES IN OTHER STUDIES

Everything in the main study consent you signed and dated above still applies to your participation unless otherwise noted below.

When samples are no longer needed for this study, the AIDS CLINICAL TRIALS GROUP (ACTG) may want to use them in other studies and share them with other researchers. These samples are called "extra samples." The ACTG will only allow your extra samples to be used in other studies if you agree to this. If you have any questions, please ask.

Identifiers will be removed from your samples and from any private information that has been collected about you. This means that no one looking at the labels or at other information will know that the samples or information came from you.

Extra samples are stored in a secure central place called a repository. Your samples will be stored in the ACTG repository located in the United States.

There is no limit on how long your extra samples will be stored. ***[Site: Revise the previous sentence to insert limits, if your regulatory authority imposes them.]***

When a researcher wants to use your samples and information, their research plan must be approved by the ACTG. Also, the researcher's **I**nstitutional **R**eview **B**oard (IRB) **or ethics committee (EC) will review their plan.** ***[Site: If review by your institution's IRB/EC/RE is also required, insert a sentence stating this.]*** IRBs **and ECs** protect the rights and well-being of people in research. If the research plan is approved, the ACTG will send your samples to the researcher's location. This means that researchers who are not part of the study team may use your samples without asking you again for your consent.

You will not be paid for your samples. Also, a researcher may make a new scientific discovery or product based on the use of your samples. If this happens, there is no plan to share any money with you.

You may withdraw your consent for research on your extra samples at any time, and the specimens will be discarded.

Please choose the response that matches what you want by putting your initials in the space provided. Please ask the study staff any questions that you have before you indicate your selection.

<u>Research without Human Genetic Testing</u>
If you agree, your extra samples may be stored (as described above) and used for ACTG-approved research that does not include human genetic testing.

____ (initials) I understand and I agree to this storage and possible use of my samples.

OR

____ (initials) I understand but I do not agree to this storage and possible use of my samples.

SIGNATURE PAGE

If you have read this consent form (or had it explained to you), all your questions have been answered, and you agree to take part in this study, please sign your name below and date it.

_____
Printed Name of Participant

_____ _____
Signature of Participant **Date**

_____
Printed Name of Legally Authorized Representative (As Appropriate)

_____ _____
Signature of Legally Authorized Representative **Date**

_____
Printed Name of Study Staff Conducting Consent Discussion

_____ _____
Signature of Study Staff Conducting Consent Discussion **Date**

_____
Printed Name of Witness (As Appropriate)

_____ _____
Signature of Witness **Date**