INFORMED CONSENT FORM AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title:	**National Institutes of Health (NIH)/Division of Microbiology and Infectious Diseases (DMID) / "Phase I, Open-Label, Dose-Ranging Study of the Safety and Immunogenicity of 2019-nCoV Vaccine (mRNA-1273) in Healthy Adults"**
Protocol Number:	**20-0003**
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We are asking you to be in a research study. This form gives you information to help you decide whether to be in the study. Being in the study is voluntary. Please read this form carefully. You may ask any questions about the study. Then you can decide whether you want to be in the study.

Key Information about This Research

The purpose of this research is to test an experimental vaccine for a new coronavirus that emerged in Wuhan, China in December 2019 and that can cause serious respiratory infections. The virus was first named 2019-nCoV (novel Coronavirus) and is now named SARS-CoV-2 (due to its similarity to the Severe Acute Respiratory Syndrome [SARS] Coronavirus [CoV; SARS-CoV]). The disease caused by SARS-CoV-2 is called Coronavirus disease 2019 (COVID-19). An experimental vaccine is one that is not approved by the United States Food and Drug Administration (FDA). There is no licensed vaccine that can be used to protect against this infection.

The experimental vaccine, called mRNA-1273, is a messenger ribonucleic acid (mRNA) vaccine. This study vaccine is made of the genetic code of the virus. This genetic code will make a protein from the virus and cause your body to think you have been infected with the virus. It is not made from the SARS-CoV-2 virus and cannot cause infection. This study vaccine has not been given to humans before.

Approximately 155 people will participate in this study at up to three domestic sites over approximately 20 months. If you participate, you will be in the study for approximately 14 months. You will be assigned to one of thirteen study groups, which will each include either 10 or 15 people. You will receive two mRNA-1273 study vaccine injections, 28 days apart. The study vaccine you receive will have an mRNA dose of either 10 micrograms (mcg), 25 mcg, 50 mcg, 100 mcg, or 250 mcg. You will get the same dose for each of the two study vaccinations.

All participants will attend 11 scheduled study clinic visits that include an initial screening visit, two study vaccination visits, and eight follow-up visits. Study clinic visits may include physical exams, and all will include a blood draw. A subset of participants may have up to 2 extra visits for an additional optional study procedure called leukapheresis, a specific procedure to collect a large volume of white blood cells. Participants will be consented for this procedure separately. You can still be in the main study if you agree not to take part in the leukapheresis.

Additionally, you will complete a daily memory aid (like a diary card) at home for seven days after each study vaccination to record any side effects you may experience. We will also call you at one and two days after each study vaccination visit to ask about any reactions you may have had.

The possible risks of participating in this study include those associated with having blood drawn, reactions to the study vaccine injection, reactions to the study vaccine, and the possibility of a breach of confidentiality. These risks are detailed later in this document. Since the mRNA-1273 vaccine has not been given to humans before there may be unanticipated risks.

As part of this study, we are obtaining **extra blood samples** from you. We will use your coded information, leftover samples, and extra blood samples for **secondary research**. Secondary research is research that is not part of this study, and the research is not planned yet. This additional research is essential to understanding how the study vaccine works or developing assays (new lab tests). This type of research may include **genetic** testing. When you give consent, you will be taking part in the vaccine study and allowing for secondary research. You allow for research to continue for understanding how the body responds to this new study vaccine, or the development of assays, new vaccines, or treatments.

The remaining document describes more about the research study. Members of the study team will talk with you about the information in this document. You are encouraged to ask any questions and discuss this study with family, friends, and anyone you choose. If you decide to take part in this study, you will be asked to sign and date this consent form. A copy of this signed and dated form will be given to you to keep. Signing and dating this consent form indicates that you understand your involvement in the study, the risks of participating in the study, and that you agree to take part in the study.

Purpose of This Research Study

The purpose of this research is to test the experimental mRNA-1273 vaccine to see if it is safe and to evaluate the immune system response. Vaccines tell your germ-fighting cells to make antibodies and other substances to fight infections. The mRNA-1273 vaccine is intended to prime the immune system so that if the person is then infected with the SARS-CoV-2 virus, they have a "head start" and the infection can be stopped.

Experimental means this vaccine is not approved for routine use by the United States Food and Drug Administration (FDA); however, the FDA is allowing this vaccine to be tested in this study.

The mRNA-1273 vaccine is made using a new process that allows for a much faster production of vaccine than older methods. Typical vaccines for viruses are made from a weakened or killed virus but the mRNA-1273 vaccine is not made from the SARS-CoV-2 virus. It includes a short segment of mRNA. The mRNA is a genetic code that tells cells how to make a protein. This mRNA is entirely made in a laboratory. When injected into the body, the mRNA causes some cells to make that viral protein, which can trigger an immune response. If the person is later infected, their immune system remembers the protein from the prior vaccination, and this should help it to fight the invading virus. The vaccine mRNA degrades naturally and does not persist in the body.

Approximately 155 people will participate in this study. If you participate, you will be assigned to one of thirteen study groups. Each group will include either 10 or 15 people, who will receive two study vaccinations, 28 days apart, of the mRNA-1273 vaccine, at a dose of 10 mcg, 25 mcg, 50 mcg, 100 mcg, or 250 mcg (Table 1). You will get the same dose for each study vaccination. The group to which you are assigned will depend on when you are enrolled in this study and your age.

Table 1. Study Groups.

Group	Years of Age	Number of participants	Vaccine dose of mRNA-1273 for first and second study vaccinations
1	18-55	15	25 mcg
2	18-55	15	100 mcg
3	18-55	15	250 mcg
4	56-70	10	25 mcg
5	56-70	10	100 mcg
6	56-70	10	250 mcg
7	71 or older	10	25 mcg
8	71 or older	10	100 mcg
9	71 or older	10	250 mcg
10	18-55	15	50 mcg
11	56-70	10	50 mcg
12	71 or older	10	50 mcg
13	18-55	15	10 mcg

- Groups 1, 4 and 7 will receive the study vaccine at a dose of 25 mcg of mRNA-1273.
- Groups 2, 5 and 8 will receive the study vaccine at a dose of 100 mcg mRNA-1273.
- Group 3, and Groups 6 and 9, if enrolled, will receive the study vaccine at a dose of 250 mcg of mRNA-1273.
- Groups 10-12 will receive the study vaccine at a dose of 50 mcg of mRNA-1273.
- Group 13, if enrolled, will receive the study vaccine at a dose of 10 mcg of mRNA-1273.
- Groups 1 and 2 will be enrolled at the beginning of the study.
- Groups 3-5 and 7-8 will be enrolled afterwards in a staggered fashion.
- Groups 6 and 9, if enrolled, will also be enrolled in a staggered fashion.
- Groups 10-12 will be enrolled concurrently.
- Group 13 may be enrolled at a later date.

Groups 10-12 have been added to allow for the assessment of lower doses. Groups 6 and 9 may be enrolled depending on the results from prior groups. Group 13 may also be enrolled in the future.

At each of the study clinic visits we will take blood samples from you. These samples will be used for clinical tests to assess your health and for research tests of the immune response to the study vaccine.

This study will take place at up to three domestic sites over approximately 20 months.

Selection of Study Population

Only healthy people age 18 years or older may enroll in this study. We will screen you for eligibility before performing any further study activities or giving you a study vaccination.

You are **not** eligible for this research study if:

- You have a history of COVID-19 diagnosis
- You have received an experimental vaccine or drug in the past 60 days, OR plan to receive one during your study participation
- You have any serious chronic medical or psychiatric conditions
- You are on certain medications
- You are pregnant or breastfeeding
- You have any medical condition the study doctor feels would make your participation unsafe
- You reside in a nursing home or other skilled nursing facility or have a requirement for skilled nursing care

Procedures

If you agree to take part in this study, your involvement is expected to last for about 14 months.

Screening

You will have a Screening Visit to check if you are eligible to enroll in this study. The Screening Visit will take about 90 minutes and will include:

- Reviewing, signing and dating the consent form
- Collecting information about your medical and mental health history, medications (and for women birth control), vaccination history, and drug or alcohol use
- Having a physical exam
- Collecting vital signs (heart rate, blood pressure, temperature) and height and weight
- Testing your blood to check your kidney, pancreas, and liver functions, blood cell counts, and to perform testing for HIV, hepatitis B, and hepatitis C infections. The study doctor may be required by law to report the result of the HIV and hepatitis tests to the local health authority.
- A urine drug screen for the presence of amphetamines, barbiturates, benzodiazepines, cocaine, methadone, methaqualone, phencyclidine, propoxyphene, and opiates (cannabis use will not exclude you from the study)
- For women who can become pregnant, a blood pregnancy test

If your blood or urine lab results are not within standard, normal ranges, you will not participate in the study, and the study doctor may refer you to your regular medical provider.

Women who can become pregnant must agree to use an acceptable method of birth control from at least 30 days before the first study vaccination through 60 days after the last study vaccination. Acceptable birth control methods include abstinence from sexual activity that could lead to pregnancy, monogamous relationship with a partner who has had a vasectomy at least six months ago, successful Essure® placement (permanent, non-surgical, non-hormonal sterilization), intrauterine devices, and hormonal methods, including the birth control patch, shot (Depo-Provera), pills, the vaginal ring (NuvaRing), and the contraceptive implant (Nexplanon).

Men who are not permanently sterile must agree to use condoms with female partners who can become pregnant, and not to donate sperm, from the first study vaccination until 3 months after the last study vaccination.

General Study Visit Procedures

Study visits that include a study vaccination will generally last about 2-3 hours and other visits will generally last about 30 minutes. Visits may include:

- Questions about your recent medical history and medications, illnesses or symptoms, and side effects or reactions
- Collecting vital signs (heart rate, blood pressure, temperature)
- If applicable, reviewing use of birth control methods and pregnancy status
- Having a physical exam if needed
- Collection of blood samples at each of the study clinic visits (and, for women who can become pregnant, urine for pregnancy testing at each of the two study vaccination visits)
- Study vaccination or assessment of the site of a previous study vaccination
- Review of the memory aid

Study Vaccination Visits

Study vaccination visits occur on Study Days 1 and 29. At those visits, we will review your lab test results and medical history to confirm that you are eligible for a study vaccination.

You will be in one of thirteen study groups (Table 1) which will each include 10 or 15 participants. You will receive an injection of the same dose of study vaccine in the deltoid muscle of your upper arm at each of the two study vaccination visits. You will stay in the clinic for at least 60 minutes after the study vaccination for study staff to check for any immediate reactions.

We will give you a memory aid (like a diary card) and a thermometer, with instructions to record your temperature and any side effects. At home, you will complete the daily memory aid, beginning on the evening of the day of each study vaccination and continuing daily for the next seven days. On the first and second day after each study vaccination we will call you and ask you to report what you have recorded on the memory aid and any other symptoms that you may have. About seven days after the study vaccination visit you will return to the study clinic for a visit and will bring the form with you for the study staff to review. The memory aid will include contact information should you need to contact the study team.

If you become sick or have any reactions after a study vaccination, you should immediately contact the study staff. We may ask you to come to the clinic for an extra study visit. The staff may perform additional research or safety procedures, if needed.

Follow Up Visits

In addition to the study vaccination visits, you will also come to the clinic for follow up visits, on Days 8, 15, 36, 43, 57, 119, 209, and 394. Follow-up visits will take about 30 minutes.

The study staff will call you periodically during your study participation to check on your health status or to remind you of an upcoming visit or for other reasons. We may also contact you by email or text message when appropriate.

A subset of participants who give their consent for leukapheresis will have up to 2 extra visits as described in the separate leukapheresis consent form.

Unscheduled Visits

You may be asked to come back to the study clinic at other times if needed, for example, if you have a reaction or illness that should be evaluated before the next scheduled visit. The study doctor will determine what activities will be needed after reviewing any symptoms that you are having.

Laboratory Testing of Blood Specimens

The blood specimens collected from you will be used for two types of tests. They will be used for clinical tests to assess your health and for research tests of the immune response to the study vaccine. None of the study tests are part of your regular medical care. The clinical tests will include measures of your blood counts and kidney, pancreas, and liver function. If you have any abnormal clinical test results that may require medical care, we will share these results with you. Information about your clinical test results will be kept confidential to the best of the study staff's and sponsor's ability and as required by law.

Staff at the clinical laboratory will not know your identity, or even the study identifier you were assigned. However, the study staff who enrolled you will keep a list in a secure area with your name, contact information and the ID code (called a code key) that can link the blood samples to you, if needed. Access to the code key is limited to study staff working at the research site where your blood samples were collected.

The research tests will measure how your body developed an immune response to the study vaccine. We will look at your antibodies, which are proteins that your body uses to fight off the virus. We will also look at how different cells of your immune system help to fight the virus. We will use some samples to develop better ways to test a person's response to the study vaccine. Giving blood samples for the research tests will not benefit you. It may benefit others by leading to new approaches in vaccine development or treatments for coronavirus infection. The results of these tests are useful only for research purposes. Your individual results will not be available to you or your regular doctor and will not be placed in your medical record.

Blood samples for these research tests may be sent to a central storage facility or sent directly to the research testing laboratories. These blood samples will not be labeled with your name or initials, or any other information that could readily identify you. These blood samples will be labeled only with a barcode and a unique tracking number (ID code) to help protect your confidentiality. Staff at the central storage facility and research testing laboratories will not know your identity, or even the study identifier you were assigned. However, the study staff who enrolled you will keep a list in a secure area with your name, contact information and the ID code (called a code key) that can link the blood samples to you, if needed. Access to the code key is limited to study staff working at the research site where your blood samples were collected.

We may remove the codes (so that we cannot identify you) from your information or samples and use these in other research. These samples may be shared with other researchers without your additional consent.

Some of the blood collected for measuring immune responses to the mRNA-1273 vaccine may not be needed to do the research tests. **We plan to store and use these leftover samples and your information (identified only by ID codes) for secondary research.** Secondary research is research that is not part of this study but will be performed in the future. You will not be told about the future research**.**

Also, we will collect extra blood samples at 10 visits (between 2 and 3 teaspoons at each visit) to store and use for secondary research. Secondary research may help us understand how the mRNA-1273 vaccine works, develop tests, study other infections or diseases, or develop treatments. The types of research may include development of new immune-based laboratory tests to better understand vaccine responses or for studies to better understand virus infections, including the SARS-CoV-2 infection. **If you do not want to give leftover and extra samples for secondary research, you should not be in this vaccine study.**

Blood samples will be stored indefinitely at a site determined by the NIH, in conjunction with the study site. Leftover and extra blood samples will be labeled only with a barcode and a unique tracking number (ID code). These blood samples will not be labeled with your name or initials, or any other information that could readily identify you, and will be kept confidential to the best of the sponsor's ability within state and federal law. Staff at the storage facility and future research testing laboratories will not know your identity, or even the study identifier you were assigned. However, the study staff who enrolled you will keep a list in secure area with your name, contact information and the ID code (called a code key) that links the blood samples to you, if needed. Access to the code key is limited to study staff working at the research site where your blood samples were collected.

Leftover and extra blood samples may be used in the future for research about this study vaccine and your body's response to this study vaccine. This may include genetic testing. Genetic testing looks at the material in your cells that tells each cell in your body how to work. Future genetic testing may include whole genome sequencing (DNA testing) or other types of genetic testing. These blood samples might be used in new or different laboratory tests, to give information for the development of new vaccines, or for the studies of coronavirus or other infections, including using tests that have yet to be developed. You will not be contacted about the types of future research. After this study is over, leftover blood samples may be shared with other investigators/institutions and used for future research, including genetic testing. At any time during this study or after this study is over, extra blood samples may be shared with other investigators/institutions and used for secondary research, including genetic testing.

Following future genetic testing, your future genetic information (data) may be shared with other researchers. We will share your future genetic information through a "closed" database, also called a restricted data repository. NIH gives permission to other researchers to use your future genetic information only for research purposes. To qualify, researchers must receive approval from NIH to access and use the future genetic information. A summary of data from all participants may be shared in an "open" database, also called an unrestricted data repository, but this will not contain your individual data. The risk of anyone identifying you with this information is very unlikely. However, there is still a risk of loss of confidentiality. Types of future research using your data may be related to the research in this study or other types of research. Your individual data will not contain information that can easily identify you. It may be possible to identify you with your DNA; however, the researchers must follow rules specifically to not identify you. If you change your mind and want to remove your data from the database, you should contact the research site that collected your data. If possible, your data can be removed for further research. Your data cannot be removed if it has already been used.

Leftover and extra blood samples will be used only for research purposes. This may include reproducing or growing your cells. These blood samples will not be sold or used directly for production of any commercial product. However, the research studies in this study or in the future may lead to identification of antibodies or other treatments that could indirectly lead to a commercial product that protects against viral infection or disease.

Although the results of any future research may be patentable or have commercial profit, you will not receive payment if this happens. You will have no legal or financial interest in any commercial development resulting from any future research.

If these blood samples are tested in the future, the results may be published. You will not be identified in such publication. In other words, the publication will not contain any information about you that would enable someone to determine your identity.

By signing and dating this consent form, you are agreeing to the collection, storage and future research use of your blood samples and information collected for this study. There are no benefits to you in the collection, storage and future research use of your blood samples. Future research tests may benefit others by leading to new approaches in the development of vaccines or treatments for coronavirus infection. The results of any future research testing will be kept confidential in the same way as the results of other testing done for this study. The results of any future research will not be available to you or your regular doctor and will not be placed in your medical record.

You may change your mind about secondary research and withdraw consent for the storage and use of your coded samples or information at any time. You will need to contact the study doctor using the contact information listed on page 1 of this form. If you have visits after this, we will stop collecting extra blood.

Your samples will be removed from future use when the vaccine study is completed. Only stored samples with an ID code and not used in this research can be removed or destroyed. Research that has already begun using your specimens cannot be withdrawn. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw the specimens and data.

Ask us if you have questions about how your blood samples may be used.

How will the vaccine be provided?

The vaccine that you receive will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will administer the vaccine to you. If you have questions about the vaccine, you should ask the principal investigator or study nurse.

Potential Risks and Discomforts

There may be some risks to participation in this study. You may experience one or more of the risks or side effects explained below. You should discuss these with the study doctor or study staff. Many side effects go away shortly if treated, but in some cases, side effects can be serious, long lasting, or permanent. The study vaccine is experimental and has not been given to humans before and there may be risks that we do not know about right now. Side effects may occur more frequently with higher doses of the study vaccine or with the second dose compared with the first.

The possible risks of participating in this study include those associated with having blood drawn, reactions to the injection, adverse effects (side effects) of the study vaccine, and the possibility of a breach of confidentiality.

Having your blood taken can cause pain and may also cause lightheadedness or fainting. The needle stick can cause bruising, which can be prevented or reduced by putting pressure on the site for a few minutes after the needle is removed. It is possible to get an infection at the site of the needle stick. To reduce the risk of infection after the blood draw or study vaccine injection, the study doctor or study staff will wipe the area clean with alcohol and use sterile equipment.

There is a small risk to people who have an unknown health problem at the screening visit. Your blood will be taken at the screening visit to check for health problems. We will review your results before giving you the first study vaccination.

Data placed in the NIH-designated database will have identifiers removed, such as name, address, and identification numbers. Because it may be possible to re-identify genetic data, even if access to data is controlled, confidentiality cannot be guaranteed. There may be other risks that are unknown.

Since your genetic data and health information may be stored and shared with other researchers, there may be a risk that data from genetic testing could be misused. However, state and federal laws give some protections against genetic discrimination. If you have any questions, please ask the study doctor. Researchers who will have access to genetic information about you will take measures to maintain the confidentiality of your data as described above. Risks may also result if you disclose information yourself or give separate consent to have your research records released.

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this consent form. Please ask us if you would like to know more about how your information will be protected while you are in this study.

There may be risks and discomforts we do not know about right now. It is possible that we will learn new information on the risks and discomforts of being in this study. If this happens, the study doctor will tell you about them. Then you can decide if you want to continue to be in this study or not.

Risks and side effects you may experience with the study vaccine

After a study vaccination, a person might experience:

- **Mild to moderate events:**
    - A sore arm
    - Redness, swelling, hardness, or itching at injection site
    - Fever, chills, or fatigue (feeling tired)
    - Flu-like illness, runny nose, or cough
    - Headache, muscle aches, pain and stiffness in the joints
    - Nausea or vomiting
    - Temporary abnormal lab test results, including blood clotting abnormalities
    - Fainting
    - Swelling of lymph nodes in the neck or armpit

- **Severe events could occur very rarely:**
    - In prior studies with related vaccines, up to 1/3 of people receiving the vaccine had local pain and soreness around the vaccination site that was considered "severe," meaning that it prevented them from performing their usual activities for some period of time.
    - Rarely, an injection could cause ulceration (open sore), abscess (a pocket of pus caused by the body fighting infection) or necrosis (dead tissue) at the injection site.
    - Additionally, any reaction other than the above events could be severe.
    - A small number of people (about 1 in 4 million people) have an immediate allergic reaction called anaphylaxis (also known as allergic shock) after receiving vaccines or medications. This type of reaction may include symptoms such as:
        - Skin rash (hives)
        - Sweating
        - A feeling of dread
        - Swelling around the mouth, throat and eyes
        - Wheezing
        - Difficulty breathing
        - Increased pulse
        - Fainting or feeling dizzy due to low blood pressure
        - Inability to breathe without assistance

If these reactions occur, emergency medications administered by study personnel can usually stop them. Most people who experience anaphylaxis recover completely. Rarely, people can die.

If you had an allergic reaction after being vaccinated in the past, or if you are allergic to any product, you must tell the study doctor or study staff before you decide to sign and date this informed consent form. If you have an allergy to some products, you will not be able to take part in this study. Serious allergic reactions can be life-threatening.

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

It is possible that receiving the study vaccine may change how your regular medications, vaccines, or supplements work. It is very important that you tell the study doctor about any medications, supplements, or vaccines before you take them during the study.

If you stop or change the dose of your regular medication, therapy, or supplements to be in the study, your health might get worse. Please tell the study doctor or study staff right away if you have any problems when you stop or change your regular medication, therapy, or supplements.

Throughout this study, the amount of blood collected will be approximately 32 tablespoons (476 mL) in any 8-week period (which is the less than the amount of blood allowed to be drawn during that time frame under the American Association of Blood Banks standards).

A subset of participants who give their consent for leukapheresis will have blood specimens collected as described in the separate leukapheresis consent form.

Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study vaccine.

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

Ask the study doctor if you have questions about the signs or symptoms of any side effects that you read about in this consent form.

For Women, Risks Related to Pregnancy

If you are a woman, you cannot be enrolled in this study if you are:

- Pregnant
- Planning to become pregnant during the study
- Nursing a child

If you are pregnant or nursing a child during the study, there may be risks to you, the embryo, fetus, or nursing child. Nobody knows what all of these risks are right now. Some vaccines could cause women to have their babies prematurely (early) or to have babies with birth defects.

If you can become pregnant, you must use an acceptable method of birth control, as previously described, from 30 days before your first study vaccination through 60 days after last study vaccination. You should not participate in this study if you can become pregnant but cannot use one of these birth control methods. Some methods of birth control will not work when you are taking certain drugs. Be aware that women can still become pregnant even if using an acceptable birth control method. You must have a negative urine pregnancy test before each study vaccination. You should not plan to breastfeed from the time of your first study vaccination through 60 days after the last study vaccination.

If you become pregnant while you are in this study, you should report this immediately to the study staff and you will not receive any further study vaccinations. With your permission, the study doctor or study staff will ask about your health, collect information from you through the outcome of your pregnancy, and collect scheduled blood samples. The study doctor may share this information with the study sponsor and with the Advarra Institutional Review Board (IRB), a group of people who review research studies to protect the rights and welfare of research participants.

For Males

Men who are not permanently sterile must agree to use condoms with female partners, and not to donate sperm, from the first study vaccination until 3 months after the last study vaccination.

Benefits of Being in The Study

You will not benefit from being in this study. However, the results of this research might benefit others by contributing knowledge that could lead to development of a vaccine for the SARS-CoV-2 virus.

Alternatives to Participating in This Study

You can choose to not participate in this study.

Early Withdrawal from the Study and Follow-Up

Your participation in this study is completely voluntary. You can stop at any time. There is no penalty or loss of any benefits to which you are otherwise entitled if you choose not to enroll, stop or change your mind. Always tell the study staff if you wish to stop. They will discuss any concerns about your safety, and whether you need any follow up or medical care.

Also, the study doctor may take you out of the study if this research is not in your best interest for the following reason(s):

- You miss research visits
- You are unable to comply with study procedures or instructions (including use of effective birth control)
- You withhold information about your health history or medication taken, or
- You have a severe or unexpected reaction

If you decide to stop or the study doctor withdraws you, we may ask you to come for a final visit. This visit may include activities listed in the general study visits.

We will stop collecting your information and specimens for research when you withdraw your consent for the research or are withdrawn by the study doctor. However, any information and specimens collected prior to withdrawal may continue to be used for this study.

The Institutional Review Board (IRB), the FDA, other regulatory agencies, or the sponsor (NIH) who oversee the conduct of this study can stop the study at any time for safety concerns or other issues.

New Findings

We will contact you about any new information and explain how this may affect your health, wellbeing, or willingness to stay in this study.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Compensation for Participation

You will be compensated while you are in this clinical trial for your time, travel, and inconvenience with $75 for the screening and vaccination visits (3 total). We will reimburse you $50 for the other clinic visits (8 total), and $20 for the telephone calls (4 total). We will reimburse you these amounts for each study visit. If you complete all 11 of the scheduled clinic visits and 4 telephone visits, you will receive a total of $705. If you have additional unscheduled visits, for example, for evaluation of possible reaction or illness that should be evaluated before the next scheduled visit, you will also receive $20 per visit for those visits. The total payment will depend on the number of study visits you attend. If you are withdrawn from the study for any reason, or if the study is halted, you will be paid for the visits that you have completed.

We are planning to provide compensation to you by a personal payment card. We issue this to you for free. The payment card is a prepaid debit card. It can be used exactly like a MasterCard. We load money onto your card electronically every time you need to be paid. You will be paid following each completed visit. The card scheme is run by Greenphire, an independent company specializing in payments for research studies and clinical trials. To issue your card, we need to give Greenphire some of your personal information. Banks and other financial institutions can access this information if they need to verify your identity when you use your card. Emory University is required by law to report any payments we make to the IRS. To do this, Emory University Department of Finance needs to keep your Social Security Number on file. We are asking you to allow us to communicate your name, address, date of birth, research study name and Social Security Number to Greenphire and Emory University Department of Finance. If you want to receive e-mail or text alerts when payments are made to you, we will ask you to provide your

e-mail or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card.

We would also like the option of compensating you in the form of cash, check or gift card if ClinCard accessibility is not available. You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options. You will need to fill out a W-9 form.

You will not share in the commercial profit, if this study or your samples provided for research lead to a licensed product.

You will not be paid for uncompleted visits.

Compensation for a subset of participants who give their consent for leukapheresis is described in the separate leukapheresis consent form.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

In Case of Research-Related Injury

If you believe you have become ill or injured from this research, you should contact the study doctor at the telephone number listed on the first page of this form. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Neither Emory nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory and the sponsor have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the Federal Government.

You do not give up any of your legal rights by signing and dating this form.

A Declaration under the Public Readiness and Emergency Preparedness (PREP) Act was issued by the Secretary of the United States Department of Health and Human Services on March 10, 2020. This Declaration limits the legal rights of a subject participating in clinical studies utilizing COVID-19 countermeasures, such as the vaccine, mRNA-1273, used in this study. Because this study is covered by the Prep Act Declaration, covered persons, such as the manufacturers, study sponsor, researchers, healthcare providers and others have liability immunity (that is, they cannot be sued by you or your family under the laws of the United States).

If you believe that you may have been harmed as a result of this study, certain claims for serious injury or death caused by the countermeasure may be eligible for compensation through the Countermeasures Injury Compensation Program (CICP). This is a program set up by the Health Resources and Services Administration (HRSA) of the United States Government. Information about this program can be found at https://www.hrsa.gov/cicp/about/index.html or by calling 1-855-266-2427. If you are eligible for this program, you must file a claim within one year of the administration or use of the covered countermeasure. A factsheet on CICP and how to file a Request for Benefits Package to the CICP Summary, will be provided to you.

Study Information

When the results of this study are available, which will likely be a year or more after your last visit, we will attempt to provide you with a summary of those results, and a summary will be posted on http://www.ClinicalTrials.gov. If you move after your last study visit, it is your responsibility to provide us with your new address if you want to receive this information.

Source of Funding

Funding for this research study will be provided by the NIH, Division of Microbiology and Infectious Diseases, the sponsor of the study. NIH is paying the study doctor to do this study.

Subject's Rights

Your signature and date on this consent form means that you have received the information about this study and that you agree to be a part of the study. Your participation in this study is voluntary. You may decide not to participate, or you may discontinue participation at any time without penalty if you agree to participate and then decide that you no longer want to be in the study. Your decision will not result in any penalty or loss of benefits to which you are entitled.

You will be given a copy of this signed and dated consent form to keep. You are not giving up any of your rights by signing and dating this consent form. Even after you have signed and dated this consent form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

The study doctor or sponsor may decide to stop you from taking part in this study at any time, without your consent. You could be removed from the study for any of the following reasons:

- Reasons related to you (for example, if you move to another city or if you do not agree to receive your study vaccination)
- Reasons related to your health (for example, if you have a serious reaction to the study vaccine)

- Because the entire study is stopped (the sponsor may stop the study at any time)
- If you do not later consent to any future changes that may be made to how the study is done
- If you become pregnant
- Any other reason

If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. To help you leave the study safely, the study doctor may ask you to participate in more telephone assessments or come into the research clinic for assessments or blood tests.

If you withdraw from the study, the study doctor or study staff can still use your information that they have already collected.

New Findings

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or might change your decision to be in this study. You may be asked to sign and date a revised consent form if this occurs.

Confidentiality

Paper documents containing personal information about you will be maintained in locked file cabinets. Computerized information will be maintained in password-restricted files. Only people who are involved in the conduct, oversight, or auditing of this study will be allowed access.

The authority to collect this information is provided by Title 42, Section 285f, of the US Code of Laws, which specifies that the general purpose of the National Institute of Allergy and Infectious Diseases is the conduct and support of research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders and infectious diseases, including tropical diseases.

By signing and dating this consent form you are giving permission for representatives of the NIH, the Office for Human Research Protections (OHRP), the FDA, and the Advarra IRB (a group of people who review research studies to protect the rights and welfare of research participants), as well as the Investigator (study doctor) and other employees of the study site involved with this research study, to inspect sections of your medical and research records related to this study.

The FDA may choose to inspect your records since you are a participant in this research study. When a study is submitted to the FDA, the study doctor agrees to allow the FDA access to the study records. The FDA will treat the information as confidential, but on rare occasions disclosure to third parties may be required by law. Therefore, absolute protection of confidentiality cannot be promised.

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.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you (protected health information).

What information may be used and given to others?

If you choose to be in this study, the study doctor and study staff will get personal information about you. This will include information that might identify you, such as your name and address.

The study staff will also get information about your health including:

- Past and present medical records. If you receive regular care at the study site, the study staff will periodically review your medical record to identify new health events, medications, or vaccinations. The information reviewed will include clinic visit notes, hospitalization records, email exchanges with providers, laboratory results, medication prescriptions, and vaccinations. If you receive regular care at the study site, we may ask you for a release of information to obtain your medical records if you have a new health event or if we need additional information about your health, medications, or vaccinations.
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research
- Records about any study vaccination you received

Who may use and give out information about you?

Information about your health may be used and given to others by the study doctor, the study staff, and the research center, both during and after the study.

Who might get this information?

Your information may be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor and any companies that are owned by the sponsor. The sponsor of this research study is the NIH. For this study, “sponsor” also includes ICON, an agent for the sponsor.

Information about you and your health which might identify you may be given to:

- The FDA
- Department of Health and Human Services (DHHS) agencies
- The OHRP
- Additional governmental agencies in the United States or other countries
- Advarra IRB
- Your regular doctor (If you receive regular care at the study site)
- A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

If you sign and date this form, you allow the study doctor to share your records with your health care payer to resolve your claim if you are hurt because of being in this study. If this happens, the study doctor or the sponsor may share your records with their insurance carriers to resolve your insurance claim, and the study doctor may also request medical records from your other health care providers to learn more about your condition.

Why will this information be used and/or given to others?

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, employees of the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may be given to the FDA. It may also be given to other governmental agencies in the United States or other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research and so these agencies can monitor the study. The information may also be used to meet the reporting requirements of governmental agencies. The Advarra IRB may also use records to check how researchers are doing the study, the study information, and participants' safety.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

Please note that the study doctor or study staff may share personal information about you if required by law. (For example, if the study doctor or study staff suspects that you are going to harm someone or yourself.) If you have questions about this, please ask the study doctor or study staff.

What if I decide not to give permission to use and give out my health information?

By signing and dating this authorization, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research study.

May I review or copy the information obtained from me or created about me?

You have the right to review and copy your health information as held by the study doctor and study staff. However, if you decide to be in this study and sign and date this authorization form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?

This permission will be good until December 31, 2050 unless you cancel it before that time.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address listed on the first page of this form. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?

If you give permission to give your identifiable health information to one of the entities listed above, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Your study records will be kept at the study site for at least 2 years after licensing (if granted) of the investigational vaccine or for at least 2 years after the end of research with this study vaccine.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

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 Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

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

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

Please reference the following number when contacting the Study Subject Adviser: Pro00042094.

You may also contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have any questions about this study or your part in it
- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

For emergencies: Please call the emergency phone number at [redacted]

- if you feel you have had a research-related injury or a bad reaction to the study vaccine

CONSENT AND AUTHORIZATION

Information describing this research study has been explained to me. I have read this consent form. All the questions that I have at this time have been answered by the study doctor or study staff to my satisfaction. I voluntarily consent to participate in this research study. My consent includes allowing storage of samples and/or use of my information and samples for an indefinite period of time for **genetic** secondary research. I understand that this may include reproducing and/or growing my cells.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described in this form.

By signing and dating this consent form, I have not given up any of my legal rights. I will get a signed and dated copy of this consent form for my records.

Future Use Acknowledgement

_____ (Initials) I understand, if I take part in this study, that my blood samples will be stored indefinitely and may be used for future research and potentially genetic research as described above.

Contact for Future Studies

Emory may want to contact you in the future to see if you would be interested in participating in future studies. If and when you are contacted, you can decide if you want to participate in any of the other studies and you will sign another consent form to participate in those studies. Your decision regarding future contacts will not affect your participation in this study. Agreeing to be contacted does not obligate you to participate in any future studies.

Please initial your decision about permission for possible participation in future research studies (select only ONE option):

_____ YES, you may contact me about future studies.

_____ NO, you may not contact me about future studies.

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing and dating this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed and dated form to keep.

Name of Subject

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion **Date** **Time**