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 1, Open-Label, Randomized Study of the Safety and Immunogenicity of a SARS-CoV-2 Variant Vaccine (mRNA-1273.351) in Naïve and Previously Vaccinated Adults"**
Protocol Number:	**21-0002**
Principal Investigator: (Study Doctor)	**Nadine Rouphael, MD**
Telephone:	**[redacted]** **[redacted] pager number [redacted] (24 Hours)**
Address:	**Emory Children's Center** **2015 Uppergate Drive** **3rd Floor** **Atlanta, GA 30322** **The Hope Clinic of Emory University** **500 Irvin Ct.** **Suite 200** **Decatur, GA 30030** **The Hope Clinic of Emory University - Satellite Site** **484 Irvin Ct.** **Suite 230** **Decatur, GA 30030**

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 mRNA-1273 vaccine, with a dose of 100 micrograms (mcg) of mRNA, was granted Emergency Use Authorization (EUA) by the United States Food and Drug Administration (FDA) in December 2020 and is being used in the national COVID-19 vaccination campaign.

The purpose of this research is to test an experimental vaccine for a new strain of the SARS-CoV-2 virus, the virus that causes COVID-19 disease. This new strain, **called B.1.351**, was first found in South Africa in late 2020 and has since spread to other countries, including the United States. The B.1.351 strain contains mutations in the gene for the spike protein (this is the protein that allows the virus to enter human cells) on the surface of the virus. This change in the spike protein makes it easier for the virus to cause infection and spread more easily. It may also cause more severe COVID-19 disease. COVID-19 vaccines now being used in the United States may be less effective against the B.1.351 strain. An experimental vaccine is one that is not approved by the FDA. There is no licensed vaccine directed against the B.1.351 strain.

The experimental vaccine, called mRNA-1273.351, is a messenger ribonucleic acid (mRNA) vaccine. This study vaccine is made of the genetic code of the virus. This genetic code will make the spike protein 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 but is made in the same way as the mRNA-1273 vaccine.

The mRNA code in the experimental mRNA-1273.351 vaccine is different from the mRNA code of the mRNA-1273 vaccine. The mRNA code in the mRNA-1273.351 matches the code for the spike protein of the B.1.351 strain whereas the mRNA code of the mRNA-1273 vaccine matches the code for the spike protein of the original SARS-CoV-2 strain that began circulating in the United States in early 2020.

This study will include two experimental vaccines given in a two or three dose series, either alone or combined, and at different dose levels. Therefore, in total, there are eight different experimental vaccine approaches:

- The first is a 100 mcg dose of the mRNA-1273 study vaccine, which is the same dose as the authorized mRNA-1273 that has been given to millions of people; but its use in this study is experimental.
- The second is a 50 mcg dose of the mRNA-1273 study vaccine that has been tested in human studies. This is half the dose of the vaccine authorized under the EUA, thus its use in this study is experimental.
- The third is a 100 mcg dose of the mRNA-1273.351 study vaccine that has never been given to humans before.
- The fourth is a 50 mcg dose of the mRNA-1273.351 study vaccine that has never been given to humans before.
- The fifth and sixth are to give a 100 mcg or 50 mcg dose of mRNA-1273 study vaccine as the first study vaccination followed by a 100 mcg or 50 mcg dose of mRNA-1273.351 given as the second study vaccination, and this combination has never been given to humans before.
- The other two experimental vaccine approaches include a combination of mRNA-1273.351 and mRNA-1273, with a dose of either 25 mcg or 50 mcg of each study vaccine, and this combination has never been given to humans before.

All study vaccines will be given with injection volumes of 0.5 milliliters (mL).

This study will include two groups, called Cohorts. The first, Cohort 1, will only include people who are currently participating in another study (20-0003 study) of the mRNA-1273 study vaccine and received two mRNA-1273 study vaccinations with doses of 50 mcg, 100 mcg or 250 mcg, at the Kaiser Washington site in Seattle or the Emory University sites in Atlanta. They will be offered the option of leaving the 20-0003 study and joining this study at the same study site. If they decide to join this follow-up study, they will no longer participate in the 20-0003 study. We estimate about 60 of those participants will join Cohort 1 of this study.

The second, Cohort 2, will include about 150 people who have not participated in a COVID-19 vaccine study, received a COVID-19 vaccine, nor had COVID-19 disease. Cohort 2 participants will be enrolled at the Seattle and Atlanta sites and at approximately three other domestic sites.

Cohort 1 participants will be randomly (by chance, like flipping a coin) assigned to one of two study Arms (groups). Arm 1A will receive a 50 mcg dose of the mRNA-1273.351 study vaccine. Arm 1B will receive a combination study vaccine that includes 25 mcg of mRNA-1273 and 25 mcg of mRNA-1273.351. All Cohort 1 participants will attend 7 or 8 scheduled study clinic visits that include an initial screening visit (that may be combined with the first study vaccination visit), one study vaccination visit, and six follow-up visits. Study clinic visits may include a physical exam, if needed, and all will include a blood draw. Cohort 1 participants will be in the study for approximately 13 months, if they have a separate screening visit, or 12 months, if the screening visit is combined with the first study vaccination visit.

- Arm 1A: One injection of 50 mcg mRNA-1273.351
- Arm 1B: One injection of a combination of 25 mcg mRNA-1273 and 25 mcg of mRNA-1273.351

Cohort 2 participants will be randomly assigned to one of eight study Arms, which will include 15-20 people in each Arm. Participants in Arms 2A and 2B will receive three vaccinations, 28 days apart. Participants in Arms 2C, 2D, 2E, 2F, 2G, and 2H will receive two vaccinations, 28 days apart. Participants in Arms 2G and 2H will receive combination study vaccines that include both mRNA-1273.351 and mRNA-1273, with doses of either 25 mcg of each study vaccine (Arm 2G) or 50 mcg of each study vaccine (Arm 2H).

Cohort 2 Study Treatment Arms

Arm	Number of Participants	First Study Vaccination	Second Study Vaccination	Third Study Vaccination
2A	15	100 mcg mRNA-1273	100 mcg mRNA-1273	50 mcg mRNA-1273.351
2B	15	50 mcg mRNA-1273	50 mcg mRNA-1273	50 mcg mRNA-1273.351
2C	20	100 mcg mRNA-1273.351	100 mcg mRNA-1273.351	None
2D	20	50 mcg mRNA-1273.351	50 mcg mRNA-1273.351	None
2E	20	100 mcg mRNA-1273	100 mcg mRNA-1273.351	None
2F	20	50 mcg mRNA-1273	50 mcg mRNA-1273.351	None
2G	20	50 mcg mRNA-1273 + 50 mcg mRNA-1273.351	50 mcg mRNA-1273 + 50 mcg mRNA-1273.351	None
2H	20	25 mcg mRNA-1273 + 25 mcg mRNA-1273.351	25 mcg mRNA-1273 + 25 mcg mRNA-1273.351	None

The second vaccination will be given approximately 28 days after the first and the third vaccination (Arms 2A and 2B) will be given approximately 28 days after the second.

Arm 2A and 2B participants will attend 13 or 14 scheduled study clinic visits that include an initial screening visit (that may be combined with the first study vaccination visit), three study vaccination visits, and 11 follow-up visits and will be in the study for approximately 15 months, if they have a separate screening visit, or 14 months, if the screening visit is combined with the first study vaccination visit.

Participants in Arms 2C through 2H will attend 10 or 11 scheduled study clinic visits that include an initial screening visit (that may be combined with the first study vaccination visit), two study vaccination visits, and eight follow-up visits and will be in the study for approximately 14 months, if they have a separate screening visit, or 13 months, if the screening visit is combined with the first study vaccination visit. Study clinic visits may include a physical exam, if needed, and all will include a blood draw.

All participants will complete a daily memory aid (like a diary card) at home for seven days after each study vaccination to record any side effects that you may experience.

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 vaccines work and to 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 the study vaccines and for 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-1273.351 vaccines, alone, alternating with, or in combination with, the experimental 25 mcg, 50 mcg, and 100 mcg mRNA-1273 vaccines, to see if the study vaccines and the study vaccine schedules are safe and to evaluate the immune system responses. Vaccines tell your germ-fighting cells to make antibodies and other substances to fight infections. The mRNA-1273 and mRNA-1273.351 study vaccines are 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 the study vaccine is not approved for routine use by the FDA; however, the FDA is allowing the eight different experimental vaccine approaches to be tested in this study.

The mRNA-1273 and the mRNA-1273.351 study vaccines are made using a 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 and the mRNA-1273.351 study vaccines are not made from the SARS-CoV-2 virus. They include a short segment of mRNA that is a genetic code that tells cells how to make the spike protein of the virus. The mRNA in the study vaccines is entirely made in a laboratory. When injected into the body, the mRNA causes some cells to make the viral spike 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 breaks down naturally and does not persist in the body.

Selection of Study Population

Cohort 1 includes healthy people age 18 years or older and Cohort 2 includes healthy people 18 through 55 years of age. We will screen you for eligibility before performing any further study activities or giving you a study vaccination.

You are **not** eligible for either Cohort 1 or Cohort 2 in 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 have a body mass index (BMI) over 40 kg/m^2
- You are on certain medications
- You are pregnant or breastfeeding a child
- You have a history of hypersensitivity or a severe allergic reaction to any medication or vaccine or to polyethylene glycol (PEG), which is a component of the vaccines
- You have any medical condition the study doctor feels would make your participation unsafe

Procedures

If you agree to take part in this study, your involvement is expected to last for up to 15 months.

Screening

You will have a Screening Visit to check if you are eligible to enroll in this study. The Screening Visit may be combined with the first study vaccination visit. If it is a separate visit, it will take about 60 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), and vaccination history
- A physical exam if needed
- Measuring height and weight

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 (IUDs), and hormonal methods, including the birth control patch, shot (Depo-Provera), pills, the vaginal ring (NuvaRing), and the contraceptive implant (Nexplanon).

General Study Visit Procedures

Study visits that include a study vaccination will generally last about 2-3 hours and follow-up visits will generally last about 20-30 minutes. The first study vaccination visit may be combined with the screening visit and will include the screening visit procedures. 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) before and after a study vaccination and at follow-up visits if needed
- If applicable, reviewing use of birth control methods and pregnancy status
- Having a physical exam if needed

- Collection of blood samples at almost all of the study clinic visits (and, for women who can become pregnant, urine for pregnancy testing at each of the study vaccination visits)
- Study vaccination or assessment of the site of a previous study vaccination
- Review of the memory aid during telephone calls

Study Vaccination Visits

Cohort 1.

The single study vaccination will be given on Day 1.

Cohort 2.

Arms 2A and 2B. The three study vaccinations will be given on Days 1, 29, and 57.
Arms 2C, 2D, 2E, 2F, 2G, and 2H. The two study vaccinations will be given on Days 1 and 29.

At the study vaccination visits we will review your medical history to confirm that you are eligible for a study vaccination.

You will receive an injection of the designated dose and type of study vaccine in the deltoid muscle of your upper arm at each vaccination visit. You will stay in the clinic for at least 30 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), a thermometer, and a ruler (to measure the size of any redness or swelling at the vaccination site) 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. About seven days after each study vaccination visit the study staff will call you to review the information on your memory aid. The memory aid will include contact information should you need to contact the study team. You will be instructed to bring the memory aid with you to your next scheduled clinic visit.

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 as described below.

Cohort 1.

Days 8 (phone call only), 15, 29, 85, 169, and 366.

Cohort 2.

Arms 2A and 2B. Days 8 (phone call only), 15, 29, 36 (phone call only), 43, 57, 64 (phone call only), 71, 85, 147, 237, and 422.
Arms 2C, 2D, 2E, 2F, 2G, and 2H. Days 8 (phone call only), 15, 29, 36 (phone call only), 43, 57, 119, 209, and 394.

Follow-up visits will take about 20-30 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.

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 research tests of the immune response to the study vaccine. These 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. Some of the testing in this study will include genetic testing to see how your cells work to develop immune responses. We will not do genetic tests that check for diseases or biomarkers for cancer. You will not receive the results of the genetic testing. Your genetic information may be shared with other researchers, as described in the secondary research section below.

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 study 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 each visit (about 3 teaspoon) to store and use for secondary research. Secondary research may help us understand how the mRNA study vaccines work, 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 cannot 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 collected at each of the scheduled study visits from the time of the first study vaccination through the last scheduled visit 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 study doctors/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 study doctors/institutions and used for secondary research, including genetic testing. The genetic testing is for research purposes only and it will not be able to tell you about relatives, paternity, or country of origin. The genetic research testing done in this study will not tell you about diseases that you may get in the future. We will not give you the results from the genetic research 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 will take 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 provide 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 or third 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. Throughout this study, the amount of blood collected will not exceed 28 tablespoons (416 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).

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. The Genetic Information Nondiscrimination Act (GINA) is a federal law that prohibits plans and health insurers from requesting genetic information or using genetic information. It also prohibits employment discrimination based on your health information. However, GINA does not address discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed condition or disease that has a genetic component. 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)
    - Headache, muscle aches, pain and stiffness in the joints
    - Nausea or vomiting
    - Fainting
    - Swelling of lymph nodes in the neck or armpit

Events such as a sore arm, fever, chills, fatigue, headache, muscle aches, pain and stiffness in joints, and nausea are more common after a second mRNA study vaccination and with higher doses of the study vaccine (for example, a 100 mcg study vaccine instead of a 50 mcg study vaccine).

In previous studies of the mRNA-1273 study vaccine, given as a 100 mcg dose in a two-vaccination series 28 days apart, headache, fatigue, muscle aches, joint aches, nausea or vomiting, chills, or a combination of those events, occurred in about half of people receiving the first study vaccination and in about three-quarters of people receiving a second study vaccination. Fever occurred in about one in six people receiving a second study vaccination. Pain at the injection site occurred in about eight in ten people after the first and after the second study vaccination.

There is limited experience with administration of a third dose of the mRNA COVID-19 study vaccines, and it is possible that the third dose may be associated with more frequent or more severe adverse events.

About one in a one hundred people who received the mRNA-1273 study vaccine, given as a 100 mcg dose in a two-vaccination series, had a delayed reaction in the vaccinated arm, with redness and/or pain and/or itching starting about seven days after the vaccination. These events usually resolved over several days.

Infrequently, people who have received dermal fillers might experience swelling at or near the site of filler injection (usually face or lips) following administration of a dose of an mRNA COVID-19 study vaccine. The swelling appears to be temporary and resolves with medical treatment, including corticosteroid therapy. COVID-19 study vaccines can be administered to people who have received injectable dermal fillers who have no contraindications or precautions for vaccination. You should contact the study team if you experience swelling at or near a dermal filler site following study vaccination.

- **Severe events could occur very rarely:**
    - In prior studies with related study vaccines, up to one-third of people receiving the study 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 an 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.
    - An immediate allergic reaction called anaphylaxis (also known as allergic shock) may occur 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

Anaphylaxis reactions have occurred after administration of the Moderna and the Pfizer mRNA COVID-19 vaccines in vaccination campaigns under Emergency Use Authorization (EUA) in the United States. Most of these reactions started within 30 minutes of vaccination, most of those people had a prior history of allergy, and nearly all were women. The currently estimated risk of an anaphylactic reaction to the Moderna EUA COVID-19 vaccine is about 3 events per million vaccinations.

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, including polyethylene glycol (PEG), which is in the study vaccines, 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 vaccines that have been authorized by the FDA for emergency use in the United States to protect against SARS-CoV-2 virus infection. Receipt of the experimental mRNA variant vaccine (mRNA-1273.351) in this study may affect your ability to receive and respond to other vaccines against the SARS-CoV-2 virus. It is unknown if these experimental mRNA vaccines will protect you from getting infected or developing illness from the infection. Sometimes vaccines are not protective or may not work as well as the 2 doses of the mRNA-1273 study vaccine that is currently approved under an EUA by the FDA. It is possible that these study vaccines could cause you to have more severe illness after virus exposure, but this has not been seen in the studies to date. Based on all available data about this study vaccine and prior animal studies with similar types of vaccines, we do not think this study 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 vaccines 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.

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.

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 cannot participate in this study if you are breastfeeding.

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.

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 B.1.351 strain of the SARS-CoV-2 virus.

Alternatives to Participating in This Study

You can choose to not participate in this study. If you wish to receive the SARS-CoV-2 vaccine through other places or do not want to take part in research, do not enroll 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 Advarra 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

To help us protect your privacy, we have a Certificate of Confidentiality (Certificate) from the NIH. Study staff cannot provide to any person not connected with the research your name, or any materials that contain identifiable, sensitive information about you, unless permitted by a legal exception, such as state laws that require reporting of some contagious diseases. The most important protection provided by the Certificate is that the study staff cannot be forced to provide any of your identifiable, sensitive information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, such as if there is a court subpoena, without your permission.

The study team will use the Certificate to resist any demands for information that would identify you.

Your information protected by the Certificate may still be disclosed or used when the information:

1. is disclosed to people connected with the research; for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the FDA. This does not include disclosure for use during legal proceedings as noted above;
3. is necessary for your medical treatment and you have consented to this disclosure;
4. is for other scientific research as allowed by applicable federal regulations;
5. is disclosed with your consent.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing and dating below you consent to those disclosures.

Compensation for Participation

You will be compensated while you are in this clinical trial for your time, travel, and inconvenience with [redacted] for the vaccination visit (up to 3 total depending on Cohort). We will reimburse you [redacted] for other non-vaccination clinic visits (5-7 total depending on Cohort), and [redacted] for each telephone visit (up to 3 total).If you complete all scheduled clinic visits and telephone visit(s), you will receive a total of [redacted] if you are randomly assigned to the Cohort that receives 1 vaccination, [redacted] if you are randomly assigned to the Cohort that receives 2 vaccinations and [redacted] if you are randomly assigned to the Cohort that receives 3 vaccinations. If you have additional unscheduled visits (or illness visits) you will receive [redacted] for each of those visits. The total reimbursement will depend on the number of study visits you attend. You will only be reimbursed 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.

Cost to the Participant

While you are in the study, you still need to get regular medical care. You (and/or your health care payer) will still have to pay for the costs of your regular medical care that are not a part of this study.

You will not have to pay to receive the study vaccine. There are no costs for the study visits, tests or procedures performed as part of this study.

To find out more about costs, ask the study staff.

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.

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 participant in clinical studies utilizing COVID-19 countermeasures, such as the study vaccines, mRNA-1273 and mRNA-1273.351, 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. ModernaTX, Inc, the company that makes the study vaccine, is providing the vaccine to the NIH without charge.

Participant'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 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.

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. 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
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00050089.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will be requesting health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) to provide us with health information that identifies you ("individually identifiable health information" or "IIHI"). Because the health care entities are covered by HIPAA, we must have your authorization to obtain your IIHI from them. However, the researchers who get your IIHI from the health care entities are not covered by HIPAA. Once they receive your IIHI from the health care entities, they will put it in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not be covered by HIPAA.

Purpose of this Authorization:

By signing this form, you give us permission to get your IIHI from health care entities and to use and share your IIHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your IIHI. If you do not sign this form, then you may not participate in the research study.

Research-Related Treatment

This study involved research-related treatment that will not be electronically billed to any insurance company or government benefits program (for example, Medicare, Medicaid). You may not receive the research-related treatment unless you sign this authorization. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or share for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:

We will use and share your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

Use and Disclosure of Your IIHI That is Required by Law:

We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

People Who will Use/Disclose Your IIHI:

The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- Emory may use and disclose your IIHI to get payment for conducting the study and to run normal business operations.
- The Principal Investigator and research staff will share your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.
- The NIH is the Sponsor of the study. The Sponsor may use and disclose your IIHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- FHI360
- ICON
- The following people and groups will use your IIHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Emory University and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: [Office for Human Research Protections; Food and Drug Administration].
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be shared with that new institution and their oversight offices.

Expiration of Your Authorization

Your IIHI will be used until this research study ends.

Revoking Your Authorization

If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at the address listed on the first page of this form.

At that point, the researchers would not collect any more of your IIHI. But they may use or disclose the information you already gave them as described in this Authorization. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to research that does not include treatment that is billed to insurers or government benefit programs. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The researchers, the Sponsor, and people and companies working with them are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposed. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Nadine Rouphael, MD or Evan Anderson, MD at the contact given on the first page:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

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
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044

- or call **toll free**: [redacted]
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00050089

- 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.

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.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

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.

_____

Printed Name of Person Explaining Consent

_____ _____

Signature of Person Explaining Consent Date