**Baylor College of Medicine**
**CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY**
**AND**
**AUTHORIZATION TO DISCLOSE HEALTH INFORMATION**

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| **Sponsor / Study Title:** | **National Institutes of Health (NIH)/Division of Microbiology and Infectious Diseases (DMID) / "A Phase 1/2 Study of Delayed Heterologous SARS-CoV-2 Vaccine Dosing (Boost) after Receipt of EUA Vaccines"** |
| **Protocol Number:** | **21-0012 H-49889** |
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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**

Multiple SARS-CoV-2 vaccines have been studied in large phase 3 studies and have been granted Emergency Use Authorization (EUA) or approval (depending on primary series or boost) by the United States Food and Drug Administration (FDA) and are being used in the national COVID-19 vaccination campaign.

The purpose of this study is to learn about the safety, reactogenicity (reactions at the injection site and overall side-effects) and immunogenicity of booster vaccines to SARS-CoV-2, the virus that causes COVID-19. All the current vaccines in advanced development stages or approved and authorized under EUA deliver the spike protein (the protein that allows the virus to enter human cells) to the immune system to generate immunity to that specific viral protein. However, the spike protein was designed based on the virus from early 2020, and the spike continues to change with ongoing circulation of the virus. These changes lead to new strains, also called variants. Additionally, the vaccines use different strategies to deliver the spike protein. Booster vaccines using updated spike proteins to reflect the circulating variants, or using different vaccine delivery types, may improve the immune response to prevent infection longer, more effectively, or from more variants.

This study uses vaccines that have received FDA approval, EUA and vaccines that are still under investigation. All vaccines target the spike protein of the virus using one of three strategies:

- Messenger ribonucleic acid (**mRNA**) vaccines include the genetic code of the spike protein. Moderna and Pfizer have received EUA, and approval for vaccination in those 16 years and older and 18 years and older respectively. **Adenovirus** vaccines use defective adenoviruses (common cold viruses that cannot grow) carrying the code for spike protein inside the viral particles, delivering the instructions to make the spike protein. Johnson & Johnson in partnership with Janssen has received EUA in the U.S. for a vaccine using a human adenovirus 26 (Ad26) vector, and AstraZeneca has received approval in Europe and elsewhere for using a chimpanzee adenovirus (ChAdOx) vector.
- The spike **protein** can be used as a vaccine given with an adjuvant (an ingredient in some vaccines that helps create a stronger immune response). The Novavax study vaccine uses this strategy with a recombinant spike protein and the Matrix-M adjuvant.

Vaccines from each of these strategies (mRNA, adenovirus, and protein) will be investigated as boosters in this study.

Additionally, experimental vaccines may be included in this study. Novavax has an adjuvanted protein vaccine (NVX-CoV2373 SARS-CoV-2 rS with Matrix-M adjuvant) that has received approval in other countries but remains investigational in the United States. Novavax has submitted a request for consideration of an EUA to the FDA. Moderna has developed an updated mRNA vaccine designed to protect against one of the new variants, B.1.351, which is also called the South African or Beta variant. Additional vaccines targeting B.1.351 or other variants may be added to this study as they become available.

At this time, this study includes vaccination with one of six vaccines: the Moderna mRNA vaccine (mRNA-1273), the Pfizer mRNA vaccine (BNT162b2), the Johnson & Johnson/Janssen adenovirus vaccine (Ad26.COV2.S), a Moderna mRNA bivalent vaccine (mRNA-1273.211, containing a 1:1 mix of the Wuhan and Beta variant strains), a low dose Moderna mRNA study vaccine (mRNA-1273 50 mcg), and the Novavax adjuvanted protein study vaccine (NVX-CoV2373). All study vaccines will be given by injection into the arm.

Groups of participants who have either not received any COVID-19 vaccine, or already received the Moderna, Pfizer, or Janssen vaccine at the EUA approved doses will be enrolled.

This study will include two groups, called Cohorts. The first, Cohort 1, will only include people who have already received a COVID-19 vaccine at least 3 months prior. We anticipate about 880 individuals will join this cohort. The second, Cohort 2, will include about 250 people who have not participated in a COVID-19 vaccine study, have not received a COVID-19 vaccine, and have not had COVID-19.

**Cohort 1** participants will be assigned to one of 17 study arms, each including 50-60 people and each split approximately evenly between those 18-55 years and those greater than 56 years of age. Participants in this cohort will be enrolled into arms depending on what vaccine they already received and what study vaccine is available at the study site. They then will receive a single booster dose of either the Moderna mRNA-1273 vaccine 100 mcg, the Janssen Ad26.COV2.S vaccine, the Pfizer BNT162b2 vaccine, the Moderna mRNA-1273.211 vaccine, the Moderna mRNA-1273 50 mcg study vaccine, or the Novavax NVX-CoV2373 study vaccine. Table 1 shows the booster vaccine that will be used depending on participants' prior vaccines. **Because this is an adaptive trial, several vaccine arms have already completed enrollment and are no longer enrolling. Each site may be offering one or more study vaccines at a time. Please ask the study staff which study vaccine you may be receiving.**

**Table 1: Cohort 1 Study Treatment Arms**

| Arm | Number of participants | Prior vaccine | Study vaccination |
|---|---|---|---|
| **1E** | 50 | Janssen Ad26.COV2.S | Moderna mRNA-1273 |
| **2E** | 50 | Moderna mRNA-1273 | Moderna mRNA-1273 |
| **3E** | 50 | Pfizer BNT162b2 | Moderna mRNA-1273 |
| **4E** | 50 | Janssen Ad26.COV2.S | Janssen Ad26.COV2.S |
| **5E** | 50 | Moderna mRNA-1273 | Janssen Ad26.COV2.S |
| **6E** | 50 | Pfizer BNT162b2 | Janssen Ad26.COV2.S |
| **7E** | 50 | Janssen Ad26.COV2.S | Pfizer BNT162b2 |
| **8E** | 50 | Moderna mRNA-1273 | Pfizer BNT162b2 |
| **9E** | 50 | Pfizer BNT162b2 | Pfizer BNT162b2 |
| **10E** | 50 | Janssen Ad26.COV2.S | Moderna mRNA-1273.211 |
| **11E** | 50 | Pfizer BNT162b2 | Moderna mRNA-1273.211 |
| **12E** | 50 | Janssen Ad26.COV2.S | Moderna mRNA-1273 50 mcg |
| **13E** | 50 | Moderna mRNA-1273 | Moderna mRNA-1273 50 mcg |
| **14E** | 50 | Pfizer BNT162b2 | Moderna mRNA-1273 50 mcg |
| **15E** | 60 | Janssen Ad26.COV2.S | Novavax NVX-CoV2373 |
| **16E** | 60 | Moderna mRNA-1273 | Novavax NVX-CoV2373 |
| **17E** | 60 | Pfizer BNT162b2 | Novavax NVX-CoV2373 |

All Cohort 1 participants will attend 7 or 8 study visits including an initial screening visit (that may be combined with the first study vaccination visit), one study vaccination visit, and 6 follow-up visits. They will be in the study for up to 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. Study clinic visits may include a physical exam, and all but one (the visit seven days after the study vaccination) will include a blood draw.

**Cohort 2** will include 250 participants who have not received a COVID-19 vaccine and have not had COVID-19. These participants will receive the Moderna mRNA-1273 vaccine at the same dose and schedule as the authorized vaccine (two doses, 28 days apart). Then, after approximately 6 months, cohort 2 participants will receive a booster vaccine with the EUA-approved Moderna mRNA-1273 50 mcg vaccine. These participants will then be followed for immune responses and may be offered a future 4$^{th}$ dose. This 4$^{th}$ vaccine dose may be a different type of vaccine or designed to protect against a variant SARS-CoV-2 strain, or both. Because the available vaccines are constantly being updated, the fourth study vaccination in this group will be determined later in the course of the study. Participants will be informed at that time about the vaccine that they will receive as a booster.

**Table 2: Cohort 2 Study Treatment Arms**

| **Number of participants** | **First study vaccination (day 1)** | **Second study vaccination (day 28)** | **Third study vaccination (6 months)** | **Fourth study vaccination** |
|---|---|---|---|---|
| **250** | Moderna mRNA-1273 | Moderna mRNA-1273 | Moderna mRNA-1273 50 mcg | Different study vaccine type and/or variant spike study vaccine. |

All Cohort 2 participants will attend 12 or 13 study visits including an initial screening visit (that may be combined with the first study vaccination visit), 3 study vaccination visits, and 9 follow-up visits including 2 phone calls and 7 in-person visits. Cohort 2 participants will be in the study for up to approximately 24 months, approximately 12 months after the third study vaccine. Study clinic visits may include a physical exam, and all in-person clinic visits 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.

As part of this study, we are obtaining extra blood samples from you, and two nasal or nasopharyngeal swabs if you have symptoms consistent with COVID-19 or are infected with SARS-CoV-2. 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. When you give consent, you will be taking part in the vaccine study and allowing for secondary research.

The remaining sections describe 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 consent 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 and that you agree to take part in the study.

If you are an employee or relative of an employee of this research center, you are under no obligation to participate in this study. You may withdraw from the study at any time and for any reason, and neither your decision to participate in the study, nor any decision on your part to withdraw, will have any effect on your or your family member's performance appraisal or employment at this clinical research center. You may refuse to participate, or you may withdraw from the study at any time without penalty or anyone blaming you.

**Purpose of this Research Study**

The purpose of this research is to test vaccine booster shots that use different vaccine types and/or variant spikes to see if these new combinations are safe and to evaluate the immune system responses. Vaccines tell your germ-fighting cells to make antibodies and other substances to fight infections. All the 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. By using a different type of vaccine for a booster vaccine, a broader array of germ-fighting cells may be recruited to strengthen and prolong protection. Booster vaccines that use a variant spike, rather than the original spike from the original SARS-CoV-2 virus that was circulating in early 2020, may improve protection against variant strains.

The vaccines used in this study include different vaccine types, the variant spikes, or both together as experimental vaccine approaches. Experimental means the study vaccine is not approved for routine use by the FDA; however, the FDA is allowing the three experimental vaccine approaches to be tested in this study.

**Selection of Study Population**

Both Cohort 1 and Cohort 2 include healthy people age 18 years or older. 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 been diagnosed with COVID-19 in the past
- You have a history of receiving an antibody infusion (in the past 90 days)
- You have received non-COVID-19 coronavirus vaccine (within 28 days prior to the first dose with study vaccine, except for influenza vaccine [within 14 days])
- You have received any experimental vaccine or drug in the past 28 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 a child

- You have a history of hypersensitivity or a severe allergic reaction to 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**
The research will be conducted at the Baylor College of Medicine.

If you agree to take part in this study, your involvement is expected to last between 12 to 24 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
- Checking vital signs (blood pressure, pulse, respiratory rate)
- Measuring height and weight

Women who can become pregnant must agree to use an acceptable method of birth control from at least 28 days before the first study vaccination through 90 days after the last study vaccination (after the booster dose of the study vaccine). 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 other visits will generally last about 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 other 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**: The three study vaccinations will be given on Days 1, 29, and approximately 6 months after Day 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 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), thermometer, and 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 including blood draws, nasal swabs or nasopharyngeal swabs, if needed.

**Follow Up Visits**

In addition to the study vaccination visits, you will also come to the clinic (or speak with us by phone) for follow up visits as described below:

**Cohort 1:** Day 8 or one week (phone call only), 2 weeks, 4 weeks, 3, 6, and 12 months following vaccination.

**Cohort 2:** Day 8 or one week (phone call only), 4 weeks, 5 weeks (phone call only), and 6 weeks following first study vaccination. Then one week (phone call only), 2 weeks, 4 weeks, 3, 6 and 12 months following the last study (booster) vaccination.

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.

**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 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.

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.**

Nasal or nasopharyngeal swabs will be used to test for presence of the virus that causes COVID-19 and, if positive, for genetic sequencing of the virus, allowing us to determine if the virus was a variant.

Blood, nasal swab and nasopharyngeal swab samples for these research tests may be sent to a central storage facility or sent directly to the research testing laboratories. These samples will not be labeled with your name or initials, or any other information that could readily identify you. These 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 samples to you, if needed. Access to the code key is limited to study staff working at the research site where your samples were collected.

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

**Leftover and Extra Blood Samples:**

Some of the blood collected for measuring immune responses to the vaccines 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**.**

**We will also collect extra blood samples at each visit (about 3 teaspoons) to store and use for secondary research.** Secondary research may help us understand how the booster vaccines work, develop tests, study other infections or diseases, or develop treatments. **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. Leftover and extra blood samples will be labeled only with a barcode and an ID code (not with your name, initials, or any other information that could readily identify you). These leftover and extra blood samples will be stored with the same confidentiality measures used for the main specimens.

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 (including tests that have yet to be developed) to inform development of new vaccines, or for the studies of coronaviruses or other infections. You will not be contacted about the types of future research. 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.

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. Also, after future genetic testing, the resulting 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.

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 infections. 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.

**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. Although the study vaccines (Moderna mRNA-1273, Pfizer BNT162b2, and Janssen Ad26.COV2.S) have received EUA and FDA approval (Pfizer, Moderna) and have been given to millions of people, they are given under experimental authorization in this study. The Moderna mRNA-1273 50 mcg study vaccine is the same vaccine as the EUA-approved vaccine, just given at a lower dose. The Moderna bivalent vaccine (mRNA-1273.211) is experimental and has been given to only a few hundred humans. The Novavax adjuvanted protein vaccine (NVX-CoV2373) is experimental and has been given to several thousand individuals worldwide. There may be risks that we do not know about right now. Side effects may occur more frequently with the booster doses compared with the first vaccine.

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(s), having nasal or nasopharyngeal swab(s) collected, 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 15 tablespoons (224 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).

The risks associated with having nasal or nasopharyngeal swabs collected may include discomfort, eyes watering, bleeding, minor irritation and sneezing.

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 vaccines**

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
    - 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 vaccination and may occur more commonly after the booster vaccination.

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 the second Moderna vaccination and in about one in ten people receiving the second Pfizer vaccination. Pain at the injection site occurred in about eight in ten people after the first mRNA study vaccination, in about one in ten after the second Pfizer study vaccination, and about eight in ten after the second Moderna study vaccination.

In studies of the Janssen Ad26.COV2.S vaccine, about half of people had injection site pain, with about a third having fever, fatigue, muscle aches, and one in seven having nausea.

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. There have also been reports of skin reactions, facial and lip swelling in people who have received cosmetic dermal fillers or implants.

- **Severe events could occur very rarely:**
  - In prior studies with related study vaccines, less than 5% of people receiving the Moderna mRNA-1273 vaccine, less than 1% receiving the Pfizer BNT162b2, and less than 0.5% of people receiving the Janssen Ad26.CoV2.S 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.
  - An immediate allergic reaction called anaphylaxis (also known as allergic shock) may occur after receiving vaccines or medications. 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 mRNA vaccines is about 2-5 events per million first vaccinations.

    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.

- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the mRNA vaccines. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine: chest pain, shortness of breath, or feelings of a fast-beating, pounding, or fluttering heart
- Blood clots involving blood vessels in the brain, lungs, abdomen, and legs, along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received one dose of Janssen Ad26.COV2.S vaccine. Some of these cases have been fatal. In people who developed these blood clots and low levels of platelets, symptoms began within three weeks following vaccination. Most people who developed these blood clots and low levels of platelets were women under 60 years of age. It is not known whether receiving two doses of Ad26.COV2.S would change the level of risk or how these events present compared to receiving one dose of the vaccine.
    - Please seek **immediate medical attention** if you develop any of the following symptoms after vaccination: shortness of breath, chest pain, leg pain, leg swelling, persistent abdominal pain, severe or persistent headaches, blurred vision, mental status changes or seizures (fits), easy bruising, tiny blood spots under the skin beyond the site of vaccination.

  In the event of a suspected blood clot event or blood clot with low platelets, to facilitate diagnosis and determine treatment options, your study doctor or treating physician may decide about need of additional blood collection.
- Guillain Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:
    - Weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body
    - Difficulty walking
    - Difficulty with facial movements, including speaking, chewing, or swallowing
    - Double vision or inability to move eyes
    - Difficulty with bladder control or bowel function
- Additionally, any reaction other than the above events could be severe.

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 and Moderna and Pfizer have been approved for certain ages in the United States to protect against SARS-CoV-2 virus infection.

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 28 days before your first study vaccination through 90 days after last study vaccination (after the booster dose). 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 (through three months after the booster dose or through twelve months after the mRNA-1273.211 booster dose), you should report this immediately to the study staff. 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**

If you are in Cohort 2, you will receive a COVID-19 vaccine that has been shown to prevent COVID-19 and has received emergency use authorization or approval. If you are in Cohort 1, you may 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 booster vaccine schedules for new strain variants 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 [redacted] for each vaccine visit.
You will be compensated [redacted] for each other scheduled clinic visit.
You will be compensated [redacted] for each scheduled phone or electronic visit.

You will be compensated for the visits you complete. You will not be paid for the Screening visit, if it occurs separately from the enrollment visit.

If you participate in Cohort 1, there will be one vaccine visit (compensation total [redacted]), 5 clinic visits (compensation total [redacted], and 1 telephone visit (compensation total [redacted]. If you complete all scheduled visits, you will receive a total of [redacted]

If you participate in Cohort 2, there will be three vaccine visits (compensation total [redacted], 6 clinic visits (compensation total [redacted], and 2 telephone visits (compensation total [redacted] If you complete all scheduled visits, you will receive a total of [redacted]

If you are asked to make an unscheduled or illness visit we will pay you [redacted] per visit.

The compensation will be distributed at regular intervals during the conduct of the study. We will pay you by ClinCard.

Compensation for each research study participation is considered taxable income per Internal Revenue Service (IRS) regulations. If the total amount of payment received by you reaches or exceeds [redacted] in a calendar year, Baylor College of Medicine (BCM) will send an IRS Form 1099 to that person for tax purposes.

To issue the IRS Form 1099, BCM will collect your name, social security number, date of birth and home address. The name you provide should match the social security number. If you do not wish to provide a social security number, you can still participate in the study and decline all payment.

Please note study compensation is considered income and may or may not affect government or public assistance benefit programs you may be participating in, such as SSI (Supplemental Security Income) or TANF (Temporary Assistance for Needy Families).

Compensation for study visits will be loaded onto the ClinCard within 48-72 hours of each visit that you complete. The research study team will provide you with a handout about the ClinCard.

Your email address and/or cell phone number will be collected in the event you want email or text notifications when payments are loaded to your ClinCard. BCM and Greenphire (ClinCard Company) have entered into an agreement which requires Greenphire to protect your personal information.

BCM will replace your ClinCard free of charge if your first card is lost or stolen. After that, there is a [redacted] ClinCard replacement fee. This replacement fee will be charged to the balance on your ClinCard at the time of replacement. Your ClinCard has an expiration date. If your ClinCard expires while you are participating in this study, BCM will provide you with a new ClinCard at no cost to you. For a period of three months following your final study visit, you may request replacement of an expired ClinCard at no cost to you.

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

**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 are injured as a result of being in this study, you should notify the study doctor as soon as possible.

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured, then they will help you get the care you need.

The study site will provide short-term medical care for any injury resulting from your participation in research here. 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 participant in clinical studies utilizing COVID-19 countermeasures, such as the study vaccines, 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.

**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.

# AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

**Related Health Information**

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning alcohol abuse
- Specific information concerning drug abuse
- Specific information concerning sickle cell anemia
- Specific information concerning HIV
- Specific information concerning psychiatry notes
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Full Social Security #
- Partial Social Security # (Last four digits)

The health information listed above may be used by and or disclosed (released) to the following:

- The study sponsor or its representatives, including companies it hires to provide study-related services
- Advarra IRB and its representatives
- Other Institutional Review Boards and/or affiliate institutions where approval must be obtained and its representatives
- Regulatory and Government health agencies (such as the Food and Drug Administration, Department of Health and Human Services etc.) in the US or other countries (e.g. European Medicines Agency)
- Office of Human Research Protections (OHRP)
- Member of the research team
- Researchers at other centers taking part in the study
- Data Coordinating Center for the research study
- Data safety monitoring board/committees that are responsible for the safety of research subjects
- Other health care providers involved in your care
- Hospital or other accrediting agencies
- Greenphire (Clincard Company)

**Use or Disclosure Required by Law**

Baylor College of Medicine is required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, data coordinating center, and Data and Safety Monitoring Board may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to the study doctor at the address listed on the first page of this form.

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

**Subject's Rights**

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

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

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The study doctor, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff by contacting the study doctor or study staff at the telephone number listed on the first page of this form.

**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: Pro00053376.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The BCM IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

**CONSENT AND AUTHORIZATION**

Information describing this research study has been explained to me. I have read this consent form. All of 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** research. I understand that this may include reproducing and/or growing my cells.

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.

_____

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