Baylor College of Medicine
GIVING LIFE TO POSSIBLE

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

Sponsor / Study Title:	**Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) / A Phase 1 Open-Label Safety and Immunogenicity Trial of MPV/S-2P, a Next Generation SARS-CoV-2 Booster Vaccine, in Previously Vaccinated Adults**
Protocol Number:	**23-1101** **H-53733**
Principal Investigator: **(Study Doctor)**	**Hana El Sahly, MD**
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Baylor College of Medicine Subject Protections:

The research will be conducted at the following location(s): **Baylor College of Medicine.**

This research study is funded by the National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases.

KEY INFORMATION

You are being asked to participate in this study because we want to test the safety and immune response to an experimental COVID-19 vaccine given as a nasal spray.

- Being in the study is voluntary – it is your choice.
- Your participation in this study will last for about 12 months.
- You will have up to ten planned study visits, including a screening visit, one study vaccine visit, seven follow-up visits, and one phone call to check on you.

- There are 3 study groups. Participants in all three groups will receive the same study vaccine, starting with a low dose and moving to a medium and then a high dose if the study vaccine seems safe.
- You will receive one dose of the study vaccine by nose spray.
- During the study, you will have physical exams, blood draws, saliva collection, and nose swabs.
- Additionally, as instructed, you will complete a daily memory aid (like a diary log) at home to record any side effects that you may experience for two weeks after the study vaccination.
- You will also be asked to adjust some of your daily routines for varying periods of time. This information is described under the “Lifestyle Considerations” section below.
- You will be asked not to receive another COVID-19 vaccine (including approved or CDC-recommended vaccines) for six months after you receive the study vaccine.
- There are risks to participating.

The most common side effects of vaccines include possible cold or flu-like symptoms such as a runny nose, nasal congestion, sneezing, sore throat, tiredness, and body aches. One serious potential risk is anaphylaxis or a severe allergic reaction to the study vaccine. See the “Risks of Participation” section for more information. You should discuss these risks in detail with the study team.

There is a risk of loss of confidentiality of your health information.

This study will include genetic testing to see how well the study vaccine works. We are not looking for inherited disorders; we will explain this later in this form.

You will not benefit from being in this study.

When you participate in this study, you are asked to consent to **secondary research** (the research is not planned yet). We will use your coded information, leftover samples, and extra samples for secondary research. This may include **genetic** research to study immune responses. You should not enroll in this study if you do not want your samples and data used for secondary research.

Please read this form carefully. Take your time to ask the study team your questions. The study doctor or staff will explain words or information you do not understand. If you decide to participate in this study, you must sign and date your name at the end of this form.

BACKGROUND

COVID-19 is a disease caused by infection with the SARS-CoV-2 virus. COVID-19 can cause symptoms including fever, cough, shortness of breath, fatigue (tiredness), sore throat, body aches, nasal congestion, and/or loss of taste or smell. Researchers are looking for new vaccines to prevent or minimize COVID-19. Vaccines train germ-fighting cells to help fight infections.

Approximately 60 people will participate in this study at three sites.

The remaining sections of this form describe the research study in more detail. 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 participate 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. Signing and dating this consent form indicates that you understand your involvement in the study and the risks of participating and agree to participate.

PURPOSE OF THIS RESEARCH STUDY

The purpose of this first-in-human research study is to test an experimental COVID-19 vaccine called MPV/S-2P to evaluate its safety, its tolerability, and the immune system's response to it. MPV/S-2P is a live virus (a virus that has been weakened so it does not cause the disease the virus usually causes), making this a live virus vaccine. The study vaccine contains a piece of genetic code of the SARS-CoV-2 virus (the virus that causes COVID-19). This genetic code will make a protein from the SARS-CoV-2 virus and cause your body to think you have been infected with the virus but cannot cause a COVID-19 infection. The murine pneumonia virus (MPV) is a relative of the human respiratory syncytial virus (RSV) and causes respiratory disease in mice. There have been no reports of MPV causing disease in humans. We will take blood, swabs of your nose, and saliva from you to see how your body responds to the study vaccine. This will help us to understand how the study vaccine works.

"Experimental" means the United States Food and Drug Administration (FDA) has not approved this vaccine for routine use, but it allows it to be studied in this clinical trial.

SELECTION OF STUDY POPULATION

Adults aged 18 to 64 years who are in a stable state of health may enroll. We will screen you for eligibility before further study activities or giving you a study vaccination. You are **not** eligible for this research study if:

- You received a COVID-19 vaccine or have a history of a SARS-CoV-2 infection in the past 16 weeks before getting the study vaccine
- You are positive for COVID-19 infection at screening
- You received an investigational drug in the past 60 days OR plan to receive one during your participation in this study

- You received or plan to receive a non-live vaccine within 14 days of getting the study vaccine or a live vaccine within 28 days.
- You have certain chronic medical or psychiatric conditions
- You are on certain medications
- You are pregnant, could become pregnant, and have not been using effective contraception or breastfeeding
- You work with or have pet rodents (mice, rats, gerbils, etc.)
- You work in a nursing home or skilled nursing facility
- You live with or care for someone who:
    - Is under two years old
    - Is pregnant
    - Is immunocompromised (has weak defenses)
- You have a history of hypersensitivity or a severe allergic reaction to a vaccine
- You are a smoker or were a smoker within the last three months

There are other reasons why you may not be able to participate in this study, which we will discuss with you.

LIFESTYLE CONSIDERATIONS

During the study, you will be asked to:

- For 14 days after the study vaccination, avoid interactions with people who may be immunocompromised (have weak defenses), pregnant people, and children under two years of age.
- Wear a surgical mask (or KN-95 or N-95) when around others (within 6 feet) for 14 days or longer, as necessary, after study vaccination.
- Within the first month after study vaccination, wear a surgical mask (or KN-95 or N-95) when around others if you feel sick with flu-like symptoms (for example, fever or feeling unwell) or respiratory symptoms.
- Not receive a COVID-19 vaccine until after your 6-month visit.
- Not participate in another study evaluating investigational vaccines.
- Not travel internationally until you complete your 1-month visit.
- Not donate blood or plasma outside of the study until your 6-month visit.
- Avoid use of nasal medications or rinses after study vaccination.

WHAT WILL HAPPEN DURING THE STUDY?

This study will enroll participants in a staged fashion. There are 3 study groups, starting with a low study vaccine dose and moving to a medium and then a higher dose if the study vaccine seems safe. We will give the study vaccine to 3 people for each dose group using a VaxINator, a device that will be used to deliver the study vaccine in the nose. A review of safety data will take place one week later before asking others to enroll:

Group	Number of participants	Study Vaccine Dose
1	20	1 x 10^4 PFU Intranasal using the VaxINator
2	20	1 x 10^5 PFU Intranasal using the VaxINator
3	20	1 x 10^6 PFU Intranasal using the VaxINator

PFU = Plaque forming units

Your participation in this study will last approximately 12 months with approximately 10 study visits, including one phone call.

Screening

You will have a Screening Visit to check if you are eligible to enroll in this study, which will take about two hours and will include:

- Learning about the study and asking questions
- Reviewing, signing, and dating the consent form
- Collecting information about your health, medications, vaccination history, and any drug and alcohol use
- A physical exam
- Checking vital signs (temperature, blood pressure, heart rate, and oxygen level in the blood)
- Measuring height and weight
- A nasal swab to test for SARS-CoV-2 infection. The study doctor may be required by law to report the result of this test to the local health authority.
- For people of childbearing potential, a urine pregnancy test will be obtained.
- Blood sampling will be performed to check your kidney and liver function, blood cell counts, and for HIV, hepatitis B, and hepatitis C infections. The study doctor may be required by law to report the result of these tests to the local health authority.

If you are excluded because your screening results require medical attention, the study doctor will ask you to follow up with your regular doctor.

Study Visits

The study vaccination visit will generally last about 2-3 hours. Other visits will generally last about 30 minutes. Visits may include the following procedures:

- Questions about your recent medical history and medications, illnesses or symptoms, and side effects or reactions
- Measuring vital signs (heart rate, blood pressure, temperature, and oxygen level in the blood) before the study vaccination and at other visits if needed
- Having a physical exam if needed
- Collection of blood, nasal, and saliva samples (this may include testing for other respiratory viruses)
- For people who can become pregnant, urine for pregnancy testing before the study vaccination

At the study vaccination visit, we will review your medical history to confirm your eligibility for a study vaccination. You will get the study vaccination on that visit. The study vaccine is a nasal spray into both nostrils. You will stay in the clinic for at least 30 minutes after the study vaccination so that the study staff can check for any possible immediate reactions.

We will give you a thermometer and a memory aid with instructions to record your temperature, medications, and any side effects. You will complete the daily memory aid at home, beginning on the evening of the day of study vaccination and continuing for the next fourteen days. Study staff will call you the day after the study vaccination visit to ask about any side effects. The memory aid will include the study team's contact information. You will be asked to bring the memory aid to your next clinic visit.

We will ask you to keep track of any symptoms (expected or not) that you develop after being vaccinated. You will also visit the clinic (or speak with us by phone) for follow-up visits.

We will also give you masks to wear when you are around others, as needed, or if you get sick.

We may ask you to visit the clinic for an extra study visit. The study staff will perform visit procedures and may collect additional samples if needed. This may be for your safety or for research purposes.

The study staff will call you after your study vaccination to check on your health status, 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

If you become sick or have any significant or concerning reactions after the study vaccination, you should immediately contact the study staff. You may be asked to return to the study clinic or have a remote visit 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, which may include drawing your blood, collecting nasal samples, and/or performing an electrocardiogram (ECG).

Collection of Samples for Research Purposes

Blood: We will collect 5 tablespoons or less at most visits to assess your general health and for research purposes.

Saliva: We will ask you to keep a small sponge inside your mouth for approximately two minutes.

Nasal mucous: We will use a swab to collect mucus from inside your nose.

Lab Testing of Specimens

The blood, saliva, and nasal specimens collected from you will be used for research tests of the 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. Nasal specimens will also be tested for SARS-CoV-2, the presence of the study vaccine virus, and other respiratory viruses, if needed.

Giving blood, saliva, and nasal samples for the research tests will not benefit you. It may help others by leading to new vaccines or treatments for COVID-19. The results of these tests are useful only for research purposes.

Your results will not be available to you or your regular doctor and will not be included in your medical record.

Genetic Testing:

For this study, we will perform genetic testing on your biological samples. This genetic testing will focus on COVID-19 and provide information about how your body responds to the study vaccine and/or disease. We will not do genetic tests that check for disorders or biomarkers for other diseases.

You will not receive the results of the genetic testing.

A summary of the genetic results from all participants in this study without personal identifiers may be placed in a public, open-access database that anyone can freely use.

No individual genetic testing information or results will be placed in an open-access database, so the risk of anyone identifying you with this information is very unlikely.

We will share your genetic information (data) through a “closed” database, also called a restricted data repository. NIH may give permission to qualified researchers to access and use your genetic information for other research. Types of research using your data may be related to COVID-19, infectious diseases, or other types of research. Your 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 not to 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 information and specimens. If possible, your information can be removed for secondary research. Your data cannot be removed if it has already been used.

We may remove the codes from your information or samples so that we cannot identify you and may then use these samples in other research. These samples with no codes may be shared with other researchers without your additional consent.

USE OF SAMPLES OR DATA IN OTHER RESEARCH STUDIES

Biological Samples

Some of the biological samples collected for measuring immune responses to the study vaccine may not be needed for the research tests. We will store and use these leftover samples and your information for secondary research. Secondary research 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 biological samples at each visit to store and use for secondary research. Secondary research may help us understand how the study vaccine works, develop tests, study other infections or diseases, or develop treatments. **You cannot enroll in this study if you do not want to give your leftover and extra samples for secondary research.**

Your biological samples will be stored indefinitely at a site determined by the NIH. Leftover and extra samples will be labeled only with a barcode and an ID code (not your name, initials, or any other information that could readily identify you). These leftover and extra samples will be stored using the same confidentiality measures as the main specimens.

Leftover and extra biological 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 the 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 cannot 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 of the genetic research testing.**

At any time during or after this study is over, biological 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 called a restricted data repository. NIH may give permission to qualified researchers to access and use your genetic information for other research. A summary of participant data may be shared in an “open-access” database, but this will not contain your data. The risk of anyone identifying you with this information is very unlikely. However, there is still a risk of loss of confidentiality.

Your data will not contain information that can easily identify you. Although it may be possible to identify you with your DNA, the researchers must follow rules specifically not to identify you. If you change your mind and want to remove your data from the database, you should contact the research site that collected it. If possible, your data can be removed for further research. However, your data cannot be removed if already used.

Leftover and extra biological 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 to make commercial products. However, the research studies in this study or in the future may lead to identifying 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 commercially profitable, 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 biological samples are tested in the future, the results may be published. You will not be identified in such a 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 agree to the collection, storage, and future research use of your biological samples and information collected for this study. There are no benefits to you in the collection, storage, and future research use of your biological samples. Future research tests may benefit others by leading to new approaches in developing vaccines or treatments for coronavirus infections. The results of any future research testing will be kept confidential like 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 to store and use your coded samples or information anytime. To do so, you must contact the study doctor using the contact information listed on page 1 of this form. If you have study visits after this, we will stop collecting extra biological samples.

When the vaccine study is completed, your samples will be removed from future use. Only stored samples with an ID code that are 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, if the specimens and data have been shared already with other researchers, withdrawing the specimens and data might not be possible.

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

POTENTIAL RISKS AND DISCOMFORTS

There may be some risks to participating in this study. You may experience one or more 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, they can be serious, long-lasting, or permanent.

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

Since this study vaccine is made from a live virus that carries the genetic material of spike protein of SARS-CoV-2, the virus that causes COVID-19, there is a possible risk of transmitting the study vaccine virus to other people, though this risk is thought to be low. To further lower this risk, you will be asked to wear a mask for 14 days after study vaccination when around other people and avoid contact with people with compromised immune systems, pregnant individuals, and children under 2 years of age, also for 14 days after study vaccination.

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 removing the needle. It is possible to get an infection at the site of the needle stick. To reduce the risk of infection after the blood draws or study vaccine injection, the study staff will wipe the area, clean the area with alcohol, and use sterile equipment.

Throughout this study, the amount of blood collected will not exceed 13 tablespoons (181 mL) in any 8-week period (which is less than the amount of blood allowed to be drawn during 8 weeks under the American Association of Blood Banks standards).

The risks associated with having nasal swabs/strips or mouth swabs collected may include discomfort, gagging, coughing, eyes watering, nose bleeding, minor irritation, and sneezing.

Risks and possible side effects that you may experience with the study vaccine.

The study vaccine's potential risks and side effects are anticipated to be like those of other vaccines given in the nose. They could include runny nose, irritation of the nose, stuffy nose, scratchy or sore throat, sneezing, and teary or watery eyes.

Possible side effects that are like those seen with other vaccines for respiratory infections include wheezing and coughing.

Other possible side effects that could be like those of COVID-19 vaccines given by injection include fever, chills, fatigue (tiredness), body aches, nausea, vomiting, swollen lymph nodes, headache, inflammation of the heart muscle, and inflammation of the lining outside the heart.

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received COVID-19 mRNA vaccines, usually in the first 4 weeks after receiving the vaccine. Most of these people's symptoms began within a few days after vaccination. You should seek medical attention immediately if you have any of the following symptoms after receiving the study vaccine: chest pain, shortness of breath, or feelings of a fast beating, pounding, or fluttering heart.

In this study, we will be monitoring for myocarditis and pericarditis because this is a COVID-19 vaccine, although we anticipate that the chance of this is very low.

This study vaccine is made of a live virus, and when it was tested in animals, there were no concerning side effects.

However, there is a risk that the study vaccine could cause an infection of the lower airways and lungs (bronchitis or pneumonia). Facial Nerve Palsy (face drooping) was a side effect of another research nasal flu vaccine that was mixed with an adjuvant. (An adjuvant is a substance used to increase the study vaccine’s potency.) Even though this study vaccine is not mixed with an adjuvant, we will monitor for facial nerve palsy in this study.

Sometimes, vaccines are not protective. Rarely, they can cause more severe illness after virus exposure. Based on prior animal studies with this study vaccine, we do not think it should increase your risk of severe illness. The vaccine tested in this study cannot cause COVID-19 infection.

As with any vaccine, there is a risk of allergic reaction. Serious allergic reactions can be life-threatening. Some symptoms of allergic reactions are:

- Rash

- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

Please tell the study staff immediately if you have any side effects. Please tell them if you have any other health problems, how you feel during the study, and whether you think these problems are related to the study vaccine.

For Participants of Childbearing Potential, Risks Related to Pregnancy

You cannot be enrolled in this study if you are:

- Pregnant
- Breastfeeding/chestfeeding

There may be unknown risks to the embryo, fetus, or breastfed/chestfed child. If you can become pregnant, you must have a negative urine pregnancy test at screening and before study vaccination. You must use one acceptable primary form of contraception during your study participation and for at least 60 days after the dose of the study vaccine.

If you become pregnant while in this study, you should report this immediately to the study staff. With your permission, the study staff will ask about your health, collect information from you through the outcome of your pregnancy, and collect scheduled biological samples. The study staff 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.

Risks of Storage and Sharing of Samples and Data

When we store your *data and samples,* we take precautions to protect your information from others who should not have access to it. When we share your data and samples, we will do everything we can to protect your identity by removing information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known, or someone may gain unauthorized access to your information.

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.

Risks of Genetic Testing

Since your genetic data and health information may be stored and shared with other researchers, there may be a risk that information resulting from research genetic testing could be misused for discriminatory purposes. However, state and federal laws provide some protection against genetic discrimination. If you have any questions, please ask your Principal Investigator. Researchers who have access to your genetic information will take measures to maintain the confidentiality of your information, as described below. Risks may also result if you disclose the information yourself. New methods may be created in the future that could make it possible to identify you by your data or samples.

BENEFITS

You may not benefit from being in this study. However, the results of this research might help others by contributing knowledge that could lead to the development of next-generation COVID-19 vaccines and/or findings that could be helpful for the development of future vaccines.

ALTERNATIVES TO PARTICIPATION

The only alternative is to not participate in this study.

NEW FINDINGS

We will contact you about any new information and explain how this may affect your health or willingness to stay in this study. If this occurs, you may be asked to sign and date a revised consent form.

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. If you move after your last study visit, you must provide us with your new address if you want to receive this information.

SOURCE OF FUNDING FOR THE STUDY

The study site is receiving payment from the NIH, National Institute of Allergy and Infectious Diseases, the study's sponsor.

COMPENSATION FOR PARTICIPATION

You will be paid for your time and expenses related to participation in the study. You will receive payment for the following study visits:

- $125 for the study vaccination in-person study visit.
- $75 for each in-person study visit where a blood draw is collected.

- $50 for each in-person study visit where a blood draw is not collected.
- $25 for safety telephone call.
- $75 for each unscheduled in-person study visit with blood draw collected.
- $25 for each unscheduled in-person study visit with no blood draw or nasal swab collected.
- $75 for illness in-person visits.

You will receive up to approximately $750 for all completed study visits. You will not be compensated for any missed visits.

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

Payments for research participation are considered taxable income per Internal Revenue Service (IRS) regulations. If the total amount of payment received by you reaches or exceeds $600 in a calendar year, Baylor College of Medicine will send an IRS Form 1099 to that person for tax purposes.

In order to issue the IRS Form 1099, Baylor will collect your first and last 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 payments are 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).

A ClinCard will be used for study payments. Payments will be loaded onto the ClinCard within 48-72 hours of visit completion. 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 notification when payments are loaded to your ClinCard. Baylor College of Medicine and Greenphire (ClinCard Company) have entered into an agreement which requires Greenphire to protect your personal information.

The College will replace your ClinCard free of charge if your first card is lost or stolen. After that, there is a $7 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, Baylor 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 OF PARTICIPATION

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.

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.

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

COMPENSATION FOR INJURY

If you are injured because of being in this study, you should notify the study doctor as soon as possible. If there is an emergency, call 911 immediately or go to the emergency room and contact your study doctor as soon as possible. Tell the study staff you think you have been injured and they can help you get the care you need.

If you are directly injured by the vaccine being studied or by medical procedures needed because of this study, and you receive medical care for the injury, you may need to pay for that care.

The study site will provide short-term medical care for any injury resulting from your participation in research here. No long-term medical care or financial compensation for research-related injury 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, MPV/S-2P, 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.**

CONFIDENTIALITY

Paper documents containing personal information about you will be kept in locked file cabinets, and computerized information will be kept in password-restricted files. Only people who are involved in the conduct, oversight, or auditing of this study will be allowed access to personal information with your identifiers.

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.

CERTIFICATE OF CONFIDENTIALITY

To help us protect your privacy, we have a Certificate of Confidentiality 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:

- Is disclosed to people connected with the research; for example, information may be used for auditing or program evaluation internally by the NIH or
- 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;

- Is necessary for your medical treatment, and you have consented to this disclosure;
- Is for other scientific research as allowed by applicable federal regulations;
- 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.

Research 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 #
- Billing or financial records

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)
- Members 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 does not involve treatment. Baylor College of Medicine may not condition (withhold or refuse) treating you on whether you sign this Authorization.

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 Advarra Institutional Review Board (Advarra IRB), 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/committees responsible for the safety of the research subjects 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.

The data coordinating center will have access to the research records including your health information.

A Data and Safety Monitoring Board/committees responsible for safety will have access to the research records including your health information.

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 such, as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor’s or study site’s decision to withdraw you from participation;
- Results of tests and/or procedures;

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, 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: Pro00078702.

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.

VOLUNTARY PARTICIPATION / WITHDRAWAL

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 stop your participation at any time without penalty if 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 anytime. Please contact the study staff if you decide to stop participating 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:

- You miss research visits
- You are unable to comply with study procedures or instructions

- You withhold information about your health history or medications
- Reasons related to your health
- 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 the study
- If you become pregnant
- Any other reason

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 before withdrawal may continue to be used for this study.

The Advarra 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.

STATEMENT OF CONSENT AND AUTHORIZATION

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 signed and dated copy of this consent form.

I am not giving up any of my legal rights by signing this form.

_____ _____
Signature of the Subject (if applicable) Date

_____
Printed name of the Subject (if applicable)

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.

_____ _____
Signature of Study Doctor or Designee Obtaining Consent Date

_____
Printed name of Study Doctor or Designee Obtaining Consent

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____ _____
Signature of Witness (if applicable) Date

_____
Printed name of Witness (if applicable)