[redacted]

**INFORMED CONSENT FORM**

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|---|---|
| **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 Dose Escalation Study To Assess The Safety, Reactogenicity, And Immunogenicity Of STX-S For Prevention Of SARS-COV-2 Infection As A Booster Dose"** |
| **Protocol Number:** | **24-1104** |
| **Principal Investigator: (Study Doctor)** | [redacted] |
| **Telephone:** | [redacted] |
| **Address:** | [redacted] |

## 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 booster dose.

- Being in the study is voluntary – it is your choice.
- Your participation in this study will last for about 6 to 7 months.
- You will have up to nine planned study visits, including a screening visit, one study vaccine visit, five follow-up visits, and two phone calls to check on you.
- There are three 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 vaccine seems safe.
- You will receive one dose of study vaccine given by injection in your upper arm.
- 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 one week after the 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 effect of injected vaccines is pain at the injection site. One of the most serious risks 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 also 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** (research that 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, 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.

## PURPOSE OF THIS RESEARCH STUDY

The purpose of this first-in-human research study is to test an experimental COVID-19 vaccine called STX-S to evaluate its safety, its reactogenicity, and the immune system's response to it. STX-S is a new type of experimental vaccine called an exosome vaccine. Exosomes are tiny particles naturally made by human cells that carry messages between cells. They are used in vaccines because they are small and can carry virus proteins to teach your immune system how to fight infection. STX-S is an exosome vaccine containing the Wuhan spike protein of the SARS-CoV-2 virus (the virus that causes COVID-19). The study vaccine will cause your body to develop immune responses to those proteins, but it cannot cause a COVID-19 infection. We will

take blood and saliva samples and swabs of your nose 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 allows it to be studied in this research study.

## SELECTION OF STUDY POPULATION

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

- You have not received a complete COVID-19 primary vaccine series and at least one subsequent COVID-19 vaccine booster
- You received a COVID-19 vaccine or have had a SARS-CoV-2 infection in the 16 weeks before the study vaccination
- 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 or a live vaccine within 28 days of getting the study vaccine
- You have certain chronic medical or psychiatric conditions
- You are on certain medications
- You are pregnant, or you are breastfeeding
- You are a female who could become pregnant and you have not been using effective contraception for the past 30 days, or you are not willing to use effective contraception through 60 days after the study vaccination
- You are a male and you are not willing to use effective contraception and to stop donating sperm for 60 days after the study vaccination
- You have a history of hypersensitivity or a severe allergic reaction to a vaccine
- You are a current smoker (including cigarettes, marijuana, or vaping) or have smoked 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:

- Not receive a COVID-19 vaccine outside of the study until after your 6-month visit.
- Avoid the use of nasal irrigation or sinus rinsing treatments (e.g., neti pots, saline washes) for 28 days after study vaccination and for 7 days before visits to the clinic for the remainder of the study.
- Follow public health guidance on preventing SARS-CoV-2 infection.
- Not donate blood or plasma outside the study until 6-months after your study vaccine.
- Not participate in another study evaluating investigational products.
- Not travel internationally until you complete your 1-month visit.

## 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 first give the study vaccine to 3 people for each dose group. A review of safety data will take place one week later before asking others to enroll in that dose group.

| Group | Number of participants | Study Vaccine Dose |
|---|---|---|
| 1 | 20 | 25ng STX-S administered intramuscularly in a volume of 0.25 mL |
| 2 | 20 | 50ng STX-S administered intramuscularly in a volume of 0.5 mL |
| 3 | 20 | 125ng STX-S administered intramuscularly in a volume of 0.5 mL |

Your participation in this study will last approximately 6-7 months, with approximately 9 study visits, including two phone calls.

### 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
- 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 testing for HIV, hepatitis B, and hepatitis C infections. The study doctor may be required by law to report the results 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 doctor.

**Study Visits**

The study vaccination visit will generally last about 2-3 hours. Other clinic 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 given by injection in the muscle of the upper arm. You will stay in the clinic for at least 30 minutes after the study vaccination so that study staff can check for any 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 the study vaccination and continuing for the next seven days. Study staff will call you the day after and two days 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) you develop after being vaccinated. You will also visit the clinic (or speak with us by phone) for follow-up visits.

We may ask you to visit the clinic for an extra study visit. The 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**

You should immediately contact the study staff using the contact information found on the first page of this form if you become sick or have any significant or concerning reactions after the study vaccination. You may be asked to return to the study clinic or have a phone or video 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.

**Collection of Samples for Research Purposes**

Blood: We will collect blood samples at the screening visit, study vaccination visit and five other clinic visits.

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

Nasal mucus: We will use a swab and a nasal strip to collect mucus 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 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 helpful 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 allow 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, 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 if you consent to that use.

## USE OF SAMPLES OR DATA IN OTHER RESEARCH STUDIES

### Biological Samples

Some 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), which determines someone's complete DNA make-up, or other types of genetic testing (including tests that have yet to be developed) to inform the development of new vaccines or for the study 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 you may get. 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 allow 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, after you have provided consent, 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 it has already been 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 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.

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, just 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 to store and use your coded samples or information anytime. You must contact the study doctor using the contact information on page 1 of this form. If you have 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 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 having blood drawn, reactions to the injected vaccine, adverse effects (side effects) of the study vaccine(s), having nasal swabs/strips or mouth swabs 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 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 clean your skin with alcohol and use sterile equipment.

The risks associated with having nasal swabs/strips or mouth swabs collected may include discomfort, watery eyes, nosebleed, minor irritation, and sneezing.

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

After a study vaccination, a person might experience fever, chills, fatigue, body aches, joint pain, nausea/vomiting, swollen lymph nodes, headache, or redness, swelling, or pain at the injection site.

There is a small risk of a serious allergic reaction. Symptoms of allergic reaction include:

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

If this occurs, emergency medications administered by study personnel can usually stop it. Most people who experience these reactions 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 COVID-19 mRNA vaccines, usually in the first 4 weeks after receiving the study vaccine. Most of these people's symptoms began within a few days after study 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 monitor for myocarditis and pericarditis because this is a COVID-19 vaccine, although we anticipate that the chance of this is very low. The study vaccine tested in this study cannot cause COVID-19 infection.

This study vaccine was tested in animals and no concerning side effects were identified.

Sometimes, vaccines are not protective. Rarely, they can cause more severe illness after virus exposure. We do not think this study vaccine will increase your risk of severe illness, but we will continue to monitor you closely throughout the study.

In addition to these risks, there may be risks of the study vaccination that are not yet known.

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

There may be unknown risks to the embryo, fetus, or breastfed child. If you can become pregnant, you must have a negative urine pregnancy test at screening and before study vaccination. If you are female and have the potential to become pregnant you must practice birth control for 30 days before, and 60 days after the study vaccination. The study doctor can discuss with you acceptable forms of birth control.

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.

If you are a male capable of fathering a child for 60 days post study vaccination you must use acceptable birth control and not donate sperm. The study doctor can discuss with you acceptable forms of birth control.

**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 such as name, address, and

identification numbers removed. 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 the study doctor. 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.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

**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. You can receive vaccinations as recommended by the FDA or choose to receive none.

## 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. You may be asked to sign and date a revised consent form if this occurs.

## 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 receive compensation according to the table below. If you do not complete the entire study, you will be compensated for the study visits you have completed. When you are asked to come into the clinic for an unscheduled visit, you will be compensated [redacted] for each visit.

| Visit | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|---|
| Payment | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

It may take up to 4 weeks to receive your payment. Payments may be batched. Parking validation or bus tickets will be provided for each study visit.

In order to process your payment, we must enter your name, contact information for payment (e.g., email address or mailing address), and social security number into the [redacted] financial system. Your name and participation in this study will be visible to employees who handle financial transactions for [redacted]

If you earn [redacted] in participant payments from [redacted] during a calendar year, the [redacted] will report this to the Internal Revenue Service as Miscellaneous Income. This is why we ask you to provide us with your Social Security number.

## 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.

The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the [redacted] discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the [redacted] Human Subjects Division at [redacted]. Ask the researcher if you would like information about the limits and conditions of the HSAP. The [redacted] does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers.

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, STX-S, 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.

## AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

You will be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) Authorization form authorizing access, use, creation, or disclosure of health information about you.

## WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study 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: Pro00087723.

## 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 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.

**CONSENT**

I have read (or have had read to me) and understand the information in this informed consent document. I have had an opportunity to ask questions, and all of my questions have been answered to my satisfaction. I agree to participate in this study. I will receive a copy of this signed and dated consent document.

_____

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 Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date