INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**National Institute of Allergy and Infectious Diseases (NIAID) / "Safety and Immunogenicity of a dose of the Sanofi-GSK monovalent (B.1.351) CoV2 preS dTM-AS03 COVID-19 vaccine in kidney transplant recipients with a persistently low SARS CoV-2 antibody titer"**
Protocol Number:	**COVID19-TB-04**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

1. YOUR PARTICIPATION IS VOLUNTARY

We will explain this research study to you. You may ask questions.

- Taking part in this study is your decision.
- You may change your mind at any time.
- You will be given a copy of this consent form for your records.

2. KEY INFORMATION

The first pages of this document include a summary of the research study to help you decide whether or not to participate.

- You are being approached for this study because you are a kidney transplant recipient who has received a completed primary series (3 doses) and updated, bivalent booster of either the Moderna COVID-19 vaccine or Pfizer-BioNTech COVID-19 vaccine and have a low level of COVID-19 antibodies. Antibodies are proteins your body makes to fight against certain diseases.
- If you have a low level of antibodies, this may mean you have a higher chance of becoming sick if you come into contact with COVID-19.
- This consent is for permission to give you a dose of the Sanofi-GSK COVID-19 vaccine. This study vaccine uses a part of the SARS-CoV-2 virus to help your body make antibodies against the virus. This study vaccine also uses an adjuvant, which is an additional compound that helps your body build a stronger immune response. The Sanofi-GSK COVID-19 vaccine cannot give you COVID-19.
- Researchers are trying to figure out if a dose of the Sanofi-GSK COVID-19 vaccine following the Moderna or Pfizer-BioNTech COVID-19 vaccine will help kidney transplant recipients make more antibodies to help protect them against COVID-19.
- You will have a nasal swab looking for active COVID-19 infection prior to the study vaccine and 1 month after the study vaccine.

- Following the study vaccine, you will have blood drawn at Day 14, Month 1, Month 3, Month 6 and Year 1. You will also be contacted by a member of the study team at many of these timepoints to ask questions about how you are feeling and study vaccine side effects.
- Since vaccines may generally stimulate the immune system, the study will also look for any signs of rejection.
- This consent form explains all of the risks and benefits. Please read this document in its entirety so that you fully understand what is required of you in order to participate.
- According to the United States Food and Drug Administration (FDA) Emergency Use Authorization, you should not receive any pre-exposure prophylaxis (PrEP)(antibodies given to prevent getting COVID-19 infection) during the 2-week period following any dose of COVID-19 vaccine. From a study perspective, it would be best if you did not receive any PrEP until after your Day 30 study visit. However, if you and your doctor feel that it is in your best interest to receive PrEP before Day 30, please inform the study team. Receiving PrEP before Day 30 may decrease our ability to evaluate the effectiveness of the study dose of vaccine.
- Please inform your study team of any new medications prescribed by your primary transplant provider to prevent or treat COVID-19 infection during the course of the study.
- This consent form explains the risks of being in the trial. Some possible benefits of being in the trial are also described, but there may be no benefit to you from being in the trial.
- Please read the complete document and ask questions about anything you do not understand or if there is more that you want to know. The study doctor or Research Coordinator will answer your questions.

3. Why is this research being done?

Many transplant recipients do not make enough COVID-19 antibodies after a completed primary series of the Moderna or Pfizer-BioNTech COVID-19 vaccines. That means that even though they got the vaccine, they may not be fully protected from COVID-19. We will learn whether giving a dose of the Sanofi-GSK COVID-19 vaccine following a completed primary series and updated, bivalent booster of the Moderna or Pfizer-BioNTech COVID-19 vaccine will help kidney transplant recipients make additional antibodies against the virus that causes COVID-19.

4. Is there any way being in this research can hurt me?

The Sanofi-GSK COVID-19 vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

There are known risks associated with the Sanofi-GSK COVID-19 vaccine based on previous clinical studies. Some of these studies used a different dose of the study vaccine. The most common side effects associated with the study vaccine include:

- Pain, redness or swelling at the injection site
- Fatigue
- Muscle pain
- Joint pain
- Diarrhea

Fever and chills occurred but were less common. Most side effects occurred within 3 days of the study vaccine and resolved within one week. Severe allergic reactions such as anaphylaxis were extremely rare. The study team will observe you for 30 minutes after the study vaccine is given in order to start treatment in the unlikely event you have a severe early reaction.

The study team will look for problems that can occur with any type of vaccine. It is possible but unlikely that a new vaccine may cause a more severe course of disease when you are vaccinated against a disease and then become infected by that disease. This is called vaccine enhanced disease; however, this has not been seen so far with this study vaccine or any of the COVID-19 vaccines being used in the United States. Another possible side effect is worsening of a pre-existing or development of a new immune-mediated disease. Immune mediated diseases are a variety of conditions that can affect any area of the body and causes your body to fight itself. This is a risk because vaccines stimulate your immune system. This was not seen in earlier studies using this vaccine.

If you feel sick while you are participating in the study, you should let the study team know so that the study team can advise you if additional tests or other monitoring should be done.

5. Will being in this research study help me in any way?

There may be no direct benefit to you for participating in this study. If your body makes more antibodies after the additional dose of COVID-19 vaccine, you may have a lower chance of becoming infected with COVID-19.

6. What other choices do I have besides taking part in this research?

You can choose not to take part in this research. Your study doctor will discuss other options available to you.

DETAILED CONSENT INFORMATION

The rest of the consent document includes detailed information about this study.

7. INTRODUCTION/BACKGROUND

Research has found that many kidney transplant recipients who received a completed series of either the Moderna or Pfizer-BioNTech COVID-19 vaccine do not make enough antibodies to fully protect them from COVID-19 infection. Antibodies are proteins made by the body to fight off certain diseases. Transplant patients have weakened immune systems due to the anti-rejection medications taken to protect the transplanted kidney. Many kidney transplant recipients also have underlying conditions, such as diabetes or heart disease, that put them at greater risk for serious illness if they get COVID-19 infection.

The Sanofi-GSK COVID-19 vaccine contains viral proteins that helps your body make antibodies. This study vaccine also uses an adjuvant, a compound that helps stimulate an immune response. The adjuvant used in the Sanofi-GSK vaccine has been used before in certain influenza vaccines. Study doctors are trying to figure out whether a dose of the Sanofi-GSK COVID-19 vaccine will help transplant recipients make more antibodies to COVID-19. The use of Sanofi-GSK COVID-19 vaccine in this study is investigational. An investigational vaccine is one that is not approved by the FDA.

We are asking you to be part of this study because you are a kidney transplant recipient and have a low level of COVID-19 antibodies after a completed primary series (3 doses) and bivalent booster of either the Moderna or Pfizer-BioNTech COVID-19 vaccine.

8. STUDY COMPONENTS

This study is sponsored by the National Institute of Allergy and Infectious Diseases. This study plans to enroll up to 80 participants across 6 clinical sites. If you take part in this study, you will have 9 study visits over the course of 13 months.

Screening
Your study team will look at your medical record and ask you questions to make sure you meet the criteria to participate in the study. If this has not already been done, there will be a blood test to check your COVID-19 antibody level. If you are allergic to polysorbate, a component of the study vaccine, you should not get the Sanofi-GSK COVID-19 vaccine. If you have had myocarditis or pericarditis, you should not get the Sanofi-GSK COVID-19 vaccine.

COVID-19 Study Vaccination Visit
On the day of your study vaccination, you will have approximately 3.5 tablespoons of blood drawn to look at your general health and for research purposes. In addition, you will have a nasal swab to look for active COVID-19 infection. The study doctor may be required by law to report the results of the COVID-19 test to the local health authority. If you are a woman in your child-bearing years you will have a blood or urine pregnancy test to make sure you aren't pregnant.

After the blood and nasal swab collection, you will report to the clinical site for the COVID-19 study vaccine injection. You will be monitored for 30 minutes following the study vaccination for any side effects.

Follow-up Visits
After you receive the dose of Sanofi-GSK COVID-19 vaccine, your study doctor or another member of the study team will contact you at certain times to ask how you are feeling and ask about any side effects from the study vaccine. The table below outlines what will happen over the course of the study.

Study Visit	Week 1	Week 2	Month 1	Month 3	Month 6	Year 1
Contact by phone or computer	X		X	X	X	X
Blood tests for research		3 tbsp	5 tbsp	4 tbsp	5 tbsp	4 tbsp
Nasal swab for COVID-19			X			

Medications to Prevent or Treat COVID-19
According to the FDA Emergency Use Authorization, you should not receive any pre-exposure prophylaxis (PrEP) which are antibodies given to prevent getting COVID-19 infection, for example, tixagevimab plus cilgavimab (Evusheld™, AztraZeneca) during the 2-week period following any dose of COVID-19 vaccine. From a study perspective, it would be best if you did not receive any PrEP until after your Day 30 study visit. However, if you and your doctor feel that it is in your best interest to receive PrEP before Day 30, please inform the study team. Receiving PrEP before Day 30 may decrease our ability to evaluate the effectiveness of the study dose of vaccine.

If you have a known exposure to someone infected with COVID-19 or have a confirmed COVID-19 infection, your primary transplant provider will prescribe the treatment that he/she feels is in your best interest. This information will be collected for the study and you will continue to follow-up with your study team.

COVID-19 Booster Doses

You should consult with the study team regarding non-study COVID-19 booster doses in order to maintain compliance with current CDC recommendations, while not compromising your participation in the research study.

Current CDC recommendations can be found at the following link: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised. Current recommendations may change over the course of the study.

Information related to COVID-19

Measures to protect yourself and others from COVID-19 infection are outlined on the Centers for Disease Control website at the following link: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html. To decrease your risk of infection with SARS-CoV-2, we strongly recommend that you follow these recommendations, which include wearing a mask, practicing social distancing, and frequent handwashing/use of hand sanitizer.

Study Procedures

COVID-19 Study Vaccination

All participants will receive one dose of the Sanofi-GSK COVID-19 vaccine (5 microgram). It will be given as an injection (shot) in the deltoid (upper arm) muscle.

Research Blood

You will have blood drawn for research tests at the time-points indicated in the table above. The total volume of blood collected for research is also included in the table. These research tests will help us learn more about how your immune system is functioning following the additional dose of COVID-19 vaccine.

Nasal Swabs

You will be monitored for active COVID-19 infection by having nasal swabs collected at certain visits. ***In addition, if you have any testing for COVID-19 outside of the study due to suspected COVID-19 infection, please inform the study team.***

Pregnancy Test (females only)

You will have a serum or urine pregnancy test to ensure you are not pregnant prior to receiving the study intervention (Sanofi-GSK COVID-19 vaccine).

9. RISKS and/or DISCOMFORTS

As a result of participation in this research study, you are at risk for the following side effects.

COVID-19 Study Vaccine

There are known risks associated with the Sanofi-GSK COVID-19 vaccine based on previous clinical studies. Sanofi-GSK COVID-19 vaccines have been studied in thousands of generally healthy people. Some of these studies used a different dose of the study vaccine. The most common side effects associated with the study vaccine include:

- Pain, redness or swelling at the injection site
- Fatigue
- Muscle pain
- Joint pain
- Diarrhea

Fever and chills occurred but were less common. Most side effects occurred within 3 days of the study vaccine and resolved within one week. Severe allergic reactions such as anaphylaxis were extremely rare.

Myocarditis is inflammation of the heart muscle. Pericarditis is inflammation of the lining outside the heart. Myocarditis or pericarditis have occurred in some people who have received COVID-19 vaccines containing the SARS-CoV-2 spike protein, including a protein vaccine with an adjuvant like the vaccine used in this study. This is very unlikely to occur, but when it does occur, symptoms usually begin within 4-6 weeks after study vaccination.

Myocarditis and pericarditis have been reported in greatest numbers in males under the age of 40 years following a second dose of mRNA vaccines, but cases have been reported in older males and in females, and also following other doses or vaccines. While some cases required intensive care support available data from short-term follow-up suggest that symptoms resolve in most individuals with conservative management. Information is not yet available about potential long-term sequelae.

If you have any of the following symptoms that might be due to myocarditis or pericarditis, you should seek medical attention right away:

- Chest pain, chest pressure, or chest discomfort
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Please notify study team if any of the above possible myocarditis or pericarditis symptoms occur following study vaccination.

Because vaccines stimulate an immune response, there is a possibility that this study vaccine could cause a worsening of a pre-existing or development of a new immune-mediated disease. This was not observed in the clinical trials with the Sanofi-GSK COVID-19 vaccine, but participants will be monitored and any new events reported to the study team.

It is possible but unlikely that a new vaccine may cause a more severe course of disease when you are vaccinated against a disease and then become infected by that disease. This is called vaccine enhanced disease; however, this has not been seen so far with this vaccine or any of the COVID-19 vaccines being used in the US.

These may not be all the possible side effects of the COVID-19 study vaccine. Serious and unexpected side effects may occur since the study vaccine is still being studied in clinical trials.

As with any vaccine, very rarely, immediate and potentially life-threatening allergic reactions to the administered vaccine can occur. It is very unlikely that you will have a serious reaction to the vaccine. People who previously had a serious allergic reaction to the COVID-19 vaccine will not be included in this study. 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.

Blood Draw

The risks of drawing blood are:

- Pain
- Bruising
- Bleeding
- Infection
- Redness
- Swelling at the site of the needle entry
- A small chance of fainting

Nasal Swab Collection

The nasal swab collection can result in mild discomfort. Deep nasal swabs will not be used in this study.

Urine Pregnancy Test

There are no risks associated with this test.

10. POTENTIAL BENEFITS

If you agree to take part in this study there may be no direct medical benefit to you. If the extra dose of study vaccine increases your antibody levels, you might be less likely to get infected with the virus that causes COVID-19, or if you do get infected, your symptoms might be milder than if you had no antibodies. Information learned may benefit people in the future.

11. ALTERNATIVES TO PARTICIPATION

The study doctor and/or study team will talk with you about this study and other options available to you. You may choose not to be in this research study.

12. NEW FINDINGS

The study doctor will tell you about any new information that may affect your willingness to continue in this study.

13. VOLUNTARY WITHDRAWAL FROM STUDY

You may decide not to take part or to leave the study at any time. If you decide not to participate or to leave the study, there is no penalty or loss of benefits in your routine medical care or any other benefit(s) that you would otherwise be entitled to receive. In addition, you should talk to your study doctor who will discuss future treatment and procedures for your continued care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

14. REASONS WHY YOU MAY BE TAKEN OFF STUDY WITHOUT YOUR CONSENT

You may be removed from the study without your consent at any time. Reasons why you may be removed from the study include, but are not limited to, the following:

- The study doctor feels it is not in your best interest to continue in this study.
- You are unable to complete required study treatment and examinations.
- The study is stopped by the clinical site, the Sponsor(s), or by the Food and Drug Administration (FDA).

15. PREGNANCIES, BREASTFEEDING AND BIRTH CONTROL

You cannot participate in this study if you are currently pregnant. The interventions involved in this study may involve unexpected risks to your health or the health of your unborn child. If you are a female of childbearing potential, a pregnancy test will be performed prior to study entry.

If you participate in this study, you must agree to use an approved method of birth control by the U.S. Food and Drug Administration (FDA) throughout the duration of the study and for 12 weeks after the vaccine dose and while taking mycophenolate mofetil/mycophenolic acid . You and your study doctor will discuss acceptable methods of birth control.

If you or your partner should become pregnant while participating in this study, or if you suspect that you have become pregnant, you must contact your study doctor immediately. The outcome of any pregnancy will be reported to the study sponsor.

16. COSTS TO THE SUBJECT (YOU)

There is no cost to you for participating in this study. Costs related to your usual clinical care or general health will be billed to you and/or your insurance company. There will be no costs associated with the COVID-19 vaccine or research tests.

17. PAYMENTS (REIMBURSEMENT)

«Compensation»

You will be paid up to a total of $xx.xx if you complete this study. You will be paid for the visits you complete according to the following schedule:

- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.

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

You will be paid _____ ***["following each completed visit", "monthly", "quarterly", "at the end of your participation in the research study", "following each completed visit or at the end of your participation in the research study, whichever you prefer"].***

If you have any questions regarding your compensation for participation, please contact the study staff.
[OR]
You will not receive any monetary compensation for your participation in this study.

18. RESEARCH-RELATED INJURY

If you are injured or become ill because of taking part in this study, it is important to tell your study doctor. Emergency medical treatment will be available to you. The study doctor will bill you or your insurance company in the normal way for the cost of such care. The study will not pay for medical care. In case of injury resulting from this study, you will not lose any legal rights by signing this form.

A new public health declaration, called the Public Readiness and Emergency Preparedness Declaration (PREP), was issued by the Department of Health and Human Services on March 10, 2020. This declaration limits the legal rights of a subject participating in a COVID-19 clinical study that uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19. This includes the vaccine used in this study. Subjects using the vaccine in this study will have limits on their right to sue the manufacturers, the study sponsor, healthcare providers and others for significant injuries and adverse reactions.

19. HIV POLICY

We will not be testing for HIV for the purpose of the study; however, you will be asked if you ever had a positive HIV test and we will look in your medical record to determine whether you have had a positive HIV test. If you have had a positive HIV test, you will not be eligible to participate in the study. Any information about your HIV testing will be kept confidential to the extent permitted by law.

20. CONFIDENTIALITY

Your medical and research records will be confidential to the extent permitted by law. Efforts will be made to keep your personal information private. However, we cannot guarantee complete confidentiality.

You will be identified by a code, and personal information from your records will not be released without your written permission. You will not be identified in any publication or in the sharing of your data about this study. After the study is completed, the data may be placed in a central storage location. These data will not include your name or other information that can identify you. The purpose is to make study data available to other researchers. Information from this study may be put into databases along with information from other studies. There are different kinds of databases; some are publicly accessible, and some are restricted. Anyone on the internet can access publicly accessible databases. Only researchers who apply and are approved can access restricted databases. Traditionally used identifying information about you (such as name, phone number, address) will NOT be included or shared with others.

Your privacy is important to us and we will use safety measures to protect your privacy. In spite of all the safety measures that we use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.

While we will not use information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It is also possible there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. There may also be other privacy risks that we have not foreseen.

As a National Institutes of Health (NIH) funded study, you are further protected through a policy that prevents the study doctor from releasing any sensitive information about you that may identify you. This does not prevent you or a family member from voluntarily releasing information about this research.

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.

Organizations that may look at and/or copy your medical records for research, quality assurance and data analysis include:

- The National Institute of Allergy and Infectious Diseases (NIAID), sponsor of the research.
- NIAID representatives, agents, employees, contractors, and other persons assisting in conducting, monitoring or analyzing the study.
- The U.S. Food and Drug Administration,
- Other State and Local health authorities, and
- Pharmaceutical or device companies(s) and their commercial partners may review your medical and research records for regulatory purposes.
- Advarra IRB (an Institutional Review Board that reviews this study)

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

21. 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 subject;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to exclude 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 subjects. If you have any questions about your rights as a research subject, contact:

- [redacted]

Please reference the following number when contacting the Study Subject Adviser: Pro00065524.

22. STORAGE/FUTURE USE OF YOUR DATA/BIOLOGIC MATERIALS

As an NIH sponsored clinical study, we are required to share research data with the scientific community. We will store information resulting from this study in a central data repository. Data is information organized for a reason, like this study. A central data repository is a place that collects and stores data from many different studies. The purpose of this collection is to make scientific information available for future studies which may help future patients. Your data may be stored indefinitely. Any information released to a central data repository will not contain traditional information such as name, birthdate, address, etc. that is considered your personal information.

We plan to store samples of biological specimens (for example, blood) collected for this study to be used in the future for tests that are not yet planned. These tests may or may not be related to the study of COVID-19 and transplant.

Some information will always be linked to any research specimen. For example, future researchers might know a sample is from a kidney transplant recipient. Because of this, allowing for specimens to be stored for future use also means allowing for the linked information to be stored and used when the specimens are needed for any future study.

All samples will be labeled with a unique code. The coding will not contain personal information like name, initials, or date of birth. However, it is possible for study team at the clinical site where you enrolled in the study to link the specimens back to you. Results of tests performed on stored samples will not be in your medical record and will only be used for research purposes.

Genetic Testing on Stored Samples

Your samples may be used to look at genetic information related to COVID-19 and transplant or in studies NOT related to COVID-19 and transplant (for example, studies of the immune system as a whole). Results of genetic tests performed on stored samples will not be in your medical record and will only be used for research purposes.

Benefits of Stored Material and Genetic Testing

There is no benefit to you from the storage of samples and information. However, the use of your samples and information may help researchers learn more about your disease or the genetics related to any disease condition. Samples will be stored at the Johns Hopkins repository for an indefinite amount of time.

Risks of Stored Material and Genetic Testing

Although your stored research samples will not be sold, the information obtained from the research performed on your samples may in the future lead to the development of commercial products. You will not receive any money should this occur.

There may be unknown risks associated with the storage of samples and information. For example, if the future research involves genetic testing it is possible that it could be traced back to you because your genes are specific to you. We will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known.

Making a Decision for Stored Human Subject Material and Genetic Testing

Your decision regarding the storage of samples or the information resulting from the analysis of your samples will not affect your ability to participate in this study. If you do not provide permission, your samples will be destroyed once the study is completed.

Please indicate your preference below:

r**YES _____ (initials)** I agree to let my samples be used for future research.

r**NO _____ (initials)** I do not agree to let my samples be used for future research.

23. SIGNATURE PAGE

Please sign below if you agree to take part in this study.

- **You have read the informed consent and/or had it explained to you**
- **You were given the opportunity to ask questions about the information, and**
- **You voluntarily agree to take part in the study**

_____	_____	_____
Research Subject's Name *(printed)*	**Research Subject's Signature**	**Date**

OR

Signature of person explaining and obtaining the consent:

_____	_____	_____
Name and Title *(printed)*	**Signature**	**Date**

(NOTE: This consent form with the original signatures MUST be retained on file by the principal investigator. A copy must be given to the research subject. A copy should be placed in the research subject's medical record, if applicable.)

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your study doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of the National Institute of Allergy and Infectious Diseases (NIAID).
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study vaccine works and is safe.
- For other research activities related to the study vaccine.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law (HIPAA) and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____	_____	_____
Research Subject's Name *(printed)*	**Research Subject's Signature**	**Date**