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

Sponsor / Study Title:	**National Institute of Allergy and Infectious Diseases (NIAID) / "A randomized study to evaluate antibody response to an additional dose of SARS-CoV-2 vaccination with and without immunosuppression reduction in kidney and liver transplant recipients"**
Protocol Number:	**COVID19-TB-03**
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.

- We are discussing this study with you because you have had a kidney or liver transplant and also have received a completed primary series of the Moderna COVID-19 Vaccine (Spikevax®) or Pfizer-BioNTech COVID-19 Vaccine (Comirnaty®).
- The purpose of the vaccine is to protect people from COVID-19 by causing their body to make antibodies against the virus that causes COVID-19. However, you have had a blood test that shows that your body either has no antibodies or a low level of antibodies.
- The fact that you have no or low COVID-19 antibodies means you have a higher chance of becoming infected if you come into contact with the virus that causes COVID-19.
- We are asking you if you would like to take part in a research study in which you would receive a dose of the most current authorized or approved COVID-19 mRNA vaccine.
- Some people in the study will have their anti-rejection medicines lowered for a short time, starting 5 days before they get the study vaccine, and continuing for 2 more weeks. Then they will return to their usual doses of anti-rejection medicines.
- Selection of the people who will have their anti-rejection medicines lowered will be by chance (like flipping a coin).

- Any change in anti-rejection medications could result in an episode of rejection. If you are one of the people whose anti-rejection medicine is lowered, you will have blood tests every week for 6 weeks to look for any signs of organ rejection.
- At the end of the study, researchers will compare the two groups (people who had their anti-rejection medicine lowered and those who did not) to see if there is any difference in how well they make antibodies against COVID-19 after the study dose vaccine.
- If you decide to be in the study, you will have tests taken with a cotton swab ("q-tip") in your nose to see if you have a COVID infection. This will be done before you get the study vaccine, 1 month after the study vaccine and then every 3 months until one year after you get the study vaccine.
- After you get the study vaccine, you will have blood drawn for research tests at [*Day 3, subset of study sites*], 14 days, 1 month, 3 months, 6 months, and 1 year after the study vaccine. A member of the study staff will talk with you at many of these times to find out how you are feeling.
- According to the 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?

The purpose of the study is to find out whether a dose of the most current authorized or approved mRNA COVID-19 vaccine, with or without lowering an anti-rejection medicine, will help to protect people who have had a liver or kidney transplant from COVID-19 by causing their body to make antibodies against the virus that causes COVID-19. Many transplant recipients either do not make antibodies after receiving a completed primary series of the COVID-19 vaccine, or make very low levels of antibodies compared with people who are not receiving anti-rejection medications. This means that they are more likely to get infected with COVID-19 and more likely to become seriously ill if they do get infected with COVID-19. This study will help us learn whether an additional dose of COVID-19 study vaccine with or without lowering an anti-rejection medicine can help transplant recipients make more antibody to COVID-19.

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

COVID-19 Vaccines

This study is using COVID-19 vaccines/boosters manufactured by Moderna and Pfizer-BioNTech. The current mRNA vaccines are the Moderna COVID-19 2023-2024 Formula and Pfizer-BioNTech COVID-19 2023-2024 Formula. The risks listed below are associated with all formulations of the Moderna and

Pfizer-BioNTech COVID-19 vaccines. There may be additional risks associated with the COVID-19 2023-2024 formulas that become apparent over time.

The most common side effects of these vaccines include:

- Pain and/or redness at the injection site
- Tiredness
- Headache
- Fever
- Chills
- Muscle pain
- Joint pain
- Nausea/vomiting
- Swelling/tenderness under the arm

It is not known whether these side effects will be worse since you have already had 2 or more doses of these vaccines.

There are more serious side effects that are rare but include (1) severe allergic reactions that require treatment, which occurs in about 11 out of every one million people who receive the vaccine (0.001%), and (2) myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the sac that surrounds the heart), which occurs in about 5 out of every one million people who get the vaccine (0.0005%) and usually gets better within a few days, but in very rare cases can be more serious. Symptoms of myocarditis or pericarditis usually begin within 4-6 weeks after 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 (consequences).

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 site staff if any of the above possible myocarditis or pericarditis symptoms occur following vaccination.

<u>Anti-Rejection Medication Reduction</u>

If you are in the group of study subjects that has one of your anti-rejection medicines lowered or temporarily stopped, the change in medication will last for 19 days. After that, you will go back on your full dose of anti-rejection medicine. You will have weekly blood tests during this time to make see whether your transplanted organ is working properly, and to see if there are any signs of rejection.

Any lowering of your anti-rejection medication could lead to organ rejection. If you have any signs of organ rejection, your study doctor will restart your full dose of anti-rejection medication. Your study

doctor will decide whether you need additional medications to treat rejection. Rejection episodes can usually be treated successfully but can cause injury to the transplanted organ and can shorten the life of your transplanted organ.

Unknown Risks

As more people get a COVID-19 vaccine and are followed for a longer time, we may learn about more risks of getting additional doses of vaccine.

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 COVID-19 study vaccine, you might have a lower chance of becoming infected with COVID-19 or if you get infected you may not become as sick.

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 organ transplant recipients who received a completed primary series of either the Moderna or Pfizer-BioNTech COVID-19 Vaccine make no or low antibodies to COVID-19. Antibodies are proteins made by the body to fight off disease. People who have had a transplant and take anti-rejection drugs have a weakened immune system. Many organ 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. Study doctors are trying to figure out whether a dose of the most current authorized or approved mRNA vaccine, with or without lowering anti-rejection medication, can help people who have had a transplant make more antibodies to COVID-19.

We are asking you to be part of this study because you have had a kidney or liver transplant and have a low level of COVID-19 antibodies after a completed primary series 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 through a Cooperative Agreement with Johns Hopkins School of Medicine. This study plans to enroll 400 subjects at approximately 15 study sites across the United States.

If you take part in this study, you will have up to 13 visits depending on which group you are assigned to. Some of these visits will only involve a telephone or computer contact with a member of the study team. Other visits will include a blood draw, nasal swab collection and saliva collection. This is outlined in more detail below.

Screening

Blood tests will be done to make sure your transplanted organ is functioning properly. In addition, you will have blood drawn for research studies. Up to 3 tablespoons of blood will be drawn at screening. If you are a woman in your child-bearing years you will have a urine pregnancy test to make sure you

aren't pregnant. Based on the type of transplant you received, additional medical records may be requested to make sure that you qualify for the study. In addition, your transplant physician will be contacted to make sure that he or she agrees that you can take part in this study if you want to.

Randomization
You will be chosen by randomization (like flipping a coin) into a group that will have their anti-rejection medication lowered or a group that will have no change to their anti-rejection medication. Everyone in the study will receive an additional dose of COVID-19 study vaccine no matter which group they are in.

Anti-Rejection Medication Reduction Plus a COVID-19 Study Vaccine Dose
Five Days Before Your COVID-19 Study Vaccine
If you are randomized to this group, your study doctor will explain what change to make in your anti-rejection medication. This will depend on what you are taking when you enter the study. The change will begin 5 days before your planned vaccination visit and will continue for two weeks following the vaccination visit.

All Participants
COVID-19 Vaccination Visit
On the day of your vaccination, you will have approximately 3.5 tablespoons of blood drawn and will give a saliva specimen for research purposes. In addition, you will have two nasal swabs collected. The nasal swabs are collected to look for active COVID-19 infection. One will be run locally and one will be sent to a central lab for research. The study doctor may be required by law to report the results of the COVID-19 test to the local health authority.

After the research samples are collected, you will go to a vaccine clinic or other hospital location your COVID-19 injection. You will be watched for 30 minutes following the vaccination for any side effects.

Follow-up Visits
After you receive the COVID-19 study vaccine, your study doctor or another member of the study staff will contact you at certain times to ask how you are feeling and ask about any side effects from the study dose of vaccine. You will also have blood drawn for six weeks. The table below outlines what will happen over the course of the study. The clinical blood tests may be done at a local lab if you are not coming back to the study center to have research samples collected.

Day 3 *(only include if you are an assigned study site)*: On Day 3 following your additional dose of COVID-19 vaccine, you will return to the study site for a research blood collection. Approximately one tablespoon of blood will be collected at this time.

Study Visit	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Month 3	Month 6	Month 9	Year 1
Study contact	X	X	X	X	X	X	X	X		X
Clinical blood tests	X	X	X	X	X	X	X	X		X
Blood tests for research		3 tbsp		5 tbsp			4 tbsp	5 tbsp		4 tbsp
Nasal swab(s) for COVID-19				X			X	X	X	X

Study Visit	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Month 3	Month 6	Month 9	Year 1
Saliva for research				X			X	X		X

Medications to Prevent or Treat COVID-19
According to the FDA Emergency Use Authorization, you should not receive any pre-exposure prophylaxis (PrEP)(antibodies given to prevent getting COVID-19 infection) e.g. e.g. 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
The Centers for Disease Control and Prevention (CDC) continue to update the COVID-19 vaccine schedule based on new information and new vaccines. The study team can provide guidance to make sure you stay in compliance with the current recommendations without compromising your participation in the research study.

Study Procedures
COVID-19 Vaccination
The COVID-19 study vaccine 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 timepoints indicated in the table above. The total amount 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 reacting to the additional dose of study vaccine.

Research Saliva
You will have a sample of saliva collected from your mouth to look for antibodies to COVID-19. You will be provided with a swab that will be rubbed against your gums to collect the saliva.

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 staff.*** If you have a confirmed COVID-19 infection, you will be asked to collect a nasal swab at home using a kit provided by the study team. You will be provided instructions regarding how to ship the swab to the central laboratory.

Pregnancy Test
If you are a woman of childbearing age, you will have a blood or urine pregnancy test during screening.

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 Vaccine (Moderna and Pfizer-BioNTech COVID-19 Vaccines)

Both Moderna and Pfizer-BioNTech vaccines against COVID-19 are being used in this study. The most current vaccines being used in the study are the Moderna COVID-19 2023-2024 Formula and Pfizer-BioNTech COVID-19 2023-2024 Formula. The side effects associated with all formulations of the Moderna and Pfizer-BioNTech COVID-19 vaccines are listed below. There may be additional risks associated with the current 2023-2024 formulas that become apparent over time. The specific vaccine used in this study may change in the future based on FDA authorizations and CDC recommendations.

The most common side effects reported are:

- Pain and/or redness at the injection site
- Fatigue (tiredness)
- Headache
- Fever
- Chills
- Muscle pain
- Joint pain
- Nausea/vomiting
- Swelling/tenderness under the arm

These effects generally last a few days.

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) occurs in about 5 out of every one million people who get the vaccine (0.0005%) and usually gets better within a few days, but in very rare cases can be more serious. Symptoms of myocarditis or pericarditis usually begin within 4-6 weeks after 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 (consequences).

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

Symptoms of myocarditis or pericarditis usually begin within 4-6 weeks after vaccination.

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

Allergic reactions have occurred after both the Moderna and Pfizer-BioNTech COVID-19 Vaccines. Allergic reactions range from mild to severe and include life-threatening anaphylactic reactions. Severe allergic reactions are very rare (about 11 out of every one million people who get the vaccine). 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.

These may not be all the possible side effects of the COVID-19 vaccine. New side effects may be discovered as more people get the vaccines.

Anti-Rejection Medication Reduction
The lowering of your anti-rejection medicine will last for a total of 19 days. After that, you will go back to your full dose of anti-rejection medicines. You will be monitored weekly for signs of rejection from the time that your anti-rejection medicines are lowered until 4 weeks after you return to your full dose of anti-rejection medicines.

Any lowering of your anti-rejection medicine could lead to organ rejection. Organ rejection would result in a need to restart your full dose anti-rejection medicines and might require additional medicines. In addition, rejection episodes can result in injury to the transplanted organ and can shorten the life of your transplanted organ. If you show any signs of rejection, your treatment will be determined by your transplant physician. Your transplant physician will also decide whether a biopsy is needed.

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

Saliva Collection
You may have some mild irritation where you rubbed the swab against your gums.

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 staff 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 study 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. You and your study doctor will discuss acceptable methods of birth control.

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. Johns Hopkins University 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 and dating 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 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, please contact [insert study doctor] at [insert telephone number].

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, and/or concerns or complaints regarding this research study, contact:

- By mail:

[redacted]

Please reference the following number when contacting the Study Subject Adviser: Pro00058024.

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, saliva, nasal swabs and saliva) 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 an organ transplant recipient. Because of this, allowing 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 staff at the study 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.

23. SIGNATURE AND DATE PAGE

Please sign and date 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**

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**