MODERNA INFORMED CONSENT FORM
For Minor Subjects Who Reach the Age of Majority

Sponsor / Study Title:	**Division of Allergy, Immunology, and Transplantation (DAIT) National Institute of Allergy and Infectious Diseases (NIAID) / "Systemic Allergic Reactions to SARS-CoV-2 Vaccination"**
Protocol Number:	**DAIT-COVID-19-004**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

YOUR PARTICIPATION IS VOLUNTARY
We will explain this research study to you. You may ask questions at any time.

- Taking part in this study is your decision.
- If you sign and date this consent form, you agree to take part in the research study.
- You may change your mind at any time.
- You will be given a copy of this consent form to keep.

1. CONSENT SUMMARY/ KEY INFORMATION

The first pages of this document include a summary of the research study to help you decide whether - or - not to participate. Detailed information is provided after the summary/key information.

Why is this research being done?

This research is being done to determine whether highly allergic people or people with mast cell disorders (a buildup of the white blood cells that release substances causing symptoms similar to an allergic reaction) are more likely to have an allergic reaction to the new Moderna COVID-19 vaccine than other people. We would also like to understand why some people have allergic reactions to these vaccines.

How long will this research last and what will I need to do?

Your participation could be as short as 36 days or as long as 43 days.

If you choose to participate, you will receive the Moderna COVID-19 vaccine. This vaccine requires two doses. If you don't have a reaction to the first vaccine dose, you will receive the second vaccine dose. Some subjects may also receive a dose of placebo (salt water) prior to receiving vaccine. Placebo means the injection doesn't have any vaccine in it. This means that your first active vaccination may be delayed by approximately 1 week. You might be able to find

a vaccination site not connected with the study where you could be vaccinated and have protection against COVID-19 sooner. You will receive three shots total, if you receive a placebo shot. You will not get to choose whether you get the additional placebo shot.

Before your first vaccine or placebo shot, you will have blood drawn. Blood will also be collected after your last vaccination and will be collected if you have an allergic reaction. A urine sample will also be collected before and after each vaccine or placebo shot and if you have an allergic reaction. Your blood and urine will be collected to help understand why allergic reactions to the vaccines happen.

Is there any way being in this research can hurt me?
There is a risk that receiving the vaccine may cause a serious, or even fatal, allergic reaction. This research is being done by study doctors trained to recognize and treat allergic reactions. The study doctors will have medications and facilities to treat you if a reaction occurs.

There is a very low risk you may experience inflammation in your heart muscles or around your heart that causes chest pain, shortness of breath, or a rapid heartbeat.

Will being in this research study help me in any way?
You will receive the Moderna COVID-19 vaccine. The vaccine is expected to be protective against COVID-19 infection. However, the vaccine may not protect everyone who receives it.

What other choices do I have besides taking part in this research?
You can choose not to take part in this research study. You can receive this vaccine or a different vaccine at a location in your local area, when they become available to you. You can also choose not to be vaccinated.

DETAILED CONSENT INFORMATION

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

2. INTRODUCTION/BACKGROUND

The Moderna vaccine is a new type of vaccine. This new way of making a vaccine allowed it to be made and tested quickly. In clinical studies, this vaccine has been found to be very effective against COVID-19. This vaccine was tested in people before emergency authorization was given for use. There were no significant side effects after vaccination in these studies. However, after the vaccine was approved for emergency use and given to millions of people in the general population, there have been rare cases of allergic reactions happening in about 1 in 100,000 people.

We are asking you to be part of this study because you are 18 years of age and either have a history of serious allergic reaction, or no history of severe allergies, or you have a mast cell disorder. We would like to understand whether people with a history of serious allergic reactions or those with mast cell disorders are more at risk of having a reaction after getting this new type of vaccine than people without these problems.

3. STUDY COMPONENTS

The National Institute of Allergy and Infectious Diseases is sponsoring this study to enroll up to a total of 3400 people from this center and approximately another 29 centers across the United States. If you join the study, you will complete 2 to 4 clinic visits and have 3 to 4 phone calls over a period of 36 to 43 days, depending on whether you get the additional placebo dose.

You will receive the Moderna vaccine. This vaccine has a special status. It is not approved for use in all populations and age groups. The U.S. Food and Drug Administration (FDA) has approved it for emergency use while COVID-19 is infecting and killing so many people in the United States. The Moderna vaccine has been authorized by the FDA for emergency use in individuals aged 18 years or older. You will be receiving the vaccine as it is meant to be given.

Neither you nor the study team chooses if you will receive a placebo prior to receiving the vaccine. The assignment of placebo before vaccine is set by a computer and is a process like pulling a piece of paper out of a hat. You will not be told whether the first injection will be placebo or vaccine. It is possible the first shot you receive will just be salt water, followed by 2 doses of active vaccine.

On your first visit, we will ask you to review this document with your study team to decide if you want to join. You should give your permission only after you understand the study and have had all your questions answered. By signing and dating this document, you will be entered into the study. Remember that you can change your mind at any time and leave the study.

We may also talk to you over the phone about this study or send this informed consent document to you before you come into the clinic for an in-person visit. If you receive it before the clinic visit, please review the entire document. Do not sign and date the document until after we contact you to discuss the document. We may be able to discuss the consent by video or phone. If you agree to join the study, you can sign and date the document during our discussion. If you provide a signature by signing and dating with an actual pen, you will need to mail it back to us or bring it during your visit to the clinic. If you provide an electronic signature, we will give you instructions on how to return the form electronically.

After we receive your permission, the study team will ask you questions about your medical history to see if you are a good fit for this study. We may ask for your permission to ask these first screening questions over the phone, before you visit the clinic.

If you have a history of allergies or mast cell disorder, we will ask you if you have a current prescription for an epinephrine auto-injector. If you do not have a current prescription, the study doctor may provide a prescription prior to you participating in the study. You will be asked to bring your epinephrine to each study visit.

If you come to the clinic for Screening, you will complete 3 to 4 visits total, depending on whether you get a placebo dose first. If you complete Screening over the phone, you will

complete 2 to 3 visits total depending on whether you are assigned a placebo dose at first.

Injection Visits 1 and 2 (and 3 if necessary)
After your Screening Visit is complete – either by phone or in person – you will complete 2 or 3 clinic visits to receive your vaccination. During each visit to the clinic you will have:

- A physical exam and your vital signs will be checked.
- A nasal swab sample collected.
- A urine sample collected for a pregnancy test, if you are a woman who can get pregnant. If you are pregnant, you cannot be in this study.
- We will collect blood before you receive the vaccine or placebo dose at your first visit. The amount of blood will be about up to 7 tablespoons. We will also collect urine samples before and after each injection.
- **You will receive one dose of vaccine or placebo.**
- We will observe you in the clinic for at least 90 minutes after your shot. If you have a reaction, you will be treated and will be observed for a minimum of 2 hours after your symptoms resolve.
    - If you have a reaction during this period, we will collect more blood and urine samples to look at what has changed in your blood and urine during the reaction. Samples will be collected 30-60 minutes after your reaction starts and again prior to when you leave the clinic. About the same amount of blood will be collected at each time point.
    - If you do not have a reaction, we will also take this amount of blood to compare with those who had a reaction, so we can try to understand what is different between people who have a reaction and people who do not. This collection will occur after your last injection.
- A member of the study staff will review with you how to identify an allergic reaction and the steps you may need to take if you have a reaction after leaving the clinic. This information will also be summarized in an Emergency Care Plan that we will give you before you leave the clinic.
- **If you have a history of allergic reactions or a mast cell disorder and do not currently have an epinephrine auto injector,** we will provide epinephrine auto-injectors to take home and use in the event you have a reaction after you leave the clinic. We will also show you how to use the auto-injector before you leave the clinic.
- **We will ask you to complete a diary every day for the next 7 days,** and the study team will contact you in 3 days to ask how you are doing.

The nasal swab, blood, and urine samples will be tested to look for changes related to allergic reactions and will also check for 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. One blood test, called a complete blood count, or CBC, gives important information about the kinds and numbers of cells in the blood, especially red blood cells, white blood cells, and platelets.

We will share the results of the COVID-19 nasal swab and CBC tests with you.

If your first two shots were active vaccine, your participation in the study will be over after two injection visits.

If you received a shot of salt water (placebo) first, you will complete a third clinic visit. The same procedures will happen at the third visit as your second clinic visit, with the addition of blood collection about 1 hour after you receive your final injection. The amount of blood collected at this visit will be the same.

If you need to see the study doctor or have questions or concerns during the study, the study doctor may ask you to come in for an additional clinic visit and review your health status.

4. RISKS and/or DISCOMFORTS

Study treatment in this research study may involve risks that are not possible to predict. Please ask your study doctor or the research study team to explain any procedures or risks that you do not understand.

You may experience:

- Pain at the injection site
- Fatigue
- Headache
- Muscle pain
- Chills
- Joint pain
- Fever
- Redness or swelling at the injection site
- Axillary (armpit) swelling/tenderness
- Nausea/vomiting
- Diarrhea

These symptoms are temporary and usually resolve in a few days.

You might have an allergic reaction which could be mild or a severe allergic reaction, called anaphylaxis. Although no deaths have occurred from the vaccine, a severe allergic reaction could lead to death. Some symptoms of allergic reactions are rash, hives, wheezing and difficulty breathing, dizziness and fainting, swelling that is generalized or around the mouth, throat, and/or eyes, a fast pulse, or sweating. Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms, or any other side effects, during the study.

Epinephrine is used to treat severe allergic reactions and commonly causes pain where injected plus a racing heart and anxiety. If you have clogged arteries to your heart or brain, there is a risk the medication could cause a heart attack or stroke.

Other medications used to treat allergic reactions also have side effects. Antihistamines can cause sleepiness. Albuterol can cause your heart to race. Steroids can cause difficulty sleeping, increased blood pressure and blood sugar, and cause you to retain water.

You might experience inflammation of your heart muscles, known as myocarditis, or inflammation surrounding your heart, known as pericarditis. This may cause you to experience symptoms, including chest pain, shortness of breath, or feelings of a fast-beating or pounding heart a few days after receiving the vaccine. Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms, or any other side effects, during the study. The chance of having this occur is very low.

When you have your blood collected, there is a risk of pain, bleeding, bruising and/or infection at the puncture site. Some people may experience lightheadedness, nausea, or fainting.

The nasal swab collection may cause some discomfort in the nose, eyes watering, or sneezing. Rarely, you may get mild bleeding from the nose.

You may find some questions too personal during the medical history collected or the diary.

If you receive placebo as the first injection, this means your first active vaccination will be delayed by approximately 1 week. You might be able to find a vaccination site not connected with the study where you could be vaccinated and have protection against COVID-19 sooner.

5. POTENTIAL BENEFITS

If you choose to participate, you will receive the **Moderna** COVID-19 vaccine that can help protect you from COVID-19 disease. However, the vaccine may not protect everyone who receives it. Information learned may benefit people in the future.

6. ALTERNATIVES TO PARTICIPATION

You could get the same vaccine or a different vaccine outside of this study, when it becomes available to you. You could choose not to be vaccinated at all or not to be in this research study.

7. NEW FINDINGS

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

8. 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. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

If you leave the study after receiving only a single dose of vaccine, you may wish to talk to your

study doctor or your personal doctor about how much protection you may have against COVID-19 and options available to you.

9. 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 treatments and examinations.
- The study is stopped by the Institution, the National Institute of Allergy and Infectious Diseases or by the Food and Drug Administration (FDA) or other health authorities.

If you have an allergic reaction to the first active vaccination, you may not be given the second vaccination, depending on how severe the reaction was. The study doctor will discuss this with you and what your other options may be.

10. PREGNANCIES AND BIRTH CONTROL

You cannot participate in this study if:

- **You are currently pregnant.**
- **You plan to get pregnant during this study.**

Study treatments and procedures involved in this research study may involve unexpected risks to your unborn child. If you are female and of childbearing potential, a pregnancy test will be performed prior to your enrollment and periodically during this study.

If you are female of child bearing potential and participate in this study, you must agree to use birth control or to remain abstinent during your participation in the study. You and your study doctor will discuss acceptable methods of birth control.

If you should become pregnant while participating in this study, or if you suspect that you have become pregnant, you must contact the study doctor immediately. If you become pregnant during the study, after receiving the vaccine, your study doctor will discuss options about the second dose. We will ask to keep in touch with you until the end of the pregnancy.

11. COSTS TO THE SUBJECT (YOU)

The vaccines and tests related to this study are provided at no charge.

Costs related to care in the event of an allergic reaction requiring transfer to an emergency department or hospital or other medical problems will be billed to you and/or your insurance provider(s).

12. PAYMENTS (REIMBURSEMENT)

«Compensation»

As part of the screening process, you will receive $25 for completing the pre-screening visit. You

will receive $100 for each visit that you complete where you receive a study injection. You will receive $15 for each scheduled study telephone visit that you complete. If additional follow-up visits are required, you will receive $50 for each of these visits.

13. 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 site 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.

No funds have been set aside to compensate you in the event of injury.

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. There are exceptions to this limitation, see https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx#q3.

In addition, the federal government has a program that may provide compensation to you or your family for certain claims if you experience serious physical injuries or death and these costs are not covered by other payors. To find out more about this "Countermeasures Injury Compensation Program" (CICP) go to https://www.hrsa.gov/cicp/about.

In case of injury resulting from this study, you will not lose any legal rights by signing and dating this form.

14. 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 will 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.

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.

As a National Institutes of Health 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.

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.

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,
- Advarra IRB (an Institutional Review Board that reviews this study), and
- Pharmaceutical or device companies(s) and their commercial partners may review your medical and research records for regulatory purposes.

Administration of the COVID-19 vaccine will be reported to the health authorities according to local requirements**.**

15. WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research 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:
  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: Pro00049589.

16. FUTURE USE OF YOUR DATA/BIOLOGIC MATERIALS

Information about you, including your biospecimens, collected for this study may be shared with other researchers. It may also be used for other research studies. We will make sure that your identity cannot be linked to the information we share. We will not ask you for additional permission before sharing the information.

We are asking your permission to store unused samples of biological specimens (for example, blood, tissue, and urine) collected during the course of this study to be used in the future for tests that aren't yet planned.

Your stored samples may be used to obtain knowledge about genetic information in relation to related diseases, and/or the immune system.

The results of tests performed on stored samples or reports resulting from the analysis of your samples will not be given to you or your doctor, and they will not be put in your medical record. They will not identify you and will not affect your routine medical care.

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 a specific condition. The purpose of storage and sharing data is to make

information available for use in health research and to share what is stored with other researchers. Collecting, storing, sharing information and making it available for other studies may help people in the future. Coded information put into databases together with other stored information from many studies conducted in different places allow researchers to study the combined information and learn even more about health and many different diseases.

Samples will be stored at a central repository. If you decide to allow storage, your samples and information may be stored for an unknown length of time.

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 from research using your stored samples and information.

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.

You can change your mind at any time and ask to have your samples destroyed. This request should be made to the study doctor. If you make this request, all remaining stored samples will be destroyed. However, the results of any previous tests using your stored samples will be used. 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. The future use of your samples and information may contribute to learning more about disease or help to study the genetics related to a specific condition.

Please indicate your response below: I agree to the storage and sharing of samples (urine, blood and/or tissue) for genetic tests not currently planned.

☐ **Yes** ☐ **No**

_____

Initials of Research Subject

I agree to the storage and sharing of samples (urine, blood and/or tissue) and information resulting from the analysis of my samples for other tests not currently planned.

☐ **Yes** ☐ **No**

_____

Initials of Research Subject

17. SIGNATURE PAGE

FOR CHILDREN WHO BECOME ADULTS

I have been told that my parents/legal guardian agreed for me to participate in this research study as a minor. I have read 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 voluntarily agree to continue to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Research Subject's Typed or Printed Name

_____ _____

Research Subject's Signature Date

Signature of person explaining and obtaining the consent:

_____ _____ _____

Name and Title (Typed or printed) Signature Date

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