COVID-19 Vaccine Consent Form

Please print CLEARLY

Name of Recipient (First Name, Last Name)

Email_____ Sex: ☐ Male ☐ Female Date of Birth ☐☐ / ☐☐ / ☐☐☐☐ (MM / DD / YYYY)

Address: _____ Phone Number: _____

City:_____ State:_____ Zip Code:_____

I declare that I or my child is 16 years of age or older. I further declare that I or my child:

1. Have not experienced anaphylaxis (difficulty breathing) or severe allergic reactions from a previous vaccination or an injectable medication.
2. Have not had any other vaccinations in the previous 14 days (e.g. MMR, Shingrix, Varicella, or a TB skin test).
3. Is not currently sick with a fever, active respiratory infection or other moderate/severe illness.
4. Has have not received monoclonal antibodies or convalescent plasma for treatment of COVID-19 within the past ninety (90) days.
5. Is not allergic to the following ingredients in the COVID-19 vaccine: mRNA, lipids((4-hydroxybutyl)azanediyl)bis(hexane-6, 1-diyl)bis(2-hexyldecanoate), 2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide, 1, 2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate and sucrose.

I understand that if I or my child have any of the above conditions, I or my child could be at increased risk of having a negative reaction or problem from the vaccine. I further declare that if I or my child have any of the following conditions, I have had the opportunity to speak with my or my child's primary care provider and am making an informed decision to receive the vaccine or to have my child receive the vaccine:

1. Pregnant, attempting to become pregnant or breastfeeding;
2. Have a bleeding disorder or are on a blood thinner;
3. Are immunocompromised or are taking a medication that affects the immune system (such as cortisone, prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease or psoriasis; HIV/AIDS, cancer, leukemia, ankylosing spondylitis or radiation treatments).

I agree to WAIT near the clinic location for 15 minutes after receiving the vaccine. If I or my child have previously had a severe allergic reaction to a vaccine or injectable medication, I agree to WAIT near the clinic location for 30 minutes after receiving the vaccine.

I understand that the COVID-19 vaccine is a two-part vaccine series. By signing this consent, I am agreeing that I or my child will receive the first and second part of the vaccine series. ***Second Vaccine in 28 days (4 weeks)***

I understand that the common risks associated with the COVID-19 vaccine include but are not limited to pain, redness or swelling at the site of injection, tiredness, headache, muscle pain, chills, joint pain, fever, nausea, feeling unwell or swollen lymph nodes (lymphadenopathy). I understand that the vaccine may cause a severe allergic reaction which can include anaphylaxis (difficulty breathing, swelling of the face and throat, a fast heartbeat, a rash all over the body, dizziness and/or weakness). I understand that these may not be all the side effects of the COVID-19 vaccine as the vaccine is still being studied in clinical trials. I also understand that it is not possible to predict all possible side effects or complications which could be associated with the vaccine. I understand that the long-term side effects or complications of this vaccine are not known at this time.

I understand that the vaccination is being given by Dr Fame Allergy & Asthma Clinic The owner and/or operator of this site, their affiliates, officers, directors, employees and agents expressly disclaim any responsibility for the vaccination. My consent is given in light of this knowledge, and in consideration of our giving the COVID-19 vaccine. I, for myself and my heirs, administrators, trustees, executors, assigns and successors in interest do hereby agree to release and hold harmless clinic, its subsidiaries, divisions, affiliates, successors, assigns, officers, trustees, employees, volunteers and agents from and against any and all demands, damages, losses, costs, expenses, obligations, liabilities, claims, actions and cause of action (whether any of which is groundless or otherwise) of any nature whatsoever (including, without limitation, reasonable attorney's fees and court costs) by reason of or resulting, in any way, from any and all acts, accidents, events, occurrences, omissions and the like related to, or arising out of, directly or indirectly, my receipt of this COVID-19 vaccine. We make no warranties, express or implied, including but not limited to, implied warranties of merchantability or fitness for a particular purpose regarding the vaccine or its effectiveness. I acknowledge receipt of Inova's Notice of Privacy Practices.

I have read and understood "What To Do If You Have A Reaction To The COVID-19 Vaccination" and the "Fact Sheet" by the FDA regarding the COVID-19 Vaccination. I further understand and agree that we are required to submit COVID-19 vaccine administration data to the Virginia Immunization Information System (VIIS), and report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).

I understand and agree to all of the above and I give my consent to the staff of Fame Allergy PC to administer the COVID-19 vaccine to me or my child.

Signature of Patient/Parent:_____ **Date:**_____

Vaccine Lot # & Exp. Date	Route	Administered by (legal signature and title)	Amount Paid	Method
Lot # _____ Exp. Date_____	IM ☐ RD ☐ LD		$_____	☐ Cash/Check ☐ Certificate ☐ Credit ☐ Medicare

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WHAT TO DO IF YOU HAVE A REACTION TO THE COVID-19 VACCINATION

- Most people have side effects from the vaccination, but these usually only last 24 – 48 hours after receipt of the vaccination. A few people may have no side effects at all. Most people will experience pain, redness and/or soreness at the injection site. Many people will have a headache, fever, chills, muscle pain and/or fatigue from the vaccine, particularly after the second dose. A few people will have nausea or swollen lymph nodes (lymphadenopathy).
- In rare circumstances, the vaccine may cause a severe allergic reaction which can include anaphylaxis (difficulty breathing, swelling of the face and throat, a fast heartbeat, a rash all over the body, dizziness and/or weakness).

What should you do if you have a reaction?

If you experience any of the following:

- Red, sore arm at and around the injection site:
  - Apply an ice pack to the affected area for comfort.
  - If condition does not improve or worsens in 24 to 48 hours, call your physician.
- Fever, achiness, fatigue and/or headache:
  - Take the non-prescription product that you would usually use for discomfort or fever relief as needed.
  - If condition does not improve or worsens in 24 – 48 hours, call your physician.
- Unusual or severe reaction (for example, hives, difficulty breathing, wheezing, allergic reaction):
  - Immediately call your physician, call 911 or go to the emergency room or nearest urgent care center.
- If you have seen your physician or visited the emergency room or an urgent care in relation to any of the reactions listed above, please notify Inova staff by calling our hotline at 571-472-0321 to leave a message at the end of the voicemail message. A nurse will return your call within 24 hours.
- In addition, you may report vaccine side effects to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

Information about the COVID-19 Vaccine

- **The COVID-19 vaccines are <u>not</u> live virus vaccines so the vaccines cannot infect anyone with COVID-19.**
- **All needles and syringes are sterile, are one-time use and are safely discarded.**
- **According to data, the COVID-19 vaccine has approximately a 94% success rate in completely protecting those who receive it. The remainder have partial protection and will have greatly lessened symptoms if they do contract COVID-19.**
- **The vaccine will begin to provide protection about one to two weeks after the second shot of the series is given.**
- **At this time, we do not know how long the COVID-19 vaccine is effective for, so you may need future vaccines to remain protected.**
- **While the COVID-19 vaccination does provide protection against infection or greatly lessened symptoms if you contract COVID-19, you should continue to practice hand hygiene and use appropriate personal protective equipment (PPE).**

FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE MODERNA COVID-19 VACCINE?
The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE MODERNA COVID-19 VACCINE?

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?

In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?
Side effects that have been reported with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

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

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Moderna COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll in **v-safe. V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?
It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?
Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?
No. The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

HOW CAN I LEARN MORE?
- Ask the vaccination provider
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Contact your state or local public health department

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Patent(s): www.modernatx.com/patents
Revised: 12/2020

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 12/2020