CORNERSTONE CLINIC

COVID-19 Vaccine Acknowledgement and Consent Form
Moderna COVID-19 Vaccine FIRST DOSE

Recipient Information (please Print Clearly)

Last Name:	**First Name:**	**Date of Birth:**
Home Address:		**Phone:**
City:	**State:**	**Zip:**

The following questions will help us determine whether you can receive the COVID-19 Vaccine today. If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask a staff member for further explanation:

	Yes	No	N/A
Are you sick today?	□	□	
Do you have a history of severe allergies?	□	□	
Have you ever had a serious reaction after receiving a vaccination?	□	□	
Do you have a bleeding disorder or are you on a blood thinner?	□	□	
Are you immunocompromised or on a medication that affects your immune system?	□	□	
For women: Are you pregnant or planning to become pregnant?	□	□	□
For women: Are you breastfeeding?	□	□	□
Have you received any vaccinations in the past 2 weeks?	□	□	
Have you previously been diagnosed with COVID-19 and were treated with monoclonal antibodies within the last 90 days?	□	□	

I understand that the COVID-19 vaccine I will receive today requires two (2) doses from the same manufacturer to be fully effective. I understand I must return within 28 days of the first dose to receive a second dose of the vaccine. If more than 28 days have elapsed since the first dose, the second dose should be given at the earliest opportunity.

I consent to administration of the Moderna COVID-19 vaccination and acknowledge and agree with the following statements:

- I have received the Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers for the Moderna COVID-19 Vaccine (the "Fact Sheet").
- I have read the Fact Sheet or had it read to me.
- The U.S. Food and Drug Administration (FDA) has authorized emergency use of the Moderna COVID-19 vaccine, which is not an FDA-approved vaccine. At this time, there is no FDA approved vaccine to prevent COVID-19.
- I understand the known and potential risks and benefits to the Moderna COVID-19 vaccine and the extent to which such benefits and risks are unknown.

- I acknowledge that I have the option to refuse vaccination and have been informed of any available alternatives to the Moderna COVID-19 vaccine and the risks and benefits of available alternatives.
- Recipients who are Pregnant or Breastfeeding: Pregnant and breastfeeding persons were not included in the clinical trials for the Moderna COVID-19 vaccine. I have discussed the potential risks of COVID-19 infection versus the risk of vaccination with my healthcare provider and have made the informed decision to receive the Moderna COVID-19 vaccine
- I understand that it is recommended that I remain at the vaccination clinic for fifteen (15) minutes following administration of the vaccine for observation (the "Monitoring Period") to ensure I do not experience an adverse reaction. Recipients that have a history of anaphylaxis should be monitored for thirty (30) minutes post vaccination.
- I have had the opportunity to ask questions which have been answered to my satisfaction.

If you experience an adverse reaction to the COVID-19 vaccine, please contact your primary care provider or present to the nearest emergency department. If you are experiencing a medical emergency, call 911.

Signature of Recipient/Authorized Representative:	Date:
Print:	
If signed by Authorized Representative, please state relationship to Recipient:	

FOR CLINIC USE ONLY

Vaccine Administrator (Print Name):
Administration Date/Date Fact Sheet Provided:

Manufacturer	Lot Number	Expiration Date	Site of Administration
Moderna			□ Left Arm □ Right Arm

□ Monitoring period completed and no adverse reaction noted. □ Recipient declined Monitoring Period. Waiver completed.

Signature of Observer:_____

□ COVID-19 Acknowledgement and Consent Form and Monitoring Period Waiver (if applicable) uploaded.

TEXAS Health and Human Services | Texas Department of State Health Services

TEXAS IMMUNIZATION REGISTRY (ImmTrac2)
ADULT CONSENT FORM

(Please print clearly)

First Name _____ Middle Name _____ Last Name _____

Date of Birth (mm/dd/yyyy) _____ ( ) Telephone _____ Email address _____ Gender: ☐ Female ☐ Male

Address _____ Apartment # / Building # _____

City _____ State _____ Zip Code _____ County _____

Mother's First Name _____ Mother's Maiden Name _____

The Texas Immunization Registry is a free service of the Texas Department of State Health Services (DSHS). The immunization registry is a secure and confidential service that consolidates immunization records for public health purposes (e.g., giving all doctors treating a patient a central place to see that patient's immunization records). With your consent, your immunization information will be included in ImmTrac2. *For a family member younger than 18 years of age, a parent, legal guardian, or managing conservator may grant consent for participation for that minor by completing the ImmTrac2 Minor Consent Form (# C-7) available for downloading at www.ImmTrac.com.*

Consent for Registration and Release of Immunization Records to Authorized Persons / Entities

I understand that, by granting the consent below, I am authorizing release of my immunization information to DSHS and I further understand that DSHS will include this information in the Texas Immunization Registry. Once in ImmTrac2, my immunization information may by law be accessed by: a Texas physician, or other health care provider legally authorized to administer vaccines, for treatment of the individual as a patient; a Texas school in which the individual is enrolled; a Texas public health district or local health department, for public health purposes within their areas of jurisdiction; a state agency having legal custody of the individual; a payor, currently authorized by the Texas Department of Insurance to operate in Texas for immunization records relating to the specific individual covered under the payor's policy. **I understand that I may withdraw this consent at any time.**

State law permits the inclusion of immunization records for First Responders and their immediate family members (older than 18 years of age) in the Registry. A "First Responder" is defined as a public safety employee or volunteer whose duties include responding rapidly to an emergency. An "immediate family member" is defined as a parent, spouse, child, or sibling who resides in the same household as the First Responder. For a family member younger than 18 years of age, a parent, legal guardian, or managing conservator may grant consent for participation as an "ImmTrac2 child" by completing the Immunization Registry (ImmTrac2) Consent Form (# C-7).

Please mark the appropriate box to indicate whether you are a <u>First Responder</u> or an <u>Immediate Family Member</u>.

☐ I am a **<u>FIRST RESPONDER</u>**. ☐ I am an **<u>IMMEDIATE FAMILY MEMBER</u>** (older than 18 years of age) of a First Responder.

By my signature below, I **<u>GRANT</u>** consent for registration. I wish to **<u>INCLUDE</u>** my information in the Texas immunization registry.

Individual (or individual's legally authorized representative): _____ Printed Name

_____ Date _____ Signature

Privacy Notification: With few exceptions, you have the right to request and be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the state agency to correct any information that is determined to be incorrect. See *http://www.dshs.texas.gov* for more information on Privacy Notification. (Reference: Government Code, Section 552.021, 552.023, 559.003, and 559.004)

Questions? (800) 252-9152 • (512) 776-7284 • Fax: (866) 624-0180 • www.ImmTrac.com
Texas Department of State Health Services • ImmTrac2 Group - MC 1946 • P. O. Box 149347 • Austin, TX 78714-9347

PROVIDERS REGISTERED WITH ImmTrac2: Please enter client information in ImmTrac2 and **affirm** that consent has been granted. **DO NOT fax to ImmTrac2. Retain this form in your client's record.**

Stock No. F11-13366 Revised 04/2019

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