COVID-19 VACCINE SCREENING AND CONSENT FORM
Moderna COVID-19 Vaccine

SECTION 1: INFORMATION ABOUT YOU (PLEASE PRINT)

Last Name	First Name	Middle Initial	UTSA ID (abc123)

Date of Birth			Age in Years	Sex (Gender assigned at birth)
Month	Day	Year		☐ Male ☐ Female

Race
☐American Indian or Alaska Native ☐Native Hawaiian or Other ☐Other Asian ☐Other
☐Asian ☐Pacific Islander ☐Other Nonwhite
☐Black or African American ☐White ☐Other Pacific Islander

Ethnicity
☐Hispanic or Latino
☐Not Hispanic or Latino
☐Unknown

Address

City	State	Zip Code

Cell Phone Number

Is this the patient's first or second dose of the COVID-19 vaccination? ☐ First Dose ☐ Second Dose

SECTION 2: COVID-19 SCREENING QUESTIONS

Please check YES or NO for each question.	**YES**	**NO**
1. Are you sick today?	☐	☐
2. Have you had a severe allergic reaction to a previous dose of this vaccine or to any of the ingredients of this vaccine?	☐	☐
3. Do you carry an Epi-pen for emergency treatment of anaphylaxis?	☐	☐
4. For women, are you pregnant or is there a chance you could become pregnant?	☐	☐
5. For women, are you breastfeeding?	☐	☐
6. Have you had any other vaccinations in the previous 14 days?	☐	☐
7. In the past 90 days, have your received monoclonal antibodies or been diagnosed with COVID-19?	☐	☐
8. Have you had, in the last 10 days, fever, chills, cough, shortness of breath, difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea, vomiting, or diarrhea?	☐	☐

SECTION 3: IMMUNIZATION SCREENING GUIDANCE FOR COVID-19 VACCINE

Please check YES or NO for each question.	**YES**	**NO**
9. Do you have allergies or reactions to any medications, foods, vaccines, or latex? Please explain:	☐	☐
10. Are you immunocompromised or on a medicine that affects your immune system?	☐	☐
11. Do you have a bleeding disorder or are you on a blood thinner/blood-thinning medication?	☐	☐
12. Have you received a previous dose of any COVID-19 vaccine? If yes, please indicate which manufacturer's vaccine you received and date the dose was administered: ☐ Moderna COVID-19 vaccine Date administered: ☐ Pfizer-BioNTech COVID-19 vaccine _____	☐	☐
13. Did you experience a non-severe allergic reaction within 4 hours of a previous dose of COVID-19 vaccine? Non-severe allergic reactions can include: hives, swelling, redness, wheezing, GI symptoms, etc)? If yes, please explain:	☐	☐

- I certify that I am: (a) the patient and at least 18 years of age; (b) the parent or legal guardian of the patient and confirm that the patient is at least 16 years of age; or (c) authorized to consent for vaccination for the patient named above. Further, I hereby give my consent to the Sabine County Hospital (SCH) or their agents to administer the COVID-19 vaccine.
- I understand that this product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.
- I understand that it is not possible to predict all possible side effects or complications associated with receiving vaccine(s). I understand the risks and benefits associated with the above vaccine and have received, read and/or had explained to me the Emergency Use Authorization Fact Sheet on the COVID-19 vaccine I have elected to receive. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction. I also understand the need for continued masking/social distancing after receiving the COVID-19 vaccination
- I acknowledge that I have been advised to remain near the vaccination location for approximately 15 minutes after administration for observation and possibly up to 30 minutes if medical provider deems necessary. If I experience a severe reaction, I will call 9-1-1 or go to the nearest hospital.
- I acknowledge that: (a) I understand the purposes/benefits of ImmTrac2, Texas immunization registry and (b) TxDSHS will include my personal immunization information in ImmTrac2 registry and my personal immunization information will be shared with the Centers for Disease Control (CDC) or other federal agencies.
- I acknowledge receipt of the Notice of Privacy Rights.
- I voluntarily elect to receive the COVID-19 vaccination at SCH after carefully considering the risks and benefits.
- SCH advised me to consult with my medical provider to discuss my personal risks, benefits, and potential side effects of receiving the COVID-19 vaccination.
- I understand that the COVID-19 vaccinations given at SCH will be tracked and reported to ImmTrac, and as otherwise required by the local, state and federal government.

Signature of Patient or Authorized Representative: _____ **Date:** _____

Print Name of Representative and Relationship to Person Receiving Vaccine: _____

Site (LD/RD)	Route	Manufacturer	Lot #Unit of Use/ Unit of Sale	Expiration Date	Date of EUA Fact Sheet

Administered by:	Sabine County Hospital
Location Address:	2301 Worth Street Hemphill, Texas 75948
Clinic Phone Number:	409-787-1416

Vaccinator (Print Name):		Signature:		Date:	
Vaccine Administering Provider Suffix:					

For Registration Purposes Only - Patient Will NOT be Billed
Insurance Type: _____
Insured: _____
Group #: _____

***For Registration Purposes Only* - Emergency Contact/Next of Kin**
Contact Name: _____
Phone Number: _____
Relationship: _____

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

Benefits of Participating in the Texas Immunization Registry (ImmTrac2)

ImmTrac2 is Texas' opt-in registry that stores immunization records for children and adults in one convenient secure location.

The Texas Immunization Registry makes a lifetime of Immunization records accessible for:

- Anytime you move or change healthcare providers
- Childcare
- School enrollment
- Traveling
- Military enlistment
- Employment in health and safety fields
- First responders and members of military families
- Anyone displaced by a natural disaster

Who can partcipate?

Everyone in the state of Texas can register for the Texas Immunization Registry. Adults, 18 years and older, must complete an ImmTrac2 Adult Consent Form to participate. For adults consent is required one time and is valid for life, unless consent is withdrawn.

To register children 17 years and younger, parents or legal guardians must sign an ImmTrac2 Minor Consent Form. Consent is required one time and is valid until a child turns 18 years old. Once a person is 18 years old, they may submit an ImmTrac2 Adult Consent Form or their childhood records are destroyed.

Where can I register?

Visit ImmTrac.com to download and complete the ImmTrac2 Adult Consent Form (F11-13366) or Minor Consent Form (C-7).

Send your completed ImmTrac2 Adult or Minor Consent Form to your authorized healthcare provider, Local Health Department, or DSHS ImmTrac2 Service Offices.

To learn more about ImmTrac2, visit www.dshs.texas.gov/immunize/immtrac, call (800) 348-9158, or email ImmTrac2@dshs.texas.gov.

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

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