



Administration Facility Name/Facility ID: _____

COVID-19 VACCINE SCREENING AND CONSENT FORM

Moderna COVID-19 Vaccine

SECTION 1: INFORMATION ABOUT YOU (PLEASE PRINT)

Name: Last: _____ First: _____ Middle Initial: _____	
Date of Birth: Month _____ Day _____ Year _____ Mobile Phone Number (Patient or Guardian): (_____) _____	
Address: _____ Apt/Room #: _____	
City: _____ State: _____ Zip: _____	
Sex (Gender assigned at birth) <input type="checkbox"/> Female <input type="checkbox"/> Male	Race <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or other <input type="checkbox"/> Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Other Asian <input type="checkbox"/> Other Nonwhite <input type="checkbox"/> Other Pacific Islander <input type="checkbox"/> Unknown
Ethnicity <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown	
Primary Insurance Carrier ID #: _____ Grp #: _____ Insurance Company : _____ Insurance Company Phone # _____ Insured's Name: _____ Relationship: _____ Insured's Date of Birth _____	
Secondary Insurance Carrier ID #: _____ Grp #: _____ Insurance Company : _____ Insurance Company Phone # _____ Insured's Name: _____ Relationship: _____ Insured's Date of Birth _____	
Is this the patient's first or second dose of the COVID-19 vaccination? <input type="checkbox"/> First Dose <input type="checkbox"/> Second Dose	

SECTION 2: COVID-19 SCREENING QUESTIONS

Please check YES or No for each question.	Yes	No
1. Do you have today or have you had at any time in the last 10 days a 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?		
2. Have you tested positive for and/or been diagnosed with COVID-19 infection within the last 10 days?		
3. Have you had a severe allergic reaction (e.g. needed epinephrine or hospital care) to a previous dose of this vaccine or to any of the ingredients of this vaccine?		
4. Have you had any other vaccinations in the last 14 days (e.g. influenza vaccine, etc.)?		
5. Have you had any COVID-19 Antibody therapy within the last 90 days (e.g. Regeneron, Bamlanivimab, COVID Convalescent Plasma, etc.)		

SECTION 3: IMMUNIZATION SCREENING GUIDANCE FOR COVID-19 VACCINE

Please check YES or No for each question.	Yes	No
6. Do you carry an Epi-pen for emergency treatment of anaphylaxis and/or have allergies or reactions to any medications, foods, vaccines or latex?		
7. For women, are you pregnant or is there a chance you could become pregnant?		
8. For women, are you currently breastfeeding?		
9. Are you immunocompromised or on a medication that affects your immune system?		
10. Do you have a bleeding disorder or are you on a blood thinner/blood-thinning medication?		
11. Have you received a previous dose of any COVID-19 vaccine? If yes, which manufacturer's vaccine did you receive:		

- I certify that I am: (a) the patient and at least 18 years of age; (b) the legal guardian of the patient and confirm that the patient is at least 18 years of age; or (c) authorized to consent for vaccination for the patient named above. Further, I hereby give my consent to the Florida Department of Health (DOH) or its 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 acknowledge that I have been advised to remain near the vaccination location for approximately 15 minutes (or more in specific cases) after administration for observation. If I experience a severe reaction, I will call 9-1-1 or go to the nearest hospital.
- On behalf of myself, my heirs and personal representatives, I hereby release and hold harmless the State of Florida, the Florida Department of Health (DOH), and their staff, agents, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liabilities or claims whether known or unknown arising out of, in connection with, or in any way related to the administration of the vaccine listed above.
- I acknowledge that: (a) I understand the purposes/benefits of Florida SHOTS, Florida's immunization registry and (b) DOH will include my personal immunization information in Florida SHOTS and my personal immunization information will be shared with the Centers for Disease Control (CDC) or other federal agencies.
- I further authorize DOH or its agents to submit a claim to my insurance provider or Medicare Part B without supplemental coverage payment for me for the above requested items and services. I assign and request payment of authorized benefits be made on my behalf to DOH or its agents with respect to the above requested items and services. I understand that any payment for which I am financially responsible is due at the time of service or if DOH invoices me after the time of service, upon receipt of such invoice.
- I acknowledge receipt of the Notice of Privacy Rights.

Signature of Patient or Authorized Representative _____ Date: _____

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

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

Administered at location: facility name/ID	
Administered at location: Type	
Administration Address:	
CVX (product)	
Sending organization:	

Vaccinator Print Name: _____ Signature: _____ Date: _____

Vaccine administering provider suffix: _____

**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).

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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

What to Expect after Getting a COVID-19 Vaccine

Accessible version: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html>

COVID-19 vaccination will help protect you from getting COVID-19. You may have some side effects, which are normal signs that your body is building protection. These side effects **may feel like flu** and **may even affect your ability** to do daily activities, but they should go away in a few days.

Common side effects

On the arm where you got the shot:

- Pain
- Swelling

Throughout the rest of your body:

- Fever
- Chills
- Tiredness
- Headache

Helpful tips

If you have pain or discomfort, talk to your doctor about taking an over-the-counter medicine, such as ibuprofen or acetaminophen.

To reduce pain and discomfort where you got the shot: To reduce discomfort from fever:

- Apply a clean, cool, wet washcloth over the area.
- Use or exercise your arm.
- Drink plenty of fluids.
- Dress lightly.

When to call the doctor

In most cases, discomfort from fever or pain is normal. Contact your doctor or healthcare provider:

- If the redness or tenderness where you got the shot increases after 24 hours
- If your side effects are worrying you or do not seem to be going away after a few days

Remember

- Side effects may feel like flu and even affect your ability to do daily activities, but they should go away in a few days.
- With most COVID-19 vaccines, you will need 2 shots in order for them to work. Get the second shot even if you have side effects after the first one, unless a vaccination provider or your doctor tells you not to get a second shot.
- It takes time for your body to build protection after any vaccination. COVID-19 vaccines that require 2 shots may not protect you until a week or two after your second shot.
- It's important for everyone to continue using all the tools available to help stop this pandemic as we learn more about how COVID-19 vaccines work in real-world conditions. Cover your mouth and nose with a mask when around others, stay at least 6 feet away from others, avoid crowds, and wash your hands often.

HEALTHCARE PROVIDER, PLEASE FILL IN THE INFORMATION BELOW:

If your temperature is 101°F or 38.3°C or higher or if you have questions, call your healthcare provider.

Tell your healthcare provider about: any side effects that bother you and do not go away. If you experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital.

Healthcare provider phone number: Alachua County Health Department 352-334-7950

Medication (if needed):

Take Tylenol 325mg every 4-6 hours as needed.
(type and dose or amount)



Ask your healthcare provider about getting started with v-safe

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second dose

Learn more about v-safe.
www.cdc.gov/vsafe



cdc.gov/coronavirus



**Get vaccinated.
Get your smartphone.
Get started with v-safe.**

What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through **v-safe**, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And **v-safe** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's **v-safe** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in **v-safe** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from **v-safe** around 2 p.m. local time. To opt out, simply text "STOP" when **v-safe** sends you a text message. You can also start **v-safe** again by texting "START."

How long do v-safe check-ins last?

During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions **v-safe** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, **v-safe** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in **v-safe** is protected so that it stays confidential and private.*

*To the extent **v-safe** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity.



Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.



Sign up with your smartphone's browser at
vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

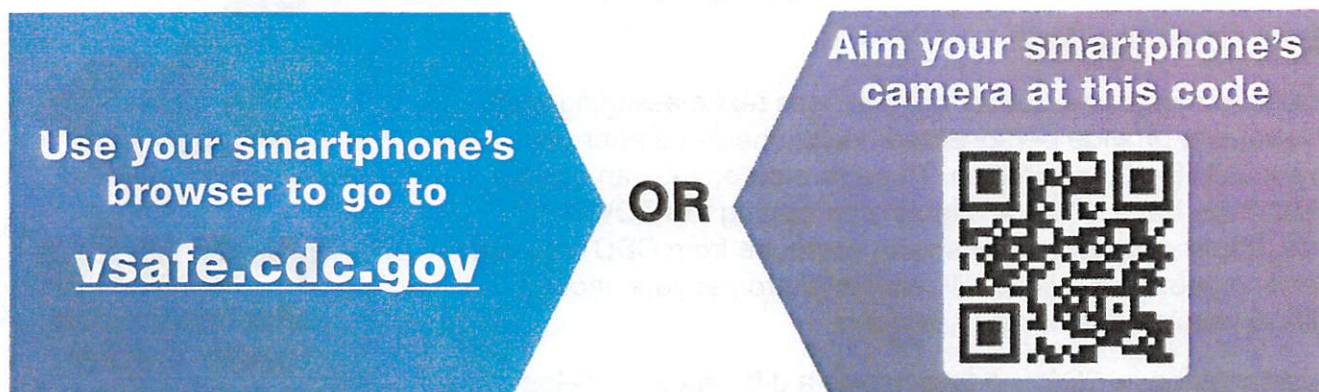


How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

Register

1. Go to the **v-safe** website using one of the two options below:



2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. You will receive a text message with a verification code on your smartphone. Enter the code in **v-safe** and click **Verify**.
5. At the top of the screen, click **Enter vaccine information**.
6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
8. **Congrats! You're all set!** If you complete your registration before 2 p.m. local time, **v-safe** will start your initial health check-in around 2 p.m. that day. If you register after 2 p.m., **v-safe** will start your initial health check-in immediately after you register — just follow the instructions. You will receive a reminder text message from v-safe when it's time for the next check-in — around 2 p.m. local time. Just click the link in the text message to start the check-in.

Complete a v-safe health check-in

1. When you receive a **v-safe** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

Troubleshooting

How can I come back and finish a check-in later if I'm interrupted?

- Click the link in the text message reminder to restart and complete your check-in.

How do I update my vaccine information after my second COVID-19 vaccine dose?

- **V-safe** will automatically ask you to update your second dose information. Just follow the instructions.

Need help with v-safe?

Call 800-CDC-INFO (800-232-4636)

TTY 888-232-6348

Open 24 hours, 7 days a week

Visit www.cdc.gov/vsafe

