Rockbridge Area
Health Center

Instructions for RAHC COVID-19 Vaccination:

Important Information:

- Below is a fact sheet for recipients of the Moderna COVID-19 Vaccine to prevent the Coronavirus Disease 2019. Please review this information prior to your appointment. Once your paperwork is submitted you will receive a copy of this information via email, and it is available on our website.
- COVID-19 Vaccinations require two doses. You will be scheduled to receive the second dose **28 days** after your first visit.
- If you are feeling unwell the morning of your appointment, please call ahead to reschedule your appointment.

Arrival/Visit:

- Please arrive 5 minutes prior to your appointment.
- Bring a photo id, and your COVID vaccine card
- You will be asked to complete a COVID-19 Vaccination screening form.
- There will be a 15-minute observation period once the dose is administered.

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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.

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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.

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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?

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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?

None of the currently authorized COVID-19 vaccines are live virus vaccines. Because data are lacking on the safety and efficacy of COVID-19 vaccines administered simultaneously with other vaccines, the vaccine series should routinely be administered alone, with a minimum interval of 14 days before or after administration of any other vaccine. However, COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration (e.g., tetanus-toxoid-containing vaccination as part of wound management, rabies vaccination for post-exposure prophylaxis, measles or hepatitis A vaccination during an outbreak) or to avoid barriers to or delays in to COVID-19 vaccination (e.g., in long-term care facility residents or healthcare personnel who received influenza or other vaccinations before or upon admission or onboarding). If COVID-19 vaccines are administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

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
http://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-legalregulatory-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).

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

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Patient Registration Form

Patient's Full Legal Name

Full Name

Date of Birth | Social Security Number

Gender ❒ Male ❒ Female ❒ Unknown | Marital Status ❒ Single ❒ Married ❒ Divorced ❒ Widowed

Mailing Address

City | State | Zip Code | County/City of Residency

House Phone | Cell Phone | Work Phone

If we are unable to contact you and you have voicemail, do we have your permission to leave a message? ❒ Yes ❒ No

Email address: _____

Patients with email addresses listed on this registration form will automatically be registered with our patient portal which can be accessed by visiting our website www.rockahc.org. You can access your vaccine record from this portal.

Additional Information

Do you have medical insurance: ❒ Yes ❒ No

Primary Medical Insurance:_____ **Subscriber Name:**_____

Policy Number:_____ **Subscriber Date of Birth:** _____

Group Number:_____

Ethnicity: ❒ Hispanic or Latin American ❒ Non-Hispanic ❒ Unreported/refused to report

Race: ❒ Asian ❒ White ❒ Black or African American ❒ Pacific Islander
❒ American Indian or Alaskan Native ❒ Other race ❒ Unreported/refused to report

Name of Emergency Contact #1 | Home or Cell Phone Number | Relationship to Patient

Signature

I understand that by signing this document, I attest to the accuracy of the information provided.. (For minor patients, parent/legal guardian completing this form sign below)

Relationship to patient | Date

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HIPAA RELEASE OF INFORMATION
Authorization to Use or Disclose Protected Health Information

RAHC Fax Number: (855) 806-0826

Patient Name: _____

Date of Birth: _____ Age: _____ SSN: _____

Home Phone: _____ Cell Phone: _____

Address: _____

City: _____ State: _____ Zip Code: _____

I give permission for RAHC to mail my COVID-19 vaccination record to the address listed in registration:

☐ Yes ☐ No

If a copy of my vaccination records are needed, I will come in at a later time to obtain them:

☐ Yes ☐ No

I understand that I have the right to revoke this authorization by submitting my request in writing. I further understand that Rockbridge Area Health Center may re-disclose records received under this authorization, except for mental health records, which require a separate re-disclosure authorization. I also understand that I may refuse to sign this authorization and it is strictly voluntary, but I also understand that certain records are needed for the best quality medical care. I fully understand and accept the terms of this authorization, which shall remain in effect one year from the date of the request unless otherwise stated.

_____

Patient/Legal Guardian Signature Relationship to Patient Date

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GENERAL CONSENT

1. HIPAA NOTICE OF PRIVACY POLICY. I acknowledge that I have received and/or have read RAHC's Notice of Privacy Policy Effective June 2, 2014. This document is available online to review or can be reviewed at our office. If you would like someone to review it with you, please let us know.

2. CONSENT FOR TREATMENT. I give my consent to the medical staff of RAHC to perform emergency medical treatment, acute or chronic medical treatment, preventive health care, dental care, behavioral/mental health care, and health maintenance care as deemed medically necessary. (If the individual is a minor at the time of consent, a parent or legal guardian must sign this consent for treatment.). There is only one electronic health record used between primary care team members in addressing your treatment plan of care and this health information is shared between these primary care team members. A "Behavioral Health Consultant" is a member of the primary care team that works closely with your medical provider to recognize and address medical conditions associated with acute and chronic mental and emotional disordered conditions.

3. CONSENT TO COMMUNICATE VIA SMS. I authorize RAHC through its texting platform and electronic health record vendor to contact me by SMS text message to serve me better. RAHC may send me text messages to help me or my child stay healthy, including:

    - timely reminders about doctor or dental appointment
    - health maintenance reminders
    - information to help manage illnesses

    - I understand that message/data rates may apply to messages sent through RAHC to my cell phone and that I may receive up to 10 texts per month.
    - I know that I am under no obligation to authorize RAHC to send me text messages as part of this program.
    - I may opt-out of receiving these communications from RAHC at any time by calling RAHC at 540-464-8700

4. DEEMED CONSENT FOR DESIGNATED BLOODBORNE PATHOGENS. Section 32.1-45.1 of the Virginia Code authorizes health care providers to test patients for HIV and Hepatitis B and C if a health care worker is exposed to blood or bodily fluids of the patient in a manner which, according to current guideline of the Center for Disease Control, may transmit HIV or Hepatitis B or C viruses. In the event of such an exposure, I am deemed to have consented to testing and release of results to person(s) exposed. However, I will be counseled before any of my blood is tested for HIV or Hepatitis B or C, as well as afterwards when I receive the results.

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5. CONSENT FOR VACCINATION. I hereby authorize the administration of the COVID-19 vaccine to myself or to the person named below for whom I am the legal representative.

- I have read or have had explained to me the information contained in the Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of COVID 19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) and understand the risks and benefits of the vaccine and alternatives to the vaccine (that is, not receiving the vaccine or waiting for other versions of the vaccine);
- I have had the opportunity to ask questions about this immunization [and any questions I had about the COVID-19 vaccine have been answered to my satisfaction.
- I believe the benefits outweigh the risks, and I accept full responsibility for any reactions that may result from my receipt of the immunization or the receipt of the immunization by the person named below for whom I am the legal representative.
- I agree that my vaccine-related health information may be required to be or may voluntarily be disclosed to my health care provider, my insurance plan, and state or federal registries or other public health authorities, for purposes of treatment, payment or health care operations. I also agree that the organization providing my vaccine may use and disclose my health information as described in its Notice of Privacy Practices.

This consent form will be used as needed. You may revoke or change any of the above consents at any time.

Participation in all of the programs offered at RAHC is voluntary and is not a requirement to receive care.

When signing the electronic signature pad at RAHC before your first visit, you acknowledge:

1) review of RAHC's Notice of Privacy Policy effective June 2, 2014
2) review of RAHC's Consent for Treatment
3) review of RAHC's Consent for Text Communication
4) review of RAHC's Consent for Bloodborne Pathogens
5) review of RAHC's Consent for Vaccination

_____

Signature of Patient or Patient's Representative Date

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