Pomperaug District Department of Health Moderna COVID-19 Vaccination – Phase 1a & 1b (Version 1/12/2021)

Please Print Clearly & Complete BOTH sides

Last Name					First Name			M.I.		
Street Address Town				1		County	State	Zip Code		
Phone # Date of Birth			Age	Gender						
				Male Female Decline to Specify Other						
Ethnic	ity 🗌	Hispanic	or Latino	Ion-Hispanic or	Latino	Unknow	vn/Not Re	eported		
Race								ic Islander		
Email	White Unknown/Not Reported									
Insurance Information: Check Name of Insurance Plan. MUST present insurance cards for person listed above – ID numbers may be different for each individual. Medicare Part B Anthem BC/BS Connecticare Cigna Aetna UnitedHealthCare Oxford – UnitedHealthCare HUSKY/Medicaid Uninsured										
mea										
Yes	No					Eligibility	Questio	ons		
		l am a r	nember of a	COVID-19 Vac	cinatio	on Priority	Group lis	sted below. Check appl	icable g	Iroup:
Phas	0.10	Healthcare providers with direct patient contact Pharmacists & pharmacy technicians (Retail)								
Phase	ela	Emergency service & public safety personnel Deublic Health Personnel								
		Age 75 or older (Age subject to revision as per State of Connecticut)								
		Education (K-12, early childhood, childcare, higher education)								
		Food & Agriculture: Agriculture & farm workers, food service workers, grocery & essential retail								
Phas	e 1b	Transportation, Logistics, Delivery: Public transit, delivery (USPS, UPS, FedEx, etc.)								
		Social & Governmental Services: food banks, meal delivery to elderly, municipal workers, elected officials, clergy offering in-person services								
		Drinking water, wastewater & solid waste workers								
		Others as currently approved by the State of Connecticut								
		Don't								
Yes	No	Know Vaccine Pre-Screening Questions								
		I have received and read the "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"								
				r received a dos				Other		
			If yes, which vaccine product? Moderna Pfizer Other Are you feeling sick today?							
			Have you ever fainted or felt dizzy after receiving an immunization?							
		Do you have any of these medical conditions: □Cancer □Chronic Kidney Disease □COPD □Downs Syndrome □Heart Condition (e.g. heart failure, cardiomyopathy, coronary artery disease) □ Immune compromised due to organ transplant □Anemia/Sickle Cell Disease □Pregnancy □ Smoking □Obesity (BMI < 30 but <40) & Severe obesity (BMI ≥40) □Type 2 diabetes								
		Have you had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?					/ID-19?			

Yes	No	Don't Know	Vaccine Pre-Screening Questions - continued
			Have you received passive antibody therapy as treatment for COVID-19?
			Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies such as steroids, biologics, or anti-cancer drugs?
			During the past year, have you received a transfusion of blood or blood products, or been given a medicine called Immuna(Gamma)globulin?
			Do you have a bleeding disorder or are you taking a blood thinner?
			Do you have a history of Guillain-Barre Syndrome?
			Are you pregnant or breastfeeding? Is there a chance that you could become pregnant during the next month?
			Have you had a seizure, brain or nerve problem?
			Have you had any vaccinations in the past 14 days? If yes, please list:
			Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something? For example, a reaction for which you were treated with epinephrine or EpiPen, or for which you had to go to the hospital?
			 Are you allergic to any of the following – if yes, please check: Milk Fish Eggs Crustacean Shellfish Peanuts Tree nuts Wheat Soybeans Latex Gelatin/Egg protein Yeast Neomycin Other:
			 Have you ever had a severe allergic reaction after receiving a COVID-19 vaccine?
			 Have you ever had a serious reaction after receiving another vaccine or another injectable medication?
			 Are you allergic to any of the components of the Moderna vaccine: 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?
-	Medica /ou are		

I declare that I am currently eligible to receive the COVID-19 Vaccine in the State of CT.

I have read or had explained to me the 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 and understand the risks and benefits. Furthermore, I have also had an opportunity to ask questions about these immunizations. I believe the benefits outweigh the risks and I voluntarily assume full responsibility for any reactions that may result from either my receipt of the immunization(s) or the receipt of the immunizations(s) by the person named below for whom I am the legal guardian ("Ward").

My medical record may be shared with my physician or other healthcare provider and the medical record of my Ward may be shared with his/her physician or other healthcare provider.

I am requesting that the immunization(s) be given to me or my Ward. I, for myself and on behalf of my Ward and each of our respective heirs, executors, personal representatives and assigns, hereby release the provisioning mass vaccination center, and its affiliates, subsidiaries, divisions, directors, contractors, agents and employees (collectively "Released Parties"), from any and all claims arising out of, in connection with or in any way related to my receipt and the receipt of my Ward of this or these immunization(s). Neither the provisioning mass vaccination center nor any of the Released Parties shall, at any time or to any extent whatsoever, be liable, responsible or any way accountable for any loss, injury, death or damage suffered or sustained by any person at any time in connection with or as a result of this vaccine program or the administration of the vaccines described above.

The provisioning vaccination center will use and disclose your personal and health information or the personal and health information of your Ward, to treat you or your Ward, to receive payment of the care we provide, and for other healthcare operations. Healthcare operations generally include those activities we perform to improve the quality of care. We have prepared a detailed NOTICE OF PRIVACY PRACTICES to help you better understand our policies in regard to you and your Ward's personal health information.

I acknowledge that I have received a copy of the Notice of Privacy Practices.

Signature	Da	ate
For Clinic Use Dose: 0.5ml IM Site: LD		Vaccine Manufacturer
Administered by:	Date:	& Lot #



Pomperaug District Department of Health 77 Main Street North • Playhouse Corner • Suite 205 • Southbury, Connecticut 06488 (203)264-9616 • Woodbury (203)266-4785 • Oxford (203)888-2543x3005 Fax (203)262-1960 • www.pddh.org

You must read the attached documents prior to receiving your COVID-19 vaccination:

- 1. 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
- 2. PDDH HIPAA Privacy Notice

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 <u>https://vaers.hhs.gov/reportevent.html</u>. 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: <u>www.cdc.gov/vsafe</u>.

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 <u>https://www.cdc.gov/coronavirus/2019-ncov/index.html</u>
- Visit FDA at <u>https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization</u>
- 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: <u>https://www.cdc.gov/vaccines/programs/iis/about.html</u>.

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 FDAapproved 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).

©2020 ModernaTX, Inc. All rights reserved. Patent(s): <u>www.modernatx.com/patents</u> 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

NOTICE

USE & DISCLOSURE OF PROTECTED HEALTH INFORMATION

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND

HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The Pomperaug District Department of Health is required by law to maintain the privacy of protected health information and to provide you with notice of its legal duties and privacy practices. The Pomperaug District Department of Health must abide by the terms of the notice currently in effect; however the Pomperaug District Department of Health reserves the right to change the terms of this notice as well as make the new provisions effective for all protected health information maintained. If there is a change, the Pomperaug District Department of Health will inform you of this change at your next scheduled appointment or upon your request. In addition, a copy of the effective notice will be posted at all times in the office, with a date notifying you of the most recent update.

The Pomperaug District Department of Health is NOT	The Pomperaug District Department of Health IS ONLY
REQUIRED TO OBTAIN CONSENT OR AUTHORIZATION	REQUIRED TO INFORM YOU IN ADVANCE AND ALLOW
TO USE AND DISCLOSE INFORMATION ABOUT YOU UNDER	YOU TO OBJECT TO THE USE AND DISCLOSURE OF
THE FOLLOWING CIRCUMSTANCES:	INFORMATION ABOUT YOU UNDER THE FOLLOWING
-For purposes of treatment, payment and healthcare	CIRCUMSTANCES:
operations, including the release of information to:	-For use in a directory of individuals served by the
-An insurance company, Medicare,Medicaid	Pomperaug District Department of Health
-Any person or entity affiliated with billing and	-To a family member, other close relative, close
quality and risk management.	personal friend, or other identified person involved
-Any hospital, nursing home, or other health care	in your care
facility in which you may be admitted.	-To a public or private entity authorized by law or
-Any assisted living or personal care facility	charter to assist in disaster relief efforts
-Any physician providing you care	
-Any business associate of the Pomperaug District	USES AND DISCLOSURES NOT SPECIFICALLY
Department of Health	ADDRESSED IN THIS NOTICE WILL BE MADE ONLY
-When the Pomperaug District Department of Health is	WITH YOUR WRITTEN AUTHORIZATION, INCLUDING:
reqired by law	-Psychotherapy notes (notwithstanding the
-For certain public health activities or health care	provisions allowing uses)
oversight activities	-Marketing, except face-to-face communication
-When the Pomperaug District Department of Health	and promotional gifts of nominal value
reasonably believes that you are a victim of abuse,	
neglect or domestic violence	YOUR RIGHTS
-In certain judicial administrative hearings	Subject to certain conditions, you have the right
-In certain circumstances, to coroners, medical	under law, to:
examiners and funeral directors	-Request restrictions on certain uses and disclosure
-For certain law enforcement purposes	of information about you (although the Pomperaug
-For cadaveric organ, eye or tissue donation purposes	District Department of Health is not required to agree
-For certain research purposes	with the request)
-For workers' compensation purposes	-Receive confidential communication of protected
-For specialized government functions, including	health information
military and veterans' activities, national security	-Inspect and copy protected health informtion
and intelligence activities, medical suitability	-Amend protected health information
determinations, correctional institution and custodial	-Receive an accounting of disclosures
situations.	-Obtain a paper copy of this notice
COMPL	AINTS

COMPLAINTS

If you believe your privacy rights have been violated, you may complain to the Pomperaug District Department of Health and the Secretary of the U.S. Department of Health and Human Services. There will be no retaliation for complaints filed. For further information or to make a complaint, contact:

THE POMPERAUG DISTRICT DEPARTMENT OF HEALTH @ (203)264-9616

or

The U.S. Department of Health and Human Services, Office of the Secretary 200 Independence Avenue, S.W. Washington, D.C. 20201 (202)619-0257 OR Toll Free: 1-877-696-6775