

**CONSENT FOR EMERGENCY USE AUTHORIZATION (EUA)
OF AN FDA INVESTIGATIONAL AGENT
MODERNA COVID-19 VACCINE - DAY 1 DOSING**

8.	SIGNATURE
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I have been given a copy of all six pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I understand the potential risks and benefits of COVID-19 vaccine and request the vaccine is given to me. I agree to hold Singing River Health System harmless from any injury, complication or side effect(s) caused by administration of said vaccine.

Patient's Primary Language (if other than English):		
___ Spanish	___ Vietnamese	___ ASL ___ Other: _____
_____	_____	_____
Printed Name of Interpreter	Signature of Interpreter	Date

Signature of Participant

Date



Signature of Person Reviewing Consent

Date

1. INFORMATION ABOUT EMERGENCY USE AUTHORIZATION TREATMENTS AND THIS DOCUMENT

The US Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to permit the emergency use of an unapproved prophylactic (preventive) vaccine *MODERNA COVID-19 Vaccine*, for prevention of SARS-CoV-2 infection and coronavirus disease 2019 (COVID-19) in individuals over age 18. We believe that the vaccine may help prevent you from developing COVID-19 if you are exposed to the SARS-CoV-2 virus that causes COVID-19. There are currently no FDA approved vaccines available to prevent COVID-19.

MODERNA COVID-19 Vaccine is an investigational agent. An investigational agent is one that researchers are still studying to find out whether it is safe and effective. Because this drug is investigational, the Food and Drug Administration (FDA) has not yet approved it for general use.

The purpose of this form is to help you understand how *MODERNA COVID-19 Vaccine* works and to give you an opportunity to decide whether you want us to use it to treat you. We will also give you the *Fact Sheet for Recipients and Caregivers provided by the FDA to support the Emergency Use Authorization (EUA) of MODERNA COVID-19 Vaccine for prevention of Coronavirus Disease 2019 (COVID-19) version 12/20/2020*.

Before you sign this form, be sure you understand how MODERNA COVID-19 Vaccine relates to your condition, as well as the risks and possible benefits of using it.

2. SPECIFIC INFORMATION ABOUT THE TREATMENT

2.1. Name of Doctor Providing Administration Oversight of the MODERNA COVID-19 Vaccine:
Dr. Randy Roth, Chief Medical Officer, Singing River Health System

2.2. Name of the DRUG:
MODERNA COVID-19 Vaccine

2.3. Title of the Emergency Use Authorization Protocol:
MODERNA COVID-19 Vaccine PROTOCOL FOR SRHS UNDER FDA EUA

2.5 Why is this Vaccine being recommended?

MODERNA COVID-19 Vaccine is an investigational vaccine developed to prevent COVID-19 illness in people potentially exposed to SARS-CoV-2 virus by attaching to the spike portion on the outside of the virus, neutralizing the virus and helping your body develop antibodies against the SAR-CoV-2 virus. The vaccine stimulates your own immune system to recognize the virus and neutralize it before it can develop into COVID-19 infection.

MODERNA COVID-19 Vaccine is investigational which means it has not been approved by the FDA to prevent COVID-19 and is still being studied in clinical research trials. There is limited information known about the safety and effectiveness of using the vaccine to prevent COVID-19. *MODERNA COVID-19 Vaccine* was tested in a randomized clinical trial/research study conducted in the US with over 30,000 participants. The vaccine was shown to stimulate the body's immune system to develop antibodies specific to the SAR-CoV-2 virus. Initial results from the clinical trials indicated an effectiveness rate of over 94% in preventing COVID-19 in people who received the vaccine.

There are no vaccines approved by the FDA as safe and effective to prevent COVID-19. Therefore, the FDA has authorized the emergency use of *MODERNA COVID-19 Vaccine* for the prevention of COVID-19 under an Emergency Use Authorization (EUA).

2.6 How is the vaccine treatment given?

MODERNA COVID-19 Vaccine is given as an intramuscular (IM) injection in the upper arm **in 2 injections 28 days apart**. You should receive both injections to give yourself the best level of prevention.

If you experience a severe allergic reaction, call 9-1-1 or go to the nearest Emergency Department.

You will be asked to contact us if you have any side effects or reactions that bother you, that don't go away or you think might be related to the vaccine by calling **228-809-5000**.

Please also report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)** at the toll-free number 1-800-822-7967 or report online at <https://vaers.hhs.gov/reportevent.html>. Please include "MODERNA COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

This and additional reporting information is included in the *Fact Sheet for Recipients and Caregivers* you will be given.

We will also be tracking for any COVID-19 related visits you make to your health care provider, the Emergency Department and admissions to the hospital.

2.6 What is usually done for patients who have this type of disease or condition?

There is no U.S. FDA approved product, including vaccines, currently available to prevent COVID-19.

3. COSTS ASSOCIATED WITH THIS TREATMENT

- 3.1 The MODERNA COVID-19 Vaccine will be provided to you at no cost; administration costs involved with the IM injection may be charged to your insurance company
- 3.2 By signing this form, you do not give up your right to seek payment if you are harmed as a result of receiving this treatment. *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. To learn more about this program visit www.hrsa.gov/cicp/ or call 1-855-266-2427.*

4. HOW INFORMATION ABOUT YOU WILL BE SHARED

- 4.1. **If you give us permission to use MODERNA COVID-19 Vaccine in preventing COVID-19 we may give the following agencies information about you and your condition:**
- The U.S. Food and Drug Administration (FDA)
 - The U.S. Center for Disease Control (CDC)
 - The Mississippi State Department of Public Health
 - ModernaTX, Inc. (the pharmaceutical company that makes the vaccine)

- 4.2 **We may provide the Institutional Review Board of the Singing River Health System (IRB) with the following kind(s) of information:**
- Any problems that occur when you receive the MODERNA COVID-19 Vaccine

We usually provide this information to the IRB with a code instead of using your name. In some instances, however, the IRB may need to review your medical records and may request your name from your doctor to access your records.

- 4.3 For more information about our use and disclosure of protected health information, please refer to the Singing River Health System Notice of Privacy Practices. This notice should already have been made available to you and you may also find this notice online, <https://singingriverhealthsystem.com/privacy-practices/>

5. RISKS AND BENEFITS

5.1. What are the risks of being treated with this Vaccine?

Possible side effects of MODERNA COVID-19 Vaccine are:

- *Injection reactions.* Rarely, Injection-related reactions have been seen following administration of the vaccine (redness and swelling at injection site). Signs and symptoms of administration-related reactions may include: fever, chills, nausea, headache, bronchospasm (wheezing, chest tightness, shortness of breath), hypotension (drop in blood pressure),

angioedema (swelling usually around mouth/lips), throat irritation, rash including urticarial (raised red welts, intense itching), pruritus, myalgia, dizziness.

- Additional side effects reported by participants who have received this vaccine in clinical trials include fatigue, muscle pain, fever, chills, joint pain, headache, nausea/ vomiting, axillary swelling/tenderness (under arm) and potential of facial swelling in vaccine recipients (1-2 days post vaccine) with history of injection of dermatologic fillers (like Botox or Juvederm).
- These are not all the possible side effects of *MODERNA COVID-19 Vaccine*. It is still being studied so it is possible that not all of the risks are known at this time. At the time the FDA issued this EUA, over 17,000 people have received the *MODERNA COVID-19 Vaccine*. Serious and unexpected side effects may happen.
- If you are Pregnant or Breastfeeding, the FDA EUA guidelines recommend you discuss your options about using this vaccine with your health care provider.

5.2. What are the possible benefits of being treated with this vaccine?

MODERNA COVID-19 Vaccine may help prevent you from developing COVID-19 if you are exposed to the SARS-CoV-2 virus.

5.3 What is the most likely outcome of being treated with this vaccine?

There is limited information known about the safety and effectiveness of using *MODERNA COVID-19 Vaccine* to prevent people from developing COVID-19. It was shown in clinical trials to stimulate the individual immune system to develop antibodies against the SARS-Co-V2 virus and prevent COVID-19 in some people.

- 5.5** You are free to cancel the administration of the Day 28 dose of *MODERNA COVID-19 Vaccine* and your treatment with this vaccine is voluntary. Before stopping, you should discuss your choice with your doctor, as stopping its use may pose additional risks to you that your doctor may need to manage. If you stop treatment before it is finished, there will be no penalty or loss of benefits to which you may otherwise be entitled. If you decide to stop treatment before it is finished, please contact your health care provider and the Singing River Health System at **228-809-5000**.

6. CONTACT INFORMATION

6.1 Who can I contact for more information about this vaccine?

- Please contact your health care provider
- Ask the vaccination provider at the Singing River Health System location where you are receiving the vaccine
- 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>
- Mississippi State Department of Health

This and additional contact information is also included in the *Fact Sheet for Recipients and Caregivers* you will be given.

Doctor Overseeing FDA/EUA for MODERNA Coronavirus-19 Vaccine at Singing River Health System: Dr. Randy Roth, Telephone: 228-809-5000

You may also express a concern about this use of the investigational drug MODERNA COVID-19 Vaccine by contacting the Institutional Review Board below:

Singing River Health System
2809 Denny Avenue Pascagoula MS 39581
Telephone: 228-809-5000 e-mail: renee.burnsed@mysrhs.com

If you are concerned about a possible violation of your privacy or concerned about use of an investigational drug you may contact the Singing River Health System Compliance Help Line at 228-809-5000.

7. RECORD OF INFORMATION PROVIDED
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7.1 What documents will I receive?

- This consent form (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential file and will be entered into your Singing River Health System Medical Record*)
- *Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of The MODERNA COVID-19 Vaccine to Prevent CORONAVIRUS DISEASE 19 (COVID-19) In Individuals 18 Years of Age and Older issued by the U.S. FDA on December 20, 2020.*