Singing River Health System

CONSENT FOR EMERGENCY USE AUTHORIZATION (EUA) OF AN FDA INVESTIGATIONAL AGENT PFIZER-BIONTECH COVID-19 VACCINE – DAY 21 DOSING

ACCORDING TO OUR RECORDS YOU HAVE ALREADY RECEIVED YOUR FIRST DOSE OF THE PFIZER-BIONTECH COVID-19 VACCINE. YOU ARE DUE TO RECEIVE THE SECOND DOSE OF THE VACCINE 21 DAYS LATER. PLEASE REVIEW THE FOLLOWING INFORMATION ON THE PFIZER-BIONTECH COVID-19 VACCINE AND SIGN THIS INFORMED CONSENT.

IF YOU DECIDE TO CANCEL DAY 21 VACCINE DOSE, please DO NOT SIGN THIS CONSENT FORM.
You should contact your health care provider and inform them of your decision.

PLEASE VERIFY THAT YOU RECEIVED DAY 1 DOSE OF YOUR VACCINE ON _____
PLEASE VERIFY THAT YOU ARE DUE TO RECEIVE DAY 21 DOSE OF YOUR VACCINE ON _____

8.	SIGNATURE

I have been given a copy of all seven pages of this consent 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 the COVID-19 vaccine and request that the vaccine be given to me. I agree to hold Singing River Health System harmless from any injury, complications 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 *Pfizer/BioNTech COVID-19 mRNA BNT162b2 RNA 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.

COVID-19 mRNA BNT162b2 RNA Vaccine is an investigational agent. An investigational agent is one that researchers are still studying to find out whether it's 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 *COVID-19 mRNA BNT162b2 RNA 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 COVID-19 mRNA BNT162b2 RNA Vaccine for prevention of Coronavirus Disease 2019 (COVID-19).*

Before you sign this form, be sure you understand how COVID-19 mRNA BNT162b2 RNA 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 *COVID-19 mRNA BNT162b2 RNA Vaccine*:
Dr. Randy Roth, Chief Medical Officer, Singing River Health System

2.2. Name of the DRUG:
COVID-19 mRNA BNT162b2 RNA Vaccine

2.3. Title of the Emergency Use Authorization Protocol:
Pfizer/BioNTech COVID-19 mRNA BNT162b2 RNA Vaccine PROTOCOL FOR SRHS UNDER FDA EUA

2.4 Project Number: COVID-19 VAC-001

2.5 Why is this Vaccine being recommended?

COVID-19 mRNA BNT162b2 RNA 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.

COVID-19 mRNA BNT162b2 RNA 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. *COVID-19 mRNA BNT162b2 RNA Vaccine* was shown in two clinical trials/research studies to neutralize the SARS-Co-V2 virus and stimulate antibody development specific to the SAR-CoV-2 virus. Initial results from the clinical trials indicated an effectiveness rate of over 90% 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 *COVID-19 mRNA BNT162b2 RNA Vaccine* for the prevention of COVID-19 under an Emergency Use Authorization (EUA).

2.6 How is the vaccine treatment given?

COVID-19 mRNA BNT162b2 RNA Vaccine is given as an intramuscular (IM) injection in the upper arm **in two injections 21 days apart.** You should receive both injections to give yourself the best level of prevention. YOU HAVE ALREADY RECEIVED DAY 1 VACCINE DOSE AND ARE NOW DUE FOR DAY 21 VACCINE DOSE.

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 "Pfizer-BioNTech 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 received after your Day 1 dose. Another copy will be given to you today if you need another copy.

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 until 29 days after the last dose of the vaccine as required by the FDA.

2.7 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 *COVID-19 mRNA BNT162b2 RNA Vaccine* will be provided to you at no cost under the FDA EUA program; 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 *COVID-19 mRNA BNT162b2 RNA 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
- Pfizer-BioNTech (the pharmaceutical company that makes the vaccine)

4.2 We may provide the Institutional Review Board of Singing River Health System (IRB) with the following kind(s) of information:

- Any problems that occur when you receive the ***COVID-19 mRNA BNT162b2 RNA 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 DRUG?

Possible side effects of ***COVID-19 mRNA BNT162b2 RNA Vaccine*** are:

- *Injection reactions*. Rarely, Injection-related reactions have been seen following administration of the vaccine. 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 drug in clinical trials include fatigue, muscle pain, fever, chills, joint pain, headache, diarrhea, vomiting.
- These are not all the possible side effects of ***COVID-19 mRNA BNT162b2 RNA 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 20,000 people have received the ***COVID-19 mRNA BNT162b2 RNA 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.
- PLEASE INFORM THE VACCINATION ADMINISTRATION TEAM OF ANY SIDE EFFECTS OR PROBLEMS YOU EXPERIENCED FOLLOWING YOUR DAY 1 DOSE OF THE VACCINE.

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

COVID-19 mRNA BNT162b2 RNA 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 ***COVID-19 mRNA BNT162b2 RNA 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 21 dose of ***COVID-19 mRNA BNT162b2 RNA 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.

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 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 ***COVID-19 mRNA BNT162b2 RNA 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

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 Pfizer-BioNTech CORONAVIRUS DISEASE 19 (COVID-19) in individuals 16 years of age and older issued by the U.S. FDA* on December 11, 2020.