

## INFORMED CONSENT MODERNA COVID-19 Vaccine – ADDITIONAL DOSE

### **Introduction**

The following is an informed consent document. Please read it carefully. It does not take the place of a conversation with the doctor regarding this proposed treatment. This document is intended to provide information that a patient should have in order to make an informed decision about a particular medical procedure, in this case whether or not to have the COVID-19 vaccine.

### **Purpose**

The purpose of a COVID-19 vaccination is to try and prevent acquiring a COVID-19 infection by immunization with an inactivated coronavirus vaccine.

Despite extensive research and safety data, vaccines are not 100% guaranteed to be safe or effective. Agreeing to have a vaccine means that you accept the very small risk of vaccine related consequences as well as the risk of acquiring COVID despite having been vaccinated.

The purpose of this form is to explain what those risks are so that you understand them. A patient should not agree to undergo any medical treatment unless and until they understand the possible risks, benefits, alternatives, and the reason for having the treatment done.

### **The Vaccine**

This consent is for an ADDITIONAL DOSE of the Moderna COVID-19 vaccine. As of August 13, 2021, the FDA approved an additional dose of this vaccine in “certain immunocompromised individuals”.

All of the relevant information about this vaccine, its mechanism of action, risks, and side effects is in the document entitled “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”, dated 8/27/21, which is provided as a separate handout. Please review this information.

### **Alternatives**

The current COVID-19 vaccine alternatives include the Pfizer version and the J&J Janssen version.

**Agreement and Consent**

To make sure that you fully understand the information contained in this Informed Consent, your physician is available to discuss the information with you after you have had a chance to read it, and before you decide whether to have the above vaccine administered. If you have questions, you are encouraged and expected to ask them, and your physician and her/his staff will be available to discuss these with you.

**Your signature on this informed consent indicates:**

- A. That you have read and understood the information provided in this form.
- B. That you have read and understood the information provided in the Moderna EUA Fact Sheet.
- C. That you believe you qualify for this additional dose based on your medical situation.
- D. That you have been verbally informed about the COVID-19 vaccine.
- E. That you have had a chance to ask questions.
- F. That you have received all the information you want concerning this treatment.
- G. That you authorize and consent to receiving the Moderna COVID-19 vaccine.

DATE: \_\_\_\_\_ TIME: \_\_\_\_\_

NAME: \_\_\_\_\_ SIGNATURE: \_\_\_\_\_

If signed by other than patient, indicate relationship: \_\_\_\_\_

**PHYSICIAN'S STATEMENT:**

The undersigned physician hereby certifies that s/he discussed the following procedure(s) with the patient and provided a full explanation of the indications for the vaccine, the benefits of getting the vaccine, the risks of the vaccine (common and remote, minor and serious), and the alternatives.

The undersigned physician further certified the patient was encouraged to ask questions, and that all of her/his questions were answered. The patient has agreed to receive the COVID-19 vaccine.

DATE: \_\_\_\_\_ TIME: \_\_\_\_\_

DR NAME: \_\_\_\_\_ SIGNATURE: \_\_\_\_\_