

VACCINE RECIPIENT NAME_____/_____/_____
Name / Date of Birth / Employee # (if applicable)**INFORMED CONSENT FOR ADMINISTRATION OF COVID-19 VACCINE**

This consent form contains important information to help you decide whether to have the Covid-19 vaccine. Please read carefully and ask any questions before you sign.

1. In order to have the Covid-19 vaccine administered (“the Covid-19 vaccine”) you must provide written informed consent by signing this document. The purpose of this informed consent is to provide you with enough information so you can understand the possible risks and benefits of receiving the Covid-19 vaccine and decide whether or not you want to receive the Covid-19 vaccine and to authorize CentraState Medical Center (“CentraState”) to use and disclose your health information for purposes related to review of the safety, efficacy and future use of Covid-19 vaccine. **READ EXHIBIT A, FACT SHEET FOR PATIENTS FROM VACCINE MANUFACTURER BEFORE SIGNING CONSENT.**
2. By signing this Informed Consent form, I am agreeing to receive the Covid-19 vaccine, which may be an investigational vaccine developed to attempt to prevent Covid-19. The Covid-19 vaccine has been manufactured by various drug makers, and the specific vaccine that I will receive is described on the Fact Sheet for Patients, along with a discussion of the vaccine and its risks.
3. **THE COVID-19 VACCINE may be investigational** if it is still being studied by the Food and Drug Administration (FDA). There is limited information known about the safety or effectiveness of using the Covid-19 vaccine to treat people with COVID-19. By signing this consent to receive the Covid-19 vaccine, I realize that there may be side effects, both immediate and/or long term, and that some may not be known at this time. Not all Covid-19 vaccines are approved by the FDA at this time, as some authorized the use of the Covid-19 vaccine under an Emergency Use Authorization (EUA).
4. The reason that I am receiving the Covid-19 vaccine is to try to prevent infection with the coronavirus (the virus that causes Covid-19). However, I may never become infected or develop symptoms, or transmit the virus, even if I do not receive the Covid-19 vaccine. Most people infected with COVID-19 will have mild to moderate respiratory illness and recover without requiring special treatment. Some people will have severe illness even resulting in death. Persons with chronic medical conditions, for example, heart disease, lung disease, and diabetes, seem to be at higher risk of problems with Covid-19.
5. **The vaccine may need two or more doses to be effective.** Therefore, if I want the vaccine to be effective, I agree that (i) I will return for the additional doses, including booster doses, if warranted by the manufacturer or my healthcare provider and my specific circumstances (e.g. immunocompromised), (ii) I will inform CentraState prior to receiving the additional dose(s) if I have had any problems with or since the prior dose(s), and (iii) this Informed Consent form shall apply and be in effect for all doses of the COVID-19 vaccine that I am administered by CentraState. **By signing this Informed Consent form, I attest that, to the best of my knowledge and belief, I am eligible for an additional dose of the COVID-19 Vaccine based on my vaccination history, public health guidance (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/immunocompromised-patients.html>) and health status (e.g. immunocompromised).**
6. Some persons should not receive the Covid-19 vaccine as outlined in the attached Patient Fact Sheet from the vaccine manufacturer.
7. There are **POTENTIAL RISKS** of the Covid-19 vaccine that include:
 - The side effects of getting any injection may include brief pain, bleeding, bruising of the skin, soreness, or swelling at the injection site.

- You could develop an allergic reaction from the Covid-19 vaccine, either during or after injection with the Covid-19 vaccine. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, dizziness, anaphylactic reaction and even death.
- **There may be other serious and unexpected side effects and risks which are unknown at this time**, as only a small number of people have been given the Covid-19 vaccine. These could be as serious as paralysis and death. Please read the Patient Fact Sheet for a description of risks that are known at this time.

8. Before agreeing to receive the Covid-19 vaccine, you know that the alternative is not to receive the Covid-19 vaccine, and you may never need it.

9. Although the vaccine manufacturer believes that the Covid-19 vaccine may reduce your ability to infect others, this is not a guaranty. Therefore, to protect others if you have symptoms or if you are exposed to Covid-19, you should still take precautions to prevent infection of others, including isolating, wearing a mask, social distancing, avoiding sharing personal items, cleaning “high touch” surfaces, and handwashing.

10. **COSTS FOR TREATMENT.** For patients, the Covid-19 vaccine you receive today will be free of cost, however, an administration fee may be charged by CentraState and submitted to patient’s insurance carrier or, for uninsured patients, to the Health Resources and Services Administration’s Provider Relief Fund for reimbursement. You will not be charged a co-pay or deductible. However, you and/or your health plan are responsible for payment of the costs associated with any future treatment, as well as costs related to any side effects you may experience as a result of the Covid-19 vaccine. Employees and Medical Staff Members of CentraState shall receive the vaccine free of cost pursuant to their duties and responsibilities at CentraState.

11. **PARTICIPATION IS VOLUNTARY.** Your receipt of this Covid-19 vaccine is voluntary. You may choose not to receive the vaccine. If you decide not to get the Covid-19 vaccine, it will have no effect on any services or treatment you are currently receiving from your physician.

12. **CONFIDENTIALITY OF RECORDS AND RELEASE TO GOVERNMENT AGENCIES.** The State of New Jersey has required that all individuals receiving the Covid-19 vaccine be enrolled in the New Jersey Immunization Information System (NJIS). Information regarding the NJIS can be found at: <https://www.njis.nj.gov/core/web/index.html#/mission>. You or your legal guardian may submit a request to the New Jersey Department of Health (NJDOH) to opt-out of the NJIS registry, but requests will not be reviewed by the NJDOH until after the end of the Covid-19 Public Health Emergency. By signing this consent, you acknowledge that CentraState will be sharing your vaccination information with the NJIS. In addition, your records and the protected health information (PHI) included in your records may be shared with the manufacturer of the Covid-19 vaccine or with public health authorities (including, but not limited to, the Centers for Disease Control, the Food and Drug Administration, the NJDOH, and New Jersey local health departments) for purposes of assessing the safety and/or effectiveness of the Covid-19 vaccine, or if adverse events related to the Covid-19 vaccine need to be reported. This information may be shared pursuant to the public health exception contained in the regulations governing the use of PHI under the Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA). The public health exception allows your health information to be shared with a public health authority for the purpose of preventing or controlling disease, injury, or disability, or conducting public health surveillance, investigations, or interventions. It may also be shared with any entity subject to the jurisdiction of the Food and Drug Administration (such as a vaccine manufacturer) for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. By signing this consent, you acknowledge that CentraState may share your vaccination information with public health authorities or with the vaccine manufacturer.

13. **RELEASE FROM LIABILITY.** I realize that the FDA has authorized use of the Covid-19 vaccines for the treatment of COVID-19 both with full approval and some still under an Emergency Use Authorization (EUA) only, which means that the Covid-19 vaccine with EUA status has not undergone the same type of review as an FDA-approved or cleared product. In consideration of CentraState’s agreement to administer the Covid-19 vaccine, **I HEREBY AGREE TO RELEASE CENTRASTATE**, and any of its employees, agents and representatives

("Releasees"), **FROM ANY AND ALL LIABILITY RELATED TO OR IN CONNECTION WITH THE ADMINISTRATION OF THE COVID-19 VACCINE**, regardless of the reason that I may wish to bring a claim against a Releasee, and even if Releasee(s) were negligent or careless with regards to the administration of the Covid-19 vaccine. This means that I will not sue Releasees for anything related to the administration of the Covid-19 vaccine including any future side effects. I realize that lawsuits relating to the Covid-19 vaccine may be precluded under federal law.

I realize that (i) this Release covers events after the signing of this document, and that the exact nature of any injury or loss that may be claimed may not be entirely foreseeable; (ii) the terms of this Release mean that I am waiving certain rights; and (iii) if any portion of this Release is determined to be invalid or unenforceable, that portion shall be severable, and the balance of the Release shall not be affected in any way and shall continue in full legal force and effect.

14. Any disputes will be governed by the laws of the State of New Jersey.

I agree to and acknowledge the above, and wish to receive The Covid-19 vaccine.

- I HAVE READ THOROUGHLY THIS CONSENT FORM AND EXHIBIT A, FACT SHEET FOR PATIENTS, AND ANY QUESTIONS I HAVE ABOUT GOING AHEAD WITH THE COVID-19 VACCINE AT THIS TIME HAVE BEEN ANSWERED TO MY SATISFACTION.
- I ACKNOWLEDGE THAT I HAVE HAD TIME TO CONSIDER HAVING THIS TREATMENT/PROCEDURE AND I AM MAKING A VOLUNTARY DECISION IN MY BEST INTEREST TO PROCEED WITH THE COVID-19 VACCINE.

Patient/Guardian or Representative Name

Signature

Date/Time

Relationship to patient if signed by person
other than patient

Lot # _____ Deltoid: L R Date: _____ Vaccinator _____

Certified Translator Used: IF PATIENT'S PREFERRED LANGUAGE IS NOT ENGLISH.

Exhibit A: Fact Sheet For Patients
(see attached from Vaccine Manufacturer)