



# Administration of COVID-19 Vaccine for Patients Who Cannot Provide Informed Consent

*Updated January 4, 2020*

## Introduction

The Rhode Island Department of Health (RIDOH) prepared this guidance for healthcare providers who are vaccinating people who cannot provide informed consent and do not have a guardian or power of attorney.

The virus Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV2) is known to cause the disease Coronavirus Disease 2019 (COVID-19). COVID-19 has a significant morbidity and mortality rate in Rhode Island, particularly in institutional settings, and is responsible for global morbidity, mortality, and disruption. A safe, effective vaccine is the best hope to end the global pandemic and eradicate COVID-19. Widespread vaccination is a critical component of the State's response to the COVID-19 pandemic.

## Background

The Food and Drug Administration issued an Emergency Use Authorization (EUA) for the use of the Pfizer-BioNTech COVID-19 vaccine on December 11, 2020 and the Moderna COVID-19 vaccine on December 18, 2020. Following the State's own internal review process, including a review by the Rhode Island COVID-19 Vaccine Subcommittee, RIDOH approved the use of these vaccines beginning on December 14, 2020 and December 21, 2020, respectively.

The Centers for Disease Control and Prevention recommends that vaccination provider partners follow all EUA Conditions of Use procedures when administering COVID-19 vaccines, including giving patients the applicable vaccine patient fact sheets. [Pfizer](#) | [Moderna](#) Providers should obtain consent or assent for vaccination from the patient or their medical proxy and must document this in the patient's chart per standard practice.

Licensed healthcare providers are expected to act in the patient's best interests at all times in all clinical situations. They should consider beneficence, respect for patient autonomy, and other ethical principles when administering COVID-19 vaccines.

[Executive Order 20-70](#) provides immunity from liability for healthcare workers who provide healthcare services to assist the State's response to the COVID-19 pandemic, so long as they do not engage in willful misconduct, gross negligence, or bad faith. The administration of approved vaccines by licensed healthcare providers is critical to the State's efforts to fight the pandemic.

## Guidance

Always secure informed consent if a patient is capable of giving that level of consent or if there is authorization from a guardian or power of attorney.

When a patient cannot provide informed consent and does not have a guardian or power of attorney, the vaccinating licensed independent healthcare provider shall educate the patient at the patient's level of ability and understanding. The provider should describe the purpose of the vaccine, explain its known benefits and risks to the patient's health, discuss the health of applicable caregivers and the general population, and obtain the patient's assent to receive the vaccine.

This education and guidance shall be provided by trained licensed healthcare providers rather than non-clinical staff.

If someone is incapacitated and does not have a power of attorney or guardian, the clinician shall use their clinical judgement and do what is in the best interest of their patient using the same ethical considerations described above. The Long-Term Care Ombudsman ([kheren@alliancebltc.org](mailto:kheren@alliancebltc.org)) and the State's Mental Health Advocate ([megan.clingham@doa.ri.gov](mailto:megan.clingham@doa.ri.gov)) are available to support clinicians who want support in this decision making.

### **Resources**

- [COVID-19 Vaccine Frequently Asked Questions](#)
- [COVID-19 Vaccine Web Page](#)