Temperature: _____

Vaccine Site: □ Right Arm □ Left Arm

□ Dose 1 □ Dose 2

COVID-19 Vaccination Consent Form

Name (print clearly): _____ **DOB**:_____

The Moderna COVID-19 Vaccine has been authorized by the Federal Drug Administration (FDA) under an Emergency Use Authorization (EUA). The FDA may issue an EUA based on a declaration by the Secretary of the Department of Health and Human Services (HHS) that circumstances justify the emergency use of drugs and biological products during the COVID-19 pandemic if certain criteria are met. Those criteria include that there are no adequate FDA approved alternatives available. There is currently not enough scientific evidence available for the FDA to fully approve this or any other COVID-19 vaccine. The FDA decision to issue an EUA is based on the totality of the scientific evidence available showing that the Moderna Vaccine may be effective to prevent COVID-19 and that the known and potential benefits of the Moderna Vaccine outweigh the known and potential risks.

Keystone Health is authorized to offer the Moderna Vaccine based on guidance from the Centers for Disease Control and the Pennsylvania Department of Public Health. The Moderna Vaccine requires **two (2) doses, given four weeks apart**, to be effective.

Moderna Vaccine side effects that have been reported in clinical trials include, but are not limited to: injection site pain • tiredness • headache • muscle pain • chills • joint pain • fever • injection site swelling • injection site redness • nausea • feeling unwell • swollen lymph nodes (lymphadenopathy). These symptoms are not severe in the majority of cases, and usually resolve within 24 hours. Certain severe allergic reactions have been reported outside of clinical trials; if you develop symptoms of an allergic reaction following vaccination (such as trouble breathing, chest pain or a fast heartbeat, dizziness, weakness, swelling of the face, throat, or tongue, or a rash all over your body), call 911 or go to the nearest Hospital Emergency Department.

I understand that if I am pregnant or am breastfeeding I have had the opportunity to speak with my primary care provider or Obstetrician and am making an informed decision to receive the vaccine.

QUESTIONS	YES	NO
1. Are you ill today? (fever, cold symptoms etc.)?		
2. Have you been diagnosed with COVID-19 with a PCR test in the past 10 days?		
3. Have you received any vaccinations in the past 2 weeks?		
4. Have you ever received any other COVID-19 Vaccine other than from Keystone Health?		
5. Have you ever had an allergic reaction to the components of the Moderna COVID-19 Vaccine?		
6. Have you received passive antibody treatment for COVID-19 in the past 90 days?		
7. Have you ever had an anaphylactic reaction(e.g. trouble breathing, broke out in hives, had facial or tongue swelling, had low blood pressure), or had other severe symptoms after receiving another vaccination or an injectable medication (a shot given intravenously, intramuscularly, or subcutaneously)?		
8. Do you have a history of an anaphylactic reaction to anything other than a vaccine or injectable medication (food, insect sting, oral medication)?		
9. Do you have a bleeding disorder or take a blood thinner?		

If you answered "Yes" to any of the questions 1 to 6, you should not have the Moderna Vaccine today:

- If you are sick, we recommend you delay vaccination until your symptoms have resolved. If you are diagnosed with COVID-19 you should delay the vaccination for 10 days after diagnosis.
- If you have received other vaccinations recently for something other than COVID-19, it is recommended that you wait 2 weeks following that vaccine(s) prior to receiving the Moderna Vaccine.
- If you have received a different COVID-19 vaccine, you should not receive the Moderna Vaccine as there is no data on safety or efficacy of combining vaccines from different manufacturers. If you were vaccinated as part of a clinical trial, you should contact the research team with any questions or concerns about receiving Moderna Vaccine.
- If you have a history of anaphylaxis to any of the ingredients in the Moderna Vaccine, you should not receive the Moderna Vaccine at any time, based on current guidance.
- If you have received passive antibody treatment for COVID-19, it is recommended to wait 90 days after treatment before receiving the Moderna Vaccine

If you answered "Yes" to question 7, 8, or 9, notify the staff before receiving the Moderna Vaccine. If you have a history of anaphylaxis to something other than the Moderna Vaccine ingredients, we will increase your monitoring time after vaccination to make sure there is no evidence of an anaphylactic reaction. If you have a history of a bleeding disorder or take a blood thinner, we will monitor for bleeding at the injection site.

If you are ready to receive the Moderna Vaccine, please read the statement below and sign your name to indicate your consent.

CONSENT FOR MODERNA VACCINE – Complete if requesting vaccination.

☐ I verify that I have been provided with and have read (or had read to me) (1) the Emergency Use Authorization Fact Sheet for the COVID-19 Moderna Vaccine; (2) this COVID-19 Vaccine Consent Form for the Moderna Vaccine; and (3) any additional information provided to me concerning COVID-19 vaccination. I acknowledge that I have had a chance to ask questions of a medical professional about the Moderna Vaccine. I understand that the Moderna Vaccine will be given in two separate doses, four weeks apart. I understand the known risks and the potential benefits of receiving the Moderna Vaccine, and I understand there may be risks to the Moderna Vaccine that are not known at this time. I understand that the FDA has authorized use of the Moderna Vaccine under an Emergency Use Authorization (EUA) and that there is currently not enough scientific evidence available for the FDA to fully approve this or any other COVID-19 vaccine. I nonetheless request and consent to the Moderna Vaccine being given to me.

I understand it is recommended that I remain on site for at least 15 minutes after receiving the Moderna Vaccine and that, depending on the recommendations of medical professionals, I may be asked to remain on site longer for monitoring.

Participant signature: _____ Date: _____

Vaccine Administered by: _____

Time administered_____

Time departed_____

Lot Number