

VIRGINIA DEPARTMENT OF BEHAVIORAL HEALTH AND DEVELOPMENTAL SERVICES
COVID-19 VACCINE CONSENT FORM FOR THE MODERNA VACCINE

Name of Recipient: _____ MRN: _____

E-mail: _____

Date of Birth: _____ Age: _____

Telephone Number: _____

Address: _____

FOR DBHDS EMPLOYEES, PERSONNEL and AFFILIATES ONLY

Mark one: DBHDS Employee External Physician/Medical Contractor/NP/PA Volunteer Contractor (if contractor, list employer): _____

DBHDS Employee ID #: _____

Department: _____ Facility/Hospital: _____

The MODERNA COVID-19 Vaccine made by Moderna (the Moderna 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.

DBHDS is authorized to offer the Moderna Vaccine to healthcare workers based on guidance from the Centers for Disease Control and Prevention and the Virginia Department of Health. The Moderna Vaccine will be provided at no charge. DBHDS is not requiring anyone to take the vaccine at this time. The decision to receive this vaccine is yours, and you may decline to receive it at this time.

The Moderna Vaccine requires two (2) doses, given 28 days month 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. Side effects should be reported to a health care provider and/or self-reported through the Vaccine Adverse Event Reporting System (VAERS). In addition, 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 declare that I or the person named below for whom I am the legal representative is 18 years of age or older. I further declare that I or the person named below for whom I am the legal representative:

- Have not experienced anaphylaxis (difficulty breathing) or severe allergic reactions from a previous COVID-19 vaccination.
- Have not had any other vaccinations in the previous 14 days (e.g. MMR, Shingrix, Varicella, Influenza, or a TB skin test).
- Is not currently sick with a fever, active respiratory infection, or other moderate/severe illness.
- Has have not received monoclonal antibodies or convalescent plasma for treatment of COVID-19 within the past ninety (90) days.
- Is not allergic to the following ingredients in the COVID-19 vaccine: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

I understand that if I or the person named below for whom I am the legal representative have any of the above conditions, I or the person named below for whom I am the legal representative could be at increased risk of having a negative reaction or problem from the Moderna Vaccine.

I further declare that if I or the person named below for whom I am the legal representative have any of the following conditions, I have had the opportunity to speak with my or the person named below for whom I am the legal representative's primary care provider and am making an informed decision to receive the Moderna Vaccine or to have the person named below for whom I am the legal representative receive the Moderna Vaccine:

- Pregnant, attempting to become pregnant or breastfeeding;
- Have a bleeding disorder or are on a blood thinner;
- Are immunocompromised or are taking a medication that affects the immune system (such as cortisone, prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease or psoriasis; HIV/AIDS, cancer, leukemia, ankylosing spondylitis or radiation treatments).

I agree to WAIT near the vaccine administration location for 15 minutes after receiving the Moderna Vaccine.

If I or the person named below for whom I am the legal representative have previously had a severe allergic reaction to a vaccine or injectable medication, I agree to WAIT near the vaccine administration location for 30 minutes after receiving the Moderna Vaccine.

I understand that the Moderna Vaccine is a two-part vaccine series.

By signing this consent, I am agreeing that I or the person named below for whom I am the legal representative will receive the first and/or second part of the Moderna Vaccine series. I understand that the common risks associated with the Moderna Vaccine include but are not limited to pain, redness or swelling at the site of injection, tiredness, headache, muscle pain, chills, joint pain, fever, nausea, feeling unwell or swollen lymph nodes (lymphadenopathy). I understand that the Moderna Vaccine may cause a severe allergic reaction which can include anaphylaxis (difficulty breathing, swelling of the face and throat, a fast heartbeat, a rash all over the body, dizziness and/or weakness). I understand that these may not be all the side effects of the Moderna Vaccine as the vaccine is still being studied in clinical trials. I also understand that it is not possible to predict all possible side effects or complications which could be associated with the Moderna Vaccine. I understand that the long-term side effects or complications of the Moderna Vaccine are not known at this time. I understand that receiving the Moderna Vaccine does not guarantee that I will not contract COVID-19.

I understand that the vaccination is being administered by DBHDS, but that DBHDS did not manufacture the Moderna Vaccine and expressly disclaims any responsibility for the vaccination. I have received, read, and understood "What to expect after getting a COVID-19 Vaccine" and the "Fact Sheet" by the FDA regarding the Moderna Vaccine. Furthermore, I have also had an opportunity to ask questions about the Moderna Vaccine. I understand the risks and benefits. I believe the benefits outweigh the risks, and I voluntarily assume full responsibility for any reactions that may result from my receipt of the Moderna Vaccine or receipt of the Moderna Vaccine by the person named below for whom I am the legal representative. My consent is given in light of this knowledge. I, for myself and my heirs, administrators, trustees, executors, assigns and successors in interest do hereby agree to release and hold harmless DBHDS, its subsidiaries, divisions, affiliates, successors, assigns, officers, employees, volunteers and agents from and against any and all demands, damages, losses, costs, expenses, obligations, liabilities, claims, actions and causes of action of any nature whatsoever (including, without limitation, reasonable attorney's fees and court costs) by reason of or resulting, in any way,

from any and all acts, accidents, events, occurrences, omissions and the like related to, or arising out of, directly or indirectly, my receipt of this Moderna Vaccine or receipt of this Moderna Vaccine by the person named below for whom I am the legal representative. DBHDS makes no warranties, express or implied, including but not limited to, implied warranties of merchantability or fitness for a particular purpose regarding the Moderna Vaccine or its effectiveness.

Medicare Part B Recipients: I understand DBHDS will process Medicare Part B claims on my behalf and accepts Medicare payment in full. I understand I must present my Medicare card prior to receiving the Moderna Vaccine. I understand that if I have assigned my Medicare benefits to a Medicare Advantage Plan (like an HMO or PPO), I must receive my COVID-19 vaccine shot from my HMO/managed care provider or pay the DBHDS charge.

Private Insurance Participants: If I have private insurance, I understand that DBHDS will not bill my insurance carrier on my behalf, and that I am responsible for paying the required fee for this Moderna Vaccine to DBHDS and for pursuing reimbursement from my health insurance carrier. DBHDS cannot guarantee that this service will be reimbursable by insurance.

I acknowledge receipt of DBHDS Notice of Privacy Practices. I further understand and agree that DBHDS is required to submit Moderna Vaccine administration data to the Virginia Immunization Information System (VIIS), and report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).

In addition, DBHDS is required by § 32.1-45.1 of the Code of Virginia (1950), as amended, to give you the following notice:

1. If any DBHDS health care professional, worker or employee should be directly exposed to your blood or body fluids in a way that may transmit disease, your blood will be tested for infection with human immunodeficiency virus (HIV), as well as for Hepatitis B and C. A physician or other health care provider will tell you the result of the test. Under Va. Code § 32.1-45.1(A), you are deemed to have consented to the release of the test results to the person exposed.
2. If you should be directly exposed to blood or body fluids of a DBHDS health care professional, worker or employee in a way that may transmit disease, that person's blood will be tested for infection with human immunodeficiency virus (HIV), as well as for Hepatitis B and C. A physician or other health care provider will tell you and that person the result of the tests.

This Notice of Deemed Consent for blood borne diseases has been explained to me and I understand it.

I understand and agree to all of the above and I hereby give my consent to the staff of DBHDS to give me or the person named below for whom I am the legal representative the Moderna Vaccine.

Signature of Patient/Parent/Legal Guardian/Authorized Representative: _____

Name (Printed): _____

Date: _____

Vaccine Lot # and Exp. Date	Route & Site of Administration	Manufacturer	Location and Person Administered by:	Dose number
Lot #:	Intramuscular (IM)	MODERNA	Location:	<input type="checkbox"/> Dose 1
Exp. Date:	Site (Deltoid): <input type="checkbox"/> R or <input type="checkbox"/> L		Administered by:	<input type="checkbox"/> Dose 2