Please return the completed document via fax at (518) 449-6912 or email at nyvfc@health.ny.gov and retain a copy for your records.

New York State Department of Health (NYSDOH) Bureau of Immunization
Vaccine Storage and Handling Plan

Primary Provider/Practice Name: _____ PIN # (if renewal) _____

Vaccine must be properly stored and administered to ensure maximum efficacy and safety. All Vaccines for Children (VFC) and Vaccines for Adults (VFA) sites must attest to their compliance with routine and emergency storage and handling procedures. Each section of this agreement includes required elements for an effective storage and handling plan. For guidance, refer to:
https://www.health.ny.gov/prevention/immunization/vaccines_for_children.htm Storage & Handling Requirements.

PERSONNEL

This site/facility has a primary vaccine coordinator and a back-up coordinator designated for this office (**NYS VFC/VFA requirement**). He/She will be responsible for ensuring that vaccines are handled and stored appropriately, that all necessary documentation is completed and that all office staff are properly trained in the handling and storage of vaccines. The medical director or equivalent has overall responsibility for the proper implementation of the storage and handling plan for this site/facility. The medical director or equivalent may be an MD, DO, NP or PA.

Name of medical director or equivalent: _____

Name of VFC or VFA coordinator: _____

Back-up coordinator: _____

EDUCATION

The vaccine coordinator, back-up coordinator and medical director or equivalent complete the NYS VFC trainings required for their enrollment status (Annual Renewal, Newly Enrolled, or Staff Change). Refer to the enclosure, "NYS VFC Training Requirements" to determine the necessary trainings. Trainings must be completed by the date this storage and handling plan is submitted.

Date of training completion for medical director or equivalent: _____

Date of training completion for primary vaccine coordinator: _____

Date of training completion for back-up coordinator: _____

Review this storage and handling plan with all staff annually and with new staff, including temporary staff, as part of their orientation.

EQUIPMENT and TEMPERATURE MONITORING

Provide the following information for each VFC or VFA vaccine refrigerator and temperature monitoring equipment in use:

Refrigerator Unit:

Unit Location/ ID#:	Refrigerator Type: ☐ Stand alone refrigerator ☐ Combination (refrigerator/freezer) ☐ Other, specify: _____
Use: ☐ Primary ☐ Backup/Overflow	Grade: ☐ Commercial ☐ Med/Lab/Pharmaceutical ☐ Household/Consumer ☐ Other, specify: _____

Thermometer Type:
☐ State supplied digital data logger, calibration expiration date: ____/____/_____
☐ Other:
Thermometer Brand: Calibration Expiration Date: ____/_____/_____

Please return the completed document via fax at (518) 449-6912 or email at nyvfc@health.ny.gov and retain a copy for your records.

New York State Department of Health (NYSDOH) Bureau of Immunization
Vaccine Storage and Handling Plan

Primary Provider/Practice Name: _____ PIN # (if renewal) _____

Notes: Newly enrolled providers are required to have stand alone refrigerator and freezer units and digital data loggers for every unit storing VFC vaccine.
All new units purchased must be stand alone units.
Dormitory style refrigerator/freezer units are never acceptable.

Additional VFC/VFA Refrigerator Unit:

Unit Location/ID #:	Refrigerator Type: ☐ Stand alone refrigerator ☐ Combination (refrigerator/freezer) ☐ Other, specify: _____
Use ☐ Primary ☐ Backup/Overflow	Grade: ☐ Commercial ☐ Med/Lab/Pharmaceutical ☐ Household/Consumer ☐ Other, specify: _____

Thermometer Type:
☐ Digital Data Logger, calibration expiration date: ____/____/_____
☐ Other:
Thermometer Brand: Calibration Expiration Date: __/__/____

VFC/VFA Freezer Unit:

Unit Location/ID #:	Freezer Type: ☐ Stand alone freezer ☐ Combination (refrigerator/freezer) ☐ Other, specify: _____
Use ☐ Primary ☐ Backup/Overflow	Grade: ☐ Commercial ☐ Med/Lab/Pharmaceutical ☐ Household/Consumer ☐ Other, specify: _____

Thermometer Type:
☐ State supplied digital data logger, calibration expiration date: ____/____/_____
☐ Other:
Thermometer Brand: Calibration Expiration Date: ____/_____/_____

Additional VFC/VFA Freezer Unit:

Unit Location/ID #:	Freezer Type: ☐ Stand alone freezer ☐ Combination (refrigerator/freezer) ☐ Other, specify: _____
Use ☐ Primary ☐ Backup/Overflow	Grade: ☐ Commercial ☐ Med/Lab/Pharmaceutical ☐ Household/Consumer ☐ Other, specify: _____

Thermometer Type:
☐ Digital Data Logger, calibration expiration date: ____/____/_____
☐ Other:
Thermometer Brand: Calibration Expiration Date: ____/_____/_____

New York State Department of Health (NYSDOH) Bureau of Immunization
Vaccine Storage and Handling Plan

Primary Provider/Practice Name: _____ PIN # (if renewal) _____

Backup Thermometer:

Thermometer Type:
☐ Data Logger, calibration expiration date: ____/____/_____
☐ Other, provide brand and calibration expiration date:
Thermometer Brand: Calibration Expiration Date: ____/____/_____

Carefully review all the following required elements. Each element is a VFC/VFA requirement.

1. Refrigerator temperatures are maintained at 36°F- 46°F (2°C-8°C), with an optimal temperature of 40°F (5°C).
2. Freezer temperatures are maintained at or below +5°F (-15°C).
3. Vaccine storage units are not connected to an outlet with a ground-flow circuit interrupter (GFCI) or an outlet activated by a wall switch. "Do Not Unplug" signs are next to the electrical outlets for the refrigerator and freezer and "Do Not Stop Power" warning labels are placed by the circuit breaker for the electrical outlets. All staff and any maintenance and custodial staff are instructed to never turn off the power to the vaccine storage units.
4. Each VFC/VFA refrigerator and freezer contains a calibrated temperature monitoring device that has a Certificate of Traceability and Calibration in accordance with National Institute of Standards and Technology (NIST) standards.
5. At least one back-up temperature monitoring device with a current certificate of calibration is on hand in case a temperature monitoring device in use is no longer working properly or calibration testing of the current equipment is required.
6. State supplied digital data loggers have a certificate of calibration for three years. At the end of the three years, thermometers are recycled or discarded.

   Any other temperature monitoring devices are re-calibrated at least every two years and a valid certificate is available for NYSDOH review at the time of a site visit. Temperature monitoring devices with Certificates of Calibration that do not specify a recalibration date will be recalibrated annually.

   Effective January 1, 2018, all temperature monitoring devices are digital data loggers with an alarm or alarm system that indicates when the temperature may be out of a preset range. All temperature monitoring devices can display minimum/maximum * temperatures.

   Temperature monitoring device probes are located in the center of the storage compartment.
   Temperature monitoring devices are inspected monthly for signs of breakage or wear.

   **Minimum and maximum temperatures are defined as the coldest (minimum) and the warmest (maximum) temperatures recorded in the storage unit since the last time the min/max was cleared.*
7. Temperatures are recorded for each VFC/VFA storage unit (refrigerator and freezer) at the beginning and end of each clinic day. The minimum and maximum temperatures for each vaccine storage unit is also recorded daily. **Twice daily temperatures and minimum and maximum temperatures are entered in the New York State Immunization Information System (NYSIIS) within 14 days of the date the temperature was read.**

REFRIGERATOR and FREEZER SET-UP

1. Vaccines are stored in the appropriate storage unit throughout the clinic day.
2. Vaccines are stored in the center of the storage unit stacked with air space between the vaccine containers and the sides and the back of the unit to allow cold air to circulate around the vaccine.
3. Vaccines are not stored on the top shelf of the refrigerator directly under a fan because it could cause the vaccine to freeze.
4. Expiration dates are monitored and stock is rotated to ensure short-dated inventory is used first.

New York State Department of Health (NYSDOH) Bureau of Immunization
Vaccine Storage and Handling Plan

Primary Provider/Practice Name: _____ PIN # (if renewal) _____

5.	All publicly-funded vaccine is labeled and can be distinguished from private stock.
6.	Filled water bottles are placed in doors and the bottom of the refrigerator and the freezer to serve as a temperature ballast in the event of a power outage.
7.	No food, drink, lab specimens, or radioactive materials in a refrigerator or freezer where vaccines are stored.
8.	Vaccines are stored in their original packaging in clearly labeled and uncovered containers with slotted sides that allow air to circulate.
9.	Vaccines are not stored on the door or in the vegetable bins as these are areas where the temperature can deviate from the rest of the storage unit (these are good places for water bottles to help stabilize temperatures).
	VACCINE DELIVERIES
1.	The office/facility is open at least one day other than Monday to receive vaccine shipments. On this day, the office/facility is open for at least 4 consecutive hours.
2.	All shipping containers are examined for any evidence of damage during transport.
3.	Cold-chain monitor cards are examined for any evidence of exposure to out-of-range temperatures.
4.	Shipments are not accepted if reasonable suspicion exists that the delivered product may have been mishandled.
5.	The manufacturer is contacted when circumstances raise questions about the efficacy of a delivered vaccine.
6.	Expiration dates are checked to be sure vaccine has not expired.
7.	Vaccine is immediately placed in an appropriate storage unit.
	VACCINE INVENTORY MANAGEMENT
1.	A physical inventory of all public vaccine supply is done within 14 days of placing an order and the inventory is confirmed in NYSIIS.
2.	Vaccine is ordered using the NYSIIS vaccine ordering module. The quantity ordered is enough for at least one month as the VFC Program cannot accept greater than one order per PIN# within 30 days. Providers are encouraged to order 2-3 months' quantity if storage units can accommondate the quantity.
3.	All immunizations, including VFC eligibility, are documented using the New York State Immunization Information System (NYSIIS) (required under Section 2168 of the Public Health Law).
4.	Reasonable efforts are made to prevent over ordering of vaccine including transfer of vaccine to an alternate facility if the vaccine will not be used.
5.	The VFC Program is notified between 60 to no later than 90 days prior to the expiration date of the vaccine (via survey monkey link) if the product will not be used.
6.	Any vaccine that needs to be returned or reported wasted is reported in the NYSIIS Returns/Wastage module.
	VACCINE ADMINISTRATION
1.	Reconstituted vaccines are discarded if not used within the interval allowed on the package insert.
2.	Only one multi-dose vial of a specific vaccine is opened at a time.
3.	Vaccines are drawn immediately before administration. Large quantities of vaccines are not predrawn as this can lead to waste and/or administration errors.

4. Single-dose vials with cap or dust cover removed are discarded. Any active manufacturer-filled syringes (i.e. syringe cap removed or needle attached) that are not used by the end of the workday are discarded.
5. The appropriate vaccine manufacturer will be contacted and the VFC Program notified if there is any question about the storage or handling of any vaccine.

VACCINE EMERGENCY PLAN

Any VFC/VFA provider that has an established practice vaccine emergency plan will submit their plan for approval when emailing or faxing this completed document to the VFC Program. Practice vaccine emergency plans must include the key elements of the vaccine emergency plan below (#1 - #4), and include signatures of key vaccine personnel at the end of this document.

All VFC/VFA providers that do not have a vaccine emergency plan are required to adhere to NYS Vaccine Program guidance for any emergency situation which may necessitate vaccine transport. Facilities with an on-site generator are also required to submit their established practice vaccine emergency plan or adhere to the NYS Vaccine Program guidance.

Failure to adhere to this guidance will result in the practice providing restitution for lost vaccine.

SELECT:

☐ Practice vaccine emergency plan attached

OR

☐ Items number 1 and 2 completed below. A copy is retained for use when vaccine emergency transfer is necessary.

In the event of site power failure, pending natural disaster, or other emergencies which could compromise vaccine viability, vaccines may need to be transported to an alternate location. **In the event of refrigerator or freezer malfunction or failure, vaccine must be relocated to an alternate location or back-up unit.** Prior approval by the Vaccine Program is not required. However, a Vaccine Tracking Transport Sheet must be completed and emailed or faxed (518-449-6912/nyvfc@health.ny.gov) to the VFC program. If vaccine temperatures go out of acceptable range for any length of time, the VFC program must be contacted (1-800-543-7468).

1. **RESPONSIBLE STAFF**

   The vaccine coordinator, or the back-up coordinator is responsible for making the decision whether vaccine relocation is necessary. These individuals must have after hour office access.

   The vaccine coordinator or back-up coordinator will be available 24/7 as the point person to contact the emergency relocation site to ensure it is prepared to accept the vaccines. The vaccine coordinator and/or back up coordinator are responsible to pack and relocate the vaccines.

   Staff Designated to Respond to Emergencies:

Position	Name	Non-office Phone contact #
Vaccine Coordinator		
Backup Coordinator		

Additional Staff		

2. ALTERNATE or BACKUP LOCATION

VFC provider sites must have a designated site to transfer all VFC vaccines to in an emergency. The alternate site must have the capacity to store the entire public vaccine inventory. The designated contact person must have 24/7 access to the alternate location.

Alternate Site	Contact Person	Telephone

3. PACKING PROCEDURE

A) Be prepared before the emergency. Know where packing supplies are located. Packing supplies include:

i. Portable vaccine refrigerator and freezer units are the best option for transport
ii. Hard sided coolers or Styrofoam™ vaccine containers are acceptable. Coolers must be large enough to accommodate an average supply of vaccine, including influenza and all required packing materials.
iii. Enough conditioned frozen water bottles for two layers inside cooler; 16.9 oz. for medium/large coolers or 8 oz. for small coolers.
iv. Cushioned insulating materials, including; bubble wrap, packing foam,
v. Corrugated cardboard
vi. Digital data logger (DDL) with buffered probe
vii. Refrigerated/Frozen Vaccine Transport Tracking Sheet

B) Once it is determined that vaccine must be transported to ensure their viability, the following procedure must be followed to pack refrigerated vaccines:

i. Open affected units only when necessary and only after all preparations for packing and moving vaccine have been made.
ii. Condition frozen water bottles by placing in a sink filled with several inches of cool or lukewarm water until a layer of water forms near the surface of the bottles. The ice block spins freely when rotated.
iii. Line bottom of the cooler with a single layer of dried, conditioned water bottles.
iv. Place one sheet of corrugated cardboard over the water bottles to cover completely.
v. Place a one inch layer of bubble wrap, packing foam, or Styrofoam™ on top to cover the cardboard completely.
vi. Place boxes of vaccine and diluents on top of insulating materials.
vii. Place DDL buffered probe in center of the vaccines. Keep DDL display outside cooler until finished packing.
viii. Cover vaccine with another inch of insulating material.
ix. Place another layer of corrugated cardboard on top of the insulating material.
x. Place another layer of dried, conditioned water bottles on top.
xi. Close and secure the lid and attach the DDL display.
xii. Document transfer information on Refrigerated/Frozen Vaccine Transport Tracking Sheet and affix to transport container. Temperatures are to be maintained between 36°F and 46°F (2°C and 8°C).

C) To pack frozen vaccine:

i. Follow steps for packing refrigerated vaccines but use FROZEN water bottles (not conditioned).
ii. If transporting frozen vaccine in the same container as refrigerated vaccine, pack refrigerated vaccine first and place insulating material around refrigerated vaccine. Place rubber bands around frozen vaccine to aid in identification.
iii. Do NOT use frozen vaccine if it was transported at refrigerated temperatures. Contact the manufacturer for guidance on viability of the vaccine.

New York State Department of Health (NYSDOH) Bureau of Immunization
Vaccine Storage and Handling Plan

Primary Provider/Practice Name: _____ PIN # (if renewal) _____

4) Procedures for Transporting Vaccine:

A) Staff responding to vaccine emergency must stay with the vaccine during transport and promptly place in appropriate storage unit(s) upon arrival.

B) If transporting vaccine in a vehicle, use the passenger compartment, never the trunk.

C) **Before opening cooler**:

i. Record time, temperature of vaccine, and temperature of receiving storage unit on the Refrigarated/Frozen Vaccine Transport Tracking Sheet.
ii. Immediately transfer vaccine to alternate storage units.
iii. Contact the VFC program (800-543-7468) if vaccine temperatures were out of normal range at any time during the vaccine emergency. Any potentially affected vaccine should be quarantined until viability is determined.

REQUIRED SIGNATURES

We agree to implement the storage and handling plan outlined in this document. In the event of any situation which could potentially compromise the efficacy of VFC or VFA vaccine we will comply with the emergency procedures provided.

Medical Director or Equivalent:

_____ _____ _____
Name (Print) **Title (Print)** **Email Address (Print)**

_____ _____
Medical Director or Equivalent Signature **Date**

Primary Vaccine Coordinator:

_____ _____ _____
Name (Print) **Title (Print)** **Email Address (Print)**

_____ _____
Primary Vaccine Coordinator Signature **Date**

Back-up Vaccine Coordinator:

_____ _____ _____
Name (Print) **Title (Print)** **Email Address (Print)**

_____ _____
Back-up Vaccine Coordinator Signature **Date**