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)_____

Vaccines need to 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. At the end of each section you will find space to provide comments on any of the required elements with which your practice/facility is currently out of compliance. In this space, indicate the element(s) the practice/facility is out of compliance with and the anticipated date that compliance will be achieved. Refer to: https://www.health.ny.gov/prevention/immunization/vaccines_for_children.htm Storage & Handling Requirements, for guidance.

PERSONNEL

1. 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:_____

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

EDUCATION

1. The medical director or equivalent, the primary and back-up VFC/VFA coordinator have participated in the CDC's You Call the Shots, Module 16, Vaccines for Children training and You Call the Shots, Module 10, Vaccine Storage and Handling training (**NYS VFC/VFA requirement**). An additional optional training is also recommended: CDC's YouTube video "Keys to Storing and Handling Your Vaccine Supply".

   Date(s) of training for the medical director or equivalent: _____

   Date(s) of training for primary coordinator: _____

   Date(s) of training for back-up: _____

If required trainings for any of the above persons is not up-to-date, provide the position and the date training is anticipated:

EQUIPMENT and TEMPERATURE MONITORING

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

Refrigerator Unit:

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

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)_____

Thermometer Type:
☐ Digital with Probe Encased in Buffered Media (glycol,sand, etc)
☐ Data Logger or Continuous Temperature Monitoring Device
☐ Other, describe:
_____

Thermometer Brand:	Calibration Expiration Date: ____/_____/_____

Notes: Newly enrolled providers are required to have stand alone refrigerator and freezer units.
All new units purchased must be stand alone units.
Dormitory style refrigerator/freezer units are never acceptable.

Additional VFC/VFA Refrigerator Unit(s):

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

Thermometer Type:
☐ Digital with Probe Encased in Buffered Media (glycol,sand, etc)
☐ Data Logger or Continuous Temperature Monitoring Device
☐ Other, describe:
_____

Thermometer Brand:	Calibration Expiration Date: ____/_____/_____

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

Thermometer Type:
☐ Digital with Probe Encased in Buffered Media (glycol,sand, etc)
☐ Data Logger or Continuous Temperature Monitoring Device
☐ Other, describe:
_____

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)_____

VFC/VFA Freezer Unit:

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

Thermometer Type:
☐ Digital with Probe Encased in Buffered Media (glycol,sand, etc)
☐ Data Logger or Continuous Temperature Monitoring Device
☐Other, describe:
_____

Thermometer Brand:	Calibration Expiration Date: ____/_____/_____

Additional VFC/VFA Freezer Unit:

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

Thermometer Type:
☐ Digital with Probe Encased in Buffered Media (glycol,sand, etc)
☐ Data Logger or Continuous Temperature Monitoring Device
☐Other, describe:

Thermometer Brand:	Calibration Expiration Date: ____/_____/_____

Backup Thermometer:

Thermometer Type:
☐ Digital with Probe Encased in Buffered Media (glycol,sand, etc)
☐ Data Logger or Continuous Temperature Monitoring Device
☐Other, describe:

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)_____

Carefully review all of the following required elements. Each element is a NYS 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 label 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 each contain 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. 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. 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. Ideally, temperature monitoring devices will have continuous temperature monitoring capability, or be a digital data logger with an alarm or alert system that indicates when the temperature may be out of a preset range. All temperature monitoring devices are capable of displaying minimum/maximum* temperatures. **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) on a temperature log (provided by the Immunization Action Coalition (IAC) at http://www.immunize.org) twice a day and entered in the New York State Immunization Information System (NYSIIS) within 14 days of the date the temperature was read.
8. Temperatures are measured and recorded at the beginning and end of each clinic day regardless of whether there is a temperature alarm system or some form of continuous temperature monitoring in place, such as a digital data logger.
In this space list any EQUIPMENT and/or TEMPERATURE MONITORING requirements that are out of compliance (by number) and provide the anticipated date that compliance will be achieved:

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.

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

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

4. Expiration dates are monitored and stock is rotated to ensure short-dated is used first..
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).
In this space list any REFRIGERATOR and/or FREEZER SET-UP requirements that are out of compliance (by number) and provide the anticipated date that compliance will be achieved:

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.
In this space list any VACCINE DELIVERY requirements that are out of compliance (by number) and provide the anticipated date that compliance will be achieved:

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# in a calendar month.
3. All immunizations, including VFC eligibility, are documented using 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.

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

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

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.

In this space list any VACCINE INVENTORY MANAGEMENTrequirements that are out of compliance (by number) and provide the anticipated date that compliance will be achieved:

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

In this space list any VACCINE ADMINISTRATION requirements that are out of compliance (by number) and provide the anticipated date that compliance will be achieved:

VACCINE EMERGENCY PLAN

If your site/facility has a Vaccine Emergency Plan, submit for approval when faxing this completed document to the VFC Program.

If your site/facility does not have a Vaccine Emergency Plan, complete the attached Vaccine Emergency Plan and submit for approval when faxing this document to the VFC Program.

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)_____

We agree to implement the storage and handling plan outlined in the previous pages. Changes will be implemented for any requirements that are listed as out of compliance by the anticipated date 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