Effective Date: _____ Annual Review Date: _____

Approved By: _____

VACCINE STORAGE AND HANDLING PLAN

This document offers guidance to develop vaccine storage and handling plans to safeguard vaccine supplies and guidance during improper vaccine storage and handling events.

VACCINE STORAGE AND HANDLING GUIDELINES

1. TRAIN STAFF/POST INFORMATION

Post the Vaccine Storage and Handling Plan on or near the vaccine storage equipment and ensure that all staff is trained regarding the plan.

- ☐ Vaccine Storage and Handling plan is posted on or near storage unit.
- ☐ All staff is trained on plan. (Minimum of yearly)

2. DESIGNATED PERSON(S)

Designate a primary and a backup person to:

a. Monitor the operation of the vaccine storage equipment and systems.
b. Set up and maintain a monitoring/notification system during times of inclement weather or other conditions that would create a shut down in power.
c. Assure the appropriate handling of the vaccine during the disaster or power outage.
d. Assure access to the building where vaccines are stored 24 hours per day.

Primary Person:	Phone:
Secondary Person:	Phone:
Additional Staff:	Phone:

3. STORAGE REQUIREMENTS

Maintain proper temperatures in the refrigerator (2-8° C or 35-46° F) and in the freezer (-15° C or 5° F or colder). To maintain even temperatures place plastic containers of water in the refrigerator and cold packs in the freezer. Store vaccine on refrigerator shelves in open containers and away from walls and the back of the unit to allow proper air circulation around the vaccine. Vaccine should never be stored in the door of the refrigerator, vegetable containers/bins (crisper) or on the bottom of the refrigerator. A primary and backup thermometer should be placed in both the refrigerator and freezer unit.

- ☐ Proper temperatures for refrigerator and freezer are posted on unit.
- ☐ Bulk water/cold packs are present in unit. (Unless otherwise specified by the manufacture of the purpose built storage unit)
- ☐ Vaccine is stored in center of unit in open containers to allow for air circulation.
- ☐ Vaccine is not stored in the door of the unit, crisper, or in the bottom of the unit.
- ☐ Primary and backup thermometer is in place in each unit (both refrigerator and freezer).

4. EQUIPMENT SAFEGUARD

Post warning signs on the refrigerator and/or on the plug to prevent inadvertent unplugging of the unit. Label fuses and circuit breakers to clearly identify power source to vaccine storage unit. Do not plug unit into ground fault interrupter (GFI) outlets. When the GFI is tripped the circuit is broken, causing electricity failure to the unit. Do not use an extension cord to plug in the storage unit. Assure doors are shut tightly.

- ☐ Warning signs (i.e., Do Not Unplug) are posted on the refrigerator and on the outlet.
- ☐ Fuses and circuit breakers that support vaccine storage units are clearly marked.
- ☐ The vaccine storage unit is not plugged into a GFI outlet or an extension cord.
- ☐ Doors close appropriately and are free from defect.

5. RECEIVING VACCINE

Develop and post a protocol for accepting vaccine deliveries that indicates who in the practice may accept vaccine shipments to ensure that vaccines are stored appropriately **IMMEDIATELY** after arrival. Train staff on how to compare the vaccine received with the vaccine invoice.

Alert the Vaccines for Children (VFC) Program at 1-800-831-6293 if the vaccine is not in proper condition or the number of doses is different than what is on the invoice. Train staff on storage and handling requirement for each vaccine.

- ☐ Protocol is posted for all staff regarding vaccine deliveries and whom to contact regarding vaccine shipments.
- ☐ Clinic staff assure vaccine shipments are stored properly immediately upon arrival.
- ☐ Clinic staff is trained on how to compare vaccine received to vaccine invoice and will alert the VFC Program if vaccine doses do not match the invoice or if they are not in proper condition upon arrival.
- ☐ Maintain vaccine packing slips for both VFC and Private vaccine inventory.
- ☐ Clinic staff is trained on storage and handling requirements for each vaccine.

6. ROTATE STOCK

Ensure that vaccine with the most current expiration dates are used first and are in front of vaccines with longer expiration dates. Check and rotate your stock monthly or when new vaccine inventory arrives.

- ☐ Clinic staff is trained regarding stock rotation.
- ☐ Clinic staff rotates stock when new vaccine is added to inventory.

7. TEMPERATURE MONITORING

The designated person checks and records refrigerator and freezer temperatures at least twice daily (at the beginning and end of each day). Storage temperatures should be recorded on a temperature log and maintained for at least 3 years. This is useful in identifying the duration of temperature variations. The backup person should review the temperature log on a weekly basis to assure proper temperature recording. If a temperature outside of the recommended range is found, immediate action should be taken to correct the problem as outlined in standard operating procedures for improper vaccine storage and handling section. Establish a protocol to alert staff to altered power supply during weekends and holidays. The protocol should include the specific methods and criteria for notifying the designated person(s) of problems.

- ☐ Refrigerator and freezer temperatures are checked and documented twice daily.
- ☐ Storage temperature logs are maintained for at least 3 years for each unit.
- ☐ The designated backup person reviews temperature logs at least weekly.
- ☐ Clinic staff is trained to take immediate action if temperatures are out of range.
- ☐ A protocol is in place to alert staff to altered power supply on weekends and holidays and notification of designated persons.
- ☐ Primary and backup thermometer is in place in each unit (both refrigerator and freezer).

8. VACCINE SPECIAL INSTRUCTIONS

Review the current guidelines for handling of individual vaccines that may include special instructions (i.e., protect from light, shelf life after reconstitution). Understand package inserts for new vaccines before using. Additional references include "Vaccine Management: Recommendations for Handling and Storage of Selected Biologicals" produced by the Centers for Disease Control and Prevention (CDC). (Pinkbook,
Appendix C)

- ☐ Staff is trained on guidelines for handling individual vaccines with special instructions.
- ☐ Staff who administer vaccine have read and understand package inserts prior to administering vaccine.
- ☐ Staff has access to Vaccine Management: Recommendations for Handling and Storage of Selected Biologicals and the CDC Pinkbook.

9. BACKUP SUPPLIES/FACILITY

It is important to have a backup plan to appropriately store vaccine which may include a backup generator or identify a location with one. This may be the local hospital, retirement home, fire station or police station. Make formal arrangements (Memorandum of Understanding) with the site to maintain vaccine if your vaccine storage equipment malfunctions or there is a power outage. Train a designated person and backup person at the facility to accept your vaccine if it must be moved. Before moving your vaccine, call the location to ensure that their backup generator is working. In situations where a location with a backup generator cannot be identified within a reasonable distance, preparations should be in place to store vaccine in coolers. (coolers, frozen ice packs and/or dry ice to temporarily store vaccine).

BACKUP FACILITIES CONTACT INFORMATION

Name of Facility	Primary & Backup Contact	Contact Phone Number Work/Home/Cell

10. EMERGENCY CONTACT LIST

List of emergency phone numbers, companies, and points of contact:

1. Electric Power Company: _____
2. Temperature Alarm Monitoring Company: _____
3. Refrigerator Repair Company: _____
4. Transportation to Backup Storage: _____
5. Dry Ice Vendor: _____
6. Emergency Generator Repair Company: _____
7. National Weather Service: _____

11. FACILITY FLOOR PLAN

Entering vaccine spaces: Describe, when necessary, how to enter the building and vaccine storage spaces in an emergency if closed or after hours. Include a simple floor diagram (does not need to be a blue print) and the locations of:

1. Storage units: _____
2. Doors: _____
3. Flash lights: _____
4. Spare batteries: _____
5. Light switches: _____
6. Keys: _____
7. Locks: _____
8. Alarms: _____
9. Circuit breakers: _____
10. Packing materials: _____

IMPROPER VACCINE STORAGE AND HANDLING
STANDARD OPERATING PROCEDURE

1. ASSESS THE SITUATION

1. Determine the cause of improper vaccine temperatures (i.e., mechanical failure, power outage, natural disaster, human error).
2. Store the vaccines at appropriate temperatures. Determine if vaccine should be moved and move if appropriate.
3. Record the current temperature of the refrigerator/freezer.
4. Mark the vaccine so that the potentially compromised vaccines can be easily identified and not used until efficacy of vaccine is determined.
5. Collect essential data on the Emergency Vaccine Response Worksheet.
6. Call all manufacturers of affected vaccine(s).
7. Call the Iowa Immunization Program (1-800-831-6293) after consultation with vaccine manufactures.

2. PACKING VACCINE

1. Open refrigerated units only when absolutely necessary and only after you have made all preparations for packing and moving the vaccine to alternative storage sites.
2. Use insulated containers. (i.e., coolers)
3. Pack the refrigerated vaccines first with an adequate supply of cold packs (add packing material so that cold packs are not in direct contact with the vaccine).
4. In a separate insulated container remove and pack varicella containing vaccine, using dry ice, immediately before it is to be transported.
5. Include a thermometer with the vaccine in each insulated container to monitor the vaccine temperature during transport.

3. MOVING VACCINE

1. If alternative storage is available within your facility transfer vaccine to that storage unit. If not, contact your backup facility to notify them of your refrigerator/freezer failure and the need to store vaccine at their location.
2. Prior to transporting vaccine, record the temperature of the refrigerator(s) and freezer(s) units. This will provide data on the maximum temperature and duration of exposure of vaccine to inappropriate temperatures.
3. Conduct an inventory before you transport the vaccine.
4. Transport the vaccine following proper cold chain procedures for storage and handling.
5. Isolate and maintain vaccines at appropriate temperatures and do not administer or discard vaccine until you have contacted the Iowa Immunization Program (1-800-831-6293) for consultation.

4. POST EVENT

Keep exposed vaccine separated from unaffected vaccine and any new vaccine you receive. Maintain vaccines at appropriate temperatures and do not administer or discard any potentially exposed vaccine until you have contacted the Iowa Immunization Program (1-800-831-6293) for consultation.

EMERGENCY VACCINE RESPONSE PLAN

Post on outside of refrigerator

Primary Person:	Phone:
Secondary Person:	Phone:
Person with 24 hour access:	Phone:
Additional Staff:	Phone:

Emergency Contact List:
If you do not have a generator, identify a location with one. (Hospital, Police or Fire Station, Retirement Facility)

Primary Location Name:	Phone:
Secondary Location Name:	Phone:

Call the backup location site to ensure the facility has power or that their generator is working.

Electric Power Company:	Phone:
Refrigerator Repair Company:	Phone:
Temperature Alarm Monitoring Company:	Phone:
Transportation to Backup Storage:	Phone:
Dry Ice Vendor:	Phone:
Emergency Generator Repair Company:	Phone:
National Weather Service:	Phone:

Vaccine Storage and Handling Events:

1. Determine the cause of improper vaccine temperatures (i.e., mechanical failure, power outage, natural disaster, human error).
2. Store the vaccines at appropriate temperatures. Determine if vaccine should be moved and move if appropriate.
3. Record the current temperature of the refrigerator/freezer.
4. Mark the vaccine so that the potentially compromised vaccines can be easily identified and not used until efficacy of vaccine is determined.
5. Collect essential data on the Emergency Vaccine Response Worksheet.
6. Call all manufacturers of affected vaccine(s).
7. Call the Iowa **Immunization Program (1-800-831-6293)** after consultation with vaccine manufactures.

EMERGENCY VACCINE RESPONSE WORKSHEET

Clinic Name: _____ VFC PIN: _____

1. Date of event: _____
2. Current temperature of refrigerator: _____ Max/min temperature reached: _____
3. Current temperature of freezer: _____ Max/min temperature reached: _____
4. Amount of time temperature was outside normal range: refrigerator _____ freezer: _____

REFRIGERATOR

Vaccine/ Manufacturer	Lot Number	Expiration Date	Number of Doses	Opened Vials	Manufacturer Recommendations

FREEZER

Vaccine/ Manufacturer	Lot Number	Expiration Date	Number of Doses	Opened Vials	Manufacturer Recommendations

VACCINE MANUFACTURERS

Vaccine	Manufacturer	Phone
IPV, Tripedia, Daptacel, TriHIBit, DT, Td, ActHib, Fluzone, RIG, Imovax, JE-VAX, Menomune, Typhim Vi, YF-VAX, Adacel, Menactra, Pentacel, Decavac, PPD	Sanofi Pasteur	1-800-822-2463
Recombivax HB, MMR, Varivax, PedvaxHIB, Comvax, Pneumovax, Vaqta, RotaTeq, Gardasil, Zostavax, ProQuad	Merck	1-800-672-6372
Infanrix, Pediarix, Engerix B, Havrix, Twinrix, Boostrix, Fluarix, Kinrix, Rotarix, FluLaval, Cervarix, Hiberix	GlaxoSmithKline	1-888-825-5249
Prevnar	Wyeth/Pfizer	1-800-999-9384
Immune Globulin	Talecris	1-800-520-2807
Nabi HB (Hep B Immune Globulin)	Nabi	1-800-458-4244
Synagis, Flumist	MedImmune	1-877-633-4411
RabAvert, Fluvirin, Agriflu, Menveo	Novartis	1-800-244-7668
Vivotif	Berna	1-800-533-5899
Afluria	CSL Biotherapies	1-888-435-8633