Temperature Excursion Protocol

If vaccines are exposed to inappropriate storage conditions, the viability of the vaccines may be affected. In the event of a temperature excursion or an alarm of the digital data logger, follow the steps below:

1. Consult your Vaccine Management Plan and ensure the primary and/or backup vaccine coordinator is notified.
2. Take an inventory of the affected vaccines, place them in a brown paper bag labeled "DO NOT USE" or label the outside of the storage unit with “DO NOT USE”.
3. If the primary storage unit is at acceptable temperatures, vaccines may remain in the unit. If the primary unit is still showing temperatures out-of-range, move the vaccines to the back-up storage location.
4. Download the digital data logger information to determine the length of the excursion and the temperatures reached.
5. Contact the vaccine manufacturers with the information gathered from the digital data logger. You will need to supply them with the vaccine name, the total amount of time they spent out of range and the temperatures that were recorded during that time. The manufacturer’s stability representative will supply you with a case number and a determination of the vaccine’s viability. If the manufacturer offers an on-line stability calculator, you may use those, include a printed copy of the results with your completed incident report.

   Merck 1-800-672-6372
   Sanofi Pasteur 1-800-822-2463
   GlaxoSmithKline 1-877-475-6448
   Seqirus 1-855-358-8966
   AstraZeneca 1-877-533-4411
   Dynavax Technologies 1-844-375-4728
   Pfizer 1-800-438-1985 or email cvgovernment@pfizer.com
   Moderna 1-866-MODERNA (1-866-663-3762) or email excursions@modernatx.com
   Janssen 1-800-565-4008 or email jscovidtempexcursions@its.jnj.com
   Bavarian Nordic 1-844-422-8274

6. Complete a Vaccine Storage & Handling Incident Report and send to your Field Representative or email to VaxColdChain@ky.gov

Inappropriate storage conditions and all mechanical malfunctions or power outages must be documented on the Incident Report.

Mark the boxes of vaccines deemed viable by the vaccine manufacturers after an excursion to easily determine if the same inventory is exposed in the event of another excursion.

Vaccines deemed non-viable and inadvertently administered should not be counted as valid doses and appropriate VAERS report should be completed.

Do not create a return or discard non-viable vaccines until your Field Representative or the Storage & Handling Coordinator provides further instructions.

Vaccine Storage Incident Report

Clinic Name: _____ PIN: _____

Vaccine Coordinator Name: _____ Phone: _____

Email: _____

Send a completed incident report, signed by the provider, to assigned Immunization Field Rep or to VaxColdChain@ky.gov

Incident Information

Date & Time of Incident: _____

Which unit was involved in the excursion?	Refrigerator		Freezer
Select the type of unit	Purpose Built	Pharmaceutical grade	Stand-Alone
Are the unit temperatures back within range?	Yes		No
Have the vaccines previously been exposed in a temperature excursion	Yes Date of previous excursion:		No
What were the minimum and maximum temperatures?	Min °F:		Max °F:
How long were the temperatures out of range?	Hours:		Mins:
Were there water bottles in this unit?	Yes		No
Have any of the vaccines been administered after the temperature incident occurred?	Yes		No

Incident Cause:

- ☐ Weather related power outage
- ☐ Failure to store properly upon receipt
- ☐ Equipment malfunction
- ☐ Damaged in shipment
- ☐ Failure to respond to out-of-range temperatures
- ☐ Other:_____

Affected Vaccines

Inventory				**Manufacturer's Instructions**		
Vaccine	Lot Number	Expiration Date	# of doses	Instructions	Case Number	Viable?

Detailed description of the incident: Please describe when, where, and how the incident occurred.

Written detailed action taken (include time and dates):

_____

_____

_____

_____

_____

_____

Corrective Action Plan: What steps are being taken to ensure similar loss does not occur in the future?

_____

_____

_____

_____

_____

_____

Signature of person completing this report: _____ Date: _____

Required Signature of Medical Director: _____Date: _____