

PFIZER BIONTECH VACCINE

SECTION 2: STORAGE AND HANDLING PER UNIT – ULTRA-COLD STORAGE

(UNIT #___)

SECTION 2 STORAGE AND HANDLING PER UNIT	
DESCRIPTION	<p>Name this unit with a description that will allow you or someone else from your program to easily identify it in the event of follow-up. We recommend using make and serial number (e.g., Thermo-Fisher-S123456789): _____</p> <p>Repeat this instrument for EACH UNIT OF ULTRA-COLD STORAGE ON SITE.</p>

QUESTION 2.3 STORAGE AND HANDLING PER UNIT: ULTRA COLD FREEZER	
INSTRUCTIONS	Determine whether there is a temperature monitoring device located in this section of the storage unit and answer the questions below.
SUBQUESTION A (Choose one)	Is there a temperature monitoring device located in the ultra-cold freezer? <input type="checkbox"/> Yes <input type="checkbox"/> No [Complete appropriate action(s) in the "Immediate Action" section below]
NOTE TO OBSERVER	If the storage unit lacks a temperature monitoring device, immediate action is required. For temperature data (i.e., temperature readings) to be <u>useable</u> , temperatures must have been assessed using an appropriate working, temperature monitoring device. Temperature data must have been assessed and recorded within the last 72 hours to be considered recent.
SUBQUESTION B (Choose one)	Is temperature data recorded for the past 72 hours showing temperature ranges between -80°C and -60°C <input type="checkbox"/> Yes <input type="checkbox"/> No [Complete appropriate action(s) in the "Immediate Action" section below]
REVIEW REQUIREMENTS	Review recommendation with site staff: Vaccination providers should have a working, temperature monitoring device and temperature log. CDC recommends a specific type of temperature monitoring device called a "digital data logger" (DDL). A DDL provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a "temperature excursion"). Unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit, a DDL provides detailed information on all temperatures recorded at preset intervals. Note that these are recommended practices but not required under current vaccine distribution awards/contracts.
SUBQUESTION C (Choose one)	Is a DDL used to record temperature data in this unit? <input type="checkbox"/> Yes <input type="checkbox"/> No
NONCOMPLIANCE	If noncompliance has been identified, complete the elements below.
IMMEDIATE ACTION	Note the specific action taken at the provider site based on your review of the current unit temperature and the recent available temperature data for this section of the storage unit: 1. If no recent, usable temperature data are available: suspend use of the vaccine, request that the vaccine provider contact Pfizer at 800-438-1985 for additional information and follow up. 2. If recent, usable temperature data indicate the unit temperature was out of range: suspend use of the vaccine, request that the vaccine provider contact Pfizer at 800-438-1985 for additional information and follow up.

QUESTION 2.4 STORAGE AND HANDLING PER UNIT: VACCINE PLACEMENT	
INSTRUCTIONS	Review the below questions visually if it can be done without temperature excursions of the ultra-cold freezer. If not possible or using a thermal shipper, confirm verbally
SUBQUESTION A (Choose one)	Are vaccines stored in their original packaging (wrapped trays)? <input type="checkbox"/> Yes <input type="checkbox"/> No
REVIEW CDC RECOMMENDATION	Review recommendation with site staff: Vaccines should be stored in their original manufacturer (or CDC centralized distributor) packaging - vaccines should only be unwrapped from their original trays immediately prior to being thawed and should be out of ultracold storage for no more than 3 minutes before it is considered thawed. It is recommended to only store vaccines in a unit, however, if other biologics must be kept in the unit the vaccines should be on a separate shelf above the biologics. Note that these are recommended practices but not required under current vaccine distribution awards/contracts.
ADDING FREEZER REMINDER	Is there another freezer? If so, please use another copy of this section to add another freezer.