COVID-19 Vaccine Guidance

Federal Bureau of Prisons Clinical Guidance

January 4, 2021

Federal Bureau of Prisons (BOP) Clinical Guidance is made available to the public for informational purposes only. The BOP does not warrant this guidance for any other purpose, and assumes no responsibility for any injury or damage resulting from the reliance thereof. Clinical guidance may be adapted for the unique situations that present within BOP correctional facilities. Proper medical practice necessitates that all cases are evaluated on an individual basis and that treatment decisions are individual-specific. Referenced Program Statement versions within this guidance are for informational purposes only. Please refer to the most current versions of any referenced Program Statement(s). Consult the BOP Health Management Resources Web page to determine the date of the most recent update to this document: http://www.bop.gov/resources/health_care_mngmt.jsp

What's New

PREVIOUS VERSIONS

- Updates to Employee and Inmate consents
- Pregnancy added to Priority 2 category

VERSION 5.0

- Addition of Moderna COVID-19 vaccination information throughout the document
- Updates to expiration dates: Unless otherwise specified, date is found on the vial.
- Updates in Vaccination of Individuals with Underlying Medical Conditions to include persons with autoimmune conditions, history of Guillain-Barré syndrome, or history of Bell's palsy.
- Updates to Appendix 4. COVID-19 Vaccine Consent Form for Employees

VERSION 6.0

- Updates to expiration dates: for Pfizer, dates is found on vial; for Moderna, date is found online
- Updates to Moderna Onsite Vaccine Preparation to include special considerations for transportation: Once thawed, the Moderna vaccine is sensitive to movement and information has been added to ensure stability of the vaccine.
- Reordering of appendices with addition of Appendix 5. COVID-19 Vaccine Consent Form for Inmates SPANISH.

VERSION 7.0

Updates to Screening for Precautions and Indications to include the following:

- Defining an immediate allergic reaction as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.
- Identifying contraindications to either of the mRNA COVID-19 vaccines as:
  - Severe allergic reaction (e.g, anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
  - Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])
  - Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)
- Expanding precautions to mRNA COVID-19 vaccines to include not only anaphylaxis but also any previous immediate allergic reaction to any other vaccine or injectable therapy
- Includes observation periods after vaccination as 30 minutes for any persons with a precaution to vaccination or a history of anaphylaxis due to any cause and 15 minutes for all other persons.
- Updates to Staff and Inmate Consent screening questions

Table of Contents

COVID-19 VACCINE

A. PURPOSE

The purpose of this guidance is to provide direction on use of the COVID-19 vaccine for all adults who meet the criteria established by the Bureau of Prisons (BOP), with guidance from the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC). The goal of this guidance is to promote vaccine use as a means of controlling pandemic transmission of SARS-CoV-2 (the virus that causes COVID-19) and reducing morbidity and mortality from this infection.

THE COVID-19 VACCINATION IS AN IMPORTANT TOOL TO HELP STOP THE PANDEMIC.

- The combination of getting vaccinated and following other CDC recommendations for protection offers the best protection from COVID-19 at the present time.

➔ *All current recommendations for preventing and managing SARS-CoV-2 infection should continue to be followed. This includes use of quarantine for vaccinated persons potentially exposed to the virus.*

- Wearing masks or cloth face coverings, whichever is appropriate given the circumstances, social distancing, avoiding larger group or public gatherings, limiting travel, and washing hands frequently help reduce the chances of being exposed to the virus or spreading it to others, but these measures are not enough. Vaccines work with the immune system so it will be ready to fight the virus if a person is exposed.
- Stopping a pandemic requires using all available tools. Recommendations will continue to be updated using the latest science.
- For general guidance related to vaccines including Immunization Key Principles and Storage and Handling of Immunizations, refer to t*he* BOP Immunization Clinical Guidance Document.

➔ *This module will be updated as new information becomes available (e.g., when new vaccine products become available and are used by the BOP and when vaccination indications change).*

COVID-19 VACCINES AUTHORIZED FOR USE

The following COVID-19 vaccines, which are mRNA-based vaccines, are authorized for use in the United States by the U.S. Food and Drug Administration through Emergency Use Authorization (EUA):

- The Pfizer-BioNTech COVID-19 vaccine: for persons 16 years of age and older
- The Moderna COVID-19 vaccine: for persons 18 years of age and older

➔ *CDC guidance for Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States is available at:* https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

PFIZER-BIONTECH COVID-19 VACCINE

The EUA fact sheets for the Pfizer-BioNTech COVID-19 Vaccine are available for the following groups:

- Recipients and caregivers: *https://www.fda.gov/media/144414/download*
- Healthcare providers administering vaccine: *https://www.fda.gov/media/144413/download*

MODERNA COVID-19 VACCINE

The EUA fact sheets for the Moderna COVID-19 Vaccine are available for the following groups:

- Recipients and caregivers: *https://www.fda.gov/media/144638/download*
- Healthcare providers administering vaccine: *https://www.fda.gov/media/144637/download*

B. PROCEDURE

Using this document, eligible healthcare professionals (as defined by scope of duty) may vaccinate adults who meet the indications below for COVID-19 vaccines upon successful completion of the manufacturer-specific COVID-19 vaccine skills checklists and signature sheets.

➔ *Appendix 1. Skills Checklist for COVID-19 Vaccine Administration*
➔ *Appendix 2. COVID-19 Vaccine Administration Signature Sheet*

1. Assess and prioritize vaccination if vaccine supplies are limited.

- Distribution and priority of vaccine administration will be directed by the Health Services Division of the BOP Central Office and through the local Clinical Director or designee based on COVID-19 risk and vaccine availability. It will align with the Centers for Disease Control and Prevention (CDC) and Advisory Committee on Immunization Practices (ACIP) recommendations for priority populations.
- Vaccine supply availability is expected to change as the BOP's COVID-19 immunization program progresses; therefore, planning should be focused and flexible. Since vaccine supply will initially be limited, allocation of vaccine doses has been prioritized by the BOP into priority levels (see below). However, vaccine supply is projected to increase over time, thus allowing for the expansion of vaccination efforts.
- Recommendations concerning BOP's priority levels and associated population groups may change based not only on vaccine availability but also on the availability of different COVID-19 vaccines, changing COVID-19 disease epidemiology, and local community factors.
- ***Testing for SARS-CoV-2 infection is NOT required prior to administering the COVID-19 vaccine*** unless otherwise clinically indicated. If SARS-CoV-2 testing is performed on a COVID-19 vaccine recipient, test results will not be adversely affected if a viral test is used (either molecular/PCR or antigen test).

EMPLOYEE VACCINATION:

Prior to initiating inmate vaccinations, vaccinations should first be offered to BOP employees, to include PHS officers assigned to the BOP.

- Vaccinating correctional staff will serve to decrease the possible introduction of SARS-CoV-2 into institutions and thus protect inmates. In the context of limited quantities of vaccine, the BOP recommends offering vaccination to staff first as the best way to achieve the greatest public health benefit to inmates, staff, and communities.
- If available vaccine supplies are low, the following ***employee sub-priorities,*** based on job functions that pose a higher risk for transmission of infection, should be considered in the order listed. These recommendations represent general guidance and may need to be adapted to meet the needs of individual institutions.
  - Staff with potential for close contact with sick persons (e.g. health care workers, workers in isolation or quarantine units, and those performing COVID-19 symptom screens and temperature checks)
  - Staff who are currently on COVID-19 related Temporary Job Modifications (TJM)
  - Staff in nursing care units and other residential health care units
  - Staff involved in R&D or performing inmate transfer or escort functions
  - Staff with other potential close contact with inmates (e.g. performing pat searches, supervising inmate work details)
  - All other staff

INMATE VACCINATION:

After offering vaccinations to all employees, institutions should proceed with offering vaccine to inmates using the following priorities.

- The following recommendations represent general guidance and may need to be adapted to meet the needs of individual institutions. For COVID-19 vaccinations, facilities must consider other local factors such as outbreak history, housing unit types, and individual clinical factors when vaccine supply is limited.
- Inmates admitted to quarantine (intake, exposure, or transfer) may be vaccinated. Using quarantine as an opportunity to vaccinate and achieve immunity can be beneficial in limiting transmission and outbreaks.
  - Inmates admitted to quarantine with mandatory release/transfer dates (e.g., full term releases or court-ordered transfers) may be considered for vaccination on a case-by-case basis. In situations where there is time to complete the multi-dose vaccine series prior to the inmate's departure, vaccination may proceed. However, if there is insufficient time to complete all doses, the COVID-19 vaccine series should not be started with the first dose unless continuity of care for the second dose can be assured at the receiving location (e.g., community or other correctional jurisdiction).
    - *CDC guidance for Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States including discussion of vaccinating patients in quarantine is available at:* https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

- *A medical hold should be placed when the first dose is administered and not removed until the due date of the second dose.*
- *Within each priority level, vaccine should be given until either all persons who requested vaccination have received it or until vaccine supply is exhausted.*

***Priority Level 1:* Inmates in health service unit job assignments and in certain housing situations**

- Inmates assigned as health service unit workers
  - Similar to correctional staff, vaccinating these inmates will serve to decrease the possible introduction of SARS-CoV-2 to an institution.
- Inmates in nursing care centers (long-term care) or other residential health care units

***Priority Level 2:* Inmates aged 65 years and older or those of any age meeting one or more of the CDC criteria for "are at increased risk" for severe illness from SARS-CoV-2**

- *Note - some inmates may have been covered in the priority one category*
- Health Services staff should use the BOP's electronic medical record (BEMR) and the COVID-19 vaccine dashboard to identify patients with the following conditions to prioritize for vaccination.
  - Inmates 65 years of age or older
  - Cancer
  - Chronic kidney disease
  - Chronic obstructive pulmonary disease (COPD)
  - Heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
  - Immunocompromised state from solid organ transplant
  - Obesity (body mass index [BMI] of 30 kg/m^2 or higher but less than 40 kg/m^2)
  - Severe obesity (BMI greater than or equal to 40 kg/m^2)
  - Sickle cell disease
  - Smoking (to include current and former smokers)
  - Type 2 diabetes mellitus
  - Pregnancy (For further discussion of vaccination of pregnant or lactating people see: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html*)

- *For the most current list of persons who are at increased risk for severe COVID-19 illness, refer to: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html*

***Priority Level 3:* Inmates aged 50 through 64 years or those of any age with certain underlying medical conditions who "might be at increased risk" for severe illness from SARS-CoV-2**

➔ *Note - some inmates may have been covered in the priority 1-2 categories*

- Health Services staff should use the BOP's electronic medical record (BEMR) and the COVID-19 vaccine dashboard to identify patients with the following conditions to prioritize for vaccination.
  - Asthma (moderate-to-severe)
  - Cerebrovascular disease (affects blood vessels and blood supply to the brain)
  - Cystic fibrosis
  - Hypertension
  - Immunocompromised state from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, or use of other immune weakening medicines
  - Neurologic conditions, such as dementia
  - Liver disease
  - Overweight (BMI greater than 25 kg/m^2 but less than 30 kg/m^2)
  - Pulmonary fibrosis (having damaged or scarred lung tissues)
  - Thalassemia
  - Type 1 diabetes mellitus

➔ *For the most current list of persons who might be at increased risk for severe COVID-19 illness, refer to: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html*

***Priority Level 4:* All other inmates**

- Upon completion of vaccine administration to all staff and inmates in the above priorities, Health Services staff should schedule vaccinations for all remaining inmates.

2. Screen patients for contraindications and precautions.

CONTRAINDICATIONS:

- ***Do not administer COVID-19 vaccines to any person with a known severe allergic reaction (e.g., anaphylaxis) OR with an immediate allergic reaction of any severity to a previous dose of the vaccine or to any component of the vaccine.***
  - An **IMMEDIATE ALLERGIC REACTION** is defined as: *any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.*
  - Both Pfizer-BioNTech and Moderna COVID-19 vaccine components include mRNA, sugars, lipids (e.g., [PEG]), salts, and buffers.
- ***Do not administer COVID-19 vaccines to any person with a known immediate allergic reaction of any severity to polysorbate.*** The PEG in the vaccines is structurally related to polysorbate and cross-reactive hypersensitivity between these compounds may occur.

- For additional information on product-specific vaccine components, refer to the:
  - FDA Emergency Use Authorization (EUA) fact sheet for the Pfizer-BioNTech COVID-19 vaccine at: *https://www.fda.gov/media/144413/download*
  - FDA Emergency Use Authorization (EUA) fact sheet for the Moderna COVID-19 vaccine at: *https://www.fda.gov/media/144637/download*
  - CDC guidance on the Interim Considerations for Clinical Use of mRNA COVID-19 Vaccines Currently Authorized in the United States (Appendix A. Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines) at: ***https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html***

PRECAUTIONS:

- ***Vaccination should be deferred for***
  - ***Patients with current SARS-CoV-2 infection until recovery from acute illness (if the person had symptoms) and criteria have been met to discontinue isolation.*** This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose. There is no minimal interval between infection and vaccination; however, evidence suggests reinfection is uncommon in the 90 days after initial infection.
  - ***Patients who received monoclonal antibody therapy*** for COVID-19 should defer vaccination for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses.
- ***Do not administer any other vaccination (e.g., seasonal influenza vaccine) 14 days before or after*** administering the first or second COVID-19 vaccine doses. If mRNA COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.
- ***Individuals with a moderate/severe acute non-COVID illness*** should be assessed clinically to determine whether they can be vaccinated or whether vaccination should be deferred. If administered a 15-minute observation period should be performed after vaccination.
- ***Individuals with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy (except those related to the COVID-19 vaccines or polysorbate, as noted above) should be assessed clinically*** to determine whether they can either be vaccinated or if vaccination should be deferred. In these situations, clinical assessment may include referral to an allergist-immunologist. If vaccine is administered, a 30-minute observation period should be performed after vaccination.
- ***Individuals with a history of anaphylaxis due to any cause that is not related to a vaccine or injectable therapy*** may proceed with vaccination provided a 30-minute observation period is completed.
- ***Those with other allergies (e.g., to oral medications, food, and pets) or a family history of anaphylaxis*** may proceed with vaccination followed by a 15-minute observation period.

For expanded guidance on the interim use of mRNA COVID-19 vaccines see:
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

3. ***Vaccination of individuals with underlying medical conditions:***
Both COVID-19 vaccines may be administered to persons with underlying medical conditions who have no contraindications to vaccination. Information on groups with specific underlying medical conditions is included below.

- ***Immunocompromised individuals:*** Data are not currently available to establish safety and efficacy of vaccine in these individuals (e.g., HIV infection, on immunosuppressive medication or therapies).
  - Immunocompromised persons may still receive the COVID-19 vaccine unless contraindicated.
  - Immunocompromised persons should be counseled about the unknown vaccine safety and efficacy profiles, the potential for a reduced immune response, and need to follow all current guidelines to protect themselves against COVID-19.
- ***Pregnant women:*** There are no data on the safety of COVID-19 vaccines in pregnant women. If a pregnant woman meets the criteria for vaccination and has no contraindications, she may choose to be vaccinated after discussion with her healthcare provider.
  - *Routine testing for pregnancy prior to COVID-19 vaccination is not recommended.*
- ***Breastfeeding/lactating women:*** There are no data on the safety of COVID-19 vaccines in these women or the effects of mRNA vaccines on the breastfed infant or milk production/excretion. mRNA vaccines are not thought to be a risk to the breastfeeding infant. If a breastfeeding/lactating woman meets the criteria for vaccination and has no contraindications, she may choose to be vaccinated after discussion with her healthcare provider.
- ***Persons with autoimmune conditions:*** No data are currently available on the safety and efficacy of COVID-19 vaccines in these individuals. Persons with autoimmune conditions who have no contraindications to vaccination may receive an mRNA COVID-19 vaccine.
- ***Persons with a history of Guillain-Barré syndrome:*** To date, no cases of Guillain-Barré syndrome (GBS) have been reported following vaccination among clinical trial participants. With few exceptions, ACIP's *general best practice guidelines for immunization* does not include history of GBS as a contraindication or precaution to vaccination. Persons with a history of GBS may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of GBS following mRNA COVID-19 vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).
- ***Persons with a history of Bell's palsy:*** Cases of Bell's palsy were reported following vaccination in participants in clinical trial participants. However, the FDA does not consider these to be above the frequency expected in the general population and has not concluded that these cases were causally related to vaccination. In the absence of such evidence, persons with a history of Bell's palsy may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of Bell's palsy following mRNA COVID-19 vaccination should be reported to VAERS.

4. Provide all patients with a copy of the approved EUA fact sheet.

- Review the manufacturer-specific COVID-19 vaccine EUA fact sheet with the patient and have them sign the BOP COVID-19 immunization consent/declination form (Refer to 7. Documentation for more information on vaccine consent).
  - *Appendix 4 and 5. COVID-19 Vaccine Consent Form for Inmates (English and Spanish versions)*
  - *Appendix 6. COVID-19 Vaccine Consent Form for Employees*
- Current COVID-19 vaccine EUA fact sheets for recipients are available only in English at this time and can be found at:
  - Pfizer- BioNTech COVID-19 Vaccine: *https://www.fda.gov/media/144414/download*
  - Moderna COVID-19 Vaccine: *https://www.fda.gov/media/144638/download*

5. On-Site vaccine receipt and storage.

PFIZER-BIONTECH COVID-19 VACCINE

- ***Vaccine allotments will be shipped directly from the manufacturer at ultra-low temperature (ULT)*** (-70˚C [-94°F], range -60°C to - 80°C [-76°F to -112°F]) to select BOP institutions, which will serve as ***hub sites*** or distribution points.
- Upon receipt, hub sites will immediately inspect vaccine for damage, then place into refrigeration storage temperatures (2˚C to 8˚C [36°F to 46°F]). Placement in refrigeration must occur as soon as feasible. If there is a delay of more than 2 hours from receipt to refrigeration, Central Office must be notified.
- The refrigerated vaccine should be collected by ***spoke site*** institutions (i.e., institutions that are within a 175 miles radius of the distribution point) as soon as possible.
- Immediately upon return to the spoke site, the vaccine should be placed into an appropriate refrigerator for storage until it is reconstituted and used.
- ***Communications will flow through the Vaccine Point of Contacts (VPOCs).*** Hub site VPOCs will be given notice prior to shipments and will coordinate the pick-up of vaccine with their spoke sites.
- ***The vaccine must be used within 5 days of removal from ULT storage, and institutions must keep up with the 5 day timeline***.
  - For institutions serving as spokes, the provided temperature data logger (temp tail) should immediately be started when the vaccine is placed into the provided cold shipper for transport. The temperature data log files created by the data logger will serve to document part of the 5-day window since they record dates and times at specific intervals. At all other times, institutions must develop their own method of documenting the 5-day timeline.
  - Vaccine doses not used after 5 days must be maintained in a separate area and labeled **"DO NOT USE"** until further instruction for disposal is available (***see Section 11 Disposal of expired or unused vaccine).***
  - If the hub institution removes the vaccine from ULT storage and places it in refrigeration before it is picked up by the spoke institution, the spoke institution must account for this time as part of the 5-day timeline in addition to the time accounted for by the data logger.

MODERNA COVID-19 VACCINE

- Vaccine allotments will be shipped by the vaccine distributor, McKesson, in a frozen state between -25°C to -15°C (-13°F to 5°F) directly to each institution.
- Upon receipt, sites will immediately inspect vaccine for damage, then place into refrigeration storage temperature (2°C to 8°C [36°F to 46°F]) using an appropriate refrigerator.
  - ***Once thawed, the vaccine CANNOT be re-frozen.***
- ***When stored refrigerated, the vaccine must be used within 30 days, and institutions must keep up with the 30-day timeline.***
  - Vaccine being transported to an administration site at temperatures others than frozen (-15 to -25°C) should begin with the vaccine in the frozen state if at all possible (i.e. if administration will begin immediately upon receipt of the vaccine.)
  - Prior to administration, thaw in refrigerator (2°C to 8°C [36°F to 46°F]) for 2 hours and 30 minutes *OR* thaw at room temperature between 15°C to 25°C (59°F to 77°F) for 1 hour.
  - Un-punctured vials may be stored between 8°C to 25°C (46°F to 77°F) for up to 12 hours.
  - Punctured vials must be used within 6 hours.
  - Refrigerated vials not used after 30 days, un-punctured vials stored between 8°C to 25°C [46°F to 77°F] not used after 12 hours, and punctured vials not used after 6 hours, must be maintained in a separate area and labeled **"DO NOT USE"** until further instruction for disposal is available (see ***Section 11. Disposal of expired or unused vaccine***).
- When thawed, the vaccine should be handled with care and protected from shocks, drops, vibration, etc.

6. On-Site Vaccine Preparation.

PFIZER-BIONTECH COVID-19 VACCINE

- ***Remove thawed vaccine from the refrigerator and allow it to come to room temperature***.
  - This will take less than 30 minutes.
  - Undiluted vaccine must *NOT* be out of the refrigerator for **more than 2 hours**.
  - Verify the vaccine and expiration date located on the vial.
- ***Reconstitute with 1.8 ml of 0.9% sodium chloride diluent prior to use.*** Prepare to add diluent to the vaccine vial in the following manner:
  - Invert the vaccine vial gently 10 times to mix. *DO NOT SHAKE*.
  - Obtain the diluent vial (i.e., sterile 0.9% Sodium Chloride Injection, USP).
  - Cleanse the vaccine and diluent vial stoppers with an alcohol swab.
  - Withdraw only 1.8 ml from the sodium chloride vial and inject that 1.8 ml into the vaccine vial using a 3 or 5 ml syringe with a 21 gauge needle found in the shipped ancillary kits. ***ONLY*** reconstitute vaccine that will be used within 6 hours.
  - Equalize pressure in the vaccine vial by withdrawing 1.8 ml of air into the empty diluent syringe prior to withdrawing the needle from the vaccine vial.
  - Engage the needle safety device (if present) prior to disposal in a sharps container.
  - Discard the remaining 0.9% sodium chloride solution regardless of fluid remaining. Do not reuse.

(steps continued on next page)

- Gently invert the vial containing the vaccine and diluent 10 times to mix. *DO NOT SHAKE.*
- Label the vial and record the date and time of dilution on the label.

➢ ***The vaccine vial now contains 5 (five) separate 0.3 ml vaccine doses, each with 30 mcg of vaccine product in a labeled, multi-dose vial***.

➢ Store the diluted, labeled, and ready to use multi-dose vaccine vial at refrigerated or room temperatures, between 2˚C to 25˚C (35˚F to 77˚F).

➔ ***Reconstituted vaccine must be used within 6 hours.***

MODERNA COVID-19 VACCINE

➢ Remove from refrigeration and allow the vaccine vial to come to room temperature for at least 15 minutes.

➢ Swirl the vaccine vial gently and between each withdrawal. *DO NOT SHAKE* and *DO NOT DILUTE* the vaccine.

➢ Visually inspect the vaccine vial before vaccine administration.

- The vaccine is a white to off-white suspension, and it may contain white or translucent product-related particulates
- If other particulate matter and/or discoloration are present, the vaccine should NOT be administered.
- Verify the vaccine and expiration date by accessing the manufacturer's website here: *https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup*. Enter the lot number and the expiration date will be displayed.

➢ The vaccine vial contains 10 (ten) separate 0.5 ml vaccine doses, each with 100 mcg of vaccine product in a labeled, multi-dose vial.

➢ Un-punctured, ready to use vials may be stored between 8°C to 25°C (46°F to 77°F) for up to 12 hours.

➢ After the first dose has been withdrawn, the vial should be held between 2°C to 25°C (36°F to 77°F) for up to 6 hours.

➢ Record the date and time of the first use on the vial label. Discard after 6 hours and do not refreeze.

- ***Special considerations for transportation:*** Once thawed, the Moderna vaccine is sensitive to movement and the following information has been provided by the manufacturer to ensure stability of the vaccine:
  - Punctured vials should not be transported.
  - Care must be taken to ensure vaccine does not re-freeze during transport.
  - Vaccine must be protected as much as possible from drops, shocks, and vibration whether in the carton, vial, case or cooler.
  - Vaccine should be transported in the carton whenever possible.
  - If transport must be conducted at the vial level, the vial should be placed with dunnage (padding material like bubble wrap or similar padding) to minimize movement during transport.
  - The vaccine should always be transported in insulated containers qualified to maintain 2-8°C for the duration of transport.
  - The transport containers must be secured when being transported to prevent unnecessary movement.
  - ***Vaccine should only be transported one time and should not be transported back again to the point of origin or to a new location.***
  - Allowable timelines for transport of thawed vaccine are shown below. Total transport time should not exceed 12 hours in total.
    - Transport while walking or using hand cart: not to exceed 1 hour
    - Vehicle transport: not to exceed 12 hours

7. Administer the COVID-19 Vaccine

COVID-19 Vaccine By Type	How Supplied	Dose/Volume/Schedule		Route	Age Indications	Key Points – See Document for Details
Pfizer-BioNTech COVID-19 Vaccine mRNA vaccine	Suspension **Multi-dose vial** (contains five, 0.3 ml doses after reconstitution)	**Dose**	30 mcg	IM	16 years of age and older	***Reconstitution and mixing required*** • When removed from ULT, vaccine must be used **within 5 days** • Once thawed, keep vaccine vial at room temp **no more than 2 hours**, *prior to dilution* • Reconstitute with **only 1.8 ml** of diluent (0.9% sodium chloride) • Use reconstituted vaccine **within 6 hours** • Egg, cell, latex and preservative free • **Contraindications:** Known severe allergy or anaphylactic reaction to any vaccine component OR to a previous dose of the vaccine • **Precautions:** 1. Current SARS-CoV-2 infection 2. Monoclonal antibody treatment within past 90 days 3. Other vaccines within the past 14 days 4. Moderate/severe acute non-COVID-19 illness 5. History of severe allergic reaction to another vaccine or injectable therapy • **Special populations:** underlying medical conditions, immunocompromised, pregnant, breastfeeding/lactating; persons with autoimmune conditions and history of Guillain-Barré syndrome or Bell's palsy.
		Volume	0.3 ml			
		Schedule	• 2-dose series, 17-21 days apart • 2nd doses should be given as close to the recommended interval as possible. However, there is no maximum interval between doses. • 2nd doses given earlier do not need to be repeated			
Moderna COVID-19 Vaccine mRNA vaccine	Suspension **Multi-dose vial** (contains ten, 0.5 ml doses)	**Dose**	100 mcg	IM	18 years of age and older	***No reconstitution required*** • Use refrigerated vaccine **within 30 days** • Use unrefrigerated and un-punctured vaccine vials **within 12 hours** • After 1st dose withdrawn, use vaccine **within 6 hours** • Egg, cell, latex and preservative free • **Contraindications, Precautions, and Special Populations: same** as **for Pfizer-BioNTech COVID-19 Vaccine** above**.**
		Volume	0.5 ml			
		Schedule	• 2-dose series, 24-28 days apart • 2nd doses should be given as close to the recommended interval as possible. However, there is no maximum interval between doses. • 2nd doses given earlier do not need to be repeated			

- ***Ancillary supply kits will be ordered automatically based on the number of vaccine orders and will arrive before or along with the vaccine***.
  - The kits will contain syringes, needles for reconstitution and administration, diluent, vaccination cards, and a limited amount of PPE supplies (i.e., face shields and gowns).
    - Employees should be provided with completed vaccination cards after being vaccinated.
  - Gloves and sharps containers are not included in the kits.
  - Institutions should store ancillary supplies for the COVID-19 vaccine separate from other similar supplies. Sharps sent in the kits should be stored and disposed of in accordance with BOP policy.
- ***Vaccine administration procedure***
  - ***To prevent syncope,*** have the patient sit or lie down for vaccination and consider observing the patient for 15 minutes after receipt of the vaccine.
  - Administer the reconstituted vaccine intramuscularly (22-25 g, 1-1½" needle) in the deltoid muscle; alternatively, the anterolateral thigh also may be used.
    ➔ See *Appendix 3. Administering Vaccines: Dose, Route, Site, and Needle Size*
  - Note: A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taut, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

- ***Specific COVID-19 vaccine considerations:***
  - The Pfizer-BioNTech COVID-19 Vaccine series is given in 2 doses (0.3 ml each) and scheduled 17-21 days apart.
  - The Moderna COVID-19 Vaccine series is given in 2 doses (0.5 ml each) and scheduled 24-28 days apart.
  - ***Second doses of the Pfizer-BioNTech and Moderna COVID-19 vaccines should be given as close to the recommended interval as possible***. However, there is no maximum interval between doses. Second doses given earlier do not need to be repeated.
  - ***No data exist on the interchangeability of COVID-19 vaccines.*** Individuals initiating a vaccine series by a particular manufacturer (i.e., Pfizer-BioNTech or Moderna) should complete the series using the same product since the vaccines are ***NOT*** interchangeable. However, if two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either vaccine are recommended at this time.
  - ***Routine prophylactic administration of antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) for the purpose of preventing post-vaccination symptoms is not currently recommended.*** Information on the impact of such use on mRNA COVID-19 vaccine-induced antibody responses is not available at this time. These medications may be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate.

8. Document administration and schedule the second vaccine dose.

- ***Inmate Vaccine Administration Documentation.*** Administration will be documented in the Patient Medical Record (BEMR). Under flow sheets and immunization, note the COVID-19 immunization administered from the drop down menu. Record the dose number, location, lot number, dosage, route, expiration date and provider.
  - If vaccine was not given, record the reason(s) (e.g., medical contraindication, refusal).
  - Utilize the comments section as needed.
  - Enter the second vaccine dose date in the scheduler and upon exiting, do not forget to save the immunization flow sheet data.
  - After administration of the first vaccine dose, place the patient on a medical hold in BEMR. **Do <u>not</u> remove the medical hold** until after the second vaccine dose has been administered.
    - *Patients refusing second doses should not be removed from a medical hold until the scheduled date of the second vaccine dose.*
- ***Employee Vaccine Administration Documentation.*** Administration will be documented in the Vaccine Administration Management System (VAMS) – a system developed by the CDC for COVID-19 vaccine management – no later than 24 hours after vaccine administration.

- ***COVID-19 Vaccine Consent Forms***
  - Document the publication date of the EUA fact sheet
  - Document the vaccine and dose being given and have the patient sign consent or declination.
  - The person administering the immunization signs and dates the form.
  - Disposition of the completed, signed consent forms:
  - ***Inmates:*** Scan a separate inmate consent form (*see Appendix 4 and 5*) for each administered or declined dose of vaccine into the Document Manager in BEMR.
  - ***Employees:*** Provide a hard copy of the signed employee consent form (*see Appendix 6*) to employee records for filing after either the second vaccine dose has been administered or the employee's refusal of vaccination has been documented.
  - **Documentation of vaccine consent or declination must be obtained from every inmate and employee***. Declinations may be obtained after all those who wish to be vaccinated have been vaccinated with their second dose.*
- ***Scheduling second doses of vaccine***
  - Facilities need to plan for clinic availability based on when initial doses of vaccine are administered.
  - ***For inmates, using BEMR is the preferred method to schedule second doses.*** The COVID-19 vaccine dashboard is a tool that may be used to monitor when a second vaccine dose should be given.
  - ***For employees, each facility will determine a method for scheduling second doses*** and what reminders to use for determining when second doses should be given (e.g., pre-determined clinic dates, use of the Manage Recipients page in VAMS to track dates for second doses, use of a spread sheet of due dates, and vaccine cards).

9. ***Medical emergency or anaphylaxis:*** Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat.

- In the event of a medical emergency related to the administration of a vaccine, ***immediately call a medical emergency.***
- ***Epinephrine 1:1000 IM/SQ and respiratory support should be immediately available.***
- BOP nursing and paramedic protocols are available for implementation and use in the management of allergic reactions and anaphylaxis when approved by the clinical director.
  - **The nursing protocol:** http://sallyport.bop.gov/co/hsd/nurse/Policy_guidance.jsp
  - ***The paramedic protocol:*** *http://sallyport.bop.gov/co/hsd/paramedic/index.jsp*

10. ***Report all clinically important vaccine adverse reactions.*** Documentation of adverse events should occur in the following two locations:

- BOP Adverse Events dashboard
- Federal Vaccine Adverse Event Reporting System (VAERS) at: *https://vaers.hhs.gov/reportevent.html*
  - Complete reports online in one sitting or by using a writable PDF form. For further assistance email *info@VAERS.org* or call: (800) 822-7967.

11. ***Disposal of expired or unused vaccine.***

- Syringes and needles used for vaccination should be placed in hard, lockable biohazard containers and bagged in biohazard bags just as any other vaccine.
- Institutions must store vaccine vials that are contaminated, expired or unused until further guidance is issued.
  - Label the vaccine vial “DO NOT USE” and store in a separate, designated area, away from any vaccine that is in use.

APPENDIX 1. SKILLS CHECKLIST FOR COVID-19 VACCINE ADMINISTRATION

The checklist on the following pages can be used as an assessment tool for healthcare staff who administer the Pfizer-BioNTech and/or Moderna COVID-19 vaccines.

SKILLS CHECKLIST FOR COVID-19 VACCINE ADMINISTRATION (*PAGE 1 OF 3*)				
FACILITY:			**EMPLOYEE:**	
Self-Assessment		**Supervisor/ Preceptor Review**		**SKILLS**
Needs to Improve	Meets or Exceeds	Needs to Improve	Meets or Exceeds	
PATIENT EDUCATION				
				Welcomes patient, verifies identification, accommodates language/literacy barriers and special needs, and explains what vaccine will be given.
				Provides Emergency Use Authorization (EUA) fact sheet and answers questions.
				Reviews potential side effects, comfort measures, and after care instructions.
SCREENING/PREPAREDNESS				
				Screens patient for vaccine eligibility (based on EUA and package insert), history of adverse reactions, allergies, contraindications, and precautions.
				Ensures consent/declination form is signed and that the current EUA date is documented. Uses a separate consent form for each vaccine dose for inmates and one consent form for both vaccine doses for employees.
				Verbalizes signs and symptoms of potential medical emergency or anaphylaxis.
				Able to initiate CPR and maintain airway, if necessary. Locates epinephrine.
				States procedure for responding to and reporting needle stick injuries.
VACCINE HANDLING AND PREPARATION, PFIZER-BIONTECH COVID-19 VACCINE				
				Documents refrigerator temperatures with a temperature data logger twice daily on clinic days. *Vaccines are not stored in dormitory style refrigerators and food and beverages are never stored in a refrigerator with vaccines.*
				Removes vaccine from refrigerator and allows to come to room temperature (< 30 minutes).
				Verifies vaccine and expiration date (Unless otherwise specified, date is found on the vial).
				Inverts vial gently 10 times to mix. *DO NOT SHAKE.*
				Obtains sterile 0.9% Sodium Chloride Injection, USP (i.e., diluent).
				Cleanses the vaccine and sodium chloride vial stoppers with an alcohol swab.
				Withdraws only 1.8 ml from the sodium chloride vial *and injects that 1.8 ml into the vaccine vial using a 3 or 5 ml syringe with a 21 or narrower gauge needle (from the shipped ancillary kits).* ***ONLY*** *reconstitute vaccine that will be used within 6 hours.*
				Equalizes pressure in the vaccine vial by withdrawing 1.8 ml of air into the empty diluent syringe prior to withdrawing the needle from the vaccine vial.
				Engages needle safety device (if present) prior to disposal in a sharps container.
				Discards remaining 0.9% sodium chloride solution regardless of fluid remaining. Do not reuse.
				Gently inverts the vial containing the vaccine and diluent 10 times to mix. *DO NOT SHAKE.*
				Labels the vial and records the date and time of dilution on the label. The vaccine vial now contains 5 (five) separate 0.3 ml vaccine doses, each with 30 mcg of vaccine product in a labeled, multi-dose vial.
				Stores the diluted, labeled, and ready to use multi-dose vaccine vial at refrigerated or room temperatures between 2˚C to 25˚C (35˚F to 77˚F) for up to 6 hours.
VACCINE HANDLING AND PREPARATION, MODERNA COVID-19 VACCINE				
				Demonstrates knowledge that vials may be stored refrigerated (2°C to 8°C [36°F to 46°F]) for up to 30 days prior to first use.
				Documents refrigerator temperatures with a temperature data logger twice daily on clinic days. *Vaccines are not stored in dormitory style refrigerators and food and beverages are never stored in a refrigerator with vaccines.*

SKILLS CHECKLIST FOR COVID-19 VACCINE ADMINISTRATION (*PAGE 2 OF 3*)				
FACILITY:		**EMPLOYEE:**		
Self-Assessment		**Supervisor/ Preceptor Review**		**SKILLS**
Needs to Improve	**Meets or Exceeds**	**Needs to Improve**	**Meets or Exceeds**	
VACCINE HANDLING AND PREPARATION, MODERNA COVID-19 VACCINE (CONTINUED)				
				Acknowledges that each multi-dose vaccine vial contains 10 (ten) separate 0.5 ml vaccine doses, each with 100 mcg of vaccine product.
				Removes vaccine from refrigerator and verifies vaccine and expiration date. For any questions, contact Central Office.
				Ensures the vaccine is thawed and that the vial has been allowed to come to room temperature for 15 minutes prior to drawing up vaccine for administration. Un-punctured vials are not stored any longer than 12 hours between 8°C to 25°C (46°F to 77°F).
				Swirls the vial gently and between each withdrawal. *DO NOT SHAKE and do not dilute.*
				Visually inspects the vial for unexpected particulate matter and/or discoloration. The vaccine is a white to off-white-suspension, and it may contain white or translucent product-related particulates. The vaccine should NOT be used if other particulate matter and/or discoloration are present.
ADMINISTERING VACCINES				
				Demonstrates knowledge of the appropriate route (IM), site (deltoid), vaccine dose, and the type of syringe safety device being utilized (glide, snap or retraction device).
				Washes or disinfects hands before and in-between patient encounters. If gloves are worn, they are changed and hand hygiene performed between patients.
				Places the labeled, unexpired, multi-dose vaccine on a hard surface, cleanses the stopper with a clean alcohol wipe and allows to dry.
				Utilizes a new and appropriate sized needle and syringe for each dose of vaccine. Opens syringe packet carefully placing safety cap on the package covering and then inserts needle into the multi-dose vaccine vial.
				Inverts vial and syringe and withdraws the following amount of vaccine from the multi-dose vial: • *Pfizer-BioNTech:* 0.3 ml • *Moderna:* 0.5 ml
				Withdraws needle from the vial. Taps syringe to float air bubbles to the syringe hub and carefully expels excess air before patient injection. Replaces syringe safety cap.
				Positions patient so that muscles are relaxed and preps injection site with alcohol wipe, allowing it to dry.
				Places a clean, dry gauze between the third and fourth fingers for easy access to a gauze pad after injection.
				Holds the syringe and needle in the dominant hand and either bunches up muscle using the non-dominant hand or gently stretches the skin around the injection site.
				Inserts the needle (all the way up to the syringe hub) at a 90-degree angle using a dart-like action to prevent accidental depression of the plunger during insertion of the needle. Aspiration is not necessary for IM injections in the deltoid site.
				Uses the thumb and forefinger of the non-dominant hand to hold the syringe and depresses the plunger with the dominant hand in a steady motion after the needle pierces the skin.
				Removes the needle at the same angle at which it was inserted once medication is completely injected. Engages the needle safety device appropriately.

SKILLS CHECKLIST FOR COVID-19 VACCINE ADMINISTRATION (*PAGE 3 OF 3*)				
FACILITY:		**EMPLOYEE:**		
Self-Assessment		**Supervisor/ Preceptor Review**		**SKILLS**
Needs to Improve	**Meets or Exceeds**	**Needs to Improve**	**Meets or Exceeds**	
ADMINISTERING VACCINES (CONTINUED)				
				Disposes of the needle and syringe in a sharps container.
				Covers injection site with the gauze, using gentle pressure and applies a Band-Aid, if needed.
				Records the date and time of first use. This information must be recorded on the vial label for the Moderna and Pfizer vaccines.
				Identifies vials that can no longer be used: • *Pfizer-BioNTech:* undiluted vaccine out of refrigeration for more than 2 hours, refrigerated undiluted vaccine not used after 5 days, or reconstituted vaccine not used within 6 hours • *Moderna* vaccine: out of refrigeration for more than 12 hours, punctured vials not used after 6 hours, or refrigerated vaccine not used after 30 days. • Does not discard vials that cannot be used.
				Maintains vials that can no longer be used in a separate area labeled *"DO NOT USE"* until further instruction is available.
DOCUMENTATION				
				Documents each vaccine dose in the appropriate place (consent forms, BEMR and VAMS) to include dose number, date, lot number, manufacturer, site, and name/initials.
				Addresses future appointments through the BEMR scheduler for inmates; places a **medical hold** until the date of the second vaccine dose. For employees, follows institution plans.
				Demonstrates the ability to properly document a vaccine adverse event (AE) in VAERS and in the BOP Medication Event dashboard, and identifies which healthcare personnel to notify in the case of an AE.
Employee Signature:				**Date:**
Supervisor Signature:				**Date:**
Adapted from: Skills Checklist for Pediatric Immunization. California Department of Health, Immunization Branch.				

APPENDIX 2. COVID-19 VACCINE ADMINISTRATION SIGNATURE SHEET

BOP HEALTH SERVICES UNIT

Institution:	
Authorization is given for the checked (✓) categories of healthcare providers to use the checked (✓) COVID-19 vaccine(s) (below) for administration without individual patient medication orders. Healthcare providers who are authorized to administer vaccines should have demonstrated vaccine administration skills (see skill checklist). File a copy of this Signature Sheet in each authorized healthcare provider's credential file.	
	Registered Nurses
	Advanced Practice Providers
	Licensed Practical Nurses
	Paramedics
	Pharmacists
	Dentists
	Other:
The following COVID-19 vaccine(s) is/are approved for use in this facility, in accordance with the FDA EUA and package insert, if the specific vaccine brand(s) is/are checked (✓) below:	
	Pfizer-BioNTech COVID-19 Vaccine
	Moderna COVID-19 Vaccine
	Other:
Signatures:	

IP&C Coordinator (Last, First) – PRINT	*Signature*	*Date*
Health Services Administrator (Last, First) – PRINT	*Signature*	*Date*
Clinical Director (Last, First) – PRINT	*Signature*	*Date*
Healthcare Provider (Last, First) – PRINT	*Signature*	*Date*

APPENDIX 3. ADMINISTERING COVID-19 VACCINES

ADMINISTERING THE VACCINE (ADULTS): DOSE, ROUTE, SITE, AND NEEDLE SIZE (PAGE 1 OF 2)				
VACCINE	**DOSE**	**ROUTE**	**INJECTION SITE**	**KEY POINTS**
Pfizer-BioNTech COVID-19 Vaccine	0.3 mL	IM	Deltoid	• Reconstitution required with 1.8 ml of 0.9% sodium chloride diluent (mixing syringe 3-5 ml with 21 gauge 1.5" mixing needle). The 1.5", 21 gauge needles included in the ancillary kits are to be used. • Each reconstituted multi-dose vial contains five (5) separate 0.3 ml vaccine doses. • Reconstituted vaccine must be used within 6 hours. • After 6 hours, label "DO NOT USE" and store in a place removed from vaccines in use. Do not discard these vials and await further guidance.
Moderna COVID-19 Vaccine	0.5 mL	IM	Deltoid	• No reconstitution needed • Each multi-dose vial contains ten (10) separate 0.5 ml vaccine doses. • Once punctured, a vial must be used within 6 hours. • Vials not refrigerated must be used within 12 hours. • After beyond use or expiration, label "DO NOT USE" and store in a place removed from vaccines in use. Do not discard these vials and await further guidance.

ADMINISTERING THE VACCINE (ADULTS): DOSE, ROUTE, SITE, AND NEEDLE SIZE (PAGE 2 OF2)

Administer IM injections in the deltoid muscle, with a 22-25 gauge needle. Choose needle length based on person's age and body mass:

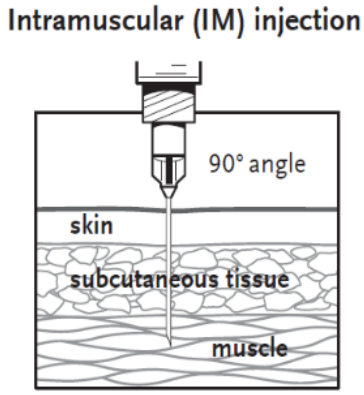
< 130 lbs.	1" length needle
130-152 lbs.	1" length needle
Female 153-200 lbs.	1-1½" length needle
Female 200+ lbs.	1½" length needle
Male 153-260 lbs.	1-1½" length needle
Male 260+ lbs.	1½" length needle

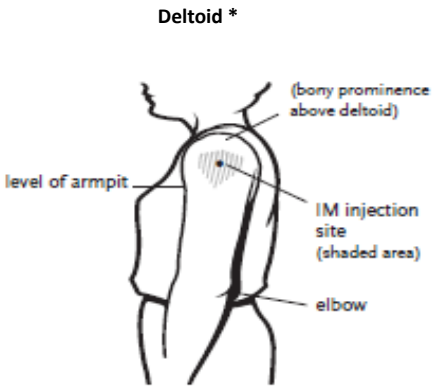
A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taut, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

NOTE: Each location will receive an ancillary kit and product information guide separate from the vaccine product. The kits will contain a variety of needles and syringes along with other supplies (e.g., diluent, if needed). When preparing and administering vaccine, staff will need to select the correct syringe size and needle gauge/length appropriate for the activity (vaccine preparation vs. vaccine administration) and for the patient's size. Guidance may be found in the ASPR/CDC "Product Information Guide for COVID-19 Vaccines and Associated Products" sent to the VPOCs and in BOP guidance.

How to administer an intramuscular vaccine*:

1. Use a needle long enough to reach into the muscle – for adults, 1-1½" needle.
2. The 1 ml syringe included in the ancillary kit is recommended for vaccine administration and not for mixing of the diluent with vaccine.
3. With the non-dominant hand, bunch up the muscle (for smaller muscle mass) or stretch the skin (for larger body mass).
4. With the dominant hand, insert the needle at a 90° angle to the skin with a quick thrust.
5. Push down on the plunger and inject the entire contents of the syringe. There is no need to aspirate.
6. Remove the needle and apply pressure to the injection site with a dry gauze. Hold in place for several seconds.
7. If there is any bleeding, cover the injection site with a bandage.
8. Engage the needle safety mechanism and put the used needle and syringe in a sharps container.





*References adapted from www.immunize.org/catg.d/Item # 2024 (9/19) and 3084 (8/20)

APPENDIX 4. COVID-19 VACCINE CONSENT FORM FOR INMATES - ENGLISH

The consent on the following page must be used to document all inmate consents or declinations of the COVID-19 vaccine.

BP-PENDING **COVID-19 VACCINE CONSENT – INMATE** CDFRM JAN
U.S. DEPARTMENT OF JUSTICE **FEDERAL BUREAU OF PRISONS**

I have been provided a copy of the COVID-19 Vaccine **Emergency Use Authorization (EUA)** fact sheet dated _____. I have had the opportunity to ask questions about the benefits and risks of vaccination, including if I am pregnant, breastfeeding or have a weakened immune system. I will agree to complete the number of vaccine doses as appropriate and indicated by the manufacturer.

Health Questions Prior to COVID-19 Vaccination (*Check yes or no*)

Yes	No	Health Questions
☐	☐	Are you sick today?
☐	☐	Have you ever had a severe allergy (i.e., anaphylaxis) or an immediate allergic reaction of any severity to any component of this vaccine or to a previous dose of this vaccine?
☐	☐	Have you ever had an immediate allergic reaction to any other vaccine/injectable therapy?
☐	☐	Have you had any other vaccinations in the last 14 days?
☐	☐	Have you received monoclonal antibody therapy for COVID-19 in the last 90 days?

☐ **I consent to receive the COVID-19 vaccination.**

Dose # (1 or 2)	Vaccine Manufacturer	Lot Number	Expiration Date	Route	Deltoid (R) Deltoid (L)

Inmate Signature	Date
Administered by Signature	**Date**
Administered by (name/title)	

☐ **I decline to receive the COVID-19 vaccination.**

Inmate Signature	Date
Witness Signature	**Date**
(PRINT) Witness Name	

(PRINT) Inmate Name (Last, First)	Register Number	
Institution	**Unit**	**Work Assignment**

DOCUMENT VACCINE ADMINISTRATION IN BEMR FLOW SHEETS.
SCAN VACCINE CONSENT IN BEMR DOCUMENT MANAGER – VACCINATION CONSENTS.

APPENDIX 5. COVID-19 VACCINE CONSENT FORM FOR INMATES - SPANISH

The consent on the following page must be used to document all inmate consents or declinations of the COVID-19 vaccine.

BP-PENDING **CONSENTIMIENTO PARA VACUNACIÓN COVID-19 PARA RECLUSOS** CDFRM JAN

U.S. DEPARTMENT OF JUSTICE **FEDERAL BUREAU OF PRISONS**

Se me ha proporcionado una copia de la hoja informativa de **autorización de Uso de Emergencia (EUA)** de la vacunación COVID-19 con fecha _____. He tenido la oportunidad de hacer preguntas sobre los beneficios y riesgos de la vacunación, incluso si estoy embarazada, amamantando o tengo un sistema inmunitario debilitado. Aceptaré completar el número de dosis de vacunas según corresponda e indicadas por el fabricante.

Preguntas de Salud Antes de la Vacunación COVID-19 (*marque sí o no*)

Sí	No	Preguntas de Salud
☐	☐	¿Estás enfermo hoy?
☐	☐	¿Alguna vez ha tenido una alergia grave o reacción anafiláctica o algún componente de esta vacuna o de una dosis previa de esta vacuna?
☐	☐	¿Alguna vez ha tenido una reacción alérgica inmediata a cualquier otra vacuna/terapia inyectable?
☐	☐	¿Has recibido alguna otra vacuna en los últimos 14 días?
☐	☐	¿Ha recibido terapia con anticuerpos monoclonales para COVID-19 en los últimos 90 días?

☐ **Yo consiento para recibir la vacunación COVID-19.**

Dosis # (1 o 2)	Fabricante de Vacuna	Número de lote	Fecha de caducidad	Ruta	Deltoides (R) Deltoides (L)

Firma de recluso	Fecha
Firma de administrado de vacunación	**Fecha**
Nombre y título de administrado de vacunación	

☐ **Yo me niego a recibir la vacunación de COVID-19.**

Firma de recluso	Date
Firma de testigo	**Date**
(Letra de molde) Nombre del testigo	

(Letra de molde) Nombre del recluso (Apellido, Nombre)	**Número de registro**	
Institución	**Unidad**	**Asignación de trabajo**

DOCUMENT VACCINE ADMINISTRATION IN BEMR FLOW SHEETS.
SCAN VACCINE CONSENT IN BEMR DOCUMENT MANAGER – VACCINATION CONSENTS.

APPENDIX 6. COVID-19 VACCINE CONSENT FORM FOR EMPLOYEES

The consent on the following page must be used to document all employee consents or declinations of the COVID-19 vaccine.

BP-PENDING **COVID-19 VACCINE CONSENT – EMPLOYEES** CDFRM JAN

U.S. DEPARTMENT OF JUSTICE **FEDERAL BUREAU OF PRISONS**

I have been provided a copy of the COVID-19 Vaccine **Emergency Use Authorization (EUA)** fact sheet dated _____. I have had the opportunity to ask questions about the benefits and risks of vaccination, including if I am pregnant, breastfeeding or have a weakened immune system. I will agree to complete the number of vaccine doses as appropriate and indicated by the manufacturer.

☐ **I consent to receive the COVID-19 vaccination.**

Dose	Employee Signature	Witness Signature	Date
#1			
#2			

Health Questions Prior to COVID-19 Vaccination (*Check yes or no*)

Dose #1		Dose #2		Health Questions
Yes	No	Yes	No	
☐	☐	☐	☐	Are you sick today?
☐	☐	☐	☐	Have you ever had a severe allergy (i.e., anaphylaxis) or an immediate allergic reaction of any severity to any component of this vaccine or to a previous dose of this vaccine?
☐	☐	☐	☐	Have you ever had an immediate allergic reaction to any other vaccine/injectable therapy?
☐	☐	☐	☐	Have you had any other vaccinations in the last 14 days?
☐	☐	☐	☐	Have you received monoclonal antibody therapy for COVID-19 in the last 90 days?

☐ **I decline to receive the COVID-19 vaccination.**

Employee Signature	Witness Signature	Date

COVID-19 Vaccine Information

Dose	Date	Vaccine Manufacturer	Lot Number	Expiration Date	Route	Deltoid (R) Deltoid (L)	Administered by (name/title):
#1		Select			IM		☐ ☐ ☐ ☐
#2		Select			IM		☐ ☐ ☐ ☐

(PRINT) Employee Name (Last, First)	Year of Birth	Institution