

## JYNNEOS VACCINE PROTOCOL for MONKEYPOX

### PURPOSE:

To reduce morbidity and mortality from monkeypox disease by vaccinating individuals who meet the criteria for monkeypox vaccine (JYNNEOS) as established by the Centers for Disease Control and Prevention (CDC).

### INTRODUCTION:

Because monkeypox virus is closely related to the virus that causes smallpox, the smallpox vaccine can protect people from getting monkeypox. Past data collected in Africa suggests that the smallpox vaccine is at least 85% effective in preventing monkeypox. The effectiveness of JYNNEOS against monkeypox was concluded from a clinical study on the immunogenicity of JYNNEOS and efficacy data from animal studies.

The CDC recommends three vaccine strategies to prevent monkeypox<sup>1</sup>:

1. **Monkeypox Vaccine Post-Exposure Prophylaxis (PEP):** For the current 2022 outbreak, this approach can be considered as “standard PEP.” People can be vaccinated following exposure to monkeypox to help prevent illness from monkeypox virus. CDC recommends that the vaccine be given within 4 days of exposure for the best chance to prevent onset of the disease. If given between 4 and 14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease. However, when coupled with self-isolation and other prevention measures when symptoms first occur, PEP is important for controlling outbreaks and preventing further transmission of monkeypox.
2. **Outbreak Response Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)++:** For the current 2022 outbreak, this expanded approach can be considered as “individual-directed PEP” for monkeypox, “expanded PEP” or “PEP++”. The PEP++ approach aims to reach people who are more likely to have been recently exposed to monkeypox, even if they don’t have documented exposure to someone with confirmed monkeypox. When coupled with self-isolation and other prevention measures when symptoms first occur, PEP++ may help slow the spread of the disease in areas with higher transmission (higher numbers of cases).
3. **Monkeypox Vaccine Pre-Exposure Prophylaxis (PrEP):** This approach refers to administering vaccine to someone at high risk for monkeypox (for example, laboratory workers who handle specimens that might contain monkeypox virus). Most clinicians in the United States and laboratorians

---

<sup>1</sup> <https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html>

not performing the orthopoxvirus generic test to diagnose orthopoxviruses, including monkeypox virus, are not advised to receive monkeypox vaccine PrEP.

Given the short supply of JYNNEOS nationally, at this time doses should be prioritized for PrEP for those at occupational high risk and “standard PEP” for those with confirmed exposure. In addition, at the current time (August 2022 and until further notice) all people approved for vaccination will be communicated to the public health office (PHO) that will be administering the vaccine by ERD or PHD/IDB medical director/RHO. Patients approved for vaccine will be those who are contacts to known/suspected cases. Finally, in order to extend the limited supply, the preferred administration route is intradermal, unless subcutaneous administration is necessary (e.g., due to age <18 years, history of keloid scar formation).

Note that clients may not choose between intradermal or subcutaneous administration.

JYNNEOS is a live, non-replicating virus, and is FDA approved for prevention of smallpox and monkeypox disease in individuals 6 months of age and older determined to be at high risk for smallpox or monkeypox infection. It is usually administered as a series of two doses given four weeks apart. Booster doses are recommended every 2 or 10 years if a person remains at continued risk for occupational exposure.

#### **SERVICE POPULATION:**

1. Adults 18 years of age and older who are recommended to receive JYNNEOS pre-exposure prophylaxis because of occupational exposure: <https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm>
2. Individuals six months of age and older are recommended to receive JYNNEOS post-exposure prophylaxis (PEP) vaccination per CDC’s [Exposure risk assessment and public health recommendations for individuals exposed to a patient with monkeypox](#).
3. When supply allows, or to avoid wasting vaccine, adults 18 years of age and older who are recommended to receive JYNNEOS pre-exposure prophylaxis because of risk for monkeypox exposure (other than occupational).

#### **METHODOLOGY:**

1. At the current time (Aug 2022 and until further notice), there are 2 groups of people (ages six months and older) approved for JYNNEOS.
  - 1.1. PEP patients (people with a known exposure in the last 14 days) – those approved for JYNNEOS PEP will be referred to the appropriate public health office (PHO) by ERD or PHD/IDB medical director/RHO. Patients approved for vaccine will be those who are contacts to known/suspected cases within 14

days. For these patients, every effort should be made to get the patient in quickly. This group of patients should still get the second dose on time.

1.2. High risk patients that have **registered for vaccine through the DOH Call Center (1-855-600-3453; option 4; option 9 for Spanish)**. The call center uses an RTS application to register people, and an algorithm determines their risk. The priority patients are visible through the registration and can be scheduled for vaccine. Other priority groups will be opened as more vaccine becomes available.

2. In general, individuals appropriate for JYNNEOS Vaccine:

2.1. Patients **recommended** for post exposure prophylaxis are those who have had:

- Exposure within the last 14 days -AND-
  - Unprotected contact with a monkeypox patient's skin, lesions, or bodily fluids (e.g., any sexual contact, saliva to the eyes or oral cavity, ungloved contact with patient), or contaminated materials (e.g., linens, clothing) -OR-
  - Being inside the patient's room or within 6 feet of a patient during any procedures that may create aerosols from oral secretions, skin lesions, or resuspension of dried exudates (e.g., shaking soiled linens), without wearing an N95 or equivalent respirator and eye protection -OR-
  - A person who has had close physical contact with someone diagnosed with monkeypox and those who know their sexual partner was diagnosed with monkeypox -OR-
  - Exposure that, at the discretion of public health authorities, was recategorized to this risk level (i.e., exposure that ordinarily would be considered a lower risk exposure, raised to this risk level because of unique circumstances) including men who have sex with men who have recently had multiple sex partners in a venue where there was known to be monkeypox or in an area where monkeypox is spreading.

2.2. Individuals **recommended** for JYNNEOS pre-exposure prophylaxis (PrEP) based on occupational exposure risk:

- For details, see the ACIP recommendations in MMWR: <https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm#T1> down
- At this time, research laboratory personnel, clinical laboratory personnel performing diagnostic testing for orthopoxviruses, designated response team members (per NMDOH), and health care personnel who administer ACAM2000 (Smallpox [Vaccinia] Vaccine, Live) or care for patients infected with orthopoxviruses are the persons to whom these recommendations apply.

2.3. Individuals six months of age and older **to consider** for JYNNEOS PEP (intermediate risk exposure) are those who have had:

- Exposure within the last 14 days -AND-
  - Being within 6 feet for 3 hours or more of an unmasked patient without wearing, at a minimum, a surgical mask -OR-
  - Activities resulting in contact between sleeves and other parts of an

- individual's clothing and the patient's skin lesions or bodily fluids, or their soiled linens or dressings (e.g., turning, bathing, or assisting with transfer) while wearing gloves but not wearing a gown -OR-
  - Exposure that, at the discretion of public health authorities, was recategorized to this risk level because of unique circumstances (e.g., if the potential for an aerosol exposure is uncertain, public health authorities may choose to decrease risk level from high to intermediate).
- Use informed clinical decision making to determine whether benefits of PEP outweigh risks for this group.

### 3. Screen for Contraindications and Precautions

#### 3.1. Contraindications

Do not give JYNNEOS vaccine to a person who has experienced a severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS vaccine or to any of its components.

#### 3.2. Precautions

- Moderate or severe acute illness with or without fever.
- If a patient presents for monkeypox postexposure prophylaxis and is experiencing any symptoms of monkeypox (including prodromal symptoms or rash), they should be referred for clinical evaluation and not receive a vaccine.
- People who have had a previous severe allergic reaction (e.g., anaphylaxis) following gentamicin or ciprofloxacin have a precaution for receiving JYNNEOS vaccine and should be informed about the potential for increased risk of allergic reaction if the vaccine is administered.
  - After discussing risks and benefits with the individual, these people may be vaccinated with a 30-minute observation period. Consider consultation with allergist.
  - For individuals who have had Stevens-Johnson syndrome (SJS) or Toxic Epidermal Necrolysis (TEN) following either ciprofloxacin or gentamicin, the risk of this type of severe allergic reaction from JYNNEOS vaccine is considered low because of the small amounts of the antibiotics in the vaccine. The risks and benefits of the vaccination should be discussed with the individual. Consider consultation with allergist.
- People who have had a severe allergic reaction (e.g., anaphylaxis) to chicken or egg protein AND are currently avoiding exposure to all chicken or egg products have a precaution for receiving JYNNEOS vaccine and should be informed about the potential for increased risk of allergic reaction if the vaccine is administered.
  - After discussing risks and benefits with the individual, these people may be vaccinated with a 30-minute observation period. Consider consultation with allergist.
- JYNNEOS typically may be administered without regard to timing of other vaccines, unless → a patient has received another live virus vaccine within the

previous 28 days in which case they should wait 28 days to receive JYNNEOS for PrEP (pre-exposure prophylaxis). JYNNEOS may still be given for PEP within 28 days of another live virus vaccine. This includes simultaneous administration of JYNNEOS and other vaccines on the same day, but at different anatomic sites if possible. See ACIP's [general best practices](#) and [Epidemiology and Prevention of Vaccine-Preventable Diseases \(Pink Book\)](#) for further information.

- **Note:** Because of the documented risk for myocarditis after receipt of both ACAM2000 and mRNA COVID-19 vaccines (12) and the unknown risk for myocarditis after JYNNEOS, persons might consider waiting 4 weeks after orthopoxvirus vaccination (either JYNNEOS or ACAM2000) before receiving an mRNA COVID-19 vaccine, particularly adolescent or young adult males. However, if an orthopoxvirus vaccine is recommended for prophylaxis in the setting of an outbreak, administration of orthopoxvirus vaccine should not be delayed because of recent receipt of an mRNA COVID-19 vaccine. No minimum interval between mRNA COVID-19 vaccination and orthopoxvirus vaccination is necessary.

### 3.3. Considerations for vaccinations administered to special populations

- **Persons with immunocompromising conditions.** JYNNEOS is safe to administer to persons with immunocompromising conditions. However, such persons might be at increased risk for severe disease if an occupational infection occurs, despite vaccination. In addition, persons with immunocompromising conditions might be less likely to mount an effective response after any vaccination, including after JYNNEOS; the risk/benefit ratio should be considered along with whether it is considered imperative to vaccinate an immunocompromised person.
- **Persons with atopic dermatitis, eczema, or other exfoliative skin conditions.** Studies evaluating JYNNEOS in persons with atopic dermatitis have demonstrated immunogenicity in eliciting a neutralizing antibody response. No safety signals were revealed. However, persons with these conditions might be at increased risk for severe disease if an occupational infection occurs despite vaccination.
- **Pregnant persons.** Available human data on JYNNEOS administered to pregnant persons are insufficient to determine vaccine-associated risks in pregnancy. However, animal models, including rats and rabbits, have shown no evidence of harm to a developing fetus.
- **Breastfeeding persons.** The safety and efficacy of JYNNEOS has not been evaluated in breastfeeding persons. It is not known whether JYNNEOS is excreted in human milk. Data are not available to assess the impact of JYNNEOS on milk production or the safety of JYNNEOS in breastfed infants. However, because JYNNEOS vaccine is replication-deficient, it likely does not present a risk of transmission to breastfed infants and can be administered to persons who are breastfeeding if vaccination is critical.
- **Children and adolescents aged <18 years.** JYNNEOS has an Emergency Use Authorization (EUA) for use in children six months of age and older.

Formatted: Font color: Black

Formatted: Font color: Black

- **Persons with multiple cardiac risk factors.** Clinical studies have not detected an increased risk for myopericarditis in recipients of JYNNEOS. Persons with underlying heart disease or three or more major cardiac risk factors should be counseled about the theoretical risk for myopericarditis following vaccination with JYNNEOS.
- **Persons with a history of keloid scars.** *Should receive JYNNEOS vaccination subcutaneously.*

#### 4. Provide Vaccine Information Statements and Obtain Consent

- 4.1. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). [Smallpox/Monkeypox Vaccine \(JYNNEOS™\): What You Need to Know](#)
- 4.2. If a federal VIS is not available, provide vaccine recipient with a copy of the JYNNEOS package insert which can be found at: [JYNNEOS | FDA](#).
- 4.3. Most common side effects include: redness, soreness, swelling, and itching where the shot is given. People can also experience fatigue, headache, and muscle pain.
- 4.4. Ensure that signed consent is obtained using the Immunization Consent form (English, Spanish). Options for consent include:
  - 4.4.1. Competent adults (>18 years of age) and emancipated minors:
    - Digital consent in online application OR paper Immunization Consent form completed prior to or at time of clinic, attested to by individual digitally or in writing.
  - 4.4.2. Adults with guardian (e.g., Power of Attorney):
    - Digital consent in online application OR paper Immunization Consent form completed prior to or at time of clinic, attested to by guardian digitally or in writing.
  - 4.4.3. Minors (<18 years of age):
    - Requires:
      - 1) Paper or digital Immunization Consent (with health evaluation); and,
      - 2) Paper or digital Parental/guardian consent form
    - Paper form(s) may be signed on site at time of vaccination by parent/guardian, or prior to event and brought by minor or minor's caregiver.
    - No verbal, including telephone, consent permitted – a physical signature by the parent/guardian is required. Telephone verification of pre-signed consent may occur if specific concern.
    - For 5 through 17 years of age: Parent/guardian or other responsible adult presence NOT required at time of vaccination, but if not accompanied by an adult, then the observation period is extended to 30 minutes (see below).
    - For ages 6 months through 4 years of age: Parent/guardian or other responsible adult presence IS required at time of vaccination

Proof of age, or proof of parent/guardianship, is not generally required unless specific concern exists.

## 5. Prepare to Administer Vaccine

JYNNEOS vaccine can be administered either subcutaneously or intradermally depending on the person's age and presence of certain medical conditions.

5.1. Each dose (0.5 mL) is supplied for subcutaneous administration in a single-dose vial.

OR

FDA EUA allows use of JYNNEOS vaccine **for adults only** as 0.1 mL administered intradermally. One 0.5 mL vial may supply up to five separate doses for intradermal use.

Note: only individuals trained and approved to do so should administer intradermal vaccine.

5.2. Allow the vaccine to thaw and reach room temperature before use (generally 15-30 minutes). Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 8 weeks. Do not refreeze.

5.3. When thawed, JYNNEOS is a milky, light yellow to pale white colored suspension. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.

5.4. Swirl the vial gently before use for at least 30 seconds.

For subcutaneous administration, withdraw a dose of 0.5 mL into a sterile syringe, OR

For intradermal administration, withdraw a dose of 0.1 mL into a sterile syringe.

5.5. Choose the needle gauge, needle length, and injection site according to the following chart:

Administration	Needle Gauge	Needle Length	Injection Site
Subcutaneous	23–25	5/8"	≥ 12 months of age: fatty tissue over triceps at 45-degree angle  Infants < 12 months of age: Fatty tissue over anterolateral thigh at 45-degree angle
Intradermal (18 years of age and older)	27	¼-3/8"	Intradermally over volar (inner surface) of forearm 2-4" below antecubital fossa (elbow) at 5-degree angle to raise wheal

NOTE: vaccines inadvertently administered intramuscularly (IM) can be considered valid and do not need to be repeated – report to manufacturer at [drug.safety@bavarian-nodic.com](mailto:drug.safety@bavarian-nodic.com)

## 6. Administer JYNNEOS Vaccine

~~6.4.~~

~~6.2-6.1.~~ Select and cleanse vaccination site.

~~6.3-6.2.~~ **Standing Order:**

Children or Adults: Administer 0.5 mL of JYNNEOS vaccine, via the **subcutaneous** route

OR

Adults only: Administer 0.1 mL of JYNNEOS vaccine, via the intradermal route

to those without contraindications/precautions according to the following criteria and schedule:

History of Previous Vaccination	Dose and Schedule for Administration of JYNNEOS
No previous documented doses, or none known	Give 0.5 mL JYNNEOS subcutaneous OR (18+ years of age) 0.1 mL JYNNEOS intradermal as dose #1. Give dose #2 at least 4 weeks (28 days) later unless patient has developed sign/symptoms of monkeypox
One previous dose of JYNNEOS	Give 0.5 mL JYNNEOS subcutaneous OR (18+ years of age) 0.1 mL JYNNEOS intradermal as dose #2 at least 4 weeks (28 days) after dose #1.
Previously vaccinated against smallpox >3 years and identified by public health to be at increased risk following a monkeypox exposure.	Give 0.5 mL JYNNEOS subcutaneous OR (18+ years of age) 0.1 mL JYNNEOS intradermal as dose #1. Give dose #2 at least 4 weeks (28 days) later unless patient has developed sign/symptoms of monkeypox

**\*Second dose not indicated for PEP if recipient develops monkeypox after receipt of first dose.**

For clients with a contraindication/precaution, contact a PHD provider for consultation.

~~6.4-6.3.~~ A bandage may be placed over the injection site (subcutaneous or intradermal) as needed.

~~6.5-6.4.~~ **Observation:** Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:

30 minutes: persons with a history of anaphylaxis to any vaccine component due to any cause

15 minutes: All other persons

## 7. Storage and Handling

7.1. Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 8 weeks. Do not refreeze.

7.2. JYNNEOS may be kept frozen until the expiration date.

7.3. For general vaccine storage and handling, see: *DOH Immunization Protocol, Appendix A, Vaccine Management.*



7.4. All approved vaccine transfers to non-PHD providers will be communicated to the HUB site (PHO) by the PHD Immunization program via email to the identified JYNNEOS vaccine point of contact (POC).

8. **Document Vaccination** in the following places:

- 8.1. **Medical record:** Document the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS or package insert and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If the vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
- 8.2. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
- 8.3. **New Mexico Immunization Information System (NMIS):** Report the vaccination to the New Mexico Immunization Information System, as required by statute.

9. **Be Prepared to Manage Medical Emergencies**

- 9.1. Always be prepared to manage a medical emergency related to the administration of vaccine by having an **emergency kit** with appropriate medication and equipment as well as a written emergency medical protocol. See [PHD Emergency Medical Response Protocol](#).
- 9.2. Appropriate medical treatments must be available to manage possible anaphylactic reactions following administration of JYNNEOS. Persons who experienced a severe allergic reaction following a previous dose of JYNNEOS or following exposure to any component of JYNNEOS may be at increased risk for severe allergic reactions after JYNNEOS. The risk for a severe allergic reaction should be weighed against the risk for disease due to smallpox or monkeypox.
- 9.3. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

10. **Report All Adverse Events to VAERS**

- 10.1. Report all adverse events following the administration of JYNNEOS vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at [www.vaers.hhs.gov](http://www.vaers.hhs.gov). To submit a VAERS report online (preferred) or to download a writable PDF form, go to <https://vaers.hhs.gov/reportevent.html>. Further assistance is available at (800) 822-7967.

This policy and procedure shall remain in effect until rescinded or until July 1, 2023.


Adapted with appreciation from Colorado Department of Health protocol and the Immunization Action Coalition (IAC).

**PUBLIC HEALTH DIVISION  
CLINICAL PROTOCOL/MANUAL APPROVAL SHEET**

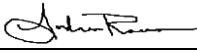
**PROGRAM/BUREAU:** Immunization Program/ Infectious Disease Bureau

**CLINICAL PROTOCOL/MANUAL TITLE:** JYNNEOS Vaccine for Monkeypox

Reviewed by: (Must have a signature from at least one clinical user of the Clinical Protocol.)

User Reviews:  \_\_\_\_\_ Date: \_\_\_\_\_  
Name: \_\_\_\_\_ Date: \_\_\_\_\_  
Name: \_\_\_\_\_ Date: \_\_\_\_\_  
Name: \_\_\_\_\_ Date: \_\_\_\_\_  
Name: \_\_\_\_\_ Date: \_\_\_\_\_  
Name: \_\_\_\_\_ Date: \_\_\_\_\_

Approved by:

Program Manager  \_\_\_\_\_ Date 7/26/22

Bureau Chief  \_\_\_\_\_ Date 7/26/22

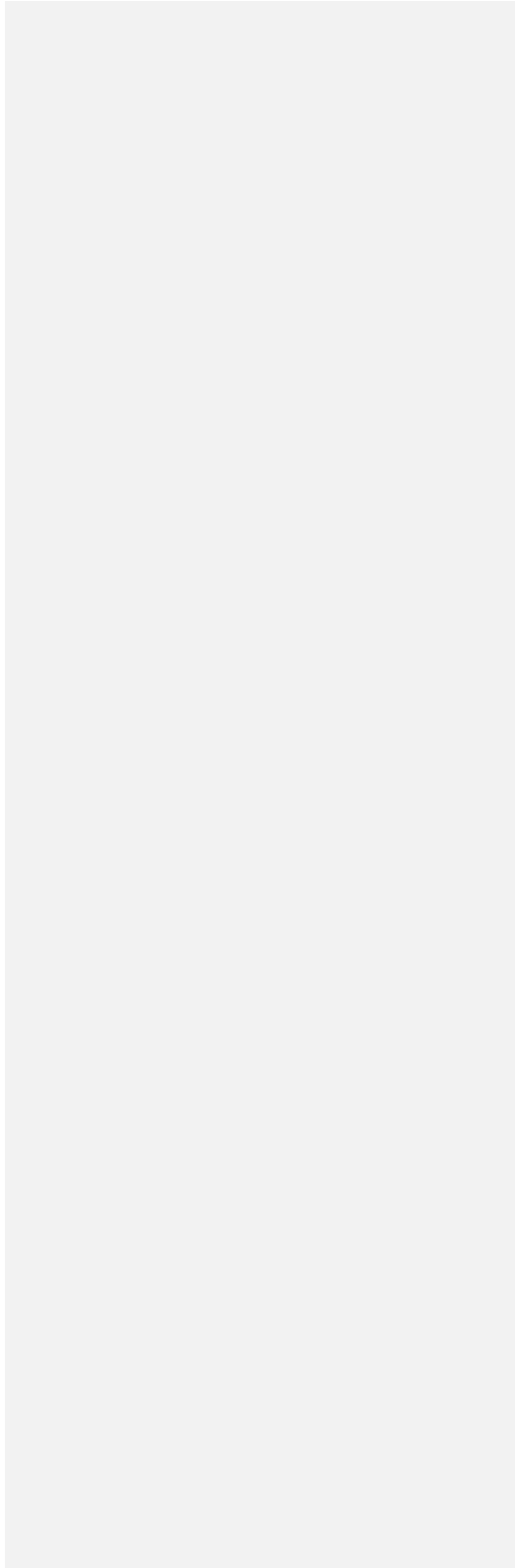
Bureau Medical Director MD/Whan, MD \_\_\_\_\_ Date 7/26/22

PHD Medical Director  \_\_\_\_\_ Date 08/15/22

Regional Health Officer  \_\_\_\_\_ (acting) Date 08/15/22

PHD Chief Nurse \_\_\_  \_\_\_\_\_

Date\_\_07/26/2022\_\_



Attachment B

**PUBLIC HEALTH DIVISION  
ACKNOWLEDGEMENT AND RECEIPT OF NEW/REVISED CLINICAL  
PROTOCOL**

**PROGRAM/BUREAU:** Immunization Program/ Infectious Disease Bureau

**CLINICAL PROTOCOL/MANUAL TITLE:** JYNNEOS Vaccine for Monkeypox

I have reviewed the document listed above and I approve it for practice in Region \_\_\_\_\_.

\_\_\_\_\_  
Regional Director Date

\_\_\_\_\_  
Regional Health Officer Date

\_\_\_\_\_  
Regional Director of Nursing Service Date

\_\_\_\_\_  
Regional Director of Nursing Service Date

I have received, reviewed, and will follow this Clinical Protocol and its Standing Orders.

Staff (Clinicians, PHNs, DPSs, etc.):

_____ Name	_____ Date	_____ Name	_____ Date
_____ Name	_____ Date	_____ Name	_____ Date
_____ Name	_____ Date	_____ Name	_____ Date
_____ Name	_____ Date	_____ Name	_____ Date
_____ Name	_____ Date	_____ Name	_____ Date
_____ Name	_____ Date	_____ Name	_____ Date
_____ Name	_____ Date	_____ Name	_____ Date
_____ Name	_____ Date	_____ Name	_____ Date

Each clinician and PHN must review the document mentioned above and sign this sheet. (Use additional sheets as necessary.) The Nurse Manager will retain the signed copy(ies) of this sheet at the clinic and submit the original(s) to the Director of Nursing Services.