**Wood County Health Department COVID-19 Vaccine Registration and Consent for JANSSEN (a.k.a. Johnson & Johnson)**

## Please read first.

Due to the risk of serious adverse events from the J&J/Janssen COVID-19 vaccine, the Centers for Disease Control and Prevention (CDC) indicates a preference for Pfizer-BioNTech or Moderna COVID-19 vaccines over the J&J/Janssen COVID-19 vaccine for primary and booster vaccinations, in most situations. The J&J/Janssen COVID-19 vaccine may be considered in some situations, including for persons who:

- Had a severe reaction after an mRNA vaccine dose or who have a severe allergy to an ingredient of Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines).
- Would otherwise remain unvaccinated for COVID-19 due to limited access to Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines).
- Wants to get the J&J/Janssen COVID-19 vaccine despite the safety concerns.

More than **17 million doses of the J&J/Janssen COVID-19 vaccine** have been administered in the United States. The J&J/Janssen COVID-19 vaccine has been found to have a rare association with the following adverse outcomes:

- **Thrombosis with thrombocytopenia syndrome (TTS) after Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccination is rare.**
  - TTS is a rare but serious adverse event that causes blood clots in large blood vessels and low platelets (blood cells that help form clots).
  - Out of the 17 million doses given, CDC and FDA identified **57 confirmed reports** of people who got the J&J/Janssen COVID-19 vaccine and later developed TTS.
  - CDC has also identified **nine (9) deaths** that have been caused by or were directly attributed to TTS following J&J/Janssen COVID-19 vaccination. **Women ages 30-49 years**, especially, should be aware of the increased risk of this rare adverse event.
  - There are other COVID-19 vaccine options available for which this risk has not been seen.
- **Guillain-Barré Syndrome (GBS) in people who have received the J&J/Janssen COVID-19 vaccine is rare.**
  - GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. Most people fully recover from GBS, but some have permanent nerve damage.
  - Out of the 17 million doses given, there have been around **283 preliminary reports of GBS** identified in VAERS as of December 16, 2021. These cases have largely been reported about 2 weeks after vaccination and mostly in men, many in those ages 50 years and older.
  - Based on the data, the rate of GBS within the first 21 days following J&J/Janssen COVID-19 vaccination was found to be **21 times higher** than after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). After the first 42 days, the rate of GBS was **11 times higher** following J&J/Janssen COVID-19 vaccination. Analysis found no increased risk of GBS after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines).
  - CDC and FDA will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination and will share more information as it becomes available.

### Screening Questions

| | | | |
|---|---|---|---|
| Are you sick today? (fever, congestion, cough) | ☐ Yes | ☐ No | ☐ Not sure |
| Have you ever had a severe allergic reaction that required epi (epinephrine)? | ☐ Yes | ☐ No | ☐ Not sure |
| Have you ever had any allergic reaction to a vaccine? | ☐ Yes | ☐ No | ☐ Not sure |
| Have you been treated for COVID-19 in the last 90 days with passive antibody therapy (monoclonal antibodies or convalescent serum)? | ☐ Yes | ☐ No | ☐ Not sure |
| Do you have a weakened immune system caused by something such as HIV or cancer? | ☐ Yes | ☐ No | ☐ Not sure |
| Do you take medications or other therapies that suppress your immune system? | ☐ Yes | ☐ No | ☐ Not sure |
| Do you have a bleeding disorder or are you taking a blood thinner? | ☐ Yes | ☐ No | ☐ Not sure |
| Females: Are you pregnant? ☐ Yes ☐ No Are you breastfeeding? ☐ Yes ☐ No | | | |

| First Name: | Middle: | Last: |
|---|---|---|
| Date of Birth: | Age: | Sex: ☐ Female ☐ Male ☐ Other ☐ Unknown |
| **The recipient must be at least 18 years old to receive this vaccine.** | | |

| | |
|---|---|
| Do you consider yourself Hispanic or Latino? ☐ Yes ☐ No ☐ Don't Know/Prefer not to say | |
| Which category or categories best describe your race? | ☐ American Indian/Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Other ☐ Unknown/Prefer not to say |
| Street address: | |
| City, State and Zip: | |
| Phone Number: | Email Address: |
| If an emergency happens today, who should we contact? | |
| Name: | Phone number: |
| List names and dates of all previous COVID vaccines: | |
| 1st dose: ☐ Pfizer ☐ Moderna ☐ Johnson & Johnson Date: | 2nd dose: ☐ Pfizer ☐ Moderna ☐ N/A Date: |

**Please select the primary reason you are receiving the COVID-19 vaccine.** (Please check only one box.)

**Age:** 18-39 ☐ 40-49 ☐ 50-59 ☐ 60-64 ☐ 65-69 ☐ 70-74 ☐ 75-79 ☐ 80 or older ☐

**Place of Residence or Occupation**

- Assisted Living Facility – Resident ☐ or Staff ☐
- Childcare Services Worker ☐
- Congregate Care Facility – Resident ☐ or Staff ☐
- Emergency Medical Services (EMTs/Paramedics) ☐
- Funeral Services Worker ☐
- Healthcare Worker
  - Hospital – Clinical ☐, Administrative ☐ or Ancillary Staff ☐
  - Non-Hospital – Clinical ☐, Administrative ☐ or Ancillary Staff ☐
- Law Enforcement, Corrections, Firefighter ☐
- School (K-12) Staff ☐
- Skilled Nursing Facility (RCF) – Resident ☐ or Staff ☐
- State of Ohio
  - Dept. of Dev. Disabilities (DODD) – Resident ☐ or Staff ☐
  - Dept. of Rehabilitation & Correction LTC – Resident ☐ or Staff ☐
  - Mental Health and Addiction Services (MHAS) – Resident ☐ or Staff ☐
  - Veterans Home – Resident ☐ or Staff ☐

**Health Condition**

- ALS (amyotrophic lateral sclerosis) ☐
- Bone marrow transplant recipients ☐
- Cancer ☐
- Chronic kidney disease ☐
- Chronic obstructive pulmonary disease (COPD) ☐
- Congenital or early onset conditions with intellectual or developmental disabilities ☐
- Congenital or early in life conditions that carried into adulthood without intellectual or developmental disabilities ☐
- Diabetes type1 ☐ or type 2 ☐
- End stage renal disease ☐
- Heart disease ☐
- Obesity ☐
- Pregnant ☐

**Informed Consent to Vaccinate**

Initial each line.

By signing below you agree that you are authorized to consent to the vaccination of the patient.

____ I am seeking the **Janssen (Johnson & Johnson)** vaccine today for:
- ____ The first dose of COVID-19 vaccine
- ____ A booster dose

____ I understand that the common risks associated with the COVID-19 vaccine include but are not limited to pain, redness or swelling at the site of the injection, tiredness, headache, muscle pain, chills, joint pain, fever, nausea, swollen lymph nodes or generally feeling unwell.

Name: _____ Date of Birth: _____

____ I understand that in most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the J&J/Janssen COVID-19 vaccine for primary and booster vaccination due to the risk of serious adverse events. Vaccine recipients must be informed of the risks and benefits of the J&J/Janssen COVID-19 vaccination. The J&J/Janssen COVID-19 vaccine may be considered in some situations, including for persons who:

- Had a severe reaction after an mRNA vaccine dose or who have a severe allergy to an ingredient of Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines).
- Would otherwise remain unvaccinated for COVID-19 due to limited access to Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines).
- Wants to get the J&J/Janssen COVID-19 vaccine despite the safety concerns.

____ I understand that the vaccine may cause a severe allergic reaction which may include anaphylaxis (difficulty breathing, swelling of the face and throat, a fast heartbeat, a rash all over the body, dizziness and/or weakness).

____ I understand that if I have had a severe allergic reaction (anaphylaxis) or an immediate allergic reaction, even if it was not severe, to any ingredient in the J&J/Janssen COVID-19 vaccine (such as polysorbate), I should not get the J&J/Janssen COVID-19 vaccine.

- A severe allergic reaction is one that needs to be treated with epinephrine or EpiPen or requires additional medical care.
- An immediate allergic reaction means a reaction within 4 hours of exposure, including symptoms such as hives, swelling, or wheezing (respiratory distress).

____ I understand that if I developed thrombosis with thrombocytopenia syndrome after my initial J&J/Janssen vaccine, I should get the Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) for my booster dose.

____ I understand that Guillain Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. I understand the chance of having this occur is very low.

____ I understand I should seek medical attention right away if I develop any of the following symptoms of Guillain Barré after receiving the Janssen COVID-19 Vaccine:

- Weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body
- Difficulty walking
- Difficulty with facial movements, including speaking, chewing, or swallowing
- Double vision or inability to move eyes
- Difficulty with bladder control or bowel function

____ I understand that blood clots involving blood vessels in the brain, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the **Janssen (Johnson & Johnson)** COVID-19 Vaccine. I understand the chance of having this occur is remote.

____ I understand that currently available evidence indicates that it is plausible that the **Janssen (Johnson & Johnson)** COVID-19 Vaccine caused these blood clots and low levels of platelets in the people who developed them.

____ I understand that in people who developed these blood clots and low levels of platelets, symptoms began approximately one-to-two-weeks following vaccination.

____ I understand that these blood clots and low levels of platelets could develop outside of the one-to-two-weeks' timeframe and that I should watch for symptoms outside of this window.

____ I understand that most people who developed these blood clots and low levels of platelets were females ages 18 through 49 years.

____ I understand that some of the people who developed these blood clots and low levels of platelets died.

Name: _____ Date of Birth: _____

____ I understand that I should seek medical attention right away if I have any of the following symptoms after receiving **Janssen (Johnson & Johnson)** COVID-19 Vaccine:

- Shortness of breath,
- Chest pain,
- Leg swelling,
- Persistent abdominal pain,
- Severe or persistent headaches or blurred vision,
- Easy bruising or tiny blood spots under the skin beyond the site of the injection.

____ I understand that I should inform my medical provider that I have received the **Janssen (Johnson & Johnson)** vaccine if I seek care for any of the symptoms listed above.

____ I understand that my medical provider may ask me about receiving the **Janssen (Johnson & Johnson)** COVID-19 Vaccine and may use one or more of its various, common names, including:

- "Janssen" (pronounced YAN-sen)
- "Janssen" (pronounced JAN-sen)
- "Johnson & Johnson"
- "J&J"
- "One-dose/One-shot vaccine"

____ I understand that the above listed side effects may not be all the side effects of the COVID-19 vaccine.

____ I understand that the vaccine is still being studied in clinical trials.

____ I understand that all possible side effects or complications associated with the vaccine cannot be predicted.

____ I understand that any long-term side effects or future complications from this vaccine are unknown at this time.

____ I acknowledge that I have been given a copy, have viewed or had explained to me the Emergency Use Authorization Fact Sheet about the vaccine to be administered to me and information about the disease.

____ I acknowledge I had the opportunity to ask questions and understand both the presently known benefits and the risks of this vaccine.

____ I acknowledge I had an opportunity to decline having this vaccine administered to me.

____ I acknowledge and understand that unless I request otherwise, a record of my vaccination shall be provided to a state-wide Immunization Registry for the purpose of immunization tracking, recall and recording.

____ I certify that I am (a) at least 18 years of age or (b) acting at the request of the patient.

____ I confirm that the person being vaccinated has not received a COVID vaccine from another manufacturer that would make receipt of a **Janssen (Johnson & Johnson) COVID-19 vaccine** today inconsistent with CDC guidance.

____ I hereby give my consent to the administration of a **Janssen (Johnson & Johnson)** COVID-19 vaccine.

By initialing and signing this COVID-19 Vaccine Informed Consent Form, I agree to receive this COVID-19 vaccine.

| Print name of person giving consent to vaccinate. | Patient consent/signature | Date of consent |
|---|---|---|
| | | |

**Turn this form in before you leave the event.**

**Vaccination and Records Staff Use Only**

| Manufacturer: Janssen (Johnson & Johnson) | Anatomical Site: ☐ Left Deltoid ☐ Right Deltoid | |
|---|---|---|
| Lot Number: | Date of vaccine: | ☐ 1st Dose<br>☐ 2nd Dose<br>☐ 3rd Dose |
| Expiration Date: | Vaccinator's Name: | |