

**Janssen (J&J) COVID-19 Vaccine Consent Form**  
**Facility: St. Mary's Medical Center - SFO Medical Clinic**

**Section 1: Personal Information (please print)**

NAME (Last)		(First)	(M.I.)
DATE OF BIRTH: month _____ day _____ year _____			
PHONE NUMBER		SEX ASSIGNED AT BIRTH	M / F
EMAIL ADDRESS:			

Address _____	
City _____	State _____
Zip Code _____	Country _____

**Section 2: Screening for Vaccine Eligibility**

	YES	NO
1. Have you had a severe allergic reaction to any ingredient in the Janssen COVID-19 vaccine? <i>Components of the Janssen COVID-19 Vaccine: recombinant replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride.</i>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are you below the minimum age requirement (18 years) for receiving the Janssen COVID-19 vaccine?	<input type="checkbox"/>	<input type="checkbox"/>
3. Have you received a previous COVID-19 vaccine made by a different manufacturer?	<input type="checkbox"/>	<input type="checkbox"/>
4. Have you received any monoclonal antibodies or convalescent plasma to treat COVID-19 in the last 90 days?	<input type="checkbox"/>	<input type="checkbox"/>
5. Have you received a single primary dose of the Janssen COVID-19 vaccine at least 2 months ago? If so, any of the currently available COVID-19 vaccines may be used for your booster dose.	<input type="checkbox"/>	<input type="checkbox"/>

If 'no' or 'N/A' answers to the first 4 questions, progress to the next section. For 'yes' answers, please seek guidance.

**Section 3: Consent for Vaccination**

- I have been offered and have read or had explained to me the COVID-19 Vaccine Screening Questions and Guidance.
  - I also have been offered and have read or had explained to me the Fact Sheet for Patients and Parents/Caregivers for the Janssen COVID-19 Vaccine that I am receiving today.
  - I understand the risks and benefits of receiving the Janssen COVID-19 Vaccine.
  - I understand the Janssen COVID-19 Vaccine went through a special process called an emergency use authorization (EUA). The Janssen COVID-19 Vaccine has not been fully reviewed and approved by the FDA.
  - I understand the potential risks, including serious allergic reactions (anaphylaxis). Other reported adverse reactions include injection site reactions (pain, swelling, or redness) and general side effects (headache, feeling very tired, muscle aches, nausea and fever). 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), occurred in some people who received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began about one to two weeks after vaccination. Most people who developed these blood clots and low levels of platelets were females ages 18-49 years. The chance of this occurring is remote. You should seek medical attention right away if you have any of the following symptoms after receiving Janssen COVID-19 Vaccine:
    - Shortness of breath,
    - Chest pain,
    - Leg swelling,
    - Constant abdominal pain,
    - Severe or nonstop headaches or blurred vision,
    - Easy bruising or tiny blood spots under the skin beyond the injection site.
  - I understand there are other potential ways to prevent COVID-19.
  - I was given the chance to ask questions and all questions were answered.
  - I agree to receive the Janssen COVID-19 Vaccine.
- I GIVE CONSENT** to The Facility and its staff to vaccinate me with the Janssen COVID-19 Vaccine (the COVID Vaccine). (If you choose this option but do not sign below, then you will not be vaccinated).

Signature of Recipient/Healthcare Proxy \_\_\_\_\_ Date: month \_\_\_ day \_\_\_ year \_\_\_

**COMPLETE THIS PAGE ONLY IF CONSENT TO RECEIVE THE COVID-19 VACCINE IS GIVEN.**

**Section 4: Notice of Privacy Practices**

- I have been offered The Facility's Notice of Privacy Practices.
- By signing below, I acknowledge receipt of the Notice of Privacy Practices.

Signature of Recipient/Healthcare Proxy \_\_\_\_\_ Date: month \_\_\_ day \_\_\_ year \_\_\_\_

**Section 5: Consent to Bill/Assignment of Benefits**

- I will not be personally responsible for any cost or fee associated with the COVID Vaccine.
- If I am a beneficiary under any insurance or health plan or government-sponsored program (Plan/Program), I understand that the Plan/Program may be billed for the administration of the COVID Vaccine.
- I assign to The Facility any benefits under my Plan/Program for the administration of the COVID Vaccine.
- I authorize The Facility to directly bill my Plan/Program for the administration of the COVID Vaccine.
- I instruct my Plan/Program to directly pay The Facility any benefits to which I am entitled for the administration of the COVID Vaccine.
- I authorize The Facility to keep any payment received from my Plan/Program for the administration of the COVID Vaccine.

Signature of Recipient/Healthcare Proxy \_\_\_\_\_ Date: month \_\_\_ day \_\_\_ year \_\_\_\_

**Section 6: Vaccination Record**

**FOR ADMINISTRATIVE USE ONLY**

Vaccine Manufacturer	Date Dose Administered	Lot Number	Dose	Name of Vaccine Administrator
Janssen 0.5 mL	/ /		<input type="checkbox"/> First dose <input type="checkbox"/> Booster dose	

Site: Left / Right Deltoid      Time: \_\_\_\_\_

## COVID-19 Vaccine Screening Questions and Guidance

Pertains to Pfizer-BioNTech, Moderna, and Janssen (J&J) COVID Vaccines

Question	Answer
<p><b>Have you had a severe allergic reaction or immediate allergic reaction after receiving a previous dose of an mRNA COVID-19 vaccine (made by Pfizer-BioNTech or Moderna)?</b></p> <p><u>Guidance:</u> If yes, you should not receive another mRNA COVID-19 vaccine dose without talking to your provider. Please ask your provider if they think your allergic reaction is severe. An immediate allergic reaction is allergic signs, such as itching, swelling of the tongue, neck or throat, wheezing, or anaphylaxis within 4 hours of the vaccine administration. Your provider should help you decide if you should receive a second dose.</p> <p>If you had a severe allergic reaction or immediate allergic reaction to an mRNA COVID-19 vaccine dose, you may be able to receive a Janssen COVID-19 vaccine dose (at least 28 days after mRNA dose). However, caution must be used. You should be vaccinated in a setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider asking your provider to refer you to an allergist-immunologist.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<p><b>Have you had a severe allergic reaction or immediate allergic reaction to any ingredient in the any COVID-19 vaccine?</b></p> <p><b>Components of the Pfizer-BioNTech COVID-19 Vaccine:</b> nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2, sodium chloride, lipids, polyethylene glycol, potassium chloride, monobasic potassium phosphate, dibasic sodium phosphate dihydrate, and sucrose</p> <p><b>Components of the Moderna COVID-19 Vaccine:</b> nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus, lipids, polyethylene glycol [PEG], tromethamine, acetic acid, sodium acetate, and sucrose.</p> <p><b>Components of the Janssen COVID-19 Vaccine:</b> recombinant replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-<math>\beta</math>-cyclodextrin (HBCD), polysorbate-80, sodium chloride.</p> <p><u>Guidance:</u> If yes, you should not receive this vaccine.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> Yes <input type="checkbox"/> No
<p><b>Do you have a personal history of a severe allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous)?</b></p> <p><u>Guidance:</u> If yes, you may receive a COVID-19 vaccine. You will be watched for 30 minutes after today's vaccination to see if you have any reactions.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p><b>Do you have a personal history of a severe allergic reaction to any oral medications, food, or environmental factors, such as pets or latex?</b></p> <p><u>Guidance:</u> If yes, you may receive a COVID-19 vaccine. If you have had a severe allergic reaction due to any cause, you will be watched for 30 minutes after today's vaccination to see if you have any reactions. If your allergic reaction was not severe, you will be watched for the usual 15-minute period.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

Question	Answer
<p><b>Are you below the minimum age requirement?</b>  <b>Pfizer-BioNTech COVID-19 vaccine: 12 years</b>  <b>Moderna COVID-19 vaccine: 18 years</b>  <b>Janssen COVID-19 vaccine: 18 years</b></p>	<p><input type="checkbox"/> Yes   <input type="checkbox"/> No  <input type="checkbox"/> Yes   <input type="checkbox"/> No  <input type="checkbox"/> Yes   <input type="checkbox"/> No</p>
<p><u>Guidance:</u> If yes, you should not receive this vaccine. To get the vaccine, you must meet the age requirement for the vaccine you are receiving.</p>	
<p><b>Have you received a previous COVID-19 vaccine made by a different manufacturer?</b></p>	<p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p>
<p><u>Guidance:</u> If yes, you should receive your second dose made by the same vaccine manufacturer. The COVID vaccines are not interchangeable.</p> <p>If you received the first dose of mRNA COVID-19 vaccine but you are unable to receive the second dose with same or different mRNA vaccine due to a contraindication, you may receive a single dose of the Janssen COVID-19 vaccine 28 days after mRNA COVID-19 vaccine dose. However, caution must be used. You should be vaccinated in a setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider asking your provider to refer you to an allergist-immunologist.</p>	
<p><b>Has too little time elapsed since your first COVID-19 vaccine dose?</b>  <b>Pfizer-BioNTech COVID-19 vaccine: 21 days</b>  <b>Moderna COVID-19 vaccine: 28 days</b>  <b>Janssen COVID-19 vaccine: not applicable, one dose only</b></p>	<p><input type="checkbox"/> Yes   <input type="checkbox"/> No   <input type="checkbox"/> N/A</p>
<p><u>Guidance:</u> If yes, you should wait the recommended amount of time to get your second dose. You may receive it 4 days earlier if needed.</p> <p>The second dose should be administered as close to the recommended interval as possible. However, if that is not feasible, the second dose may be given up to 6 weeks (42 days) after the first dose.</p>	
<p><b>Have you been diagnosed with COVID-19 infection previously?</b></p>	<p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p>
<p><u>Guidance:</u> If yes, you may receive a COVID-19 vaccine. Clinical trials indicate it is safe.</p>	
<p><b>Do you currently have COVID-19 symptoms (including fever) OR a current diagnosis of COVID-19?</b></p>	<p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p>
<p><u>Guidance:</u> If yes, wait to get the vaccine until you have recovered from your acute illness and your quarantine period has ended to avoid exposing healthcare workers (HCW) or others during your vaccination appointment. You may wait to get the vaccine after your infection, but waiting is not required.</p>	
<p><b>Have you received any monoclonal antibodies or convalescent plasma to treat COVID-19?</b></p>	<p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p>
<p><u>Guidance:</u> If yes, you should wait at least 90 days to get the vaccine to avoid having the treatment interfere with the vaccine.</p>	
<p><b>Are you moderately or severely immunocompromised?</b></p>	<p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p>
<p><u>Guidance:</u> If yes, you may receive a third dose of either the Pfizer-BioNTech or Moderna COVID-19 vaccine, at least 28 days after your second dose. Your provider is best able to assess your degree of immunocompromise and optimal timing of vaccination.</p> <p>Moderate or severe immune compromise may be caused by:</p>	

Question	Answer
<ul style="list-style-type: none"> <li>Immunosuppressive therapies, such as active cancer treatment, CART-T-cell therapy, high-dose steroids) or</li> <li>Medical conditions that affect the immune system, such as solid-organ transplant, stem cell transplant within last 2 years, moderate or severe primary immunodeficiency, advanced or untreated HIV infection.</li> </ul>	
<p><b>If you have completed a primary vaccine series with the Pfizer-BioNTech COVID-19 vaccine or the Moderna COVID-19 vaccine, do any of the below criteria apply to you?</b></p> <ul style="list-style-type: none"> <li>65 years of age or older or reside in a long-term care setting</li> <li>50 to 64 years of age with underlying medical conditions</li> </ul> <p><b>Underlying medical conditions</b> include: Cancer, chronic kidney disease, chronic lung diseases (including COPD, asthma, interstitial lung disease, cystic fibrosis, pulmonary hypertension), dementia or other neurological conditions, diabetes (type 1 or type 2), Down syndrome, heart conditions (such as heart failure, coronary artery disease, cardiomyopathies, hypertension), HIV infection, immunocompromised state (weakened immune system), liver disease, overweight and obesity, pregnancy, sickle cell disease or thalassemia, smoking (current or former), solid organ or blood stem cell transplant, stroke or cerebrovascular disease, substance use disorders.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p><u>Guidance:</u> If yes, the Centers for Disease Control and Prevention (CDC) has indicated that you <b>should</b> receive a COVID-19 vaccine booster shot at least 6 months after your primary series. Any of the currently available COVID-19 vaccines may be used for your booster dose.</p>	
<p><b>If you have completed a primary vaccine series with the Pfizer-BioNTech COVID-19 vaccine or the Moderna COVID-19 vaccine, do any of the below criteria apply to you?</b></p> <ul style="list-style-type: none"> <li>18 to 64 years of age with underlying medical conditions (see definition above)</li> <li>18 to 64 years of age and at increased risk for COVID-19 exposure because of where you work or live</li> </ul> <p><b>Occupations at increased risk for COVID-19 exposure and transmission</b> include first responders (healthcare workers, firefighters, police, congregate care staff), education staff (teachers, support staff, daycare workers), food and agriculture workers, manufacturing workers, corrections workers, U.S. Postal Service workers, public transit workers, grocery store workers.</p> <p><b>Residential settings with an increased risk of COVID-19 exposure and transmission</b> include health care settings, schools, correctional facilities, homeless shelters.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p><u>Guidance:</u> If yes, the CDC has indicated that you <b>may</b> receive a COVID-19 vaccine booster shot at least 6 months after your primary series. Any of the currently available COVID-19 vaccines may be used for your booster dose.</p>	
<p><b>If you have completed the single primary dose of the Janssen COVID-19 vaccine, has at least 2 months elapsed since your dose?</b></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p><u>Guidance:</u> If yes, the CDC has indicated that you may receive a COVID-19 vaccine booster dose. Any of the currently available COVID-19 vaccines may be used for your booster dose.</p>	
<p><b>Do you have underlying medical conditions, such as Guillain-Barré syndrome, Bell's palsy, dermal filler use?</b></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

Question	Answer
<p><u>Guidance:</u> If yes, you may receive the COVID-19 vaccine (unless otherwise contraindicated). Clinical trials show similar results for people with these underlying medical conditions.</p>	
<p><b>Are you currently taking an anticoagulant (blood thinner)?</b></p> <p><u>Guidance:</u> If yes, you may see some bleeding at your injection site.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p><b>Are you pregnant, planning on becoming pregnant, or breastfeeding?</b></p> <p><u>Guidance:</u> If yes, the Pfizer-BioNTech or Moderna COVID-19 vaccine is recommended for you.</p> <ul style="list-style-type: none"> <li>• There is no evidence that any of the COVID-19 vaccines affect current or future fertility             <ul style="list-style-type: none"> <li>▪ COVID-19 vaccines do not cause infection in pregnant women or their babies</li> <li>▪ No safety concerns in animal studies</li> <li>▪ Reassuring early safety data on the Pfizer-BioNTech and Moderna COVID-19 vaccines during pregnancy</li> <li>▪ Early data suggest the Pfizer-BioNTech and Moderna COVID-19 vaccines during pregnancy are effective</li> </ul> </li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p><b>Are you a woman younger than 50 years old?</b></p> <p><u>Guidance:</u> If yes, you should be aware of the rare risk of blood clots with low platelets after vaccination with the Janssen (J&amp;J) COVID-19 vaccine. However, after temporarily pausing the use of this vaccine to review all available safety data, CDC and FDA recommend use of this vaccine start again, given that the known and potential benefits outweigh the known and potential risks. This adverse event is rare, occurring at a rate of about 7 per 1 million vaccinated women between 18 and 49 years old. For women 50 years and older and men of all ages, this adverse event is even more rare.</p> <p>For three weeks after receiving the vaccine, you should be on the lookout for possible symptoms of a blood clot with low platelets. These include:</p> <ul style="list-style-type: none"> <li>• Severe or nonstop headaches or blurred vision</li> <li>• Shortness of breath</li> <li>• Chest pain</li> <li>• Leg swelling</li> <li>• Constant abdominal pain</li> <li>• Easy bruising or tiny blood spots under the skin beyond the injection site</li> </ul> <p>Seek medical care right away if you develop one or more of these symptoms.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

1. CDC. Interim Clinical Considerations for Use of COVID-19 Vaccines. Published online March 1, 2021. Available from: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/03-COVID-MacNeil.pdf>
2. Janssen. Fact sheet for healthcare providers administering vaccines. Emergency use authorization (EUA) of the Janssen COVID-19 Vaccine to prevent coronavirus disease 2019 (COVID-19). February 2021.
3. Moderna. Fact sheet for healthcare providers administering vaccines. Emergency use authorization (EUA) of the Moderna COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). December 2020.
4. Pfizer-BioNTech. Fact sheet for healthcare providers administering vaccines. Emergency use authorization (EUA) of the Pfizer-Biontech COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). December 2020.
5. CDC. CDC Recommends Use of Johnson & Johnson's Janssen COVID-19 Vaccine Resume. Published online 4/25/21. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html#symptoms-list-question>
6. CDC. Information about COVID-19 Vaccines for People who Are Pregnant or Breastfeeding. Published online 4/28/21. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html>
7. CDC. Clinical Considerations for Pfizer-BioNTech COVID-19 Vaccination in Adolescents. Published online 5/12/21. Available from: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/05-COVID-Woodworth-508.pdf>
8. CDC. Clinical considerations for use of an additional mRNA COVID-19 vaccine dose after a primary mRNA COVID-19 vaccine series for immunocompromised people. Published online 8/13/21. Available from: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-13/03-COVID-Goswami-508.pdf>
9. CDC. Pfizer-BioNTech COVID-19 Vaccine Booster Shot. Published online 9/24/21. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html>
10. CDC. CDC Expands Eligibility for COVID-19 Booster Shots. Published online 10/21/21. Available from: <https://www.cdc.gov/media/releases/2021/p1021-covid-booster.html>