

**Pfizer-BioNTech 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 _____

<b>Section 2: Screening for Vaccine Eligibility</b>		YES	NO	N/A
1.	Have you had a severe allergic reaction after receiving a previous dose of an mRNA (Pfizer-BioNTech or Moderna) COVID-19 vaccine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	Have you had an intermediate or severe allergic reaction to any ingredient in the Pfizer-BioNTech COVID-19 vaccine or to polysorbate? <i>Components of the Pfizer-BioNTech COVID-19 Vaccine: 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</i>	<input type="checkbox"/>	<input type="checkbox"/>	
3.	Are you below the minimum age requirement (5 years) for receiving the Pfizer-BioNTech COVID-19 vaccine?	<input type="checkbox"/>	<input type="checkbox"/>	
4.	For primary series vaccine doses (initial 2 doses, 3 doses for immunocompromised people), have you received a previous COVID-19 vaccine made by a different manufacturer? Your initial doses should be made by the same manufacturer. For booster doses, please select N/A.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	Are you moderately or severely immunocompromised (see details on page 2) and 5 years of age or older? If yes, you are eligible for a third vaccine dose, to be given at least 28 days after your second dose. If you are immunocompromised and 12 years of age or older, you may also receive a fourth (booster) dose 3 months after your third vaccine dose.	<input type="checkbox"/>	<input type="checkbox"/>	
6.	If you have completed a primary vaccine series with the Pfizer-BioNTech COVID-19 vaccine or the Moderna COVID-19 vaccine, do the below criteria apply to you? <ul style="list-style-type: none"> <li>● Pfizer-BioNTech COVID-19 vaccine:</li> <li>● 12 years of age or older and at least 5 months has elapsed since your second dose</li> <li>● 50 years of age or older and at least 4 months has elapsed since your first booster shot</li> <li>● 12 years of age or older, moderately or severely immunocompromised, and at least 4 months has elapsed since your first booster shot</li> <li>● Moderna COVID-19 vaccine:</li> <li>● 18 years of age or older and at least 5 months has elapsed since your second dose</li> <li>● 50 years of age or older and at least 4 months has elapsed since your first booster shot</li> <li>● 18 years of age or older, moderately or severely immunocompromised, and at least 4 months has elapsed since your first booster shot</li> </ul> If yes, the Centers for Disease Control and Prevention (CDC) recommends a COVID-19 vaccine booster shot for you. Any of the currently available COVID-19 vaccines may be used for your booster dose (this consent form is for the Pfizer-BioNTech COVID-19 vaccine).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	If you have completed the single primary dose of the Janssen COVID-19 vaccine, do the below criteria apply to you? <ul style="list-style-type: none"> <li>● 18 years of age or older</li> <li>● At least 2 months has elapsed since your dose</li> </ul> If yes, the CDC recommends a COVID-19 vaccine booster shot for you. Any of the currently available COVID-19 vaccines may be used for your booster dose (this consent form is for the Pfizer-BioNTech COVID-19 vaccine).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	Have you received both a single primary dose and booster dose of the Janssen COVID-19 vaccine? If yes, you may receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after your Janssen COVID-19 booster.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

For the first 4 questions, if 'no' or 'N/A' answers, 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 Pfizer-BioNTech COVID-19 Vaccine that I am receiving today.

- I understand the risks and benefits of receiving the Pfizer-BioNTech COVID-19 Vaccine.
  - I understand the Pfizer-BioNTech COVID-19 Vaccine is FDA approved for people 16 years of age and older. For people 5 to 15 years of age, the third dose for certain immunocompromised people, and the booster dose(s) for certain people 12 years of age and older, the Pfizer-BioNTech COVID-19 Vaccine is available under emergency use authorization (EUA) and 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 pain, swelling, redness, fatigue, headache, muscle pain, chills, joint pain, fever, nausea, and swollen lymph nodes.
  - I understand there may be 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 Pfizer-BioNTech COVID-19 Vaccine.
- I GIVE CONSENT** to The Facility and its staff to vaccinate me or the person named above with the Pfizer-BioNTech COVID-19 Vaccine (the COVID Vaccine). (If you choose this option but do not sign below, then you or the person named above for whom you are giving consent will not be vaccinated).

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

If signing for someone other than yourself - Printed Name: \_\_\_\_\_ Relationship: \_\_\_\_\_

#### **Section 4: Definitions**

- **Moderately or severely immunocompromised**  
Your provider is best able to assess your degree of immunocompromise and optimal timing of vaccination. Moderate or severe immune compromise may be caused by immunosuppressive or immunomodulatory therapies (for example, active cancer treatment, CART-T-cell therapy, high-dose steroids) or medical conditions that affect the immune system (for example, solid-organ transplant, stem cell transplant within last 2 years, moderate or severe primary immunodeficiency, advanced or untreated HIV infection).

#### **Section 5: 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 6: 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 7: Vaccination Record**

##### FOR ADMINISTRATIVE USE ONLY

Vaccine Manufacturer	Date Dose Administered	Lot Number	Dose	Name of Vaccine Administrator
Pfizer/BioNTech	/ /		<input type="checkbox"/> First Dose <input type="checkbox"/> Second Dose <input type="checkbox"/> Third Dose <input type="checkbox"/> Booster Dose #1 <input type="checkbox"/> Booster Dose #2	

Injection Site: Left / Right Deltoid

Time: \_\_\_\_\_ AM/ PM

## 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 COVID-19 vaccines?</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>Are you in need of COVID-19 vaccination but are unable (e.g., allergy) or unwilling to receive an mRNA COVID-19 vaccine?</b></p> <p><u>Guidance:</u> If yes, a Janssen (J&amp;J) COVID-19 Vaccine may be an option for you. However, in most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for primary and booster vaccination.</p>	<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

Question	Answer
<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>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<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>	
<p><b>Are you below the minimum age requirement (for primary vaccine series)?</b>  <b>Pfizer-BioNTech COVID-19 vaccine: 5 years</b>  <b>Moderna COVID-19 vaccine: 18 years</b>  <b>Janssen COVID-19 vaccine: 18 years</b></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><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>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p><u>Guidance:</u> If yes (for primary vaccine series), you should receive your second dose made by the same vaccine manufacturer. While any of the currently available COVID-19 vaccines may be used for your booster dose, in most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for booster vaccination.</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>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<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. An 8-week interval (between 1<sup>st</sup> and 2<sup>nd</sup> doses) may be optimal for some people ages 12 years and older, especially for males ages 12 to 39 years old. The standard interval between vaccine doses (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) remains the recommended interval for the following people: moderately to severely immunocompromised, adults ≥ 65 years of age, and others who need rapid protection due to increased concern about community transmission or risk of severe disease.</p>	
<p><b>Have you been diagnosed with COVID-19 infection previously?</b></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<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>	<input type="checkbox"/> Yes <input type="checkbox"/> No

Question	Answer
<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>Are you moderately or severely immunocompromised?</b></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<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 if you are 5 years of age or older (Pfizer-BioNTech) or 18 years of age or older (Moderna). You may also receive a fourth (booster) dose 3 months after your third vaccine dose for the Pfizer-BioNTech COVID-19 vaccine (12 years of age or older) and 3 months after the Moderna COVID-19 vaccine (18 years of age or older). You may also receive a fifth (booster) dose 4 months after your fourth vaccine dose for the Pfizer-BioNTech COVID-19 vaccine (12 years of age or older) and 4 months after the Moderna COVID-19 vaccine (18 years of age or older). Your provider is best able to assess your degree of immunocompromise and optimal timing of vaccination. If you have received a single primary vaccine dose of the Janssen COVID-19 vaccine, then you may also receive an additional primary vaccine dose (Pfizer-BioNTech or Moderna preferred) 4 weeks after your initial Janssen vaccine dose.</p> <p>Moderate or severe immune compromise may be caused by:</p> <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 the below criteria apply to you?</b></p> <ul style="list-style-type: none"> <li>• 12 years of age or older for Pfizer-BioNTech COVID 19 vaccine</li> <li>• 18 years of age or older for Moderna COVID-19 vaccine</li> <li>• The minimum amount of time has elapsed since your second dose             <ul style="list-style-type: none"> <li>○ At least 5 months for the Pfizer-BioNTech COVID-19 vaccine</li> <li>○ At least 5 months for the Moderna COVID-19 vaccine</li> <li>○ 50 years of age or older and at least 4 months has elapsed since your first booster shot for the Pfizer-BioNTech or Moderna COVID-19 vaccine</li> </ul> </li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<p><u>Guidance:</u> If yes, the Centers for Disease Control and Prevention (CDC) recommends a COVID-19 vaccine booster shot for you. While any of the currently available COVID-19 vaccines may be used for your booster dose, in most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for booster vaccination.</p>	
<p><b>If you have completed the single primary dose of the Janssen COVID-19 vaccine, do the below criteria apply to you?</b></p> <ul style="list-style-type: none"> <li>• 18 years of age or older</li> <li>• At least 2 months has elapsed since your dose</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

Question	Answer
<p>Guidance: If yes, the CDC has indicated that you may receive a COVID-19 vaccine booster dose. While any of the currently available COVID-19 vaccines may be used for your booster dose, in most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for booster vaccination.</p>	
<p><b>Have you have received both a single primary dose and booster dose of the Janssen COVID-19 vaccine?</b></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<p><u>Guidance:</u> If yes, the CDC has indicated that you may receive a 2<sup>nd</sup> booster dose using an mRNA COVID-19 vaccine (Pfizer BioNTech or Moderna COVID19 vaccine) at least 4 months after your Janssen COVID-19 booster.</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
<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>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p><u>Guidance:</u> If yes, you may see some bleeding at your injection site.</p>	
<p><b>Are you pregnant, planning on becoming pregnant, or breastfeeding?</b></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<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>	
<p><b>Are you a woman younger than 50 years old?</b></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<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>	

## References

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