

BUREAU OF IMMUNIZATIONS

## Missouri DHSS Department of Health and Senior Services

## COVID-19 VACCINATION SCREENING AND CONSENT UNDER EMERGENCY USE AUTHORIZATION

<sup>'</sup> Please complete the following information for the person receiving the COVID-19 vaccine.

PATIENT DEMOGRAPHIC INFORMATION															
LAST NAME FIRST NAME												MIDDL	E INITIAL		
DATE OF BIRTH ARE YOU A								<sup>sex</sup>				ther			
RACE Black Asian American Indian/Alaskan Native				Pacific Islander				HISPANIC ETHNICITY				DO YOU HAVE A DISABILITY?			
_															
STATE ZIP COUNTY HOME PHONE CELL PHONE															
EMAIL     WOULD LIKE A REMINDER FOR THE NEXT APPOINTMENT       Yes     No       Postcard / call / text															
	Private or employer insurance Underinsured Uninsured Medicare Medicaid														
					HEALTH HIS	TORY					YE	s	NO	UNKNOWN	
1.	Are you feeling sick today?											]			
2.	Have you ever received a dose of COVID-19 vaccine?										]				
3.	If yes, which vaccine product did you receive?														
4.	Have you received a complete COVID-19 Vaccine series (2 doses of Pfizer or Moderna/1 dose of J&J)										]				
5.	In the past 14 days have you had contact with a confirmed COVID-19 patient?									]					
6.	<ul> <li>Have you ever had an allergic reaction to: (This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)</li> <li>Polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures</li> <li>Polysorbate, which is found in some vaccines, film coated tablets, and intravenous steroids</li> <li>A previous dose of COVID-19 vaccine</li> <li>A vaccine or injectable therapy that contains multiple components, one of which is a COVID-19 vaccine component, but it is not known which component elicited the immediate reaction</li> </ul>														
7.	Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or an injectable medication? (This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)									]					
8.	Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something other than a component of COVID-19 vaccine, or any vaccine or injectable medication? This would include food, pet, venom, environmental, or oral medication allergies.														
9.	Have you ever ha	lave you ever had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?										]			
10.	Have you receive COVID-19?	Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19?								eatment for		]			
11.	Do you have a bleeding disorder or are you taking a blood thinner?									]					
12.	Have you been diagnosed with an immune mediated syndrome characterized by thrombosis and thrombocytopenia or Heparin Induced Thrombocytopenia (HIT)?									]					
13.		To you have a weakened immune system caused by something such as HIV infection or cancer or do you take nmunosuppressive drugs or therapies?								r do you take		]			
14.	Do you have derr	o you have dermal fillers?										]			
15.	Are you pregnant	e you pregnant or breastfeeding?										]			
16.		o you have or have a history of Multisystem Inflammatory Syndrome in Children or Adults (MIS-C or MIS-A)?							or MIS-A)?		]				
17.	Do you have or h	o you have or have a history of Guillain-Barré Syndrome (GBS)?										]			

	also provide benefits to cerres identified in the PREP A countermeasures are any at, diagnose, cure, prevent used in the administration of s available by calling 1-855 eparedness-and-response eparedness-and-response eparedness-and-response	cal injury tain surviv act declars antiviral n , or mitiga of and all 5-266-242 /coronavii /coronavii /coronavii /coronavii /coronavii	as the direct result of the vors of individuals who ation. The PREP Act de nedication, any other de the COVID-19, the trans components and const the covid states and const the trans of th	he administration or die as a direct resul eclaration for medica rug, any biologic, ar smission of SARS-C ituent materials of a d-19/pfizer-biontech- d-19/moderna-covid- d-19/janssen-covid-1	use of the covered It of the administration or al countermeasures against by diagnostic, any other CoV-2 or a virus mutating ny product. Information - <u>covid-19-vaccine</u> <u>-19-vaccine</u> <u>19-vaccine</u>					
PLEASE PRINT NAME of signature below										
SIGNATURE OF PATIENT			RELATIONSHIP TO CLIENT		TODAY'S DATE					
ACKNOWLEDGMENT OF RECEIPT OF NOTICE OF PRIVACY PRACTICES          I,										
CLIENT SIGNATURE/LEGAL REPRESENTATIVE			NSHIP TO CLIENT		TODAY'S DATE					
HAVE YOU OR AN IMMEDIATE FAMILY MEMBER	EVER SERVED IN THE U.S. ARMED F	ORCES?	IF YES, WOULD YOU LIKE IN	FORMATION ABOUT MILITAI	RY RELATED SERVICES IN MISSOURI?					
MANUFACTURER	BRAND	R CLINIC	USE ONLY	LOT NUMBER						
	*EXP. DATE			*DATE ADMINISTERED						
*EUA FACT SHEET DATE	*EUA FACT SHEET (	GIVEN DATE								
AGENCY ADDRESS			CLINIC ADMINISTRATION AD	DBESS						
AGENOT ADDRESS				DIEGO						

## Information for Healthcare Professionals about the health history for COVID-19 Vaccines

**Are you feeling sick today?** There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (e.g., upper respiratory infections, diarrhea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics. Vaccination of persons with current SARS-CoV-2 infection should be deferred until the person has recovered from acute illness and they can discontinue isolation. While there is no minimum interval between infection and vaccination, current evidence suggests reinfection is uncommon in the 90 days after initial infection. Persons with documented acute SARSCoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.

**Have you ever received a dose of COVID-19 vaccine?** COVID-19 vaccines are not interchangeable. COVID-19 vaccines are administered intramuscularly as either a two-dose series or single dose. For two-dose products, check medical records, immunization information systems, and vaccination record cards to help determine the initial product received. Those who received a trial vaccine should consult with the trial sponsors to determine if it is feasible to receive additional doses. If the vaccine product used for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered. Separate doses by at least 28 days. If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time. If an individual has received a COVID-19 vaccine in another country, the vaccine received was authorized by the World Health Organization (WHO) and the series completed, no further dose is needed.

## Have you ever had an allergic reaction to any component of a COVID-19 vaccine, including:

- Polyolyethylene (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures
   Polysorbate, which is found in some vaccines, film-coated tablets, and intravenous steroids
- A vaccine or injectable therapy that contains multiple components, one of which is a COVID-19 vaccine component, but if it is unknown which component elicited the immediate allergic reaction

Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and crossreactive hypersensitivity between these compounds may occur. Persons with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna). Persons with a contraindication to mRNA COVID-19 vaccine. Persons with a contraindication to Janssen COVID-19 vaccine. Persons with a contraindication to Janssen COVID-19 vaccine (including due to a known [diagnosed] allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines.

Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something? For example, a reaction for which you were treated with epinephrine or EpiPen®, or for which you had to go to the hospital? Allergic reactions, including severe allergic reactions, NOT related to vaccines or injectable therapies (e.g., food, pet, venom, environmental, or latex allergies; oral medications) are NOT a contraindication or precaution to vaccination with currently authorized COVID-19 vaccine. HOWEVER, individuals who have had severe allergic reactions to something, regardless of cause, should be observed for 30 minutes after vaccination. All other persons should be observed for 15 minutes.

**Females between 18 and 49 years of age** Women 18 through 49 years of age can receive any FDA-authorized COVID-19 vaccine. However, they should be informed of the rare but increased risk of thrombosis with thrombocytopenia syndrome (TTS) after receipt of the Janssen (J&J) COVID-19 vaccine. TTS is a rare syndrome that involves acute venous or arterial thrombosis and new onset thrombocytopenia in patients with no recent known exposure to heparin. Additional recipient education materials can be found at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html.

**Males between 12 and 29 years of age** Males 12 through 29 years of age can receive any FDA-authorized COVID-19 vaccine. However, individuals receiving an mRNA COVID-19 vaccine, especially males in this age group and their parents/legal representative should be informed of the risk of developing myocarditis (an inflammation of the heart muscle) or pericarditis have occurred predominantly in males 12-29 years within a few days after receiving the second dose of an mRNA COVID-19 vaccine. The risk of developing either myocarditis or pericarditis is low. Additional recipient education materials can be found at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html.

**History of myocarditis or pericarditis:** Experts recommend that people who develop myocarditis or pericarditis after a first dose of an mRNA COVID-19 vaccine defer receiving the second dose, until additional safety data are available. Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Decisions about proceeding with the second dose should include a conversation between the patient, their parent/legal representative (when relevant), and their clinical team, which may include a cardiologist. People who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination may receive any FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved.

Have you ever had a serious reaction after any vaccination or injectable medication including a previous dose of the COVID-19 vaccine or if receiving the J&J vaccine, any ingredient contained within the J&J vaccine? History of severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of the COVID-19 vaccine product being offered is a contraindication to that COVID-19 vaccine. If the patient answers Yes to this question, defer vaccination for 90 days from date of therapy.

In the past 14 days have you had contact with a confirmed COVID-19 patient? Wait until 14 days after quarantine period ends if the contact was in an outpatient or community setting. If person is a resident in a congregate healthcare or other congregate setting, go ahead and vaccinate.

Have you received passive antibody therapy as a treatment for COVID-19? Based on the estimated half-life of monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses.

Had multisystem inflammatory syndrome: either MIS-C or MIS-A: It is unknown if people with a history of MIS-C or MIS-A are at risk for a dysregulated immune response to COVID-19 vaccination. People with a history of MIS-C or MIS-A may choose to be vaccinated. Considerations for vaccination may include: • Clinical recovery from MIS-C or MIS-A, including return to normal cardiac function • Personal risk of severe acute COVID-19 (e.g., age, underlying conditions) • Level of COVID-19 community transmission and personal risk of reinfection • Lack of safety data of COVID-19 vaccines following these illnesses • Timing of any immunomodulatory therapies (general best practice guidelines for immunization can be consulted. Because current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection, people with a history of MIS-C or MIS-A should consider delaying vaccination until they have recovered from their infection and for 90 days after the date of diagnosis of MIS-C or MIS-A. A conversation between the patient, their guardian(s), and their clinical team or a specialist may assist with COVID-19 vaccination decisions. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment Project at https://wwwn. cdc.gov/dcs/ContactUs/Form or call 800-232-4636

Are you breastfeeding or pregnant? Is not a contraindication to current COVID-19 vaccination. While there are currently no available data on the safety of COVID-19 vaccines in pregnant people, studies and results are expected soon. Pregnant people may choose to get vaccinated. Observational data demonstrate that while the absolute risk is low, pregnant people with COVID-19 have an increased risk of severe illness. Breastfeeding is not a contraindication to current COVID-19 vaccine. Lactating people may choose to be vaccinated. There is no data available for lactating people on the effects of mRNA vaccines.

Are you immunocompromised? (taking medication or being treated for cancer, leukemia, HIV/AIDS or other immune system problems or taking medication that affects your immune system is not a contraindication to current COVID-19 vaccine, including those with cancer, leukemia, HIV/AIDS and other immune system problems or taking medication that affects their immune systems. However, patients should be informed that the vaccine might be less effective than in someone who is immunocompetent. Consider administering a 3rd dose to moderately and severely immune compromised individuals at least 28 days after the 2nd dose of completing an mRNA vaccine series (2 doses of PfizerNBioTech or Moderna). Additionally the 3rd dose should be the same mRNA that the individual received before.

**Do you have a bleeding disorder or are you taking a blood thinner?** COVID-19 vaccine may be given to these patients, if a physician familiar with the patient's bleeding risk determines that the vaccine can be administered intramuscularly with reasonable safety. ACIP recommends the following technique for intramuscular vaccination in patients with bleeding disorders or taking blood thinners: a fine-gauge needle (23-gauge or smaller caliber) should be used for the vaccination, followed by firm pressure on the site, without rubbing, for at least 2 minutes.

Have you been diagnosed with an immune mediated syndrome characterized by thrombosis and thrombocytopenia or Heparin Induced Thrombocytopenia (HIT)? Although the cause of thrombosis with thrombocytopenia syndrome (TTS) associated with the Janssen COVID-19 Vaccine is unclear, it appears to be similar to another rare immune-mediated syndrome, heparin-induced thrombocytopenia (HIT). Until more information becomes available, experts advise that people with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as HIT, should be offered another COVID-19 vaccine (i.e., mRNA vaccine) if it has been 90 days or less since their illness resolved. After 90 days, patients may be vaccinated with any FDA-authorized COVID-19 vaccine. Experts believe that the following factors do not make people more susceptible to TTS after receipt of the Janssen COVID-19 Vaccine. People with these conditions can be vaccinated with any FDA-authorized COVID-19 Vaccine.

- A prior history of venous thrombosis
- Risk factors for venous thrombosis (e.g., inherited or acquired thrombophilia including Factor V Leiden; prothrombin gene 20210A mutation; antiphospholipid syndrome; protein C., Protein S or antithrombin deficiency
- A prior history of other types of thromboses not associated with thromocytopenia
- Pregnancy, postpartum or receipt of hormonal contraceptives

**Do you have dermal fillers?** Persons who have received dermal fillers may develop temporary swelling at or near the filler injection site, usually face or lips, after a dose of a COVID-19 vaccine. Administer vaccines to persons with injectable dermal fillers who have no contraindications to vaccination. These persons should be advised to contact their healthcare provider if swelling develops at or near the site of dermal filler following vaccination.

Evidence suggests that if individuals have or have a history of MIS-C or MIS-A, providers should defer vaccination for 90 days after resolution of the illness.

**Do you have a history of Guillain-Barré Syndrome (GBS)?** People with a history of GBS can receive any FDA-authorized COVID-19 vaccine. However, given the possible association between the Janssen COVID-19 Vaccine and an increased risk of GBS, a patient with a history of GBS and their clinical team should discuss the availability of mRNA vaccines to offer protection against COVID-19.