

**Guidance for the Standards for Blood Banks and Transfusion Services, 32<sup>nd</sup> edition**

<b>Reference Standard 5.4.1A – Requirements for Allogeneic Donors</b>		
<b>Category</b>	<b>Criteria/Description/Examples</b>	<b>Deferral period</b>
14) Immunizations and Vaccinations	Receipt of other vaccines, including unlicensed vaccines	12 months unless otherwise indicated by medical director

**Q:** The SARS CoV-2 vaccine(s) is available under investigational new drug applications or emergency use authorizations, what is the deferral period for potential donors?

**A:** Reference Standard 5.4.1A (14) for unlicensed vaccines requires a 12-month deferral but allows the blood center medical director discretion to implement a shorter or longer deferral period. The BB/TS Standards Committee (BB/TS SC), based upon the January 19, 2021 communications by Food and Drug Administration (FDA): Updated Information for Blood Establishments Regarding the COVID-19 Pandemic and Blood Donation, recommends that the responsible physician may wish to consider the following:

- individuals who received a live-attenuated viral COVID-19 vaccine, refrain from donating blood for a short waiting period (e.g., 14 days) after receipt of the vaccine.
- individuals who received a nonreplicating, inactivated, or mRNA-based COVID-19 vaccine can donate blood without a waiting period,
- individuals who are uncertain about which COVID-19 vaccine was administered, refrain from donating for a short waiting period (e.g., 14 days) if it is possible that the individual received a live-attenuated viral vaccine.

<b>Category</b>	<b>Criteria/Description/Examples</b>	<b>Deferral period</b>
	• Receipt of live attenuated viral and bacterial vaccines [Measles (rubeola), Mumps, Polio (Sabin/oral), Typhoid (oral), Yellow fever]	2 weeks

BB/TS SC is in agreement with FDA’s statement that individuals who received a nonreplicating, inactivated, or mRNA-based COVID-19 vaccine can donate blood without a waiting period. (This would include Moderna and Pfizer-BioNTech vaccines).

Donors who do not know the manufacturer of the vaccine they received should also be deferred for two weeks.

**Q:** Can individuals who have received the SARS CoV-2 vaccine donate COVID-19 convalescent plasma (CCP)?

**A:** Yes, under certain circumstances, per the FDA Guidance for Industry- Investigational COVID-19 Convalescent Plasma, published January 15, 2021 these individuals can donate CCP if they have:

This guidance is based upon the latest information. BB/TS SC will continue to provide additional information as it becomes available.

- had symptoms of COVID-19 and a positive test result from a diagnostic test approved, cleared, or authorized by FDA, AND
- received the COVID-19 vaccine after diagnosis of COVID-19, AND
- are within 6 months after complete resolution of COVID-19 symptoms.

This is to ensure that COVID-19 convalescent plasma collected from donors contains sufficient antibodies directly related to their immune response to COVID-19 infection.

**Q:** Can individuals who have recovered from SARS COV-2 and received CCP donate blood and CCP?

**A:** Yes, however, since CCP is a blood component, they would be deferred for three months from the date of the last transfusion per BB/TS Reference Standard 5.4.1A (12).

This guidance is based upon the latest information. BB/TS SC will continue to provide additional information as it becomes available.

Guidance to Reference Standard 5.4.1A UPDATED - January 29,2021