

## FDA's Changes to Donor Eligibility Criteria

On April 2, 2020 the FDA [issued a new guidance on deferral criteria for men who have had sex with men](#), or MSM. The changes announced today cover a number of areas, including a revised deferral period for men who have sex with men (MSM); Variant Creutzfeldt-Jacob Disease, tattoos/piercings, travel, and others.

Bloodworks is working to quickly assess our timeline to implement these changes so more donors have the opportunity to give blood to support local patients. We applaud the FDA's decision; Bloodworks has advocated for changes.

The FDA guidance announced April 2 will not result in immediate MSM or other donations. While the FDA guidance now defines a pathway for previously deferred donors to give blood, we anticipate that it will take several months for all blood centers to update computer systems, modify processes and procedures, train staff, and implement these significant changes. We'll be working diligently to determine the process for reinstating eligible donors who were deferred under the previous MSM policy. We understand that even under the new FDA policy, some who want to donate still cannot.

We will make an announcement when we are ready to implement the new deferral criteria.

The primary changes in the guidance are, essentially changing deferral times from 12 to 3 months:

- Reduce the Risk of Transfusion-Transmitted Malaria reduces deferral time for travel by individuals who have never lived in a malarial endemic area but who travel to such an area from 12 months to 3 months
- Defer indefinitely anyone with a positive test for HIV
- Defer for 3 months from last event anyone who exchanged sex for money or drugs
- Defer for 3 months from last event anyone who engaged in non-prescription injection drug use
- Defer for 3 months from last event anyone who has a history of sex with anyone listed above
- Defer for 3 months from last transfusion of allogeneic transfusions of blood or components
- Defer for 3 months from last exposure individuals who had contact with blood through percutaneous inoculation such as needles stick of contact with open wound/mucous membranes
- Defer for 3 months from most recent tattoo, ear/body piercing excluding tattoos applied by a state regulated parlor using sterile needles and non-reusable ink and body piercing using single-use equipment.
- Defer for 3 months after completion of treatment an individual with history of syphilis or gonorrhea
- Defer for 3 months after most recent sexual contact of a man who had sex with another man
- Defer for 3 months after most recent sexual contact of a woman who had sex with a man who had sex with another man within the previous 3 months
- Defer indefinitely individuals with hemophilia or other related clotting factor deficiencies for donor safety reasons.
- Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jacob Disease and Variant Creutzfeldt-Jacob Disease by Blood and Blood Components Finalizes the draft guidance by same name from January 2020. The biggest change to this removes the deferral criteria for geographical risk of vCJD for U.S. military bases in Europe excluding time in U.K. from 1980-1996 (cumulative 3 months), and France or Ireland from 1980-2001 (cumulative 5 years).