

New evidence has led the FDA to remove the deferral requirement associated with time spent in the UK, France, and Ireland due to the risk of vCJD also known as Mad Cow Disease. Bloodworks is excited to implement the new criteria on January 18, 2023. We look forward to welcoming donors who were previously deferred based on this issue alone. Please reach out to us at (800) 398-7888 with any further questions about eligibility to donate blood.

Creutzfeldt-Jakob Disease (CJD) is a rare fatal degenerative disease of the central nervous system, belonging to a group of diseases called transmissible spongiform encephalopathies (TSEs) or prion diseases. In 1996, the U.K. reported a previously unrecognized TSE, now designated as Variant Creutzfeldt-Jakob Disease (vCJD). Distinct from CJD, vCJD is a prion disease attributed to human infection with the agent of bovine spongiform encephalopathy (BSE, sometimes referred to as "mad cow disease"), that is likely acquired from consuming contaminated beef products.

In the late 1990's in the U.K. there were a small number of vCJD infections linked to blood transfusions. In response to these cases, the U.S. Food and Drug Administration (FDA) released a guidance in 1999 outlining donor screening practices to ensure the safety of the U.S. blood supply. The guidance included the implementation of numerous donor deferrals, such as:

- Time spent in specific European countries, including U.S. military bases in Europe
- Receipt of blood transfusion in specific European countries
- Blood relatives with CJD
- Medication history such as use of bovine insulin

In recent years, based on the results of risk assessment models and taking into consideration current practices in blood component manufacturing, the FDA has determined that "the current risk of vCJD transmission by blood and blood components would expose transfusion recipients to no or minimal additional risk of vCJD" (FDA Guidance, Section II B). To reflect this determination, the FDA has simplified the donor screening process by removing numerous donor deferrals.

In 2020, the FDA removed the following donor deferrals:

- Time spent in specific European countries (not including the U.K., France, and Ireland), including
 U.S. military bases in Europe
- Receipt of bovine insulin

Most recently, in May 2022, the FDA removed the following donor deferrals:

- Time spent in the U.K., France, and Ireland
- Receipt of blood transfusion in the U.K, France, or Ireland

Bloodworks has already implemented the <u>2020 changes</u> and the newest changes implement January 18, 2023. We appreciate your patience and understanding while we updated these complex changes in our systems and look forward to welcoming new donors or others back to donating.

Donors previously deferred for the risks listed above may be eligible to donate beginning January 18, 2023. To determine your eligibility please email clinicalp@bloodworksnw.org or call (425) 656-3077.