For Immediate Release



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New Era of Blood Donor Eligibility: FDA Eases Restrictions on Donations for Gay, Bisexual Men

On December 6, 2023 Bloodworks Northwest will implement the U.S. Food and Drug Administration's new individual donor assessment guidance for all blood donors

All prospective donors will be asked the same risk-based questionnaire when signing up to give blood

SEATTLE (August 7, 2023) – Bloodworks Northwest is updating its processes to align with new Food and Drug Administration (FDA) guidance easing restrictions on donations by men who have sex with men (MSM) effective December 6, 2023. Newly eligible donors may begin booking appointments now for that date or after, when the changes take effect or people may sign up now to be notified when the change is implemented in 120 days. Until then, the current three-month restriction for men who have sex with men will remain in effect.

The new FDA guidance issued on May 11, 2023, replaces outdated blood donor restrictions based on gender and sexual orientation with individual risk-based criteria. When Bloodworks implements the new policy on December 6, 2023, all potential donors will answer the same set of questions assessing their HIV risk, regardless of their gender or sexual orientation. Questions regarding sexual history, previously targeted to MSM, will now apply to all donors.

What are the new criteria? The criteria will now focus on sexual contact associated with higher risk of disease transmission. All potential donors will be asked whether, in the three months prior to their date of donation, they have:

- Had sexual contact with a new partner. If so, they will be asked if they have had anal sex in the last three months
- Had sexual contact with more than one partner. If so, they will be asked if they have had anal sex in the last three months.

Anyone who has had sexual contact with a new partner or more than one partner AND who has had anal sex in the past three months is at increased risk for transmitting human immunodeficiency virus (HIV) and other infectious diseases and will be deferred for three months.

People who take medication to prevent HIV infection are still deferred: Based on current guidance from the FDA, individuals taking preventative HIV medications (such as PrEP or PEP) are still deferred for three months from their most recent use. Available data suggests that the use of PrEP or PEP may delay the detection of HIV in screening tests for blood donations, potentially resulting in false negative results in infected individuals. The risks must be carefully evaluated and approved by the FDA before this deferral can be lifted.

"Bloodworks Northwest's mission supports every eligible person in the community saving lives every day, and we have enthusiastically advocated for equality and inclusivity in the donation process while maintaining blood safety based on science," said Bloodworks Northwest's Co-Chief Medical Officer Dr. Kirsten Watson Alcorn. "This FDA policy change is based on the individual behavior of the prospective donor and not on their sexual orientation or gender. This means that ALL prospective donors will be asked the same risk-based questionnaire when signing up to give blood. There are many regulatory steps to do, and Bloodworks is updating these changes as fast as possible, taking effect on December 6, 2023 so that we may celebrate and welcome donors who have previously been deferred."

For more specific information, see the <u>FDA's official guidance</u>.

For a look back at Bloodworks' history of pushing for change ahead of implementing new, more inclusive guidelines, watch this video.

For the most up-to-date information on medication deferrals and other eligibility requirements, please visit www.bloodworksnw.org/eligibility.

For individual questions about eligibility status or for assistance booking an appointment, please call **425-453-5098**.

Dr. Kirsten Watson Alcorn is available for interviews. Contact John Yeager jyeager@bloodworksnw.org or 425-765-9845

About Donating Blood:

- Most people in good health, at least 18 years old, and who weigh at least 110 pounds can donate
 whole blood every 56 days. See website for ages 16 & 17. Appointments required. Donors can
 donate blood ten days after COVID symptoms resolve, and COVID and Flu vaccinations do not
 affect your ability to donate blood. Check out our detailed eligibility Q&A or call us at 425-4535098.
- It takes about an hour to give blood from check-in to post-donation cookie. Information about who can donate and where, is available at www.bloodworksnw.org.

Bloodworks Donor Centers and Blood Drives:

Appointments and information at <u>BloodworksNW.org</u> or 800-398-7888. See our list of <u>Donor</u> Centers and Blood Drives.

About Bloodworks Northwest – About Bloodworks Northwest

Donations to Bloodworks Northwest provide lifesaving blood supply to 95% of Pacific Northwest hospitals. Since 1944, Bloodworks has served the Pacific Northwest as a local, nonprofit, independent, volunteer-supported and community-based blood center and research institute. Bloodworks partners closely with local hospitals to deliver the highest level of patient care. Its comprehensive services include blood components, complex cross-matching, specialized lab services for organ transplants, care for patients with blood disorders and collection of cord blood stem cells for cancer treatment. Bloodworks Research Institute performs leading-edge research in blood biology, transfusion medicine, blood storage and treatment of blood disorders. Patients with traumatic injuries, undergoing surgeries or organ transplantation, or receiving treatment for cancer and blood disorders all depend on its services, expertise, laboratories and research. Hear lifesaving stories by subscribing to the award-winning Bloodworks 101 podcast. Blood donation appointments can be scheduled at BloodworksNW.org.

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