



Introducing a more inclusive Blood Donor History Questionnaire

In alignment with recent updated FDA guidance, RWJBarnabas Health Blood Services is pleased to announce that on **October 16, 2023**, we will be introducing a new blood donor history questionnaire.

This new questionnaire is gender-inclusive that provides individual assessment of all blood donors to reduce the risk of HIV in the blood supply. All blood donations undergo several tests to ensure that the blood donations are safe for our patients, by screening for HIV, HTLV, Hepatitis B and C, West Nile Virus and other infectious blood borne diseases.

An individual assessment of donors will make donations more inclusive, extend blood donation opportunity to more people and ensure equal treatment of all donors. All donors are asked the same questions to assess their eligibility to be a blood donor regardless of their gender, gender identity or sexual orientation.

RWJBarnabas Health Blood Services will also revise deferrals for individuals who previously spent time in certain European countries (United Kingdom and France) and military bases who were potentially at risk for CJD or vCJD, also known as “mad cow disease.”

The FDA has now determined that these potential risks are no longer a concern since investigations have not demonstrated any documented cases of vCJD transmission through a blood transfusion. Most individuals who were once deferred are now eligible to donate blood if they meet all other donor requirements.

These changes have been added to our regulated processes to allow historically ineligible donors to donate now. RWJBarnabas Health Blood Services looks forward to welcoming new and returning blood donors.

[Please see our attached FAQ page.](#)



Frequently Asked Questions



1. What are the most notable changes for individual donor assessment questions?

All donors will be asked if they've had **new and multiple** sexual partners in the past **three months**. If the answer is YES to either, they will be asked if they've had anal sex with any of these partners.

- If the answer is YES, the individual will have to wait three (3) months from the time of the most recent **anal sex** encounter.
- If the answer NO and also meet all other eligibility criteria, they will be able to donate.

2. Why the focus on anal sex?

Statistically, anal sex has a significantly higher chance of HIV transmission per sex act than vaginal or oral sex. This is evidence based and does not account for individuals' safe sex practices.

3. Why the emphasis on anal sex with multiple partners?

Data shows that the risk of a new or recent HIV infection undetectable by current testing methods increases with new sexual partners and multiple sexual partners. Having multiple sexual partners increase the likelihood of HIV transmission.

4. Why defer individuals who have used PrEP (Pre-exposure prophylaxis)/PEP (post-exposure prophylaxis) in the past three months?

PrEP, a medical intervention, is considered highly effective for HIV prevention. Low or undetectable levels of HIV may occur among individuals taking PrEP or PEP and may be missed by current testing methods. The FDA recommends a three (3) month deferral for individuals on oral PrEP or PEP. The deferral is extended to **two (2) years** with parenteral PrEP (if given by injection). More research is needed to determine the impact of PrEP and PEP on current HIV testing.

5. Can the 'individual donor assessment' ensure and maintain the safety and quality of the US blood supply?

After review of the current scientific data¹, the FDA determined that the individual donor assessment will ensure and not compromise the safety or adequacy of the United States blood supply. The new approach to donor screening will continue to defer those with a higher chance of acquiring a new HIV infection.

6. Does this change affect transgender donors?

Transgender individuals are welcome to donate blood since the new Donor History Questionnaire (DHQ) is gender-neutral. All donors regardless of gender or sexual orientation will use and answer the same DHQ.

7. Why is gender (male or female) still useful?

Donors can report the gender with which they identify at the time of donation. Individuals do not need to inform the staff if they identify as transgender. However, there are gender-specific donation eligibility criteria (like hemoglobin) that determine iron levels and method of blood product donation.

8. Why are there no questions about condom use?

Condom use, though an excellent and popular sexual health practice, is not constantly effective since it can break or slip. It is not an evidence-based method for donor screening. The updated Donor History Questionnaire (DHQ) is broad and ensures the screening of a large number of potential donors. This is useful in identifying new exposures to certain viruses within the window period of individual testing methods. However, the DHQ has certain limitations and is not comprehensive regarding safe sexual practices.

9. Why are screening questions necessary if blood donations are tested?

Every blood donation is tested for transfusion-transmitted infections. However, no test is perfect since some infections to date have no available reliable tests. Donor testing and the Donor History Questionnaire (DHQ), which includes several interrelated questions, helps to ensure ensure a safe blood supply. Testing methods have limitations called the “window period” of early infection defined as the time between donor exposure and time a laboratory test can reliably detect the infection or tests positive. If a donor has recently acquired an HIV or hepatitis infection, current testing methods may not be to detect the virus and test negative. The DHQ remains valuable and critical in helping identify people who may have had a recent new exposure to HIV or hepatitis B or C.

10. Why are HIV+ individuals with undetectable viral load NOT able to donate?

The concept of undetectable equals untransmissible (U=U) applies only to sexual HIV transmission and NOT transfusion-transmission of HIV. Blood donated by those who have an undetectable HIV viral load can still potentially transmit HIV following a blood transfusion since a unit of blood has a larger volume with possibly greater viral load.

11. Why is anal sex not differentiated as receptive or insertive anal sex since they have different risk profiles?

Receptive anal sex is associated with a higher risk of HIV transmission per sex act than insertive anal sex. However, research studies have shown that receptive anal sex is not well understood and inconsistently answered by potential donors.

12. Is the use of sex toys, fingers or hands considered anal sex?

No, the use of sex toys/fingers/hands is not considered anal sex in the context of our current donor screening criteria.

13. Are donors eligible if they have multiple partners engaged in vaginal or oral sex?

Yes, if the infectious testing remains negative and meet all other eligibility criteria. The individual donor assessment screening criteria **focus on anal sex** in the context of new or multiple partners, rather than vaginal or oral sex. As mentioned earlier, statistically, anal sex has a significantly higher chance of HIV transmission per sex act than vaginal or oral sex. Multiple sexual partners can increase the chance of HIV transmission.

14. Can I donate and still have anal sex with my partner if I am in a monogamous relationship?

Yes, as long as you have anal sex with the **same individual** for the last three months, and meet all other eligibility criteria. Donors who have only one (1) sexual partner for three (3) months or longer will not be questioned about anal sex.

15. Are gay and bisexual men now eligible to donate blood?

Yes. Under the FDA's individual donor assessment guidance, there are NO eligibility criteria related to men who have sex with men (MSM). Anyone, **regardless of gender or sexual orientation**, who has had **new or multiple sexual partners** in the last three months, and also **had anal sex** in that timeframe, will be **deferred** from blood donation for three months from the last anal sex contact. Those who engaged in anal sex in the last three months may be eligible to donate as long as they did NOT have sex with a new partner or with multiple partners during the same timeframe.

16. If I have been deferred under the previous MSM (men who have sex with men) policy, will I be able to donate blood?

The MSM policy has been eliminated under the new FDA guidance. Individuals who have been deferred under the previous MSM policy in the past may be eligible to donate after a **three-month wait period from their last MSM deferral**, providing they meet all other eligibility criteria.

17. How do you define a new sexual partner?

A new sexual partner includes someone you have sex with **a) for the first time**, or **b) an individual you had sex with, then stopped, and resumed sexual relations** in the last three (3) months.

1. Research, C. F. B. E. A. (2023). *Implementation of acceptable Full-Length and abbreviated donor history questionnaires and accompanying materials for use in screening donors of blood and blood components*. U.S. Food And Drug Administration. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/implementation-acceptable-full-length-and-abbreviated-donor-history-questionnaires-and-accompanying>

<https://www.aabb.org/news-resources/resources/donor-history-questionnaires/blood-donor-history-questionnaires>

