





## Blood Community Committed to an Inclusive Blood Donation Process

## **February 6, 2023**

The following statement has been issued by AABB, America's Blood Centers and the American Red Cross regarding the <u>new FDA proposal for an individual risk assessment for blood donations:</u>

On January 27, the U.S. Food and Drug Administration (FDA) announced a proposed policy change recommending blood donor eligibility be based on an individual's behavior and risk, regardless of the donor's gender or sexual orientation. Under the new recommendations, time-based blood donation deferrals for gay and bisexual men and women who have sex with gay and bisexual men would be eliminated. We support this important, science-driven step forward to remove unnecessary deferrals and are committed to continuing to work with FDA and other stakeholders on this important topic.

The blood community is united in its commitment to maintain the safety of the nation's blood supply while making blood donation a more inclusive process that treats all individuals with fairness, equality and respect. We are encouraged that decades of data from U.S. blood centers, the FDA's Transfusion Transmitted Infections Monitoring System (TTIMS), ongoing advocacy discussions, international experiences, and data from the recent Assessing Donor Variability and New Concepts in Eligibility (ADVANCE) Study have provided the data necessary to support this positive step toward inclusivity.

We are grateful to the many stakeholders who have participated in this effort and advocated for change, including researchers, study participants, and LGBTQ+ community partners.

Blood collection organizations across the country will work diligently to complete the complex transition to individual risk assessment and look forward to welcoming new and returning donors as soon as possible. The new recommendations will be implemented after FDA issues its final guidance and formally accepts an updated donor health history questionnaire.

This process will require coordination within the blood community and between the blood community and the FDA. We encourage members of the public to reach out to their local blood centers for additional details.

The blood community also recognizes that the FDA's draft guidance includes other evidence-based recommendations which individuals can review in full. Comments can be <u>submitted to the FDA</u> on the draft guidance through the end of the 60-day comment period.