



## **Information for Donors on Blood Centers' Implementation of Individual Risk Assessment**

AABB and blood collection facilities throughout the United States appreciate the public's interest in the recent updates regarding blood donation eligibility criteria.

The FDA released a final guidance on May 11, 2023, requiring blood collection facilities throughout the United States to implement new screening criteria for determining blood donor eligibility. The new guidelines set forth by the FDA include a shift to individual donor assessments, utilizing the same gender-inclusive questions for all individuals, and ending time-based deferrals for gay and bisexual men.

Blood centers throughout the United States are now completing the months-long process to carefully implement the new IDA eligibility criteria. The blood community in the United States looks forward to welcoming new and returning donors as soon as this extensive work is completed.

Depending on the individual blood collection facility, the process to implement the system is estimated to take between two and six months based on each facility's unique needs and resource challenges. This extensive change control process includes:

- Developing multiple new policies and procedures to align with new FDA requirements, including full review and sign off by medical director.
- Updating the FDA-regulated Blood Establishment Computer System with all changes required by FDA, including completion of FDA-required testing and system performance validations to ensure blood safety.
- Developing new donor screening materials required for IDA, including extensive updates to electronic donor screening software.
- Completion of comprehensive staff training to educate all teams on new policies and the development of new SOP documents.
- Performing and documenting all staff competency assessments to support blood safety.
- Completion of additional training of donor-facing staff on new screening questions and protocols, since they will have an important role in answering questions from donors and the public.

Until blood collection facilities complete this critical process, donor screening questions will remain as they were prior to the release of the new FDA guidance. AABB encourages individuals interested in donating blood to check with their local blood collection facilities about the timeline for implementation of an updated system.

AABB encourages the public to remain patient while blood collection facilities work to implement the changes, while continuing to collect much-needed, life-saving blood on a daily basis. The blood community looks forward to welcoming new and returning donors once the new systems are in place and is working diligently to do so safely and efficiently.