



## **Position Statement: AABB Applauds FDA’s Final Guidance Recommending Individual Donor Assessment for Blood Donor Eligibility**

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The Association for the Advancement of Blood & Biotherapies (AABB) applauds the Food and Drug Administration (FDA) for issuing a final guidance that recommends determining blood donor eligibility based on an individual assessment. Therefore, every prospective donor, regardless of gender or sexual orientation, will be evaluated using the same individual donor assessment (IDA) questions relevant to HIV. The final guidance recommends a new individualized, gender-inclusive donor assessment process, eliminating the screening questions for men who have sex with men (MSM) and women who have sex with MSM.

Along with its final recommendations, FDA has formally recognized a new version of the AABB Donor History Questionnaire, which is the tool used by blood collectors to assess donor eligibility. FDA’s formal recognition of AABB’s tool enables blood collectors to begin the extensive process of implementing IDA protocols.

“FDA’s announcement represents a momentous change for the blood community and our country,” said Debra BenAvram, CEO of AABB. “The implementation of individualized donor assessment protocols will lead to a more inclusive and diverse donor pool, an expansion of the nation’s blood supply, and more opportunities to save lives and improve health. AABB will work closely with our blood center members nationwide to implement FDA’s recommendations as quickly as possible.”

For years, AABB has led efforts to champion the adoption of inclusive, science-based eligibility criteria that support the safety and availability of life-saving blood products. AABB has long supported the adoption of blood donor deferral policies that do not unnecessarily exclude individuals who can donate blood safely. FDA’s final guidance is aligned with this goal.

AABB commends FDA for making recommendations that are informed by numerous data sources, including surveillance information from the Transfusion Transmissible Infections Monitoring System (TTIMS), several research studies, such as the FDA-funded “Assessing Donor Variability and New Concepts in Eligibility” (ADVANCE) study, and the experiences of other countries, including the United Kingdom and Canada. Importantly, FDA’s final guidance recognizes that existing testing capabilities and practices are consistent with maintaining optimal safety and availability of the blood supply.

AABB looks forward to supporting blood collectors in their efforts to welcome new and returning donors into the blood community. Eligible individuals can identify blood collectors in their communities by using AABB’s Blood Donation Site Locator at [WhereToDonateBlood.org](http://WhereToDonateBlood.org).



“To ensure the safety of the nation’s blood supply, blood donor eligibility must be based on rigorous scientific evidence. FDA’s recommendations in the new final guidance meet that threshold,” said Claudia Cohn, MD, PhD, AABB’s chief medical officer. “The latest research, along with testing capabilities and the implementation of similar protocols in other countries, shows that individualized donor assessment is both a safe and equitable method of collecting blood donations. As a physician, I welcome FDA’s recommendations and look forward to their swift implementation.”