



Association Bulletin #22-02

Date: July 29, 2022

To: AABB Members

From: Dana Devine, PhD - President
Debra BenAvram – Chief Executive Officer

Re: Emergent Standards for the 33rd edition of *Standards for Blood Banks and Transfusion Services*

Association Bulletins provide a mechanism for publication of documents that have been approved by the Board of Directors for distribution to individual and institutional members, such as:

- Standards that were adopted after publication of the most recent edition of *Standards*
- Statements of AABB policy intended for distribution to members
- Guidance, recommendations, and reports that have been developed by AABB Committees or National Office staff for distribution to members

This bulletin describes updated requirements to Reference Standards 5.4.1A, Donor Qualification, in the 33rd edition of *Standards for Blood Banks and Transfusion Services (BB/TS Standards)* as follows:

- 1) Removing the requirement to defer donors who were considered at risk for transfusion transmission of variant Creutzfeldt-Jakob disease (vCJD),
- 2) Updating the deferrals concerning a family genetic history of Creutzfeldt-Jakob disease and finally, and
- 3) Updating deferrals for individuals who have received human cadaveric pituitary growth hormone (hGH).

On Tuesday, May 24, 2022 the Food and Drug Administration (FDA) updated the August 2020 guidance for industry, “Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components.” To read more on the FDA’s decision to update the Guidance, please click [here](#).

As a result of the update to the FDA Guidance, AABB is making changes to the *BB/TS Standards* to remove the requirement to defer donors who have been considered a risk for transfusion-transmitted vCJD in row 16 of Reference Standard 5.4.1A. There is updated language for row 10, which revised the requirement to mirror the language in the FDA Guidance requiring deferral of donors based on their volunteering a familial genetic history of prion disease.



Finally, in row 12 to mirror the language in the FDA Guidance, the entry has been edited to require that donors who voluntarily share that they have received cadaveric pituitary-derived hGH should be deferred in accordance with the FDA Guidance referenced.

Please note that as it relates to the requirements for row 10 and 12, the facility is not required to ask for this information from the donor.

Reference Standard 5.4.1A—Requirements for Allogeneic Donor Qualification

Category	Criteria/Description/Examples	Deferral Period
10) Medical History and General Health	<ul style="list-style-type: none"> For Donors who volunteer that they have one or more blood relatives with familial prion disease a previously deferred for a family genetic history of Creutzfeldt-Jakob disease (CJD)¹ 	Defer in accordance with FDA Guidance ¹
12) Receipt of Blood, Blood Component, or Human Tissue	<ul style="list-style-type: none"> Donors who volunteer that they received previously deferred for cadaveric pituitary-derived human growth hormone 	Permanent Defer in accordance with FDA Guidance ¹
16) Travel	<ul style="list-style-type: none"> The prospective donor’s travel history shall be evaluated for potential risks^{4,15-17} 	
	<ul style="list-style-type: none"> Donors recommended for deferral for risk of vCJD, as defined in most recent FDA Guidance¹ 	In accordance with FDA Guidance

¹FDA Guidance for Industry: Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components (**May 23, 2022**~~August 2020~~).

These changes to Reference Standard 5.4.1A take effect immediately. For facilities using the donor history questionnaire developed by AABB’s Donor History Task Force and formally



recognized by FDA, the AABB has created a toolkit outlining some options for implementation of these changes which can be found [here](#).