CURRENT STATUS OF CELLULAR THERAPY PRODUCTS RELATED TO COVID-19

AABB continues to monitor the situation related to coronavirus disease 2019 (COVID-19) and is working to support professionals in the industry with helpful tools and resources.

The Food and Drug Administration has noted that routine screening methods are currently in place to evaluate donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps) for respiratory infection. FDA suggests that establishments in the United States that are considering additional donor screening measures in response to the virus consider the following donor history in the 28 days prior to HCT/P recovery:

- Cared for, lived with or came into contact with individuals diagnosed with or suspected of having COVID-19 infection.
- Diagnosis with or suspicion of having COVID-19.

The Donor History Questionnaire (DHQ) Task Force for HPC, Apheresis and Marrow, and for Cord Blood has met to discuss whether additional screening questions should be added. At this time, the Task Force has made no changes to the DHQ related to these products. Please note these are different than the DHQ for blood products.

Below are additional key resources and recommendations from AABB partner organizations:

- FDA: Updated Information for Human Cell, Tissue, or Cellular or Tissue-based Product (HCT/P) Establishments Regarding the Coronavirus Disease 2019 Pandemic
- FDA: FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic
- American Society for Transplantation and Cellular Therapy: Resources and Guidelines
- National Marrow Donor Program (NMDP): Response to COVID-19. NMDP has a novel coronavirus infection assessment questionnaire.
- World Marrow Donor Association: COVID-19 - Impact on Registry Operations. This document addresses changes in registry operations that are affected by the coronavirus outbreak.

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