

## REFERENCES

Donor qualification requirements are located in 21 CFR 1271, Subpart C – Donor Eligibility.

Listed below are FDA final rules and guidance documents:

U.S. Department of Health and Human Services, Food and Drug Administration, Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Final Rule (69 FR 29785, May 25, 2004)

<https://www.gpo.gov/fdsys/pkg/FR-2004-05-25/pdf/04-11245.pdf>

U.S. Department of Health and Human Services, Food and Drug Administration, Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) dated August 2007.

<https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM091345.pdf>

U.S. Department of Health and Human Services, Food and Drug Administration, Guidance for Industry

Investigational New Drug Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System dated March 2014.

<https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM415907.pdf>

U.S. Department of Health and Human Services, Food and Drug Administration, Guidance for Industry

Guidance for Industry Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System dated March 2014.

<https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM357135.pdf>

U.S. Department of Health and Human Services, Food and Drug Administration, Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) dated December 2011.

<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM285223.pdf>

U.S. Department of Health and Human Services, Food and Drug Administration, Guidance for Industry: Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products dated May 2018.

<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM488582.pdf>

U.S. Department of Health and Human Services, Food and Drug Administration, Guidance for Industry: Revised Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products Who Have Received Human-Derived Clotting Factor Concentrates dated November 2016.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/revised-recommendations-determining-eligibility-donors-human-cells-tissues-and-cellular-and-tissue>

U.S. Department of Health and Human Services, Food and Drug Administration, Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) dated May 2017.

<https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM372084.pdf>

U.S. Department of Health and Human Services, Food and Drug Administration, Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products dated August 2016.

<https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/UCM516650.pdf>

Additional references include:

The Yellow Book, “Health Information for International Travel”, CDC. Includes information on malaria. <https://wwwnc.cdc.gov/travel/page/yellowbook-home>

AABB Standards for Cellular Therapy Product Services, current edition

FACT/JACIE International Standards for Cellular Therapy Product Collection, Processing & Administration, current edition