HPC, Apheresis and HPC, Marrow Donor History Questionnaire Materials version 2.0 June 2019. Chart Detailing Changes from version 1.9, August 2018

User Instructions	**Change**	**Rationale**
User Instructions	Updated the name of the interorganizational Task Force to the current name, "Uniform Donor History - HPC Task Force"	To provide the current name of the Task Force.
User Instructions	Updated the organizations participating on the Task Force.	To provide the current names of the organizations participating on the Task Force.
Questionnaire	**Change**	**Rationale**
Question 5	Updated the question to say 8 weeks, instead of 12 weeks.	In this DHQ, question 5 asks about <u>any</u> vaccine. The NMDP Health History Questionnaire (HHQ) has a similar question, relating to if the donor has had any shots or other vaccinations in the past eight (8) weeks. The Task Force decided to be consistent with the NMDP's HHQ. In addition, the 2007 FDA Guidance document, "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)", references specifically the smallpox vaccine. See section E, "What risk factors or conditions do I look for when screening a donor?", number 13 (page 16). "Persons who have had smallpox vaccination (vaccinia virus) in the preceding 8 weeks…."
Flowcharts	**Change**	**Rationale**
Question 2	To provide clarification in the donor eligibility summary and flowchart that medication use (not just antibiotic use) must be evaluated to determine if the donor has an infection (not just bacterial infection) that could be transmissible by HCT/Ps.	To clarify in the donor eligibility summary and flowchart that this question is for any medication for an infection, not limited to an antibiotic. Additionally, in the donor eligibility summary, clarifies that the donor should be evaluated for an infection, not limited to a bacterial infection.
Question 5	Updated the question and flowchart to say 8 weeks, instead of 12 weeks.	In this DHQ, question 5 asks about <u>any</u> vaccine. The NMDP Health History Questionnaire (HHQ) has a similar question, relating to if the donor has had any shots or other vaccinations in the past eight (8) weeks. The Task Force decided to be consistent with the NMDP's HHQ. In addition, the 2007 FDA Guidance document, "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)", references specifically the smallpox vaccine. See section E, "What risk factors or conditions do I look for when screening a donor?", number 13 (page 16). "Persons who have had smallpox vaccination (vaccinia virus) in the preceding 8 weeks…."

Question 16	Removed the mention of Hepatitis A from the flowchart.	In the 2007 FDA Guidance document, "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)", section IV.E, question 5, Hepatitis A is not mentioned.
Question 17	Removed the mention of Hepatitis A from the flowchart.	In the 2007 FDA Guidance document, "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)", section IV.E, question 5, Hepatitis A is not mentioned.
Question 33	Added additional information in the donor eligibility summary that *T. cruzi* is not considered a relevant communicable disease agent or disease (RCDAD) with the FDA and therefore is not a required disease to screen or test for according to the FDA. It is the responsibility of the user/reader of this document to check FDA's current requirements for screening and/or testing donors of HCT/Ps to ensure that risk factors for all RCDADs are evaluated, and to note any new RCDADs. A donor will be considered ineligible if they are screened or tested for *T. cruzi*, and the screening and/or testing results are positive or shows risk.	Provide additional clarification. A donor will be considered ineligible if they are screened or tested for *T. cruzi*, and the screening and/or testing results are positive or shows risk.
Question 34	Added additional information in the donor eligibility summary that babesiosis is not considered a relevant communicable disease agent or disease (RCDAD) with the FDA and therefore is not a required disease to screen or test for according to the FDA. It is the responsibility of the user/reader of this document to check FDA's current requirements for screening and/or testing donors of HCT/Ps to ensure that risk factors for all RCDADs are evaluated, and to note any new RCDADs. A donor will be considered ineligible if they are screened or tested for babesiosis, and the screening and/or testing results are positive or shows risk.	Provide additional clarification. A donor will be considered ineligible if they are screened or tested for babesiosis, and the screening and/or testing results are positive or shows risk.

Appendix – HIV Group O countries of risk - Africa	**Change**	**Rationale**
Appendix – HIV Group O countries of risk - Africa	Updated the website link to the FDA guidance document, "Recommendations for Management of Donors at Increased Risk for Human Immunodeficiency Virus Type 1 (HIV-1) Group O Infection, dated August 2009."	To provide the updated link.
Appendix – vCJD countries of risk – Europe	**Change**	**Rationale**
Appendix – vCJD countries of risk – Europe	Added Montenegro and Serbia to the list of countries in Europe. Added clarifying information about Yugoslavia.	Yugoslavia became the federated union of Serbia and Montenegro in 2003 (which further separated into its component parts in 2006). Since this appendix is based on geographic areas of risk, Montenegro and Serbia have been added to this list, since they exist in Yugoslavia's former geographic region.
Appendix – vCJD countries of risk – Europe	Added clarifying information that deferral of donors is based on geographic risk.	To clarify that deferral of donors is based on geographic risk.
Appendix – vCJD countries of risk – United Kingdom	**Change**	**Rationale**
Appendix – vCJD countries of risk – United Kingdom	Added clarifying information that deferral of donors is based on geographic risk.	To clarify that deferral of donors is based on geographic risk.
References	**Change**	**Rationale**
References	Updated the website link to the FDA guidance document, "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."	To provide the updated link.