National Marrow Donor Program **Record of Change 23nd Edition Standards**

22nd Edition Standard #/Section	22nd Edition Standard	Draft 23rd Edition Standard	Rationale for Change
Cover page	National Marrow Donor Program®	National Marrow Donor Program®/Be the Match®	Per Office of General Counsel to align with HRSA contract
Notice and Disclaimer	These standards set forth only the basic guidelines for programs working through the NMDP to facilitate hematopoietic cell transplants	These standards set forth only the ~~basic guidelines~~ minimal requirements for programs working through the NMDP to facilitate hematopoietic cell transplants	More correct.
1.1000	These standards apply to activities performed by National Marrow Donor Program® (NMDP) participating centers and include processes from donor recruitment to distribution and administration of cellular therapy products facilitated through NMDP.	Moved to Notice and Disclaimer	More appropriate place, rather than being listed as a standard.
Renumbering Standards	1.1100 1.1200 1.2000 1.3000 1.3100 1.3110 1.3200	1.1000 1.2000 1.3000 1.4000 1.4100 1.4110 1.4200	1.1000 moved to Notice and Disclaimer; standards renumbered accordingly.

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22nd Edition Standard #/Section	22nd Edition Standard	Draft 23rd Edition Standard	Rationale for Change
	1.4000 1.5000 1.5100 1.5200 1.5300 1.6000 1.7000 1.7100 1.7200 1.7300 1.8000 1.9000 1.10000	1.5000 1.6000 1.6100 1.6200 1.6300 1.7000 1.8000 1.8100 1.8200 1.8300 1.9000 1.10000 1.11000	
2.1500 NEW		2.1500 Center shall be registered with FDA for applicable manufacturing functions.	Added to align with participation criteria and requirements for other centers.
4.0000	Criteria for Participating Cord Blood Banks 4.1000 Facility Characteristics Facility Characteristics 4.1100 Bank shall be registered with the FDA.	Criteria for Participating Cord Blood Banks ~~4.1000 Facility Characteristics~~ ~~Facility Characteristics~~ ~~4.1100 Bank shall be registered with the FDA.~~	AABB and NetCord-FACT requirements cover most all of what was required by NMDP standards. Anything else will be added to Participation Criteria.

DRAFT

22nd Edition Standard #/Section	22nd Edition Standard	Draft 23rd Edition Standard	Rationale for Change
	4.1200 Bank shall have experience in cord blood recruitment. 4.1300 Bank shall have adequate and secure facilities for manufacturing HPC(CB). 4.1400 Bank shall have written agreements to collect cord blood. 4.1500 Bank shall maintain accreditation by AABB, FACT-JACIE, and/or NetCord-FACT (See Resources). 4.2000 Medical Director 4.2100 Bank medical director shall have postdoctoral training in hematopoietic cell transplantation, blood or tissue banking, basic or clinical immunology, immunohematology or cryobiology. 4.2200 Bank medical director shall be responsible for review of the medical evaluation of the donor and biologic mother for evidence of disease transmissible by transplantation. 4.2300 Bank medical director shall be responsible for: recruitment, informed consent, evaluation and follow-up of the potential donor, and shall participate in the development of the procedures for the	~~4.1200 Bank shall have experience in cord blood recruitment.~~ ~~4.1300 Bank shall have adequate and secure facilities for manufacturing HPC(CB).~~ ~~4.1400 Bank shall have written agreements to collect cord blood.~~ 4.1000~~500~~ Bank shall maintain accreditation by AABB, and or ~~FACT-JACIE, and/~~or NetCord-FACT (See Resources). 4.2000 ~~Medical Director4.2000~~ Bank shall follow NMDP Member Cord Blood Bank Participation Criteria. ~~4.2100 Bank medical director shall have postdoctoral training in hematopoietic cell transplantation, blood or tissue banking, basic or clinical immunology, immunohematology or cryobiology.~~ ~~4.2200 Bank medical director shall be responsible for review of the medical evaluation of the donor and biologic mother for evidence of disease transmissible by transplantation.~~ ~~4.2300 Bank medical director shall be responsible for: recruitment, informed consent, evaluation and follow-up of the~~	

22nd Edition Standard #/Section	22nd Edition Standard	Draft 23rd Edition Standard	Rationale for Change
	collection, processing, testing, banking, selection and release of the unit. 4.3000 Personnel 4.3100 Bank shall designate a coordinator to work with the NMDP. 4.3200 Bank shall have adequate trained and competent personnel available to perform tasks related to HPC(CB) manufacturing and sample management. 4.3300 Bank should have a designated, independent Quality Unit to audit, monitor, and authorize release of cord blood units as defined in facility-specific procedures. 4.4000 Support Services 4.4100 Bank shall use the following facilities for NMDP activities: 4.4110 HLA-typing laboratory(ies) accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), the European Federation for Immunogenetics (EFI), and/or the College of American Pathologists (CAP) for HLA typing required by NMDP. 4.4120 Laboratory(ies) that perform eligibility testing for evidence of infection due to relevant communicable disease agents must use donor screening tests that the FDA has	~~potential donor, and shall participate in the development of the procedures for the collection, processing, testing, banking, selection and release of the unit.~~ ~~4.3000 Personnel~~ ~~4.3100 Bank shall designate a coordinator to work with the NMDP.~~ ~~4.3200 Bank shall have adequate trained and competent personnel available to perform tasks related to HPC(CB) manufacturing and sample management.~~ ~~4.3300 Bank should have a designated, independent Quality Unit to audit, monitor, and authorize release of cord blood units as defined in facility-specific procedures.~~ ~~4.4000 Support Services~~ ~~4.4100 Bank shall use the following facilities for NMDP activities:~~ ~~4.4110 HLA-typing laboratory(ies) accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), the European Federation for Immunogenetics (EFI), and/or the College of American Pathologists (CAP) for HLA typing required by NMDP.~~ ~~4.4120 Laboratory(ies) that perform eligibility testing for evidence of infection due to~~	

22nd Edition Standard #/Section	22nd Edition Standard	Draft 23rd Edition Standard	Rationale for Change
	approved, licensed or cleared for such use and testing shall be performed in accordance with the manufacturer's instructions (See Resources). 4.4130 Cord blood collection sites accredited by an organization granted deemed status by Centers for Medicare & Medicaid Services (CMS) or non-U.S. equivalent and/or birth centers accredited by the Commission for the Accreditation of Birth Centers (CABC). 4.5000 Policies and Procedures 4.5100 Bank shall have written procedures for the qualification of cord blood collection facilities and personnel. 4.5200 Bank shall have written procedures for recruitment, donor selection, obtaining maternal health and family history, infectious disease marker testing, and for HPC(CB) collection, processing, labeling, storage and transportation. 4.5300 Bank shall have written policies and procedures for the release and issue of HPC(CB) units and for the return to inventory of unused cryopreserved units.	~~relevant communicable disease agents must use donor screening tests that the FDA has approved, licensed or cleared for such use and testing shall be performed in accordance with the manufacturer's instructions (See Resources).~~ ~~4.4130 Cord blood collection sites accredited by an organization granted deemed status by Centers for Medicare & Medicaid Services (CMS) or non-U.S. equivalent and/or birth centers accredited by the Commission for the Accreditation of Birth Centers (CABC).~~ ~~4.5000 Policies and Procedures~~ ~~4.5100 Bank shall have written procedures for the qualification of cord blood collection facilities and personnel.~~ ~~4.5200 Bank shall have written procedures for recruitment, donor selection, obtaining maternal health and family history, infectious disease marker testing, and for HPC(CB) collection, processing, labeling, storage and transportation.~~ ~~4.5300 Bank shall have written policies and procedures for the release and issue of HPC(CB) units and for the return to inventory of unused cryopreserved units.~~	

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5.3300	Center shall provide anesthesia under supervision of a licensed, board-certified anesthesiologist.	Center shall provide anesthesia under supervision of a licensed, board-certified anesthesiologist or certified nurse anesthetist.	More inclusive.
5.4100	Center shall have a surgical operating room and a medical intensive care unit.	Center shall have a surgical operating room and a medical or surgical intensive care unit.	If there is a SICU, a donor may go there after harvest, if need be.
6.4200	Center shall have appropriate apheresis equipment, supplies and pharmaceuticals.	~~Center shall have appropriate apheresis equipment, supplies and pharmaceuticals.~~	Covered under 1.1100
Renumbering standard	6.4300	6.4200	Renumbered because 6.4200 deleted in 23rd Edition
7.1400	Center shall have a designated area for outpatient evaluation and treatment that reduces the risk of transmission of infectious agents and is available 24 hours per day, seven days per week.	Center shall have a designated process ~~area~~ for outpatient evaluation and treatment that reduces the risk of transmission of infectious agents and is available 24 hours per day, seven days per week.	"Process" is more inclusive.
7.2400	Center shall have at least two attending physicians, one of whom may be the medical director, who are licensed and qualified by training and experience in allogeneic hematopoietic cell transplantation.	Center shall have at least two attending physicians, one of whom may be the medical director, ~~who are licensed and qualified by training and experience in allogeneic hematopoietic cell transplantation.~~	Addressed in 7.2420 and 7.2100

DRAFT

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7.2420	Attending physicians should be board certified or eligible as specified in 7.2110.	Attending physicians should be board certified (or non-U.S. equivalent) or eligible as specified in ~~7.2110~~ 7.2100.	*Non-US equivalent* allows for internationally trained physicians.
7.5100	Center shall maintain written policies, procedures and clinical practice guidelines to address aspects of allogeneic transplantation.	Center shall maintain written policies, procedures and clinical practice guidelines for management of allogeneic transplantation.	Better description of what is required.
7.5200	Each recipient of hematopoietic cells from an NMDP donor shall be enrolled in a clinical research protocol or treated according to a written clinical practice guideline.	Each recipient of hematopoietic cells from an NMDP donor shall be enrolled in a clinical research protocol or treated according to ~~a~~ written clinical practice guidelines.	There are guidelines for transplant processes but not necessarily in one document called a guideline.
8.000	Recruitment of Marrow or Hematopoietic Cell Adult Donors and Cord Blood Donors	Recruitment of Marrow or Hematopoietic Cell Adult Donors. ~~and Cord Blood Donors~~	Deleted reference to Cord Blood.

DRAFT

22nd Edition Standard #/Section	22nd Edition Standard	Draft 23rd Edition Standard	Rationale for Change
8.1000	Marrow or Apheresis Donor 8.1100 8.1200 8.1300 8.1400 8.1500 8.1600 8.1610 8.1620 8.1630 8.1640 8.1650 8.1700 8.1800	~~Marrow or Apheresis Donor~~ 8.1000 8.2000 8.3000 8.4000 8.5000 8.6000 8.6100 8.6200 8.6300 8.6400 8.6500 8.7000 8.8000	Deleted; see 8.0000; Subsequent standards renumbered accordingly.

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22nd Edition Standard #/Section	22nd Edition Standard	Draft 23rd Edition Standard	Rationale for Change
8.1630	Donor shall be informed that additional HLA testing may be performed on stored samples.	Donor shall be informed that additional ~~HLA~~ testing for donor selection may be performed on stored samples.	Allows for other testing for matching that is not HLA.
8.2000	Cord Blood Donor 8.2000 Cord Blood Donor 8.2100 Consent shall be obtained from the biologic mother for collection and voluntary donation of the HPC(CB) to a cord blood bank for use in unrelated cellular therapies per cord blood bank specific policies. 8.2110 Consent for collection shall be obtained before delivery. 8.2120 Biologic mother shall be given a general explanation of the indications for and results of cellular therapies and reasons for using unrelated donors. 8.2130 Biologic mother shall be given a general description of the donation process and the risks of cord blood donation. 8.2140 Biologic mother shall acknowledge and document that she has read and understood the elements of participation, has been given ample opportunity to ask questions, and has had those questions answered satisfactorily.	~~Cord Blood Donor~~ ~~8.2000 Cord Blood Donor~~ ~~8.2100 Consent shall be obtained from the biologic mother for collection and voluntary donation of the HPC(CB) to a cord blood bank for use in unrelated cellular therapies per cord blood bank specific policies.~~ ~~8.2110 Consent for collection shall be obtained before delivery.~~ ~~8.2120 Biologic mother shall be given a general explanation of the indications for and results of cellular therapies and reasons for using unrelated donors.~~ ~~8.2130 Biologic mother shall be given a general description of the donation process and the risks of cord blood donation~~. ~~8.2140 Biologic mother shall acknowledge and document that she has read and understood the elements of participation, has been given ample opportunity to ask questions, and has had those questions answered satisfactorily.~~	AABB and NetCord-FACT requirements cover most all of what was required by NMDP standards. Anything else will be added to Participation Criteria.

22nd Edition Standard #/Section	22nd Edition Standard	Draft 23rd Edition Standard	Rationale for Change
	8.2200 Biologic mother shall not be coerced to donate cord blood.	~~8.2200 Biologic mother shall not be coerced to donate cord blood.~~	
9.1000	Adult Donor Additional Testing/Information	~~Adult~~ Donor Additional Testing/Information	"Adult" not needed since removing cord standards.
9.1100	Donor shall provide signed consent for additional testing according to NMDP policy.	~~Donor shall provide signed consent for additional testing according to NMDP policy.~~	There is really no NMDP policy. There are processes in place for signed consent. SAG thought that removing the words about the NMDP policy makes it not a standard.
9.1200	Customized HLA Typing 9.1210 If a stored sample is used for customized HLA typing, the potential donor shall be informed that the typing is in progress and shall be given the opportunity to continue or withdraw. 9.1220 Donor center shall obtain from the donor a medical history that meets NMDP requirements for a marrow or apheresis donor 9.1221 Donor center shall keep a written record of the medical history. 9.1222 Medical history indicative of disease shall be evaluated by a physician before acceptance of the donor.	~~Customized HLA Typing~~ ~~9.1210 If a stored sample is used for customized HLA typing, the potential donor shall be informed that the typing is in progress and shall be given the opportunity to continue or withdraw.~~ ~~9.1220 Donor center shall obtain from the donor a medical history that meets NMDP requirements for a marrow or apheresis donor~~ ~~9.1221 Donor center shall keep a written record of the medical history.~~ ~~9.1222 Medical history indicative of disease shall be evaluated by a physician before acceptance of the donor.~~	Donor is not necessarily notified as stated; NMDP is working to reduce the number of HHSQs; CT HHSQ may be eliminated.

22nd Edition Standard #/Section	22nd Edition Standard	Draft 23rd Edition Standard	Rationale for Change
Renumbering standards	9.1300 9.1310 9.1320 9.1321 9.1322 9.1330 9.1340 9.1350 9.1351 9.1352 9.1360 9.1370 9.1380	9.1100 9.1110 9.1120 9.1121 9.1122 9.1130 9.1140 9.1150 9.1151 9.1152 9.1160 9.1170 9.1180	***9.1100-9.1222 deleted; standards renumbered accordingly.***
9.1322	Medical history indicative of disease shall be evaluated by a physician before acceptance of the donor.	Medical history indicative of disease shall be evaluated by a physician before proceeding ~~acceptance of the donor.~~	There isn't "acceptance" of the donor; the donor moves through the donation process after evaluation by a physician. 23rd Edition this becomes 9.1222
9.1351	Donors with a confirmed positive test for relevant communicable disease agents (e.g.	Donors with a confirmed positive test for relevant communicable disease agents (e.g.	Revised so both examples are disease agents.

DRAFT

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	HBsAg or HCV) shall not be used unless urgent medical need is documented.	~~HBsAg~~ HBV or HCV) shall not be used unless urgent medical need is documented.	23rd Edition this becomes 9.1251
9.2420	Possibility of central venous catheter placement, along with its risks and discomforts.	Possibility of central venous catheter placement, along with its risks, ~~and~~ discomforts, and mental/emotional stress.	Revised to align with 9.2320
9.3330	Examining practitioner shall not be part of the transplant team of the center performing the transplant.	Examining practitioner shall not be the primary practitioner overseeing the care of the recipient. ~~part of the transplant team of the center performing the transplant.~~	Practitioner could be considered part of the transplant team, but not be involved with the recipient; and would be appropriate to examine the donor.
9.3350	Examining practitioner shall obtain and evaluate at a minimum the results of the following tests: 9.3351 Chest X-ray 9.3352 Electrocardiogram 9.3353 Urinalysis 9.3354 Complete blood count 9.3355 Electrolytes, glucose 9.3356 Blood urea nitrogen and creatinine 9.3357 Serum protein plus albumin or serum protein electrophoresis 9.3358 Screening for Hemoglobin S	Examining practitioner shall obtain and evaluate donor testing per NMDP policies and procedures. ~~and evaluate at a minimum the results of the following tests:~~ ~~9.3351 Chest X-ray~~ ~~9.3352 Electrocardiogram~~ ~~9.3353 Urinalysis~~ ~~9.3354 Complete blood count~~ ~~9.3355 Electrolytes, glucose~~ ~~9.3356 Blood urea nitrogen and creatinine~~ ~~9.3357 Serum protein plus albumin or serum protein electrophoresis~~	Criteria are outlined in the protocol and MOP.

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22nd Edition Standard #/Section	22nd Edition Standard	Draft 23rd Edition Standard	Rationale for Change
		~~9.3358 Screening for Hemoglobin S~~	
9.7110	Telephone call or direct conversation with the donor shall be made within 48 hours of the donation.	Telephone call or direct conversation with the donor shall be made within 48 hours ~~of the donation~~ after discharge from the collection facility.	Revised to clarify that some time should elapse; a conversation an hour after collection doesn't suffice.
9.7210	The maximum number of donations from a given donor is limited according to NMDP policy	~~The maximum number of donations from a given donor is limited according to NMDP policy.~~	Information on subsequent donations is spelled out in this standard and exceptions statement added (9.7225)
Renumbering standards	9.7220 9.7221 9.7222 9.7230 9.7231 9.7232 9.7233 9.7234	9.7210 9.7211 9.7212 9.7220 9.7221 9.7222 9.7223 9.7224	9.721 deleted; standards renumbered accordingly.
New 9.7225		9.7225 NMDP Medical Director may authorize exceptions to these standards	See 9.7210 NMDP allows for Medical Director to authorize subsequent donation.

DRAFT

22nd Edition Standard #/Section	22nd Edition Standard	Draft 23rd Edition Standard	Rationale for Change
9.7230 In 23rd Edition this becomes 9.7220	Donor should not be asked to donate HPC for a second recipient unless no other equally compatible donor is available and the following conditions are met:	A donor ~~should~~ may ~~not~~ be asked to donate HPC for a second recipient only if ~~unless~~ no other equally compatible donor is available and the following conditions are met:	Revised to be consistent with wording of 9.7210
9.8000	Cord Blood Donation 9.8100 Consent shall be obtained from the biologic mother for testing and storage of the HPC(CB) to a cord blood bank for use in unrelated cellular therapies per cord blood bank specific policies. 9.8200 Bank shall document from the biologic mother, a family medical history to identify genetic disorders and a personal medical history to identify infections or risk behaviors for infections that are transmissible by transplantation. 9.8210 Medical history shall reflect the biologic mother's health status at the time of delivery. 9.8220 Bank shall define criteria used to assess the infant donor for infection or other abnormalities that may potentially affect the safety of the recipient or the therapeutic value of the cellular therapy product.	~~Cord Blood Donation~~ ~~9.8100 Consent shall be obtained from the biologic mother for testing and storage of the HPC(CB) to a cord blood bank for use in unrelated cellular therapies per cord blood bank specific policies.~~ ~~9.8200 Bank shall document from the biologic mother, a family medical history to identify genetic disorders and a personal medical history to identify infections or risk behaviors for infections that are transmissible by transplantation.~~ ~~9.8210 Medical history shall reflect the biologic mother's health status at the time of delivery.~~ ~~9.8220 Bank shall define criteria used to assess the infant donor for infection or other abnormalities that may potentially affect the safety of the recipient or the therapeutic value of the cellular therapy product.~~	AABB and NetCord-FACT requirements cover most all of what was required by NMDP standards. Anything else will be added to Participation Criteria.

DRAFT

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	9.8300 Bank shall test a blood sample from the biologic mother of cord blood donor for infectious diseases as defined by NMDP. 9.8310 Blood sample from biologic mother of cord blood donor used for infectious disease testing shall be obtained within 7 days prior to or within 7 days after collection (Standard 1.4000 applies). 9.8320 Bank shall inform, counsel and document counseling of biologic mother regarding any clinically significant abnormal findings. 9.8400 Medical director or designee shall evaluate medical history and testing results, and document the review prior to listing the HPC(CB) unit with the NMDP.	~~9.8300 Bank shall test a blood sample from the biologic mother of cord blood donor for infectious diseases as defined by NMDP.~~ ~~9.8310 Blood sample from biologic mother of cord blood donor used for infectious disease testing shall be obtained within 7 days prior to or within 7 days after collection (Standard 1.4000 applies).~~ ~~9.8320 Bank shall inform, counsel and document counseling of biologic mother regarding any clinically significant abnormal findings.~~ ~~9.8400 Medical director or designee shall evaluate medical history and testing results, and document the review prior to listing the HPC(CB) unit with the NMDP.~~	
10.3000	10.3000 HPC(CB) Collection and Processing 10.3100 Testing, collection and processing of the HPC(CB) units shall be consistent with AABB Standards and/or NetCord-FACT Standards (See Resources). 10.3200 HPC(CB) units shall be stored with at least two integrally attached cryopreserved product samples available for additional testing.	~~10.3000 HPC(CB) Collection and Processing~~ ~~10.3100 Testing, collection and processing of the HPC(CB) units shall be consistent with AABB Standards and/or NetCord-FACT Standards (See Resources).~~ ~~10.3200 HPC(CB) units shall be stored with at least two integrally attached cryopreserved product samples available for additional testing.~~	AABB and NetCord-FACT requirements cover most all of what was required by NMDP standards. Anything else will be added to Participation Criteria.

22nd Edition Standard #/Section	22nd Edition Standard	Draft 23rd Edition Standard	Rationale for Change
Renumbered Standards	10.4000 10.4100 10.4110 10.4200 10.4210 10.4220 10.4230 10.4240 10.5100 10.5110 10.5200 10.5300 10.5400 10.6000 10.6100 10.6200	10.3000 10.3100 10.3110 10.3200 10.3210 10.3220 10.3230 10.3240 10.4100 10.4110 10.4200 10.4300 10.4400 10.5000 10.5100 10.5200	10.3000 deleted; standards renumbered accordingly.
10.5000	Labeling and Documentation [HPC(M); HPC(A); MNC(A); HPC(CB); Cryopreserved HPC(CB)]	Labeling and Documentation [HPC(M); HPC(A); MNC(A); ~~HPC(CB); Cryopreserved HPC(CB)]~~	AABB and NetCord-FACT requirements cover most all of what was required by NMDP standards. Anything else will be added to Participation Criteria.

DRAFT

22nd Edition Standard #/Section	22nd Edition Standard	Draft 23rd Edition Standard	Rationale for Change
10.7000	HPC(M); HPC(A); MNC(A); and HPC(CB)	HPC(M); HPC(A); and MNC(A); ~~and HPC(CB)~~	AABB and NetCord-FACT requirements cover most all of what was required by NMDP standards. Anything else will be added to Participation Criteria.
10.7200	HPC(CB) units shall be infused as soon as possible after thawing and preparing the product for administration per manufacturer's instructions or validated local procedure(s).	~~HPC(CB) units shall be infused as soon as possible after thawing and preparing the product for administration per manufacturer's instructions or validated local procedure(s).~~	AABB and NetCord-FACT requirements cover most all of what was required by NMDP standards. Anything else will be added to Participation Criteria.
12.1500	All records and communications relating to patients, recipients, donors/donor mothers or potential donors shall be kept strictly confidential.	All records and communications relating to patients, recipients, donors~~/donor mothers~~ or potential donors shall be kept strictly confidential.	AABB and NetCord-FACT requirements cover most all of what was required by NMDP standards. Anything else will be added to Participation Criteria
12.1700	Relevant to the processes performed at each site, records shall be maintained to ensure the identification and traceability/trackability of each donor/ donor mother and cellular therapy product and all related samples from their initial source, through each processing and testing step to their final disposition and from final disposition, through each processing	Relevant to the processes performed at each site, records shall be maintained to ensure the identification and traceability/trackability of each donor~~/ donor mother and~~ cellular therapy product and all related samples from their initial source, through each processing and testing step to their final disposition and from final disposition, through each	Removed reference to cord blood donor.

22nd Edition Standard #/Section	22nd Edition Standard	Draft 23rd Edition Standard	Rationale for Change
	and testing step to the initial source (12.3000 applies).	processing and testing step to the initial source (12.3000 applies).	
12.3200-12.3260	12.3200 The following Cord Blood Bank records on units collected under NMDP Investigational New Drug application (IND) or listed with NMDP shall be retained indefinitely: 12.3210 All maternal consent documents for the collection, screening, testing, and storage of cord blood for unrelated allogeneic use 12.3220 Maternal health history and family medical history screening and eligibility determinations, including reasons for permanent or temporary deferral 12.3230 Infectious disease testing and other laboratory results 12.3240 Documentation of abnormal findings and notification/counseling of relevant parties 12.3250 Records pertaining to collection and all manufacturing steps though final distribution of cord blood products 12.3251 Records pertaining to qualification, monitoring and use of reagents, supplies and materials shall be traceable to cord blood product.	~~12.3200 The following Cord Blood Bank records on units collected under NMDP Investigational New Drug application (IND) or listed with NMDP shall be retained indefinitely:~~ ~~12.3210 All maternal consent documents for the collection, screening, testing, and storage of cord blood for unrelated allogeneic use~~ ~~12.3220 Maternal health history and family medical history screening and eligibility determinations, including reasons for permanent or temporary deferral~~ ~~12.3230 Infectious disease testing and other laboratory results~~ ~~12.3240 Documentation of abnormal findings and notification/counseling of relevant parties~~ ~~12.3250 Records pertaining to collection and all manufacturing steps though final distribution of cord blood products~~ ~~12.3251 Records pertaining to qualification, monitoring and use of reagents, supplies and materials shall be traceable to cord blood product.~~	AABB and NetCord-FACT requirements cover most all of what was required by NMDP standards. Anything else will be added to Participation Criteria.

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	12.3252 Records pertaining to qualification, monitoring, calibration, maintenance and use of equipment shall be traceable to the cord blood product. 12.3253 Records pertaining to the traceability and tracking of all aspects of the manufacture of the cord blood unit with the exception of facility cleaning and sanitation records which are retained minimally for 3 years. 12.3260 Records of reported recipient adverse reactions and post-administration complications.	~~12.3252 Records pertaining to qualification, monitoring, calibration, maintenance and use of equipment shall be traceable to the cord blood product.~~ ~~12.3253 Records pertaining to the traceability and tracking of all aspects of the manufacture of the cord blood unit with the exception of facility cleaning and sanitation records which are retained minimally for 3 years.~~ ~~12.3260 Records of reported recipient adverse reactions and post-administration complications.~~	
12.3400	12.3400 Transplant Center recipient records which must be retained indefinitely:	12.3400 Transplant Center recipient records which ~~must~~ shall be retained indefinitely:	More correct term for a standard.
12.5100	Records, preferably originals, of all transferred donors shall be forwarded to the receiving donor center	Records~~, preferably originals~~, of all transferred donors shall be forwarded to the receiving donor center	Often originals are not forwarded.
Cord Blood Bank	An NMDP network organization that meets participation criteria with experience, staff and facilities to collect, process and store HPC, Cord Blood [HPC(CB)]for transplant.	An NMDP network organization accredited by NetCord-FACT or AABB, that meets participation criteria with experience, staff and facilities to collect, process and store HPC, Cord Blood [HPC(CB)]for transplant.	Changed to align with requirements.
Glossary		Definitions reordered so they are in alphabetical order.	

DRAFT

22nd Edition Standard #/Section	22nd Edition Standard	Draft 23rd Edition Standard	Rationale for Change
Glossary FDA	A United States government agency under the direction of the Department of Health and Human Services charged with protecting American consumers by enforcing the Federal Food, Drug and Cosmetic Act.	A United States government agency ~~under the direction of~~ within the Department of Health and Human Services charged with protecting and promoting the health of American consumers. ~~by enforcing the Food Drug and Cosmetic Act.~~	Revised for accuracy.
Glossary Complaint	Any communication referencing a problem associated with a cellular therapy product or the collection, screening, testing, processing, storage, distribution or infusion of a cellular therapy product	Any communication referencing a problem associated with a cellular therapy product or the collection, screening, testing, processing, labeling, storage, distribution or infusion of a cellular therapy product	Added for completeness.
Glossary Confirmed Positive Test	A donor infectious disease screening test that tested as positive, was repeated using a confirmatory test and was found to be positive.	A donor infectious disease screening test that tested as positive, and was confirmed positive ~~was repeated~~ using a supplementary ~~confirmatory~~ test. ~~and was found to be positive.~~	Supplementary is the correct term.

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