National Marrow Donor Program **Record of Change 24th Edition Standards**

23rd Edition Standard #/Section	23rd Edition Standard	Draft 24th Edition Standard	Rationale for Change
1.3000	Participating programs and support laboratories shall comply with all applicable federal and governmental laws and regulations.	Participating programs and support laboratories shall comply with all applicable ~~federal and~~ governmental laws and regulations.	Removed "federal", is redundant.
1.4000	U.S. Centers participating in human subject research must hold a Federalwide Assurance (FWA) with the Office of Human Research Protections (OHRP). (See Resources).	~~U.S. Centers participating in~~ Human Subjects Research ~~must hold a Federalwide Assurance (FWA) with the Office of Human Research Protections (OHRP). (See Resources).~~	1.4000-1.4300 changed to consolidate and separate sections
1.4100	Research protocols that include human subjects shall be approved by a designated institutional review board (IRB).	Research protocols that include human subjects ~~shall be approved by a designated institutional review board (IRB).~~ as well as any associated consent forms or forms for data/sample collection and submission shall be approved by a designated institutional review board (IRB) and appropriate regulatory agency, if applicable.	1.4000-1.4300 changed to consolidate and separate sections
1.4200	Non-U.S. centers shall provide evidence of compliance with Independent Ethics Committees (IEC) within their country.	~~Non-~~U.S. centers ~~shall provide evidence of compliance with Independent Ethics Committees (IEC) within their country.~~ participating in human subject research must hold a Federalwide Assurance (FWA) with the Office of Human Research Protections (OHRP). (See Resources)	1.4000-1.4300 changed to consolidate and separate sections

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1.4300	Added section	Non-U.S. centers shall provide evidence of compliance with Independent Ethics Committees (IEC) within their country.	1.4000-1.4300 changed to consolidate and separate sections
2.1300	Center shall have a secure information management system and shall merge data according to NMDP requirements.	Center shall have a secure information management system ~~and shall merge data~~ according to NMDP requirements.	Clarify statement, "merge" doesn't make sense
5.2300	Center medical director shall be responsible for reviewing the medical evaluation of the donor for risks of donation and evidence of disease transmissible by transplantation.	Center medical director or designee ~~the physician performing the collection~~ shall perform and/or review a complete medical evaluation of the donor to determine if the donor is an acceptable candidate for HPC(M) collection including ~~Center medical director shall be responsible for reviewing the medical~~ evaluation of the donor for risks of donation and evidence of disease transmissible by transplantation.	Clarify who can perform collection/review medical evaluation of donor
5.3400	Physician responsible for the HPC(M) collection shall have documented operating room privileges at the collection center.	Deleted	Not necessary, a hospital is not going to let someone in an operating room if they are not cleared to do it.
5.4200	Center shall have capability to perform NMDP HPC(M) collections in a timely fashion.	Deleted. Fixed numbering.	Too vague
5.4300 – 5.5600		Fixed numbering	

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5.5200	Center medical director or the physician performing the collection shall perform and/or review a complete medical evaluation of the donor to determine if the donor is an acceptable candidate for HPC(M) collection.	Deleted	Redundant to 5.2300
5.5300-5.5600	5.5300	Fixed numbering	
5.5300	Center shall verify that the donor has autologous red cell units available prior to the HPC(M) collection appropriate to the anticipated volume of HPC(M) to be collected.	Center shall verify that if ~~the donor has~~ autologous ~~red cell~~ units have been collected the units are available prior to the HPC(M) collection. ~~appropriate to the anticipated volume of HPC(M) to be collected.~~	Changed based on public comment, NMDP does not require collection of autologous units
5.5310	Use of allogeneic blood shall be avoided unless deemed medically necessary by the collection physician.	~~Use of allogeneic blood shall be avoided unless deemed medically necessary by the collection physician.~~ The center should have the capability to collect and store autologous red cells prior to HPC(M) collection if necessary.	Changed to align with 5.5300
6.2200	Center medical director shall be responsible for reviewing the medical evaluation of the donor for risks of donation and evidence of disease transmissible by transfusion or transplantation	Center medical director or designee shall perform and/or review complete ~~be responsible for reviewing the~~ medical evaluation of the donor to determine if the donor is an acceptable candidate for HPC(A) collection including evaluation of the donor for risks of donation and evidence of disease transmissible by ~~transfusion or~~ transplantation.	Make more complete, same wording as 5.2300 as these two address the same issue NMDP Board changed HPC(M) to HPC(A)

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7.1300	Center shall have a designated inpatient unit that minimizes the risk of infection.	Center shall have processes in place defined in an SOP to ~~a designated inpatient unit that~~ minimize~~s~~ the risk of infection for transplant patients.	Very vague, make specific for transplant patients
7.1400	Center shall have a designated process 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.	Deleted	Combined with 7.1300
7.1410	If the patient care units are located in more than one institution, at least one of the institutions shall satisfy all transplant center participation criteria. Patient care units at the other institutions shall have performed allogeneic transplants for at least five different patients per year	Deleted	This is too specific to be in Standards, there are contracts in place and participation criteria to deal with this
7.1500 (7.1510)		Number changed to 7.1400 (7.1410)	
7.2400	Center shall have at least two attending physicians, one of whom may be the medical director.	Center shall have at least two attending physicians of adequate clinical training, one of whom may be the medical director.	Clarify and align wording with 7.2410
9.1000	Donor Additional Testing/Information	~~Donor Additional Testing/Information~~ Confirmatory Typing Stage	Section is really about confirmatory testing, changed title to reflect contents
9.1100	Confirmatory Testing Stage	Deleted	This is now title of section

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9.1110-9.1700	Changed numbering	9.1100-9.1900	
9.5240	Donor center and collection center shall agree on the volume of autologous blood to be collected by the donor center.	Donor center and collection center shall agree on the volume of autologous blood to be collected by the donor center if needed.	NMDP Board added "if needed" for clarification.
10.2110	Hematopeietic mobilizing agent shall be given to donors only when approved by the NMDP.	Only ~~Hematopeietic~~ mobilizing agents approved by NMDP shall be used. ~~given to donors only when approved by the NMDP.~~	Poorly written, rewritten to clarify that type of mobilizing agent needs NMDP approval
11.3000	Complaints	Product Complaints	Be more specific
11.3100	Participating Center shall have processes and procedures for capturing, evaluating, documenting and follow-up of reported complaints relative to products or services provided by Center.	Participating Center shall have processes and procedures for capture ~~capturing~~, evaluation ~~evaluating~~, documentation ~~documenting~~ and follow-up of reported product complaints relative to products or services provided by Center.	Fix syntax issues
11.4132	The facility of final distribution shall have policies and procedures to address cellular therapy products with positive microbial culture, including: 1) Product labeling 2) Investigation of cause 3) Notification of recipient physician 4) Recipient	The facility of final distribution shall have policies and procedures to address cellular therapy products with positive microbial culture, including: 1) Product labeling 2) Investigation of cause 3) Notification of recipient physician 4) Recipient	Differentiate between the NMDP and other regulatory agencies

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	follow-up and outcome analysis 5) Reporting to regulatory agencies as applicable	follow-up and outcome analysis 5) Reporting to NMDP 6) Reporting to regulatory agencies, as applicable	
12.3100	Donor center records pertaining to donors, who have been activated for a formalized search and have any of the following records, shall be retained indefinitely:	Donor center records pertaining to donors, who have been activated for workup ~~a formalized search and have any of the following records~~, shall be retained indefinitely:	Only need to retain records for donors activated for workup, do not need to keep records for all donors indefinitely
12.3160	All source documents for any formalized search.	All source documents. ~~for any formalized search.~~	Revised to align with 12.3100
12.4300	Recipient search requests and preliminary results of recipient searches that are never formalized	~~Recipient search requests and preliminary results of recipient searches that are never formalized~~	TCs do not want to keep these searches as it creates too much paperwork
Food and Drug Administration (FDA)	A United States government agency within the Department of Health and Human Services charged with protecting and promoting the health of American consumers..	A United States government agency within the Department of Health and Human Services charged with protecting and promoting the health of American consumers.	Extra period at end of statement
Manufacture	Manufacture	Product Manufacture	Make more specific

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Nonconforming Product, Supply/Material or Service	A failure of cellular characteristic, supply, reagent, dose or test results to meet specified requirements.	A failure of cellular therapy product ~~characteristic~~, supply, reagent, dose or test results to meet specified requirements.	Therapy product is more appropriate
Participating Center	Donor, collection, apheresis or transplant center, recruitment center or cord blood bank that has submitted an NMDP application, meets NMDP criteria, and become a member of the NMDP network. Term references the facility, policies, staff, etc. composing the network entity.	Donor, collection, apheresis or transplant center, recruitment center or cord blood bank that has submitted an NMDP application, meets NMDP Participation Criteria ~~criteria~~, and become a member of the NMDP network. Term references the facility, policies, staff, etc. composing the network entity.	Specifying type of criteria