

NMDP Standards Cross Reference Tool

Purpose: This document serves as a resource for documents and materials which were included in both the 24th edition NMDP Standards and our policies and procedures. Users may find this listing a helpful reference as a companion to the 25th ed. NMDP Standards.

Background: Continued participation as an NMDP network partner requires adherence to NMDP membership requirements, federal or state laws and regulations (or non- U.S equivalent) or the standard of care prevailing in the relevant community. Each facility and individual must determine and follow additional laws, regulations, practices and procedures that apply in their community.

The NMDP Standards document sets forth the minimal requirements for programs working through the NMDP to facilitate hematopoietic stem cell transplants. Many of the requirements in previous editions of Standards were also contained in other documents and policies. Operational processes have become standardized within the cellular therapy industry and no longer require specific requirements in the NMDP Standards. In a continued effort to streamline and avoid duplication of the compliance requirements in multiple documents, the 25th Edition of the Standards has been simplified. Information previously found in the 24th Edition of the Standards can be found in the documents outlined below. Please contact NMDP department representatives below or membership@nmdp.org with questions related to the below referenced documents.

	24 th Edition Chapter Heading	Content and Document Reference
1.0000	General	<ul style="list-style-type: none"> • Relevant Accreditation requirements <ul style="list-style-type: none"> ○ AABB (Association for the Advancement for Blood & Biotherapies) ○ ASHI (American Society for Histocompatibility and Immunogenetics) ○ CAP (College of American Pathologists) ○ EFI (European Federation for Immunogenetics) ○ FACT (Foundation for the Accreditation of Cellular Therapy) ○ WMDA (World Marrow Donor Association) • Center-type specific Participation Criteria <ul style="list-style-type: none"> ○ Donor Center Participation Criteria*

		<ul style="list-style-type: none"> ○ U.S. Apheresis and Collection Center Participation Criteria* ○ Cord Blood Bank Participation Criteria* ○ Transplant Center Participation Criteria* • Agreements as applicable** • Center-type specific Manuals of Operation <ul style="list-style-type: none"> ○ Donor Center Manual of Operations* ○ Cord Blood Bank Manual of Operations* ○ Product Collection Manual* ○ Member Engagement, Enrollment and Experience (ME3) Manual of Operations* ○ TC Manual of Operations*
2.0000	Criteria for Participating Donor Centers	<ul style="list-style-type: none"> • WMDA (World Marrow Donor Association) Standards • Donor Center Participation Criteria* • Donor Center Manual of Operations*
3.0000	Criteria for Participating Network Centers that Perform Donor Recruitment Activities	<ul style="list-style-type: none"> • Member Engagement, Enrollment and Experience (ME3) Manual of Operations*
4.0000	Criteria for Participating Cord Blood Banks	<ul style="list-style-type: none"> • AABB or FACT Accreditation Requirements <ul style="list-style-type: none"> ○ AABB (Association for the Advancement for Blood & Biotherapies) ○ FACT (Foundation for the Accreditation of Cellular Therapy) • Cord Blood Banks Participation Criteria*

5.0000	Criteria for Participating in Marrow Collection Centers	<ul style="list-style-type: none"> • AABB or FACT Accreditation Requirements <ul style="list-style-type: none"> ○ AABB (Association for the Advancement for Blood & Biotherapies) ○ FACT (Foundation for the Accreditation of Cellular Therapy) • U.S. Apheresis and Collection Center Participation Criteria* • Product Collection Manual*
6.0000	Criteria for Participating Apheresis Collection Centers	<ul style="list-style-type: none"> • AABB or FACT Accreditation Requirements <ul style="list-style-type: none"> ○ AABB (Association for the Advancement for Blood & Biotherapies) ○ FACT (Foundation for the Accreditation of Cellular Therapy) • U.S. Apheresis and Collection Center Participation Criteria* • Product Collection Manual* • Quality Agreements, as applicable**
7.0000	Criteria for Participating Transplant Centers	<ul style="list-style-type: none"> • Transplant Center Participation Criteria* • TC Manual of Operations*
8.0000	Recruitment of Marrow or Hematopoietic Cell Donors	<ul style="list-style-type: none"> • Member Engagement, Enrollment and Experience (ME3) Manual of Operations* • WMDA (World Marrow Donor Association) Standards
9.0000	Donation Process	<ul style="list-style-type: none"> • AABB or FACT Accreditation Requirements <ul style="list-style-type: none"> ○ AABB (Association for the Advancement for Blood & Biotherapies) ○ FACT (Foundation for the Accreditation of Cellular Therapy) • WMDA (World Marrow Donor Association) • Donor Center Manual of Operations* • Product Collection Manual* • Certification by ASHI, CAP or EFI for HLA testing

		<p>laboratories</p> <ul style="list-style-type: none"> ○ ASHI (American Society for Histocompatibility and Immunogenetics) ○ CAP (College of American Pathologists) ○ EFI (European Federation for Immunogenetics)
10.0000	Hematopoietic Cell Collection, Processing, Labeling, and Transportation	<ul style="list-style-type: none"> • Donor Center Manual of Operations/Product Collection Manual Chapter 9: PBSC Workup and Donation Process* • Donor Center Manual of Operations/Product Collection Manual Chapter 12: Cellular Product Labeling, Release, and Transport* • Product Labeling and Release Resources* • Accreditation requirements of AABB or FACT <ul style="list-style-type: none"> ○ AABB (Association for the Advancement for Blood & Biotherapies) ○ FACT (Foundation for the Accreditation of Cellular Therapy)
11.0000	Adverse Events, Deviations, Complaints and Nonconforming Products, Materials or Services	<ul style="list-style-type: none"> • AABB or FACT Accreditation Requirements <ul style="list-style-type: none"> ○ AABB (Association for the Advancement for Blood & Biotherapies) ○ FACT (Foundation for the Accreditation of Cellular Therapy) • Donor Center Manual of Operations/Product Collection Manual Chapter 15: Adverse Events Adverse Events* • PBSC Protocol describes adverse events and reporting requirements PBSC Protocol Resources*

12.0000	Records and Record Retention	<ul style="list-style-type: none"> • AABB or FACT Accreditation Requirements <ul style="list-style-type: none"> ○ AABB (Association for the Advancement for Blood & Biotherapies) ○ FACT (Foundation for the Accreditation of Cellular Therapy) • WMDA (World Marrow Donor Association) Standards • NMDP/Be The Match® Participating Network Centers Record Retention Policy (P00143)*
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* Indicates documents that are proprietary and only available to Network Members. Contact representatives for additional information.

**At time of publication, not all partners have quality agreements in place. This requirement applies only to those that have agreements in place.

NMDP Contact email information:

1. Donor workup and collection questions: PartnerLiasons@nmdp.org
2. Cord blood management questions: Cordliaisons@nmdp.org
3. Transplant Center questions: lpp@nmdp.org

Accreditation:

Various accrediting agencies provide specific requirements in their standards. Standards setting and voluntary accreditation organizations include:

Accreditation Body	Scope
AABB Association for the Advancement for Blood & Biotherapies	Cord Blood Bank Operations, Apheresis Collection Centers, Cellular Starting Material, Transplant programs
ASHI/EFI/CAP American Society for Histocompatibility and Immunogenetics/ European Foundation for Immunogenetics/ College of American Pathologists	Histocompatibility & Immunogenetics Laboratory accreditation , credentialling of doctoral and non-doctoral technical staff and providing continuing professional development.
FACT Standards Foundations for the Accreditation of Cellular Therapy	Cord Blood Banks; Requirements: NetCord-FACT Standards
FACT Standards Foundations for the Accreditation of Cellular Therapy	Cellular Therapy Programs (clinical activities, collection, and cell processing); Requirements FACT-JACIE Hematopoietic Cell Therapy Standards, FACT IEC Standards, and FACT Common Standards
WMDA World Marrow Donor Association	Cord Blood Registry Operations and Donor Registry Operations WMDA Standards 2021

Disclaimer:

Each facility must determine and follow any additional laws, regulations, practices and procedures that apply in their particular community. The NMDP disclaims all representations or warranties, expressed or implied, that compliance with NMDP requirements will fulfill the requirements of all applicable federal or state laws and regulations (or their non-U.S. equivalents) or the standard of care prevailing in the relevant community.