National Marrow Donor Program®/Be The Match®

24th Edition

Standards

And

Glossary

January 1, 2018

Notice and Disclaimer

NMDP/Be The Match Standards

These standards apply to activities performed by National Marrow Donor Program (NMDP)/Be The Match (referred to as NMDP throughout the remainder of the document) participating centers and include processes from donor recruitment to distribution and administration of cellular therapy products facilitated through NMDP. These standards set forth only the minimal requirements for programs working through the NMDP to facilitate hematopoietic cell transplants. These standards do not set forth all that may be required of a facility or individual to conform to NMDP membership requirements, federal or state laws or regulations (or non-U.S. equivalent) or the standard of care prevailing in the relevant community. Each facility and individual 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 the NMDP Standards will fulfill the requirements of all applicable federal or state laws and regulations (or their non-U.S. equivalent) or the standard of care prevailing in the relevant community.

The nomenclature throughout these Standards is consistent with ISBT 128 terminology published by ICCBBA, Inc. However, acronyms such as HPC(CB), HPC(A) and HPC(M) are not intended to be used in labeling process or on product labels.

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NATIONAL MARROW DONOR PROGRAM®

24th EDITION STANDARDS

1.0000 General

1.1000 Centers shall have adequate staff, resources, space, equipment and supplies to perform and manage activities.

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1.2000 Centers shall establish and maintain written policies and procedures to define activities.

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1.3000 Participating programs and support laboratories shall comply with all applicable governmental laws and regulations.

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1.4000 Human Subjects Research

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1. 4100 Research protocols that include human subjects 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.

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1.4110 Clinical research protocols and the informed consent forms for data and sample collection and submission shall be approved by an institutional review board (IRB) and appropriate regulatory agency, if applicable.

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1. 4200 U.S. centers participating in human subject research must hold a Federalwide Assurance (FWA) with the Office of Human Research Protections (OHRP). (See Resources)

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1. 4300 Non-U.S. centers shall provide evidence of compliance with Independent Ethics Committees (IEC) within their country.

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1.5000 Centers shall use laboratory(ies) certified by Centers for Medicare & Medicaid Services (CMS) (or non-U.S. equivalent) for all clinical tests required by NMDP.

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1.6000 Participating programs and support laboratories shall comply with these Standards, as well as NMDP policies and procedures.

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1.6100 Participating programs shall participate in an NMDP or other quality program.

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1.6200 Participating programs shall participate in the NMDP Continuous Process Improvement (CPI) program, when applicable.

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1.6300 Participating programs shall complete their network renewal annually.

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1.7000 Director of a participating program shall be responsible for compliance with these Standards.

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1.8000 Center medical director shall be a licensed physician qualified by training and experience to perform and/or supervise defined center activities.

1.8100 Any responsibility(ies) of the center medical director may be fulfilled by a designated center physician.

1.8200 Center medical director is responsible for assuring that physician designees are trained and qualified.

1.8300 Center physicians shall participate regularly in educational activities related to the field of hematopoietic cell collection or transplantation.

1.9000 Significant changes in personnel, facilities and/or support services shall be reported promptly to the NMDP in accordance with NMDP Participation Criteria.

1.10000 Participating programs shall maintain a system of strict confidentiality of records to protect the privacy of potential donors, donors and patients.

1.11000 Staff and volunteer training, continuing education, and continued competency for relevant skills shall be documented.

2.0000 Criteria for Participating Donor Centers

2.1000 Facility Characteristics

2.1100 Center shall have experience in the management of blood, apheresis or marrow donors, including education, counseling, confidentiality issues and medical screening.

2.1200 Center shall have a private space for donor counseling sessions.

2.1300 Center shall have a secure information management system according to NMDP requirements.

2.1400 Center shall have written agreement(s) defining roles and responsibilities with participating apheresis and/or marrow collection center(s).

2.1500 Center shall be registered with FDA for applicable manufacturing functions.

2.2000 Medical Director

2.2100 Center shall have a medical director who is a licensed physician qualified by training and experience to evaluate and determine donor medical suitability and supervise donor management.

2.2110 The medical director or physician designee shall determine donor medical suitability.

2.2200 Center medical director shall be responsible for interpretation of NMDP eligibility criteria.

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2.3000 Personnel

2.3100 Center shall designate a coordinator to work with the NMDP.

2.3110 Center shall provide staff for each working day and coverage for emergencies.

2.4000 Support Services

2.4100 Center shall use the following facilities for NMDP activities:

2.4110 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.

2.4120 Laboratory(ies) that perform eligibility testing for evidence of infection due to relevant communicable disease agents must use donor screening tests that the Food and Drug Administration (FDA) has approved, licensed or cleared for such use and testing shall be performed in accordance with the manufacturer's instructions (See Resources).

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2.4130 Blood Bank licensed by or registered with the FDA, (or non-U.S. equivalent) for collection of autologous blood.

2.5000 Policies and Procedures

2.5100 Center shall maintain written procedures and policies for the management of volunteer donors.

3.0000 Criteria for Participating Network Centers that Perform Donor Recruitment Activities

3.1000 Center Characteristics

3.1100 Center shall have experience in donor recruitment activities, including education, confidentiality issues and preliminary donor evaluation.

3.1200 Center shall recruit new donors in accordance with priorities of the NMDP.

3.1300 Center shall have a written agreement defining roles and responsibilities with each NMDP donor center that has agreed to accept the recruited HLA-typed donors.

3.1400 Center shall recruit donors for inclusion only in the Be The Match Registry®.

3.2000 Medical Director

3.2100 Center shall have access to a donor center medical director for assistance with preliminary donor evaluation.

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3.3000 Personnel

3.3100 Center shall designate a coordinator to work with the NMDP network.

3.3200 Center shall have staff sufficient to perform required activities.

3.4000 Policies and Procedures

3.4100 Center shall maintain written policies and procedures for the recruitment of volunteer donors.

4.0000 Criteria for Participating Cord Blood Banks

4.1000 Bank shall maintain accreditation by AABB, and/or NetCord-FACT (See Resources).

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4.2000 Bank shall follow NMDP Member Cord Blood Bank Participation Criteria.

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5.0000 Criteria for Participating Marrow Collection Centers

5.1000 Facility Characteristics

5.1100 Center shall be accredited by an organization granted deemed status by Centers for Medicare & Medicaid Services (CMS) or non-US equivalent.

5.1200 Center shall have an experienced team that has collected HPC(M) at least three times in the past three years at the center.

5.1300 Center shall have written agreement(s) defining roles and responsibilities with participating donor center(s).

5.2000 Medical Director

5.2100 Center medical director shall have postdoctoral training in hematopoietic cell collection or transplantation.

5.2200 Center medical director shall have at least one year experience in the collection procedure.

5.2300 Center medical director or designee 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 evaluation of the donor for risks of donation and evidence of disease transmissible by transplantation.

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5.3000 Personnel

5.3100 Center physician performing the HPC(M) collection shall have performed at least 10 prior collections of HPC(M) for transplantation with at least three collections in the previous three years. Any person assisting in the marrow aspiration (physician, nurse, technician) shall have documented adequate training in HPC(M) collections for transplantation.

5.3200 Center shall provide daily and emergency coverage by designated coordinator(s), sufficient in number to meet the needs of the center's activities.

5.3300 Center shall provide anesthesia under supervision of a licensed, board-certified anesthesiologist or certified nurse anesthetist.

5.4000 Support Services

5.4100 Center shall have a surgical operating room and a medical or surgical intensive care unit.

5.4200 Center shall have irradiated and leukoreduced blood components available in the event that the use of allogeneic blood cannot be avoided.

5.5000 Policies and Procedures

5.5100 Center shall maintain written procedures for the collection, testing and labeling of HPC(M).

5.5200 Center shall verify that if autologous units have been collected the units are available prior to the HPC(M) collection.

5.5210 The center should have the capability to collect and store autologous red cells prior to HPC(M) collection if necessary.

5.5300 Physician responsible for the collection shall be present for the duration of the HPC(M) collection.

5.5400 Donor shall be admitted and discharged from the collection center the same day unless the medical status precludes it.

5.5410 Physician shall be responsible for determining that the donor's health is appropriate for discharge.

5.5500 At time of discharge, the center shall provide to the donor post-donation care instructions with contact names and phone numbers.

6.0000 Criteria for Participating Apheresis Collection Centers

6.1000 Facility Characteristics

6.1100 Center shall be registered with the FDA.

6.1200 Center shall have experience in the collection of cellular components by apheresis, and shall have performed at least three collections of mononuclear cells by apheresis in the past year.

6.1300 Center shall have written agreement(s) defining roles and responsibilities with participating donor center(s).

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6.2000 Medical Director

6.2100 Center shall have a medical director who is a licensed physician qualified by training and experience to supervise mononuclear cell collections:

6.2110 Center medical director shall have at least one year experience in the collection procedure.

6.2200 Center medical director or designee shall perform and/or review complete 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 transplantation.

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6.3000 Personnel

6.3100 Center shall designate a coordinator to work with the NMDP.

6.3200 Center shall have apheresis collection staff experienced in the collection of mononuclear cells and in the management of apheresis donors including those with central venous catheters.

6.3300 Administration of mobilization agents shall be under the supervision of a licensed physician experienced in their administration and in the management of complications in persons receiving these agents.

6.3400 A licensed physician qualified by training and experience, shall place any central venous catheters.

6.4000 Support Services

6.4100 Center shall use a laboratory with documented proficiency for measuring the quantity of CD34-positive cells in the component collected.

6.4200 Center shall use a hospital accredited by an organization granted deemed status by Centers for Medicare & Medicaid Services (CMS) or non-U.S. equivalent for placement of central venous catheters.

6.5000 Policies and Procedures

6.5100 Center shall maintain written procedures and policies for donor evaluation, mobilizing agent administration, and management of adverse events, and for the collection, testing, storage, labeling, and transport of hematopoietic cells and for the maintenance of apheresis equipment.

6.5200 Center shall have a process for treating donor adverse events and providing for emergency medical care.

6.5300 Center shall maintain written procedures to prevent or minimize adverse effects of citrate administration during apheresis.

6.5400 Center shall have a written policy on peripheral venous access assessment and placement of central venous catheters.

6.5410 Central venous catheters shall only be used when peripheral venous access is not deemed feasible after skilled assessment or cannot be obtained or has failed.

6.5420 Placement of central venous catheters shall require a written justification.

6.5430 Adequacy of line placement shall be verified prior to use.

7.0000 Criteria for Participating Transplant Centers

7.1000 Facility Characteristics

7.1100 Center shall be accredited by an organization granted deemed status by Centers for Medicare & Medicaid Services (CMS) or non-U.S. equivalent.

7.1200 Center shall have an experienced team that has performed allogeneic transplants for at least 10 different patients per year.

7.1210 Centers performing pediatric transplants shall have a transplant team trained in the management of pediatric patients.

7.1300 Center shall have processes in place defined in an SOP to minimize the risk of infection for transplant patients.

7.1400 Center with more than one patient care unit shall be considered a single transplant center if the patient care units demonstrate functional unity.

7.2000 Medical Director

7.2100 Center medical director should be board certified (or non-U.S. equivalent) in one or more of the following specialties: Hematology, Immunology, Medical Oncology or Pediatric Hematology/Oncology.

7.2110 Non-board certified physicians who completed medical training prior to 1985 may serve as medical directors if they have documented experience in the field of hematopoietic cell transplantation extending over ten years.

7.2200 Center medical director shall have had at least two years of experience as an attending physician responsible for clinical management of allogeneic transplant recipients in the inpatient and outpatient settings.

7.2300 Transplant center medical director shall be responsible for search management activities and protecting the safety of the recipient.

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7.2400 Center shall have at least two attending physicians of adequate clinical training, one of whom may be the medical director.

7.2410 Adequate clinical training in allogeneic hematopoietic cell transplant shall be defined as a minimum of one year experience in the management of transplant recipients in both the inpatient and outpatient settings.

7.2420 Attending physicians should be board certified (or non-U.S. equivalent) or eligible as specified in 7.2100.

7.3000 Personnel

7.3100 Center shall provide daily and emergency coverage by designated transplant coordinator(s), sufficient in number to meet the needs of the center's activities.

7.3200 Center shall have nurses qualified by training and experience in the care of transplant recipients, sufficient in number to meet patient needs.

7.3300 Center shall have sufficient data management personnel to comply with NMDP and Center for International Blood and Marrow Transplant Research (CIBMTR) data submission requirements (See Resources).

7.3400 Center shall identify a patient advocate who is familiar with the center's program and issues of unrelated donor hematopoietic cell transplantation.

7.4000 Support Services

7.4100 Center shall use 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. The laboratory designated by the transplant center is responsible for the final HLA typing of the patient and donor.

7.4200 Center shall have access to a person qualified by training and experience in human histocompatibility testing to assist in the selection of unrelated hematopoietic cells or donors.

7.4300 Center shall use a transfusion service providing 24-hour blood component support for transplant patients, including irradiated blood components and components suitable for CMV-negative recipients.

7.4400 Center shall use an experienced hematopoietic cell processing laboratory.

7.4500 Center shall have experienced physicians who provide consultative services in at least the following disciplines: Cardiology, Gastroenterology, Infectious Diseases, Intensive Care, Nephrology, Pathology, Pulmonary Medicine, Psychiatry, Surgery, Transfusion Medicine, and, if applicable, Radiation Therapy.

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7.4600 Center shall have sufficient staff from at least the following services: Dentistry, Dietary, Pharmacy, Physical Therapy, and Social Services.

7.5000 Policies and Procedures

7.5100 Center shall maintain written policies, procedures and clinical practice guidelines for management of allogeneic transplantation.

7.5200 Each recipient of hematopoietic cells from an NMDP donor shall be enrolled in a clinical research protocol or treated according to written clinical practice guidelines.

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7.5300 Center shall have a mechanism to obtain written consent from the recipient for submission of data to NMDP and Center for International Blood and Marrow Transplant Research (CIBMTR) and blood samples to the NMDP prior to use of hematopoietic cells from an NMDP donor.

7.5400 Center shall have policies to ensure timely communication with patients, families and physicians, including the progress of the search and other treatment options.

8.0000 Recruitment of Marrow or Hematopoietic Cell Donors

8.1000 Donor shall be between the ages of 18 and 60.

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8.2000 Donor shall appear to be in good health.

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8.3000 Donor shall provide a medical history and shall document that the history is accurate.

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8.4000 Pertinent donor medical history shall be evaluated for acceptance or deferral according to the current NMDP procedures and criteria of local donor center medical director.

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8.5000 Donor shall be given educational materials regarding the risks of infectious disease transmission by hematopoietic cell transplants.

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8.6000 Donor shall provide informed consent.

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8.6100 Donor shall be given a general explanation of the indications for and results of hematopoietic cell transplantation and reasons for using unrelated donors.

8.6200 Donor shall be given a general description of the different types of donation processes and the risks of hematopoietic cell donation associated with each.

8.6300 Donor shall be informed that additional testing for donor selection may be performed on stored samples.

8.6400 Donor shall acknowledge and document that he/she has read and understood the educational material, has been given ample opportunity to ask questions and has had those questions answered satisfactorily.

8.6500 Donor shall be informed that he/she has the right to decline or withdraw from NMDP participation at any time without prejudice.

8.7000 Donor shall not be coerced to register with NMDP.

8.8000 Donor's sample shall be HLA typed using criteria established by NMDP.

9.0000 Donation Process

9.1000 Confirmatory Typing Stage

9.1100 Donor center shall provide potential donor with educational materials including the risks of infectious disease transmission by transplantation.

9.1200 Donor center shall obtain from the donor a medical history that meets NMDP requirements for a marrow or apheresis donor.

9.1300 Donor center shall keep a written record of the medical history.

9.1310 Medical history indicative of disease shall be evaluated by a physician before proceeding.

9.1400 The donor center shall perform and/or review the results of the screening tests for evidence of infection due to the relevant communicable diseases as defined by NMDP.

9.1500 ABO grouping and Rh typing of the potential donor shall be performed if the donor has not been previously typed by the donor center.

9.1600 Results of the ABO grouping, Rh typing and infectious disease testing shall be reported to the transplant center that requested the confirmatory testing sample.

9.1610 Donors with a confirmed positive test for relevant communicable disease agents (e.g. HBV or HCV) shall not be used unless urgent medical need is documented.

9.1620 Donors with a confirmed positive test for HIV shall not be used.

9.1700 Transplant Center shall verify the HLA typing of the donor in accordance with NMDP policy, using a new sample.

9.1800 Confirmatory testing shall have been completed prior to hematopoietic cell donation.

9.1900 Results of the confirmatory HLA typing shall be sent to the NMDP.

9.2000 Donor Information Session

9.2100 Information as required by the NMDP shall be provided to the selected potential marrow or apheresis donor before consent is obtained.

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9.2200 Prospective marrow or apheresis donor shall be informed of at least the following:

9.2210 The donation process and associated risks to the donor.

9.2220 The transplant process for the recipient.

9.2230 Right to withdraw at any time, but extreme risk of death for the recipient if the donation is not completed once the preparative regimen is begun.

9.2240 Possibility that he/she may be asked to provide other cellular therapy products for the same recipient.

9.2300 Prospective marrow donor shall be informed about the procedure of HPC(M) donation and the following risks of HPC(M) donation:

9.2310 Risks of anesthesia.

9.2320 Risks and discomforts of HPC(M) donation including mechanical injury, prolonged pain, infection, transfusion and mental/emotional stress.

9.2400 Prospective apheresis donor shall be given detailed information about the apheresis procedure and the following risks of the procedure.

9.2410 Risks and side effects of mobilizing agent (if applicable).

9.2420 Possibility of central venous catheter placement, along with its risks, discomforts, and mental/emotional stress.

9.2430 Risks and discomforts of the apheresis procedure.

9.3000 Medical Evaluation of the Prospective HPC(M) or HPC(A) Donor

9.3100 Donor center shall provide prospective donor with educational materials regarding the risks of infectious disease transmission by transplantation.

9.3200 Medical history

9.3210 Donor center shall obtain from the donor a medical history that meets NMDP requirements.

9.3220 Medical history indicative of disease or risk of infectious disease shall be evaluated by a donor center medical director or designee to determine the donor's suitability to donate and eligibility status.

9.3300 Medical examination

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9.3310 Examining practitioner is responsible for protecting the safety of the donor and for delineating conditions in the donor that may be transmissible by transfusion or transplantation.

9.3320 Examining practitioner shall be designated by medical director of donor, collection, or apheresis center.

9.3330 Examining practitioner shall not be the primary practitioner overseeing the care of the recipient.

9.3340 Examining practitioner shall perform and/or evaluate a complete medical history and physical examination to include special notation of the following:

9.3341 Pregnancy assessment.

9.3342 Deferral from blood donation.

9.3343 Contraindications to HPC(M) or HPC(A) donation.

9.3344 Findings that would increase the anesthesia risk for the prospective donor.

9.3345 Examining practitioner shall obtain and evaluate donor testing per NMDP policies and procedures.

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9.3350 Examining practitioner shall report results of the medical evaluation in writing to the donor center.

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9.3360 Final approval of the donor shall not occur until the medical director/physician designee of the collection center or apheresis center and the donor center medical director or designee document that the donor meets the criteria for collection and the donor has signed the consent to donate.

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9.3361 Donor center shall notify the NMDP case manager that the donor is medically suitable and has signed the consent to donate.

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9.3370 Donor center shall ensure repeat infectious disease testing is performed if previous results were obtained more than 30 days prior to HPC(M) or HPC(A) donation (Standard 2.4120 applies).

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9.4000 Prospective Donors with Abnormal Findings

9.4100 Donor center medical director or designee shall report to the donor any clinically significant abnormal findings discovered during donor evaluation.

9.4110 Donor shall be notified of the findings and documentation of donor notification shall be maintained.

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9.4120 Donor has the right to decline donation based on the abnormal findings and keep the reason(s) confidential.

9.4200 Clinically significant abnormal finding that may increase risk to the donor.

9.4210 Donor center medical director and apheresis or marrow collection center medical director (or examining practitioner) shall determine whether any finding constitutes unacceptable risk to the donor.

9.4220 If the donor agrees to donate, any clinically significant finding that may increase risk in the prospective donor shall be reported by the donor center to the NMDP.

9.4300 Abnormal finding that may increase risk to the recipient.

9.4310 Transplant center medical director shall determine whether hematopoietic cells from a donor with an abnormal finding pose unacceptable risk to the recipient.

9.4320 Decision to use hematopoietic cells from a donor with an abnormal finding that may increase risk to the recipient shall be communicated by the transplant center, in writing, to the NMDP.

9.4330 Abnormal finding that may increase recipient risk shall be reported to the recipient or recipient's representative, who shall be counseled as to the potential impact of the abnormality.

9.4331 Documentation of counseling shall be maintained at the transplant center.

9.5000 Pre-Collection Communication

9.5100 HPC(M) or HPC(A) Donation

9.5110 Transplant center shall provide signed acknowledgment to the NMDP that the donor's ABO group and Rh type, degree of HLA match, and test results are acceptable.

9.5120 Initiation of the recipient's preparative regimen shall not occur until the donor has received final approval and infectious disease testing, performed within 30 days of HPC(M) or HPC(A) donation, and has been reported to the NMDP.

9.5200 HPC(M)Donation

9.5210 Donor center, collection center, and transplant center shall agree in writing on the volume and nucleated cell count of HPC(M) to be collected before start of preparative regimen.

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9.5220 Transplant center and collection center shall agree on the medium, anticoagulant and additives used for collection and transport of HPC(M).

9.5230 Number of nucleated cells to be used for quality assurance and research shall be included and identified separately on the marrow request form.

9.5240 Donor center and collection center shall agree on the volume of autologous blood to be collected by the donor center if needed.

9.5300 HPC(A) and MNC(A) Donation

9.5310 For HPC(A), donor center, apheresis center and transplant center shall agree in writing on the following before the start of the recipient's preparative regimen:

9.5311 Volume of whole blood to be processed or total CD34 positive cells to be collected.

9.5312 Number of apheresis procedures to be performed.

9.5320 For MNC(A), donor center, apheresis center and transplant center shall agree in writing on the volume of whole blood to be processed.

9.6000 Pre-Collection Donor Blood Samples

9.6100 Pre-collection donor blood samples in excess of those required for autologous units and samples needed to assess the physical well-being of the donor should be:

9.6110 Limited to a maximum volume defined in current NMDP guidelines.

9.6120 Obtained more than 10 days prior to HPC(M) collection.

9.7000 Subsequent Donor Contacts

9.7100 Following the donation, donor center shall evaluate the well-being of the donor in the following manner:

9.7110 Telephone call or direct conversation with the donor shall be made within 48 hours after discharge from the collection facility.

9.7120 Contact with the donor shall be repeated between five and seven days after donation.

9.7130 If the donor has any unusual clinical complaints, donor shall be referred to an appropriate source of medical care.

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9.7140 Contacts with donor shall continue until the donor is free of clinical complaints related to the collection.

9.7200 Subsequent Donations

9.7210 Donor may be asked to provide an additional cellular therapy product for the same recipient following NMDP guidelines.

9.7211 Donor suitability and eligibility determination requirements apply for each donation occurrence.

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9.7212 Donor should not provide more than two subsequent donations for a given recipient, of which only one may be an HPC(A) or HPC(M) donation.

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9.7220 A donor may be asked to donate HPC for a second recipient only if no other equally compatible donor is available and the following conditions are met:

9.7221 At least one year has elapsed since the first HPC(M) or HPC(A) donation for the first recipient.

9.7222 At least three years have elapsed since a subsequent HPC(M) or HPC(A) donation.

9.7223 No donor shall provide more than two HPC(M) donations.

9.7224 Donation of HPC to a third recipient is not permitted.

9.7225 NMDP Medical Director may authorize exceptions to these standards

9.7230 Donor has the right to refuse consent for any subsequent request.

9.7300 Donor/Recipient Direct Contact

9.7310 If the donor registry or transplant program allows direct contact between donor and recipient, contact is allowed only after both donor and recipient or recipient's representative have signed a consent authorizing release of personal information.

9.7311 Direct contact shall not occur until after the first anniversary of the transplant.

10.0000 Hematopoietic Cell Collection, Processing, Labeling, and Transportation

10.1000 HPC(M) Collection

10.1100 Collection shall be performed only after it has been determined that the intended recipient is suitable for immediate transplant.

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10.1110 Collection shall not be requested for transplantation at an undetermined future date.

10.1200 Collection shall be performed with a needle designed specifically for HPC(M) collection.

10.1300 HPC(M) shall be taken from the posterior aspect of the iliac crest.

10.1400 Collected marrow volume shall not exceed 20 ml/kg donor body weight.

10.1500 HPC(M) shall be harvested with only the types and amounts of anticoagulants, media and additives agreed on by transplant and collection centers.

10.1600 HPC(M) should contain the number of nucleated cells agreed upon by the transplant center, donor center, and collection center.

10.1610 Collection center shall count the nucleated cells collected.

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10.1700 HPC(M) shall be filtered during collection using sterile filters made of materials that do not deplete leukocytes.

10.1800 HPC(M) shall be divided into approximately equal portions and packaged in at least two sterile, closed, labeled blood bags appropriate for HPC(M) collection, each with ports that can be entered aseptically.

10.2000 HPC(A) and MNC (A) Collection

10.2100 HPC(A) collection

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10.2110 Only mobilizing agents approved by NMDP shall be used.

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10.2120 Apheresis shall be performed only after it is determined that the intended recipient is suitable for immediate transplantation.

10.2121 Apheresis shall not be requested for transplantation at an undetermined future date.

10.2130 For central venous access see Section 6.5400.

10.2200 Collection shall be performed using an instrument and software designed for mononuclear cell collection.

10.2300 Collection shall be performed using ACD-A anticoagulant in a ratio sufficient to prevent extracorporeal clotting.

10.2400 Total volume of whole blood processed per collection shall be set by NMDP protocols and procedures.

10.2500 Target parameters shall be specified in writing.

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10.2510 Apheresis center shall obtain component cell counts, including CD34 counts for HPC(A), and promptly transmit results to NMDP and to the transplant center.

10.2600 Cells shall be suspended in sufficient donor plasma to maintain viability of the cells during transport.

10.2700 Cells shall be aseptically collected in a sterile, labeled container with a port that can be entered aseptically.

10.3000 HPC(M) or HPC(A) Processing

10.3100 Collection center and/or apheresis centers shall not add anything, process or cryopreserve product except as requested by the transplant center and approved by the NMDP.

10.3110 Any further processing shall only be performed by transplant center or laboratory designated by the transplant center.

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10.3200 Transplant center shall perform the following testing:

10.3210 Count the number of nucleated cells in the product.

10.3220 Confirm ABO grouping and Rh typing of HPC(M) or HPC(A) product or blood obtained from the donor at the time of collection.

10.3230 Fungal and bacterial cultures.

10.3240 CD34-positive cell quantitation of HPC(A) products.

10.4000 Labeling and Documentation [HPC(M); HPC(A); MNC(A);

10.4100 Labeling shall conform to applicable regulations and labeling information in the Circular of Information (COI) or package insert for licensed products and shall be consistent with AABB, FACT-JACIE and/or NetCord-FACT Standards, as applicable (See Resources).

10.4110 Center shall complete the product-specific, NMDP-supplied label and tie-tag, and affix or attach to each bag, as applicable for "HPC(M)" "HPC(A)" and "MNC(A)" products.

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10.4200 Biohazard and Warning Labels, as required by the US Food and Drug Administration, shall conform with labeling as outlined in 10.4100 (See Resources).

10.4300 Documents accompanying the product shall conform to applicable regulations and labeling information in the Circular of Information (COI) or package insert for licensed products and shall be consistent with AABB, FACT-JACIE and/or NetCord-FACT Standards, as applicable (See Resources).

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10.4400 Each item recorded on the label and accompanying documents shall be verified for accuracy by two individuals or by one individual and a validated electronic equivalent and verification documented.

10.5000 Transportation

10.5100 Each non-cryopreserved product shall be placed inside a secondary container which is sealed to prevent leakage (e.g. an outer bag).

10.5200 Products shall be enclosed in a rigid shipping container with temperature insulating properties.

10.5210 The rigid shipping container shall include a document on the inside of the container and a label on the outside of the container according to NMDP policies and procedures.

10.5300 Non-cryopreserved products shall be transported at the temperature specified by the transplant center or NMDP.

10.5400 Cryopreserved products shall be shipped in a liquid nitrogen "dry shipper" properly charged to maintain temperature of -150ºC or colder at least 48 hours beyond the expected arrival time at the receiving facility.

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10.5410 The temperature of the shipping container during shipment shall be continuously monitored.

10.5500 All non-cryopreserved HPC(A) and HPC(M) shall be hand carried by a suitably trained courier in the passenger compartment of the transport vehicle.

10.5600 Transported cellular therapy products should not be passed through X-ray or other irradiation devices.

10.6000 Infusion: HPC(M); HPC(A); and MNC(A);

10.6100 HPC(M); HPC(A); and MNC(A) products shall be infused as soon as feasible. HPC(M) and HPC(A) products should be infused within 48 hours of collection.

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11.0000 Adverse Events, Deviations, Complaints and Nonconforming Products, Materials or Services

11.1000 Adverse Events

11.1100 Participating Center shall have processes and procedures for capturing, evaluating, documenting and reporting suspected donor or recipient adverse events.

11.1110 Center shall document and investigate adverse events associated with the use of a mobilizing agent and/or the collection or administration of a cellular therapy product.

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11.1120 Center shall notify NMDP of serious adverse events possibly related to the product as defined in NMDP protocols and procedures.

11.1130 Fatal or potentially life threatening adverse events possibly related to the product shall be reported to NMDP by close of the next business day following determination of the event.

11.1140 Center shall maintain a record of adverse events and follow-up.

11.2000 Deviations

11.2100 Participating Center shall have processes and procedures for capturing, documenting, investigating and reporting deviations from established procedures, NMDP Standards, NMDP protocols, facility-defined acceptance criteria or applicable laws and regulations.

11.2110 Center shall have process to document and obtain pre-approval for planned deviations.

11.2111 Centers shall obtain NMDP pre-approval for planned deviations from NMDP-defined protocols.

11.2120 Center shall have a process to evaluate unplanned deviations to assess the need to determine the cause of the event and document the corrective and preventive actions, when applicable.

11.2121 Centers shall report unplanned deviations from NMDP-defined protocols per NMDP-defined processes.

11.2130 To facilitate follow-up, center shall report to NMDP as soon as possible the deviations that affect the safety, purity, potency or identity of the product or the safety or identity of the donor or recipient.

11.2131 Deviations involving transport that potentially affect the integrity of the product or delay the availability of product for a patient shall be reported promptly to facilitate immediate corrective action.

11.2140 Center shall maintain a record of deviations and follow-up.

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11.2150 Requests for variances from these Standards shall be submitted in accordance with NMDP policies and procedures.

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11.3000 Product Complaints

11.3100 Participating Center shall have processes and procedures for capture, evaluation, documentation and follow-up of reported product complaints relative to products or services provided by Center.

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11.4000 Nonconforming Product/Materials/Service

11.4100 Participating Center shall have processes and procedures to prevent the release or unintended use of nonconforming products, supplies/materials or services.

11.4110 Center shall have processes to identify, document, control and prevent release/use of nonconforming products, supplies/materials or services pending evaluation.

11.4111 NMDP shall be notified as soon as possible of nonconforming products, supplies/materials or services that impact NMDP donors, products or recipients to facilitate timely follow-up.

11.4120 Center shall have process to assess safety, quality, identity, purity and/or potency, as applicable, of nonconforming products, supplies/materials or services.

11.4130 Center shall have a process for documented evaluation and disposition of affected nonconforming products, supplies/materials or services.

11.4131 Authority for determining disposition of nonconforming products, supplies/materials or services shall be documented.

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 follow-up and outcome analysis
5) Reporting to NMDP
6) Reporting to regulatory agencies, as applicable

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11.4140 NMDP shall be notified as soon as possible when released products or services applicable to NMDP business are determined to be unsuitable to facilitate timely follow-up and consignee notification and reporting.

11.5000 General Reporting Requirements

11.5100 Center shall have processes that support the reporting of adverse reactions, deviations and nonconforming products, supplies/materials or services to affected parties and regulatory agencies in accordance with applicable laws and regulations.

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12.0000 Records and Record Retention

12.1000 General Record Requirements for All Participating Centers

12.1100 Center shall have secure record storage.

12.1200 Records shall be created concurrently with the performance of each critical activity. The work performed, the individual performing the work, and when it was performed shall be identified.

12.1300 Records shall be legible, indelible, complete and retrievable in a reasonable period of time.

12.1400 Records shall be preserved and protected from accidental or unauthorized destruction or modification.

12.1500 All records and communications relating to patients, recipients, donors or potential donors shall be kept strictly confidential.

12.1600 Records shall be made available for inspection by authorized individuals.

12.1700 Relevant to the processes performed at each site, records shall be maintained to ensure the identification and traceability/trackability of each donor 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 and testing step to the initial source (12.3000 applies).

12.2000 Computerized Record Requirements

12.2100 Center shall maintain the authenticity, integrity and confidentiality of all records, access to which is limited to authorized individuals.

12.2110 Center shall have technical and operational support for information systems management.

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12.2200 Records shall be maintained in a way to ensure their integrity and preservation for the duration of the defined retention period and be retrievable.

12.2210 Before destruction of original records, copies of such records shall be verified as legible, indelible, and complete.

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12.2300 If not using NMDP developed computer systems, centers shall document the following:

12.2310 System development, if done internally.

12.2320 Numerical designation of system versions with inclusive dates of use.

12.2330 Validation of system functionality (hardware, software and database).

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12.2340 Validation and monitoring of data integrity.

12.2350 All modifications to the system shall be authorized according to institutional procedures.

12.2400 All centers shall document the following:

12.2410 Installation and upgrades of the system.

12.2420 Training and continuing competency of personnel.

12.2430 Policies and procedures for system maintenance and operations.

12.2440 Ongoing backup procedures.

12.2450 Documented and tested procedures for data restoration.

12.2460 Offsite storage of electronic data records.

12.2500 Computer records shall be protected to enable their accurate and ready retrieval throughout the period of required record retention.

12.2600 Center shall have an alternative system that permits continuous operation in the event that computerized data are not available.

12.3000 Retention of Records – Indefinite

12.3100 Donor Center records pertaining to donors, who have been activated for workup, shall be retained indefinitely:

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12.3110 Consent documents for all stages of the search process

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12.3120 Health history screenings including reasons for permanent or temporary deferral

12.3130 Infectious disease testing and/or laboratory results.

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12. 3140 Documentation of abnormal findings and the notification/counseling of the relevant parties

12. 3150 Records of adverse reactions and post donation complications and recovery.

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12.3160 All source documents

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12.3200 Apheresis and Collection Center records which shall be retained indefinitely:

12.3210 Consent documents from donors for the collection of products for unrelated allogeneic use

12.3220 Screening and testing records

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12.3230 Records pertaining to collection, processing, labeling, packaging, storage, distribution and final disposition of collected product

12.3231 Records pertaining to qualification, monitoring and use of reagents, supplies and materials shall be traceable to collected product.

12.3232 Records pertaining to qualification, calibration, maintenance, monitoring and use of equipment shall be traceable to collected product.

12.3233 Records pertaining to the traceability and tracking of all aspects of the manufacture of the HPC product performed at the site with the exception of facility cleaning and sanitation records which are retained minimally for 3 years.

12.3240 Records of adverse reactions and post-donation complications, treatment interventions and recovery

12.3300 Transplant Center recipient records which shall be retained indefinitely:

12.3310 Informed consent documents related to NMDP facilitated cellular therapy products

12.3320 For recipient formal (activated) search activity, results of donor and recipient HLA typing and other test results at the Transplant Center including the identification numbers of participating donor(s).

12.3330 Records pertaining to any NMDP facilitated search including:

12.3331 The identification numbers of participating donor(s)/cord blood unit(s)

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12.3332 Abnormal donor/cord blood unit or recipient findings and notification/counseling of relevant parties

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12.3333 Product testing results, including ABO/Rh typing and microbial cultures

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12.3340 Records related to adverse events associated with NMDP facilitated cellular therapy products

12.3350 Records related to final disposition of NMDP facilitated cellular therapy products

12.4000 Retention of Records – Finite (retain for a minimum of three years)

12.4100 Donor center donor records pertaining to individuals who have been deleted from the Be The Match Registry® and had never been activated for a formalized search

12.4200 Records of donors who have been activated but deleted or deferred from the Be The Match Registry® prior to signing a search stage consent form or initiation of a health history questionnaire

12.5000 Retention of Records – Donor Center Transferred Donors

12.5100 Records of all transferred donors shall be forwarded to the receiving donor center

12.5200 Copies of records pertaining to transferred donors who did not donate may be discarded by the transferring center after three years

12.6000 Retention of Records – Donor Center Closing Centers

12.6100 Any center that ceases affiliation with the NMDP shall make provisions for maintenance or transfer of records as approved by the NMDP.

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RESOURCES

AABB: http://www.aabb.org/Pages/Homepage.aspx

American Society for Histocompatibility and Immunogenetics: http://www.ashi-hla.org/

Center for International Blood and Marrow Transplant Research (CIBMTR): http://www.cibmtr.org/

Centers for Medicare & Medicaid Services (CMS)-Approved Accreditation Organizations: https://www.cms.gov/

Circular of Information: http://www.aabb.org/Pages/Homepage.aspx (Search for "Circular of Information")

College of American Pathologists (CAP): http://www.cap.org/apps/cap.portal

Food and Drug Administration: http://www.fda.gov/

European Federation for Immunogenetics (EFI): http://www.efiweb.eu/

ICCBBA: United States Consensus Standard for the Uniform Labeling of Cellular Therapy Products Using ISBT 128: http://www.iccbba.org/

Office of Human Research Protections (OHRP) requirements for a Federalwide Assurance (FWA): http://www.hhs.gov/ohrp/ (Search for "Federalwide Assurance")

The Foundation for the Accreditation of Cellular Therapy: NetCord-FACT: International Standards for Cord Blood Collections, Processing and Release for Administration; or FACT-JACIE: International Standards for Cellular Therapy Product Collection, Processing and Administration: http://www.factweb.org

NOTE: The 24th Edition of the NMDP Standards contains a list of internet resources that are provided as a courtesy. At the time of publication of this Edition, the website addresses were current. The NMDP does not control the content of all referenced websites, however, and the website addresses and associated content are subject to change. NMDP does not guarantee the accuracy of information provided on the websites, nor is it liable for reliance on the information.

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GLOSSARY	
Abnormal Donor Findings	An underlying condition or unusual test result that is identified as a result of the donor evaluation, which may increase risk for the donor or recipient, but is not necessarily a cause for deferral.
Adverse Event (AE)	Adverse event means any untoward medical occurrence associated with the donation or administration of a cellular therapy product.
Apheresis Center	Network facility that meets participation criteria for the collection of hematopoietic cells by apheresis from NMDP volunteer donors.
Apheresis Collection: • **HPC, Apheresis [HPC(A)]**	Hematopoietic cells collected using apheresis techniques after the donor has received growth factor.
• **MNC, Apheresis [MNC(A)]**	Leukocyte collection using apheresis techniques without the administration of growth factor. The cell product contains mononuclear cells.
Center/Bank	A specific type of NMDP network entity.
Centers for Medicaid and Medicare Services (CMS)	The federal agency responsible for administering the Clinical Laboratory Improvement Amendments (CLIA). The Joint Commission (TJC), the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP), and Det Norske Veritas Healthcare (DNV) are examples of organizations which have been granted deemed status by the Centers for Medicare & Medicaid Services (CMS) for hospitals.
Circular of Information	The *Circular of Information for the Use of Cellular Therapy Products* (hereafter referred to as the *Circular*) is an extension of container labels, as the space on those labels is limited. The focus of this *Circular* is restricted to unlicensed cellular therapy products that are minimally manipulated. The *Circular* is intended to provide general information to those who administer cellular therapy products and serves as an extension and enhancement of the label found on the cellular therapy product.
Clinical Practice Guideline	Standardized disease-specific treatment plan used in lieu of a research protocol when use of an unrelated donor transplant is considered standard of care.
Collection Center	NMDP network hospitals that meet participation criteria with experience and facilities to collect HPC, Marrow and care for donors before and after the collection procedure.

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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
Confirmatory Testing Stage	The designation of the stage in the search process during which a potential donor is being evaluated as a donor for a specific patient, commonly called CT.
Confirmed Positive Test	A donor infectious disease screening test that tested as positive and was confirmed positive using a supplementary test.
Consent	Prospectively obtained permission for the collection and use of data, information, specimens or products, for the intended purpose or to conduct an approved research project.
Continuous Process Improvement (CPI) Program	A method of analyzing and managing the improvement of the NMDP Network's operations.
Cord Blood Bank	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.
Customized Typing	A service offered by the NMDP which allows transplant centers to select HLA loci, typing resolution and lab turnaround times for individual patients. The service is designed to reduce search times and increase flexibility during the search process on a case-by-case basis.
Deviation	A departure from applicable regulations or laws, procedures, protocols, standards or established specifications/requirements. Deviations can be planned or unplanned and may or may not result in unacceptable/unsuitable product or adverse result or outcome.
Disposition	The status assigned to a cellular therapy product based on evaluation of specific characteristics.
Donor Center	An NMDP network organization that meets participation criteria with the experience, staff and facilities to manage interaction with potential volunteer donors listed on the Be The Match Registry®.

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GLOSSARY	
Eligibility	A determination whether a potential allogeneic cellular therapy donor meets all donor screening and testing requirements related to transmission of infectious disease as defined by applicable laws and regulations.
Examining Practitioner	A licensed physician, physician's assistant, or nurse practitioner, consistent with applicable law.
Federalwide Assurance (FWA)	A document filed by the institution with the Department of Health and Human Services (HHS) stating that the institution will comply with HHS regulations for the protection of human subjects.
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.
Hematopoietic Progenitor Cells (HPC)	Primitive pluripotent cells capable of self-renewal as well as maturation into any of the blood cell lineages, and committed, lineage-restricted cells, regardless of the tissue source. Marrow: HPC, Marrow; HPC(M) PBSC: HPC, Apheresis; HPC(A) Cord Blood: HPC, Cord Blood; HPC(CB)
Hematopoietic Cells	An all-inclusive term for hematopoietic progenitor cells and their progeny, e.g., differentiating cells and mature cells.
HPC, Cord Blood [HPC(CB)]	Hematopoietic cells collected from umbilical cord blood and placenta after delivery that has been typed and stored for potential future transplant.
Human Leukocyte Antigen (HLA) Typing	The procedure by which HLA alleles (in the case of DNA-based typing) or HLA antigens (in the case of serological typing) are identified.
Indefinite Record Retention	Records identified as having an "indefinite" or similar retention requirement shall be retained for an indefinite period. For purposes of this definition, "indefinite" means retention shall be permanent and ongoing, unless and until a different retention period is specified for the documents at issue.

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GLOSSARY	
Independent Ethics Committees (IEC)	An independent body whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in research.
Informed Consent	The process of obtaining permission from an individual to participate in research or other operations of the NMDP, where the individual is informed of and has an opportunity to discuss the benefits, risks, and alternatives to his/her participation. Consent is based upon a clear appreciation and understanding of the relevant facts, implications, and future consequence of the decision. The consent is given voluntarily and free from undue influence or coercion.
Institutional Review Board (IRB)	An administrative body established in accordance with Title 45 CFR Part 46 to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.
Product Manufacture	Manufacture means, but is not limited to, any or all steps in the recovery, transport, processing, storage, labeling, packaging, shipping, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor.
MNC, Apheresis	A cell product containing mononuclear cells obtained by apheresis.
Nonconforming Product, Supply/Material or Service	A failure of cellular therapy product, supply, reagent, dose or test results to meet specified requirements.
Office of Human Research Protections (OHRP)	An office within the Department of Health and Human Services, which is responsible for oversight of the broad system to protect humans participating in research.
Participating Center	Donor, collection, apheresis or transplant center, recruitment center or cord blood bank that has submitted an NMDP application, meets NMDP Participation Criteria, and become a member of the NMDP network. Term references the facility, policies, staff, etc. composing the network entity.
Processing	Manipulation of the product in the laboratory setting.
Record	Information captured in writing or electronically that provides objective evidence of activities that have been performed or results that have been achieved, such as test records. Records do not exist until the activity has been performed and documented.
Recruitment Center	An NMDP network organization meeting participation criteria that performs donor recruitment. May also be known as a Recruitment Group.

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GLOSSARY	
Shall	Indicates a standard that is to be complied with at all times.
Shipping	The physical act of transferring a cellular therapy product within or between facilities. During shipping the product leaves the control of trained personnel at the originating or receiving facility.
Should	Indicates an activity that is highly recommended or advised, but for which there may be effective alternatives.
Subsequent Donation:	Collection of HPC, Apheresis; HPC, Marrow; MNC, Apheresis; or other cellular therapy product from a donor for his/her original recipient or another recipient.
Suitability, Medical	The medical fitness of a potential allogeneic cellular therapy donor to proceed to donation, based on established criteria relative to medical risk associated with donation, as determined by medical evaluation and physician judgment.
System	Refers to computer systems for management of donor or recipient information and records.
Traceability	The ability to follow the history of a process, product or service by review of documents.
Trackability	The ability to follow a cellular therapy product from donor to consignee or final distribution and from consignee or final distribution to donor by review of documents.
Transplant Center	An NMDP network hospital based program that meets participation criteria with experience, staff and facilities to perform allogeneic stem cell transplantation.
Transportation	The physical act of transferring a cellular therapy product within or between facilities. During transportation the product does not leave the control of trained personnel at the originating or receiving facility.
Variance From Standards	A pre-approved short or long term deviation from a standard, which once approved by the NMDP, is in place prospectively for the specific standard. It must be demonstrated that donor/patient safety and product integrity are not negatively impacted prior to approval by the NMDP.

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