

National Marrow Donor Program[®]

20th Edition

Standards

And

Glossary

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Notice and Disclaimer

NMDP Standards

These standards set forth only the basic guidelines 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.

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NATIONAL MARROW DONOR PROGRAM® 20TH EDITION STANDARDS

1.0000 General

- 1.1000 These standards apply to donor recruitment, donor screening, collection, storage, processing, release, transportation, and administration of marrow, peripheral blood, and cord blood hematopoietic cells facilitated through the National Marrow Donor Program®.
- 1.2000 Participating programs and support laboratories shall comply with all applicable federal and governmental laws and regulations.
- 1.3000 Participating programs and support laboratories shall comply with these Standards, as well as NMDP policies and procedures.
- 1.3100 Participating programs shall participate in an NMDP or other quality program.
- 1.3200 Participating programs shall participate in the NMDP Continuous Process Improvement (CPI) program, when applicable.
- 1.3300 Participating programs shall complete their network renewal annually.
- 1.4000 Director of a participating program shall be responsible for compliance with these Standards.
- 1.5000 Deviation reports and requests for variances from these Standards shall be submitted in accordance with NMDP policies and procedures.
- 1.6000 Significant changes in personnel, facilities and/or support services shall be reported to the NMDP Coordinating Center in a timely fashion.
- 1.7000 Participating programs shall establish a system of strict confidentiality of records to protect the privacy of potential donors, donors and patients.
- 1.8000 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.
- 1.9000 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 adequate resources to support its donor management and recruitment activities, as applicable.
- 2.1300 Center shall have a designated site for donor management activities, a private space for donor counseling sessions and secure record storage.
- 2.1400 Center shall have a secure information management system and shall merge data according to NMDP requirements.
- 2.1500 Center shall have collaborative agreement(s) with participating marrow collection center(s).
- 2.1600 Center shall have collaborative agreement(s) with participating apheresis collection center(s).

2.2000 *Medical Director*

- 2.2100 Center shall have a medical director who is a licensed physician qualified by training and experience to evaluate donor suitability and supervise donor management.
- 2.2200 Center medical director shall have at least one year experience in donor management.
- 2.2300 Center medical director shall participate regularly in educational activities related to the field of hematopoietic cell collection or transplantation.
- 2.2400 Center medical director shall be responsible for interpretation of NMDP medical eligibility criteria for donor participation.
- 2.2500 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.

2.3000 *Personnel*

- 2.3100 Center shall designate a coordinator to work with the NMDP.
- 2.3200 Center shall have staff sufficient to manage daily activities.

2.3210 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) or the European Federation for Immunogenetics (EFI) for techniques required by NMDP

2.4120 Laboratory (ies) certified by Centers for Medicare & Medicaid Services (CMS) (or non-U.S. equivalent) for infectious disease marker testing, ABO/Rh typing, red cell antibody screening, and for other tests required by NMDP

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

2.4200 Center shall have technical support for information systems.

2.5000 *Policies and Procedures*

2.5100 Center shall maintain written procedures and policies for the management and recruitment of volunteer donors, as applicable.

3.0000 **Criteria for Participating Network Centers that Perform Recruitment Activities**

3.1000 *Center Characteristics*

3.1100 Center shall have experience in donor recruitment activities, including education, counseling, confidentiality issues and medical screening.

3.1200 Center shall have permanent or preliminary IRS designation as a 501(c) (3) tax exempt non-profit organization.

3.1300 Center shall recruit new donors in accordance with priorities of the NMDP.

3.1400 Center shall have a written collaborative agreement with each NMDP donor center that has agreed to accept the recruited HLA-typed donors.

3.1600 Center shall only recruit donors for inclusion in the NMDP.

3.2000 ***Medical Director***

3.2100 Center shall have access to a donor center medical director for assistance with donor suitability and eligibility issues.

3.3000 ***Personnel***

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

3.3200 Center shall have staff sufficient to appropriately target group(s) sought for recruitment and to manage daily 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 ***Facility Characteristics***

4.1100 Bank shall be an institution that is appropriately registered with the Food and Drug Administration (FDA) or in compliance with the appropriate non-U.S. equivalent laws and regulations.

4.1200 Bank shall have experience in the recruitment and management of cord blood collections, including education, counseling, assuring confidentiality and medical screening.

4.1300 Bank shall have adequate resources to support its recruitment and management activities.

4.1400 Bank shall have adequate and secure facilities for processing, storing and retrieving cord blood units and samples.

4.1500 Bank shall have a designated site for secure record storage.

4.1600 Bank shall have a secure information management system and exchange data according to NMDP requirements.

4.1700 Bank shall have written collaborative agreements with facilities collecting cord blood units.

4.1800 Bank shall maintain accreditation by either AABB or Foundation for Accreditation for Cellular Therapy (FACT/NetCord for Cord Blood Banking).

4.2000 ***Medical Director***

- 4.2100 Bank shall have a medical director who is a licensed physician.
- 4.2200 Bank medical director shall have postdoctoral training in hematopoietic cell transplantation, blood or tissue banking, basic or clinical immunology, immunohematology or cryobiology.
 - 4.2210 Bank medical director shall participate regularly in educational activities related to the field of hematopoietic cell collection, processing, transplantation or cord blood banking
- 4.2300 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.
- 4.2400 Bank medical director shall be responsible for the protocols pertaining to: recruitment, informed consent, evaluation and follow-up of the potential donor, and 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 staff sufficient to manage daily activities.
 - 4.3210 Bank shall provide staff for each working day and coverage for emergencies
 - 4.3220 Bank shall have adequate trained and competent personnel available to perform processing, cryopreservation, storage and retrieval of cord blood units and samples

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) or the European Federation for Immunogenetics (EFI) for techniques required by NMDP
 - 4.4120 Laboratory certified by Centers for Medicare & Medicaid Services (CMS) (or non-U.S. equivalent) for infectious disease marker testing

4.4130 Cord blood collection sites accredited by The Joint Commission (TJC), the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) (or non-U.S. equivalent)

4.4200 Bank shall have technical support for information systems.

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 cord blood collection, processing, labeling, storage and transportation.

4.5300 Bank shall have written policies and procedures for the release and issue of cord blood units and for the return to inventory of unused cryopreserved units.

5.0000 **Criteria for Participating Marrow Collection Centers**

5.1000 *Facility Characteristics*

5.1100 Center shall be accredited by The Joint Commission (TJC) or the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) (or non-U.S. equivalent).

5.1200 Center shall have an experienced team that has collected marrow at least four times in the past year at the center.

5.1300 Center shall have adequate resources to support its collection and management activities.

5.1400 Center shall have a designated site for management of collection activities.

5.1500 Center shall have written collaborative agreement(s) with participating donor center(s).

5.2000 *Medical Director*

5.2100 Center shall have a medical director who is a licensed physician qualified by training and experience to supervise marrow collections.

5.2110 Center medical director shall have postdoctoral training in hematopoietic cell collection or transplantation

5.2120 Center medical director shall have at least one year experience in the collection procedure

5.2130 Center medical director shall participate regularly in educational activities related to the field of hematopoietic cell collection or transplantation

5.2200 Center medical director shall be responsible for reviewing the medical evaluation of the donor for risks of donation and evidence of disease transmissible by transplantation.

5.3000 Personnel

5.3100 Center physician performing the marrow collection shall have performed at least 12 prior collections of marrow for transplantation with at least four collections in the previous three years. Any person assisting in the marrow aspiration (physician, nurse, technician) shall have documented adequate training in marrow 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.

5.3400 Physician responsible for the marrow collection shall have documented operating room privileges at the collection center.

5.4000 Support Services

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

5.4200 Center shall have capability to perform NMDP marrow collections in a timely fashion;

5.4210 Donor shall be admitted and discharged from the collection center the same day, if the medical status permits

5.4300 Use of allogeneic blood shall be avoided unless deemed medically necessary by the collection physician.

5.4310 Center shall have irradiated and leukoreduced blood components available in the event that the use of allogeneic blood cannot be avoided

5.4400 At time of discharge, the center shall provide to the donor post-donation care instructions with contact names and phone numbers.

5.5000 ***Policies and Procedures***

- 5.5100 Center shall maintain written procedures for the collection, testing and labeling of marrow.
- 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 marrow collection.
- 5.5300 Center shall verify that the donor has autologous red cell units available prior to the marrow collection appropriate to the anticipated volume of marrow to be collected.
- 5.5400 Physician responsible for the collection shall be present for the duration of the marrow collection.
- 5.5500 Physician shall be responsible for determining that the donor's health is appropriate for discharge.

6.0000 **Criteria for Participating Apheresis Collection Centers**

6.1000 ***Facility Characteristics***

- 6.1100 Center shall be an institution that is appropriately licensed and/or registered with the Food and Drug Administration (FDA) (or non-U.S. equivalent).
- 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 adequate resources to support its collection and management activities.
- 6.1400 Center shall have a designated site for management of collection activities.
- 6.1500 Center shall have written collaborative agreement(s) with participating donor center(s).

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 postdoctoral training in hematopoietic cell collection or transplantation

- 6.2120 Center medical director shall have at least one year experience in the collection procedure
- 6.2130 Center medical director shall participate regularly in educational activities related to the field of hematopoietic cell collection or transplantation
- 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.

6.3000 ***Personnel***

- 6.3100 Center physician supervising the apheresis collection shall be qualified by training and experience:
 - 6.3110 Center supervising physician shall have at least one year experience in the collection procedure
 - 6.3120 Center supervising physician shall participate regularly in educational activities related to the field of hematopoietic cell collection or transplantation
- 6.3200 Center shall designate a coordinator to work with the NMDP.
- 6.3300 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.
- 6.3400 A licensed physician, qualified by training and experience, shall supervise the administration of mobilizing agent and be available for donor monitoring.
- 6.3500 A licensed physician qualified by training and experience, shall place any central venous catheters.

6.4000 ***Support Services***

- 6.4100 Center shall use the following facilities:
 - 6.4110 Laboratory(ies) certified by Centers for Medicare & Medicaid Services (CMS) (or non-U.S. equivalent) for assessing cell counts, blood chemistries, infectious disease markers, ABO group, Rh type, red cell antibodies, and for other tests required by NMDP
 - 6.4120 Laboratory with documented proficiency for measuring the quantity of CD34-positive cells in the component collected
- 6.4200 Center shall have appropriate apheresis equipment, supplies and pharmaceuticals.

- 6.4300 Center shall use The Joint Commission (TJC), the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) accredited hospital (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 Responsible physician shall perform and/or review a complete medical evaluation to determine if the donor is an acceptable candidate for mononuclear cell donation.
- 6.5300 Center shall have a process for treating donor adverse events and providing for emergency medical care.
- 6.5400 Center shall maintain written procedures to prevent or minimize adverse effects of citrate administration during apheresis.
- 6.5500 Center shall have a written policy for skilled assessment of peripheral venous access. There shall be a written justification for placement of central venous catheters.

7.0000 **Criteria for Participating Transplant Centers**

7.1000 *Facility Characteristics*

- 7.1100 Center shall be accredited by The Joint Commission (TJC), or the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) (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 a designated inpatient unit that minimizes airborne microbial contamination.
- 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.

- 7.1500 Center with more than one patient care unit shall be considered a single transplant center if the patient care units demonstrate functional unity.
- 7.1510 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
- 7.1600 Center shall have adequate resources to support its search management activities.
- 7.1700 Center shall have a designated site for management of search activities.

7.2000 *Medical Director*

- 7.2100 Center shall have a medical director who is a licensed physician.
- 7.2110 Center medical director shall be board certified (or non-U.S. equivalent) in one or more of the following specialties: Hematology, Medical Oncology, Immunology, or Pediatric Hematology/Oncology. 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
- 7.2120 Center medical director shall have had at least two years experience as an attending physician responsible for clinical management of allogeneic transplant recipients in the inpatient and outpatient settings
- 7.2130 Center medical director shall participate regularly in educational activities related to the field of hematopoietic cell transplantation
- 7.2200 Center medical director shall be responsible for search management activities and protecting safety of recipient.

7.3000 *Personnel*

- 7.3100 Center shall have at least two attending physicians who are licensed and qualified by training and experience in allogeneic hematopoietic cell transplantation.
- 7.3110 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

- 7.3120 Attending physicians should be board certified or eligible as specified in 7.2110
- 7.3130 Center attending physicians shall participate regularly in educational activities related to the field of hematopoietic cell transplantation
- 7.3200 Center shall provide daily and emergency coverage by designated transplant coordinator(s), sufficient in number to meet the needs of the center's activities.
- 7.3300 Center shall have nurses qualified by training and experience in the care of transplant recipients, sufficient in number to meet patient needs.
- 7.3400 Center shall have sufficient data management personnel to comply with NMDP and Center for International Blood and Marrow Transplant Research (CIBMTR) data submission requirements.
- 7.3500 Center shall identify a patient advocate who is familiar with the center's program and issues of unrelated donor hematopoietic cell transplantation, but is not a member of the transplant team.
- 7.3600 Center shall utilize a person qualified by training and experience in human histocompatibility testing to assist in the selection of unrelated hematopoietic cells or donors.

7.4000 *Support Services*

- 7.4100 Center shall use the following facilities for NMDP activities:
 - 7.4110 HLA typing laboratory(ies) accredited by the American Society for Histocompatibility and Immunogenetics (ASHI) or the European Federation for Immunogenetics (EFI) for techniques required by NMDP. The laboratory designated by the transplant center is responsible for the final HLA typing of the patient and donor
 - 7.4120 Laboratory (ies) certified by Centers for Medicare & Medicaid (CMS) (or non-U.S. equivalent) for all clinical laboratory tests required by NMDP
- 7.4200 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.
- 7.4300 Center shall use an experienced hematopoietic cell processing laboratory.
- 7.4400 Center shall have experienced physicians who provide consultative services in at least the following disciplines: surgery, pulmonary medicine, intensive care, gastroenterology, nephrology, infectious diseases, cardiology, pathology, psychiatry, and, if applicable, radiation therapy.

7.4500 Center shall have sufficient staff from at least the following services: pharmacy, dentistry, dietary, social services and physical therapy.

7.5000 Policies and Procedures

7.5100 Center shall maintain written policies and procedures to address at least the following:

7.5110 Donor or product selection

7.5120 Financial approval

7.5130 Infection prevention and control

7.5140 Processing ABO incompatible hematopoietic cell products to reduce red cell content

7.5150 Hematopoietic cell product infusion

7.5160 Blood component transfusion to include transfusion of blood components when the donor and recipient are ABO mismatched

7.5170 Education of the patient pre and post transplant

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.

7.5210 Clinical research protocols shall be approved by the center's institutional review board (IRB)

7.5211 U.S. Centers shall provide evidence of compliance with the Office of Human Research Protection (OHRP) requirements for a Federal Wide Assurance (FWA), or have a multiple project assurance or single project assurance that has not expired

7.5212 Non-U.S. centers shall provide evidence of compliance with Independent Ethics Committees (IEC) within their country

7.5220 Written clinical practice guidelines shall include at least the following:

7.5221 Criteria for recipient selection

7.5222 Procedures for recipient evaluations

- 7.5223 Preparative regimen
- 7.5224 Procedures for the prevention and treatment of graft-versus-host disease
- 7.5225 CMV prophylaxis, surveillance and treatment
- 7.5226 Procedures for post-transplant care

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.

7.6000 *Patient Advocacy*

7.6100 Center shall communicate appropriate information about the progress of a search to patients, families and physicians.

7.6200 If a compatible donor or product is not found, according to the criteria of the transplant center, the patient shall be informed of other options, including:

- 7.6210 Referral to transplant centers whose criteria for unrelated transplant are different
- 7.6220 Repeated NMDP search results
- 7.6230 Search results of other registries

8.0000 Recruitment of Hematopoietic Cell Donors

8.1000 *Marrow or Apheresis Donor*

8.1100 Donor shall be between the ages of 18 and 60.

8.1200 Donor shall appear to be in good health.

8.1300 Donor shall provide a medical history and shall document that the history is accurate.

8.1400 Pertinent donor medical history shall be evaluated for acceptance or deferral according to the current NMDP medical eligibility chart and criteria of local donor center medical director.

8.1500 Donor shall be given educational materials regarding the risks of infectious disease transmission by hematopoietic cell transplants including high risk behaviors for exposure to Human Immunodeficiency Virus (HIV).

- 8.1600 Donor shall provide informed consent.
 - 8.1610 Donor shall be given a general explanation of the indications for and results of hematopoietic cell transplantation and reasons for using unrelated donors
 - 8.1620 Donor shall be given a general description of the different types of donation processes and the risks of hematopoietic cell donation associated with each
 - 8.1630 Donor shall be informed that additional HLA testing may be performed on stored samples
 - 8.1640 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
 - 8.1650 Donor shall be informed that he/she has the right to decline or withdraw from NMDP participation at any time without prejudice
- 8.1700 Donor shall not be coerced to register with NMDP
- 8.1800 Donor's sample shall be HLA typed using criteria established by NMDP

8.2000 ***Cord Blood Donor***

- 8.2100 Bank shall obtain and 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.
 - 8.2110 Medical history shall reflect the biologic mother's health status at the time of delivery
- 8.2200 Informed consent shall be obtained from the biologic mother for collection, testing, and donation of the cord blood to a cord blood bank for use in unrelated cellular therapies. Consent for collection shall be obtained before delivery.
 - 8.2210 Biologic mother shall be given a general explanation of the indications for and results of cellular therapies and reasons for using unrelated donors
 - 8.2220 Biologic mother shall be given a general description of the donation process and the risks of cord blood donation

- 8.2230 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
- 8.2300 Biologic mother shall not be coerced to donate cord blood.
- 8.2400 Bank shall test a blood sample from the biologic mother of cord blood donor for infectious diseases as defined by NMDP.
 - 8.2410 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
 - 8.2420 Bank shall inform, counsel and document counseling of biologic mother regarding any abnormal findings
- 8.2500 Medical director or designee shall evaluate medical history and testing results prior to listing the cord blood unit with the NMDP.

9.0000 Donation Process

9.1000 *Additional Testing/Information*

- 9.1100 Customized HLA Typing
 - 9.1110 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
 - 9.1120 Donor center shall obtain from the donor a medical history that meets NMDP requirements for a marrow or apheresis donor
 - 9.1121 Donor center shall keep a written record of the medical history
 - 9.1122 Medical history indicative of disease shall be evaluated by a physician before acceptance of the donor
- 9.1200 Confirmatory Testing
 - 9.1210 Donor center shall provide potential donor with confirmatory testing educational materials including the risks of infectious disease transmission by transplantation
 - 9.1220 Donor shall provide signed consent each time a new sample is collected for additional testing

- 9.1230 Donor center shall obtain from the donor a medical history that meets NMDP requirements for a marrow or apheresis donor
- 9.1231 Donor center shall keep a written record of the medical history
- 9.1232 Medical history indicative of disease shall be evaluated by a physician before acceptance of the donor
- 9.1240 Testing for evidence of infection due to communicable disease agents shall be performed using screening tests that the Food and Drug Administration (FDA) has approved, licensed or cleared for such use and shall be performed in accordance with the manufacturer's instructions
- At confirmatory testing, 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
- 9.1250 At confirmatory testing, ABO grouping and Rh typing of the potential donor shall be performed if the donor has not been previously typed by the donor center
- 9.1260 At confirmatory testing, results of the ABO grouping, Rh typing and infectious disease testing shall be reported to the transplant center that requested the confirmatory testing sample
- 9.1261 Donors with a confirmed positive test for HBsAg or HCV shall not be used unless extraordinary medical need is documented
- 9.1262 Donors with a confirmed positive test for HIV shall not be used
- 9.1270 Transplant Center shall perform HLA typing sufficient to confirm the identity of the donor, in accordance with NMDP requirements, using a new sample
- 9.1280 Confirmatory testing shall have been completed prior to hematopoietic cell donation
- 9.1290 Results of the confirmatory HLA typing shall be sent to the NMDP

9.2000 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.

- 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 anytime, 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 blood components or another hematopoietic cell donation for the same recipient
- 9.2300 Prospective marrow donor shall be informed about the procedure of marrow donation and the following risks of marrow donation:
 - 9.2310 Risks of anesthesia
 - 9.2320 Risks and discomforts of marrow 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 discomforts of the apheresis procedure
 - 9.2420 Possibility of central venous catheter placement, along with its risks and discomforts
 - 9.2430 Risks and side effects of mobilizing agent (if applicable)

9.3000 *Medical Evaluation of the Prospective Marrow or Mobilized Apheresis 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 physician to determine the donor's eligibility

- 9.3300 Medical examination
 - 9.3310 Examining physician shall be a licensed physician or appropriately licensed supervised mid-level practitioner
 - 9.3311 Examining physician is responsible for protecting the safety of the donor and for delineating conditions in the donor that may be transmissible by transfusion or transplantation
 - 9.3312 Examining physician shall be designated by medical director of donor, collection, or apheresis center
 - 9.3313 Examining physician shall not be part of the transplant team of the center performing the transplant
 - 9.3320 Examining physician shall perform and/or evaluate a complete medical history and physical examination to include special notation of the following:
 - 9.3321 Pregnancy assessment
 - 9.3322 Deferral from blood donation
 - 9.3323 Contraindications to marrow or apheresis donation
 - 9.3324 Findings that would increase the anesthesia risk for the prospective donor
 - 9.3330 Examining physician shall obtain and evaluate at a minimum the results of the following tests:
 - 9.3331 Chest X-ray
 - 9.3332 Electrocardiogram
 - 9.3333 Urinalysis
 - 9.3334 Complete blood count
 - 9.3335 Electrolytes, glucose
 - 9.3336 Blood urea nitrogen and creatinine
 - 9.3337 Serum protein plus albumin or serum protein electrophoresis
 - 9.3338 Screening for Hemoglobin S

- 9.3340 Examining physician shall report results of the medical evaluation in writing to the donor center including presence or absence of abnormal findings for the specifically mentioned history and physical elements
- 9.3350 Examining physician or appropriately licensed supervised mid-level practitioner shall assess changes in donor history and physical exam according to NMDP guidelines
- 9.3360 Final approval of the donor shall not occur until the medical directors of the collection center or apheresis center and the donor center document that the donor meets the criteria for collection and the donor has signed the consent to donate
 - 9.3361 Donor center shall notify the Search Coordinating Unit that the donor is medically eligible and has signed the consent to donate
- 9.3370 Donor center shall perform repeat infectious disease testing if previous results were obtained more than 30 days prior to marrow or mobilized apheresis donation
 - 9.3371 Donor center shall perform repeat infectious disease testing if previous results were obtained more than 7 days prior to non-mobilized apheresis donation

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 counseled about the potential impact of the abnormality
 - 9.4120 Documentation of counseling regarding abnormal finding shall be maintained at the donor center
 - 9.4130 Donor has the right to decline donation based on the abnormal findings and keep the reason(s) confidential
- 9.4200 Abnormal finding that may increase risk to the donor
 - 9.4210 Donor center medical director and collection center medical director (or examining physician) shall determine whether an abnormal finding constitutes unacceptable risk to the donor
 - 9.4220 If the donor agrees to donate, any abnormal 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 appropriately 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 Marrow or Apheresis 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 marrow or mobilized apheresis donation, and has been reported to the NMDP
- 9.5200 Marrow Donation
 - 9.5210 Donor center, collection center, and transplant center shall agree in writing on the volume and nucleated cell count of marrow to be collected before start of preparative regimen
 - 9.5220 Transplant center and collection center shall agree on the medium, anticoagulant and additives used for collection and transport of marrow
 - 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

9.5300 Apheresis Donation

9.5310 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

9.5312 Number of apheresis procedures to be performed

9.5313 Total nucleated cell count for non-mobilized apheresis

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 marrow 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 of the donation

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

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

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

9.7200 Subsequent Donations

9.7210 Donor shall be asked to provide subsequent donations for the recipient after the transplant only for NMDP approved indications

9.7220 Donor may be asked to provide an additional whole blood, marrow or apheresis collection for the same recipient following NMDP guidelines

- 9.7230 Donor should not be asked to donate for a second recipient unless no other equally compatible donor is available and the following conditions are met:
 - 9.7231 At least one year has elapsed between the most recent marrow or apheresis donation for the first recipient and the donor's availability for a second recipient
 - 9.7232 At least three years have elapsed between a second and third subsequent donation
- 9.7240 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 should not occur until after the first anniversary of the transplant

10.0000 Hematopoietic Cell Collection, Storage, Transportation, Processing and Labeling

10.1000 Marrow Collection

- 10.1100 Collection shall be performed only after it has been determined that the intended recipient is suitable for immediate transplant.
 - 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 marrow collection.
- 10.1300 Marrow shall be taken from the posterior aspect of the iliac crest.
- 10.1400 Marrow shall be harvested with only the types and amounts of anticoagulants, media and additives agreed on by transplant and collection centers.
- 10.1500 Marrow should contain the number of nucleated cells agreed upon by the transplant center, donor center, and collection center.
 - 10.1510 Collection center shall count the nucleated cells collected

- 10.1600 Collected marrow volume shall not exceed 20 ml/kg donor body weight.
- 10.1700 Marrow shall be filtered during collection using sterile filters made of materials that do not deplete leukocytes.
- 101800 Marrow shall be divided into approximately equal portions and packaged in at least two sterile, closed, labeled blood bags appropriate for HPC, Marrow collection, each with ports that can be entered aseptically.

10.2000 *Apheresis Collection (mobilized and non-mobilized)*

- 10.2100 Apheresis collection shall be performed using an instrument and software designed for mononuclear cell collection.
- 10.2200 Apheresis collection shall be performed using ACD-A anticoagulant in a ratio sufficient to prevent extracorporeal clotting.
- 10.2300 Total volume of blood processed per collection shall be set by NMDP protocols and procedures.
- 10.2400 Target parameters of apheresis collection shall be specified in writing.
 - 10.2410 Apheresis center shall obtain count of nucleated cells and CD34+ cells collected and promptly transmit results to NMDP and, if requested, to the transplant center
- 10.2500 After collection, the apheresis center shall not further process or cryopreserve product without the direct consent of the transplant center and approval of the NMDP.
 - 10.2510 Any further processing shall only be performed by transplant center or laboratory designated by the transplant center
- 10.2600 Mobilized hematopoietic cell collection
 - 10.2610 Hematopoietic mobilizing agent shall be given to donors only when approved by the NMDP
 - 10.2620 Apheresis shall be performed only after it is determined that the intended recipient is suitable for immediate transplantation
 - 10.2621 Apheresis shall not be requested for transplantation at an undetermined future date
 - 10.2630 Hematopoietic cells shall be suspended in sufficient donor plasma to maintain viability of the cells during transport per NMDP protocol

- 10.2640 Hematopoietic cells shall be packaged in a sterile, labeled pack with a port that can be entered aseptically

10.3000 Cord Blood Collection and Processing

- 10.3100 Cord blood units shall not be collected or stored with non-human sources of blood or blood components.
- 10.3200 Cord blood units shall have the following testing:
- 10.3210 Weight to determine volume
 - 10.3220 Nucleated cell count
 - 10.3230 ABO group and Rh type
 - 10.3240 HLA A, B and DR typing by serology or DNA based methods
 - 10.3250 Fungal and aerobic bacterial cultures
- 10.3300 Cord blood units shall be stored with at least one cryopreserved product sample available for additional testing.

10.4000 Marrow or Apheresis Processing

- 10.4100 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.
- 10.4200 Transplant center shall perform the following testing:
- 10.4210 Count the number of nucleated cells in the product
 - 10.4220 Repeat ABO grouping and Rh typing of either blood, marrow or apheresis product obtained from the donor at the time of collection
 - 10.4230 Fungal and aerobic bacterial cultures
 - 10.4240 CD34-positive cell quantitation of mobilized apheresis products

10.5000 Marrow or Apheresis Infusion (HPC, Marrow; HPC, Apheresis)

- 10.5100 Marrow and Apheresis products shall be infused as soon as feasible. Marrow should be infused within 24 hours and apheresis products should be infused within 48 hours of collection.

10.6000 *Labeling and Documentation*

- 10.6100 Marrow and Apheresis Products (HPC, Marrow; HPC, Apheresis)
 - 10.6110 Center shall complete the product-specific, NMDP-supplied adhesive label and tie-tag, and affix to each bag
 - 10.6120 Labels are supplied for the following specific products:
 - 10.6121 For marrow collection: “HPC, Marrow”
 - 10.6122 For mobilized leukapheresis: “HPC, Apheresis”
 - 10.6123 For non-mobilized leukapheresis: “TC, Apheresis”
 - 10.6130 Documents accompanying the product shall contain at least the following (unless otherwise present on the label):
 - 10.6131 Circular of Information
 - 10.6132 “Rx Only”
 - 10.6133 Donor ABO group and Rh type
 - 10.6134 Results and interpretation of required most recent infectious disease markers
 - 10.6135 Nucleated cell count
 - 10.6136 Processing description, if applicable
 - 10.6137 Records as required by the FDA. Note: although HPC, Marrow is not regulated by the FDA, the NMDP requires the same documentation as required by FDA regulated products
 - 10.6140 Second individual shall verify each item recorded on the label and accompanying documents for accuracy
 - 10.6141 Identity of both individuals verifying information shall be documented
 - 10.6150 Warnings/information, as required by the FDA

10.7000 *Cord Blood Products (HPC, Cord Blood)*

- 10.7100 The product label and tie-tag shall include at least the following:
- 10.7100.01 “HPC, Cord Blood”
 - 10.7100.02 Unit ID number
 - 10.7100.03 ABO and Rh type
 - 10.7100.04 “For Use by Intended Recipient Only”
 - 10.7100.05 Collection date and time
 - 10.7100.06 Process date
 - 10.7100.07 Total nucleated cell count per mL
 - 10.7100.08 Product volume
 - 10.7100.09 Name and volume of anticoagulant(s) and other additive(s) (if applicable)
 - 10.7100.10 If under FDA IND: “Caution: New Drug-Limited by Federal Law to Investigational Use”
 - 10.7100.11 “Warning: This product may transmit infectious agents”
 - 10.7100.12 “Do Not Irradiate”
 - 10.7100.13 “Do Not X-Ray”
 - 10.7100.14 “Properly Identify Intended Recipient and Product”
 - 10.7100.15 Storage temperature
 - 10.7100.16 Name and address of cord blood bank issuing the cord blood unit
 - 10.7100.17 Warnings/information, as required by the FDA
- 10.7200 Documents accompanying the product shall contain at least the following (unless otherwise present on the label):
- 10.7210 Circular of Information
 - 10.7220 “Rx Only”
 - 10.7230 Donor ABO group and Rh type

- 10.7240 Results and interpretation of required most recent infectious disease markers
- 10.7250 Nucleated cell count
- 10.7260 Processing description, if applicable
- 10.7270 Records as required by the FDA
- 10.7280 Instructions for thawing and administration
- 10.7300 Second individual shall verify each item recorded on the label and accompanying documents for accuracy.
- 10.7310 Identity of both individuals verifying information shall be documented

10.8000 *Transportation*

- 10.8100 Each product shall be placed inside an outer bag which is sealed to prevent leakage.
- 10.8200 Products shall be enclosed in a rigid container with temperature insulating properties.
- 10.8300 Non-cryopreserved products shall be transported at the temperature specified by the transplant center or NMDP.
 - 10.8310 Product shall be insulated from direct contact with wet ice or reusable cooling packs
 - 10.8320 Dry ice shall not be used
- 10.8400 Cryopreserved products shall be shipped in a liquid nitrogen “dry shipper” that contains adequate adsorbed liquid nitrogen to maintain temperature at least 48 hours beyond the expected arrival time at the receiving facility.
 - 10.8410 Dry ice shall not be used unless this maintains the indicated storage temperature of the product being shipped
 - 10.8420 The temperature of the shipping container during shipment shall be continuously monitored
- 10.8500 All non-cryopreserved hematopoietic cells shall be hand carried by a suitably trained courier in the passenger compartment of the transport vehicle.
- 10.8600 Hematopoietic cells should not be passed through X-ray irradiation devices.

11.0000 Records and Record Retention

11.1000 General Record Requirements for All Participating Centers

- 11.1100 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.
- 11.1200 Records shall be legible, indelible, complete and retrievable in a reasonable period of time.
 - 11.1210 Legible microfilm copies are acceptable
- 11.1300 Records shall be preserved and protected from accidental or unauthorized destruction or modification.
- 11.1400 All records and communications relating to patients, recipients, donors or potential donors shall be kept strictly confidential.
- 11.1500 Records shall be made available for inspection by authorized individuals.

11.2000 Computerized Record Requirements

- 11.2100 Center shall maintain the authenticity, integrity and confidentiality of all records, access to which is limited to authorized individuals.
- 11.2200 Written procedures shall be established for record entry, verification and revision.
- 11.2300 If not using NMDP developed computer systems, centers shall document the following:
 - 11.2310 System development, if done internally
 - 11.2320 Numerical designation of system versions with inclusive dates of use
 - 11.2330 Validation of system functionality (hardware, software and database)
 - 11.2340 Validation and monitoring of data integrity
 - 11.2350 All modifications to the system shall be authorized and documented
- 11.2400 All centers shall document the following:
 - 11.2410 Installation and upgrades of the system

- 11.2420 Training and continuing competency of personnel
- 11.2430 Policies and procedures for system maintenance and operations
- 11.2440 Ongoing backup procedures
- 11.2450 Documented and tested procedures for data restoration
- 11.2460 Offsite rotational storage of electronic data records
- 11.2500 Computer records shall be protected to enable their accurate and ready retrieval throughout the period of required record retention.
- 11.2600 Center shall have an alternative system that permits continuous operation in the event that computerized data are not available.

11.3000 *Retention of Records – Indefinite*

- 11.3100 Donor Center records pertaining to donors who have been activated for a formalized search and have any of the following records, and cord blood donor records, shall be retained indefinitely:
 - 11.3110 Consent documents for all stages of the search process
 - 11.3120 Health history screenings including reasons for permanent or temporary deferral
 - 11.3120 Infectious disease testing and/or laboratory results
 - 11.3130 Documentation of abnormal findings and the notification/counseling of the relevant parties
 - 11.3140 Records of adverse reactions and post donation complications and recovery
 - 11.3150 All source documents for any formalized search
- 11.3200 Transplant Center recipient records which must be retained indefinitely:
 - 11.3210 Consent documents required by the transplant center policies/procedures
 - 11.3220 Records related to the preliminary search request and recipient HLA typing for all searches that become formal at a given transplant center
 - 11.3230 Records indicating the identification numbers of donor(s) requested to participate in specific testing

- 11.3240 Records pertaining to any search in which the NMDP facilitates the collection
- 11.3250 Records pertaining to donor abnormal findings and the notification/counseling of relevant parties
- 11.3260 ABO and Rh typing of the hematopoietic cells and results of fungal and bacterial cultures of the hematopoietic cells
- 11.3270 Informed consent document concerning participation in NMDP research and consent to release personal information (if applicable)
- 11.3280 Forms used for data entry pertaining to any recipient who receives marrow, cord blood, or peripheral blood cells
- 11.3290 Records concerning reporting of recipient post transplant clinical data

11.4000 *Retention of Records – Finite (retain for a minimum of three years)*

- 11.4100 Donor center donor records pertaining to individuals who have been deleted from the Registry and had never been activated for a formalized search
- 11.4200 Records of donors who have been activated but deleted or deferred from the NMDP Registry prior to signing a search stage consent form or initiation of a health history questionnaire
- 11.4300 Recipient search requests and preliminary results of recipient searches that are never formalized

11.5000 *Retention of Records – Donor Center Transferred Donors*

- 11.5100 Records, preferably originals, of all transferred donors shall be forwarded to the receiving donor center
- 11.5200 Copies of records pertaining to transferred donors who did not donate may be discarded by the transferring center after three years

11.6000 *Retention of Records – Donor Center Closing Centers*

- 11.6100 Any center that ceases affiliation with the NMDP shall make provisions for maintenance or transfer of records as approved by the NMDP

GLOSSARY

**American Osteopathic Association
Healthcare Facilities Program
(HFAP)**

A voluntary accreditation program in the United States authorized by the Centers for Medicare and Medicaid Services to survey hospitals under Medicare and their clinical laboratories under the Clinical Laboratory Improvement Amendments.

Apheresis Center

Network facility that meets participation criteria for the collection of hematopoietic cells by apheresis from NMDP volunteer donors.

Apheresis Collection:

Mobilized

Hematopoietic cells collected using apheresis techniques after the donor has received growth factor (HPC, Apheresis)

Non-mobilized

Leukocyte collection using apheresis techniques without the administration of growth factor (TC, Apheresis). These are nucleated cells intended for therapeutic use other than as hematopoietic cells.

Center/Bank

A specific type of NMDP network entity

**Center for Medicare & Medicaid
Services (CMS)**

The federal agency responsible for administering the Clinical Laboratory Improvement Amendments (CLIA).

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 bone marrow and care for donors before and after the collection procedure.

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.
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 that meets participation criteria with experience, staff and facilities to, collect, process and store umbilical cord blood for transplant.
Cord Blood Unit (HPC, Cord Blood)	Blood collected from the umbilical cord and placenta following delivery that has been determined to meet eligibility standards, typed and stored for potential future 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.
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 Registry.
Deviation From Standards	Not following the standards. Deviations are considered to be individual one-time events, which may be planned or unplanned.
Donor Abnormal 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.

Federal Wide Assurance	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	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.
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.
Hematopoietic Cells	An all inclusive term for hematopoietic progenitor cells and their progeny, e.g., differentiating cells and mature cells.
HLA (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.
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.
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.
Mid-Level Practitioner	Physician Assistant, Nurse Practitioner or Advanced Practitioner who provides primary patient care with physician oversight.

National Coordinating Center	The NMDP Coordinating Center, located in Minneapolis, Minnesota, establishes standards, policies, and procedures for its network of transplant, donor, apheresis and collection centers, cord blood banks, recruitment groups and cooperative registries.
Office of Human Research Protection (OHRP)	An office within the Department of Health and Human Services, which is responsible for oversight of the board system to protect humans participating in research.
Participating Program	Donor, collection, apheresis or transplant center, recruitment group 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.
Recruitment Center	An NMDP network organization meeting participation criteria that performs donor recruitment. May also be known as a Recruitment Group.
Shall	Indicates a standard that is to be complied with at all times.
Should	Indicates an activity that is highly recommended or advised, but for which there may be effective alternatives.
System	Refers to computer systems for management of donor or recipient information and records.
Transplant Center	An NMDP network hospital based program that meets participation criteria with experience, staff and facilities to perform allogeneic stem cell transplantation.
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.
