

National Marrow Donor Program[®] 19th Edition Standards

June 23, 2004

Notice and Disclaimer

NMDP Standards

These standards set forth only the basic guidelines for programs working through the NMDP to facilitate hematopoietic progenitor 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.

NMDP STANDARDS
19th Edition, June 23, 2004
TABLE OF CONTENTS

NMDP Standards	1
1.0000 General	4
2.0000 Criteria for Participating Donor Centers	5
2.1000 Facility Characteristics.....	5
2.2000 Medical Director	5
2.3000 Personnel.....	6
2.4000 Support Services	6
2.5000 Policies and Procedures	6
2.6000 Applicant Center	7
3.0000 Criteria for Participating Donor Recruitment Groups	7
3.1000 Group Characteristics	7
3.2000 Medical Director	8
3.3000 Personnel.....	8
3.4000 Support Services	8
3.5000 Policies and Procedures	8
3.6000 Applicant Group	8
4.0000 Criteria for Participating Cord Blood Banks	9
4.1000 Facility Characteristics.....	9
4.2000 Medical Director	9
4.3000 Personnel.....	10
4.4000 Support Services	10
4.5000 Policies and Procedures	10
4.6000 Applicant Bank	11
5.0000 Criteria for Participating Marrow Collection Centers	11
5.1000 Facility Characteristics.....	11
5.2000 Medical Director	11
5.3000 Personnel.....	12
5.4000 Support Services	12
5.5000 Policies and Procedures	13
5.6000 Applicant Center	13
6.0000 Criteria for Participating Apheresis Collection Centers	13
6.1000 Facility Characteristics.....	13
6.2000 Medical Director	14
6.3000 Personnel.....	14
6.4000 Support Services	15
6.5000 Policies and Procedures	15
6.6000 Applicant Center	16
7.0000 Criteria for Participating Transplant Centers.....	16
7.1000 Facility Characteristics.....	16
7.2000 Medical Director	17
7.3000 Personnel.....	17
7.4000 Support Services	18
7.5000 Policies and Procedures	19
7.6000 Applicant Center	20
7.7000 Patient Advocacy	21
8.0000 Recruitment of Hematopoietic Progenitor Cell Donors	21
8.1000 Marrow or Apheresis Donor	21
8.2000 Cord Blood Donor	22
9.0000 Donation Process.....	23
9.1000 Additional Testing/Information	23
9.1100 Patient Directed DR Typing.....	23
9.1200 Customized HLA Typing	23
9.1300 Confirmatory Testing	24

9.2000	Information Session	26
9.3000	Medical Evaluation of the Prospective Marrow or Apheresis Donor	27
9.4000	Prospective Donors with Abnormal Findings	29
9.5000	Pre-Collection Communication	30
9.6000	Pre-Collection Donor Blood Samples	31
9.7000	Subsequent Donor Contacts	31
10.0000	Hematopoietic Progenitor Cell Collection, Transportation, Processing and Labeling	33
10.1000	Marrow Collection	33
10.2000	Apheresis Collection (stimulated and unstimulated)	33
10.3000	Cord Blood Collection and Processing	35
10.4000	Marrow or Apheresis Processing	35
10.5000	Labeling and Documentation	36
10.6000	Transportation	38
11.0000	Records and Record Retention	39
11.1000	General Record Requirements for All Centers	39
11.2000	Computerized Record Requirements	40
11.3000	Retention of Records – Indefinite	41
11.3100	Donor Records	41
11.3200	Recipient Records	41
11.4000	Retention of Records – Finite (retain for a minimum of three years)	42
11.5000	Retention of Records - Transferred Donors	42
11.6000	Retention of Records – Closing Centers	42
GLOSSARY		43

NATIONAL MARROW DONOR PROGRAM®
19TH EDITION STANDARDS
June 23, 2004

1.0000 General

- 1.1000 These standards apply to donor screening, collection, processing, release and transplantation of marrow, peripheral blood and cord blood progenitor cell and donor lymphocyte activities 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 NMDP standards, policies and procedures that include but are not limited to:
- 1.3100 Completion of all applicable NMDP data forms
 - 1.3200 Participation in the NMDP Continuous Process Improvement (CPI) program
 - 1.3300 Provision of annual documentation that NMDP participation and CPI criteria are met
- 1.4000 Director of a participating program shall be responsible for compliance with these Standards.
- 1.5000 Deviations from these Standards shall be approved according to NMDP policies and procedures.
- 1.6000 Significant changes in personnel, facility or support services shall be reported promptly to the National Coordinating Center.
- 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).

- 1.9000 Staff 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 recruitment and 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 recruitment and management activities.
- 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 or affiliated 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.
- 2.2110 Center medical director shall have post doctoral training in hematopoietic cell collection or transplantation.
- 2.2120 Center medical director shall have at least one year experience in donor management.
- 2.2130 Center medical director shall participate regularly in educational activities related to the field of hematopoietic cell collection or transplantation.

- 2.2200 Center medical director shall be responsible for interpretation of NMDP medical eligibility criteria for donor participation.
- 2.2300 Center medical director shall be responsible for reviewing the medical evaluation of the donor for risks of donation and evidence of disease transmissible by 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.
- 2.3300 Center shall identify a donor advocate who is familiar with the center's program and shall offer the advocate's services to all donors.

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 CLIA (or non-US 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 or registered by the Food and Drug Administration (FDA), (or non-US equivalent) for collection of autologous blood.
- 2.4200 Center shall provide technical support for computer-related issues.
- 2.4300 Center shall use trained phlebotomists.

2.5000 Policies and Procedures

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

2.6000 Applicant Center

- 2.6100 Applicant shall meet all criteria for participating donor centers.
- 2.6200 Applicant shall demonstrate that its donor management abilities, recruitment strategies, and its geographic location or population demographics warrant the establishment of a new center.
- 2.6300 Applicant shall have documented HLA-A, B typing on at least 1000 persons meeting NMDP donor eligibility who could be approached as hematopoietic progenitor cell donors, or be able to show community support for funding the HLA-A, B typing of at least 500 new donors.
- 2.6400 Applicant organization established to recruit donors for a specific patient shall be eligible for consideration as a donor center after the needs of that patient have been resolved.

3.0000 Criteria for Participating Donor Recruitment Groups

3.1000 Group Characteristics

- 3.1100 Group shall have experience in donor recruitment activities, including education, counseling, confidentiality issues and medical screening.
- 3.1200 Group shall have permanent or preliminary IRS designation as a 501(c) (3) tax exempt non-profit organization.
- 3.1300 Group shall have a Board of Directors with at least five members including individuals with outreach to the targeted group(s) sought for recruitment.
- 3.1400 Group shall recruit new donors in accordance with priorities of the NMDP.
- 3.1500 Group shall have a written collaborative agreement with each NMDP donor center that has agreed to accept the recruited HLA-typed donors.
- 3.1600 Groups shall only recruit donors for inclusion in the NMDP.

3.2000 *Medical Director*

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

3.3000 *Personnel*

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

3.3200 Group shall have staff sufficient to manage daily activities.

3.4000 *Support Services*

3.4100 Group shall use trained phlebotomists.

3.5000 *Policies and Procedures*

3.5100 Group shall maintain written policies and procedures for the recruitment of volunteer donors.

3.6000 *Applicant Group*

3.6100 Applicant shall meet all criteria for a participating recruitment group.

3.6200 Applicant shall demonstrate that its recruitment strategies and geographic location or population demographics warrant the establishment of a new recruitment group.

3.6300 Applicant organization established to recruit donors for a specific patient shall be eligible for consideration as a recruitment group after the needs of the patient have been resolved.

3.6400 Applicant shall have recruited 1000 HLA-typed donors who have been entered into the NMDP through participating donor centers.

4.0000 Criteria for Participating Cord Blood Banks

4.1000 Facility Characteristics

- 4.1100 Bank shall have experience in the recruitment and management of cord blood collections, including education, counseling, confidentiality issues and medical screening.
- 4.1200 Bank shall have adequate resources to support its recruitment and management activities.
- 4.1300 Bank shall have adequate and secure facilities for processing, storing and retrieving cord blood units and samples.
- 4.1400 Bank shall have a designated site for management activities and secure record storage.
- 4.1500 Bank shall have a secure information management system and merge data according to NMDP requirements.
- 4.1600 Bank shall have collaborative agreements with facilities collecting cord blood units.

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 progenitor 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 transfusion or 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.
- 4.3300 Bank shall identify an advocate for the biologic mother of the cord blood donor and offer the advocate's services.

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 CLIA (or non-US equivalent) for infectious disease marker testing, ABO/Rh typing, red cell antibody screening, and for other tests required by the NMDP.
 - 4.4130 Cord blood collection sites accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) or non-US equivalent.
- 4.4200 Bank shall have technical support for computer-related issues.

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.

4.6000 Applicant Bank

- 4.6100 Applicant shall meet all criteria for participating cord blood banks.
- 4.6200 Applicant shall have stored a minimum of 100 cryopreserved cord blood units that each meet NMDP criteria.

5.0000 Criteria for Participating Marrow Collection Centers

5.1000 Facility Characteristics

- 5.1100 Center shall be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) or non-US 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 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 transfusion or transplantation.

5.3000 Personnel

- 5.3100 Collection 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 assisted in at least four prior 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 by 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 a flexible schedule for NMDP marrow collections.
- 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, or irradiated CMV seronegative 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, appropriate to the anticipated volume of marrow to be collected, available prior to the marrow collection.
- 5.5400 Center physician responsible for the collection shall be present for the duration of the marrow collection.
- 5.5500 Center physician shall be responsible for determining that the donor's health is appropriate for discharge.

5.6000 Applicant Center

- 5.6100 Applicant shall meet all criteria for participating marrow collection centers.
- 5.6200 Applicant shall provide documentation of need from an existing donor center.

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 be in compliance with the appropriate non-US equivalent laws and regulations.

- 6.1200 Center shall have experience in the collection of cellular components by apheresis, and shall have performed at least three collections of blood 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 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 blood 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 growth factor administration and be available throughout growth factor administration and 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 CLIA (or non-US 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 provide for emergency care as needed.
- 6.4400 Center shall use a Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) or non-US equivalent accredited hospital for placement of central venous catheters.

6.5000 Policies and Procedures

- 6.5100 Center shall maintain written procedures and policies for the collection, testing, storage, labeling, and transport of blood components 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 apheresis donation.
- 6.5300 Physician shall be available on-site for the duration of each collection procedure and for follow-up as needed.

6.6000 Applicant Center

- 6.6100 Applicant shall meet all criteria for participating apheresis centers.
- 6.6200 Applicant that is not part of a donor center shall provide documentation of need from an existing donor center.

7.0000 Criteria for Participating Transplant Centers

7.1000 Facility Characteristics

- 7.1100 Center shall be accredited by a Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) or non-US 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 contamination.
- 7.1400 Center shall have a designated area for outpatient evaluation and treatment available 24 hours per day, seven days per week that reduces the risk of transmission of infectious agents.
- 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 institution shall satisfy all transplant center participation criteria individually.

Patient care units at any other institution shall have performed allogeneic transplants for at least four 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-US 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 progenitor 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 hematopoietic cell 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 progenitor 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 progenitor cell transplantation.
 - 7.3110 Adequate clinical training in allogeneic hematopoietic progenitor 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 in one of the specialties listed in 7.2110.
- 7.3130 Center attending physicians shall participate regularly in educational activities related to the field of hematopoietic progenitor 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 the NMDP 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 progenitor cell 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 CLIA (or non-US 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 progenitor 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 selection
 - 7.5120 Financial approval
 - 7.5130 Infection prevention and control
 - 7.5140 Processing ABO incompatible progenitor cell products to reduce red cell content
 - 7.5150 Hematopoietic cell infusion
 - 7.5160 Blood component transfusion to include transfusion of blood components when the donor and recipient are ABO mismatched
 - 7.5170 Post-transplant care
- 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 US Centers shall provide evidence of compliance with the Office of Human Research Protection (OHRP) requirements for a Federalwide Assurance, or have a multiple project assurance or single project assurance that has not expired.
- 7.5212 Non-US 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
 - 7.5227 Pre and post-transplant education for the patient
- 7.5300 Use of hematopoietic progenitor cells from an NMDP donor shall require provision to obtain written consent from the recipient for the submission of data and blood samples to the NMDP.

7.6000 Applicant Center

- 7.6100 Applicant shall meet all criteria for participating transplant centers.
- 7.6200 Applicant facility and medical team, including medical director and at least one other attending physician experienced in allogeneic transplantation shall have been performing transplantation at that site for at least one year.

- 7.6300 Applicant shall have performed at least 10 allogeneic transplants per year during the previous 24 months or 20 allogeneic transplants in the last 12 months.

7.7000 Patient Advocacy

- 7.7100 Center shall communicate appropriate information about the progress of a search to patients, families and physicians.
- 7.7200 If a compatible donor is not found, according to the criteria of the transplant center, the patient shall be informed of other options, including:
- 7.7210 Referral to approved transplant centers whose criteria for unrelated transplant are different
 - 7.7220 Repeated NMDP search results as more donors are added
 - 7.7230 Search results of other registries

8.0000 Recruitment of Hematopoietic Progenitor 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 acknowledge in writing 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 progenitor 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 progenitor cell transplantation and reasons for using unrelated donors.
- 8.1620 Donor shall be given a general description of the donation process and the risks of hematopoietic progenitor cell donation.
- 8.1630 Donor shall be informed that additional HLA testing may be performed on stored samples.
- 8.1640 Donor shall acknowledge in writing 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 shall be typed for at least HLA-A and B by serology or DNA based methods.

8.2000 Cord Blood Donor

- 8.2100 Bank shall obtain and document from the biological 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 biological mother's health status at the time of delivery.
- 8.2200 Informed consent shall be obtained from the biological mother for collection, testing, and donation of the cord blood to a cord blood bank for use in unrelated hematopoietic progenitor cell transplantation.
- 8.2210 Biologic mother shall be given a general explanation of the indications for and results of hematopoietic progenitor cell transplantation and reasons for using unrelated donors.

- 8.2220 Biologic mother shall be given a general description of the donation process and the risks of hematopoietic progenitor cell donation.
- 8.2230 Biologic mother shall acknowledge in writing that she has read and understood the educational material, 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 Cord blood bank shall test a blood sample from the biological mother of cord blood donor for infectious diseases as defined for marrow or apheresis donor.
- 8.2410 Blood sample from biological mother of cord blood donor used for infectious disease testing shall be obtained within 7 days prior to or within 7 days after hematopoietic progenitor cell collection.
- 8.2420 Cord blood bank shall inform, counsel and document counseling of biological 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 Patient Directed DR Typing

- 9.1110 If a stored sample is used for DR testing, the potential donor should be informed that DR typing is in progress and given the opportunity to continue or withdraw.
- 9.1120 If a new sample is required, potential donor shall provide signed consent agreeing to provide a sample for additional testing.

9.1200 Customized HLA Typing

- 9.1210 If a stored sample is used for customized HLA typing, the potential donor shall be informed that the typing is in progress and shall be given the opportunity to continue or withdraw.
- 9.1220 Donor 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.

9.1300 Confirmatory Testing

- 9.1310 Donor center shall provide potential donor with confirmatory testing educational materials including the risks of infectious disease transmission by transplantation.
- 9.1320 Donor shall provide signed consent each time a new sample is collected for additional testing.
- 9.1330 Donor center shall obtain from the donor a medical history that meets NMDP requirements for a marrow or apheresis donor.
- 9.1331 Donor center shall keep a written record of the medical history.
- 9.1332 Medical history indicative of disease shall be evaluated by a physician before acceptance of the donor.
- 9.1340 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 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 following communicable disease agents:

- 9.1341 Human immunodeficiency virus, type 1
- 9.1342 Human immunodeficiency virus, type 2
- 9.1343 Hepatitis B virus
- 9.1344 Hepatitis C virus
- 9.1345 Human T-lymphotropic virus, type I
- 9.1346 Human T-lymphotropic virus, type II
- 9.1347 *Treponema pallidum* (syphilis)
- 9.1348 Cytomegalovirus (unless previously documented to be positive)

- 9.1350 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.

- 9.1360 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.
 - 9.1361 Donors with a confirmed positive test for HBsAg or HCV shall not be used unless urgent medical need is documented.
 - 9.1362 Donors with a confirmed positive test for anti-HIV 1/2 or HIV-1 antigen shall not be used.

- 9.1370 Transplant Center shall perform HLA-A, B and DR typing using a fresh sample on every donor requested for confirmatory testing.

- 9.1380 Confirmatory testing shall have been completed prior to hematopoietic progenitor cell donation.

9.1390 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 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

9.2220 Opportunity to discuss his/her decision with a donor advocate

9.2230 Further tests and examinations to be done

9.2240 Time commitment involved in the donation process

9.2250 Possibility that he/she may be asked to provide other blood components or another hematopoietic progenitor cell donation for the same recipient

9.2260 Extent to which the donor's expenses will be compensated and by whom

9.2270 Potential adverse consequences of publicity

9.2280 Pregnancy is an absolute contraindication for marrow donation and growth factor stimulated apheresis.

9.2290 Pregnancy is a relative contraindication for unstimulated apheresis donation.

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 procedure for mononuclear cell collection by apheresis and the following risks of the collection procedure.

9.2410 Risks and discomforts of the apheresis collection procedure

9.2420 Possibility of central venous catheter placement, along with its risks and discomforts, if antecubital venous access is unsuitable

9.2430 Risks and side effects of growth-factor (if applicable)

9.3000 *Medical Evaluation of the Prospective Marrow or 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

9.3311 Examining physician shall be a licensed physician and 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 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 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
 - 9.3336 Blood urea nitrogen or creatinine
 - 9.3337 Bilirubin
 - 9.3338 Serum protein plus albumin or serum protein electrophoresis
 - 9.3339 Screening for Hemoglobin S
- 9.3340 Examining physician shall evaluate the peripheral venous access for potential apheresis donors.
- 9.3350 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.

- 9.3360 Examining physician shall take an interval history and perform an appropriate physical exam if more than eight weeks have elapsed since the prior evaluation.
- 9.3370 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.
 - 9.3371 Donor center shall notify the Search Coordinating Unit that the donor is medically eligible and has signed the consent to donate.
- 9.3380 Donor center shall perform repeat infectious disease testing if previous results will have been obtained more than 30 days prior to marrow or apheresis donation.

9.4000 *Prospective Donors with Abnormal Findings*

- 9.4100 Donor center medical director or designee shall report to the donor any abnormal findings discovered during donor evaluation.
 - 9.4110 Donor shall be counseled about the potential impact of the abnormality.
 - 9.4120 Written 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, who shall be appropriately counseled as to the potential impact of the abnormality.
- 9.4331 Written 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 Coordinating Center 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 apheresis donation, and has been reported to the Search Coordinating Unit.
- 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 prescription 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 unstimulated 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 of 100 mL in the month prior to marrow donation
 - 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 blood components for the recipient after the transplant only for NMDP approved indications.
- 9.7220 Donor may be asked to provide an additional marrow or apheresis collection for the same recipient following NMDP Second Donation Request Policy.
- 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 Before any direct contact is allowed both donor and recipient or recipient's family shall 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 Progenitor Cell Collection, 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 to store 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 only be taken from the iliac crest.
 - 10.1310 Marrow should 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 target number of nucleated cells specified by the verified marrow prescription.
 - 10.1510 Collection center shall count the nucleated cells collected.
- 10.1600 Marrow volume shall not exceed 20 ml/kg donor body weight.
 - 10.1610 Marrow volume should not be so large as to potentially require transfusion of allogeneic blood.
- 10.1700 Marrow shall be filtered during collection using sterile filters made of materials that do not deplete leukocytes.
- 10.1800 Marrow shall be divided into approximately equal portions and packaged in at least two sterile, closed, labeled blood bags appropriate for hematopoietic progenitor cell collection, each with ports that can be entered aseptically.

10.2000 Apheresis Collection (stimulated and unstimulated)

- 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 anticoagulant in a volume sufficient to prevent extracorporeal clotting.
- 10.2300 Total volume of blood processed per collection shall be set by NMDP protocols and procedures.
- 10.2400 After collection, the apheresis center shall not further process or freeze collection without the direct consent of the transplant center and approval of the NMDP.
 - 10.2410 Any further processing shall only be performed by transplant center or laboratory designated by the transplant center.
- 10.2500 Target parameters of apheresis collection shall be specified by prescription.
 - 10.2510 Apheresis center shall obtain count of nucleated cells collected.
- 10.2600 Growth factor stimulated hematopoietic progenitor cell collection
 - 10.2610 Hematopoietic growth factors shall be given to donors only when approved by the NMDP and the IRB at the recipient and the donor facilities.
 - 10.2620 Collection shall be performed only after it is determined that the intended recipient is suitable for immediate transplantation.
 - 10.2621 Collection shall not be requested to store for transplantation at an undetermined future date.
 - 10.2640 Hematopoietic progenitor cells shall be suspended in sufficient donor plasma to maintain viability of the cells during transport per NMDP protocol.
 - 10.2650 Hematopoietic progenitor cell collection shall be packaged in a sterile, labeled pack appropriate for hematopoietic progenitor cell collection with a port that can be entered aseptically.

10.3000 Cord Blood Collection and Processing

- 10.3100 Units shall not be collected or stored with non-human sources of blood or blood derivatives.
- 10.3200 Cord blood unit 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 bacteria cultures
 - 10.3251 Antibiotic sensitivities shall be performed on each positive culture and results available prior to listing the cord blood unit with the NMDP.
- 10.3300 Cord blood HPC 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 shall not add anything, process or freeze collection except as requested by the transplant center and approved by the NMDP.
- 10.4200 Collection center shall count the number of nucleated cells in the product.
- 10.4300 Transplant center shall perform the following testing:
 - 10.4310 Count the number of nucleated cells in the product
 - 10.4320 Repeat ABO grouping and Rh typing of either blood or marrow obtained from the donor at the time of collection
 - 10.4330 Fungal and aerobic bacterial cultures

- 10.4340 CD34-positive cell quantitation of stimulated apheresis products
- 10.4400 Marrow collection should be infused within 24 hours and apheresis collection should be infused within 48 hours of collection.
- 10.4410 Aliquots of marrow or apheresis hematopoietic progenitor cells collection that are cryopreserved may be infused at a later date.

10.5000 Labeling and Documentation

- 10.5100 Marrow and Apheresis Products
 - 10.5110 Center shall complete the product-specific, NMDP-supplied adhesive label and tie-tag, and affix to each bag.
 - 10.5120 Labels are supplied for the following specific products:
 - 10.5121 For marrow collection “Hematopoietic Progenitor Cells, Marrow”
 - 10.5122 For stimulated leukapheresis “Hematopoietic Progenitor Cells, Apheresis”
 - 10.5123 For unstimulated leukapheresis collection “Therapeutic Cells, T-cells”
 - 10.5130 Documents accompanying the product shall contain at least the following (unless otherwise present on the label):
 - 10.5131 Circular of Information
 - 10.5132 “Rx Only”
 - 10.5133 Donor ABO group and Rh type
 - 10.5134 Results of most recent infectious disease markers required for marrow or apheresis donors
 - 10.5135 Nucleated cell count
 - 10.5136 Processing description, if applicable

10.5140 Second individual shall verify each item recorded on the label and accompanying documents for accuracy.

10.5141 Identity of both individuals verifying information shall be documented.

10.5150 Affix biohazard label to product if infectious disease testing has not been performed within 30 days prior to collection, or when infectious disease marker test is repeatedly reactive and the confirmatory test is either positive or has not been performed. Note: CMV is excluded from this requirement.

10.5200 Cord Blood Products

10.5210 The product label and tie-tag shall include at least the following:

10.5210.1 “Hematopoietic Progenitor Cells, Cord Blood”

10.5210.2 Unit ID number

10.5210.3 ABO and Rh type

10.5210.4 “For Use by Intended Recipient Only”

10.5210.5 Collection date and time

10.5210.6 Process date

10.5210.7 Total nucleated cell count per mL

10.5210.8 Product volume

10.5210.9 Additive name and volume

10.5210.10 If under FDA IND “Caution: New Drug-Limited by Federal Law to Investigational Use”

10.5210.11 “Warning: This product may transmit infectious agents”

10.5210.12 “Do Not Irradiate”

- 10.5210.13 “Do Not X-Ray”
- 10.5210.14 “Properly Identify Intended Recipient and Product”
- 10.5210.15 Storage temperature
- 10.5210.16 Name and address of registry
- 10.5220 Documents accompanying the product shall contain at least the following (unless otherwise present on the label):
 - 10.5221 Circular of information
 - 10.5222 “Rx Only”
 - 10.5223 Donor ABO group and Rh type
 - 10.5224 Results of most recent infectious disease markers required for marrow or apheresis donors
 - 10.5225 Nucleated cell count
 - 10.5226 Processing description, if applicable
- 10.5230 Second individual shall verify each item recorded on the label and accompanying documents for accuracy.
 - 10.5231 Identity of both individuals verifying information shall be documented.
- 10.5240 Affix biohazard label to product when infectious disease marker test is repeatedly reactive and the confirmatory test is either positive or has not been performed. Note: CMV is excluded from this requirement.

10.6000 *Transportation*

- 10.6100 Each collection bag shall be placed in an outer bag which is sealed to prevent leakage.
- 10.6200 Collection bag(s) shall be enclosed in a rigid container with temperature insulating properties.

- 10.6300 Transportation conditions
 - 10.6310 Non-cryopreserved products shall be transported at the temperature specified by the transplant center or NMDP.
 - 10.6311 Product shall be insulated from direct contact with wet ice or frozen gel packs.
 - 10.6312 Dry ice shall not be used.
 - 10.6320 Cryopreserved hematopoietic progenitor cell collections (storage temperature below -80°C) 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.
 - 10.6321 Dry ice shall not be used unless this maintains the indicated storage temperature of the component being shipped.
- 10.6400 NMDP shall ensure that primary and alternate hematopoietic cell transportation arrangements by a means which minimizes transit time have been made.
 - 10.6410 Transportation arrangements may be delegated upon mutual agreements between the donor center and transplant center.
- 10.6500 All non-cryopreserved hematopoietic progenitor cell collections shall be hand carried by a suitably informed courier in the passenger compartment of the transport vehicle.
- 10.6600 Products shall not be passed through X-ray irradiation devices.

11.0000 Records and Record Retention

11.1000 General Record Requirements for All Centers

- 11.1100 Records shall be created contemporaneously and dated with each step in the NMDP management process.
- 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 Program 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 data base)
 - 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 Records

- 11.3110 Consent documents for all stages of the search process
- 11.3120 All health history screenings including infectious disease testing
 - 11.3121 Reasons for permanent or temporary deferral
 - 11.3122 Records documenting abnormal findings and the notification/counseling of the relevant parties
- 11.3130 All records pertaining to any donor who donates marrow, cord blood, or peripheral blood progenitor cells
 - 11.3131 Records of adverse reactions and post donation complications and recovery
- 11.3140 All forms used for data entry

11.3200 Recipient Records

- 11.3210 Consent documents for all stages of the search process
- 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 All 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 progenitor cells and results of fungal and bacterial cultures of the hematopoietic progenitor cells
- 11.3270 Informed consent document concerning participation in NMDP research and consent to release personal information (if applicable)
- 11.3280 All forms used for data entry
- 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 Recipient search requests and preliminary results of recipient searches that are never formalized
- 11.4200 Records pertaining to donors that have been deleted from the NMDP and have never donated marrow

11.5000 *Retention of Records - 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 – Closing Centers*

- 11.6100 Any center that ceases affiliation with the Program shall make provisions for maintenance or transfer of records to a facility designated by the closing center and approved by the NMDP.

GLOSSARY

Affiliated Apheresis Center Apheresis center that is not an NMDP approved facility but is capable of meeting all the collection requirements set forth in the NMDP protocol for collection of blood cells by apheresis (applicable to apheresis center designation only)

**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 Facility approved by the NMDP for the collection of blood progenitor cells by apheresis from NMDP volunteer donors

**Apheresis Collection:
Stimulated** HPC collection using apheresis techniques after the donor has received growth factor

Unstimulated Leukocyte collection using apheresis techniques without the administration of growth factor

**Clinical Laboratory Improvement
Amendments (CLIA)** A federal statute and a series of federal rules and regulations for clinical laboratories initially published in the Federal Register in 1988 and subsequently modified

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 associated hospitals with experience and facilities to collect bone marrow and care for donors before and after the collection procedure

Confirmatory Testing After a potential donor has been identified, the individual will be contacted by the donor center for additional testing to confirm if he or she is the best match for the patient.

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's Network operations
Cord Blood Bank	An NMDP associated organization with experience, staff and facilities to collect, process and store umbilical cord blood for transplant
Cord Blood Unit	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 associated organization with the experience, staff and facilities to recruit and manage interaction with potential volunteer donors listed on the Registry
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 Cell	As used in these standards, 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 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
National Coordinating Center	The NMDP <i>Coordinating Center</i> , 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)	Located within the Department of Health and Human Services, this office 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 has received the designation of an NMDP approved program

Recruitment Group An organization associated with the NMDP that recruits donors

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

Transplant Center An NMDP associated, hospital based program with experience, staff and facilities to perform allogeneic stem cell transplantation
