National Marrow Donor Program®

21st Edition

Standards

And

Glossary

Effective Date: October 1, 2011

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

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NATIONAL MARROW DONOR PROGRAM®
21ST EDITION STANDARDS

1.0000 General

1.1000 These standards apply to donor recruitment, donor screening, collection, storage, processing, labeling, release, transportation, and administration of cellular therapy products 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.

1.4100 Center medical director shall participate regularly in educational activities related to the field of hematopoietic cell collection or transplantation.

1.5000 Significant changes in personnel, facilities and/or support services shall be reported promptly to the NMDP in accordance with NMDP Participation Criteria.

1.6000 Participating programs shall maintain a system of strict confidentiality of records to protect the privacy of potential donors, donors and patients.

1.7000 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.

1.8000 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 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 be responsible for interpretation of NMDP medical eligibility criteria for donor participation.

2.2400 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), the European Federation for Immunogenetics (EFI), and/or the College of American Pathologists (CAP) for HLA typing 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, and for other tests required by NMDP

2.4130 Laboratory(ies) that perform eligibility testing for evidence of infection due to relevant communicable disease agents must use donor screening tests that the Food and Drug Administration (FDA) has approved, licensed or cleared for such use and testing shall be performed in accordance with the manufacturer's instructions. (See References)

2.4140 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 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, confidentiality issues and preliminary donor evaluation.

3.1200 Center shall have adequate resources to support its recruitment activities.

3.1300 Center shall have permanent or preliminary IRS designation as a 501(c) (3) tax exempt non-profit organization.

3.1400 Center shall recruit new donors in accordance with priorities of the NMDP.

3.1500 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 medical director for assistance with preliminary donor evaluation.

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).

4.1200 Bank shall have experience in the recruitment and management of cord blood donors.

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 HPC(CB) 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 and/or individuals collecting HPC(CB) products

4.1800 Bank shall maintain accreditation by AABB and/or Foundation for Accreditation for Cellular Therapy: NetCord-FACT. (See References)

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.

4.2300 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 the HPC(CB) 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), the European Federation for Immunogenetics (EFI), and/or the College of American Pathologists (CAP) for HLA typing 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 Laboratory(ies) that perform eligibility testing for evidence of infection due to relevant communicable disease agents must use donor screening tests that the Food and Drug Administration (FDA) has approved, licensed or cleared for such use and testing shall be performed in accordance with the manufacturer's instructions. (See References)

4.4140 Cord blood collection sites accredited by an organization granted deemed status by Centers for Medicare & Medicaid Services (CMS) 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 HPC, Cord Blood [HPC(CB)] collection, processing, labeling, storage and transportation.

4.5300 Bank shall have written policies and procedures for the release and issue of HPC(CB) 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 an organization granted deemed status by Centers for Medicare & Medicaid Services (CMS) or non-US equivalent.

5.1200 Center shall have an experienced team that has collected HPC, Marrow [HPC(M)] at least three times in the past three years 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 HPC, 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

5.2200 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 HPC, Marrow [HPC(M)] collection shall have performed at least 10 prior collections of HPC(M) for transplantation with at least three collections in the previous three years. Any person assisting in the marrow aspiration (physician, nurse, technician) shall have documented adequate training in HPC(M) collections for transplantation.

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

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

5.3400 Physician responsible for the HPC(M) 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 HPC, Marrow collections in a timely fashion.

5.4210 Donor shall be admitted and discharged from the collection center the same day unless the medical status precludes it

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 HPC, Marrow [HPC(M)].

5.5200 Center medical director or the physician performing the collection shall perform and/or review a complete medical evaluation of the donor to determine if the donor is an acceptable candidate for HPC(M) collection.

5.5300 Center shall verify that the donor has autologous red cell units available prior to the HPC(M) collection appropriate to the anticipated volume of HPC(M) to be collected.

5.5400 Physician responsible for the collection shall be present for the duration of the HPC(M) 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 U.S. Food and Drug Administration (FDA).

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

6.1300 Center shall have 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

6.2200 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 Administration of mobilization agents shall be under the supervision of a licensed physician experienced in their administration and in the management of complications in persons receiving these agents.

6.3500 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.

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6.4300 Center shall use a hospital accredited by an organization granted deemed status by Centers for Medicare & Medicaid Services (CMS) or non-U.S. equivalent for placement of central venous catheters.

6.5000 Policies and Procedures

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

6.5200 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 on peripheral venous access assessment and placement of central venous catheters.

6.5510 Central venous catheters shall only be used when peripheral venous access is not deemed feasible after skilled assessment or cannot be obtained or has failed

6.5520 Placement of central venous catheters shall require a written justification

6.5530 Adequacy of line placement shall be verified prior to use

7.0000 Criteria for Participating Transplant Centers

7.1000 Facility Characteristics

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

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

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

7.1300 Center shall have a designated inpatient unit that minimizes 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

7.2200 Transplant center medical director shall be responsible for search management activities and protecting the safety of the 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. (See References)

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), the European Federation for Immunogenetics (EFI), and/or the College of American Pathologists (CAP) for HLA typing required by NMDP. The laboratory designated by the transplant center is responsible for the final HLA typing of the patient and donor

7.4120 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 the risk of hemolysis

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. (See References)

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

8.2120 Bank shall define criteria used to assess the infant donor for infection or other abnormalities that may potentially affect the safety of the recipient or the therapeutic value of the cellular therapy product

8.2200 Informed consent shall be obtained from the biologic mother for collection, testing, and donation of the HPC, Cord Blood [HPC(CB)] 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 (Standard 4.4130 applies)

8.2420 Bank shall inform, counsel and document counseling of biologic mother regarding any clinically significant abnormal findings

8.2500 Medical director or designee shall evaluate medical history and testing results prior to listing the HPC(CB) unit with the NMDP.

9.0000 Marrow or Apheresis 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 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 relevant communicable disease agents (e.g. HBsAg or HCV) shall not be used unless urgent 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 HPC, Marrow [HPC(M)] donation and the following risks of HPC(M) donation:

9.2310 Risks of anesthesia

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

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

9.2410 Risks and 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 HPC, Marrow [HPC(M)] or HPC, Apheresis [HPC(A)] 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 suitable and has signed the consent to donate

9.3370 Donor center shall ensure repeat infectious disease testing is performed if previous results were obtained more than 30 days prior to marrow or mobilized apheresis donation (Standard 2.4130 applies)

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 HPC, Marrow or HPC, 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 HPC, Marrow [HPC(M)] or HPC, Apheresis [HPC(A)] donation, and has been reported to the NMDP

9.5200 HPC, Marrow Donation

9.5210 Donor center, collection center, and transplant center shall agree in writing on the volume and nucleated cell count of HPC, 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 HPC(M)

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

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

9.5300 HPC, Apheresis & TC, Apheresis Donation

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

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

9.5312 Number of apheresis procedures to be performed

9.5320 For TC, Apheresis, donor center, apheresis center and transplant center shall agree in writing on the volume of blood to be processed.

9.6000 Pre-Collection Donor Blood Samples

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

9.6110 Limited to a maximum volume defined in current NMDP guidelines

9.6120 Obtained more than 10 days prior to HPC, 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 clinical 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 clinical complaints related to the collection

9.7200 Subsequent Donations

9.7210 The maximum number of donations from a given donor is limited according to NMDP policy. Refer to Appendix I.

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

9.7221 Donor suitability and eligibility determination requirements apply for each donation occurrence

9.7222 Donor center shall ensure repeat infectious disease testing is performed if previous results were obtained more than 7 days prior to TC, Whole Blood or TC, Apheresis donation (Standard 2.4130 applies)

9.7223 Donor should not provide more than two subsequent donations for a given recipient, of which only one may be an HPC, Apheresis or HPC, Marrow donation

9.7230 Donor should not be asked to donate HPC for a second recipient unless no other equally compatible donor is available and the following conditions are met (refer to Appendix I):

9.7231 At least one year has elapsed since the first HPC, Marrow or HPC, Apheresis donation for the first recipient

9.7232 At least three years have elapsed since a subsequent HPC, Marrow or HPC, Apheresis donation

9.7233 No donor shall provide more than two HPC, Marrow donations

9.7234 Donation of HPC to a third recipient is not permitted

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 shall not occur until after the first anniversary of the transplant

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

10.1000 HPC, Marrow [HPC(M)] 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 HPC(M) collection.

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

10.1400 HPC(M) shall be harvested with only the types and amounts of anticoagulants, media and additives agreed on by transplant and collection centers.

10.1500 HPC(M) 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 HPC(M) shall be filtered during collection using sterile filters made of materials that do not deplete leukocytes.

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

10.2000 HPC, Apheresis [HPC(A)] & TC, Apheresis [TC(A)] Collection

10.2100 Collection shall be performed using an instrument and software designed for mononuclear cell collection.

10.2200 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 shall be specified in writing.

10.2410 Apheresis center shall obtain component cell counts and promptly transmit results to NMDP and, if requested, to the transplant center

10.2500 After collection, the apheresis center shall not cryopreserve product or manipulate the 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 HPC, Apheresis [HPC(A)] 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

10.2700 Cells shall be suspended in sufficient donor plasma to maintain viability of the cells during transport

10.2800 Cells shall be aseptically collected in a sterile, labeled container with a port that can be entered aseptically

10.3000 HPC, Cord Blood [HPC(CB)] Collection and Processing

10.3100 HPC, Cord Blood [HPC(CB)] units shall not be collected or stored with non-human sources of blood or blood components.

10.3200 Testing of the HPC(CB) units shall be consistent with AABB Standards and/or NetCord-FACT Standards. (See References)

10.3300 HPC(CB) units shall be stored with at least two integrally attached cryopreserved product samples 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 marrow or apheresis product or blood obtained from the donor at the time of collection

10.4230 Fungal and bacterial cultures

10.4240 CD34-positive cell quantitation of HPC, Apheresis products

10.5000 Labeling and Documentation (HPC, Marrow; HPC, Apheresis; TC Apheresis, and TC, Whole Blood)

10.5100 Labeling of HPC, Marrow; HPC, Apheresis; TC, Apheresis; and TC, Whole Blood shall conform with labeling information in the Circular of Information (COI) and be consistent with AABB and/or FACT-JACIE Standards. (See References)

10.5110 Center shall complete the product-specific, NMDP-supplied label and tie-tag, and affix or attach to each bag, as applicable

10.5120 Labels are supplied for the following specific products:

10.5121 For marrow collection: "HPC, Marrow"

10.5122 For mobilized leukocytapheresis: "HPC, Apheresis"

10.5123 For non-mobilized leukocytapheresis: "TC, Apheresis"

10.5124 For non-mobilized peripheral whole blood collections: "TC, Whole Blood"

10.5200 Biohazard and Warning Labels for HPC, Marrow; HPC, Apheresis; TC, Apheresis and TC, Whole Blood shall conform with labeling information in the Circular of Information (COI) and be consistent with AABB and/or FACT-JACIE Standards. (See references)

10.5210 For products collected in or designated for allogeneic use in the U.S., documents accompanying the product shall contain at least the elements listed in the Accompanying Documents at Distribution Table in Appendix II (unless otherwise present on the label)

10.5300 Each item recorded on the label and accompanying documents shall be verified for accuracy by two individuals or the electronic equivalent.

10.5310 Label verification shall be documented

10.6000 Cord Blood Products (HPC, Cord Blood; Cryopreserved HPC, Cord Blood)

10.6100 Labeling of HPC, Cord Blood and Cryopreserved HPC, Cord Blood shall conform to labeling information in the Circular of Information (COI) and be consistent with AABB and/or NetCord-FACT Standards. (See References)

10.6200 Biohazard and Warning Labels, as required by the US Food and Drug Administration, for HPC, Cord Blood and Cryopreserved HPC, Cord Blood shall conform to labeling information in the Circular of Information (COI) and be consistent with AABB and/or NetCord-FACT Standards. (See References)

10.6300 For products collected in or designated for allogeneic use in the U.S., documents accompanying the product shall contain at least the elements listed in the Accompanying Documents at Distribution Table in Appendix II (unless otherwise present on the label).

10.6400 Each item recorded on the label and accompanying documents shall be verified for accuracy by two individuals or the electronic equivalent.

10.6410 Label verification shall be documented

10.7000 Transportation

10.7100 Each non-cryopreserved product shall be placed inside an outer bag which is sealed to prevent leakage.

10.7200 Products shall be enclosed in a rigid container with temperature insulating properties.

10.7210 The shipping container shall include a document on the inside of the container and a label on the outside of the container with at least the elements as defined in Appendix III, "Requirements for Shipping Containers at Distribution".

10.7300 Non-cryopreserved products shall be transported at the temperature specified by the transplant center or NMDP.

10.7310 Product shall be insulated from direct contact with wet ice or reusable cooling packs

10.7320 Dry ice shall not be used

10.7400 Cryopreserved products shall be shipped in a liquid nitrogen "dry shipper" that contains adequate adsorbed liquid nitrogen to maintain temperature of -150ºC or colder at least 48 hours beyond the expected arrival time at the receiving facility.

10.7410 The temperature of the shipping container during shipment shall be continuously monitored

10.7500 All non-cryopreserved HPC, Apheresis and HPC, Marrow shall be hand carried by a suitably trained courier in the passenger compartment of the transport vehicle.

10.7600 Transported cellular therapy products should not be passed through X-ray or irradiation devices.

10.8000 HPC, Marrow; HPC, Apheresis; TC, Apheresis; TC, Whole Blood and HPC, Cord Blood Infusion

10.8100 HPC, Marrow; HPC, Apheresis; TC, Apheresis and TC, Whole Blood products shall be infused as soon as feasible. HPC(M) should be infused within 48 hours and HPC(A) products should be infused within 48 hours of collection.

10.8200 HPC, Cord Blood units shall be infused as soon as possible after thawing the product and preparation for administration per manufacturer's instructions or validated local procedure(s).

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

11.1000 Adverse Reactions

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

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

11.1120 Center shall notify NMDP of serious adverse reactions that are caused by or probably caused by the donation or the product as soon as possible after detection and cooperate with evaluation and follow-up in a timely manner

11.1130 Fatal or potentially life threatening adverse reactions shall be reported to NMDP by close of the next business day following determination of the event

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

11.2000 Deviations

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

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

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

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

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

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

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

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

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

11.3000 Complaints

11.3100 Participating Center shall have processes and procedures for capturing, evaluating, documenting and follow-up of reported complaints relative to products or services provided by Center.

11.4000 Nonconforming Product/Materials/ Service

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

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

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

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

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

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

11.4132 The facility of final distribution shall have policies and procedures to address cellular therapy products with positive microbial culture,including:

1) Product labeling
2) Investigation of cause
3) Notification of recipient physician
4) Recipient follow-up and outcome analysis
5) Reporting to regulatory agencies, if appropriate

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

11.5000 General Reporting Requirements

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

12.0000 Records and Record Retention

12.1000 General Record Requirements for All Participating Centers

12.1100 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.

12.1200 Records shall be legible, indelible, complete and retrievable in a reasonable period of time.

12.1300 Records shall be preserved and protected from accidental or unauthorized destruction or modification.

12.1400 All records and communications relating to patients, recipients, donors or potential donors shall be kept strictly confidential.

12.1500 Records shall be made available for inspection by authorized individuals.

12.1600 Relevant to the processes performed at each site, records shall be maintained to ensure the identification and traceability/trackability of each donor and cellular therapy product and all related samples from their initial source, through each processing and testing step to their final disposition and from final disposition, through each processing and testing step to the initial source. (12.3000 applies)

12.2000 Computerized Record Requirements

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

12.2200 Written procedures shall be maintained for record entry, verification and revision.

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

12.2310 System development, if done internally

12.2320 Numerical designation of system versions with inclusive dates of use

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

12.2340 Validation and monitoring of data integrity

12.2350 All modifications to the system shall be authorized and documented

12.2400 All centers shall document the following:

12.2410 Installation and upgrades of the system

12.2420 Training and continuing competency of personnel

12.2430 Policies and procedures for system maintenance and operations

12.2440 Ongoing backup procedures

12.2450 Documented and tested procedures for data restoration

12.2460 Offsite rotational storage of electronic data records

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

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

12.3000 Retention of Records – Indefinite

12.3100 Donor Center records pertaining to donors who have been activated for a formalized search and have any of the following records, shall be retained indefinitely:

12.3110 Consent documents for all stages of the search process

12.3120 Health history screenings including reasons for permanent or temporary deferral

12.3130 Infectious disease testing and/or laboratory results

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

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

12.3160 All source documents for any formalized search

12.3200 The following Cord Blood Bank records on units collected under NMDP IND or listed with NMDP shall be retained indefinitely:

12.3210 All maternal consent documents for the collection, screening, testing, and storage of cord blood for unrelated allogeneic use

12.3220 Maternal health history and family medical history screening and eligibility determinations, including reasons for permanent or temporary deferral

12.3230 Infectious disease testing and other laboratory results

12.3240 Documentation of abnormal findings and notification/counseling of relevant parties

12.3250 Records pertaining to collection, receipt, processing and cryopreservation, labeling, packaging, storage, distribution and final disposition of cord blood products

12.3251 Records pertaining to qualification, monitoring and use of reagents, supplies and materials shall be retained and traceable to cord blood product

12.3252 Records pertaining to qualification, monitoring, calibration, maintenance and use of equipment shall be retained and traceable to the cord blood product

12.3253 Records pertaining to the traceability and tracking of all aspects of the manufacture of the cord blood unit with the exception of facility cleaning and sanitation records which are retained minimally for 3 years

12.3260 Records of reported recipient adverse reactions and post-administration complications

12.3300 Apheresis and Collection Center records which shall be retained indefinitely:

12.3310 Consent documents from donors for the collection of products for unrelated allogeneic use

12.3320 Screening and testing records

12.3330 Records pertaining to collection, processing, labeling, packaging, storage, distribution and final disposition of collected product

12.3331 Records pertaining to qualification, monitoring and use of reagents, supplies and materials shall be traceable to collected product

12.3332 Records pertaining to qualification, monitoring and use of equipment shall be traceable to collected product

12.3333 Records pertaining to the traceability and tracking of all aspects of the manufacture of the HPC product performed at the site with the exception of facility cleaning and sanitation records which are retained minimally for 3 years

12.3340 Records of adverse reactions and post-donation complications, treatment interventions and recovery

12.3400 Transplant Center recipient records which must be retained indefinitely:

12.3410 Consent documents

12.3420 Records related to the preliminary search request and recipient HLA typing for all formal searches at the transplant center

12.3430 Records indicating the identification numbers of donor(s) requested to participate in specific testing

12.3440 Records pertaining to any search in which the NMDP facilitates the collection

12.3450 Records pertaining to abnormal donor findings and the notification/counseling of relevant parties

12.3460 ABO/Rh typing, and bacterial and fungal culture results, where performed, of the hematopoietic cells

12.3470 Informed consent document concerning participation in NMDP research and consent to release personal information (if applicable)

12.3480 Forms used for data entry pertaining to any recipient who receives cellular therapy product

12.3490 Records concerning reporting of recipient post transplant clinical data

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

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

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

12.4300 Recipient search requests and preliminary results of recipient searches that are never formalized

12.5000 Retention of Records – Donor Center Transferred Donors

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

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

12.6000 Retention of Records – Donor Center Closing Centers

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

REFERENCES

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

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

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

Centers for Medicare & Medicaid Services (CMS)-Approved Accreditation Organizations:
https://www.cms.gov/surveycertificationgeninfo/07_Accreditation.asp

Circular of Information: https://network.nmdp.org/TRAINING/SHIP/coi_ctp.pdf

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

Food and Drug Administration:
Tissues and Tissue Products:
http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm
Testing HCT/P Donors for Relevant Communicable Disease:
http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm095440.htm

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

International Council for Commonality in Blood Banking (ICCBBA):
United States Consensus Standard for the Uniform Labeling of Cellular Therapy Products Using ISBT 128:
http://iccbba.org/usconsensusstandard_cellulartherapy.pdf

Office of Human Research Protection (OHRP) requirements for a Federal Wide Assurance (FWA):
http://www.hhs.gov/ohrp/assurances/assurances_index.html

The Foundation for the Accreditation of Cellular Therapy:
NetCord-FACT: International Standards for Cord Blood Collections, Processing and Release for Administration;
http://www.factweb.org/forms/store/CommercePlusFormPublic/search?action=Publications

FACT-JACIE: International Standards for Cellular Therapy Product Collection, Processing and Administration:
http://www.factweb.org/forms/store/CommercePlusFormPublic/search?action=Publications

World Marrow Donor Association (WMDA): Standards: http://www.worldmarrow.org/

GLOSSARY	
Adverse Reactions	A suspected or proven unfavorable response to the collection or administration of a cellular therapy product or mobilizing agent manifested by clinically significant signs or symptoms.
Apheresis Center	Network facility that meets participation criteria for the collection of hematopoietic cells by apheresis from NMDP volunteer donors.
Apheresis Collection:	
● **HPC, Apheresis [HPC(A)]**	Hematopoietic cells collected using apheresis techniques after the donor has received growth factor.
● **TC, Apheresis [TC(A)]**	Leukocyte collection using apheresis techniques without the administration of growth factor. These are nucleated cells intended for therapeutic use other than as hematopoietic cells.
Center/Bank	A specific type of NMDP network entity
Centers for Medicare & Medicaid Services (CMS)	The federal agency responsible for administering the Clinical Laboratory Improvement Amendments (CLIA). The Joint Commission (TJC), the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP), and Det Norske Veritas Healthcare (DNV) are examples of organizations which have been granted deemed status by the Centers for Medicare & Medicaid Services (CMS) for hospitals.
Circular of Information (COI)	The COI is a document intended to provide general information to those who administer cellular therapy products and serves as an extension and enhancement of the label found on the product. The COI is a jointly prepared document containing definitions; descriptions; indications and contraindications; and instructions for dosage, administration, storage, labeling, and documentation of cellular therapy products such as hematopoietic progenitor cells and other leukocytes that are minimally manipulated.
Clinical Practice Guideline	Standardized disease-specific treatment plan used in lieu of a research protocol when use of an unrelated donor transplant is considered standard of care.

Collection Center	NMDP network hospitals that meet participation criteria with experience and facilities to collect HPC, Marrow and care for donors before and after the collection procedure.
Complaint	Any communication referencing a problem associated with a cellular therapy product or the collection, screening, testing, processing, storage, distribution or infusion of a cellular therapy product.
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.
Consent	Prospectively obtained permission for the collection and use of data, information, specimens or products, for the intended purpose or to conduct an approved research project.
Continuous Process Improvement (CPI) Program	A method of analyzing and managing the improvement of the NMDP Network's operations.
Cord Blood Bank	An NMDP network organization that meets participation criteria with experience, staff and facilities to collect, process and store HPC, Cord Blood [HPC(CB)]for transplant.
Cord Blood Unit (HPC, Cord Blood [HPC(CB)])	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.
Deviation	A departure from applicable regulations or laws, procedures, protocols, standards or established specifications/requirements. Deviations can be planned or unplanned and may or may not result in unacceptable/unsuitable product or adverse result or outcome.
Protocol Deviation	A planned or unplanned departure from defined protocol(s)
Deviation From Standards	Not following the standards. Deviations are considered to be individual one-time events, which may be planned or unplanned.

Disposition	The status assigned to a cellular therapy product based on evaluation of specific performance and eligibility requirements.
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 NMDP Registry.
Abnormal Donor Findings	An underlying condition or unusual test result that is identified as a result of the donor evaluation, which may increase risk for the donor or recipient, but is not necessarily a cause for deferral.
Donor Medical Suitability	An allogeneic cellular therapy product donor who meets established criteria relative to medical risk associated with donation and is determined to be medically fit to proceed to donation per medical evaluation and physician judgment.
Eligibility	An allogeneic cellular therapy product donor who meets all donor screening and testing requirements related to transmission of infectious disease as defined by applicable laws and regulations.
Federal Wide Assurance (FWA)	A document filed by the institution with the Department of Health and Human Services (HHS) stating that the institution will comply with HHS regulations for the protection of human subjects.
Food and Drug Administration	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. Marrow: HPC, Marrow; HPC(M) PBSC: HPC, Apheresis; HPC(A) Cord Blood: HPC, Cord Blood; HPC(CB)
Hematopoietic Cells	An all inclusive term for hematopoietic progenitor cells and their progeny, e.g., differentiating cells and mature cells.
Human Leukocyte Antigen (HLA) Typing	The procedure by which HLA alleles (in the case of DNA-based typing) or HLA antigens (in the case of serological typing) are identified.

Independent Ethics Committees (IEC)	An independent body whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in research.
Informed Consent	The process of obtaining permission from an individual to participate in research or other operations of the NMDP, where the individual is informed of and has an opportunity to discuss the benefits, risks, and alternatives to his/her participation. Consent is based upon a clear appreciation and understanding of the relevant facts, implications, and future consequence of the decision. The consent is given voluntarily and free from undue influence or coercion.
Institutional Review Board (IRB)	An administrative body established in accordance with Title 45 CFR Part 46 to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.
Manipulation	An ex vivo procedure(s) that selectively removes, enriches, expands or functionally alters elements or components of HPC products.
Manufacture	Manufacture means, but is not limited to, any or all steps in the recovery, transport, processing, storage, labeling, packaging, shipping, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor.
Medical Suitability	An allogeneic cellular therapy product donor who meets established criteria relative to medical risk associated with donation and is determined to be medically fit to proceed to donation, as determined by medical evaluation and physician judgment.
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 centers and cooperative registries.
Nonconforming Product, Supply / Material or Service	A failure of cellular characteristic, supply, reagent, dose or test results to meet specified requirements.

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 Center	Donor, collection, apheresis or transplant center, recruitment center or cord blood bank that has submitted an NMDP application, meets NMDP criteria, and become a member of the NMDP network. Term references the facility, policies, staff, etc. composing the network entity.
Processing	Manipulation of the product in the laboratory setting.
Record	Information captured in writing or electronically that provides objective evidence of activities that have been performed or results that have been achieved, such as test records. Records do not exist until the activity has been performed and documented.
Recruitment Center	An NMDP network organization meeting participation criteria that performs donor recruitment. May also be known as a Recruitment Group.
Shall	Indicates a standard that is to be complied with at all times.
Shipping	The physical act of transferring a cellular therapy product within or between facilities. During shipping the product leaves the control of trained personnel at the originating or receiving facility.
Should	Indicates an activity that is highly recommended or advised, but for which there may be effective alternatives.
Subsequent Donation:	Collection of HPC, Apheresis; HPC, Marrow; TC, Apheresis; TC, Whole Blood; or blood from a donor for his/her original recipient or another recipient.
System	Refers to computer systems for management of donor or recipient information and records.
TC, Apheresis	Nucleated cells obtained by an apheresis procedure intended for therapeutic use other than HPCs. Non-mobilized unless otherwise stated in the modifier.
TC, Whole Blood	Whole blood collected as a source of nucleated cells intended for therapeutic use other than HPCs.

Traceability	The ability to follow the history of a process, product or service by review of documents.
Trackability	The ability to follow a cellular therapy product from donor to consignee or final distribution and from consignee or final distribution to donor by review of documents.
Transplant Center	An NMDP network hospital based program that meets participation criteria with experience, staff and facilities to perform allogeneic stem cell transplantation.
Transportation	The physical act of transferring a cellular therapy product within or between facilities. During transportation the product does not leave the control of trained personnel at the originating or receiving facility.
Variance From Standards	A pre-approved short or long term deviation from a standard, which once approved by the NMDP, is in place prospectively for the specific standard. It must be demonstrated that donor/patient safety and product integrity are not negatively impacted prior to approval by the NMDP.

Appendix I

Subsequent Donation: Maximum number of donations

Product	Recipient 1	Recipient 2
HPC (*Marrow or Apheresis)*	1-2	1-2
TC, Apheresis or TC, Whole Blood	1-2	1-2
Total donations *(HPC, TC,)*	3 Max 2 HPC	3 Max 2 HPC

Lifetime max for marrow donation = 2

Note: A single "donation" episode may include more than one procedure. For example, a two-day apheresis or a failed leukocytapheresis followed by a marrow collection is equal to one donation episode.

Appendix II

Minimum Accompanying Records at Distribution (unless otherwise present on the label)
[Applicable for units collected in or designated for use in the U.S.]

* Documentation	Allogeneic Donor Eligible	Allogeneic Donor Ineligible
Statement that donor has been determined to be eligible or ineligible based on results of donor screening and testing	X	X
Summary of records used to make the donor eligibility determination	X	X
Name and address of facility that made donor eligibility determination	X	X
Listing and interpretation of results of all communicable disease testing performed	X	X
Statement that lab meets CLIA (or CMS equivalent) regulatory requirements	X	X - if applicable
A statement noting reason(s) for donor being ineligible		X
Circular of Information (COI)	X	X
Statement: "Caution: New Drug – Limited by Federal Law to Investigational Use", if distributed under an FDA Approved IND	X - if applicable	X - if applicable
For Cryopreserved HPC, Cord Blood: Instructions for thawing and preparation for administration, as applicable	X	X
Customs communications and paperwork, as applicable	X	X
▲ Nucleated cell counts, when available	X	X
▲ Collection information, as applicable	X	X

▲If applicable and not available at time of transport, information is provided as soon as possible to consignee while product is in transit.

Note: FACT/JACIE and NetCord-FACT also include the following in accompanying records, where applicable:
Listing and interpretation of results of all communicable disease screening performed.
Documentation of notification of physician using the product of all testing and screening

Note: Although not regulated by FDA, NMDP requires the same accompanying records for HPC, Marrow as for FDA-regulated products

***** NMDP adult donor forms meet the requirements of this table:

- *Final Declaration of Donor Eligibility (F00315)*
- *NMDP Product Labeling Checklist and Record of Delivery (F00202)*
- *Peripheral Blood Stem Cell Product Analysis (Form 770/771); Marrow Product Analysis (Form 772); or Therapeutic T-cells, T Cells, Apheresis Procedure and Product Analysis (Form 773), as applicable*
- *Repeat Donor Infectious Disease Markers (Form 50)*
- *Guide to the Interpretation of Infectious Disease Marker (IDM) Testing Results for Stem Cell Donors (A00347)*
- *Verification of Marrow Request (F00070); Verification of PBSC Request (F00071);* or *NMDP Prescription for T cells (F00243), as applicable*
- *Courier paperwork as applicable*

Appendix III

Minimum Requirements for Shipping Containers at Distribution

Required Element	Inner Container Document (1)	Outer Shipping Container Label (2)
Date of distribution	X	X
Statement "Do Not X-Ray"	X	X
Statement "Medical Specimen" or "Human Cells for Transplantation" or equivalent	N/A	X
Shipping facility name, street address and phone number	X	X
Receiving facility name, street address and phone number	X	X
Identity of person or position responsible for receipt of shipment	X	X
Biohazard and / or Warning Labels, as applicable	X	N/A
Shipper Handling instructions, if shipped	X	X

(1) Accompanying records in container
(2) Affixed or Attached to container

Note: NetCord-FACT includes time of shipment as part of outside container labeling.
NetCord-FACT requires statement "Cord Blood for Transplantation" or equivalent as part of outside container labeling.

Note: FACT/JACIE and NetCord-FACT require both "Medical Specimen" and "Handle with Care" as part of accompanying records and outside container labeling.

Note: As applicable, AABB requires "Do Not Irradiate" as part of the accompanying records and outside container labeling.