Unrelated Donor/Patient Confidential Information Policy

POLICY STATEMENT
It is National Marrow Donor Program® (NMDP) policy to protect against the unauthorized disclosure or use of confidential information of the NMDP or of others with whom the NMDP deals.

BUSINESS SECTION/DEPARTMENT
Legal Affairs

PURPOSE
The use of confidential information is integral to the NMDP’s mission and business. In the course of providing services, the NMDP requires routine access to Personally Identifiable Information about Recipients, Patients, Donors, and potential Donors. The NMDP’s business also involves the use of technological, financial, and operational information that is the property of NMDP or others and that is essential to the NMDP’s success in providing its services. Finally, the NMDP also maintains and uses confidential information relating to its employees or other personnel.

This Unrelated Donor/Patient Confidential Information Policy in particular supports protection of confidential information owned by the NMDP or others with whom the NMDP deals; contracting entities; and Be The Match Registry® or other registry members, unrelated Donors, Patients, and Recipients in Hematopoietic Stem Cell Product transplants in which the NMDP participates.

SCOPE
This policy applies to NMDP Personnel and, where relevant, the NMDP Network. The requirements of this policy additionally may extend to other entities and persons, pursuant to contract.

DEFINITIONS
Apheresis Center (AC) means and refers to an organization that collects peripheral blood stem cells and provides care for peripheral blood stem cell donors before and after the donation procedure, as part of the NMDP Network. As used here, Apheresis Center may refer to and include NMDP Cooperative Registries.

Collection Center (CC) means and refers to an organization that collects bone marrow and provides care for bone marrow donors before and after the donation procedure, as part of the NMDP Network. As used here, Collection Center may refer to and include NMDP Cooperative Registries.

Confidential means or refers to information that is provided, entrusted, held, or treated as being held in strict privacy, secrecy, or confidence.

Confidentiality means or refers to the protected status of specified information, through developed, implemented, and enforced standards and requirements, by which
accessibility to or provision of such information is limited only to those authorized to have and use the information.

**Confidentiality Incident** means any disclosure of Personal Information, Donor-Identifying Information, or Patient-Identifying Information, to an unauthorized person.

**Confidentiality Concern** means any unauthorized disclosure of Personal Information, Donor-Identifying Information, or Patient-Identifying Information, wholly within NMDP, that did not cause and could not have caused a significant injury, and that was not intentional.

**Confirmatory Typing or CT** means and refers to a repeat tissue typing test done to confirm the human leukocyte antigen (HLA) type of both the donor and patient and determine the locations of allele matches or mismatches between the donor and patient. This is one of the final tests done before transplant.

**Cord Blood Bank (CBB)** means and refers to an organization that helps to collect and store umbilical cord blood for transplant, as part of the NMDP Network. As used here, Cord Blood Bank may refer to and include NMDP Cooperative Registries.

**Donor** means a person donating any Hematopoietic Stem Cell Product, or a product related to that donation, for transplant into a recipient. For purposes of the Unrelated Donor/Patient Confidential Information Policy and Confidential Information Standard Operating Procedure, “Donor” includes the infant whose cord blood is being considered for donation or has been donated, as well as the infant’s mother or, where applicable, legal guardian. “Donor,” “potential Donor,” or a reference to a registrant or person seeking registration on the Be The Match Registry shall be deemed equivalent, and use of one shall include and not exclude the other(s).

**Donor Center (DC)** means and refers to an organization that recruits and manages interaction with Hematopoietic Stem Cell Product donors, as part of the NMDP Network. As used here, Donor Center may refer to and include NMDP Cooperative Registries.

**Donor-Identifying Information** means Personal Information of any registrant or person seeking registration on the Be The Match Registry or other hematopoietic stem cell registries or any Donor of Hematopoietic Stem Cell Product(s), as well as information relating particularly to that transplant, without limitation including the identification of any such person’s registry, managing Donor Center, Cord Blood Bank, day and month of cord blood unit collection, location, gender, age, blood group and Rh antigens (ABO/Rh type), HLA type and locations of matches or mismatches, infectious disease marker (IDM) results, health history information, medical conditions, test results, medications, treatments, and photographs. Donor-Identifying Information does not include the country of origin for a donated Hematopoietic Stem Cell Product.

**DR Typing** means and refers to tissue typing to determine the HLA-DR determinants carried or expressed by a donor or patient.

**Hematopoietic Stem Cell Product**, as used here, means bone marrow, peripheral blood stem cells, and/or umbilical cord blood.
HR Typing or High Resolution Typing means and refers to a tissue typing test done to establish the HLA allele level type of the donor and patient.

NMDP means the National Marrow Donor Program and NMDP Personnel.

NMDP Network means Apheresis Centers (ACs), Collection Centers (CCs), Cooperative Registries, Cord Blood Banks (CBBs), Donor Centers (DCs), Recruitment Centers, and Transplant Centers (TCs), where such entities have participation agreements with the NMDP. Personnel of these entities are within the scope of this definition.

NMDP Personnel means NMDP employees, consultants, contingent workers, independent contractors, volunteers, and interns.

NMDP Quality Incident Management System means the quality software process implemented by the Regulatory & Quality Assurance department to report, resolve, monitor, and track/trend quality related incidents and concerns that occur within or related to operations of the NMDP. The process includes a formal mechanism for management, documentation, and monitoring corrective action/preventive action (CAPA).

NMDP Vendor means any laboratory, tissue repository, courier service, product shipping service, home health agency, or other person or entity contracted to provide defined services to the NMDP.

Patient means the potential or intended Recipient of a transplanted Hematopoietic Stem Cell Product or products, prior to transplant. “Patient” and “Recipient” shall be deemed equivalent, and use of one shall include and not exclude the other.

Patient-Identifying Information means Personal Information of any Patient or Recipient in a Hematopoietic Stem Cell Product transplant, as well as information relating particularly to that transplant, without limitation including the identification of any such person’s managing Transplant Center, location, gender, age, blood group and Rh antigens (ABO/Rh type), HLA type and locations of matches or mismatches, health history information, medical conditions, test results, medications, treatments, and photographs. Patient-Identifying Information does not include the destination country for a donated Hematopoietic Stem Cell Product.

Personal Information means any information that identifies, describes, or is capable of being associated with a particular individual, without limitation including an individual’s name, full or partial address, birth date, telephone number, driver’s license or identification card number, Social Security number, passport number, electronic mail addresses, financial account numbers, information access passwords, or employment information.

Personally Identifiable Information means and refers to Personal Information, Donor-Identifying Information, and/or Patient-Identifying Information.
Primary Donor Identifier(s) means and refers to Donor Identifier, Coop Donor ID, Donor ID (DID), Global Registration Identifier for Donors (GRID), and other similar means of identifying a Donor by a unique numeric or alphanumeric identifier assigned to that Donor. “Primary Donor Identifier(s)” is a generic term that can be used to reference all such Donor identifiers.

Problem Management Form is an internal NMDP document used for reporting events that affect the quality of products and services provided through the NMDP, and which may serve as a source document for incident reporting through the NMDP Quality Management System.

Recipient means a person who is undergoing or has undergone a transplant of a Hematopoietic Stem Cell Product or products. “Patient” and “Recipient” shall be deemed equivalent, and use of one shall include and not exclude the other.

Recruitment Center means and refers to an organization that recruits donors, as part of the NMDP Network. As used here, Recruitment Center may refer to and include NMDP Cooperative Registries.

Search Process means the stages or activities involved in identifying a potential donor of a Hematopoietic Stem Cell Product. Depending on the product, the Search Process may include any or all of the following stages or activities: DR Typing, High Resolution Typing, Confirmatory Typing, and/or Workup.

Transplant Center (TC) means and refers to an organization that performs Hematopoietic Stem Cell Product transplantation, as part of the NMDP Network. As used here, Transplant Center may refer to and include NMDP Cooperative Registries.

Workup means the process that a closely matched potential donor undergoes to determine whether he or she is healthy and prepared to donate a Hematopoietic Stem Cell Product. Workup includes an information session with Donor Center staff, a physical examination, a donation of blood samples for testing and/or research, and sometimes a donation of autologous blood.

RESPONSIBILITIES

Responsibilities for carrying out the policy directives are identified in the Unrelated Donor/Patient Confidential Information Standard Operating Procedure.

This policy and the Unrelated Donor/Patient Confidential Information Standard Operating Procedure shall be managed by Legal Affairs personnel, within the Office of General Counsel.

REQUIREMENTS

This Unrelated Donor/Patient Confidential Information Policy is required by, and furthers the requirements of, legal authority that includes but is not limited to:

- 5 U.S.C. § 552a of the Privacy Act, which limits the disclosure of any item, collection, or grouping of information about an individual that is maintained by any federal agency that keeps such records;
• 42 U.S.C. § 274k(f)(5)(A), which requires the Department of Health & Human Services/Health Resources & Services Administration to enforce, for participating entities including the NMDP, “standards that require the establishment of a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with Federal and State law”;

• 42 U.S.C. §§ 274k(d)(4)(D) and 274k(d)(4)(F), which define a “qualified cord blood bank” as, respectively, one that has established “a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with Federal and State law” and “a system to confidentially maintain linkage between a cord blood unit and a maternal donor”;

• 42 U.S.C. § 274k(n), which provides that persons who disclose the contents of records referred to in §§ 274k(d)(4)(D) and 274k(f)(5)(A), without prior written consent of the Donor or in violation of standards described in § 274k(f)(5)(B), “shall be imprisoned for not more than 2 years,” fined in accordance with federal law, or both.

• Statutory and/or regulatory provisions in federal and multiple state jurisdictions, which commonly prohibit and punish disclosure of private information that includes identifying information, financial or credit information, and possibly medical information;

• Common law (i.e., law that is case-based and not legislation- or regulation-based) restrictions that may impose liability for disclosure of personal information based on “publication of private facts,” “intrusion on seclusion,” or similar grounds; and

• Contracts entered into in the course of NMDP business.

REFERENCES
Not Applicable

REVISION HISTORY

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<td>Revisions to definitions</td>
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Revision to referenced NMDP department/function titles and processes

ADDENDA
Not Applicable