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Related 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 Related 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 Related 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 when managing a related donor request. The requirements of this policy additionally may extend to other entities and persons, pursuant to contract.

RELATED DOCUMENTS

Confidential Information Standard Operating Procedure (Related Donor/Patient Confidentiality) (S00621)

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.

Donor means a person donating any Hematopoietic Stem Cell Product, or a product related to that donation, for transplant into a recipient.

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 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 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.

Hematopoietic Stem Cell Product, as used here, means bone marrow and/or peripheral blood stem cells.

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 Management System means the quality software process implemented by the Quality and Regulatory Affairs department to report, resolve, monitor, and track/trend quality related incidents 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).

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.

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.

Related Donor means a person donating any Hematopoietic Stem Cell Product, or a product related to that donation, for transplant into a recipient who is a first or second degree blood relative of the Donor. For the purposes of this SOP "Related Donor" and "Donor" shall be deemed equivalent, and use of one shall include and not exclude the other.

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.

RESPONSIBILITIES

Responsibilities for carrying out the policy directives are identified in the Related Donor Confidential Information Standard Operating Procedure

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

REQUIREMENTS

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

- 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

Revision	Brief Description of Revision
P00087 Rev. 1	New Policy
P00087 Rev. 2	Modifications of Definitions. Added a definition for primary donor identifier. Replaced Incident Management System with Quality Management system. Removed Incident Capture Form. Replaced confidentiality breach with confidentiality incident. Updated the dept title for QRA.

ADDENDA

Not Applicable