Related Donor/Patient Confidential Information Standard Operating Procedure

TABLE OF CONTENTS

OBJECTIVE/SCOPE ........................................................................................................... 2
MATERIALS ......................................................................................................................... 2
SAFETY ................................................................................................................................. 2
DEFINITIONS ....................................................................................................................... 2
RESPONSIBILITIES ........................................................................................................... 4
PROCEDURE ......................................................................................................................... 4

1. Related Donor and Patient Confidentiality ................................................................. 4
   1.1. Donor and Patient Confidentiality in General (All Hematopoietic Stem Cell Products) ................................................................. 4
   1.2. Communications and Correspondence ................................................................. 5
   1.3. Disclosures of Patient Search Status by NMDP Patient and Health Professional Services ................................................................. 6
   1.4. NMDP Staff Responsibilities for SOP on Related Donor and Patient Confidentiality ................................................................. 7

2. Training ......................................................................................................................... 10

3. Confidentiality Breaches ............................................................................................ 10
   3.1. Internal Reporting of Confidentiality Breaches ................................................ 10
   3.2. NMDP Network Reporting of Confidentiality Breaches .................................. 10
   3.3. Investigation and Corrective Actions ................................................................ 11

REFERENCES .................................................................................................................... 11

ADDENDA .......................................................................................................................... 11
OBJECTIVE/SCOPE

To describe the procedures for protection of confidential information and responses to disclosures of such information by NMDP Personnel and the NMDP Network when managing activities associated with related donors and recipients.

MATERIALS


SAFETY

Not applicable

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 Breach 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.

**Incident Capture 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 Incident Management System.

**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 Incident Management System** is a process implemented by the Quality & Regulatory Services department to report, resolve, monitor, and track/trend quality related incidents that occur within or related to operations of the NMDP. The Incident Management System 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.

**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**

See Procedure section of this SOP for specific responsibilities.

**PROCEDURE**

1. **Donor and Patient Confidentiality**
   
   1.1. **Donor and Patient Confidentiality in General (All Hematopoietic Stem Cell Products)**
   
   1.1.1. This SOP applies to NMDP Personnel and the NMDP Network.
   
   1.1.2. Except as provided in this SOP, all Donor-Identifying Information and Patient-Identifying Information must be kept Confidential.
   
   1.1.3. Access to Donor and Patient file information must be limited to those personnel whose job functions require access to those files and/or the information they contain.
   
   1.1.4. Persons or entities possessing or controlling Donor-Identifying Information or Patient-Identifying Information may disclose the information only where a legitimate business or medical purpose exists. In such circumstances, the information may be disclosed only as permitted by this SOP, and the disclosure must be limited to the minimum information that is necessary and appropriate to the purpose in question.
   
   1.1.5. Persons or entities possessing or controlling Donor-Identifying Information or Patient-Identifying Information shall not disclose the information to any other person or entity, except as permitted by this SOP. In such circumstances, the disclosed information may be disclosed only as permitted by this SOP, and the disclosure
must be limited to the minimum information that is necessary and appropriate to the purpose in question.

1.1.6. Disclosure of Donor-Identifying Information or Patient-Identifying Information in a manner not permitted by this SOP is a Confidentiality Breach.

1.2. Communications and Correspondence

1.2.1. In communications or correspondence within the NMDP, within the NMDP Network, or otherwise, all persons or entities possessing or controlling Donor-Identifying Information or Patient-Identifying Information must adhere to the following requirements, in addition to other applicable requirements within this SOP.

1.2.1.1. In electronic communications (including email, e-faxes, e-forms, or other similar communications), such persons or entities must:

1.2.1.1.1. Use DID and RID instead of names, whenever possible.

1.2.1.1.2. Use NMDP Secure Email for correspondence containing Donor-Identifying Information or Patient-Identifying Information, in accord with applicable email security policies, SOPs, and processes identified by NMDP.

1.2.1.1.3. Not use Donor-Identifying Information or Patient-Identifying Information in email or e-fax subject, title, or description lines. Use of DID or RID is acceptable.

1.2.1.1.4. Use an automatic notice of confidentiality and disclaimer statement in each sent email that contains Donor-Identifying Information or Patient-Identifying Information.

1.2.1.2. In paper communications (including paper correspondence, faxes, forms, files, labels, or other similar communications), such persons or entities must:

1.2.1.2.1. Use DID and RID rather than Donor-Identifying Information or Patient-Identifying Information, whenever possible.

1.2.1.2.2. Store paperwork containing Donor-Identifying Information or Patient-
1.2.1.2.3. Not leave paperwork containing Donor-Identifying Information or Patient-Identifying Information in common areas, e.g., copy center, fax machine, meeting rooms, and on desktops in non-work hours.

1.2.1.3. In verbal communications (including telephone and face-to-face conversation), such persons or entities must:

1.2.1.3.1. Take necessary steps to ensure the privacy of the communications, without limitation including conducting such communications only in private settings or circumstances, avoiding use of Donor-Identifying Information or Patient-Identifying Information in the communications, or providing such information in other appropriate forms or when the verbal communications are known to be private.

1.2.1.3.2. Avoid casual verbal communications that include Donor-Identifying Information or Patient-Identifying Information.

1.3. Disclosures of Patient Search Status by NMDP Patient and Health Professional Services

1.3.1. When communicating with a Patient, a Patient’s spouse, a person having the Patient’s or other legal authorization to receive such information, or the parent or legal guardian of a minor Patient, an NMDP Patient Services Coordinator can confirm (a) previous contacts with the Patient, (b) the Patient’s search status for preliminary or formal searches, and (c) the Patient’s Transplant Center.

1.3.1.1. Information on the detailed search activity of a Patient’s search cannot be shared with anyone. This information may be obtained only from the Patient’s Transplant Center.

1.3.2. When communicating with a person not within the scope of § 1.3.1, NMDP Patient and Health Professional Services can
provide only general education and information about the search and transplant process.

1.3.2.1. Information on previous contacts with the Patient, the Patient’s search status for preliminary or formal searches, or identification of the Patient’s Transplant Center can be shared with these persons only with the Patient’s consent allowing disclosure. The consent must be provided to NMDP Patient and Health Professional Services.

1.3.2.2. A Patient’s consent to allow disclosure of this information to identified persons can be obtained through:

1.3.2.2.1. A notarized document allowing the individual at issue to receive information on behalf of the Patient; or

1.3.2.2.2. Medical or other verified record authorization by the Patient or parent/legal guardian of a minor Patient, allowing the individual at issue to receive information about the Patient.

1.3.2.3. Information on the detailed search activity of a Patient’s search cannot be shared with anyone. This information may be obtained only from the Patient’s Transplant Center.

1.3.3. When communicating with NMDP employees or NMDP Network personnel, NMDP Patient and Health Professional Services can provide only the information that is necessary for the individual to perform his or her professional responsibilities. This may include an NMDP Patient Services Coordinator confirming (a) previous contacts with the Patient, (b) the Patient’s search status for preliminary or formal searches, and/or (c) the Patient’s Transplant Center.

1.3.3.1. Information on the detailed search activity of a Patient’s search cannot be shared with anyone. This information may be obtained only from the Patient’s Transplant Center.

1.4. **NMDP Staff Responsibilities for SOP on Related Donor and Patient Confidentiality**

1.4.1. The responsibilities of the NMDP Patient Services Manager include, but are not necessarily limited to:

1.4.1.1. Be available to all NMDP Personnel to answer questions or concerns regarding the policy and procedures;
1.4.1.2. Accept and record reports of patient confidentiality incidents from NMDP Personnel, the NMDP Network, or others;
1.4.1.3. Compile or supervise compilation of information in support of reporting outlined in § 3 (“Confidentiality Breaches”) of this SOP;
1.4.1.4. Assist in investigation of incidents, at the request of Quality & Regulatory Services and/or other appropriate departments; and
1.4.1.5. Assist in the corrective action/preventive action (CAPA) process, if requested by Quality & Regulatory Services and/or other appropriate departments.

1.4.2. The responsibilities of the Donor Advocacy Manager include, but are not necessarily limited to:
1.4.2.1. Be available to all NMDP Personnel to answer questions or concerns regarding the policy and procedures;
1.4.2.2. Accept and record reports of donor confidentiality incidents from NMDP Personnel, the NMDP Network, or others;
1.4.2.3. Compile or supervise compilation of information in support of reporting outlined in § 3 (“Confidentiality Breaches”) of this SOP;
1.4.2.4. Assist in investigation of incidents, at the request of Quality & Regulatory Services and/or other appropriate departments; and
1.4.2.5. Assist in the corrective action/preventive action (CAPA) process, if requested by Quality & Regulatory Services and/or other appropriate departments.

1.4.3. The responsibilities of the Director of Quality & Regulatory Services include, but are not necessarily limited to:
1.4.3.1. File and maintain Incident Capture Forms and related documentation of confidentiality incidents in the NMDP Incident Management System database;
1.4.3.2. Coordinate the investigation for each reported incident;
1.4.3.3. Coordinate the corrective action/preventive action (CAPA) process for each reported incident; and
1.4.3.4. Record resolution/outcome of each reported incident.
1.4.4. The responsibilities of the HR Managers include, but are not necessarily limited to:

1.4.4.1. Be available to all NMDP Personnel to answer questions or concerns regarding the policy and procedures;

1.4.4.2. Assist in investigation of incidents, at the request of Quality & Regulatory Services and/or other appropriate departments;

1.4.4.3. Assist in the corrective action/preventive action (CAPA) process, if requested by Quality & Regulatory Services and/or other appropriate departments; and

1.4.4.4. Assist NMDP managers in taking appropriate disciplinary action against an offending employee, per provisions set forth in the corrective action/preventive action (CAPA) process procedure, and document activities related to that.

1.4.5. The responsibilities of the Director of Legal Affairs & Risk Management include, but are not necessarily limited to:

1.4.5.1. Be available to all NMDP employees to answer questions or concerns regarding the policy and procedures;

1.4.5.2. Assist in investigation of incidents, per request from Quality & Regulatory Services and/or other departments;

1.4.5.3. Assist in the corrective action/preventive action (CAPA) process, if requested by Quality & Regulatory Services and/or other departments; and

1.4.5.4. Evaluate Confidentiality Breaches for reporting to the Chief Executive Officer report Confidentiality Breaches, where appropriate.

1.4.6. The responsibilities of other department Senior Vice Presidents, Vice Presidents, Directors, Managers, and/or Supervisors include, but are not necessarily limited to:

1.4.6.1. Assist employees in reporting Confidentiality Breaches;

1.4.6.2. Assist in the corrective action/preventive action (CAPA) process, if requested by Quality & Regulatory Services and/or other departments; and

1.4.6.3. With guidance from the appropriate Human Resource Manager, take appropriate disciplinary action toward an offending employee, per provisions set forth in the corrective
2. Training

2.1. The NMDP requires all employees to complete basic confidentiality training as a condition of their employment.

2.1.1. Confidentiality training will be given at commencement of the employee’s employment or re-employment with NMDP and annually thereafter.

2.1.2. Education & Training shall be responsible for provision of the training and maintenance of documentation evidencing completion of that training by employees.

2.2. The NMDP additionally may require non-employee NMDP Personnel to complete basic confidentiality training, in relation to the particular projects, services, advice, or work being provided by such persons.

2.2.1. Education & Training shall be responsible for provision of the training and maintenance of documentation evidencing completion of that training by such persons.

2.3. The NMDP requires relevant staff at NMDP Network centers to complete confidentiality training as a condition of membership renewal.

2.3.1. Education & Training shall be responsible for provision of the training and establishing training compliance criteria.

2.3.2. Network Membership (Operations), in collaboration with Education & Training, shall be responsible for confirming that network centers comply with NMDP confidentiality training requirements, for network center staff, where applicable.

3. Confidentiality Breaches

3.1. Internal Reporting of Confidentiality Breaches

3.1.1. All NMDP Personnel are required to report incidents that involve or may involve a Confidentiality Breach.

3.1.2. NMDP Personnel should report such incidents in accord with the reporting identified in § 1.4 of this SOP (“NMDP Staff Responsibilities for SOP on Related Donor and Patient Confidentiality”), for the type of information and Confidentiality Breach at issue.

3.1.3. NMDP Personnel may report such incidents to a supervisor.

3.1.4. Incidents additionally may be reported by email or telephone communication.

3.2. NMDP Network Reporting of Confidentiality Breaches

3.2.1. NMDP Network members are required to report incidents that involve or may involve a Related Donor and Patient Confidentiality
3.2.2. NMDP Network members should report, to the extent possible, the identification of each individual whose unsecured Individually Identifying Data has been, or is reasonably believed by Center to have been, accessed, acquired, used, or disclosed during the Individually Identifying Data security breach.

3.2.3. Incidents may be reported by email or telephone communication.

3.3. Corrective Actions

3.3.1. Corrective and/or disciplinary action may be taken, based on the investigation and evaluation.

3.3.1.1. Responsive actions may include, without limitation, the following:

3.3.1.1.1. In the case of NMDP employees, employment action up to and including termination.

3.3.1.1.2. In the case of non-employee NMDP Personnel, action affecting the relationship of such persons with the NMDP, up to and including termination/cessation of that relationship.

3.3.1.1.3. In the case of the NMDP Network, training and education, policy/procedure modifications, and/or actions pursuant to the NMDP “Non-Compliance Policy for Network Centers.”

REFERENCES

Not applicable

Revision History

<table>
<thead>
<tr>
<th>Revision</th>
<th>Brief Description of Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>S00621 rev. 1</td>
<td>New SOP</td>
</tr>
</tbody>
</table>

ADDENDA

Not applicable